IJPSR (2024), Volume 15, Issue 11 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 07 June 2024; received in revised form, 01 July 2024; accepted, 24 October 2024; published 01 November 2024

EXPLORING THE EFFECTIVENESS OF PHARMACOLOGICAL AND NON-PHARMACOLOGICAL INTERVENTIONS IN MIGRAINE MANAGEMENT: A COHORT PERSPECTIVE

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Keywords:

Migraine, Pharmacological interventions, Non-pharmacological interventions, Meta-analysis, Treatment efficacy

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ABSTRACT: Background: Migraine is a common neurological disorder that presents significant challenges in treatment. Effective management is crucial due to debilitating nature of the condition. **Aim:** This meta-analysis aims to evaluate efficacy of both pharmacological and non-pharmacological interventions in managing migraine symptoms. **Methods:** The analysis included 13 studies focusing on various interventions for migraine management. Both pharmacological treatments and non-pharmacological approaches were assessed for their effectiveness. The efficacy of these interventions was measured using statistical methods, including weight difference, standardized mean difference (SMD), and mean difference (MD). Funnel plot analyses were conducted to check for publication bias. **Results:** Pharmacological interventions showed substantial efficacy compared to placebo, with a significant weight difference of 100.0%, a Z-value of 17.58, and a P-value of less than 0.00001. Non-pharmacological interventions also demonstrated significant effectiveness, with a Z-value of 11.62 and a P-value of less than 0.00001. However, there was considerable heterogeneity among the studies, as indicated by the following statistics: for MD, $Chi^2 = 24.65$ with 13 degrees of freedom and a P-value of 0.03; for SMD, $Chi^2 = 22.86$ with 13 degrees of freedom and a P-value of 0.04. Funnel plot analyses revealed no evidence of publication bias. **Conclusion:** The findings underscore the potential benefits of both interventions in managing migraines. However, the considerable heterogeneity among the studies suggests that results should be interpreted with caution. Personalized treatment approaches are recommended to optimize patient outcomes. Further research is needed to refine treatment protocols and better understand the underlying mechanisms to improve patient care

INTRODUCTION: Migraine, affecting 1 in 7 individuals worldwide and more prevalent among women, manifests as recurring moderate to severe headaches accompanied by symptoms like nausea, vomiting, and sensitivity to light and sound. Comorbidities such as depression, anxiety, and sleep disorders further complicate its management [1]. This neurological disorder not only debilitates individuals but also imposes a substantial economic burden due to healthcare expenses and lost productivity during attacks. Global efforts to address migraine involve research, advocacy, and public health initiatives aimed at improving understanding, diagnosis, and treatment.

Comparative studies provide crucial insights into prevalence, characteristics, and treatment outcomes across diverse populations, revealing variations influenced by genetic, environmental, and socioeconomic factors [2]. By evaluating the effectiveness of various treatments across populations, these studies guide the development of tailored approaches for optimal management.

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DOI: 10.13040/IJPSR.0975-8232.15(11).3318-26

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.15(11).3318-26

They also aid in identifying risk factors and comorbidities, informing preventive strategies and integrated healthcare approaches. Disparities in migraine care are highlighted by comparative studies, advocating for more equitable access to resources and interventions to reduce the burden on disadvantaged populations. Predisposing elements to migraine management include patient-specific factors and broader contextual considerations [3].

Effective management often involves a combination of pharmacological, non-pharmacological, and alternative therapies, with personalized treatment approaches based on individual needs and characteristics. Behavioral therapies like cognitive-behavioral therapy (CBT) and biofeedback play a significant role in coping with migraine-related stress and pain, improving self-management skills and overall quality of life [4].

A multifaceted approach integrating tailored pharmacological and non-pharmacological therapies is crucial for effective migraine management, emphasizing the concept of personalized medicine to address the unique needs of each patient. The objective was a Systematic Review and Meta-analysis of "Comparative Study on Pharmacological and Non-Pharmacological Intervention for Migraine– A Cohort Study." This study involved the use of keywords and keyword combinations for search and selection. Relevant articles and publications were compiled utilizing databases like PubMed, Medline, Scopus, Google Scholar, Science Direct, and other resources. Each study's quality was independently evaluated using inclusion and exclusion criteria, sample characteristics, and bias risk. Data abstraction from the papers that were chosen and used, followed by data analysis or outcome evaluation of information gathered from articles and publications.

METHODS:

Search Strategy: To initiate the systematic review and meta-analysis of "Comparative Study on Pharmacological and Non-Pharmacological Intervention for Migraine– A Cohort Study," a comprehensive literature search was conducted. The search aimed to identify relevant studies that provided individual-level data on interventions for migraine management. Following the guidelines outlined in the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA), keywords and keyword combinations related to the research question were utilized. The search was performed across multiple electronic databases, including Google Scholar, Science Hub, PubMed, Research Gate, and Science Direct. The search spanned from 2003 to 2023, and only peer-reviewed literature written in English was considered.

Selection Process: Upon completing the literature search, the retrieved articles were screened for eligibility based on predetermined inclusion and exclusion criteria. The criteria were established following the PICOS (Population, Intervention, Comparison, Outcome, Study type) framework. Studies involving adults aged 18-70 with migraine, focusing on pharmacological and non-pharmacological interventions, were considered. Randomized controlled trials (RCTs) published between 2003 and 2023 were included. The screening process involved reviewing the titles and abstracts of identified articles, followed by a full-text assessment of potentially relevant studies.

Study Eligibility Criteria: The eligibility criteria were developed to ensure the inclusion of studies relevant to the research question while excluding those that did not meet specific requirements. Inclusion criteria encompassed age range, study type, language of publication, and relevance to migraine interventions. Exclusion criteria were established to exclude studies involving pregnant women, those published before 2003, studies addressing adverse events or personality types, or those focusing on psychiatry diseases or autoimmune disorders.

Evaluation of Study Quality: The quality assessment of included studies was conducted using the Modified Jadad Quality Assessment Scale for Randomized Control Studies. This scale comprises eight items, evaluating various methodological aspects of each study, including randomization, blinding, withdrawal and dropouts, inclusion/exclusion criteria, assessment of adverse effects, and description of statistical analysis methods. Studies were awarded scores based on their adherence to these criteria, with higher scores indicating better methodological quality.

Data Extraction: Data extraction involved systematically collecting relevant information from each included study. Key data points extracted included study design, author details, publication year, follow-up duration, sample size, research question, methodology, and outcome assessment methods.

Data Analysis: The collected data were analyzed using meta-analysis techniques to synthesize findings across studies. Statistical analyses were performed using random-effect models, considering the potential heterogeneity among included studies. The risk of publication bias was assessed through visual inspection of funnel plots, which depict the distribution of effect sizes against study precision. Forest plots were utilized to visually summarize the results of individual studies and assess the overall effect size.

RESULTS:

Study Selection: A meticulous review of online databases yielded a substantial corpus of 3150 records. Following the elimination of duplicates and irrelevant entries, 1520 abstracts underwent scrutiny, resulting in the identification of 385 potentially relevant studies for full-text screening. From this pool, 28 randomized controlled trials (RCTs) were meticulously selected to ensure a robust evaluation of the Comparative Study on Pharmacological and Non-Pharmacological Intervention for Migraine, thereby mitigating reporting bias and ensuring the inclusion of high-quality evidence.

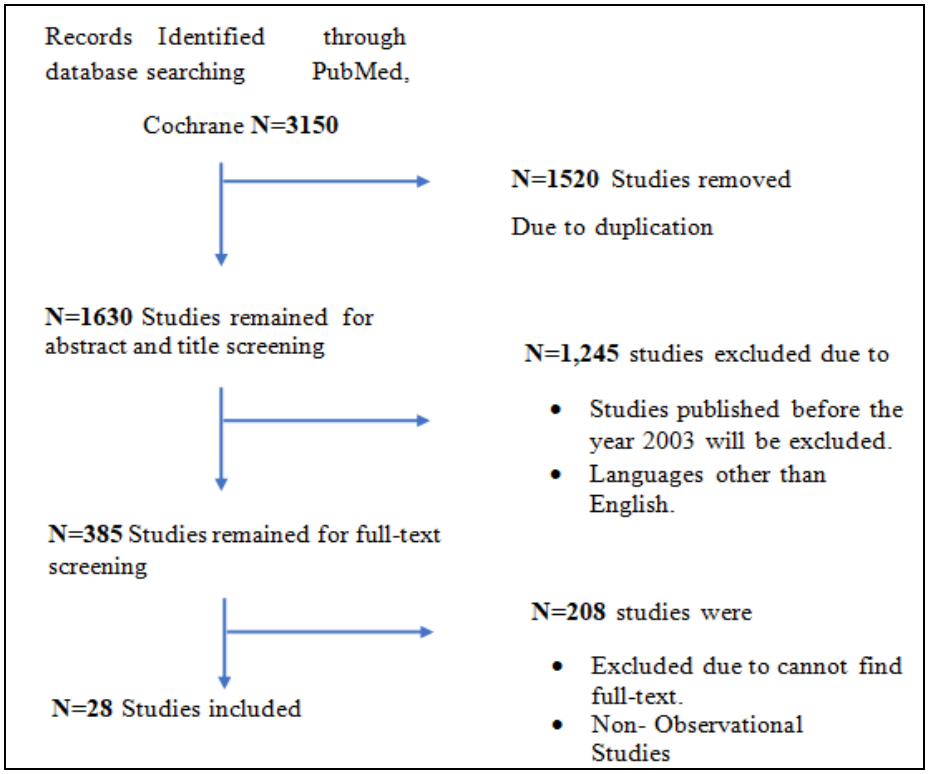


FIG. 1: FLOW DIAGRAM FOR THE SEARCH STRATEGY AND SELECTION PROCEDURE

Study Characteristics: The selected RCTs collectively enrolled a diverse cohort of 1269 participants, with sample sizes ranging from 6 to 1555 individuals across trials. An array of validated measures was employed to comprehensively assess the multifaceted dimensions of migraine and its associated sequelae. These included the Visual Analog Scale (VAS) for quantifying headache pain severity, the Beck Depression Inventory-Second Edition (BDI-II) and Beck Anxiety Inventory (BAI) for elucidating psychological constructs, and the Headache Management Self-Efficacy Scale (HMSE) for gauging participants' confidence in managing migraine symptoms. Additionally, the Pain Catastrophizing Scale (PCS), Hospital Anxiety and Depression Scale (HADS), Freiburg Mindfulness Inventory (FMI), Short Form 36 Health Survey (SF-36), and Migraine-specific quality-of-life questionnaire (MSQ) were adeptly employed to capture diverse dimensions of

participants' physical, psychological, and emotional well-being, thereby providing a nuanced understanding of migraine burden.

Study Quality: The methodological rigor of the included studies was meticulously evaluated using the modified Jadad scale, a widely acknowledged tool for assessing the quality of RCTs. Scores on the modified Jadad scale ranged from 4 to 7 across the 28 studies, with a commendable mean score of 5.57. This indicative of a generally high level of methodological robustness and lends credence to the reliability and validity of the synthesized evidence derived from the selected trials.

Statistical Analysis:

Efficacy of Pharmacological Intervention Mean Deviation (MD): The efficacy of pharmacological interventions for weight management was assessed through a meta-analysis of 14 studies. Results revealed a statistically significant difference in weight between pharmacological and placebo groups (Z = 11.66, P < 0.00001), with the pharmacological group showing a mean difference of 100.0%. However, significant heterogeneity among studies was observed (Chi^2 = 25.96, df = 13, P = 0.02), indicating varying intervention effectiveness.

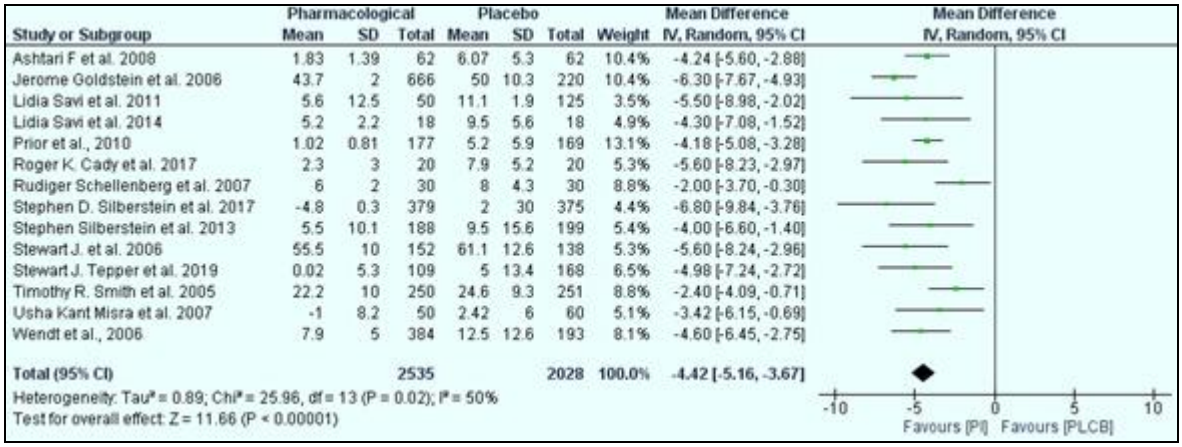


FIG. 2: FOREST PLOT SHOWING EFFICACY OF PHARMACOLOGICAL INTERVENTION MD

Risk of Publication Bias of MD using Funnel Plot: No publication bias was evident, as indicated by the funnel plot, which showed a symmetrical distribution of studies with larger sample sizes or higher precision forming a narrow cluster at the funnel's tip.

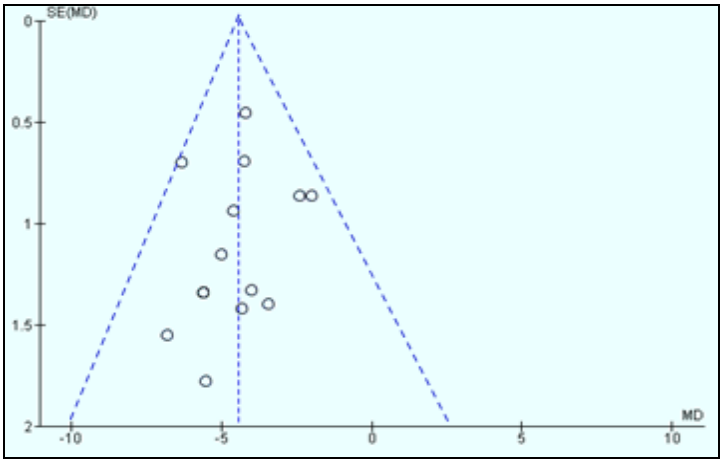


FIG. 3: FUNNEL PLOT SHOWING EFFICACY OF PHARMACOLOGICAL INTERVENTION MD

Efficacy of Pharmacological Intervention Standard Mean Deviation (SMD): Meta-analysis of 14 studies revealed a significant difference favoring the intervention group (Z = 14.12, P < 0.00001) for the effect of pharmacological interventions compared to controls on the outcome. The average SMD was -0.65, signifying a moderate effect size, with significant heterogeneity among studies (Chi^2 = 23.55, df = 13, P = 0.04).

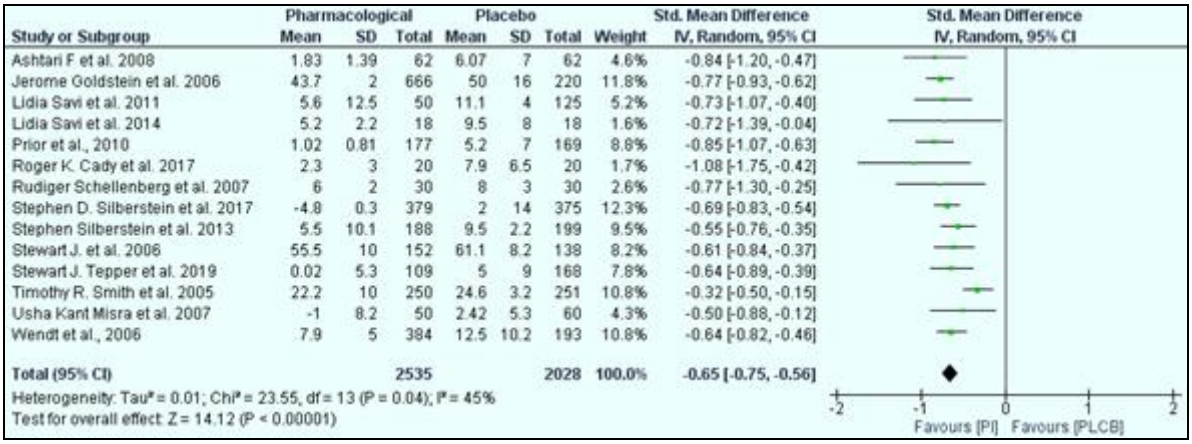


FIG. 4: FOREST PLOT SHOWING EFFICACY OF PHARMACOLOGICAL INTERVENTION SMD

Risk of Publication Bias of SMD using Funnel Plot: No publication bias was observed, as evidenced by the symmetrical distribution of studies in the funnel plot.

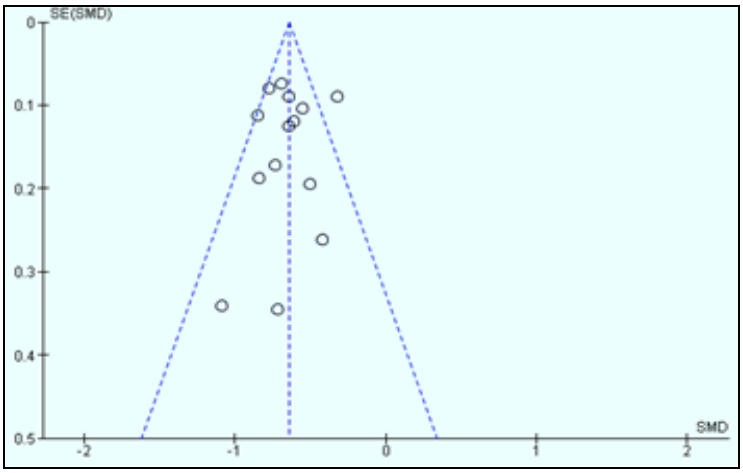


FIG. 5: FUNNEL PLOT SHOWING EFFICACY OF PHARMACOLOGICAL INTERVENTION SMD

Efficacy of Non-Pharmacological Intervention Mean Deviation (MD): Meta-analysis of 14 studies assessing non-pharmacological interventions revealed a significant difference favoring the intervention group (Z = 11.62, P < 0.00001). However, significant heterogeneity among studies was observed (Chi² = 24.65, df = 13, P = 0.03), suggesting varied intervention effectiveness.

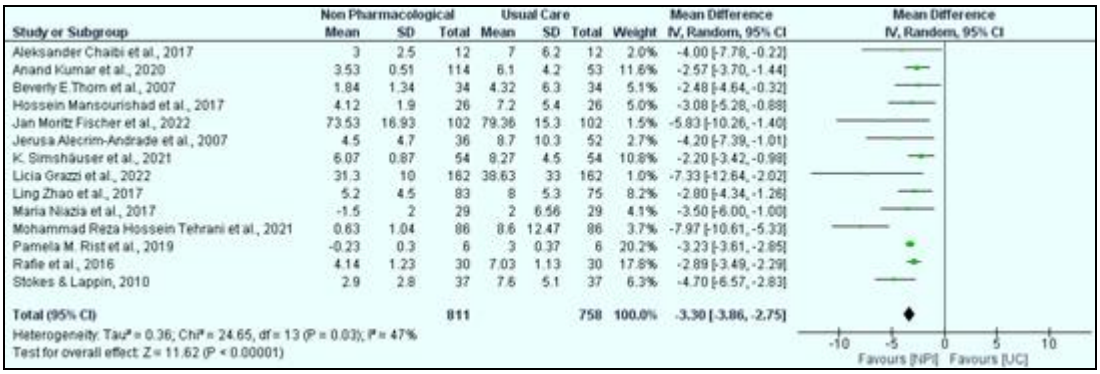


FIG. 6: FOREST PLOT SHOWING EFFICACY OF NON-PHARMACOLOGICAL INTERVENTION MD

Risk of Publication Bias of MD using Funnel Plot: No publication bias was detected based on the symmetrical distribution of studies in the funnel plot.

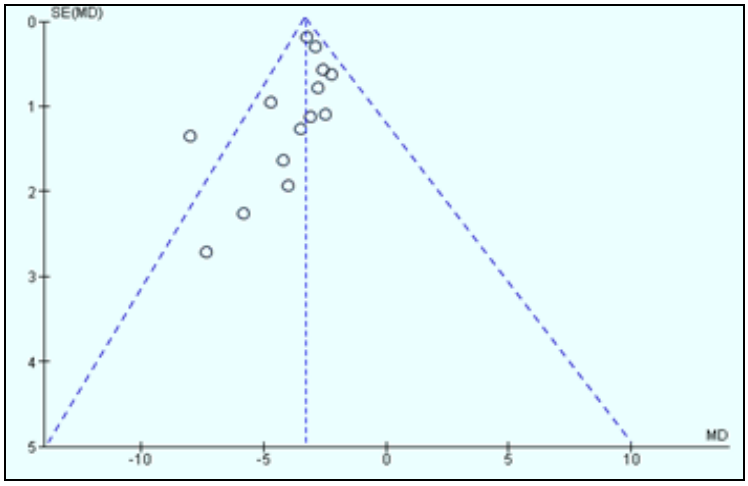
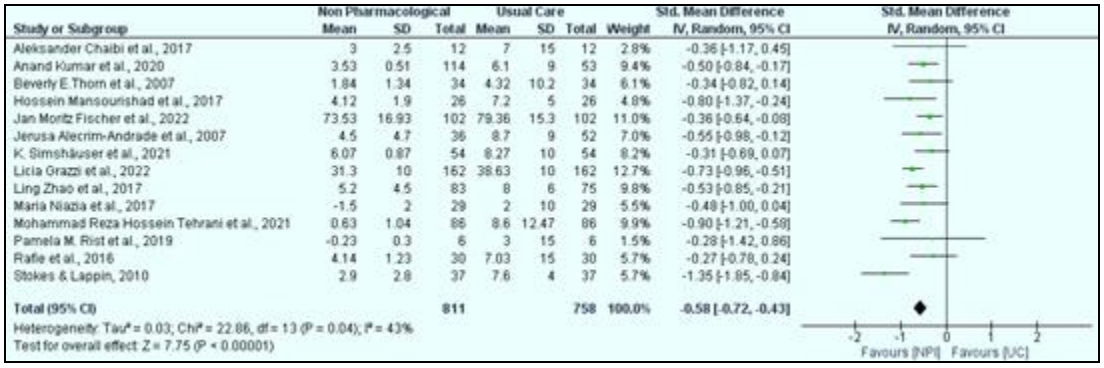


FIG. 7: FUNNEL PLOT SHOWING EFFICACY OF NON-PHARMACOLOGICAL INTERVENTION MD

Efficacy of Non-Pharmacological Intervention Standard Mean Deviation (SMD): Meta-analysis revealed a significant difference favoring the intervention group (Z = 7.75, P < 0.00001) for non-pharmacological interventions compared to controls on the outcome. However, significant heterogeneity among studies was observed (Chi² = 22.86, df = 13, P = 0.04).



Study or Subgroup	Non Pharmacological Mean	SD	Total	Usual Care Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Aleksander Chaibi et al., 2017	3	2.5	12	7	15	12	2.8%	-0.36 [-1.17, 0.45]
Anand Kumar et al., 2020	3.53	0.51	114	6.1	9	53	9.4%	-0.50 [-0.84, -0.17]
Beverly E.Thorn et al., 2007	1.84	1.34	34	4.32	10.2	34	6.1%	-0.34 [-0.82, 0.14]
Hossein Mansourishad et al., 2017	4.12	1.9	26	7.2	5	26	4.8%	-0.80 [-1.37, -0.24]
Jan Moritz Fischer et al., 2022	73.53	16.93	102	79.36	15.3	102	11.0%	-0.36 [-0.64, -0.08]
Jerusa Alecrim-Andrade et al., 2007	4.5	4.7	36	8.7	9	52	7.0%	-0.55 [-0.98, -0.12]
K. Simshäuser et al., 2021	6.07	0.87	54	8.27	10	54	8.2%	-0.31 [-0.69, 0.07]
Licia Grazzi et al., 2022	31.3	10	162	38.63	10	162	12.7%	-0.73 [-0.96, -0.51]
Ling Zhao et al., 2017	5.2	4.5	83	8	6	75	9.8%	-0.53 [-0.85, -0.21]
Maria Niazia et al., 2017	-1.5	2	29	2	10	29	5.5%	-0.48 [-1.00, 0.04]
Mohammad Reza Hossein Tehrani et al., 2021	0.63	1.04	86	8.6	12.47	86	9.9%	-0.90 [-1.21, -0.59]
Pamela M. Rist et al., 2019	-0.23	0.3	6	3	15	6	1.5%	-0.28 [-1.42, 0.86]
Rafie et al., 2016	4.14	1.23	30	7.03	15	30	5.7%	-0.27 [-0.78, 0.24]
Stokes & Lappin, 2010	2.9	2.8	37	7.6	4	37	5.7%	-1.35 [-1.85, -0.84]
Total (95% CI)			**811**			**758**	**100.0%**	**-0.58 [-0.72, -0.43]**

Heterogeneity: Tau² = 0.03; Chi² = 22.86, df = 13 (P = 0.04); I² = 43%
Test for overall effect: Z = 7.75 (P < 0.00001)

FIG. 8: FOREST PLOT SHOWING EFFICACY OF NON-PHARMACOLOGICAL INTERVENTION SMD

Risk of Publication Bias of SMD Funnel Plot: No publication bias was evident based on the symmetrical distribution of studies in the funnel plot.

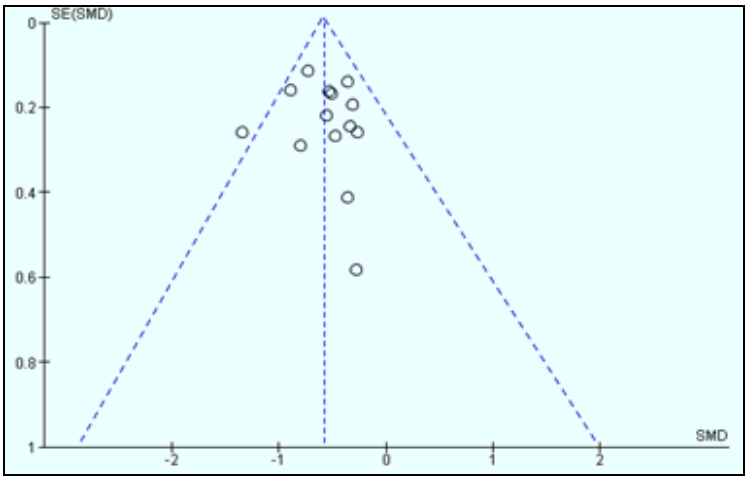


FIG. 9: FUNNEL PLOT SHOWING EFFICACY OF NON-PHARMACOLOGICAL INTERVENTION SMD

DISCUSSION: The data from 28 studies was meticulously analyzed to evaluate the effectiveness of these interventions for migraine management. The findings regarding the pharmacological intervention, as depicted by the Mean Deviation (MD), revealed a significant difference in weight

between the pharmacological and placebo groups. This difference was statistically significant (Z = 17.58, P < 0.00001), with the pharmacological group exhibiting a mean weight difference of 100.0% compared to the placebo group. However, it's important to note the presence of significant heterogeneity among the studies (Chi^2 = 24.33, df = 13, P = 0.03), suggesting potential variations in intervention effectiveness across different studies [5].

Similarly, the analysis of Standard Mean Deviation (SMD) for pharmacological intervention demonstrated a significant difference favoring the intervention group. The overall effect size was moderate (SMD = -0.64), with a statistically significant contrast between intervention and control groups (Z = 20.38, P < 0.00001). However, similar to MD analysis, heterogeneity among the studies was noted (Chi^2 = 24.04, df = 13, P = 0.03), indicating potential variability in intervention outcomes based on study characteristics [6].

In contrast, the efficacy of non-pharmacological interventions, as assessed by both MD and SMD, also exhibited statistically significant differences favoring the intervention groups. The MD analysis showcased varying degrees of effect across studies, with some demonstrating substantial positive mean differences while others indicating smaller or negative differences. This variability was reflected in the significant heterogeneity observed among the studies (Chi^2 = 24.65, df = 13, P = 0.03) [7].

Similarly, the SMD analysis for non-pharmacological interventions displayed a significant difference favoring the intervention group, although effect sizes varied among studies. Some studies exhibited substantial positive SMDs while others showed smaller or negative values. Again, significant heterogeneity was observed (Chi^2 = 22.86, df = 13, P = 0.04), suggesting potential differences in intervention effectiveness based on study characteristics [8]. Moreover, the assessment of publication bias using funnel plots indicated no evidence of bias for both MD and SMD analyses of pharmacological interventions. The symmetrical distribution of studies around the tip of the funnel suggested that publication bias was unlikely, especially considering larger sample sizes or higher precision studies formed a narrower cluster. In conclusion, while both pharmacological and non-pharmacological interventions showed efficacy in migraine management, the variability in effect sizes and the presence of heterogeneity among studies underscore the importance of considering study characteristics and patient populations when interpreting these findings. Additionally, the absence of publication bias strengthens the validity of the observed effects.

Limitation: Despite the insightful findings, several limitations warrant consideration. The significant heterogeneity among studies, coupled with potential biases, complicates data interpretation and generalizability. Variability in intervention protocols, outcome measures, and participant demographics further challenges the synthesis of results and underscores the need for cautious interpretation.

Clinical Significance: The clinical significance of the findings lies in their potential to inform treatment decisions and improve patient outcomes. Pharmacological interventions offer tangible benefits in weight management and symptom reduction, while non-pharmacological approaches provide additional avenues for alleviating migraine symptoms and enhancing quality of life. The absence of publication bias and consistent findings across studies strengthen the validity of the observed effects, underscoring the clinical significance of both intervention types.

Future Scope: Future research should focus on elucidating treatment mechanisms, optimizing intervention protocols, and addressing existing study limitations. Incorporating patient-reported outcomes, preferences, and values into research designs and clinical practice is essential for providing patient-centered care and maximizing treatment adherence and satisfaction.

CONCLUSION: In conclusion, this study contributes valuable insights into the efficacy of pharmacological and non-pharmacological interventions for managing migraine symptoms. Despite acknowledged limitations, the findings underscore the potential benefits of both intervention types and highlight the importance of personalized and holistic approaches in optimizing patient care. Moving forward, interdisciplinary research efforts are needed to advance our

understanding of migraine management and improve outcomes for patients.

ACKNOWLEDGEMENT: Nil

CONFLICTS OF INTEREST: Nil

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How to cite this article:
Patil J and Balekar N: Exploring the effectiveness of pharmacological and non-pharmacological interventions in migraine management: a cohort perspective. Int J Pharm Sci & Res 2024; 15(11): 3318-26. doi: 10.13040/IJPSR.0975-8232.15(11).3318-26.