tinnitus, severe hearing loss or Menier's disease, middle ear disease, diagnosed mental disorder, suicidality, alcohol or drugs addictions, clinically relevant neurological disorder, and standard rTMS exclusion criteria.

Sample size: 52 in HR rTMS H7-coil arm, and 52 in sham control arm.

Primary outcome: Adjusted median of differences in total THI score. We will adjust the means for the distribution of age, gender, tinnitus severity, duration, and treatment.

Secondary outcomes: Change in TQ score, change in VAS score, the proportion of patients with clinically relevant lowering of total THI score ≥ 7 points, percentage of the awake time aware of tinnitus, percentage of awake time annoyed, distressed or irritated by tinnitus, change in BDI-II score, change in BAI score, change in PSQI score.

Data analysis: Within-between subjects ANCOVA or multivariable quantile regression of outcome measure score after the therapy to the treatment group, adjusted for baseline outcome measure score and all preplanned possible confounding variables in the intention-to-treat population.

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INTERIM ANALYSIS OF EFFICACY AND SAFETY OF HIGH-FREQUENCY REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION WITH H7-COIL IN TREATMENT OF NEGATIVE SYMPTOMS OF SCHIZOPHRENIA SPECTRUM DISORDERS: A RANDOMIZED, SHAM-CONTROLLED TRIAL

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Background: At present, the main treatment for schizophrenia relies on antipsychotic medication. Antipsychotics, although relatively effective on positive symptoms, have no consistent, reliable, and satisfactory effect on negative and cognitive symptoms. High frequency repetitive transcranial magnetic stimulation (HF rTMS) with H7-coil represents a safe, non-invasive technique that has been hypothesized to improve negative symptoms in this population.

Objectives: The purpose of this randomized sham-controlled, two-arms, double-blind superiority clinical trial with concealed allocation and masked independent outcome assessment study is to examine the efficacy and safety of HF rTMS with H7-coil applied once daily during the twenty days, augmentative to the standard antipsychotic and other pharmacotherapy of negative symptoms in schizophrenia.

Methods: This is a report of the interim analysis after completing 50% of the planned sample size. The target population was outpatients diagnosed with SSD (ICD-10: F20-F29), both genders, age 18-55 years, with PANSS negative symptoms subscale score > 24, and PANSS positive symptoms subscale score < 20, stable during at least three months and with the antipsychotic therapy unchanged for at least three months. The primary outcome was adjusted mean of total score on The Scale for the Assessment of Negative Symptoms (SANS).

Results: We randomized 25 patients in active, H7-coil arm, 44% of them women, and 26 in inactive, sham-coil arm, 38% of them women. The median (interquartile range) of age was 38 (27-48) years in H7 and 34 (24-44) years in sham arm. During the intervention total SANS score was lowered in both study groups [-45% (95% CI -55; -35%) lowering of SANS score in H7, and -33% (95% CI -43; -23%) in sham arm]. Time x group interaction was significant p=0.035; η^2=0.11; false discovery rate <5%). We observed significant effects on blunting and alogia SANS subscales, and no significant effects on avolition/apathy, anhedonia, and attention subscales.

Conclusion: This interim analysis indicated a possible effect of HF rTMS with H7-coil on the overall severity of negative symptoms and acceptable safety and tolerability in the population of patients diagnosed with schizophrenia and pronounced negative symptoms.

Key words: *transcranial magnetic stimulation - schizophrenia spectrum and other psychotic disorder - psychotic disorder - negative symptoms*

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GENDER DIFFERENCES IN THE EFFICACY OF rTMS TREATMENT ON MAJOR DEPRESSIVE DISORDER

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Repetitive transcranial magnetic stimulation (rTMS) is a non-invasive brain stimulation technique that is effective in treatment of major depressive disorder (MDD). A probable association of short-term antidepressant properties of rTMS with gender has been observed.

Objective of our study was to investigate gender differences in the efficacy of 8-coil rTMS on major depressive disorder (MDD).

We performed an industry-independent, unicentric, randomized, controlled, single-blinded study in Psychiatric Hospital "Sveti Ivan" in Zagreb. Patients were randomized into two groups: experimental group treated with 8-coil rTMS (n=47) and standard pharmacotherapy and the control group (n=43) treated with the standard pharmacotherapy alone. The primary outcome was HAM-D17. Variables whose possible confounding effect we controlled by multivariable statistical analysis were: age, diagnosis, age at MDD onset, treatment with SSRIs, SNRIs and other antidepressants.

After the adjustment for all preplanned possible confounding variables, the lowering of HAM-D17 score after 4-weeks treatment was statistically significantly different between experimental and control group. In women, the lowering of HAM-D17 score was statistically significantly and clinically relevantly larger in the experimental group than in the control group. The interaction of the study group and gender on the change in HAM-D17 scores was not statistically significant after adjustment for confounding variables. It cannot be reasonably reliably claimed that there are differences in the effect of rTMS between men and women using the 8-coil, but the results indicate the need for further research.

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BINGE-EATING DISORDER AND TRANSCRANIAL MAGNETIC STIMULATION – STATE OF KNOWLEDGE

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Binge-eating disorder (BED) is characterized by repetitive episodes of excessive food consumption in the absence of regular compensatory behaviors used to avoid weight gain. As the most common eating disorder, BED is an important public health problem, associated with obesity, life impairment, poor outcomes and significant psychopathology and comorbidity. Due to its complex multifactorial etiology, BED represents a challenge in terms of treatment strategies, with limited therapeutic options.

Neurostimulation strategies, such as Transcranial magnetic stimulation (TMS), modulate cortical or subcortical excitability producing therapeutic effects. There are several studies that suggest a possible positive effect of brain stimulation on the neural mechanisms underlying BED, especially on the increased neural activity in the orbitofrontal cortex and decreased regulatory influence in dorsolateral prefrontal cortex (DLPFC).

The objective of this poster is to describe the state of literature and to asses clinical and scientific findings of the use of TMS procedures for modulating food cravings and food consumption in treating BED.

With respect to BED, several TMS trials have been published and have yielded promising results. Furthermore, application of multi-session Non-invasive brain stimulation (NIBS), predominantly Repetitive transcranial magnetic stimulation (rTMS) to BED has also yielded promising, but ultimately inconclusive results. These results provide a rationale for further exploring TMS as a treatment option for BED as more clinical trials should be conducted in order for more definite conclusions to be made.

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