

ExoTMS transcranial magnetic stimulation for the reduction of binge eating symptoms

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Funding information

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Abstract

Aim: Transcranial magnetic stimulation (TMS) is an emerging treatment for binge eating (BE). TMS uses noninvasive magnetic pulses to stimulate the prefrontal cortex, which plays a role in decision-making and self-regulation. Early research suggests that TMS can reduce BE episodes by modulating brain activity linked to cravings and compulsive behavior. This article aims to evaluate the efficacy and safety of a novel TMS device with ExoTMS™ Technology for alleviating BE symptoms.

Methods: Subjects underwent six TMS sessions and a 1-month follow-up. The Binge Eating Scale (BES) was administered at baseline, posttreatment, and follow-up to assess symptom severity. Weight was recorded at the same intervals. Therapy comfort was evaluated after the sixth session. The Subject Satisfaction Questionnaire was completed posttreatment and at follow-up. Adverse events and side effects were monitored throughout the study. Data from two identically designed studies were pooled for analysis.

Results: A total of 38 subjects were analyzed. BES scores significantly decreased posttreatment (-37.8% , $p < 0.001$) and at follow-up (-47.9% , $p < 0.001$). At 1 month, 73.7% of subjects achieved BE remission. Average weight loss was -1.3 ± 1.1 kg post-treatment and -1.8 ± 1.3 kg at follow-up. Comfort was rated positively by 92.1% of participants. At follow-up, 89.5% reported reduced cravings and snacking, 86.8% noted improved self-control and well-being, and 94.7% were satisfied with the treatment.

Conclusion: TMS shows promise as a safe and effective intervention for reducing BE symptoms, supported by both objective clinical measures and subjective patient-reported outcomes.

KEYWORDS

BES, binge eating, ExoTMS, symptom reduction, TMS

The clinical investigation was sponsored by BTL Industries, who also funded the study, designed the protocol, and supplied the device.

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INTRODUCTION

Binge eating (BE) is characterized by recurrent episodes of consuming vast amounts of food, often until feeling uncomfortably full, with a sense of loss of control over food consumption.¹ It is believed to result from an altered reward circuit and changes in the brain's corticostriatal circuits, which are linked to the prefrontal cortex and involved in decision-making and self-control.² Dysregulation in the prefrontal cortex leads to increased impulsivity and loss of control.

One significant aspect of BE is its strong connection to food cravings. Cravings are strongly correlated with the amount of food consumed during binge episodes, suggesting that cravings may predict overeating in BE.³ Another factor that can influence BE behavior is the emotional state. BE can be perceived as a coping mechanism to escape negative self-perceptions and emotional distress, including feelings of inadequacy or social anxiety. This suggests that BE helps individuals temporarily shift focus from their emotional distress to the immediate act of eating.^{4–6} However, because the brain of these individuals is less sensitive to dopamine,² the hormone mediating pleasure⁷; binge eaters may need to eat more to experience an equal level of pleasure from eating as healthy individuals. Moreover, the consequent feeling of guilt, shame, or disgust after BE episodes reinforces the cycle of BE, making it harder for individuals to regulate both mood and food intake.⁸

Although BE is often associated with obesity, a significant proportion of individuals with BE are nonobese. These patients tend to be younger and more frequently engage in both healthy and unhealthy weight management behaviors,⁹ which may exacerbate BE symptoms.¹⁰ This highlights the importance of early BE treatment to prevent weight progression to overweight or obesity.^{9,11} Despite their normal weight, these individuals still face BE-related health risks, such as insulin resistance, hypertension, and diabetes, and a higher likelihood of chronic headaches.^{12,13}

Transcranial magnetic stimulation (TMS) is a noninvasive neuromodulation therapy that uses electromagnetic fields to modulate

specific brain regions. The mechanism of action of TMS is rooted in its ability to alter neural activity by generating magnetic pulses, which induce an electric current in the underlying brain tissues.¹⁴ TMS influences synaptic plasticity—the brain's ability to adapt and reorganize neural pathways.¹⁵ This occurs through long-term potentiation (LTP) and long-term depression (LTD) of synaptic connections. High-frequency TMS tends to enhance excitatory neural circuits, promoting an LTP-like mechanism, whereas low-frequency TMS is more likely to reduce excitatory activity and induce LTD.^{16,17} This modulation of synaptic strength can lead to changes in the functional connectivity of brain networks, beneficial especially in regions involved in mood regulation, cognition, and motor control.¹⁸ Previous research suggests that TMS therapy may positively affect and reduce the severity of BE.^{19,20}

Although the TMS method has been demonstrated to be effective, a novel TMS device with ExoTMS™ Technology was developed to improve therapy efficiency and comfort further. ExoTMS™ uses the principle of gradual energy delivery to the nervous tissue (see Figure 1). This method improves patient comfort during therapy by using ramp-up shaped pulse trains, which provide a smoother introduction to TMS.²¹ Additionally, the device 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.

This article aims to evaluate the efficacy and safety of a novel TMS device with ExoTMS™ Technology for alleviating BE symptoms.

METHODS

Two European studies, one in the Czech Republic (CZ) and the second in Bulgaria (BG), were conducted from July to December 2023. Each study received local and state approval from the ethical committees. Both studies had identical designs and methodologies; therefore, the collected data were pooled and analyzed.

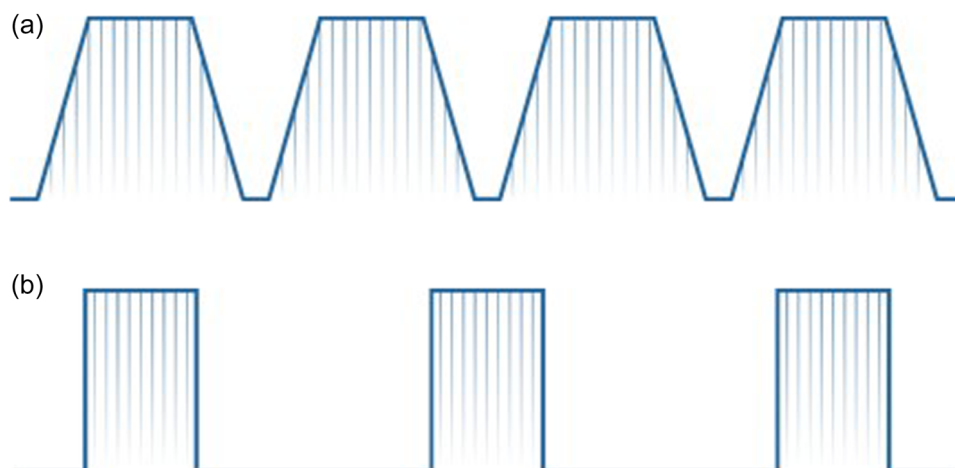


FIGURE 1 Visualization of the train: (above) ramp-up pulse train and (below) standard transcranial magnetic stimulation pulse train.

The inclusion criteria required a score of at least 18 points in the Binge Eating Scale (BES) questionnaire on the baseline visit to ensure that all subjects exhibited at least moderate BE behavior. Other inclusion criteria were the ability to determine motor threshold (MT) and willingness to comply with the study regime and abstain from participating in other trials. Exclusion criteria included standard contraindications for the application of electromagnetic energy, such as metal or magnetic sensitive implants in the proximity of the treatment area, cardiac pacemakers, defibrillators, or neurostimulators. On top of that, subjects with heart problems, pregnant or nursing women, and cancer patients were excluded. Compliance with inclusion/exclusion criteria was confirmed by a medical history review. All enrolled subjects were introduced to the study protocol and willingly signed the informed consent. All subject-facing documents (such as the Informed Consent Form or questionnaires) were in the subjects' native language to ensure content comprehension.

Study procedure and collected data

Subjects were treated by a novel TMS device, EXOMIND™ (BTL Industries Inc., Boston, MA). Subjects underwent six treatments, twice a week. A follow-up visit was scheduled 1 month post-treatment. During the treatment, subjects were in a semi-reclined position with the applicator placed over the left prefrontal cortex (IPFC). The IPFC was located according to the 5 cm method, which involves locating the motor cortex hotspot and measuring 5 cm anteriorly along the parasagittal plane.²² The treatment area was stimulated by a frequency of 12–18 Hz with 2 s train durations and 5 s inter-train intervals, and a maximal intensity of 70% of the subjects' MT.

At baseline, demographic information about the subjects (age, height, and weight) was collected, with additional weight measurements taken after the last treatment and at the 1-month follow-up visit. BE scores based on the validated BES questionnaire were collected at baseline, as part of the inclusion criteria, and then after the last treatment and 1-month follow-up to determine the treatment-related change in BE behavior. The questionnaire included 16 questions, with 3–4 possible answers with assigned numerical values. The score range is 0–46, with a score of less than 17 points indicating no present BE behavior. Scores between 18 and 26 suggest moderate BE behavior, whereas a score of 27 or higher signifies severe BE behavior. Improvement in BE was defined as a decrease in score. After the last therapy, subjects filled out the Therapy Comfort Questionnaire (TCQ) asking about the level of their agreement with the statement “I found the treatment comfortable” using the 5-point Likert scale (1 = strongly disagree, 5 = strongly agree), with a second question concerning the pain experienced during the treatments assessed by using the Numerical Analog Scale (NAS) ranging from 0 (no pain) to 10 (worst pain possible). The Subject Satisfaction Questionnaire (SSQ) was filled out after the last therapy and subsequently at 1-month follow-up. The SSQ contained 20 statements such as “I am satisfied with the treatment results” or “My urge to

overeat is reduced after treatments.” The level of agreement was again based on the 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). During the study, the procedure's safety was monitored by visually evaluating the treatment area and recording any adverse events or side effects that may occur during the treatment.

Statistical analysis

Unless stated otherwise, the descriptive analysis is reported as average \pm standard deviation (SD). Before pooling, the two data sets were tested for normality using the Shapiro–Wilk test. Non-Gaussian distribution was detected for some variables; therefore, multiple Mann–Whitney tests with Holm–Šidak's method for multiple comparisons were used. The test revealed no statistically significant differences between the data sets from the two studies, justifying their pooling for further analysis. Pooled data were tested for normality using the Shapiro–Wilk test. As a non-Gaussian distribution was detected, the Friedman test with Dunn's post hoc test was used to detect a significant change in weight and BES data throughout the time points. The family-wise α threshold and confidence level were set at 0.05 for all tests.

RESULTS

Thirty-nine subjects ($n = 39$) were enrolled: 16 in the CZ study and 23 in the BG study. One male subject was excluded from the CZ study at baseline, as he did not meet the inclusion criteria when scoring only 6 points in the BES at baseline. When pooled, data from 38 subjects ($n = 38$, 8 males, 30 females, age range of 24–66 years, body mass index [BMI] range of 19.6–44.4 kg/m²) that underwent all six treatment sessions and attended the 1-month follow-up visit were analyzed. Four subjects reported mild side effects, such as somnolency or tingling sensation in the treated area; however, no serious adverse event occurred.

Binge Eating Scale

All 38 subjects were included in the analysis. The average BES score at baseline was 25.9 ± 7.2 points. Zero subjects showed no BE behavior, but 22 subjects (57.9%) showed moderate symptoms, with 16 subjects (42.1%) showing severe BE symptoms. After the treatments, 32 out of the 38 subjects showed decreased BE symptoms, with an average decrease of 9.8 ± 4.5 points (37.8%, $p < 0.001$). In total, 24 subjects showed no BE behavior (63.2%), whereas 9 (23.7%) and 5 (13.2%) subjects showed moderate and severe BE symptoms, respectively. One month after the treatments, the average decrease was 12.4 ± 4.3 points (47.9%, $p < 0.001$). In total, 36 out of the 38 subjects showed an improvement in the BES score, with 28 subjects (73.7%) showing no BE behavior, 8 subjects (21.1%) being in the

moderate BE category, and only 2 out of the original 16 subjects showed severe BE behavior (see Figure 2). Despite remaining in the severe category, both subjects showed a decrease in scores. One subject showed a gradual decrease of 8 and 10 points after the treatment and 1-month follow-up, respectively, with a baseline score of 40 points. The second subject had a baseline score of 41 points, and showed a decrease of 15 and 14 points after the treatments and 1-month follow-up, respectively, balancing on moderate/severe cutoff values. While showing improvement, one subject with a baseline score of 28 points moved to the no BE category after the treatments with 13 points, while showing moderate BE symptoms 1 month posttreatment with 21 points.

Weight and BMI

The subjects had an average weight of 84.5 ± 19.9 kg and a BMI of 29.2 ± 6.4 kg/m² at baseline. 32 out of the 38 subjects showed a weight reduction after the treatments, averaging at -1.5 ± 1.0 kg. Of the six remaining subjects, two maintained their weight, whereas the other four subjects gained less than 1 kg (range of 0.2–0.7 kg). The average change after the last treatment for all subjects was -1.3 ± 1.1 kg ($p < 0.001$). Further weight loss was observed at the 1-month follow-up, where 36 subjects showed a weight reduction, with an average of -1.9 ± 1.2 kg. Two subjects remained at their baseline weight. The average 1-month follow-up change for all subjects was -1.8 ± 1.3 kg (p -value < 0.0001).

At baseline, nine subjects were in the normal BMI category (18.5 – 24.9 kg/m²). These patients lost on average -0.5 ± 0.6 kg after the treatments and -1.1 ± 1.0 kg 1-month posttreatment. 17 subjects in the overweight (BMI of 25 – 29.9 kg/m²) category displayed the

biggest weight loss of -1.5 ± 1.3 kg after the therapies and -2.2 ± 1.4 kg 1-month posttreatment. Obese subjects ($n = 12$, BMI > 30 kg/m²) showed weight loss of -1.5 ± 1.0 kg after the treatments and -1.7 ± 1.0 kg 1-month posttreatment. Overall, at baseline, 29 subjects (76.3%) were in the categories of overweight or obese. After the treatments, 25 subjects (65.8%) remained in these categories, with one subject moving from the obese category to the overweight category and remaining there 1-month posttreatment. Three subjects moved from the overweight category to the normal BMI category. One month posttreatment, two more subjects moved to the normal BMI category, leaving only 23 subjects (60.5%) in the overweight or higher BMI categories.

Therapy Comfort Questionnaire

Overall, 92.1% (35 subjects) found the treatments comfortable. One subject answered “neither agree nor disagree,” and two subjects “disagreed.” A numerical evaluation of pain followed the question about comfort. The average NAS score was 0.74 ± 1.3 points, with only three subjects reporting moderate pain (4/10). In total, 24 subjects (63.2%) reported no pain, and 11 (28.9%) reported mild discomfort (1–3/10), see Figure 3.

Subject Satisfaction Questionnaire

The SSQ consisted of 20 questions (Table 1). Satisfaction is represented as agreement or strong agreement with the statements. The overall satisfaction after the treatments was 74.6%. This overall satisfaction increased 1 month after the treatments to 82.1%.

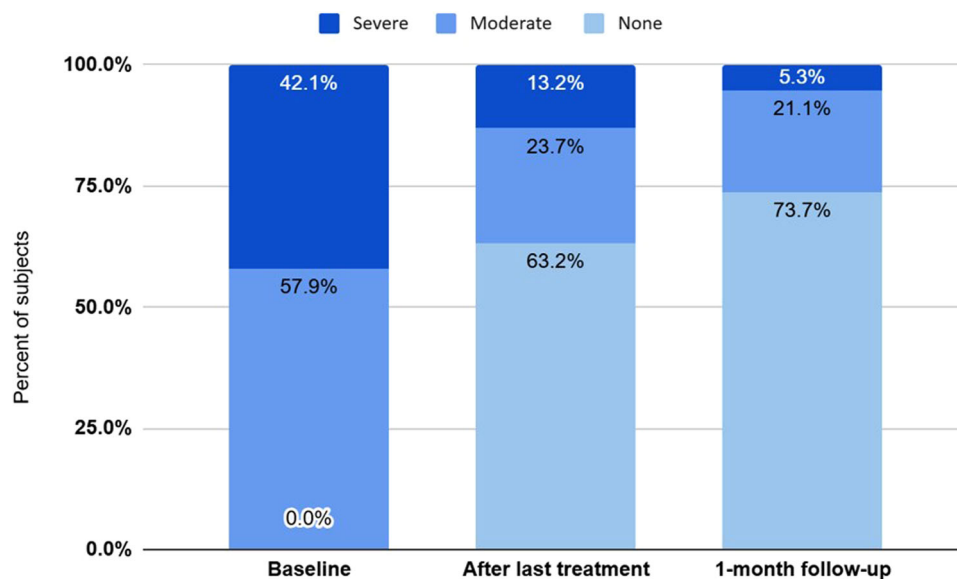


FIGURE 2 Symptom severity distribution by time point: the percentage of subjects displaying none, moderate, and severe binge eating symptoms at each time point. With each follow-up, the percentage of subjects with severe and moderate symptoms decreased, whereas subjects with no binge eating behavior increased from 0.0% at baseline to 73.7% at 1-month follow-up.

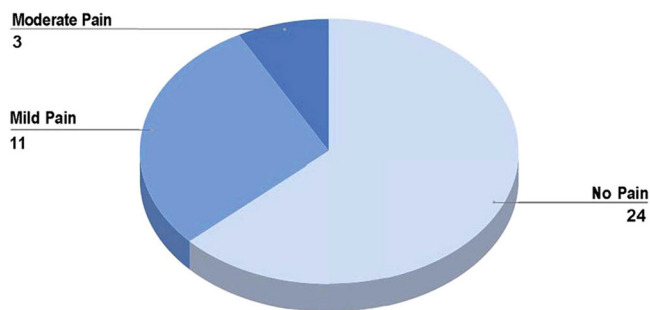


FIGURE 3 Visual analog scale: the number of subjects reporting various pain severity of the treatments.

One month posttreatment, 94.7% of subjects were satisfied with the results, 89.5% had diminished food cravings and urge to snack during the day, and 86.8% felt stronger self-control over their eating habits and improved mental well-being. In total, 84.2% of subjects felt a reduction in self-hate after eating food. In total, 81.6% of subjects reported a reduction in habits to eat when bored, and 78.9% of subjects reported reduced urges to eat when sad and/or depressed. In total, 76.3% of subjects tend to overeat less after the treatments. In total, 71.1% of subjects reported improvement in stress-eating habits, and finally, 68.4% reported a reduction in excessive calorie intake.

DISCUSSION

This study focused on the effectiveness, comfort, satisfaction, and safety of a novel TMS device in the reduction of BE behavior. Effectiveness was measured using the validated BES, which demonstrated a 47.9% reduction in scores (equivalent to a 12-point decrease). Participant satisfaction, assessed through a self-reported SSQ, revealed that 94.7% of subjects were satisfied with the treatment outcomes. Therapy comfort was reported by 92.1% of participants, reflected in a low average NAS score of 0.74 ± 1.3 points. The procedure's safety was supported by the absence of serious adverse events and side effects.

The participants' self-reports further support the treatment's efficacy in addressing BE. Most participants reported reduced food cravings (89.5%), enhanced self-control over eating habits (86.8%), and rarely eating to the point of discomfort (81.6%), all critical factors in BE. These changes translated into favorable outcomes with an average weight loss of 1.8 ± 1.3 kg 1 month posttreatment, a notable finding given BE's association with weight gain and obesity. The gradual weight loss, with participants losing 1.3 kg immediately posttreatment and 1.8 kg at 1 month, aligns with the recommended pace for healthy and sustainable weight loss.²³

Current standard treatment options for BE include psychological methods, such as cognitive-behavioral therapy (CBT) and interpersonal therapy (IPT), as well as pharmacological interventions. Remission rates for CBT and IPT, following 20 therapy sessions, have

been reported as 79% and 73%, respectively.²⁴ Although pharmacological treatments show promise, their associated side effects, such as dry mouth, headache, insomnia, and sexual dysfunction in the usage of sertraline and fluvoxamine, or gastrointestinal symptoms in taking sibutramine and orlistat, contribute to high dropout rates ranging from 16% to 57%.²⁵ Behavioral therapies, although free from such side effects, still experience dropout rates of 11%–27%.²⁵ In comparison, the novel TMS treatment offers an alternative approach, achieving a remission rate of 73.7% with just six sessions without dropouts. Additionally, it demonstrates high participant satisfaction (82.1%) and comfort levels (92.1%), making it a promising option alongside conventional therapies.

The IPFC was selected as the TMS stimulation target based on converging evidence implicating this region in impaired inhibitory control and dysregulated reward processing characteristic of BED. Neuroimaging studies have identified hypoactivation in the IPFC during tasks requiring inhibitory control in individuals with BED.^{26,27} Functionally, the IPFC exerts top-down modulation over limbic and striatal circuits involved in reward valuation and impulsivity.^{28–30} TMS studies targeting the IPFC in related conditions, such as obesity and bulimia nervosa,^{19,20,31} have demonstrated reductions in impulsive behavior and compulsive consumption. Specifically in BED, preliminary trials have shown that TMS over the IPFC can attenuate binge episodes and improve inhibitory control.³² These findings align with a neurocircuitry model in which the IPFC serves as a critical region for exerting cognitive control over maladaptive reward-driven behaviors. Accordingly, targeting this region with ExoTMS™ may strengthen cognitive control over eating behavior and reduce BE symptoms.

Previous studies with other TMS devices reported discomfort or pain at the TMS application site in almost 47% of subjects,³³ and some participants even dropped out due to the pain.³⁴ Pain or discomfort at the treatment application site may be a common effect to report³⁵; however, a positive treatment experience can help motivate patients to adhere to treatment protocol and further improve the treatment outcomes.³⁶ Within this study, 92.1% of patients reported the treatment as comfortable and less than mild pain. This comfort profile can be attributed to the TMS setting. The ramp-up pulse onset of the trains allows the subjects to adapt to the sensation without the initial shock. The second attribute is the 70% of MT intensity. Research showed that the higher the MT stimulation intensity, the more scalp discomfort and pain are perceived.³⁴ Although 70% can be perceived as conventional, it is not commonly used.³⁷ One of the reasons may be worries about the effectiveness of the stimulation; however, a meta-analysis by Gorelick et al.³⁸ found that the number of pulses was positively associated with treatment efficacy. In combination with subthreshold stimulation, it allows for a more comfortable treatment.

The TMS treatment protocol used in this study differs from those reported in existing literature for eating disorders and weight loss. Although research on the effects of TMS treatment for BE is scarce,³⁹ one case study⁴⁰ reported an 11-point decrease in BES score after 20 sessions of 30-min 10 Hz TMS (2400 stimuli per day).

TABLE 1 The Subject Satisfaction Questionnaire, percentages represent the percentage of subjects in agreement with the statement.

No.	Statement	After the treatments (%)	1-Month follow-up (%)
Q1	I am satisfied with the treatment results.	81.60	94.70
Q2	My food cravings have diminished after the treatments.	81.60	89.50
Q3	The urge of snacking multiple times during the day has been reduced after the treatment.	68.40	89.50
Q4	I think about food less often during the day after the treatments.	86.80	81.60
Q5	My habit of eating food when bored has reduced after the treatments.	60.50	81.60
Q6	The feeling of self-hate/guilt after eating food has reduced after the treatments.	73.70	84.20
Q7	I tend to overeat less often after the treatments.	81.60	76.30
Q8	I think this treatment can help me reduce weight.	78.90	86.80
Q9	The urge to eat food to feel better when I am sad or depressed has reduced after the treatments.	68.40	78.90
Q10	The urge to eat sweets, chocolates or sugary food has been reduced after the treatments.	52.60	68.40
Q11	I feel that I have a stronger self-control over my eating habits after the treatments.	86.80	86.80
Q12	I feel that my stress-eating habits have improved after the treatments.	81.60	71.10
Q13	I feel that these treatments have helped elevate my mood.	81.60	81.60
Q14	I rarely eat so much food that I feel uncomfortably stuffed after the treatments.	71.10	81.60
Q15	My habit of excessive calorie intake has reduced after the treatments.	57.90	68.40
Q16	The urge to have a late-night snack has reduced after the treatments.	68.40	84.20
Q17	My urge to overeat is reduced after treatments.	86.80	84.20
Q18	My well-being (the state of feeling healthy and happy) is improved after the treatments.	73.70	86.80
Q19	I feel more motivated to maintain a healthy lifestyle after the treatments.	84.20	86.80
Q20	I feel less anxious about the appearance of my body after the treatments.	65.80	78.90

Abbreviation: Q, question.

In contrast, the novel device delivers 6300 pulses per session, allowing for a shortened treatment protocol of 6 sessions while maintaining the efficiency profile of the treatment, both in reducing BE symptoms by 12.4 ± 4.3 points (47.9%) and in weight reduction of 1.8 ± 1.3 kg 1 month posttreatment.

Although the outcomes demonstrated by validated questionnaires and subject self-reported questionnaires are promising, the study is not without limitations. A key consideration in interpreting the findings of this pilot open-label study is the lack of a sham or control group, as the primary objective was to explore safety and preliminary efficacy. Although this design is appropriate for early-phase investigations, it inherently limits the ability to differentiate between treatment effects and potential placebo responses fully. Further randomized, sham-controlled studies will be essential to confirm and expand upon these initial observations. Additionally, the sample size, while equivalent to those given by other studies,¹⁹ limits the generalizability of the findings. A short follow-up of 1 month restricts understanding of the long-term efficacy and sustainability of the observed benefits. Future research with larger, more diverse populations and extended follow-up periods of at least 6–12 months is warranted to confirm these results, observe the durability of the outcomes, as well as explore mechanisms underlying TMS's effects on BE.

Despite its limitations, this study demonstrates several strengths. First, the inclusion of participants from two diverse European cultures enhances the generalizability of the findings, offering insight into the treatment's effectiveness across varied demographic and cultural contexts, as well as a wide range of ages and BMI categories. Second, the study provides further evidence of the potential for TMS as an intervention for BE, addressing an important gap in the literature. Moreover, the use of a novel TMS technology delivering a higher number of pulses per session in fewer sessions demonstrates an innovative approach that optimizes efficiency without compromising outcomes. The study included both objective measures and participant self-reports, strengthening the reliability of the results. Lastly, the focus on both BE symptoms and associated weight loss outcomes provides a comprehensive evaluation of the treatment's impact.

CONCLUSION

The findings suggest that the novel TMS device is a promising and safe therapeutic option for individuals with BE, demonstrating significant symptom reduction after six treatments over 3 weeks. The

treatments contributed to weight loss and were well-received by participants. The results indicate the potential of this noninvasive intervention to expand the limited treatment options currently available for eating disorders.

AUTHOR CONTRIBUTIONS

David Pánek and Toni Slavchev Donchev conducted the study, including patient recruitment, data collection, and data analysis. David Pánek prepared the manuscript draft with important intellectual input from Toni Slavchev Donchev. Both authors have reviewed and approved the manuscript.

ACKNOWLEDGMENTS

The authors have nothing to report.

CONFLICT OF INTERESTS STATEMENT

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article. Both authors are medical consultants to BTL Industries.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS APPROVAL STATEMENT

The study was carried out in accordance with the Declaration of Helsinki and received local and state approval from the ethical committees.

PATIENT CONSENT STATEMENT

All participants were instructed about study procedures and willingly signed an informed consent form.

CLINICAL TRIAL REGISTRATION

This study is registered on clinicaltrials.gov under NCT06910592 and NCT06894615.

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How to cite this article: Pánek D, Donchev TS. ExoTMS transcranial magnetic stimulation for the reduction of binge eating symptoms. *Psychiatry Clin Neurosci Rep.* 2025; 4:e70200. <https://doi.org/10.1002/pcn5.70200>