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Research on non-invasive neuromodulation technique: A data audit of International Clinical Trials Registry Platform

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Summary

Background: *Neuromodulation techniques have emerged as promising interventions for various neurological and psychiatric disorders. Understanding the global landscape of neuromodulation research is crucial for advancing therapeutic interventions and addressing regional healthcare needs. This study aimed to conduct a data audit of neuromodulation-related clinical trials registered in the International Clinical Trials Registry Platform (ICTRP), with a focus on comparing global trends with those in India.*

Subjects and Methods: *Data were extracted from the ICTRP website using predefined keywords related to neuromodulation techniques. The database was searched on 31st March 2024 at 8:00 am. A total of 5849 records were analyzed. Data were extracted for time (year of study), type of study, country of the study, trial registry, and disease studied. Descriptive statistics and comparative analyses were conducted to examine the frequencies.*

Results: *The study found that ClinicalTrials.gov hosts the majority of global neuromodulation trials (53.63%) and China leads in research (23.53%), with India contributing 4.14% percent share of global neuromodulation studies. There was a sharper rise in Indian studies in comparison to global trends. Neurological diseases are being studied in the world whereas psychiatric disorders are higher studied in India.*

Conclusion: *This study reveals key trends in neuromodulation research, with India emerging as a significant contributor alongside China and the USA, showing a notable increase in trials. Indian research strongly focuses on interventional studies, particularly in psychiatric disorders like schizophrenia and major depressive disorder. The findings highlight the need for continued support and investment to enhance India's contribution to global neuromodulation research.*

Keywords: *Neuromodulation, brain stimulation, TMS, tDCS, Electroconvulsive therapy, mental illness.*

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INTRODUCTION

Neuromodulation refers to the alteration of nerve activity through targeted delivery of a stimulus, such as electrical signals or pharmacological agents, to specific neurological sites (Arca et al., 2024). In recent years, advancements in technology and a deeper understanding of neural circuits have expanded the potential applications of neuromodulation (Denison & Morrell, 2022). These therapies offer the promise of symptom relief for patients who do not respond to conventional treatment and become resistant to treatment, thereby improving their quality of life (Mohapatra et al., 2022; Ranjan et al., 2021). As such, there has been a surge in clinical research aimed at evaluating the efficacy, safety, and mechanisms of various neuromodulation techniques (Davidson et al., 2024).

Regional disparities in disease burden necessitate tailored approaches to effectively address specific health challenges. Additionally, cultural, genetic, and environmental factors can influence the presentation and progression of these conditions, requiring localized research to optimize treatment efficacy (National Academies of Sciences et al., 2017). Neuromodulation-related research is particularly necessary in countries like India due to the high prevalence of neurological and psychiatric disorders (Venkatasubramanian et al., 2021). India faces a significant burden of conditions such as chronic pain, epilepsy, depression, and Parkinson's disease. Advancing neuromodulation research can provide alternative and potentially more effective treatment options for these conditions, improving patient outcomes and quality of life (Krishna & Fasano, 2024). However, the current landscape of the research on this topic and a comparison with Indian research is not available currently.

There are various clinical trial registries in different zones of the world. However, the International Clinical Trials Registry Platform (ICTRP), managed by the World

Health Organization (WHO), is a global initiative that aims to combine the majority of the database in a single platform to ensure that a complete view of research is accessible to all those involved in health care decision-making (Namiot et al., 2023). Conducting a data audit of the ICTRP specifically focused on neuromodulation clinical trials can offer valuable insights into the current landscape of research in this field.

With this background, the present study aimed to perform an audit of neuromodulation-related clinical trials registered in the ICTRP and compare the global trends with Indian research trends on the same topic. This comparison of global and Indian trends in neuromodulation can provide stakeholders with valuable insights regarding the disparities and commonalities in research focus, funding, and clinical outcomes. This would also help researchers identify gaps in Indian neuromodulation research that need addressing. For policymakers, it would help in strategic planning to enhance research on potential areas where it is being less explored in India.

SUBJECTS AND METHODS

Ethical considerations

Given that this study utilized publicly available data from the ICTRP, it did not require ethical approval. Nevertheless, the research team adhered to ethical standards by ensuring the accurate and responsible use of data, maintaining confidentiality, and upholding the integrity of the research process. The analysis was conducted with a commitment to transparency and reproducibility.

Data source

The data for this study were sourced from the International Clinical Trials Registry Platform (ICTRP), a comprehensive database managed by the World Health Organization (WHO) (Namiot et al., 2023). The search portal is available for free access at https://trialsearch.who.int. The ICTRP consolidates clinical trial information from various national and international registries, ensuring transparency and accessibility of global clinical research data. This platform was selected due to its extensive coverage and the reliability of its data, making it an ideal source for a thorough audit of neuromodulation-related clinical trials (Juneja et al., 2019).

Study selection criteria

We used the following keywords to search the database – (Transcranial magnetic stimulation) OR (repetitive Transcranial magnetic stimulation) OR (TMS) OR (rTMS) OR (neuromodulation) OR (non-invasive brain stimulation) OR (brain stimulation) OR (H-coil) OR (theta burst stimulation) OR (theta burst). The database was searched on 31st March 2024 at 8:00 am from a personal computer connected to a personal broadband internet connection. We included all the studies found with the keywords. According to the aim of the study, only the therapeutic modes (neuromodulation technique) were considered. The search was not restrictive to any particular disease or condition. Only incomplete entries with some errors that could not be resolved were excluded from the study in the data cleaning phase. A total of 5849 records were analyzed.

Data extraction

Two individuals first cleaned the data as there were some incomplete, incorrect, and obscure data. Studies related to invasive technology was omitted. After the cleaning by individuals, a consensus was reached for finalizing the data set for analysis. A total of 5849 records were retrieved from the database and finalized for analysis. These two individuals categorized the data according to the time (year of study), type of study, design of the study, country of the study, trial registry, disease studied, the age range of the participants, and gender distribution.

From the database, the studies registered in the clinical trial registry of India, crawled by ICTRP were separated and the same data was extracted for the comparison.

Data analysis

The extracted data were analyzed using both quantitative and qualitative methods. Descriptive statistics were computed to provide an overview of the data. A comparative analysis was then conducted to highlight differences and similarities between global trends and those specific to India. We used Microsoft Excel 2021 (Microsoft Corporation, Washington, United States) for initial data organization and cleaning. We used GraphPad Prism 9.5.0 (GraphPad Software Inc., USA) for statistical analysis. For all tests, a p-value <0.05 was considered statistically significant.

RESULTS

The majority of the trials are registered in ClinicalTrials.gov (53.63%) followed by ChiCTR (16.87%). The Indian clinical trial registry contributes 3.74% of the trials. The source clinical trial database is shown in Table 1.

The global research studies registered from various countries are shown in Figure 1. The top five countries are China (23.53%), USA (22.99%), Germany (5.15%), Netherlands (4.49%), and Iran (4.34%). India is the very next country with a 4.14% percent share of global neuromodulation studies.

Clinical trials registered in India are available from 2012. Hence, global data (excluding 12.19% of data that was before 2012) was also plotted from 2012 to till date in comparison to Indian data in Figure 2. There is a gradual increase in the number of studies in both global and Indian trial registries. However, the exponential trend line shows a sharper rise in Indian studies.

The studies that are registered are shown in Figure 3. Globally 90.23% interventional and 8.91 are observational studies. Only 0.86% are other studies like basic science, diagnostic tests, or relative factor studies. Indian studies are only interventional (96.44%) and observational (3.56%). When compared by Chi-square test among the global and Indian data with integer percentages, there was no significant difference between the global and Indian studies category (P = 0.21).

A wide spectrum of diseases and disorders were studied upon in these neuromodulation trials. The diseases and disorders when categorized under the broad heading of neurological, psychiatric disorders, and other diseases,

Table 1 Clinical trial database according to their relative contribution to worldwide neuromodulation trials

Registry name	Number (%)
ClinicalTrials.gov	3137 (53.63)
ChiCTR	987 (16.87)
JPRN	277 (4.74)
NL-OMON	277 (4.74)
ANZCTR	224 (3.83)
IRCT	223 (3.81)
CTRI	219 (3.74)
GCTR	163 (2.79)
ISRCTN	95 (1.62)
ReBEC	73 (1.25)
CRIS	60 (1.03)
ITMCTR	46 (0.79)
TCTR	24 (0.41)
EUCTR	17 (0.29)
PACTR	12 (0.21)

Cut-off date 31st March 2024. The full form of the registry is available from: https://trialsearch.who.int/Default.aspx
N.B: ChiCTR-Chinese Clinical Trial Register, JPRN-Japan Primary Registries Network, NL-OMON-Overview of Medical Research in Netherlands, ANZCTR-Australian New Zealand Clinical Trials Registry, IRCT-Iranian Registry of Clinical Trials, CTRI-Clinical Trial Registry of India, GCTR-German Clinical Trials Register, ISRCTN-International Standard Randomised Controlled Trial Number, ReBEC-Brazilian Registry of Clinical Trials, CRIS-Clinical Research Information Service, ITMCTR-International Traditional Medicine Clinical Trial Registry, TCTR-Thai Clinical Trials Registry, EUCTR-European Union Clinical Trials Register, PACTR-Pan African Clinical Trials Registry.

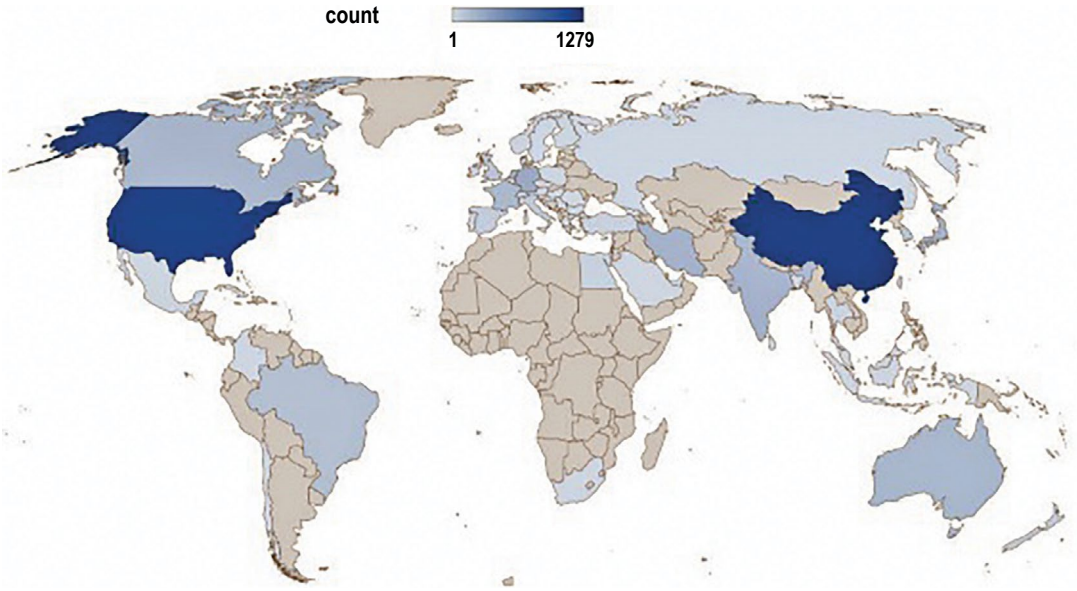


Figure 1 Global neuromodulation studies in International Clinical Trials Registry Platform (cutoff date 31st March 2024)

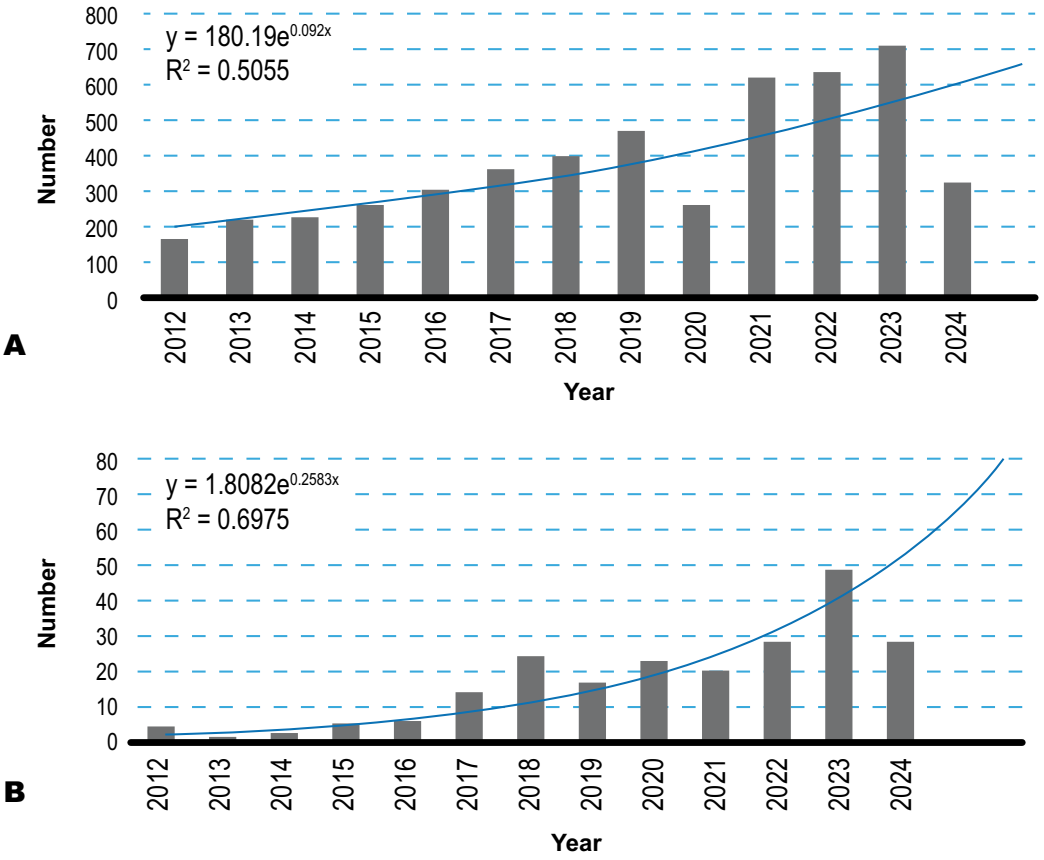


Figure 2: Number of trials according to years – (a) global data and (b) Indian data

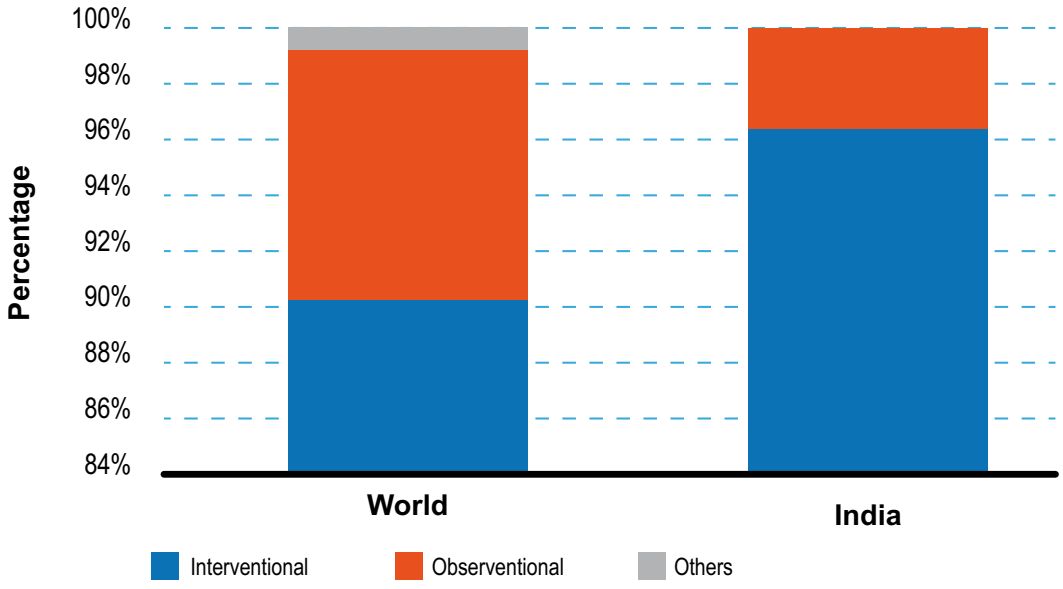


Figure 3 Type of study in global and Indian trial registry (cutoff date 31st March 2024)

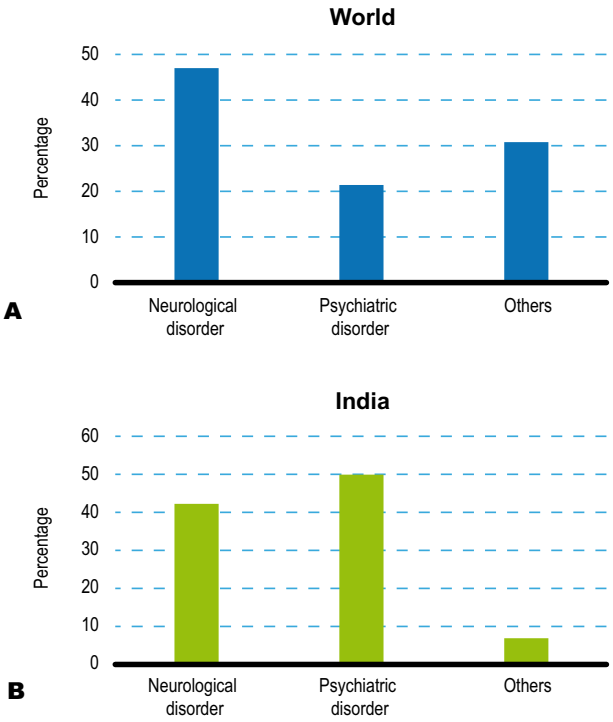


Figure 4 Trials according to diseases in global and Indian trial registry (cutoff date 31st March 2024)

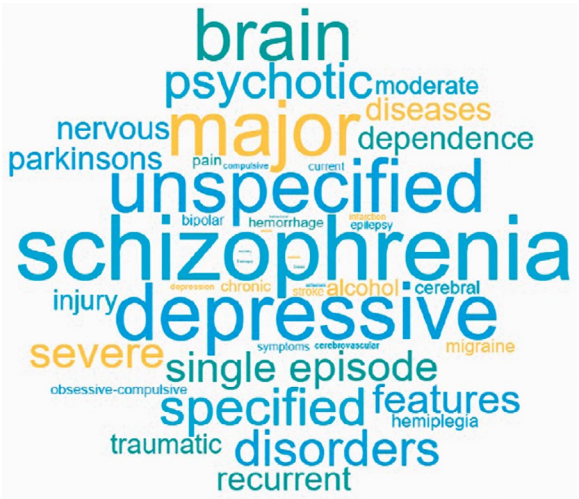


Figure 5 Word cloud made from the text of disease of trial available in CTRI

the percentage-wise comparison of global and Indian data shows the trends as depicted in Figure 4. There was a significant difference between the global and Indian trials (P<0.0001) – Neurological diseases and other diseases are being studied in the world whereas psychiatric disorders are highly studied in India.

In India, clinical studies focus on neurological disorders like Parkinson's disease and stroke, psychiatric conditions such as schizophrenia and major depressive disorder, and other diseases including fibromyalgia, diabetic neuropathy, low back pain, migraine, and others.

The disease or condition studied has been used to create a word cloud and it is shown in Figure 5. From the word cloud, it is evident that schizophrenia and major depressive disorders are the top diseases being studied in India.

DISCUSSION

The analysis of neuromodulation studies reveals trends in both global and Indian contexts. ClinicalTrials.gov dominates as the primary registry for global neuromodulation trials, with a substantial representation from China and the USA. Despite contributing a smaller overall percentage, India demonstrates a significant presence in the global landscape, reflecting a growing engagement with neuromodulation research.

Although Indian studies started being systematically registered only from 2012, they have shown a robust increase over the years. This increase is more pronounced than the global trend, suggesting a burgeoning interest and investment in neuromodulation research within India. [5] This trend indicates a strong and expanding research infrastructure that is increasingly aligned with global scientific endeavours.

Both globally and in India, the vast majority of trials are interventional (Aggarwal & Ranganathan, 2019), which highlights a predominant focus on testing new treatments and therapies rather than merely observing disease progressions or identifying biomarkers. The similarity in study types between global and Indian trials suggests that India's research methodologies are consistent with international standards, underscoring the quality and relevance of Indian neuromodulation research.

A more detailed comparison of disease focus reveals significant differences. Globally, there is a broader distribution of studies across various neurological and other diseases, whereas in India, psychiatric disorders, particularly schizophrenia and major depressive disorder, are more prominently studied. This may reflect specific public health priorities and disease burdens unique to India, where mental health issues are increasingly recognized as critical areas requiring focused research and intervention (Jaiswal et al., 2023). A detailed list of diseases on which trials are going on can be obtained from https://www.neuromodulation.com/conditions.

The novelty of this study lies in its comprehensive comparison of neuromodulation research trends between India and the global landscape. It uniquely highlights the

rapid growth and specific focus areas of Indian neuromodulation studies, particularly the emphasis on psychiatric disorders. By analyzing data from various international clinical trial registries and identifying distinct patterns in disease focus and research methodologies, this study provides valuable insights for stakeholders.

Limitations:

The study has some limitations. A key limitation of this study is its reliance on the completeness and accuracy of the data available from clinical trial registries, which may vary in terms of registration practices and reporting standards across different countries. ICTRP data being dependent upon the inputs from the individual country trial registries, irregularity in such inputs affects the total number of trials retrieved from ICTRP. Our data is based on a single date search as mentioned before in the 'methods' section. Additionally, the study does not delve into the quality or outcomes of the registered trials, focusing solely on their quantity and categorization. This may overlook important nuances regarding the impact and efficacy of the research being conducted. Furthermore, the analysis is constrained to registered trials, potentially missing unregistered or unpublished studies that could provide a more comprehensive picture of the neuromodulation research landscape.

CONCLUSION

This study highlights significant trends and insights into the landscape of neuromodulation research globally and in India. While global studies are predominantly conducted in China and the USA, India is emerging as a significant contributor, with a higher increment rate. The research in India is characterized by a strong emphasis on interventional studies, aligning with global practices, but distinctly prioritizes psychiatric disorders such as schizophrenia and major depressive disorder. The growing number of neuromodulation studies in India, coupled with their alignment with international research standards, indicates a promising trajectory for the country's contribution to this field. This study underscores the importance of continued support and investment in neuromodulation research to address both global and local health challenges effectively.

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