

Regulating Together in Tuberous Sclerosis Complex

NCT06105736

Status	RECRUITING
Phase	Not Applicable
Sponsor	Children's Hospital Medical Center, Cincinnati
Enrollment	105 participants

Key Eligibility Criteria

Inclusion (5)

- 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 (2)

- 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.

Locations (2 total)

University of North Carolina Chapel Hill-Carolina Institute for Developmental Disabilities, Carrboro, North Carolina, United States
Cincinnati Children's Hospital Medical Center (CCHMC), Cincinnati, Ohio, United States

<https://clinicaltrials.gov/study/NCT06105736>

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