

Mind Body Balance for Pediatric Migraine

NCT04715685

Status	RECRUITING
Phase	Not Applicable
Sponsor	Children's Hospital Medical Center, Cincinnati
Enrollment	260 participants

Key Eligibility Criteria

Inclusion (5)

- Diagnosis: Migraine with or without aura or chronic migraine that meets the International Classification of Headache Disorders (ICHD) criteria
- Frequency: Headache frequency based upon prospective headache diary of 28 days must be ≥ 4 and ≤ 28 .
- PedMIDAS: PedMIDAS Disability Score ≥ 4 , indicating at least mild disruption in daily activities and ≤ 140 , indicating extreme disability that may require more comprehensive, multi-component therapy
- Use of one or more of the following prescribed nutraceuticals and/or preventive anti-migraine medications at the time of randomization or be on a stable dose of one or more of the following throughout the 12 weeks of the study [Vitamin B2 (Riboflavin), Co-Q 10 (Coenzyme Q10), Magnesium (Mg), Vitamin D2 or D3 (Erocalciferol/Cholecalciferol), Depakote (Divalproate), Inderal (Propranolol), Elavil (Amitriptyline), Topamax (Topiramate), Periacin (Cyproheptadine)]
- Language: English speaking, able to complete interviews and questionnaires in English

Exclusion (5)

- Continuous migraine defined as unrelenting headache for a 28 day period
- Must agree not to take non-specific acute medication, such as NSAIDs (e.g., ibuprofen), more than 3 times per week, or migraine specific acute medications, such as triptans, more than 6 times per month (to prevent medication overuse headache)
- PedMIDAS Disability Score ≥ 140 , indicating extreme disability that may require more comprehensive, multi-component therapy
- Youth who are pregnant, or those who are sexually active and not using a medically accepted form of contraception (barrier or hormonal methods)
- Present severe psychiatric disease, alcohol or drug dependence, or documented developmental delays or impairments (e.g., autism, cerebral palsy, or mental retardation) or other circumstances, that, in the opinion of the investigator, would interfere with adherence to study requirements or safe participation in the study

Locations (2 total)

University of Colorado/Children's Hospital Colorado, Aurora, Colorado, United States
Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, United States

<https://clinicaltrials.gov/study/NCT04715685>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).