



LETTER TO THE EDITOR

Review of mental health research in Turkiye: A view from ClinicalTrials.gov

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Dear Editor,

The World Health Organization (WHO) recognizes the registration of clinical trials as a requirement of research ethics and a moral obligation. This registry aims to provide a reliable presentation of research methods, data, modifications made during the research process, and the results of the research. ClinicalTrials.gov, managed by the National Institutes of Health (NIH) in the United States, is the largest trial protocol registry in the world (1).

It is now widely accepted that protocol registries hold significant importance. For example, the Food and Drug Administration Amendments Act (FDAAA) mandated that certain clinical trials be registered in the ClinicalTrials.gov database and that results be disclosed (2, 3). An increasing number of academic journals now require that trials be registered before they can be considered for publication (4). The Declaration of Helsinki also emphasizes that every clinical trial should be registered in a publicly accessible database before the recruitment of the first subject (5).

In Turkiye, there is no national protocol registration system, nor is there a requirement to register in international databases. However, ethics committee approval and authorization from the Turkish Medicines and Medical Devices Agency are required to conduct clinical research. Previous studies examining research conducted in Turkiye and registered in international

databases in 2019 and 2023 have shown a gradual increase in the number of studies from Turkiye (6, 7). This study aimed to examine the characteristics of trials conducted in Turkiye on various mental disorders and registered in ClinicalTrials.gov. The goal was to raise awareness about the importance of registration systems and to encourage the registration of studies in the field of mental health, thereby increasing transparency and reliability in scientific research.

The open-access ClinicalTrials.gov database was searched using the keywords "depressive disorder," "bipolar disorder," "schizophrenia," and "anxiety disorders" to identify relevant studies up to April 2024. Additional search terms included "depression," "depressive," "anxiety," and "manic-depression" (8). We also conducted searches for other mental health conditions, including obsessive-compulsive disorder, substance use disorders, and post-traumatic stress disorder. However, these conditions were not included in the final analysis due to the relatively low number of studies found. Characteristics such as the number of centers, clinic types, enrollment dates, study start and completion dates, study types (observational or clinical), designs, final status (completed, ongoing, early termination, withdrawn, suspended, status unknown, not yet started recruiting patients, or in the process of recruiting patients), number of participants, and funding institutions (government, private company, industry, or pharmaceutical company) were recorded. Studies on child mental health were

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Table 1: Masking strategies of randomized controlled trials by individual keyword analysis

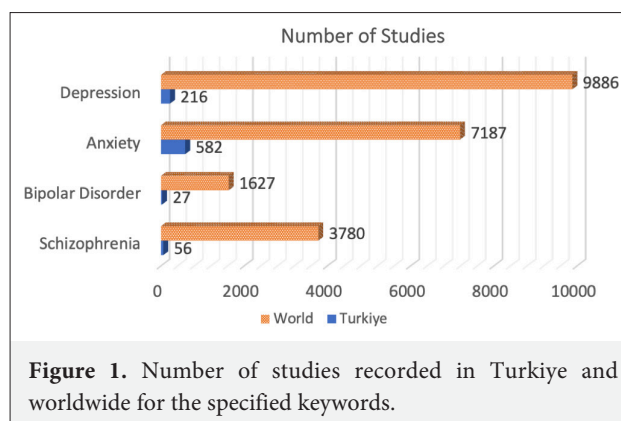
Keyword	Non-masking	Single masking	Double masking	Triple masking	Quadruple masking
Anxiety	36.5%	41.1%	16.1%	4.2%	2.1%
Bipolar disorder	33.3%	11.1%	27.8%	5.6%	22.2%
Schizophrenia	46.8%	23.4%	19.1%	4.3%	6.4%
Depression	33.1%	43.7%	17.2%	2.6%	3.3%

not included, and duplicate entries (26 entries) were excluded. Statistical analyses were performed using SPSS version 25.0 for macOS. Categorical variables were expressed as numbers and percentages. Due to incomplete data in some studies, the number of data points varied across different parameters. This work was designed as a descriptive study; thus, no specific analytical statistical tests were conducted.

A total of 881 studies from Turkiye were included, of which 620 (70.4%) were completed and 50 (5.7%) had an unknown final status. The remaining studies were at various recruitment stages, terminated, suspended, or withdrawn. Among these, 71 (8.1%) were multicenter-international, 9 (1%) were multicenter-national, and 801 (90.9%) were single-center. Most studies (79.1%) were interventional, while 20.9% were observational. Universities, training and research hospitals, and the government sponsored the majority of the studies, while 57 studies were funded by pharmaceutical companies. The number of studies in the world and Turkiye is shown in Figure 1.

For observational studies, 36.08% were cohort studies. In interventional studies, masking strategies varied: 36.4% had no masking, 39.7% used single masking, 16.8% used double masking, 3.9% used triple masking, and 3.2% used quadruple masking. When the disorder groups were examined separately, the masking strategies of randomized controlled trials are shown in Table 1. Of the studies, 34% had more than 100 participants, while 66% had 100 or fewer. Notably, 80.8% of the studies were recorded in the database after the study start date, while 19.2% were recorded before the start date. The median study duration from start to completion was 215 days (range: 0-4,728 days).

Principal investigators were from the nursing, physiotherapy, and psychiatry departments. The breakdown by department was as follows: nursing (42.9%), physiotherapy (11.6%), psychiatry (9.8%), midwifery (7.5%), anesthesiology and reanimation (6.9%), physical therapy and rehabilitation (4%), obstetrics (3%), psychology (1.6%), among others. In anxiety disorder studies, nursing had the highest representation at 52.4%, followed by midwifery (9.3%) and anesthesiology (8.3%). In bipolar

**Figure 1.** Number of studies recorded in Turkiye and worldwide for the specified keywords.

disorder studies, psychiatry led at 70.4%, followed by nursing at 18.5%. For depression studies, the distribution included physiotherapy (25%), nursing (24.5%), psychiatry (10.2%), and physical therapy and rehabilitation (8.8%). In schizophrenia studies, psychiatry accounted for 64.3%, nursing for 26.8%, and physiotherapy for 7.1%.

There is no national protocol registry in Turkiye, and ClinicalTrials.gov remains the most recognized and widely used system. This study provides the first detailed analysis of mental health research from Turkiye registered in ClinicalTrials.gov. It highlighted that most studies were funded by universities and hospitals, involved fewer than 100 participants, and used some form of masking. The findings are consistent with global trends, where most studies are small-scale, university-funded, and use masking strategies (9). The study highlights the multidisciplinary nature of mental health research in practice, as indicated by the diverse range of departments involved in these studies. Recently, research has shown a decline in pharmaceutical company funding for mental health research over the years (1). Pharmaceutical companies can offer substantial financial support for the development of new drugs and treatments, while studies funded by universities and research hospitals may face financial constraints, potentially hindering innovative projects. However, government-funded trials are often considered more reliable due to the absence of commercial interests, and they tend to focus on basic, non-profit interventions.

It is important to establish a national registration system and to adopt multidisciplinary approaches more widely to improve the conformity of mental health research in Türkiye with international standards. Future studies should take steps to address the current shortcomings in this area and enhance the quality of mental health research. This study has contributed to a better understanding of the current state of mental health research in Türkiye and provides an important foundation for future improvements.

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