Patients, participants, or subjects: A systematic analysis of descriptors used in migraine and major depression clinical trials published in the last decade

Poster 45

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Introduction

- Terms used to describe individuals participating in clinical trials may influence how the trials are perceived.[1–3]
- Calling individuals enrolled in clinical trials "subjects" implies passive acquiescence and exploitation rather than voluntary involvement; whereas, "participant" implies voluntary contribution.[4]
- There is an increasing effort to reduce stigmatizing language; however, the recommended descriptors for clinical trials among different disease states are not well established.[1–3]

Objective

- To evaluate 10-year trends in population descriptor(s) used in clinical trial publications, using migraine and major depressive disorder (MDD) disease states as examples.

Research design and methods

- A systematic literature review (SLR) was performed to examine the descriptor term(s) authors used to describe a clinical trial population (i.e., "patients", "participants", and/or "subjects"), with a focus on migraine and MDD.
- Two PubMed searches of primary research publications across 2014–2024 were conducted, both comprising a 3-part search string specifying key inclusion/exclusion criteria. Article details were exported into Microsoft Excel for screening and analysis (**Figure 1**).

Figure 1. Research design

01 STEP

Created search strings for PubMed:
- ("Migraine"[title]) AND ("2014/01/01"[Date - Publication]: "2024/12/31" [Date - Publication]) AND "clinical trial"[Publication Type]
- ("Major depressive disorder"[title] OR "Major depression"[title] OR "MDD"[title]) AND ("2014/01/01"[Date - Publication]: "2024/12/31"[Date - Publication]) AND "clinical trial"[Publication Type]

02 STEP

Performed search in PubMed, applying the following filters for inclusion criteria:
- *Publication date*: ≤10 years
- *Article type*: Clinical Trial, Phase I–IV; Randomized Controlled Trial; Controlled Clinical Trial

03 STEP

PubMed2XL was used to extract the full abstract and publication dates to include in the Excel file for analysis

04 STEP

Manually excluded articles that met any of the exclusion criteria:
- *Publication type*: "review" or "comment"
- *Earliest publication year (print or electronic)*: <10 years
- *Abstract*: none

05 STEP

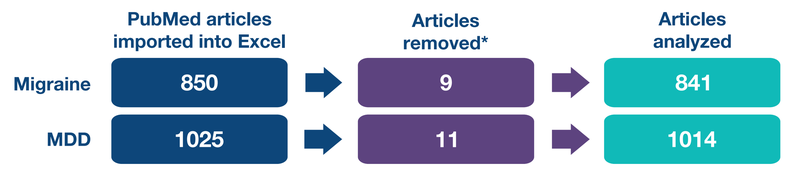
Analyzed the trial population descriptor(s) used in the title/abstract of publications, with instructions for ChatGPT-4o mini to:
- Generate Excel formulas that can extract the desired information
  - A. Identify descriptor(s) within the title/abstract
  - B. Measure the number of publications across all 10 years (2014–2024) that include ≥1 descriptor(s) in the title/abstract, as well as the number by year
- Analyze the uploaded Excel file

MDD, major depressive disorder.

Results

- The search for migraine-related publications yielded 850 results, of which 841 were analyzed; the search for MDD-related publications yielded 1025 results, of which 1014 were analyzed (**Figure 2**).

Figure 2. Migraine and MDD clinical trial publications included in the analysis



*Articles were removed due to publication type (comment or review), publication year (not within 2014–2024), or lack of an abstract. MDD, major depressive disorder.

- Over the ten-year period in both migraine and MDD clinical trial publications, "patients" was the most commonly used, followed by "participants", then "subjects" (**Table 1**).

Table 1. Prevalence of migraine and MDD clinical trial publications across 2014–2024 using each descriptor in the title/abstract

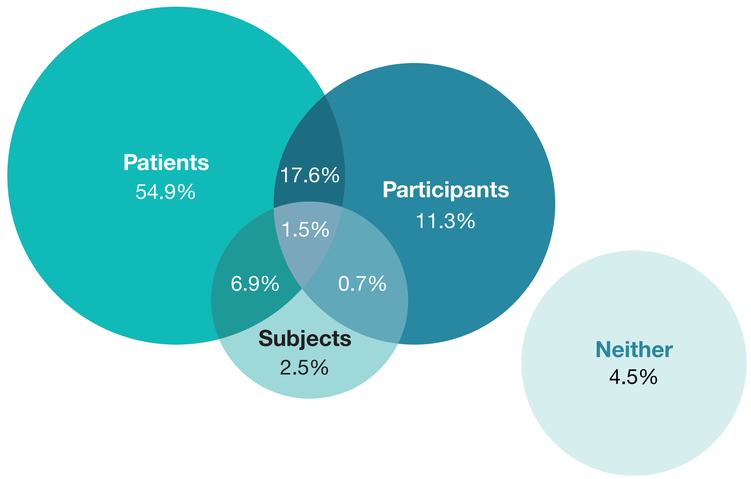
	Migraine (N=841 articles)		MDD (N=1014 articles)	
Descriptor Term	**# of articles**	**% of articles**	**# of articles**	**% of articles**
Patients, participants, subjects				
Patients	681	81.0%	805	79.4%
Participants	262	31.2%	357	35.2%
Subjects	98	11.7%	103	10.2%
Other descriptors (included in ≥10% of articles)*				
Group(s)	511	60.8%	546	53.8%
Adults	170	20.2%	211	20.8%
Population(s)	128	15.2%	119	11.7%
Individuals	61	7.3%	149	14.7%
Women	88	10.5%	63	6.2%

*The prevalence of descriptors other than "patients", "participants", or "subjects" are listed in this table if they met the threshold of appearing in ≥10% of the 841 migraine or 1014 MDD publications. Each identified descriptor was counted only once per article, regardless of how many times it appeared in the title/abstract. All terms were recognized as individual words within the abstract/title, except "patients" could include the term "outpatients" or "inpatients". MDD, major depressive disorder.

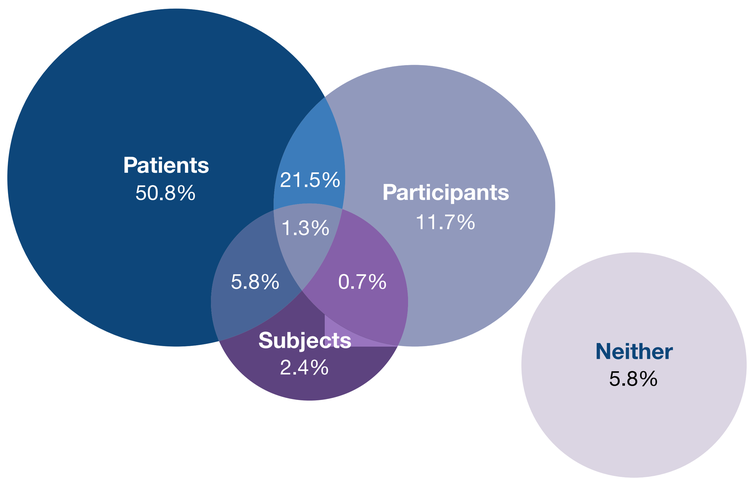
- Analysis of any combination of one or more of the terms "patients" vs "participants" vs "subjects" revealed that 54.9% of the migraine publications across 2014–2024 used "patients" only, 11.3% used "participants" only, 2.5% used "subjects" only, and 4.5% used none of the 3 descriptors (**Figure 3A**).
- A similar pattern was observed for MDD publications, with most publications using "patients" only (**Figure 3B**).

Figure 3. Percentage of clinical trials using any combination (of ≥1 term) of "patients" vs "participants" vs "subjects" in the title or abstract

(A) Migraine-related clinical trials (2014–2024; N=841)



(B) MDD-related clinical trials (2014–2024; N=1014)

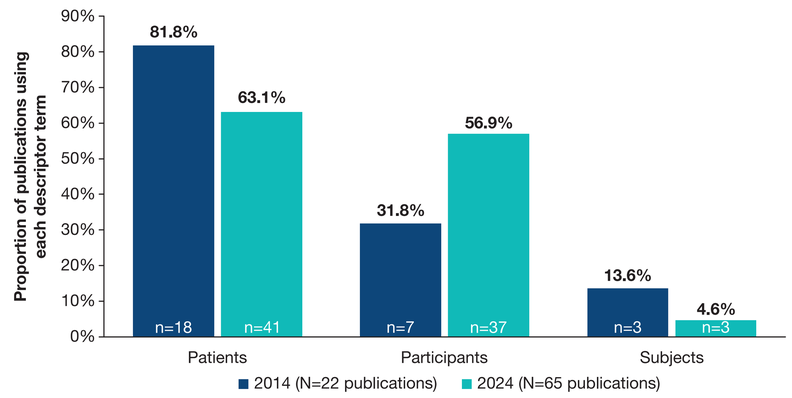


Each identified descriptor was counted only once per article, regardless of how many times it appeared in the title/abstract. All terms were recognized as individual words within the abstract/title, except that "patients" could include the term "outpatients" or "inpatients". MDD, major depressive disorder.

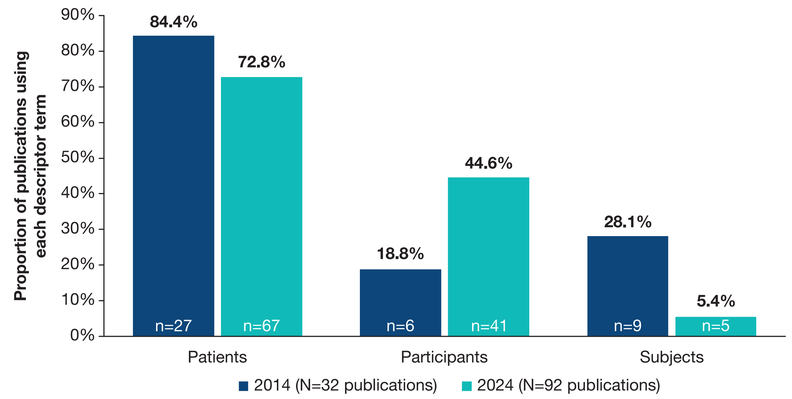
- From 2014–2024, the percentage of migraine publications containing "patients" decreased 23%, "participants" increased 79%, and "subjects" decreased 66% (**Figure 4A**).
- Similarly, from 2014–2024, the percentage of MDD publications containing "patients" decreased 14%, "participants" increased 137%, and "subjects" decreased 81% (**Figure 4B**).

Figure 4. Change over time in population descriptors used

(A) Descriptors used in migraine clinical trials published in 2014 vs 2024



(B) Descriptors used in MDD clinical trials published in 2014 vs 2024



Each identified descriptor was counted only once per article, regardless of how many times it appeared in the title/abstract. All terms were recognized as individual words within the abstract/title, except that "patients" could include the term "outpatients" or "inpatients". MDD, major depressive disorder.

Limitations

- Only clinical trials related to migraine and MDD from PubMed were analyzed, so these findings may not be representative of all clinical trial publications in other disease states across the past 10 years.
- The method of analyzing a large set of literature with Excel formulas may be constrained by the prompts provided to AI for generating the formulas. As a result, some descriptor terms may not have been appropriately captured depending on the specific contexts and terms in the titles and abstracts.

Conclusions

- Consistent with efforts to decrease stigmatizing language, there was a notable decrease in using "subjects" and a substantial increase in using "participants" in migraine and MDD clinical trial publications over the past decade.
- Though there was a decrease in use over time, "patients" remained the most prevalent.
- Further analyses should evaluate the impact of trial design (e.g., phase 1 vs phase 3; inpatient vs outpatient care) and article characteristics (e.g., primary vs secondary report; government vs commercial funding) on these results.

References

1. Boynton PM. *BMJ*. 1998;317(7171):1521.
2. Corpuz JC. *Subst Abuse*. 2023;17.
3. Fernandez-Sanchez H, et al. *Glob Qual Nurs Res*. 2024;11:23333936241275266.
4. Bromley E, et al. *Am J Public Health*. 2015;105(5):900-8.

Disclosures

All authors are full-time employees of The Medicine Group LLC, New Hope, PA, United States.

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Poster presented at the 21st Annual Meeting of ISMPP May 11–14, 2025 Washington, D.C.