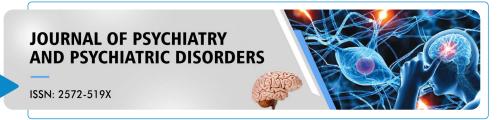


#### **Research Article**



# ExoTMS<sup>TM</sup> Technology: A Novel Breakthrough in Transcranial Magnetic **Stimulation for Enhancing Mental Well-Being**

Michelle Dees1\*, Yael Halaas2, JD McCoy3

#### **Abstract**

Background: Mental well-being encompasses emotional, psychological, and social health. In today's world, new stressors and challenges continue to emerge, contributing to a decline in overall well-being. This study aims to evaluate the effects of ExoTMS<sup>TM</sup> brain stimulation technology on enhancing mental well-being and assessing subject satisfaction, therapy comfort, and procedural safety.

**Methods:** 33 subjects (n= 33, 26 females, 7 males, 49.8±15.1 years) received 4 ExoTMS<sup>TM</sup> sessions. The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) was used to assess mental well-being at baseline, after the final treatment, and at the 1-month and 3-month followups. Subject satisfaction, therapy comfort and procedural safety were also

Results: The observed changes in WEMWBS scores were statistically significant (p<0.001), with an average increase of 6.7±6.4 points posttreatment, 7.6±8.0 points at 1 month, and 6.8±8.0 points at 3 months. The percentage of participants experiencing an increase in WEMWBS scores was 78.8% post-treatment, 84.8% at 1 month, and peaked at 87.5% at 3 months. Subjects self-reported improvements in mood, confidence, mental energy, the feelings of stress, depression, anxiety, as well as sleep onset and quality. 90.9% of subjects found the treatments comfortable.

Conclusion: The study results indicate ExoTMS<sup>TM</sup> treatments as a promising approach in enhancing mental well-being, showing efficacy across all WEMWBS well-being categories, from low to high. The noninvasive treatment reached significant results with four sessions, while ensuring high therapy comfort and subject satisfaction.

**Keywords:** Transcranial magnetic stimulation; TMS; Well-being; ExoTMSTM.

# Introduction

Mental well-being encompasses emotional, psychological, and social health and is a fundamental component of overall health [1]. It extends beyond the absence of mental illness, representing a state of mind that enables individuals to cope with life's stresses, recognize their abilities, learn and work effectively, build meaningful relationships, and contribute to their communities [2]. Enhancing well-being, therefore, benefits both individuals and society as a whole. Various factors contribute to mental well-being, ranging from protective psychological and biological factors, to strong social ties and favorable environmental conditions [2]. In today's world, new stressors and challenges are emerging, including demanding work environments,

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financial instability, and environmental uncertainties, all contributing to declining well-being [1]. Additionally, the prevalence of loneliness and mental illnesses, significant risk factors of poor well-being, are rising [3, 4]. The decline in mental health can be partly attributed to social media's negative impact on self-esteem [5, 6]. This is evident in the increasing number of performed cosmetic procedures, with studies indicating that nearly 50% of patients undergoing such treatments meet diagnostic criteria for a psychiatric disorder [7]. Among crucial factors influencing mental wellbeing are the brain's functioning and its cells, particularly in the dorsolateral prefrontal cortex (DLPFC). The adequate functioning of this brain region is necessary for behavioral regulation, fostering emotional resilience and effective coping strategies [1]. Hypoactivity in this area results in the lack of regulatory influence of prefrontal circuits, [8] compromising mental well-being. Decreased or dysregulated DLPFC activity has been associated with various mental health conditions. [8] Conversely, increased DLPFC activation is associated with more positive interpretations of negative experiences, improved mood, and overall mental well-being [9-12]. However, in today's fast-paced world, chronic stress, overstimulation from technology can also negatively impact the DLPFC in otherwise healthy individuals [13-15].

Strategies for improving mental health predominantly include psychological interventions. These methods, however, often require significant effort and commitment from patients, with long treatment durations (20 sessions on average) and sometimes limited effectiveness [16, 17]. As a result, high dropout rates are common [18, 19], highlighting the need for alternative approaches. One such alternative is transcranial magnetic stimulation (TMS), a well-established, safe, and non-invasive method for enhancing brain function. The TMS coil emits an electromagnetic field, which surpasses the skull and induces an electric field in the underlying cortical neurons, modulating their excitability [20]. Based on the applied TMS protocol, neural excitation can be increased or decreased. TMS pulses delivered at lower frequencies (≤1 Hz) are considered to have an inhibitory effect on neurons, while higher frequencies (≥5 Hz) an excitatory effect [21]. The altered excitability extends beyond the stimulation, leading to long-lasting effects through neuroplastic changes [20-22]. Beyond localized cortical stimulation, TMS exerts widespread effects on neural networks by modulating connectivity between different brain regions [22]. TMS has been proven effective in treating several mental illnesses, including major depression, substance addiction, and obsessive-compulsive disorder [21]. Although TMS is a safe method with few associated side effects, some patients may experience mild discomfort during or after the procedure [23]. A novel advancement in TMS is represented by the ExoTMS™ technology. This technology was developed to enhance patient comfort using ramp-up shaped TMS pulses,

which, compared to traditional rectangular pulses, gradually delivers magnetic energy to brain cells. Additionally, the technology features patented parallel wiring with dual cores in the applicator coil, optimizing magnetic field efficiency. Its advanced air-cooling system further enhances performance by reducing energy loss and maximizing magnetic field delivery. By stimulating the DLPFC, ExoTMS<sup>TM</sup> increases the excitation in this area, thereby supporting emotion processing and regulation [10]. This study aims to evaluate the effects of ExoTMS<sup>TM</sup> brain stimulation technology on enhancing mental well-being, as well as assessing subject satisfaction, therapy comfort, and procedural safety.

# **Materials and Methods**

This prospective, multicenter, interventional, open-label study was approved by the institutional review board Advarra (Pro00079676) and adhered to the Declaration of Helsinki. The study is registered at the clinicaltrials.gov site under NCT06899646, and was conducted according to the protocol. Criteria for selecting the subjects were as follows: age of 22 and over; the ability to determine the motor threshold of the participant; willingness and ability to abstain from partaking in any treatments other than the pre-procedure therapy regimen for the improvement of mental well-being; willingness to comply with study instructions; and usage of birth control measures in women of childbearing age. Exclusion criteria included any contraindications for the application of TMS, such as the presence of electronic implants in or near the head, drug pumps, a tendency to seizures, ongoing anticoagulation therapy, or vascular, traumatic, tumoral, infectious, or metabolic lesions of the brain. Pregnant or nursing women, and individuals diagnosed with eating disorders, post-traumatic stress disorder, psychotic disorders or current psychotic symptoms, bipolar disorder, obsessivecompulsive disorder, or borderline personality disorder were excluded from the study. Participants were recruited from three centers (Arizona, Florida and New York, USA) from July through October 2024. All subjects were informed about study procedures and signed written informed consent. Demographic characteristics such as age, gender, relationship and employment status, self-perceived physical health, presence of psychiatric diagnosis, and psychiatric medication were collected at the baseline visit using a questionnaire.

Participants underwent four treatments targeting the left dorsolateral prefrontal cortex (DLPFC) using the EXOMIND device (BTL Industries, Boston, MA, USA) with ExoTMS<sup>TM</sup> Technology. The individual treatments were spaced 5–10 days apart. Each stimulation lasted 24.5 minutes. Applied frequencies were 12 Hz, 15 Hz and 18 Hz. Each train lasted 2s, inter-train duration was 5s. The intensity was set according to the subject's feedback, up to 100% of their motor threshold (MT). The MT was defined as the minimum single-pulse energy required to observe a contraction in the abductor



muscle of the thumb. Follow-up visits were scheduled 1 month and 3 months after the final treatment. The validated Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) was administered at baseline, after the final treatment, and at both follow-up visits to assess post-treatment changes in mental well-being. The WEMWBS is a 14-item self-report questionnaire covering both the hedonic perspective, which refers to the subjective experience of happiness and life satisfaction, and the eudaimonic perspective, which focuses on psychological functioning and self-realization24. Items are rated on a 5-point Likert scale (0 = none of the time, 5 = all of the time). The total score ranges from 14 to 70, with higher scores indicating greater mental well-being. Based on WEMWBS scores, mental well-being can be categorized into three levels: low well-being (≤43), moderate well-being (44-60), and high well-being (≥61). A score below 44 is indicative of depression.25 Improvement was defined as an increase in score.

Subject satisfaction with outcomes and self-reported changes in mental well-being was assessed using the Subject Satisfaction and & Mental Wellness Questionnaire (SSMQ), given to participants after the final treatment and at followup visits. The 22-item SSMO included statements addressing various aspects of mental wellness, such as mood, anxiety, stress, motivation, sleep quality, cognitive function, eating behaviors, and social engagement. Participants expressed their level of agreement with the statements based on a 5-point Likert scale (0= strongly disagree, 5= strongly agree). Evaluation of therapy comfort was performed using the Therapy Comfort Questionnaire (TCQ), which included the level of agreement with the statement "I found the treatment comfortable" based on the 5-point Likert scale (0= strongly disagree, 5= strongly agree) and the Numerical Rating Scale for pain (NRS), where 0 indicates no pain and 10 indicates the worst possible pain. The TCQ was completed after the final treatment. Descriptive statistics were generated for all variables. Statistical significance was assessed using Friedman's test (GraphPad Prism, GraphPad Software, Boston, MA), with the significance level set at  $\alpha$ = 0.05. Regression analysis was conducted to examine the relationship between demographic variables and 1-month WEMWBS percentual change, as well as the association between baseline score and the 1-month percentual change, as this time point exhibited the greatest change.

#### **Results**

Thirty-eight participants (n=38) were enrolled in the study. Five participants were excluded due to dropout: personal reasons (n=2), ineligibility (n=1), and dislike of treatment sensation (n=2). Thirty-three subjects (n=33, 26 females, 7 males, 49.8±15.1 years) completed all treatments and the 1-month follow-up. One subject was lost to the 3-month follow-up. Thirteen subjects (n=13) had a psychiatric

diagnosis, among them twelve (n=12) were diagnosed with depression and one with anxiety. The demographic characteristics are detailed in Table 1. The average measured motor threshold was  $73.3\pm12.1\%$ . Participants were, on average, treated by the intensity of  $98.3\pm4.8\%$  on the  $1^{st}$  treatment,  $98.3\pm4.6\%$  on the  $2^{nd}$  treatment,  $99.1\pm3.6\%$  on the  $3^{rd}$  treatment and  $97.8\pm7.8\%$  on the last treatment.

**Table 1:** Demographic characteristics of the study sample, N-number, SD-standard deviation

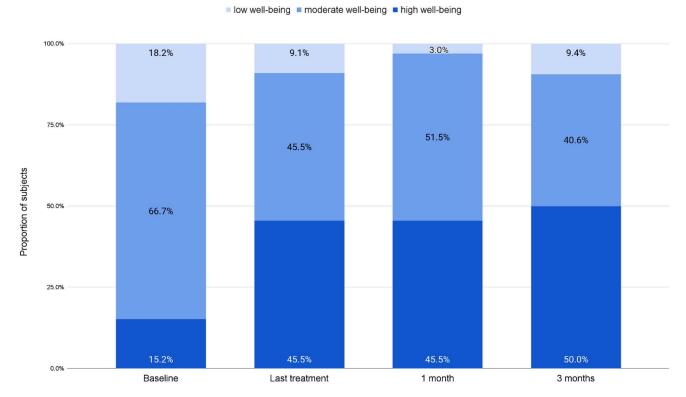
|                                 | N  | Percent | Mean | SD   |
|---------------------------------|----|---------|------|------|
| Age                             |    |         | 49.8 | 15.1 |
| Gender                          |    |         |      |      |
|                                 | _  | 04.00/  |      |      |
| Male                            | 7  | 21.2%   |      |      |
| Female                          | 26 | 78.8%   |      |      |
| Employment status               |    |         |      |      |
| In work                         | 26 | 78.8%   |      |      |
| Unemployed                      | 1  | 3.0%    |      |      |
| Student                         | 0  | 0.0%    |      |      |
| Retired                         | 6  | 18.2%   |      |      |
| Other                           | 0  | 0.0%    |      |      |
| Relationship status             |    |         |      |      |
| Single                          | 6  | 18.2%   |      |      |
| In romantic relationship/dating | 4  | 12.1%   |      |      |
| Married/living as couple        | 19 | 57.6%   |      |      |
| Divorced                        | 2  | 6.1%    |      |      |
| Separated                       | 1  | 3.0%    |      |      |
| Widowed                         | 1  | 3.0%    |      |      |
| Self-perceived health           |    |         |      |      |
| Very good                       | 12 | 36.4%   |      |      |
| Good                            | 18 | 54.5%   |      |      |
| Fair                            | 3  | 9.1%    |      |      |
| Poor                            | 0  | 0.0%    | 0.0% |      |
| Very poor                       | 0  | 0.0%    |      |      |
| Psychiatric diagnosis           |    | l       |      |      |
| Currently ongoing               | 12 | 36.4%   |      |      |
| In the past                     | 1  | 3.0%    |      |      |
| Absent                          | 20 | 60.6%   |      |      |
| Psychiatric Medication          |    | l       |      |      |
| Currently ongoing               | 14 | 42.4%   |      |      |
| In the past                     | 1  | 3.0%    |      |      |
| Negative                        | 18 | 54.6%   |      |      |



# Warwick-Edinburgh Mental Well-Being Scale

Initially, 6 subjects were categorized as having low well-being, 22 with moderate well-being, and 5 with high well-being. The average baseline WEMWBS scores were 50.6±9.7 for all subjects, 34.5±5.2 for subjects with low well-being, 52.3±4.9 points for those with moderate wellbeing, and 62.6±1.7 points for those with high well-being. The average baseline score for depressive subjects (n=12) was 43.7±10.0. Multiple regression analysis did not show any significant differences between the baseline scores and demographic variables (p> 0.05). Among participants with initial low well-being, 50.0% improved to the moderate category post-treatment. At the 1-month follow-up, the proportion of participants who transitioned to the moderate category increased to 66.7%, while 16.7% advanced to the high well-being category. By the 3-month mark, the proportion of participants who changed categories remained consistent with the final treatment assessment, with 50.0% moving to the moderate category. Their score increased on average by 11.7±6.3 points post-treatment, by 15.7±9.5 points at 1 month, and by 10.4±10.1 points at the 3-month follow-up. Among participants classified initially as having moderate well-being, 50.0% transitioned to the high wellbeing category post-treatment. This proportion remained stable at 1 month and further increased to 54.5% at the 3-month follow-up. Their mean score increase was  $6.4\pm5.9$  points post-treatment,  $6.9\pm5.9$  points at 1 month, and  $7.0\pm7.6$  points at 3 months. Participants with high well-being at baseline exhibited a mean score increase of  $1.8\pm4.9$  points post-treatment,  $0.8\pm8.0$  points at 1 month, and  $2.2\pm6.7$  points at 3 months. The proportional distribution of mental well-being categories across time points is illustrated in Figure 1.

The subgroup with depression diagnosis demonstrated an increase of 7.6±6.3 points post-treatment, 10.3±9.3 points after 1 month, and 8.1±10.3 points at 3 months. Among these subjects, 4 subjects had initially low well-being, 7 had moderate well-being, and 1 had high well-being. Of those with low well-being and a depression diagnosis, 25.0% improved to the moderate well-being category after treatment, with this proportion increasing to 50.0% at both follow-ups. Additionally, 25.0% of this group reached high well-being at 1 month post-treatment. Among participants who began with moderate well-being, 28.6% transitioned to high well-being following treatment and maintained this improvement at both follow-ups. Across all subjects, the observed changes in WEMWBS scores were statistically significant (p<0.001), with an average increase of 6.7±6.4 points post-treatment, 7.6±8.0 points at 1 month, and 6.8±8.0 points at 3 months. The proportion of participants experiencing an increase in WEMWBS scores was 78.8%



**Figure 1:** The percentage of subjects in individual mental well-being categories, as measured by the WEMWBS score, changed over time. The graph illustrates the gradual increase in the percentage of individuals with high well-being and a corresponding decrease in those with low well-being.

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post-treatment, 84.8% at 1 month, and peaked at 87.5% at 3 months. Several subjects experienced unexpected negative life events (such as illness, bereavement or divorce). Three reported such events at the final treatment visit; nonetheless, all three showed improvement (on average by 12.0 points). At the one-month follow-up, four subjects reported a negative life event. Among them, one showed a decrease in WEMWBS score by 12.0 points, two showed improvements averaging 10.0 points, and one maintained their baseline score. At the three-month follow-up, five subjects reported a negative life event. Of these, two experienced a decrease in WEMWBS score averaging 7.0 points, while the remaining three showed improvements averaging 4.0 points. Multiple regression analysis examining the relationship between demographic variables and the 1-month percentual change in WEMWBS score identified unemployment ( $\beta = 0.607$ , p = 0.022) and being in a romantic relationship or dating ( $\beta$  = 0.634, p = 0.033) as significant predictors of improvement. No other demographic variables significantly predicted the change in well-being scores. Additionally, simple linear regression indicated that the lower baseline WEMWBS score was a significant predictor of the 1-month percentual score improvement ( $R^2 = 0.533$ , F(1,31) = 35.38,  $\beta = -1.650$ , p < 0.001).

# Subject Satisfaction and Mental Wellness Ouestionnaire

The average satisfaction score across all 22 items of the SSMQ was consistently 4 out of 5 both after the final treatment and at both follow-up visits. Notably, at 3 months, over 70% of participants reported that the treatments improved their mental wellness and mood. They felt less stressed, happier, in a good mood, more calm, had more mental energy, were able to stay more focused, thought more positively, found it easier to fall asleep and their sleep quality improved. Additionally, 60-70% of participants reported feeling less nervous, anxious and depressed, more motivated and confident, as well as handling challenging situations better, and being more engaged with daily activities, see Table 2.

Among participants diagnosed with depression, at 3 months, over 80% reported the treatments improved their mental wellness and mood, feeling less depressed and stressed, being in a good mood after the treatments, thinking more positively, and finding it easier to fall asleep. Meanwhile, 75.0% reported feeling less anxious, more confident, having more mental energy, being able to stay focused more, handle challenging situations better, and recall names and where they left their keys better, as well as improved sleep quality. Additionally, 66.7% felt more calm, happier and less nervous.

Table 2: Percentage of subjects in agreement with selected items of the Subjects Satisfaction and Mental Wellness Questionnaire across time points in all participants

| Otatamant   | Percentage of subjects in agreement with the statement |         |          |  |
|---|--|---------|----------|--|
| Statement   | Last treatment   | 1 month | 3 months |  |
| I feel less depressed after the treatments.                                 | 69.7%  | 69.7%   | 65.6%    |  |
| I feel less anxious after the treatments.                                   | 66.7%  | 66.7%   | 65.6%    |  |
| I feel more calm after the treatments.                                      | 84.8%  | 75.8%   | 75.0%    |  |
| I feel less stressed after the treatments.                                  | 72.7%  | 72.7%   | 78.1%    |  |
| I feel I can better handle challenging situations after the treatments.     | 60.6%  | 66.7%   | 68.8%    |  |
| I feel happier after the treatments.  | 63.6%  | 75.8%   | 75.0%    |  |
| My quality of sleep has improved after the treatments.                      | 60.6%  | 60.6%   | 71.9%    |  |
| I find it easier to fall asleep after the treatments.                       | 66.7%  | 66.7%   | 78.1%    |  |
| I am able to stay more focused after the treatments.                        | 75.8%  | 63.6%   | 71.9%    |  |
| I feel more confident about myself after the treatments.                    | 72.7%  | 63.6%   | 68.8%    |  |
| I think more positively after the treatments.                               | 78.8%  | 69.7%   | 75.0%    |  |
| I feel I am in a good mood after the treatments.                            | 87.9%  | 84.8%   | 81.3%    |  |
| I have more mental energy after the treatments.                             | 78.8%  | 75.8%   | 75.0%    |  |
| I feel the treatments have improved my mood.                                | 81.8%  | 72.7%   | 71.0%    |  |
| I feel this treatment has improved my mental wellness.                      | 72.7%  | 75.8%   | 71.9%    |  |
| My ability to remember people's names or where I left my keys has improved. | 51.5%  | 54.5%   | 59.4%    |  |

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68.3% reported feeling more motivated and at ease at social gatherings. For the full descriptions, see Table 3. For the full description of the SSMQ results, see Supplementary Table S1.

# Therapy Comfort Questionnaire and Procedure Safety

90.9% of subjects found the treatment comfortable. The

average score on the Numerical Rating Scale for pain was 0.2±0.8 out of 10 points, indicating the treatment was painless. No serious adverse events or side effects occurred throughout the study. One subject, however, reported mild side effects in the form of headache, nausea and mood changes after the 1st treatment.

Table 3: Percentage of subjects in agreement with selected items of the Subjects Satisfaction and Mental Wellness Questionnaire across time points in the subgroup with depression diagnosis

| Statement   | Percentage of subjects with depression diagnosis in agreement with the statement |         |          |  |
|---|--|---------|----------|--|
|   | Last treatment   | 1 month | 3 months |  |
| I feel less depressed after the treatments.                                 | 66.7%  | 91.7%   | 83.3%    |  |
| I feel less anxious after the treatments.                                   | 66.7%  | 91.7%   | 75.0%    |  |
| I feel more calm after the treatments.                                      | 75.0%  | 91.7%   | 66.7%    |  |
| I feel less stressed after the treatments.                                  | 66.7%  | 83.3%   | 83.3%    |  |
| I feel I can better handle challenging situations after the treatments.     | 58.3%  | 75.0%   | 75.0%    |  |
| I feel happier after the treatments.  | 58.3%  | 75.0%   | 66.7%    |  |
| My quality of sleep has improved after the treatments.                      | 66.7%  | 75.0%   | 75.0%    |  |
| I find it easier to fall asleep after the treatments.                       | 75.0%  | 75.0%   | 83.3%    |  |
| I am able to stay more focused after the treatments.                        | 75.0%  | 58.3%   | 75.0%    |  |
| I feel more confident about myself after the treatments.                    | 75.0%  | 50.0%   | 75.0%    |  |
| I think more positively after the treatments.                               | 83.3%  | 75.0%   | 83.3%    |  |
| I feel I am in a good mood after the treatments.                            | 83.3%  | 91.7%   | 83.3%    |  |
| I have more mental energy after the treatments.                             | 83.3%  | 91.7%   | 75.0%    |  |
| I feel the treatments have improved my mood.                                | 75.0%  | 91.7%   | 81.8%    |  |
| I feel this treatment has improved my mental wellness.                      | 75.0%  | 100.0%  | 83.3%    |  |
| My ability to remember people's names or where I left my keys has improved. | 58.3%  | 66.7%   | 75.0%    |  |

### **Discussion**

This study evaluated the effect of the novel ExoTMS<sup>TM</sup> Technology on the improvement of mental well-being, participant's satisfaction with outcomes, therapy comfort and safety. At the 3-month follow-up, 87.5% of subjects demonstrated improved mental well-being, with a statistically significant mean increase of 6.8 points. Treatment outcomes were rated on average 4/5 based on the SSMQ questionnaire. Therapy comfort was expressed by 90.9% of subjects, with a mean NRS score of 0.2/10. The absence of serious adverse events or notable side effects supports the safety and tolerability of the procedure. Increases in WEMWBS scores were observed across all well-being categories, from low to high. However, the most pronounced improvements occurred in the low well-being group, which demonstrated a 15.7 points increase in scores at the 1-month follow-up. Regression analysis further supported this finding, which revealed that baseline WEMWBS scores significantly predicted 1-month outcomes. Several subjects experienced negative life events, such as divorce or bereavement, which affected the mental well-being of some participants, consistent with findings by Cleland et al [26]. However, in this study, more than half either improved or maintained their WEMWBS scores, suggesting that the treatment may help mitigate the effects of such events. Participants with lower baseline well-being showed greater improvement, which may explain why, a factor associated with poorer well-being [1.27], emerged as a positive predictor of the outcome. Contrary to prior research suggesting that being married predicted higher well-being [28-30], in this study the positive relationship was found only between being in a romantic relationship/dating and the 1-month improvements. One explanation may be that during data collection, being married and cohabitation was considered a single variable. There are conflicting findings on the well-being of married couples versus couples living in cohabitation, while some studies found no differences [31, 32], others report higher satisfaction among married individuals [30, 33, 34]. Another potential explanations may be the duration of the make it as relationship [30]. Those who are in marriages or cohabitation are assumed to be in the relationship for longer duration than individuals reporting



being in romantic relationships/dating. Indeed, some studies suggest that life satisfaction decreases with the length of the relationship [35, 36], potentially influencing the study outcomes as well.

In this study, the subgroup of participants diagnosed with depression overlapped with the low well-being group, with four out of six individuals in the low well-being category also having a depression diagnosis. According to the WEMWBS, scores below 44 are indicative of depression [25], and the average baseline score of 43.7 points in the depression subgroup supports this classification. Following treatment, the average score in this subgroup increased, shifting into the moderate well-being category (51.8 at 3 months). Selfreported improvements in mood, confidence, the feelings of depression, anxiety, sleep onset and quality suggest an alleviation of depression symptoms [37]. The improvements in well-being measured by the WEMWBS were reflected in the SSMQ as well, with the majority of participants (>50%) being in agreement with 20 out of 22 items in the questionnaire. The SSMQ covered additional aspects to WEMWBS, and revealed the treatments had a beneficial effect on enhancing focus, mental energy, sleep onset and quality. Improving mental well-being is crucial, as it enhances stress resilience, supports better decision-making, and fosters the development of healthier interpersonal relationships [2]. Moreover, higher levels of mental well-being have been linked to improved recovery from both mental and physical illnesses, as well as increased longevity [38, 39]. While conventional psychological approaches to improving mental well-being often require long-term commitment and considerable effort from patients to be effective [40], the ExoTMS<sup>TM</sup> treatment demonstrated significant results after just four sessions. Notably, this was achieved with minimal effort required from participants and high reported levels of treatment comfort. The mean pain score was only 0.2 on a 10-point Numerical Rating Scale, which is considerably lower than reported in prior studies using other rTMS devices, where pain was described as high as 6 out of 10 [23].

The improvements in WEMWBS as well as subject satisfaction, were observed to progress at one and three months post-treatment. These delayed but sustained gains suggest that the intervention initiates neuroplastic changes that continue to develop over time [20], supporting longer-term enhancements in mental well-being. This study has several limitations that should be considered when interpreting the findings. First, the sample size was relatively small. However, the sample size was sufficient to detect statistically significant changes in the WEMWBS score. Second, the absence of a sham or control group limits the ability to distinguish the observed effects from potential placebo responses. Finally, the follow-up period was relatively short, with assessments conducted only up to 3 months post-treatment. While positive outcomes were sustained during this period, longer-term

follow-up is necessary to determine the durability of the treatment outcomes. Future studies with larger and more diverse participant populations, as well as the inclusion of a sham group, are needed to confirm and extend these findings. Despite limitations, this study has several notable strengths. To our knowledge, it is the first to evaluate the use of TMS, specifically ExoTMS<sup>TM</sup>, for the enhancement of mental wellbeing in a non-clinical and mixed population, expanding the potential applications of TMS beyond traditional psychiatric disorders. Second, the study employed the Warwick-Edinburgh Mental Well-being Scale (WEMWBS), a widely used and psychometrically validated instrument, ensuring reliable and comprehensive assessment of mental wellbeing. Finally, the inclusion of participants with a broader spectrum of well-being categories, from low to high, allowed for an evaluation of treatment effects across different baseline levels of mental well-being, improving generalizability and applicability of the findings.

# **Conclusion**

The study results indicate ExoTMS<sup>TM</sup> treatments as a promising approach in enhancing mental well-being, showing efficacy across all WEMWBS well-being categories, from low to high. The non-invasive treatment reached significant results with four sessions, while ensuring high therapy comfort and subject satisfaction.

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#### **Conflict of Interest**

The authors declare no potential conflicts of interest related to the research, authorship, or publication of this article. However, all three authors received speaker honoraria and compensation from BTL Industries, the study sponsor, for conducting the clinical trial and participating in educational events. Additionally, Dr. McCoy and Dr. Halaas are the Advisory Board Members at BTL Industries.

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Table S1: Percentage of subjects in agreement with the items of the Subjects Satisfaction and Mental Wellness Questionnaire across time points in all participants and the subgroup with depression diagnosis

|   | Percentage of subjects in agreement with the statement |              |          |                |                 |             |
|---|--|--------------|----------|----------------|-----------------|-------------|
| Statement   |  | All subjects |          | Subjects v     | vith depression | n diagnosis |
|   | Last<br>treatment                                      | 1 month      | 3 months | Last treatment | 1 month         | 3 months    |
| feel less depressed after the treatments.                                   | 69.7%  | 69.7%        | 65.6%    | 66.7%          | 91.7%           | 83.3%       |
| feel less anxious after the treatments.                                     | 66.7%  | 66.7%        | 65.6%    | 66.7%          | 91.7%           | 75.0%       |
| feel more engaged with my daily activities after the treatments.            | 75.8%  | 75.8%        | 65.6%    | 66.7%          | 91.7%           | 58.3%       |
| I feel more calm after the treatments.                                      | 84.8%  | 75.8%        | 75.0%    | 75.0%          | 91.7%           | 66.7%       |
| feel less stressed after the treatments.                                    | 72.7%  | 72.7%        | 78.10%   | 66.7%          | 83.3%           | 83.3%       |
| feel I can better handle challenging situations after the treatments.       | 60.6%  | 66.7%        | 68.8%    | 58.3%          | 75.0%           | 75.0%       |
| feel happier after the treatments.  | 63.6%  | 75.8%        | 75.0%    | 58.3%          | 75.0%           | 66.7%       |
| I feel more in control of my eating habits after the treatments.            | 54.5%  | 57.6%        | 46.9%    | 41.7%          | 41.7%           | 33.3%       |
| My quality of sleep has improved after the treatments.                      | 60.6%  | 60.6%        | 71.9%    | 66.7%          | 75.0%           | 75.0%       |
| I find it easier to fall asleep after the treatments.                       | 66.7%  | 66.7%        | 78.1%    | 75.0%          | 75.0%           | 83.3%       |
| I feel more motivated after the treatments.                                 | 69.7%  | 63.6%        | 62.5%    | 66.7%          | 66.7%           | 58.3%       |
| am able to stay more focused after the treatments.                          | 75.8%  | 63.6%        | 71.9%    | 75.0%          | 58.3%           | 75.0%       |
| My food cravings have improved after the treatments.                        | 39.4%  | 45.5%        | 43.8%    | 33.3%          | 33.3%           | 25.0%       |
| feel more confident about myself after the treatments.                      | 72.7%  | 63.6%        | 68.8%    | 75.0%          | 50.0%           | 75.0%       |
| think more positively after the treatments.                                 | 78.8%  | 69.7%        | 75.0%    | 83.3%          | 75.0%           | 83.30%      |
| feel I am in a good mood after the treatments.                              | 87.9%  | 84.8%        | 81.3%    | 83.3%          | 91.7%           | 83.3%       |
| have more mental energy after the treatments.                               | 78.8%  | 75.8%        | 75.0%    | 83.3%          | 91.7%           | 75.0%       |
| feel less nervous after the treatments.                                     | 63.6%  | 57.6%        | 62.5%    | 50.0%          | 58.3%           | 66.7%       |
| feel the treatments have improved my mood.                                  | 81.8%  | 72.7%        | 71.0%    | 75.0%          | 91.7%           | 81.8%       |
| feel more at ease in social gatherings.                                     | 54.5%  | 66.7%        | 59.4%    | 66.7%          | 75.0%           | 58.3%       |
| feel this treatment has improved my mental wellness.                        | 72.7%  | 75.8%        | 71.9%    | 75.0%          | 100.0%          | 83.3%       |
| My ability to remember people's names or where I left my keys has improved. | 51.5%  | 54.5%        | 59.4%    | 58.3%          | 66.7%           | 75.0%       |

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