

Study Protocol

Date: April 16, 2025

Study Title:

HEARTS R34 Feasibility Study, Autistic Participants

Background and Rationale:

Many autistic adults are interested in having more and better-quality friendships and dating relationships, but there are too few evidence-based interventions that support building healthier peer relationships. Healthy Relationships on the Autism Spectrum (HEARTS) is a six-session, online class co-developed with autistic people and co-delivered by teams that include at least one autistic expert that operates from the core idea that autistic people can be their authentic selves and can create and maintain healthy, supportive, mutual intimate partnership and friendship relationships. This randomized controlled trial (RCT) study investigated the effects of HEARTS for autistic individuals age 18 years old and older. Autistic individuals (N=92) were randomly assigned to either HEARTS or an active control condition (ACC). The purpose of this study was to find out if the HEARTS class had an impact on participants' self-directed relationship satisfaction goals, social motivation, experiences with aggressive acts in dating relationships, attitudes towards rejection, or hostile automatic thoughts after the HEARTS class ended.

Study Design:

This was a randomized controlled trial. Participants were allocated to either the intervention ("HEARTS Now") or the active control condition ("HEARTS Later"). There was a 1:1 allocation.

Arms and Interventions:

Participants in the HEARTS condition received 6 weeks of online group-based psychoeducation about healthy relationships from a teaching team that included one autistic and one non-autistic facilitator. Participants in the HEARTS Later ACC condition received 6 weeks of online group-based social time on topics of interest such as hobbies and pets from a facilitation team that included one autistic and one non-autistic facilitator.

Outcome Measures: Defines the primary and secondary measures, including the specific time frame for assessment.

This study assessed changes in three primary measures from baseline to 12-week follow-up, including Hostile Automatic Thoughts (HATS), Rejection Sensitivity (RSQ), and Social Motivation (ASHI). The study also assessed improvement in relationship satisfaction from baseline to 12-week follow-up (CGI-I).

Eligibility Criteria:

Inclusion criteria were: (1) ≥ 18 years old; (2) proficient in English; (3) Diagnosed with autism by a healthcare provider or other professional; (4) willing to be randomized; and (5) not having participated in the HEARTS class previously. Being actively suicidal was an exclusion criterion because HEARTS was not designed to provide safety to those in crisis.

Contacts and Locations:

The study sponsor was NIH (NIMH).

The collaborating organizations were Boston University and University of Alabama.

The research location was Boston, MA.