

Responding With Evidence and Access for Childhood Headaches

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 10 years to 17 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Diagnosis: Migraine with or without aura that meets the International Classification of Headache Disorders (ICHD) criteria 5 or presentation of continuous headache that includes migranous 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 Criteria:

- 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
- Any and all other diagnoses or conditions which, in the opinion of the site investigator, would prevent the patient from being a suitable candidate for the study or interfere with the medical care needs of the participant

Conditions & Interventions

Interventions:

BEHAVIORAL: CBT, DRUG: Amitriptyline

Conditions:

Headache, Headache Disorders, Headache, Migraine, Migraine, Migraine Disorders, Migraine With Aura, Migraine Without Aura, Chronic Migraine

Keywords:

headache, migraine, cognitive behavioral therapy, pediatrics, diaphragmatic breathing, progressive muscle relaxation, imagery, relaxation, biofeedback

More Information

Description:

This comparative effectiveness study will clarify current first-line preventive treatment approaches for use by neurologists, psychologists, and primary care providers in the context of real world care, and will demonstrate the feasibility of Cognitive Behavioral Therapy (CBT) via telehealth for youth with migraine. The focus is on applying evidence-based care and enhancing access to it. CBT via telehealth while taking a clinically-prescribed, pill-based prevention therapy (amitriptyline) will be compared to CBT via telehealth alone.

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Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT05889624

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