

# **The effectiveness of rTMS on improving food craving and weight control in adults without serious mental illness**

## **Background**

Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-invasive brain stimulation technique that uses magnetic fields to modulate neural activity in targeted brain regions. Over the years, rTMS has shown promise in treating various mental health conditions, including depression<sup>1,2</sup>, obsessive-compulsive disorder (OCD)<sup>3,4</sup> and eating-related disturbance<sup>5,6</sup>.

Food cravings are a common experience that can significantly impact an individual's mental and physical health. These intense desires for specific foods often lead to overconsumption of unhealthy foods, contributing to obesity, poor nutritional intake, and associated health conditions. Understanding the neural mechanisms behind food cravings is crucial for developing effective interventions to manage them.

Prior research on rTMS and food craving has primarily focused on clinical populations, particularly individuals with obesity or eating disorders. While these studies have provided valuable insights, there is a burgeoning interest in exploring the effects of rTMS on food craving and weight control in the general population, specifically targeting those who report eating or weight problems but do not meet the criteria for clinical disorders.

This research proposal aims to investigate the effects of rTMS on food craving and weight control among healthy adults experiencing subclinical eating and weight issues. By focusing on this population, we hope to uncover the potential of rTMS as a preventive intervention, offering individuals a non-pharmacological option to enhance diet and weight control without the side effects often associated with medications.

## **Methodology**

### *Study Design*

This open-label pilot study aims to evaluate the effectiveness of repetitive transcranial magnetic stimulation (rTMS) in improving food craving and weight control among healthy adults with eating or weight issues. The study will enrol 30 participants who meet the inclusion criteria.

### *Hypothesis*

rTMS significantly improves food cravings and weight control among healthy adults with food craving or weight control issues.

### *Participants*

Participants will be recruited based on the following criteria:

- Healthy adults aged 18-65
- Self-reported food craving or weight control issues

### *Exclusion criteria*

- People with serious mental illness, severe neurological conditions, and contraindications for rTMS.
- People on weight-reduction medications

## **Intervention setting**

Participants will undergo a treatment protocol involving six sessions of rTMS using the EXOMIND™ device, administered once or twice a week. Each session will deliver 6,300 pulses at alternating frequencies of 12, 15, and 18 Hz, with a total duration of 24 minutes and 30 seconds. The target site would be left dorsolateral prefrontal cortex (DLPFC), determined by the most common used 5-cm rule. The procedure would be conducted in our research centre with medical staff supported.

## **Baseline Assessments**

The subjects' basic demographic data, including age, gender, years of education, place of birth, marital status, number of children, financial condition, household income, family history of eating difficulties will be collected upon study entry. Medical history in relation to mental illnesses and medications will also be assessed.

## **Outcome Measures**

Assessments will be conducted at three time points: baseline (pre-intervention), post-intervention, and four weeks post-intervention.

### *Primary Outcome*

- Food Cravings Questionnaire—Trait (FCQ-T): Measures food cravings.

### *Secondary Outcomes*

- Perceived Stress Scale (PSS): Evaluates perceived stress levels.
- Patient Health Questionnaire-9 (PHQ-9): Assesses depressive symptoms.
- Body weight & BMI: Monitoring changes in body weight and BMI because of reduced cravings

### *Adverse effects*

A checklist of potential adverse effects from TMS administration will be referenced from existing literature to monitor tolerability and adverse events during each session. Blood pressure and heart rate will be recorded at the beginning and end of each session.

### *Sample size:*

- We aim to recruit **30** participants in this study.
- An existing literature studying the effects of rTMS on food cravings in overweight or obese patients with similar outcome measures, has sample size of 37.

## **Statistical Analysis**

Data will be analyzed using SPSS version 26.0 or a similar statistical software package.

All the descriptive data including the age and educations will calculate means and standard deviations for continuous variables and frequencies and percentages for categorical variables. Repeated measures ANOVA will be used to assess changes in FCQ-T, PSS and PHQ-9 scores, as well as BMI across the three time points (baseline, post-intervention, and 4 weeks post-intervention). A p-value of <0.05 will be considered statistically significant.

## **Impact of the study**

This study contributes to the growing body of literature on non-pharmacological interventions for improvement in food craving and weight control. By focusing on a non-clinical population, it expands the understanding of how rTMS enhance individuals' diet and weight control. Results could pave the way for integrating rTMS as a preventive intervention in clinical practice, offering an alternative to traditional medications. This could be particularly beneficial for individuals who are sensitive to medication side effects or those who prefer non-drug therapies. As a pilot study, this research sets the groundwork for larger, more comprehensive trials. Positive findings could lead to further exploration of rTMS applications across different populations and settings, encouraging innovation in eating disorder treatments.

#### **Handling and storage of personal data and study data**

Personal data will be anonymized and kept in password protected computers during and after the study; raw data will be anonymized and kept in locked rooms. Only principal investigator and authorized research assistants will have access to and are responsible for safekeeping of the stored data.

Personal data will be kept for 5 years after completion of study and publications to keep track on potential side effects related to the intervention, and will be destroyed after completion of publications.

#### **Compliance with the ICH-GCP**

This study complies with ICH-GCP.

#### **Compliance with Declaration of Helsinki**

It declares that the research was conducted according to ethical standards, including the Declaration of Helsinki and its amendments.

#### **Conflicts of Interests**

There are no conflicts of interest regarding the use of the rTMS machine in this study that influenced the design, implementation, or interpretation of the research.

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References:

1. Sabé, Michel, et al. "Transcranial magnetic stimulation and transcranial direct current stimulation across mental disorders: a systematic review and dose-response meta-analysis." *JAMA network Open* 7.5 (2024): e2412616-e2412616.
2. Voineskos, Daphne, et al. "Neurophysiological effects of repetitive transcranial magnetic stimulation (rTMS) in treatment resistant depression." *Clinical Neurophysiology* 132.9 (2021): 2306-2316.
3. Fitzsimmons, Sophie MDD, et al. "Repetitive transcranial magnetic stimulation for obsessive-compulsive disorder: A systematic review and pairwise/network meta-analysis." *Journal of affective disorders* 302 (2022): 302-312.
4. Liang, Kaili, et al. "Efficacy and tolerability of repetitive transcranial magnetic stimulation for the treatment of obsessive-compulsive disorder in adults: a systematic review and network meta-analysis." *Translational psychiatry* 11.1 (2021): 332.
5. Dalton, B., Maloney, E., Rennalls, S. J., Bartholdy, S., Kekic, M., McClelland, J., Campbell, I. C., Schmidt, U., & O'Daly, O. G. (2021). A pilot study exploring the effect of repetitive transcranial magnetic stimulation (rtms) treatment on cerebral blood flow and its relation to clinical outcomes in severe enduring anorexia nervosa. *Journal of Eating Disorders*, 9(1). <https://doi.org/10.1186/s40337-021-00420-w>
6. Hall, P. A., Vincent, C. M., & Burhan, A. M. (2018). Non-invasive brain stimulation for food cravings, consumption, and disorders of eating: A review of methods, findings and controversies. *Appetite*, 124, 78–88. <https://doi.org/10.1016/j.appet.2017.03.006>