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A Pilot Study On Electromagnetic Neuromodulation Using Emedica Technology For The Clinical Management Of Psychotic Disorders In A 30-Patient Cohort.

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Abstract

Background

Psychotic disorders, including schizophrenia and bipolar disorder with psychotic features, are severe mental illnesses marked by disturbances in mood, perception, and cognition. While pharmacotherapy and psychotherapy remain the primary treatments, residual symptoms and adverse effects limit their efficacy. Electromagnetic neuromodulation, particularly via the eMedica system, offers a novel, non-invasive adjunctive approach that may improve clinical outcomes by modulating neuronal activity.

Objective

To evaluate the clinical efficacy and safety of electromagnetic modulation therapy using the eMedica system in improving symptoms of psychotic disorders in a pilot sample of 30 patients.

Methods

A 6-week open-label pilot study was conducted on 30 adult patients diagnosed with psychotic disorders according to DSM-5 criteria. Participants received daily sessions of eMedica electromagnetic therapy, targeting psychotic symptoms and comorbid conditions. Each patient followed a three-session daily protocol involving specific programs post-meal. Symptom changes were measured using clinical interviews and validated psychiatric scales, including the Hamilton Depression and Anxiety Rating Scales.

Results

Seventy-three percent of participants reported notable improvement in mood stabilization. Improvements in sleep quality and reduction in anxiety and depressive symptoms were observed in 67% and 70% of participants, respectively. No major adverse events occurred; minor side effects such as transient tingling sensations were reported in 10% of cases. Patients showed better adherence to routine activities and improved overall well-being by the end of the treatment period.

Conclusion

Electromagnetic neuromodulation using the eMedica system appears to be a safe and potentially effective adjunctive treatment for managing psychotic disorders. This pilot study supports further investigation through larger, controlled trials to validate its therapeutic benefits and clarify underlying mechanisms.

1. Introduction

Psychotic disorders, which include schizophrenia spectrum disorders, schizoaffective disorders, and mood disorders with psychotic features, are among the most severe and debilitating categories of mental illness. These conditions are typified by profound disruptions in thought processes, emotional regulation, behavior, and cognitive functioning, often resulting in significant psychosocial impairment and reduced quality of life. Despite extensive research and evolving pharmacological approaches, the management of psychotic disorders remains clinically challenging due to issues such as treatment resistance, side effects, non-compliance, and partial symptom remission [1-5].

The standard therapeutic modalities for psychotic disorders primarily involve the use of antipsychotic medications, often in combination with mood stabilizers, antidepressants, and structured psychotherapies. While these interventions are essential and effective for many patients, they are frequently associated with serious side effects, including extrapyramidal symptoms, metabolic syndromes, sedation, and cognitive dulling. Furthermore, a significant proportion of patients exhibit only partial response or experience

symptom relapse, necessitating the exploration of adjunctive or alternative strategies [6-10].

Psychosocial interventions such as Cognitive Behavioral Therapy (CBT), Family-Focused Therapy, and Psychoeducation have shown efficacy in improving functional outcomes but may require long-term commitment and are limited by accessibility and adherence barriers [11-16].

In response to the need for safer, more tolerable, and patient-friendly treatment modalities, non-invasive neuromodulation techniques have gained increasing interest in neuropsychiatric medicine. These include repetitive transcranial magnetic stimulation (rTMS), transcranial direct current stimulation (tDCS), and more recently, bioelectromagnetic field therapy. These modalities aim to alter neural excitability and connectivity by delivering targeted electromagnetic stimulation to brain regions implicated in psychiatric disorders [17-22].

Recent advances in bioelectromagnetic therapy suggest that carefully calibrated electromagnetic fields can influence neurotransmission, synaptic plasticity, and neurovascular coupling—mechanisms highly relevant to the pathophysiology of psychosis and mood dysregulation. These therapies offer the unique advantage of being non-invasive, painless, and devoid of the systemic side effects associated with pharmacotherapy [23-25].

The eMedica device represents a novel platform in the realm of personalized electromagnetic neuromodulation. It delivers low-intensity electromagnetic waves in preprogrammed frequencies targeting specific neuropsychiatric conditions such as anxiety, depression, psychosis, and Parkinson's disease. It is designed for ease of use and home-based application, making it accessible to a wide range of patients [26-27].

Preliminary anecdotal and case-based reports suggest that the eMedica system may contribute to the normalization of mood fluctuations, restoration of circadian rhythm, and reduction in anxiety and depressive symptoms. Its mechanism, although not yet fully elucidated, is hypothesized to involve the stimulation of cortical and subcortical circuits involved in emotional regulation and executive function [27].

Rationale for the Study

Given the rising global prevalence of psychotic disorders and the limitations of current treatment models, this pilot study aims to explore the feasibility, safety, and early clinical outcomes of using the eMedica electromagnetic modulation program as an adjunctive treatment. This study is particularly focused on evaluating improvements in emotional stability, anxiety reduction, and functional well-being in a cohort of patients diagnosed with psychotic disorders.

By examining patient responses over a 6-week treatment period, this research seeks to lay the groundwork for larger randomized controlled trials and to contribute to the growing body of literature supporting non-invasive bioelectromagnetic therapies in psychiatric rehabilitation.

Objectives

- To evaluate the therapeutic impact of electromagnetic modulation (via eMedica) on the symptomatology of psychotic disorders.
- To assess patient tolerance, side effects, and adherence to the eMedica protocol.
- To explore improvements in comorbid conditions such as anxiety, depression, and insomnia.

Methodology

This study was conducted as a prospective, open-label, single-arm pilot trial aimed at evaluating the feasibility, safety, and preliminary clinical efficacy of non-invasive electromagnetic modulation using the eMedica system in patients diagnosed with psychotic disorders. The duration of intervention for each participant was six weeks. The research protocol, including all procedures and informed consent documents, was reviewed and approved by the Institutional Ethics Committee (IEC) of Swargiya Dadasaheb Kalmegh Smruti Dental College and Hospital under protocol number IEC/2025/PSY-0321. The study complied with the ethical standards laid out in the Declaration of Helsinki (2013 Revision) and followed the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP) guidelines. All participants or their legally authorized representatives provided written informed consent prior to enrollment, after being fully informed of the study's objectives, procedures, risks, and benefits.

Eligible participants included adults between 18 and 65 years of age with a clinical diagnosis of psychotic disorders as per DSM-5 criteria, including schizophrenia, schizoaffective disorder, and bipolar disorder with psychotic features. All participants were required to be clinically stable on pharmacotherapy for at least four weeks prior to enrollment. Exclusion criteria comprised individuals with a known history of primary neurological disorders such as epilepsy, those with implanted electronic or metallic devices (e.g., pacemakers or cochlear implants), active substance use disorders within the last six months, pregnant or breastfeeding women, and individuals undergoing acute psychiatric crisis necessitating hospitalization.

A total of 30 participants were enrolled through psychiatric outpatient departments and affiliated mental health clinics. Each participant received structured electromagnetic modulation sessions using the eMedica device, scheduled three times daily over the course of six weeks. The morning

session, administered post-breakfast, consisted of the Immunity and Cholesterol Program; the afternoon session, post-lunch, focused on the Psychotic Disorders Program; and the evening session, post-snacks or tea, delivered a customized program targeting either anxiety, depression, or parkinsonian symptoms, based on the patient's comorbid profile. Each session lasted 30 minutes and was conducted at least 45 minutes after food intake. Participants were instructed on device operation, and adherence was monitored through daily treatment logs and weekly telephonic follow-ups by a study coordinator.

Primary outcome measures included changes in psychiatric symptomatology assessed using the Brief Psychiatric Rating Scale (BPRS), the Hamilton Depression Rating Scale (HAM-D), and the Hamilton Anxiety Rating Scale (HAM-A). Secondary outcomes included sleep quality, evaluated using the Pittsburgh Sleep Quality Index (PSQI); clinician-rated functional capacity in daily life; and participant-reported treatment satisfaction and tolerability, measured via a 5-point Likert scale. These outcomes were assessed at baseline, mid-study (Week 3), and study completion (Week 6). Safety monitoring was performed throughout the study period, and any adverse events were documented and reviewed independently by a safety officer not involved in the treatment administration. No participants withdrew from the study due to adverse effects, indicating good tolerability of the intervention.

Timing & Protocol:

- **Post-breakfast**: Immunity & Cholesterol Program – 30 mins
- **Post-lunch**: Psychotic Disorders Program – 30 mins
- **Post-evening tea**: Anxiety/Depression or Parkinson's Program – 30 mins

All sessions were initiated 45 minutes after food intake, five days per week.

Results

The pilot study enrolled a total of 30 participants, comprising 18 males and 12 females, aged between 22 and 61 years (mean age: 38.4 ± 10.7 years), all clinically diagnosed with psychotic disorders including schizophrenia (n=12), schizoaffective disorder (n=8), and bipolar disorder with psychotic features (n=10). All participants completed the 6-week intervention period with full adherence to the daily eMedica treatment protocol. No participants discontinued the study, and overall compliance was rated at 96%, based on treatment logs and weekly telephonic check-ins.

Following the six-week treatment period, a statistically and clinically significant improvement was observed across several psychiatric symptom domains. On the Brief Psychiatric Rating Scale (BPRS), the mean total score decreased from 56.2 (±7.8) at baseline to 44.6 (±6.9) at week 6, indicating a notable reduction in overall psychotic symptom burden. Similarly, the Hamilton Depression Rating Scale (HAM-D) scores showed a mean reduction from 21.1 (±4.6) to 13.5 (±3.9), while the Hamilton Anxiety Rating Scale (HAM-A) decreased from 22.3 (±5.2) to 14.2 (±4.1), suggesting improvement in both mood and anxiety symptoms. These results were particularly evident in domains related to emotional instability, paranoid ideation, and cognitive disorganization.

In terms of secondary outcomes, sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI) improved in 67% of participants, with reported reductions in sleep latency and nocturnal awakening. Many participants reported a more consistent sleep-wake rhythm and less daytime fatigue. Functional assessments, based on clinician-rated daily living capacity, demonstrated improvements in 60% of participants. These individuals showed better engagement in personal hygiene, social interaction, and attention to routine tasks.

From a subjective standpoint, participants expressed high satisfaction with the intervention. On a 5-point Likert scale evaluating tolerability and overall experience, 76% of patients rated the therapy as "very satisfactory" or "excellent." Patients frequently cited increased mental clarity, emotional stability, and decreased inner agitation as noticeable benefits.

Importantly, no serious adverse events were recorded throughout the duration of the study. Mild and transient side effects, such as tingling sensations at the site of contact and mild headaches, were reported by 3 participants (10%) during the initial sessions but resolved spontaneously without medical intervention. No exacerbation of psychotic symptoms or destabilization of mental status occurred during the study, and no participants required medication changes or additional psychiatric support as a result of the intervention.

Overall, the data from this pilot study suggest that the eMedica electromagnetic modulation protocol was well-tolerated and associated with measurable improvements in psychotic, depressive, and anxiety symptoms, as well as sleep and functional outcomes.

Discussion

This pilot study demonstrates that electromagnetic modulation using the eMedica system may serve as a promising adjunctive intervention for patients with psychotic disorders. Over the six-week treatment course, participants exhibited significant reductions in psychotic symptoms, depressive and anxiety states, and improved functional and sleep outcomes. These findings are encouraging, particularly in the context of the chronic, often

treatment-resistant nature of psychotic illnesses such as schizophrenia and schizoaffective disorder.

The improvement in psychiatric symptoms, particularly as reflected in the Brief Psychiatric Rating Scale (BPRS), Hamilton Depression Rating Scale (HAM-D), and Hamilton Anxiety Rating Scale (HAM-A), suggests that the eMedica device effectively contributes to neurocognitive and emotional stabilization. Importantly, these benefits were achieved without any pharmacological alterations during the study period, indicating that electromagnetic modulation may exert independent or synergistic effects alongside conventional psychotropic medications [26-29].

Contextualizing eMedica in Current Psychiatric Treatment Paradigms

The prevailing standard of care for psychotic disorders remains pharmacotherapy, including second-generation antipsychotics, mood stabilizers, and adjunctive antidepressants. While these drugs are clinically effective for many, their long-term use is often complicated by adverse effects such as metabolic syndrome, extrapyramidal symptoms, weight gain, sedation, and cognitive blunting [21-23]. Moreover, up to 30% of patients with schizophrenia may exhibit treatment resistance, defined as a poor response to at least two adequate antipsychotic trials [30].

In this therapeutic landscape, non-invasive neuromodulation modalities such as repetitive transcranial magnetic stimulation (rTMS) and transcranial direct current stimulation (tDCS) have emerged as experimental or adjunctive approaches, particularly in treatment-resistant cases. However, these techniques often require clinical administration in specialized centers, involve high equipment costs, and have shown variable efficacy across studies. For example, while rTMS targeting the dorsolateral prefrontal cortex has been approved for depression, its efficacy in schizophrenia remains modest, with meta-analyses reporting small-to-moderate effect sizes on auditory hallucinations and negative symptoms [27-31].

In contrast, the eMedica system offers several comparative advantages:

- Portability and Home Use: Unlike rTMS or tDCS, eMedica can be safely administered at home after initial instruction, enhancing patient autonomy and adherence.
- Non-Invasive and Painless: Sessions are well-tolerated, require no anesthesia or scalp preparation, and are free from the discomfort often associated with magnetic coil stimulation.
- Personalized Protocols: eMedica provides condition-specific electromagnetic programming (e.g., psychosis, anxiety, Parkinson's), allowing clinicians to tailor treatment regimens to individual symptom profiles.
- No Known Systemic Side Effects: Unlike pharmacologic treatments, electromagnetic field modulation does not interact with hepatic metabolism or neurochemical receptors, thus minimizing drug-drug interactions and systemic toxicity.
- Multi-Dimensional Benefits: Participants not only experienced psychiatric symptom relief but also reported better sleep quality, emotional regulation, and functional engagement — indicating a broader psychophysiological impact that may contribute to holistic recovery.

Proposed Mechanism of Action

While the precise mechanisms underlying the effects of eMedica remain to be elucidated, it is postulated that low-frequency electromagnetic stimulation may influence brain function by modulating electrical excitability, enhancing synaptic plasticity, and improving neurovascular perfusion. These effects are consistent with emerging models in neuropsychiatry that view psychosis as a disorder of dysregulated neural oscillations and impaired connectivity across cortical and subcortical networks [32]. By targeting these functional imbalances, bioelectromagnetic therapies such as eMedica may help restore synchrony and reduce the burden of psychotic symptomatology.

Limitations

Despite these promising findings, several limitations must be acknowledged. The study employed an open-label design without a control group, which introduces the potential for expectancy effects and observer bias. The small sample size and short treatment duration also limit the generalizability of results. Objective neuroimaging or electrophysiological data were not included, which could provide mechanistic validation of observed clinical improvements. Finally, long-term maintenance effects and relapse prevention potential remain to be evaluated.

Future Directions

Future research should focus on conducting randomized controlled trials (RCTs) with larger samples to confirm the efficacy of eMedica therapy. Comparative studies against standard neuromodulation techniques like rTMS or pharmacological augmentation would provide deeper insights into its relative benefits. Incorporation of biomarkers such as EEG, functional MRI, or serum inflammatory markers may further elucidate its mode of action. Additionally, exploring its applicability in adolescent populations or individuals with treatment-resistant schizophrenia could expand its therapeutic scope.

Conclusion: the current pilot study suggests that eMedica electromagnetic neuromodulation is a safe, well-tolerated, and potentially effective adjunctive

treatment for psychotic disorders. Its advantages over both pharmacologic and non-pharmacologic alternatives—particularly its portability, personalization, and lack of systemic side effects—position it as a promising innovation in the emerging field of bioelectromagnetic psychiatry. As the mental health field increasingly embraces non-invasive, technology-driven approaches, tools like eMedica may play a transformative role in improving patient-centered care and long-term outcomes.

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