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Enhancing the mental well-being of postmenopausal women using ExoTMS®

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Abstract

Mental well-being may be adversely affected during menopause. This study examines the effects of a novel ExoTMS® technology on its improvement. Postmenopausal female participants (n=14; 61.8±7.8 years; body mass index: 22.5±2.5 kg/m²) were retrospectively selected from a multi-center study. Participants underwent four transcranial magnetic stimulation (TMS) sessions. Evaluation was performed using the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS), Subject Satisfaction and Mental Wellness Questionnaire, and Therapy Comfort Questionnaire. WEMWBS significantly increased (p=0.001) from a baseline of 54.4±9.4 (moderate well-being) to 62.8±8.8 (high well-being) at 3 months post-treatment. 92.9% of participants reported feeling happier and experiencing greater mental energy. All participants reported feeling less stressed and found the treatment comfortable. These findings suggest that ExoTMS may serve as an effective intervention for enhancing mental well-being in postmenopausal women.

Key words: postmenopausal, mental well-being, mental health, ExoTMS, transcranial magnetic stimulation.

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Introduction

Mental well-being extends beyond the mere absence of illness. According to the American Psychological Association, it is a state of emotional well-being, effective behavioral adjustment, relative freedom from anxiety and debilitating symptoms, and the capacity to form constructive relationships and cope with everyday life stressors.¹ It is closely interrelated with both physical and mental health and behavior.

Menopause represents a life stage during which mental well-being may be adversely affected due to physical, emotional, and psychological strain.² The decline in estrogen levels characteristic of this period increases numerous physical health risks, such as cardiovascular diseases, metabolic syndrome, or osteoporosis.³ Additionally, the decline in estrogen levels and its modulatory effects on the structure and function of the prefrontal cortex, particularly the dorsolateral prefrontal cortex (DLPFC), have been implicated in cognitive and psychological symptoms such as depression and anxiety,^{4,5} which have been observed to be up to three times more prevalent with the onset of menopause.⁶ DLPFC is critical for working memory, attention, decision-making, and emotional and behavioral regulation, which are key components for fostering mental well-being.⁷⁻⁹ Collectively, these changes substantially affect women's quality of life and mental health.

Transcranial magnetic stimulation (TMS), a non-invasive brain stimulation technique developed in the 1980s, has demonstrated efficacy in modulating DLPFC activity and promoting neuroplastic

changes, with established use in the treatment of various psychiatric disorders.¹⁰

More recently, a novel TMS employing ExoTMS® technology has been introduced. This technology improves treatment comfort and magnetic field delivery through ramp-up shaped pulses, parallel coil wiring with dual cores, and an advanced air-cooling system. Findings from a recent study suggest ExoTMS® may show promise in enhancing mental well-being in general non-clinical populations.¹¹

This retrospective analysis aims to examine the mental well-being of postmenopausal women and evaluate the effects of ExoTMS® on its improvement.

Materials and Methods

This retrospective analysis was based on data from a multi-center, single-arm, open-label study (ClinicalTrials.gov ID: NCT06899646). Postmenopausal female participants were selected from the original study cohort based on their medical histories.

The study was approved by the institutional review board Advarra (Pro00079676) and conducted between July and October 2024 at three centers (Arizona, Florida, and New York, USA). Inclusion criteria were: age ≥22 years; ability to determine the participant's motor threshold; willingness and ability to abstain from other mental well-being treatments during the study; compliance with study instructions; and use of birth control in women of child-bearing age. Exclusion criteria included contraindications to TMS, such as electronic implants or metallic objects in or near the head,

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seizure history, current anticoagulation therapy, or brain lesions. Pregnant or nursing women and individuals diagnosed with eating disorders, post-traumatic stress disorder, psychotic disorders or symptoms, bipolar disorder, obsessive-compulsive disorder, or borderline personality disorder were also excluded. Written informed consent was obtained from all participants.

Participants received four TMS treatments (EXOMIND, BTL Industries, Boston, MA, USA) with ExoTMS® technology targeting the left DLPFC, spaced 5-10 days apart. Treatment parameters included: 24.5-minute stimulation sessions with frequencies of 12 Hz, 15 Hz, and 18 Hz; train duration of 2 seconds; inter-train interval of 5 seconds; and intensity up to 100% of the individual's motor threshold. A total of 25,200 pulses were delivered to each participant.

Mental well-being was assessed using the validated 14-item Warwick-Edinburgh Mental Well-Being Scale (WEMWBS), which employs a 5-point Likert scale (0 = none of the time, 5 = all of the time), yielding total scores between 14 and 70, with higher scores indicating greater well-being. Well-being was categorized as low (≤ 43), moderate (44-60), or high (≥ 61). Assessments were conducted at baseline, final treatment visit, and at 1-month and 3-month follow-ups.

Subject satisfaction and self-reported changes in well-being were evaluated using the 5-point Likert-based Subject Satisfaction and Mental Wellness Questionnaire (SSMQ), administered at the final treatment visit and at both follow-ups.

Treatment comfort was evaluated using the Therapy Comfort Questionnaire, which included agreement with the statement "I found the treatment comfortable" (0 = strongly disagree, 5 = strongly agree) and the Numerical Rating Scale for pain (NRS) (0 = no pain, 10 = worst possible pain), completed after the final session.

Descriptive statistics were calculated. Friedman's test was performed for the statistical analysis, with a significance threshold set at $\alpha=0.05$.

Results

A total of 14 postmenopausal participants (mean age: 61.8 ± 7.8 years; body mass index: 22.5 ± 2.5 kg/m²) were included. All sub-

jects completed the treatments and both follow-up visits. Eight participants were employed, five were retired, and one was unemployed. Relationship status included seven participants who were married or cohabiting, four singles, one dating, one divorced, and one widowed. Nine participants rated their health as very good, and five as good. Two had a diagnosis of depression, and five were on psychiatric medications. No adverse events or side effects were reported in this cohort.

Warwick-Edinburgh Mental Well-Being Scale

The average baseline WEMWBS score was 54.4 ± 9.4 , which increased significantly ($p=0.001$) to 61.4 ± 8.2 (by 7.0 ± 5.6) post-treatment, 62.2 ± 8.0 (by 7.9 ± 8.8) at 1-month follow-up, and 62.8 ± 8.8 (by 8.4 ± 8.0) at the 3-month follow-up.

At baseline, 4 participants were categorized as having high well-being, 8 as moderate, and 2 as low. At the final-treatment and 1-month assessments, 10 participants were in the high category, 3 in moderate, and 1 in low. By the 3-month follow-up, 11 participants were classified as having high well-being, 2 as moderate, and 1 as low. All individuals initially in the moderate category improved to high well-being at 3 months, corresponding to a 2.75-time increase in the number of participants classified as having high well-being. In total, 92.9% of participants (13 out of 14) showed improvement in their WEMWBS scores by the 3-month follow-up (see Figure 1 for category distribution over time).

Subject satisfaction and therapy comfort

The mean agreement across all SSMQ items, subjects, and time points was 4.1 out of 5. The average percentage of participants' agreement with SSMQ items was 76.9% post-treatment, 74.7% at 1 month, and increased to 80.8% at 3 months.

At the 3-month follow-up, all participants reported feeling less stressed, and 92.9% felt happier, thought more positively, and had more mental energy. 85.7% reported being more engaged in daily activities, feeling calmer, having an improved ability to handle challenging situations, falling asleep more easily, being more focused, and having an improved mood. 78.6% felt less depressed, anxious, and nervous, reported greater motivation and confidence, and stated

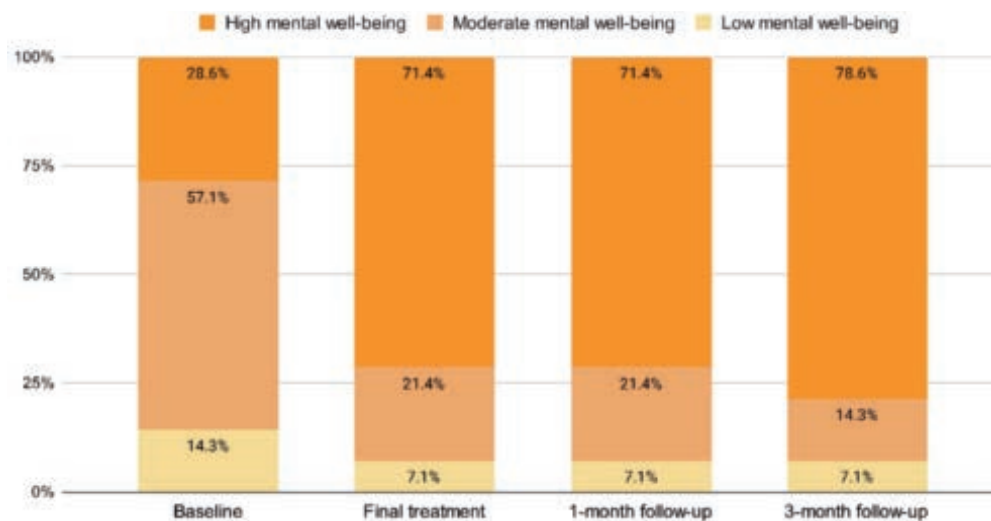


Figure 1. Percentage distribution of participants in individual Warwick-Edinburgh Mental Well-Being Scale categories over time. The proportion of participants with high well-being increased 2.75 times at the 3-month follow-up.

improved sleep quality. Notably, all participants diagnosed with depression expressed feeling less depressed, anxious, and stressed, while feeling more motivated, focused, confident, and having more mental energy. See Table 1 for SSMQ results.

All participants reported the treatment as comfortable, with a mean pain score of 0.0 ± 0.0 on the NRS.

Discussion

This study examined mental well-being among postmenopausal women and evaluated the effects of ExoTMS® technology on its enhancement. All levels of well-being were represented within the sample, with most participants (57%) initially classified as having moderate well-being, 29% as high, and 14% as low. Following ExoTMS® intervention, WEMWBS scores progressively and significantly increased, reaching a mean score of 62.8 ± 8.8 at the 3-month follow-up, indicative of high well-being.

At 3 months, 92.9% of participants demonstrated improvement in WEMWBS scores, and all individuals initially classified with moderate well-being transitioned to the high well-being category. This finding contrasts with the results reported by Huang *et al.*,¹² who observed no improvement in depressive symptoms among postmenopausal participants. Although depression and mental well-being represent distinct constructs, both are dependent on adequate activity within the DLPFC, with increased activation in this region consistently linked to improvements in both depressive symptoms and mental well-being.¹³⁻¹⁵ Huang *et al.* suggested that the reduced responsiveness to TMS observed in their study may be attributed to postmenopausal hormonal changes, specifically the altered estrogen to progesterone ratio, along with elevated levels of follicle-stimulating hormone and luteinizing hormone. Indeed, higher estrogen levels have been linked to increased cortical excitability and enhanced

responsiveness to TMS, whereas elevated progesterone levels are associated with reduced cortical excitability.¹⁶ However, the hormonal profile of the cohort in the present study is unlikely to differ significantly from that of Huang *et al.*'s participants, suggesting that hormonal status alone does not account for the divergent outcomes.

In addition to hormonal influences, TMS efficacy is dependent on stimulation parameters, which may explain the more favorable results observed in this study. Prior evidence indicates that higher stimulation frequencies (>10 Hz) and an increased number of pulses are associated with improved therapeutic response.¹⁷ In the present study, both the stimulation frequency and intensity were consistent with these parameters. Moreover, the ExoTMS system's air-cooling mechanism and dual-core coil applicator enabled a higher number and efficiency of delivered pulses per session, which may have further contributed to the observed improvements in mental well-being.

In comparison with the original study population, postmenopausal participants in the present analysis exhibited slightly greater gains in WEMWBS scores, as well as higher self-reported improvements and satisfaction with treatment outcomes. These findings further support the efficacy of ExoTMS technology in this demographic. High self-reported improvements in stress reduction, mood, motivation, confidence, mental energy, and sleep quality suggest a potential mitigation of menopause-related cognitive and psychological symptoms.

Higher levels of mental well-being have been associated with stress resilience, better recovery outcomes from both physical and mental illnesses, as well as with improved quality of life and increased longevity.^{14,18,19} Given that women spend approximately one-third of their lives in the postmenopausal phase, during which they are at elevated risk for various health challenges, supporting mental well-being serves as a proactive strategy for promoting overall health and longevity.

Table 1. Percentage of subjects in agreement with the statements of the Subject Satisfaction and Mental Wellness Questionnaire across time points.

SSMQ Item	Percentage of subjects in agreement with the statement (%)		
	Final treatment	1 month	3 months
I feel less depressed after the treatments	78.6	78.6	78.6
I feel less anxious after the treatments	85.7	71.4	78.6
I feel more engaged with my daily activities after the treatments	78.6	85.7	85.7
I feel more calm after the treatments	92.9	85.7	85.7
I feel less stressed after the treatments	78.6	85.7	100.0
I feel I can better handle challenging situations after the treatments	71.4	71.4	85.7
I feel happier after the treatments	64.3	85.7	92.9
My quality of sleep has improved after the treatments	71.4	57.1	78.6
I find it easier to fall asleep after the treatments	78.6	71.4	85.7
I feel more motivated after the treatments	78.6	85.7	78.6
I am able to stay more focused after the treatments	85.7	71.4	85.7
I feel more confident about myself after the treatments	85.7	78.6	78.6
I think more positively after the treatments	92.9	85.7	92.9
I feel I am in a good mood after the treatments	100.0	85.7	85.7
I have more mental energy after the treatments	85.7	71.4	92.9
I feel less nervous after the treatments	71.4	71.4	78.6
I feel the treatments have improved my mood	92.9	78.6	85.7
I feel more at ease in social gatherings	64.3	78.6	78.6
I feel this treatment has improved my mental wellness	71.4	71.4	78.6

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Despite these promising results, several limitations must be acknowledged. The study sample was relatively small, the follow-up period was limited to 3 months, and no control or sham group was included. However, notable strengths include the use of the psychometrically validated WEMWBS and the integration of both objective and subjective outcome measures. Future research should incorporate larger sample sizes, extended follow-up periods, and appropriate control conditions to further validate these findings.

Conclusions

At baseline, postmenopausal women demonstrated, on average, moderate levels of mental well-being. Following ExoTMS® treatment, participants attained high levels of well-being, with continued improvement observed through the 3-month follow-up. These findings suggest that ExoTMS® may be an effective intervention for enhancing mental well-being in postmenopausal women.

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Informed consent: each patient signed a written informed consent form.

Patient consent for publication: each patient provided consent for publication.

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