

Objectives: We hypothesize that the combination of “Almond Therapy™” with intranasal ketamine will result in a statistically significantly better outcome as demonstrated by a greater reduction in MADRS scores and/or response rates and/or remission rates in TRD patients compared with those who receive esketamine plus TAU. Secondary outcome measures include PHQ-9, GAD-7, PCL-5, Assessment of Quality of Life - 8D (AQOL-8D), and Rosenberg Self-Esteem Scale.

Methods: We have developed a research protocol combining a unique and specifically-designed, multi-modal psychotherapy program, “Almond Therapy™”, with intranasal esketamine in a randomized, controlled, single-blind 28-day study. The therapy utilizes an individualized, evidence-informed approach for each participant consisting of a number of modules selected using a shared decision-making process determined at the first study visit. This uniquely tailored approach ensures that the chosen modules are personally meaningful to the participant, and thus, promotes therapeutic adherence. The proprietary therapy combines elements of cognitive behavioral therapy (CBT), trauma focused-CBT, Dialectical Behavioral Therapy (DBT), and mindfulness, together with biofeedback. In addition to in-clinic sessions, participants also receive standardized remote therapy sessions by trained therapists.

Results: Patient recruitment and enrolment has begun. Interim results are anticipated.

Conclusions: This study is the first examination of the potential additional clinical benefit of adding a specific therapy program to existing intranasal esketamine treatment. If demonstrated to be of clinical benefit then further studies may potentially provide comparison to other therapy programs and in conjunction with other agents.

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EPP0605

Linked patterns of symptoms and cognition with brain controllability in major depressive disorder

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Introduction: Major depressive disorder (MDD) is characterized by both clinical symptoms and cognitive deficits. Prior studies have typically examined either symptoms or cognition correlated with brain measures, thus causing a notable paucity of stable brain markers that capture the full characteristics of MDD. Brain controllability derived from newly proposed brain model integrating both metabolism (energy cost) and dynamics from a control perspective has been considered as a sensitive biomarker for characterizing brain function. Thus, identifying such a biomarker of controllability related to both symptoms and cognition may provide a promising state monitor of MDD.

Objectives: To assess the associations between two multi-dimensional clinical (symptoms and cognition) and brain controllability data of MDD in an integrative model.

Methods: Sparse canonical correlation analysis (sCCA) was used to investigate the association between brain controllability at a network level and both clinical symptoms and cognition in 99 first-episode medication-naïve patients with MDD. The potential medication effect of cognition on relationship between controllability and symptoms was also tested.

Results: Average controllability was significantly correlated with both symptoms and cognition ($r_{\text{mean}}=0.54$, $P_{\text{Bonferroni}}=0.03$). Average controllability of dorsal attention network (DAN) ($r=0.46$) and visual network ($r=0.29$) had the highest correlation with both symptoms and cognition. Among clinical variables, depressed mood ($r=-0.23$), suicide ($r=-0.25$), work and activities ($r=-0.27$), gastrointestinal symptoms ($r=-0.25$) were significantly negatively associated with average controllability, while cognitive flexibility ($r=0.29$) was most strongly positively correlated with average controllability. Additionally, cognitive flexibility fully mediated the association between average controllability of DAN and depressed mood (indirect effect= -0.11 , 95% CI $[-0.18, -0.04]$, $P=0.001$) in MDD.

Conclusions: Brain average controllability was correlated with both clinical symptoms and cognition in first-episode medication-naïve patients with MDD. The results suggest that average controllability of DAN and visual network reached high associations with clinical variates in MDD, thus these brain features may serve as stable biomarkers to control the brain functional states transitions to be relevant to cognitions deficits and clinical symptoms of MDD. Additionally, altered average controllability of DAN in patients could induce impairment of cognitive flexibility, and thus cause severe depressed mood, indicating that controllability of DAN may be a potential intervention target for alleviating depressed mood through improving cognitive flexibility in MDD.

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Eating Disorders 01

EPP0606

The medical consequences of eating disorders: the correlation between the severity of the disease and the degree of the cardiological changes in paediatric patients with anorexia nervosa

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Introduction: Anorexia nervosa (AN) is associated with several medical complications. The cardiac changes represent the most severe complications and are associated with higher mortality. For this reason, periodic evaluation is necessary, by ECG and echocardiography. Moreover, there is not a protocol that defines the timelines or how to select higher risk patients that must be evaluated more frequently.