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Rosemary extract improves neuropsychiatric symptoms in methadone-maintained patients

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Abstract

Recent studies have demonstrated the neuropharmacological effects of *Rosmarinus officinalis* L. (rosemary) on cognitive and psychiatric functioning. Given the high prevalence of psychiatric disorders—including anxiety and depression—as well as cognitive deficits among patients maintained on methadone, this double-blind, randomized, placebo-controlled clinical trial aimed to evaluate the efficacy of rosemary extract in alleviating neuropsychological symptoms in this population. A total of 47 patients aged 18-60 years attending an addiction treatment clinic were randomly assigned to receive either 500 mg rosemary extract capsules or a placebo daily for 8 weeks. Standardized questionnaires were used to assess outcomes, including anxiety, depression, sexual dysfunction, sleep quality, and cognitive performance. Data were analyzed using GraphPad Prism version 10.3.1. Results indicated that rosemary extract administration led to significant improvements in anxiety symptoms, and favorable effects were observed in depression scores, cognitive functioning, and sleep quality compared to placebo. These findings suggest that rosemary extract may be a beneficial adjunctive therapy for neuropsychiatric symptoms in methadone-maintained patients, warranting further investigation in larger samples and longer-term studies.

Key words: rosemary, methadone maintenance, neuropsychiatric manifestations.

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Introduction

Substance use disorder remains a pervasive global challenge, exerting profound social, economic, and health-related consequences on societies worldwide. Among the foremost priorities in addressing this crisis is the effective rehabilitation of patients following diagnosis and cessation of drug use.[1,2] Methadone maintenance treatment (MMT) has emerged as a comprehensive, cost-effective, and evidence-based strategy for the management of opioid dependence, with the dual aims of harm reduction and improvement of social functioning and quality of life in affected individuals.[3,4] Despite its widespread implementation, MMT is frequently accompanied by a range of neuropsychiatric complications, including depression,[3,5] anxiety,[3,5] sleep disturbances,[3,6] sexual dysfunction,[4,6] and cognitive deficits,[3,7] which can undermine recovery, increase the risk of relapse, and drive patients to seek alternative therapies.[2,8] Thus, the development of effective therapeutic approaches to manage these adverse effects remains a crucial clinical concern.[1,9]

In recent years, growing attention has been directed toward herbal medicines as adjunctive therapies in addiction medicine, owing to their promising efficacy and favorable safety profiles.[8] Historical evidence supports the traditional use of medicinal plants in the management of addiction and withdrawal symptoms.[1] Furthermore, emerging research suggests that natural compounds may offer safe and effective therapeutic options for substance dependence.[1] Among such botanicals, *Rosmarinus officinalis* L. (rosemary) has demonstrated notable neuropharmacological properties. The proposed mechanisms of action for rosemary include modulation of the GABAergic system and enhancement of central γ-aminobutyric acid (GABA) levels, which may underlie its neuroprotective and anxiolytic effects.[8] The bioactive constituents of rosemary—comprising monoterpenes (such as α-pinene, 1,8-cineole, camphor) and phenolic compounds (including carnosol, carnosic acid, and rosmarinic acid)—are credited with its anti-inflammatory, antioxidant, analgesic, and neuroprotective activities.[10]

A growing body of preclinical and clinical studies has reported beneficial effects of rosemary and its extracts on mood,[11-14] cognitive performance,[15-17] anxiety,[8,17] and sleep quality.[10,18] For instance, recent clinical findings by Alvarado-García *et al*. demonstrated that rosemary essential oil could reduce anxiety symptoms by up to 40%, depressive symptoms by 25%, and improve sleep quality by 35% in human subjects.[19] Similarly, recent evidence has also highlighted rosemary's potential to enhance cognitive function and modulate neurotransmitter systems.[13,19] However, many of these findings are derived from animal studies, and further well-designed clinical trials are needed to establish effective and safe dosing regimens and to evaluate the long-term safety of rosemary in human populations.[10,13,19]

Given the high prevalence of opioid addiction and the substantial burden of neuropsychiatric complications among patients undergoing MMT, it is imperative to explore adjunctive interven-

tions that can ameliorate these symptoms and improve overall treatment outcomes. Despite encouraging preclinical and preliminary clinical evidence, research specifically addressing the potential of rosemary extract to alleviate neuropsychiatric symptoms in methadone-maintained patients remains scarce. Accordingly, the present study was designed as a randomized, double-blind, placebo-controlled clinical trial to evaluate the effects of standardized rosemary (*Rosmarinus officinalis* L.) extract on anxiety, depression, sexual function, sleep quality, and cognitive performance in this vulnerable population.

Materials and Methods

This study was designed as a randomized, double-blind, placebo-controlled, crossover clinical trial conducted in 2024 at the Addiction Treatment Clinic of Shahid Beheshti Hospital, Kerman, Iran. The study protocol was approved by the Institutional Review Board and Ethics Committee of the University of Medical Sciences (IR.KMU.AH.REC.1403.021), and written informed consent was obtained from all participants prior to enrollment. Patient confidentiality was strictly maintained throughout the study, and results were made available to participants upon request.

Participants

The study population consisted of methadone-maintained outpatients aged 18-60 years who met the inclusion criteria. Inclusion criteria were: age between 18 and 60 years, ability to read and write in Persian, no history of cardiovascular disease, diabetes, hepatic or renal failure, epilepsy, or other life-threatening conditions, not being pregnant, no use of antidepressants, benzodiazepines, melatonin, or other hypnotics in the past month, and no history of allergic reaction to rosemary. Exclusion criteria included development of allergic reactions during the trial or unwillingness to continue participation. Sample size was calculated using G*Power software, considering an effect size of 0.8, a confidence level of 95%, and a power of 80%, resulting in a total of 54 patients (27 per group). Participants were recruited using convenience sampling, and random allocation to intervention and control groups was performed using a random numbers table. Allocation was concealed from both researchers and participants until completion of statistical analysis, ensuring double-blinding.

Interventions

Dried *Rosmarinus officinalis* L. (rosemary) was obtained from a reputable pharmacy and authenticated by a pharmacognosy specialist. Quality control and standardization were performed based on the quantification of rosmarinic acid content using high-performance liquid chromatography. The essential oil was extracted *via* hydrodistillation, and major components were characterized by gas chromatography-mass spectrometry. Capsules were formulated with standardized rosemary powder, sieved through a specified mesh, and subjected to physicochemical quality control for content uniformity. In the intervention group, participants received 500 mg capsules of standardized rosemary powder every 12 hours (*i.e.*, twice daily) for 4 weeks. The control group received visually identical placebo capsules containing starch and a similar odor. Both capsules were indistinguishable in appearance and scent.

Outcome measures and data collection

Demographic data (Table 1) were collected using a structured questionnaire, including age, gender, marital status, education level, employment, duration of methadone maintenance, history of drug or food allergies, comorbid diseases (*e.g.*, cardiovascular, neurological, gastrointestinal disorders), and current medications. Neuropsychiatric outcomes were assessed with the following validated instruments.

Hospital Anxiety and Depression Scale

A 14-item questionnaire with two subscales for anxiety and depression, each comprising 7 items rated on a four-point Likert scale. The Hospital Anxiety and Depression Scale (HADS) has established reliability and validity in Iranian clinical populations, with good internal consistency and construct validity.[20]

Pittsburgh Sleep Quality Index

An 18-item tool that evaluates sleep quality over the past month across seven subscales. Each item is rated on a four-point Likert scale (0-3), generating a global score (0-21), with higher scores indicating poorer sleep quality. The Pittsburgh Sleep Quality Index (PSQI) has demonstrated high reliability (Cronbach's $\alpha = 0.83$) and validity in Iranian populations.[21,22]

Montreal Cognitive Assessment

A 30-point tool administered in approximately 10 minutes, assessing several cognitive domains including short-term memory, executive function, attention, language, abstraction, and orientation. Montreal Cognitive Assessment (MoCA) scores ≥ 26 are considered normal. The instrument shows high sensitivity (90%) and specificity (87%) for detecting mild cognitive impairment and has been validated in Persian.[23,24]

Table 1. Demographic characteristics of participants.

Variables		Rosemary (n=26)	Placebo (n=21)	p*
Age (years, mean±SD)		43.15±9.12	42.24±9.48	0.72
Gender	Male	24 (92.31%)	20 (95.24%)	0.67
	Female	2 (7.69%)	1 (4.76%)	
Marital status	Single	9 (34.62%)	6 (28.57%)	0.63
	Married	17 (65.38%)	15 (71.43%)	
Level of education	Elementary	2 (7.69%)	2 (9.52%)	0.94
	Middle school	5 (19.23%)	3 (14.29%)	
	High school diploma	12 (46.15%)	10 (47.62%)	
	Associate degree	5 (19.23%)	5 (23.81%)	
	Bachelor's or higher	2 (7.69%)	1 (4.76%)	

*An independent t-test and chi-square test were applied.

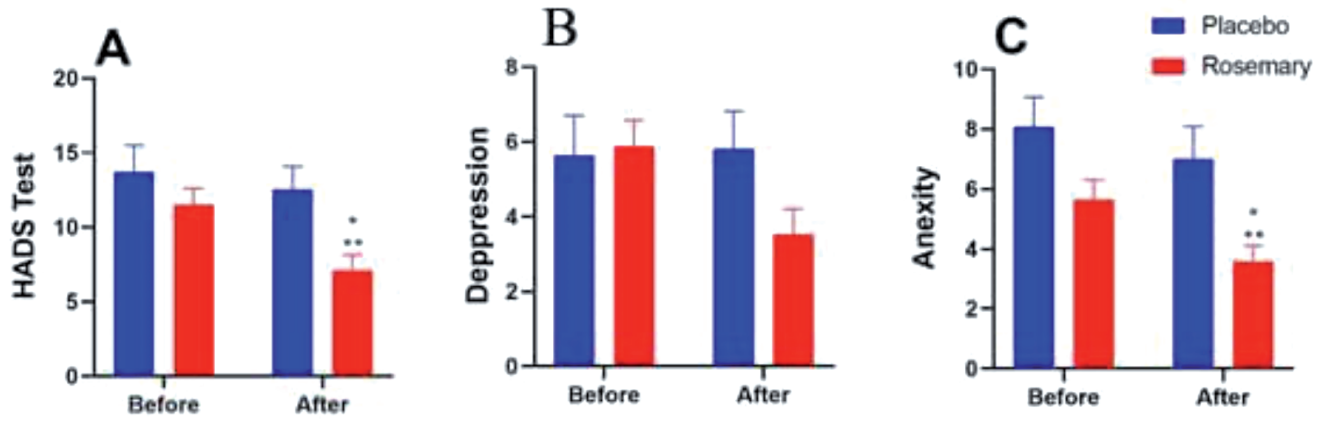

Figure 1. Comparison of the Hospital Anxiety and Depression Scale (HADS) test, depression, and anxiety in two study groups pre- and post-intervention. *p<0.05 compared to the placebo group after the intervention; **p<0.01 compared to the placebo group before the intervention.

Changes in Sexual Functioning Questionnaire-14 (CSFQ-14)

A 14-item instrument measuring sexual functioning across four domains: desire, arousal, orgasm, and pleasure. Each item is rated on a five-point Likert scale (1-5), with higher scores denoting better sexual function. The Changes in Sexual Functioning Questionnaire-14 (CSFQ-14) demonstrates high internal consistency (Cronbach's $\alpha = 0.89$ for men) and has been validated for divergent validity.[25,26]

Statistical analysis

Data were analyzed using GraphPad Prism software version 10.3.1. Descriptive statistics were calculated for demographic variables. Between-group comparisons were performed using independent t-tests and chi-square tests, depending on the normality of data distribution. Statistical significance was set at $p<0.05$.

Ethical considerations

This study was conducted in accordance with the Declaration of Helsinki. The study protocol received approval from the university's ethics committee. All participants provided written informed consent, and all data were kept confidential.

Results

A total of 54 participants who met the inclusion criteria were enrolled in the study. Upon entry, all participants were fully briefed regarding the intervention procedures, and informed consent was obtained. Subsequently, baseline assessments were conducted using the HADS, PSQI, CSFQ-14, and MoCA. During the course of the study, 7 participants discontinued due to lack of interest or irregular medication adherence, resulting in a final sample size of 47 completers. Of these, 26 participants received the active drug (rosemary) and 21 received a placebo.

There were no significant differences in demographic characteristics between the placebo and rosemary groups ($p>0.05$). The mean age was 42.24±9.48 years in the placebo group and 43.15±9.12 years in the rosemary group. The majority of participants in both groups were male (placebo: 95.24%, rosemary: 92.31%) and married (placebo: 71.43%, rosemary: 65.38%). Levels of education were similar between groups.

No serious or life-threatening adverse events were reported during the trial. The most common side effects in the rosemary group included an unpleasant rosemary aftertaste and mild dizziness during the initial days of treatment; however, none of these led to drug discontinuation.

Anxiety and depression

Analysis demonstrated a statistically significant reduction in anxiety scores (HADS) following intervention with rosemary compared to the placebo group ($p<0.05$, Figure 1A and C). There were no significant differences in depression scores between the groups before and after the intervention (Figure 1B).

Cognitive function

Post-intervention MoCA scores were significantly improved in the rosemary group compared to placebo ($p<0.05$, Figure 2), indicating a positive effect of rosemary on cognitive performance.

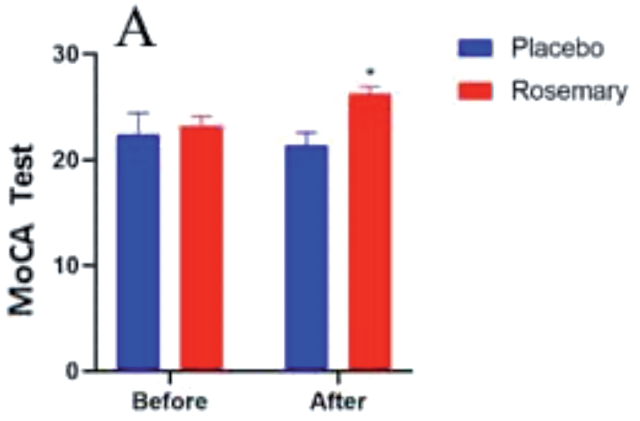

Figure 2. Comparison of patients' Montreal Cognitive Assessment (MoCA) test in two study groups pre- and post-intervention. *p<0.05 compared to the placebo group after the intervention.

Sleep quality

No significant differences were observed in overall sleep indices between the two groups before and after the intervention (Figure 3). However, the morning dysfunction component of the PSQI showed a significant reduction after rosemary administration compared to placebo ($p<0.05$, Figure 3H).

Sexual function

No statistically significant changes were found in sexual functioning parameters, including total CSFQ-14 scores, sexual desire, arousal, pleasure, or orgasm, between the rosemary and placebo groups before or after the intervention (Figure 4).

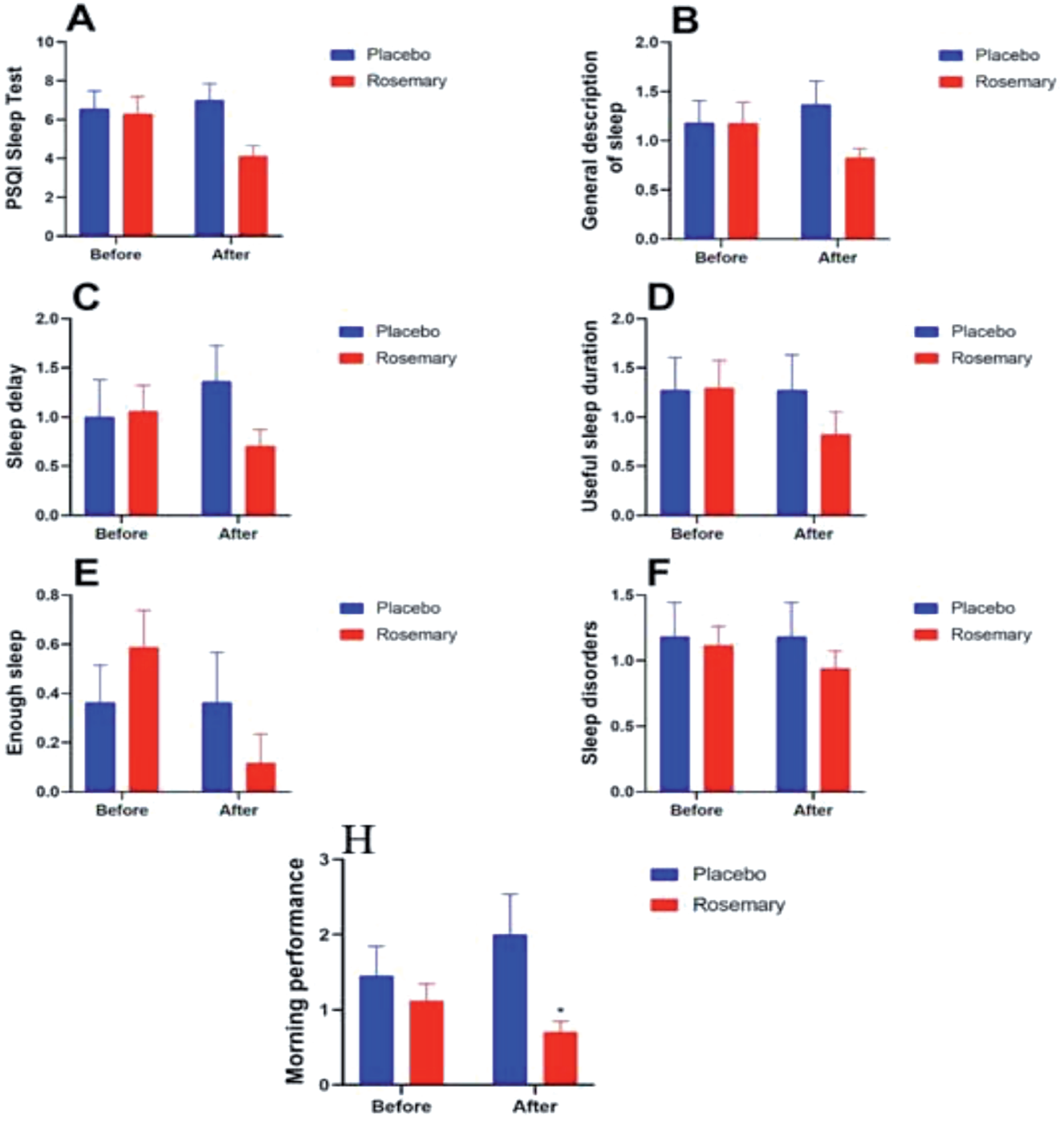

Figure 3. Comparison of sleep indices (A-H) in two study groups pre- and post-intervention. *$p<0.05$ compared to the placebo group after the intervention.

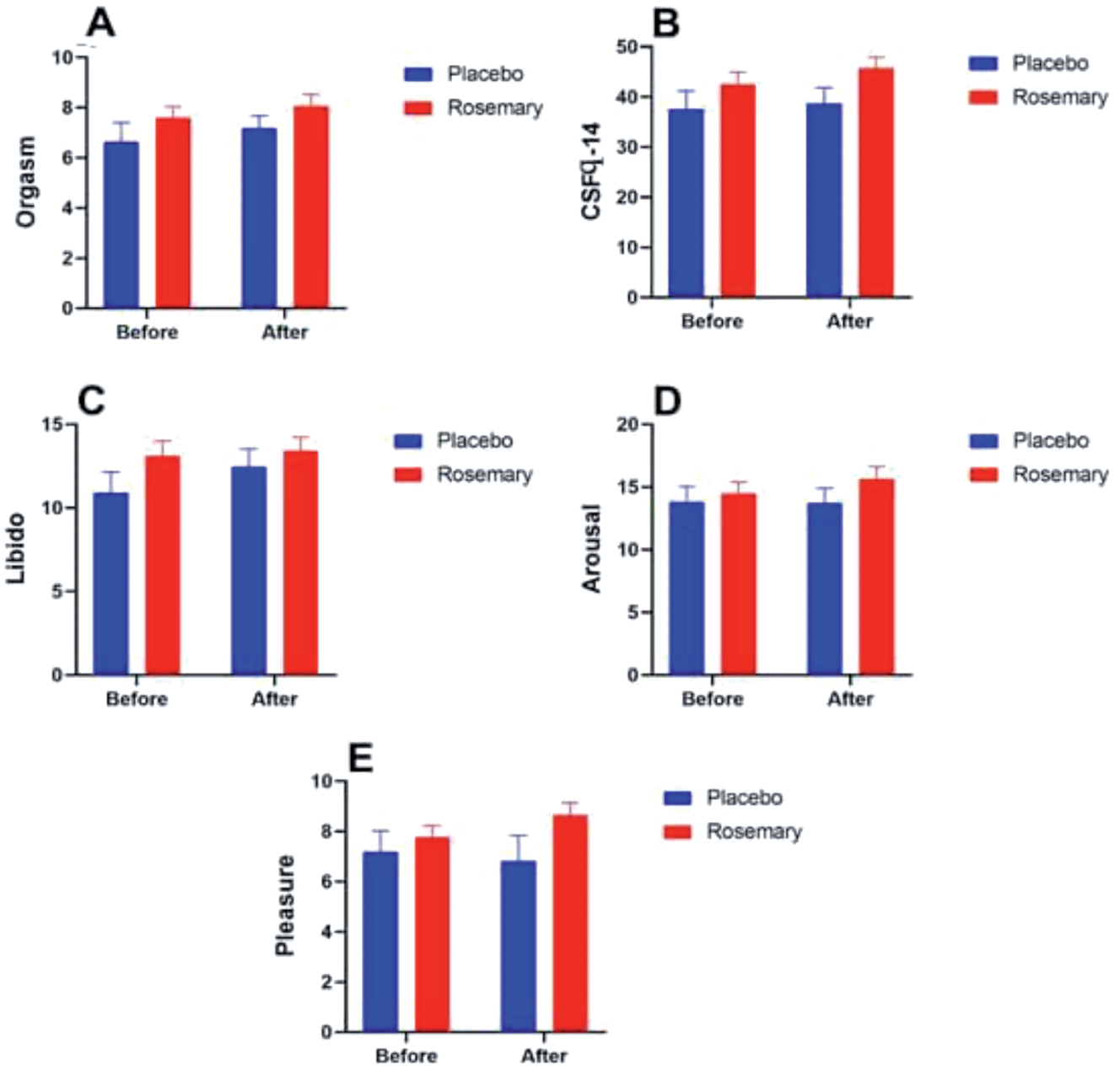

Figure 4. Comparison of sexual performance indices (A-E) in the studied groups in two study groups, pre- and post-intervention. *p<0.05 compared to the placebo group after the intervention.

Discussion

This study is the first to explore the effects of rosemary (*Rosmarinus officinalis* L.) on anxiety, depression, sexual dysfunction, sleep quality, and cognitive impairment among patients undergoing MMT. Our findings indicate that rosemary supplementation exerts a significant anxiolytic effect, improves certain aspects of cognitive function, but does not show substantial effects on depression, sexual function, or most sleep parameters in this patient population.

The observed reduction in anxiety scores, as measured by the HADS, suggests that rosemary possesses notable anxiolytic properties. This is consistent with preclinical investigations; for instance, Noori Ahmad Abadi *et al*. demonstrated that hydroalcoholic extract of rosemary leaves increased open arm entries in the elevated plus maze in mice, indicating anxiolytic activity possibly due to the flavonoid and antioxidant content in rosemary.[27] Similarly, Ghasemzadeh Rahbardar and Hosseinzadeh,[10] in their review, emphasized the anxiolytic and memory-enhancing effects of rosemary extract. Given the high prevalence of anxiety disorders among individuals with opioid use disorder, and the limited efficacy or significant side effects of current pharmacotherapies,

rosemary may represent a promising adjunctive treatment in this context.

Contrary to its effect on anxiety, rosemary supplementation did not significantly influence depressive symptoms in our cohort. This result contrasts with Malik *et al*.,[17] who reported antidepressant effects of rosemary in a murine model, as well as Alvarado-García *et al*.,[19] who found similar benefits in human subjects. This discrepancy may be attributable to differences in study populations, intervention duration, or the unique neurobiological profile of MMT patients, suggesting that rosemary's antidepressant effects may be context-dependent and warrant further exploration.

Regarding cognitive function, our results indicate that rosemary supplementation led to improvements as assessed by the MoCA scale. This aligns with previous reports, such as Malik *et al*.,[17] who found significant cognitive enhancement in an Alzheimer's mouse model following rosemary administration, and Pengelly *et al*.,[28] who reported dose-dependent effects of dried rosemary leaf powder on cognitive performance in elderly adults. Interestingly, Pengelly *et al*. observed that lower doses of rosemary improved memory speed, whereas higher doses had detrimental effects, highlighting the importance of dose optimization in future clinical applications.[28]

With respect to sexual function, our study did not detect significant differences between the rosemary and placebo groups. Although no prior clinical trials have directly examined rosemary's effects on sexual desire, arousal, orgasm, or satisfaction, molecular and preclinical data suggest potential benefits of rosemary on reproductive system function.[29-31] Our findings suggest that these effects may not translate to clinically meaningful improvements in sexual function within the context of MMT, or that a longer intervention period may be required to observe such effects.

In terms of sleep, rosemary did not significantly improve overall sleep quality, except for a decrease in morning dysfunction scores. This limited effect may reflect either a lack of direct impact of rosemary on sleep regulation or insufficient duration of intervention. Previous studies have reported mixed results regarding rosemary's influence on sleep; for example, Solhi *et al*. found that rosemary improved sleep and reduced insomnia in patients undergoing opium withdrawal,[9] and Hosseinzadeh and Nourbakhsh reported reductions in morphine withdrawal syndrome using aqueous and alcoholic extracts of rosemary.[32] Furthermore, Nematolahi *et al*. observed significant improvements in most PSQI components, except sleep latency and duration, after a month of rosemary supplementation in students.[33] The variation in findings across studies suggests that the effect of rosemary on sleep may be context- and population-specific.

Limitations and future directions

Our study is subject to several limitations. First, the sample size was relatively small, which may limit the generalizability of the findings and the statistical power to detect small-to-moderate effects, particularly regarding sexual function and sleep outcomes. Second, the intervention period may have been insufficient to observe the full spectrum of rosemary's potential benefits, especially for parameters such as sexual function and sleep quality. Third, the lack of assessment of biochemical or neurobiological markers precludes mechanistic insights into rosemary's effects. Finally, the study population was limited to MMT patients, and caution should be exercised in extrapolating the results to other populations or settings. Future research should include larger, multi-center randomized controlled trials with longer intervention durations, varying doses, and incorporation of mechanistic assessments (*e.g*., neuroimaging, inflammatory markers, hormonal profiles). Comparative studies with other herbal or pharmacological agents may further clarify rosemary's therapeutic potential. Given the context-dependent effects observed, subgroup analyses based on baseline psychiatric comorbidity, sex, and duration of opioid use may also be informative. Ultimately, elucidating the optimal dosing regimens and mechanistic pathways will be crucial for the clinical translation of rosemary as an adjunctive therapy in MMT and potentially other clinical populations.

Conclusions

This randomized, double-blind, placebo-controlled trial demonstrates that standardized rosemary extract supplementation offers significant anxiolytic and cognitive benefits for patients undergoing MMT, without notable effects on depression, sexual function, or overall sleep quality. The anxiolytic and cognitive-enhancing properties observed align with preclinical and limited clinical evidence, suggesting rosemary may serve as a promising adjunct for addressing the neuropsychiatric burden associated with opioid dependence. Importantly, rosemary was well-tolerated, with no serious adverse events reported. However, the absence of significant improvements in depressive symptoms, sexual function, and most sleep parameters highlights the complexity of neuropsychiatric sequelae in MMT patients and underscores the need for further research. Future large-scale, multi-center studies with longer intervention periods, mechanistic assessments, and dose optimization are warranted to fully elucidate rosemary's therapeutic potential and to define its role within comprehensive addiction treatment regimens. In summary, rosemary extract represents a safe and accessible adjunctive option with specific neuropsychiatric benefits that could enhance recovery and quality of life for individuals receiving methadone maintenance therapy.

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Ethics approval and consent to participate: the current study has an ethics approval code with ID number IR.KMU.AH.REC.1403.021 in the Ethics Committee of Kerman University of Medical Sciences.

Informed consent: informed consent was obtained from participants for their involvement in the study, and their information was used with complete confidentiality.

Patient consent for publication: all participants provided informed consent, were fully informed about the study, and their anonymized data were used ethically, following all research guidelines.

Availability of data and materials: data and materials are available from the corresponding author upon request.