Epilepsy Journey-An Executive Functioning Intervention for Teens With Epilepsy

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 13 years to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Age between 13-17 years at the time of enrollment
2. Child lives at home with primary caregiver and is enrolled in school (excluding summer breaks).
3. Confirmed diagnosis of epilepsy with seizures that are categorized as either generalized or focal in onset. Epilepsy is defined as: 1) At least two unprovoked seizures occurring more than 24-hours apart; or 2) One unprovoked seizure and a probability of further seizures similar to the general recurrence risk after two unprovoked seizures.
4. Primary language of English
5. Screening Inclusion: On the parent-reported Behavior Rating Inventory of Executive Function-2nd edition (BRIEF-2), have executive functioning deficits defined as at least 2 subclinical (60<T<65) or one clinical BRIEF-2 subscale T scores (T≥65).
6. Parent/legal guardian(s) willing to sign an IRB approved informed consent
7. Participant willing to sign an Institutional Review Board approved assent

Exclusion Criteria:

1. Parent or clinician-reported history in the adolescent of:
    1. developmental delay (e.g., autism spectrum disorder, pervasive development disorder, history of services for developmental delay or intellectual impairment in the past 5 years, known IQ<70)
    2. severe mental illness (e.g., schizophrenia, bipolar disorder, eating disorder within the past 12 months, depression with active suicidal ideation or suicidal ideation/intent in the past 3 months)
    3. prior (3-months) or current history of trauma and/or stressor-related disorders (e.g. PTSD)
    4. recent or current significant medical disease (i.e., cardiovascular, hepatic, renal, gynecologic, musculoskeletal, metabolic or endocrine)
    5. brain injury or brain tumor; and/or
    6. epilepsy surgery
    7. any other medical and/or psychological condition that takes treatment precedence over the study intervention
2. Clinician-reported diagnosis in the adolescent of
    1. epilepsy whose seizures are categorized only as either unknown onset or unclassified onset (defined as insufficient information to determine onset)
    2. epilepsy currently being treated at the time of enrollment by 3 or more antiseizure medications (ASMs) (excluding rescue medication use)
    3. epilepsy with a history of failure to achieve seizure freedom despite adequate use of 4 different anti-seizure medications
    4. a confirmed or suspected epileptic encephalopathy (e.g., electrical status epilepticus in sleep, Landau Kleffner syndrome, West syndrome)
    5. a confirmed or suspected progressive and degenerative disorder (e.g., mitochondrial disorders, metabolic disorders, autoimmune disorders)
    6. one or more episodes of status epilepticus within the 24 weeks prior to enrollment; and/or
    7. treatable causes of seizures, for example identified etiologies including metabolic, neoplastic, or active infectious origin.
    8. non-epileptic event/seizures
3. Adolescents currently on the ketogenic diet
4. Participation in a trial of an investigational drug or device within 30 days prior to screening

Conditions & Interventions

Interventions:
BEHAVIORAL: Epilepsy Journey web-based modules, BEHAVIORAL: Telehealth with a therapist
Conditions:
Epilepsy in Children, Executive Dysfunction
Keywords:
adolescents, executive functioning, seizures, epilepsy, behavioral trial, web-based intervention

More Information

Description:
The goal of this multi-site clinical trial is to determine the effectiveness of two components of a web-based intervention (Epilepsy Journey) to improve executive functioning in adolescents with epilepsy. The two components include web-based modules and problem-solving telehealth sessions with a therapist focused on executive functioning. This trial aims to answer the following questions: 1. Which components of Epilepsy Journey (web-based modules or telehealth sessions with a therapist) are essential for improving executive functioning in adolescents with epilepsy? 2. Which components of Epilepsy Journey (web-based modules or telehealth sessions with a therapist) are essential for improving quality of life in

2. Which components of Epilepsy Journey (web-based modules or telehealth sessions with a therapist) are essential for improving quality of life in adolescents with epilepsy? Participants will be randomly assigned to one of four groups: 1) Epilepsy Journey web-based modules and telehealth sessions, 2) Epilepsy Journey web-based modules only, 3) telehealth sessions with a therapist only, or 4) treatment as usual. Participants will: * Independently review Epilepsy Journey web-based modules focused on executive functioning skills (\~15-30 minutes) and/or have weekly telehealth sessions (\~30-45 minutes) with a therapist for 14 weeks. * Complete measures of executive functioning (parent and teen-report) and quality of life (teen-report) at the start of the study, 14-, 26-, and 66- weeks after randomization. The NIH toolbox will be completed at the start of the study and 26-weeks after randomization. Additional measures will also be collected.

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IRB Number:
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