

Responding With Evidence and Access for Childhood Headaches

NCT05889624

Status	RECRUITING
Phase	Not Applicable
Sponsor	Children's Hospital Medical Center, Cincinnati
Enrollment	400 participants

Key Eligibility Criteria

Inclusion (4)

- Diagnosis: Migraine with or without aura that meets the International Classification of Headache Disorders (ICHD) criteria 5 or presentation of continuous headache that includes migrainous episodes based upon headache history obtained by site PI or designee. (includes presentation with or without medication overuse headache as well)
- Headache Frequency: 4 or more headache days based upon prospective headache diary of 28 days prior to randomization
- Amitriptyline Eligible: Site PI or medical staff determined participant to be eligible for clinical prescription of amitriptyline as a preventive treatment for migraine
- English fluency: Able to complete the study visits and questionnaires in English

Exclusion (6)

- Current treatment includes amitriptyline and/or CBT specific to headache care
- Current prescribed preventive antimigraine medication within a period equivalent to ≤ 5 half-lives of that medication before entering the baseline phase
- Current treatment with onabotulinumtoxinA (Botox) or CGRP-based monoclonal antibody medications for migraine prevention
- Youth who are pregnant
- Report of current or ongoing suicidal thoughts. Suicide attempt within the past six months. History of bipolar disorder, prolonged QT, or pre-existing significant constipation or gastroparesis

... and 1 more (see full listing online)

Locations (15 total)

University of Alabama at Birmingham Children's of Alabama, Birmingham, Alabama, United States

Phoenix Children's Hospital - Barrow Neurological Institute, Phoenix, Arizona, United States

University of California San Francisco, San Francisco, California, United States

... and 12 more locations