EVALUATION OF TELEHEALTH SERVICES ON MENTAL HEALTH OUTCOMES
for People with Intellectual and Developmental Disabilities

Telehealth Study QA Protocol for START Programs

Study Introduction

START recipients are eligible for the study if they are:

- Age 12-45
- Live in a family setting as defined in SIRS (with family, alternative family living, host home, etc.) or live independently and are their own guardian/ non-conserved
- Newly enrolled in START (within the last 120 days)

Every Tuesday, the study team emails each START program with a list of eligible START recipients organized into two categories:

- First 60 days of enrollment in START: Intake period; study introduction is not recommended as the focus is on completing the initial intake/assessment period, first draft of the cross systems crisis plan, and developing rapport with the START recipient and family.
- Days 60-120 of enrollment in START: Invite the study team to attend a scheduled outreach meeting with the START recipient and their family to introduce the study.

How to talk to families about scheduling the study intro:

- *Our team is participating in a study about START that you and your family are eligible for. The study is trying to understand if some planned START services delivered over telehealth are as effective as in-person. Telehealth means any services provided over the phone, computer, or tablet. The study does not change the amount of START services you will receive or the help you get from START in a crisis. People who agree to be in the study receive gift cards. A member of the study team would like to join our next meeting to tell us more about it. It will only take about 15 minutes. Would that be ok?*
  - If the family is not interested in a meeting, inform the study team as soon as possible.
  - If the family is interested in a meeting, the study team will work with you to schedule a time to meet.

Enrollment in the study

Introduction: After the study introduction, the family can choose to participate or not in the study.

- If the family is not interested, no further communication is needed.
- If the family is interested, the study team will complete the consent session with the START recipient and their family.

Informed Consent: The study team meets with the START recipient and family to review the study procedures, risks, and benefits. START recipients with guardians will have the opportunity to provide informed assent. If START recipients are unable to provide informed assent, they may qualify to enroll under an assent waiver.

Group Assignment: Within 24 business hours of providing informed consent, the START recipient is randomly assigned to receive therapeutic coaching and outreach over telehealth or in-person.

- The study team notifies the family and the START coordinator of group assignment via email.

Once someone is enrolled in the study

Data monitoring:

- All START protocols and assessment should be completed as outlined by NCSS (START Plan, FEIS, PEIS, ABC).
- The study team checks to be sure at least 75% of coaching and outreach is delivered using the randomly assigned approach (either in-person or telehealth).
  - Ensure all coaching and outreach contacts are documented in SIRS.
  - Resources for telehealth delivery are located in Moodlerooms
  - If you are unable to deliver coaching and outreach within the assigned group, our team will ask you to tell us why for our study documentation.

Participant monitoring: We meet with START program leadership monthly to review eligible START recipients, monitor adverse events, and to complete a QA review.

- Six months after enrollment, the study team checks in with the START coordinator, the START recipient, and the family.

Completion of study: The START recipient will be in the study for 1 year or until inactivation from START.

- If a person is inactivated prior to 1 year in the study, re-assessments should be completed prior to inactivation.
- If the START recipient remains active after 1 year in the study, you and the family will receive an e-mail informing everyone that the START recipient completed

If at any time you or the START recipient and their family have questions or are concerned about their participation in the study, please call 866 807-0987 or email (start.telehealthstudy@unh.edu) to speak to someone from the study team.

PROJECT LEADS

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