Community-based Adaptive Autism Intervention for Toddlers (CAIT)

NCT04283045

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CAIT Study Protocol Overview

This study will use a Sequential Multiple Assignment Randomized Trial (SMART) design to assess when to examine initial response to treatment, as well as whether and how best to augment the current first line of intervention for children demonstrating a slower response.

First, at program entry, the investigators will assess all toddlers using both standardized and experimental assessments as they enroll in the NYCIT program. After entry assessments, the investigators will randomize each child with equal probability to early response assessment at either six weeks or 12 weeks (timing). This early response assessment will be used to determine whether children are considered fast or slow responders to treatment.

Children who are considered early responders will continue to receive JASPER. Children responding slowly to the initial intervention will be randomized to continue JASPER or to add JASPER Plus+ to their JASPER sessions.

Approximately 200-300 toddlers (24-36 months) with a diagnosis of ASD, as confirmed by clinical evaluation records required for placement at the NYCIT will participate. Children will be assessed prior to intervention, immediately after Stage 1(early response) at either six or twelve weeks, exit Stage 2 intervention, and follow up.

CAIT Statistical Analysis Plan

SMARTs are factorial designs. This SMART has a total of four embedded adaptive interventions arising from a cross between the randomized Stage 1 intervention components (6 weeks vs. 12 weeks), and the randomized Stage 2 components among slow responders (JASPER+ vs. continuing JASPER).

For the Primary Aim, a single data analytic approach (i.e. Linear Mixed Models) will be used that compares change in outcomes from end of Stage 1 (week 6 or week 12) to treatment end (week 24) among slow responders. Secondary Aim 1 will adopt a similar data analysis plan as Primary Aim, but will include measurements from baseline to exit. The Secondary Aim 2 will use an extension of moderated regression analysis to multiple stages of treatment. All analyses will adjust for the baseline demographic characteristics.

For the Implementation Aim, standard regression analyses will be utilized to examine how attrition differs by child's and TA's characteristics and whether child outcomes are associated with TA implementation of the adaptive interventions.

Intent-To-Treat. All subjects, once randomized, will be included in the intent-to-treat sample, and every effort will be made to collect all primary and secondary outcomes. Children will not be purposefully dis-enrolled from the study for any reason.