

Adjunctive *Cinnamomum Tamala* for Reduced Libido and Sexual Dysfunction in Women Taking SSRIs: A Single-Centre, Double-Blind, Randomized Placebo-Controlled Trial

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Abstract

Background: Sexual dysfunction is a Prevalent and distressing adverse effect of selective serotonin reuptake inhibitors (SSRIs) and frequently leads to poor treatment adherence and medication discontinuation. *Cinnamomum Tamala* has traditionally been used in Persian medicine as an aphrodisiac. This study aimed to assess the efficacy and safety of *C. Tamala* as a complementary treatment for SSRI-induced sexual dysfunction in women.

Methods: This was an 8-weeks parallel-group, double-blind, randomized, placebo-controlled trial conducted at outpatient psychiatry clinics affiliated with Iran University of Medical Sciences between September 2024 and February 2025. Fifty-eight married women aged 18–45 years receiving stable SSRI therapy and reporting decreased libido were randomly assigned in a 1:1 allocation ratio to receive either *C. Tamala* capsules (1000 mg/day) or placebo. The primary endpoint was the change in the total Arizona Sexual Experience Scale (ASEX) score from baseline to week 8. Between-group analyses were performed using ANCOVA adjusted for baseline ASEX scores.

Results: Forty-eight participants completed this study (23 in the *C. Tamala* group and 25 in the placebo group). Baseline ASEX total scores were comparable between groups (26.70 ± 4.52 vs. 28.20 ± 3.19 ; $*P = 0.134$). After 8 weeks, the *C. Tamala* group demonstrated significantly better improvement in total ASEX score compared with placebo (mean change: -8.26 ± 6.13 vs. -1.28 ± 2.59 ; adjusted mean difference: -7.11 ; 95% CI: -9.88 to -4.34 ; $P < 0.001$). The effect size was large (Cohen's $d = 1.53$, 95% CI: 0.94 to 2.12). Sensitivity intention-to-treat analysis using multiple imputations yielded consistent Findings (adjusted mean difference -6.70 ; 95% CI -8.39 to -5.01 ; $P < 0.001$). No serious adverse events occurred.

Conclusion: Adjunctive treatment with *Cinnamomum Tamala* (1000 mg/day for 8 weeks) significantly improved SSRI-induced sexual dysfunction in women with acceptable tolerability.

Keywords: *Cinnamomum Tamala*, Selective serotonin reuptake inhibitors, Sexual dysfunction, Phytotherapy, Persian medicine, Randomized controlled trial

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Introduction

Major depressive disorder (MDD) is a major contributor to disability globally and affects approximately 280 million individuals globally (1). Selective serotonin reuptake inhibitors (SSRIs) remain First-choice pharmacotherapy for MDD In view of their established efficacy and safety (2).

However, sexual dysfunction is among the most frequently observed adverse effects of SSRIs and affects approximately 50–70% of users (3). SSRI-induced sexual dysfunction may manifest as decreased libido, impaired arousal, delayed orgasm, and reduced sexual satisfaction

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Key Messages:

↑What is “already known” in this topic:

SSRI-induced sexual dysfunction is common and frequently leads to poor adherence or discontinuation of antidepressant therapy. Current management strategies have limited efficacy or tolerability.

→What this article adds:

Adjunctive *Cinnamomum Tamala* (1000 mg/day for 8 weeks) significantly improved multiple domains of Sexual functioning among women with SSRI-induced sexual dysfunction and demonstrated good tolerability, with no serious adverse events.

(4). These complications frequently result in medication non-adherence, impaired quality of life, and premature discontinuation of antidepressant treatment (5, 6).

The pathophysiology of SSRI-induced sexual dysfunction is multifactorial (7). Increased serotonergic activity may inhibit dopaminergic and noradrenergic pathways involved in sexual arousal and orgasm (8). Chronic SSRI exposure may also contribute to endothelial dysfunction and oxidative stress, potentially impairing genital blood flow (7).

Current management strategies include dose reduction, drug holidays, switching antidepressants, or augmentation with medications such as bupropion or phosphodiesterase inhibitors (9). Nevertheless, these strategies may be ineffective, poorly tolerated, or clinically impractical (10, 11).

Cinnamomum Tamala (Lauraceae) has traditionally been used in Persian medicine as an aphrodisiac and vitality-enhancing herb (12, 13). Previous phytochemical studies have demonstrated antioxidant, anti-inflammatory, nitric oxide-enhancing, and potential dopaminergic effects for compounds found in *C. Tamala* (14, 15).

The 8-week duration of the present study was selected based on previous herbal medicine trials demonstrating that clinically meaningful changes in sexual function generally appear after 4–6 weeks of treatment (16, 17).

Despite its traditional use, clinical evidence regarding the therapeutic effects of *C. Tamala* on SSRI-induced impaired sexual function remains limited. The objective of this study was to determine the efficacy and safety of adding *C. Tamala* to existing treatment in women with SSRI-induced impairment in sexual function.

Methods

Study Design

This was an 8-week parallel-group, double-blind, randomized, placebo-controlled clinical trial carried out in an outpatient setting at psychiatry clinics affiliated with Iran University of Medical Sciences (Tehran, Iran) between September 2024 and February 2025. The study adhered to CONSORT 2010 guidelines.

Participants

Eligible participants included married women aged 18–45 years who had been taking SSRI treatment.

for at least 8 weeks and reported decreased libido following SSRI initiation. Participants were not required to meet a predefined ASEX cutoff score at baseline. Sexual dysfunction was identified based on patients' self-reported reduction in sexual desire after antidepressant initiation, with each patient serving as their own reference for pre-treatment sexual function.

Exclusion criteria included pregnancy, breastfeeding, cardiovascular disease, diabetes mellitus, bipolar disorder, psychotic disorders, substance use disorders, concurrent aphrodisiac herbal therapies, and known allergies to cinnamon species.

Sample Size Calculation

According to a previous clinical trial of herbal medicine with an anticipated effect size of 0.9, $\alpha = 0.05$, and

statistical power of 80%, the minimum required sample size was calculated as 22 Individuals in each group. (16). Considering approximately 20% attrition, 58 participants were ultimately enrolled.

Randomization and Blinding

An independent statistician prepared a computer-generated block randomization sequence with variable block sizes of 4 and 6, and participants were randomly assigned in a 1:1 allocation ratio. Allocation concealment was performed using sequentially numbered opaque sealed envelopes (SNOSE method). Participants, investigators, outcome assessors, and data analysts were blinded to treatment allocation. Because both formulations were administered in opaque gelatin capsules and looked and were labeled identically, sensory differentiation between groups was minimized.

Intervention

Cinnamomum Tamala leaves were obtained from a Local provider in Tehran, Iran, and authenticated by a botanist. A voucher specimen (PMP-1404) Was archived at the Herbarium of the School of Persian Medicine, Tehran University of Medical Sciences, Faculty of Pharmacy.

Each active capsule contained 500 mg of powdered *C. Tamala* leaves. Participants received two capsules daily (1000 mg/day). Placebo capsules contained toasted wheat flour and were identical to active capsules in appearance, packaging, and labeling. Since both formulations were administered in opaque gelatin capsules, the characteristic odor and taste of the herbal preparation were not detectable, supporting sensory blinding. Adherence was monitored using pill counts at weeks 4 and 8. Participants were monitored for adverse events throughout the trial and documented when reported or identified during participant follow-up. The nature of each event and whether it resulted in treatment discontinuation were recorded.

Outcome Measures

The primary endpoint was the change in the total ASEX score between baseline and week 8.

The ASEX questionnaire comprises five items covering sex drive, arousal, penile erection or vaginal lubrication, ability to achieve orgasm, and satisfaction with orgasm. Scores range from 5 to 30, with higher values indicating greater sexual dysfunction. The validated Persian version was used (18). The questionnaire was completed by participants, and the main outcome measure was the difference in total ASEX scores from baseline to the end of the 8-week intervention. No predefined ASEX cutoff was used for study inclusion.

Secondary outcomes included:

1. Changes in ASEX subdomain scores
2. Incidence of adverse events.

The main outcome measure was the difference in total ASEX scores from baseline to the end of the 8-week intervention. The ASEX evaluator was blinded to treatment allocation.

Adverse Event Monitoring

Mild gastrointestinal discomfort was reported in two participants in the *C. Tamala* group and one participant in the placebo group. There were no reports of serious adverse events during the trial. These events cannot be definitively attributed to the study intervention.

Statistical Analysis

All analyses were carried out using IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, NY, USA). Continuous data were described using the mean and SD, while categorical data were summarized as counts and percentages. The Shapiro–Wilk test was applied to assess the normality of the data distribution.

Baseline characteristics were compared between the two groups using the independent-samples t-test for normally distributed continuous variables and the chi-square test or Fisher's exact test for categorical variables, as appropriate.

The primary outcome measure was the change in the total Arizona Sexual Experiences Scale (ASEX) score from baseline to the end of the 8-week study period.

The intention-to-treat (ITT) approach was used for the primary analysis, including all 58 randomized participants (29 in each group), including the 10 participants who discontinued the study (6 in the *C. Tamala* group and 4 in the placebo group). Missing week 8 ASEX scores were handled using multiple imputation by chained equations (MICE), assuming that data were missing at random. The imputation model included baseline ASEX score, age, and treatment group. Twenty imputed datasets were generated, and estimates were pooled using Rubin's rules. Between-group differences were assessed using analysis of covariance (ANCOVA), with treatment group as the fixed factor and baseline ASEX score as the covariate. The adjusted mean difference between groups with 95% confidence intervals (CI) was reported. Effect size was calculated using Cohen's d with 95% CI. The per-protocol analysis was retained as a supportive analysis, including participants who

completed the intervention and had available outcome data using the same ANCOVA model.

For secondary outcomes, between-group comparisons of ASEX subdomain scores at week 8 were performed using the Mann–Whitney U test because the data were not normally distributed. Within-group changes from baseline to week 8 were assessed using the Wilcoxon signed-rank test. Changes in subdomain scores were calculated as week 8 scores minus baseline scores and were presented descriptively in the tables. The reported between-group P-values for the ASEX subdomains correspond to comparisons of week 8 scores, not comparisons of change scores.

All statistical tests were two-sided, and a p-value < 0.05 was considered statistically significant.

Ethical Approval

Ethical approval was obtained from the Ethics Committee of Iran University of Medical Sciences (IR.IUMS.REC.1403.399). The study was registered in the Iranian Registry of Clinical Trials (IRCT20240813062746N1) before enrollment of the first participant.

Informed Consent

Written informed consent was obtained from all participants before enrollment. The study was conducted in accordance with the Declaration of Helsinki (2013 revision).

Results

Participant Flow

Eighty women were assessed for eligibility, and 58 participants were randomized. 29 participants were allocated to the *C. Tamala* group, and 29 participants were allocated to the placebo group. Forty-eight participants completed the study (23 participants in the *C. Tamala* group and 25 participants in the placebo group).

Six participants in the *C. Tamala* group and four participants in the placebo group discontinued the study. Reported gastrointestinal discomfort occurred in two participants in

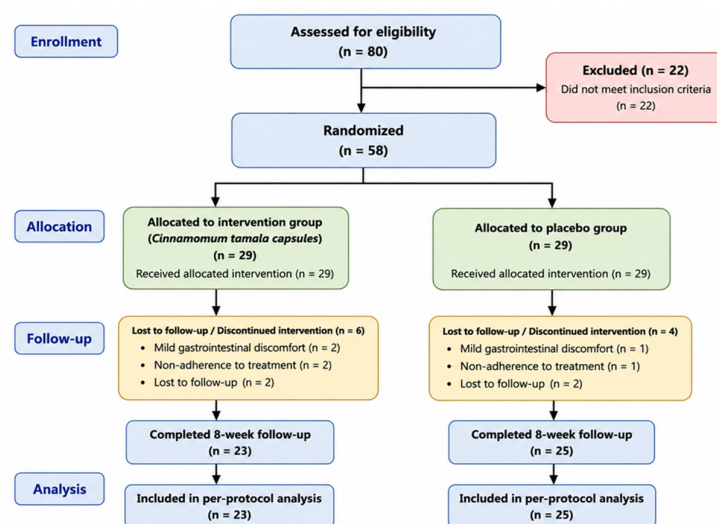


Figure 1. CONSORT flow diagram of participants through the trial

the *C. Tamala* group and one participant in the placebo group. Other reasons for discontinuation included loss to follow-up ($n = 2$ in each group) and medication non-adherence ($n = 2$ in the *C. Tamala* group and $n = 1$ in the placebo group) (Figure 1).

Baseline Characteristics

Baseline demographic and clinical characteristics were balanced between groups. Baseline ASEX total scores were also comparable between groups (Table 1). Mean participant age was 37.43 ± 6.16 years in the intervention group and 35.00 ± 6.29 years in the placebo group ($P = 0.429$). The distribution of SSRI subtypes was comparable between groups.

Primary Outcome

After 8 weeks, participants receiving *C. Tamala* demonstrated significantly greater reductions in total ASEX scores compared with the placebo group (Table 2).

The primary intention-to-treat (ITT) analysis, including all randomized participants ($n = 58$), was performed using multiple imputation by chained equations (MICE). Analysis of covariance (ANCOVA), with baseline ASEX score

entered as the covariate, demonstrated a significant treatment effect ($P < 0.001$). The adjusted mean difference between groups was -6.70 (95% CI: -8.39 to -5.01 ; $P < 0.001$). The effect size was Cohen's $d = 1.53$ (95% CI: 0.94 to 2.12), indicating a large treatment effect.

The per-protocol analysis, including 48 participants who completed the study (23 in the *C. Tamala* group and 25 in the placebo group), yielded consistent results (adjusted mean difference: -7.11 ; 95% CI: -9.88 to -4.34 ; $P < 0.001$) (Table 3).

Secondary Outcomes

Significant improvements were observed across all ASEX subdomains including desire, arousal, lubrication, orgasm, and satisfaction (Table 4). Responder analysis demonstrated that 75% of participants in the *C. Tamala* group achieved at least 50% reduction in ASEX total score compared with 12.5% in the placebo group (Fisher's exact test, $P < 0.001$).

Adverse Events

Mild gastrointestinal discomfort led to treatment discontinuation in three participants: two in the *Cinnamomum*

Table 1. Baseline demographic and clinical characteristics

Variable	<i>C. Tamala</i> (N=29 randomized; 23 completed)	Placebo (N=29 randomized; 25 completed)	*P* value
Age (years)	36.43 ± 6.16	35.00 ± 6.29	0.429*
Fluoxetine, n (%)	12 (41.4)	11 (37.9)	0.78**
Sertraline, n (%)	9 (31.0)	10 (34.5)	0.80**
Citalopram, n (%)	5 (17.2)	5 (17.2)	1.00**
Escitalopram, n (%)	3 (10.3)	3 (10.3)	1.00**

Percentages were calculated using the number of randomized participants as the denominator. *Data presented as mean $\pm$ standard deviation or n (%). *Independent t-test; **Chi-square test.

Table 2. Changes in ASEX total scores

Time point	<i>C. Tamala</i> (n=23)	Placebo (n=25)	*P* value
Baseline	26.70 ± 4.52	28.20 ± 3.19	0.134*
Week 8	18.43 ± 7.44	26.82 ± 3.76	$< 0.001^*$
Change in ASEX score	-8.26 ± 6.13	-1.28 ± 2.59	$< 0.001^*$

*Baseline, Week 8, and change scores are presented as observed (unadjusted) means $\pm$ SD. Baseline values were compared using the independent-samples t-test. Between-group comparisons for Week 8 and change scores were performed using analysis of covariance (ANCOVA) with baseline ASEX score as the covariate.

Table 3. Comparison of per-protocol and intention-to-treat analyses for the primary outcome

Analysis	n	Adjusted mean difference (95% CI)	P value
Per-protocol	48	-7.11 (-9.88 to -4.34)	< 0.001
ITT (Multiple Imputation)	58	-6.70 (-8.39 to -5.01)	< 0.001

ITT = intention-to-treat; Multiple Imputation was performed using chained equations (MICE). The adjusted mean differences were estimated using analysis of covariance (ANCOVA) with baseline ASEX score as the covariate.

Table 4. ASEX subdomains' scores at baseline, week 8, and changes in intervention and control groups

ASEX Subdomain	Intervention Group (n=23)			Control Group (n=25)			Between-group P-value (Week 8)
	Baseline	Week 8	Change	Baseline	Week 8	Change	
Desire	5.30 ± 0.97	3.78 ± 1.34	-1.52 ± 1.12	5.64 ± 0.64	5.38 ± 0.72	-0.26 ± 0.52	< 0.001
Arousal	5.52 ± 0.66	3.65 ± 1.49	-1.87 ± 1.32	5.59 ± 0.59	5.34 ± 0.68	-0.25 ± 0.50	< 0.001
Lubrication	5.13 ± 1.18	3.52 ± 1.67	-1.61 ± 1.40	5.63 ± 0.64	5.37 ± 0.70	-0.26 ± 0.51	< 0.001
Orgasm	5.43 ± 0.84	3.86 ± 1.45	-1.57 ± 0.24	5.58 ± 0.60	5.33 ± 0.67	-0.25 ± 0.49	< 0.001
Satisfaction	5.26 ± 1.17	3.61 ± 1.67	-1.65 ± 1.49	5.64 ± 0.64	5.38 ± 0.71	-0.26 ± 0.53	< 0.001

Data are presented as mean $\pm$ standard deviation (SD). Between-group comparisons of ASEX subdomain scores at week 8 were performed using the Mann-Whitney U test. Changes are presented descriptively as week 8 minus baseline scores; no between-group statistical comparisons of change scores are represented by the reported P-values.

Tamala group and one in the placebo group. In all three participants, gastrointestinal symptoms resolved spontaneously without specific treatment. No other adverse events were observed in either group, or no serious adverse events were reported during the study. Nothing else led to treatment discontinuation.

Discussion

This randomized double-blind placebo-controlled trial demonstrated that adjunctive treatment with *Cinnamomum Tamala* significantly improved sexual function in women experiencing SSRI-induced sexual dysfunction. The observed improvement was supported by a large effect size (Cohen's $d = 1.53$, 95% CI: 0.94 to 2.12).

Improvements were consistently observed across all ASEX domains, including desire, arousal, lubrication, orgasm, and satisfaction.

The present findings are generally consistent with previous studies investigating herbal medicines for antidepressant-associated sexual dysfunction. Farnia et al. found that *Rosa damascena* 500 mg/day improved sexual function and libido (16). Mansoori et al. reported that saffron (*Crocus sativus*) 30 mg/day improved SSRI-induced erectile dysfunction in men (19). Doording et al. studied maca root (*Lepidium meyenii*) for SSRI-induced sexual dysfunction and reported improvements in libido (20). Shahmoradi et al. studied an herbal compound containing *Panax ginseng* and *Tribulus terrestris* in women with SSRI-induced sexual dysfunction (17).

Notably, the observed effect size was larger than that reported in previous studies evaluating herbal interventions for antidepressant-induced sexual dysfunction. Although this finding suggests a potentially substantial treatment effect, it should be interpreted cautiously because effect-size estimates derived from relatively small per-protocol samples may overestimate the true magnitude of benefit.

Confirmation in larger multicenter randomized trials is therefore warranted. Similar findings in the sensitivity ITT analysis further support the robustness of the observed treatment effect despite participant attrition.

Potential mechanisms underlying the observed effects of *C. Tamala* may include nitric oxide pathway enhancement via eugenol and cinnamaldehyde (12), dopaminergic modulation via linalool (14), antioxidant and anti-inflammatory effects reducing oxidative stress (15), and potential androgen modulation (21).

Limitations

The study has several limitations. First limitation is that sexual dysfunction was identified primarily through participants' self-reported symptoms, without a predefined ASEX eligibility threshold or a systematic assessment of pre-SSRI sexual functioning. Consequently, the extent to which the observed sexual dysfunction was specifically attributable to SSRI treatment remains uncertain. Although baseline ASEX scores indicated substantial sexual dysfunction, the absence of a standardized diagnostic assessment limits the specificity of case identification.

Future studies should consider applying a predefined severity threshold when enrolling participants. Second, the study was conducted at a single center with a relatively modest sample size, which may limit the generalizability of the findings. Third, depressive symptom severity was not systematically reassessed, limiting our ability to determine whether mood changes contributed to the observed improvement in sexual function.

Fourth, subgroup analyses according to SSRI subtype were not feasible because of the limited sample size. Finally, the follow-up duration was limited to 8 weeks, and no objective biomarkers of sexual function (e.g., vaginal photoplethysmography) were measured; therefore, the long-term efficacy and underlying biological mechanisms remain to be established.

Despite these limitations, important strengths of the study include its randomized double-blind placebo-controlled design, standardized outcome assessment, ANCOVA adjustment for baseline differences, a priori sample size calculation, and successful sensory blinding.

Clinical Implications

These findings suggest that *C. Tamala* (1000 mg/day for 8 weeks) is a safe, well-tolerated, and effective adjunctive treatment for women with SSRI-induced sexual dysfunction. Physicians may consider adding *C. Tamala* to stable SSRI therapy as an alternative to dose reduction or medication switching.

Conclusion

Adjunctive treatment with *Cinnamomum Tamala* (1000 mg/day for 8 weeks) significantly improved SSRI-induced sexual dysfunction in women with acceptable tolerability and no serious adverse effects. Larger multicenter studies with longer follow-up durations are warranted to confirm these findings and explore long-term safety.

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Conflict of Interests

The authors declare that they have no competing interests.

Authors' Contributions

All authors met the three conditions for authorship according to MJIRI guidelines: (1) substantial contribution to conception and design (MB and HMK and AG), analysis and interpretation of data (MB and HMK and AG); (2) drafting the article or revising it critically for important intellectual content (MB and HMK and AG and AJ); and (3) final approval of the version to be published (all authors).

Ethical Considerations

The study protocol was reviewed and approved by the Ethics Committee of Iran University of Medical Sciences (Approval No. IR.IUMS.REC.1403.399). The trial was prospectively registered in the Iranian Registry of Clinical

Trials (IRCT20240813062746N1) before enrollment of the first participant. Written informed consent was obtained from all participants prior to study participation. All procedures involving human participants were performed in accordance with the ethical standards of the institutional research committee and the Declaration of Helsinki (2013 revision).

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Data Availability

The anonymized dataset generated during the current study is available from the corresponding author upon reasonable request.

AI Use Statement

Artificial intelligence tools (ChatGPT and DeepSeek) were used exclusively for English language editing and grammatical revision. No AI tools were used for data analysis, data interpretation, hypothesis generation, or scientific content creation. All authors have reviewed and taken full responsibility for the final manuscript.

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