European Psychiatry

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e-Poster Presentation

Depressive Disorders

Abstract

Cite this article: (2026). e-Poster Presentation. *European Psychiatry* **69**(S1), S121–S417.

EPP001

A randomised, single-blind, sham-controlled clinical trial on the effects of intermittent Theta-Burst Stimulation (iTBS) on depressive and cognitive symptoms in patients with Treatment-Resistant Depression

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doi: 10.1192/j.eurpsy.2026.10620

Introduction: Major Depressive Disorder (MDD) is a severe psychiatric disorder characterised by persistent low mood, anhedonia, cognitive impairment, and social cognition (S-Cog) deficits, which reduce quality of life and hinder recovery. Notably, up to 50% of patients develop Treatment-Resistant Depression (TRD), with limited therapeutic options. Transcranial magnetic stimulation has emerged as a promising treatment for TRD, with intermittent theta-burst stimulation (iTBS) showing advantages in promoting neuroplasticity while requiring shorter sessions. This study will apply this innovative medical technology to evaluate the efficacy of an iTBS protocol in improving depressive symptoms and S-Cog deficits in patients with TRD.
Objectives: Forty patients with TRD will be recruited and randomised to receive either active iTBS to the lDLPFC or sham stimulation (20 sessions in 4 weeks). The iTBS protocol will be in line with the FDA guidelines. Patients will undergo extensive socio-demographic, clinical, neurocognitive/social cognitive, and functioning evaluation at baseline (T0), post-treatment (T1), and 4 weeks post-treatment (T2). Standardised questionnaires and batteries will be used for this purpose, including HDRS-21 and BDI-II (depression); SCL-90 (psychopathology); WHODAS 2.0 (functioning); SF-36 (quality of life); BAC-A (neurocognition); Reading the Mind in the Eyes test; Ekman Test, Faux Pas Test (S-Cog). Forty healthy controls (HC) will also be recruited and undergo only the clinical and cognitive/social-cognitive evaluation at T0. Data collected from HC will serve as a benchmark for interpreting the effects of active-iTBS and sham-iTBS on patients.
Methods: Data will be analysed using mixed-effect models for repeated measures (T0, T1, T2); Intra-group effect sizes (Cohen's d) will be calculated using performance change scores (mean score T1 – mean score T0) and standard deviations to quantify treatment impact within each group.
Results: The primary expected outcome is an improvement of ≥50% in depressive symptoms and 30% in S-Cog, calculated as the percentage change between the mean scores at T1 and T0 on measures of depression and S-Cog. *Secondary* are - i) maintenance of the improvements at T2; ii) changes in pre-to-post measures of functioning, quality of life, and other cognitive measures;
Conclusions: The project will start in November 2025 and very preliminary findings will be presented at the upcoming conference.

Disclosure of Interest: None Declared

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EPP002

The Association Between Depression and Headache Characteristics in Adults

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doi: 10.1192/j.eurpsy.2026.10619

Introduction: Depression and headaches are among the most common global health burdens, often co-occurring and significantly impairing individuals' quality of life. Emerging evidence

suggests a bidirectional relationship between mood disorders and chronic pain syndromes, particularly tension-type headaches (TTH) and migraines. Understanding the interrelationship between depression and headache characteristics may inform more effective, integrated treatment approaches.

Objectives: To investigate the association between depression and headache frequency, intensity, and type in adult populations, and to explore shared pathophysiological mechanisms contributing to comorbidity.

Methods: A cross-sectional observational study was conducted with 250 adults aged 18–65, recruited from primary care and neurology clinics. Participants completed the Beck Depression Inventory-II (BDI-II) and the Headache Impact Test-6 (HIT-6). Depression diagnoses were confirmed using DSM-5 criteria, and headache types were classified per the International Classification of Headache Disorders (ICHD-3). Statistical analysis included Pearson correlation and multiple regression using SPSS version 26.0.

Results: Depression severity was significantly positively correlated with both headache intensity and frequency ($r = 0.62$, $p < 0.01$). Participants with moderate to severe depression showed a higher prevalence of migraines and experienced diminished response to conventional headache treatments. Comorbid individuals reported higher HIT-6 scores, reflecting greater headache-related disability.

Conclusions: The findings highlight a strong association between depression and chronic headache parameters, suggesting overlapping neurobiological mechanisms, such as serotonin dysregulation and HPA axis dysfunction. Routine screening for depressive symptoms in headache patients—and vice versa—is recommended to improve diagnosis and treatment outcomes. Integrated, multidisciplinary management strategies may yield better clinical results. Further longitudinal research is warranted to examine causality and therapeutic interventions targeting both disorders.

Disclosure of Interest: None Declared

EPP003

Effectiveness of Cognitive Remediation in Subjects with Major Depressive Disorder: 3-Month Follow-Up Results of a Multicenter Randomized Controlled Study

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doi: 10.1192/j.eurpsy.2026.10618

Introduction: Major Depressive Disorder (MDD) is among the most prevalent psychiatric conditions worldwide. Cognitive impairment is a core feature, often persisting after remission and worsening with relapses. Cognitive Remediation (CR) is a structured psychosocial intervention targeting cognition and psychosocial functioning. This study reports the 3-month follow-up (T2) results of a previously conducted RCT, which assessed outcomes at baseline (T0) and post-treatment (T1).

Objectives: To evaluate the sustained effects at 3 months (T2) of computerized CR versus an active control (computer games, CG) in adults with MDD experiencing a Major Depressive Episode (MDE), focusing on cognitive performance, depressive symptoms, and functioning.

Methods: This single-blind, multicenter RCT randomized patients to either CR, delivered by trained therapists, or CG. Outcomes were measured with validated instruments by blind assessors at T0, T1, and T2. Mixed models for repeated measures (MMRM) with an intent-to-treat analysis were applied. Inclusion criteria required ≥8 years of education; exclusions included neurological disorders, severe head injury, or intellectual disability. Drop-out was defined as>5 days interruption of antidepressant therapy or ≥2 consecutive missed sessions with declared discontinuation.

Results: Of 142 screened patients, 101 were randomized (CR n = 52, CG n = 49), and 81 completed the study through T2 (CR n = 45, CG n = 36). At the 3-month follow-up, CR showed superior outcomes in self-reported depression (BDI, Figure 1, $p = 0.003$), subjective cognitive impairment (PDQ-5, $p = 0.007$), executive function (TMT-B, $p = 0.032$), and processing speed (DSST, Figure 2, $p = 0.009$), with significantly greater improvements compared to CG. No significant between-group differences were observed for clinician-rated depression (MADRS, $p = 0.112$) or verbal memory (CVLT, $p = 0.083$), although CR patients showed greater within-group improvements. While no statistically significant effects were found for TMT-A ($p = 0.349$) or Clinical Global Impression (CGI-S, $p = 0.458$), CR patients exhibited trends toward improved processing speed (TMT-A, $p = 0.055$) and a more pronounced reduction in clinical severity (CGI-S), suggesting potential non-specific benefits of the intervention.

Image 1:

