

Regulating Together in Tuberous Sclerosis Complex

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 8 years to 17 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Children ages 8-17 years inclusive with a documented clinical and/or genetic diagnosis of TSC and exhibiting symptoms of behavioral dysregulation (identified on the TAND Checklist having temper tantrums, aggressive outbursts, self-injury, and/or impulsivity) are eligible for inclusion.

Additional inclusion/eligibility criteria include:

- Participants and their caregivers have access to a computer, phone, or tablet with video capability and stable internet connection. If lack of a device or internet service is the sole barrier to eligibility/participation, interested individuals will be connected to a TSC Clinic social worker to link them to existing government and charity programs specifically addressing this disparity in underserved communities and households in need (e.g., the Affordable Connectivity Program).
- Participants must also be willing to participate in treatment sessions and have minimal levels of functional verbal communication (child and their caregiver must be fluent in English)
- Child must have a minimum IQ>65 on the WASI-II at the screening/baseline visit).

Exclusion Criteria:

- Participants be on a stable medication regimen at least 4 weeks prior to enrollment
- Do not have a plan to start a new psychosocial intervention (e.g., individual psychotherapy, family psychotherapy, group psychotherapy or social skills training) or behavior medication within 30 days prior to enrollment or at any point during the study. ----Participants with significant disruptive, aggressive, self-injurious or sexually inappropriate behaviors deemed potentially dangerous or overly disruptive to the group dynamic/session, having significant co-occurring neuropsychiatric illness warranting other treatment approaches as determined by study clinician (e.g., substance use disorders, psychotic disorders, schizophrenia), or having significant sensory impairment that would limit participation in intervention curriculum/materials (e.g., blindness or uncorrected hearing loss) also will be excluded.

Conditions & Interventions

Interventions:

BEHAVIORAL: Behavioral Intervention in a small group platform

Conditions:

TSC, Behavioral Symptoms

More Information

Description:

The purpose of this study is to use a program called Regulating Together (RT), a remote, non-pharmacologic intervention to treat symptoms of emotion dysregulation in children and adolescents with Tuberous Sclerosis Complex (TSC) and TSC-Associated Neuropsychiatric Disorder (TAND).

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Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT06105736

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