Study Protocol and Statistical Analysis Plan

Title: Providing Accessible Diagnostic Evaluations and Psychoeducation for Autism Spectrum Disorder in Rural Southwest Virginia

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Brief Description

This study will be the pilot/feasibility phase of a future clinical trial. The proposed feasibility and pilot study aims to bridge the barriers to diagnosis by providing easy-to-access assessment for free, through a mobile unit that travels to rural locations and telehealth assessments. The diagnostic evaluation will confirm or rule out a diagnosis of ASD, followed by purposeful ASD psychoeducation for parents whose children are diagnosed.

Parents of children who meet criteria for a diagnosis of autism spectrum disorder (ASD) or are suspected to have ASD will be randomized into one of three groups (i.e., in-person psychoeducation, telehealth psychoeducation, or "psychoeducation as usual" with paper psychoeducation materials). Parents will complete outcome measures related to their satisfaction, empowerment, and autism spectrum disorder knowledge. Changes in empowerment and ASD knowledge from pre- to post-psychoeducation will be measured using t-tests. The investigators will also track if participants sought and/or received additional ASD-related services throughout the study, up to 6-months post-psychoeducation. Results from this study will help to guide a future, fully powered efficacy trial with a larger sample.

Added April 2020:

In light of the Virginia governor's stay-at-home order in response to the COVID-19 outbreak, which reached pandemic status approximately halfway through data collection, all in-person research and clinical services have been paused at Virginia Tech as of March 13, 2020. To continue to provide services to families in this time, in line with Executive Order 53 from the VA Governor to ensure that the stay-at-home orders do not limit the provision of health care or medical services, this study will begin exploring the feasibility of conducting tele-assessment, a comprehensive assessment battery via a secure video platform and phone.

As such, the protocol is altered to be in line with the university's request to move to remote conduct of research where possible. For the remaining half of participants, the investigators will replace the mobile assessment battery with a tele-assessment battery, delivered via secure online video platform ZoomHIPAA and/or by phone (totaling up to 7 hours of assessment). As such, the protocol is revised to include tele-assessments (no in-person assessments) and randomly assigning eligible participants to either the telehealth or paper materials psychoeducation groups. All outcome measures will remain the same, but will be collected online or by telephone. The investigators and participants may return to in-person assessments if and when it is possible, but reserve the right to continue tele-assessment even once stay-at-home orders are lifted.

The primary aim remains the feasibility and satisfaction with psychoeducation, as this is a pilot feasibility study. The secondary aim will be significantly underpowered to analyze the differences between psychoeducation conditions (i.e., in-person vs. telehealth pychoeducation), therefore in person and telehealth conditions will be combined into one psychoeducation (PE) group with clinician-led sessions. The mean differences between the PE group and the

psychoeducation as usual (i.e., paper materials) formats will be preliminarily explored in terms of changes in outcome measures (i.e., FES and ASK-Q).

Protocol

Participants: Participants will be recruited primarily from locales served by the Mount Rogers Community Services Board (MRCSB), including Smyth, Wythe, Bland, Carroll, and Grayson counties, and Galax City, in rural southwest Virginia, but we will also accept families from other local communities who contacted us to participate. We aim for 21 children between 2-15 years of age and one primary caregivers. Following a diagnostic feedback session, caregivers of children who receive an ASD diagnosis will be randomized to either attend psychoeducation sessions or receive comparable psychoeducation materials about ASD, with the goal of assessing feasibility and satisfaction of psychoeducation and of improving caregiver ASD knowledge and empowerment to seek and provide care for their child. Initially, families were going to be randomized to the following three psychoeducation conditions. Following the stay-at-home orders during the COVID-19 pandemic, however, we had to combine the first two conditions into one psychoeducation (PE) condition with clinician-led sessions. The psychoeducation as usual (PAU) condition, remained the same.

1) In-person Psychoeducation Sessions: Caregivers in this group attended two 90-minute, in-person psychoeducation sessions on our mobile autism clinic (MAC), in or near their hometown. During these sessions, a clinician presented a series of psychoeducation topics supplemented with PowerPoint slides. The first session covered signs/symptoms of ASD, risk factors associated with developing ASD (e.g., heritability, neurobiology, social motivation), and navigating the service systems (e.g., Individualized Education Program (IEP) process, insurance, and Medicaid waivers), while the second psychoeducation session covered evidence-based best practices and a basic introduction to behavior management principles. This delivery method allowed caregivers an opportunity to ask questions and receive immediate, live, and detailed answers from an expert clinician, to focus on specific examples relevant to their child.

2) Telehealth Psychoeducation Sessions: Caregivers in this group also attended two 90-minute sessions, but remotely via a video chat platform, rather than in-person. Otherwise, it followed the same format and PowerPoint materials as the in-person group. Sessions were still facilitated by a clinician, thereby maintaining the option to ask questions, discuss personalized examples, etc. This telehealth method of delivery allowed for more flexibility in scheduling, as sessions could be conducted on days when the MAC was not in-service, but required additional consideration for families who did not have a computer and Internet access. In these cases, a family was randomized to one of the other two psychoeducation groups.

3) Psychoeducation as usual (PAU) - Informational Materials: Caregivers in this group received basic paper psychoeducation resources, distributed at their feedback session. It was up to each caregiver how frequently and diligently they reviewed these resources, but they were encouraged to review them over the course of the following two weeks. These materials were intended to be akin to what a family might have access to at their pediatrician or primary care office, or perhaps on a website, if they were to look for ASD information on the Internet. To be consistent across study groups, the materials produced for these caregivers were comprehensive and included the same span of content as the PowerPoint slides used in the other two groups, but without structured sessions facilitated by a clinician. Upon distribution of materials, caregivers

were encouraged to reach out via phone or email if they had any questions, but only one caregiver did so.

Procedures

To track outcomes, caregivers completed a series of measures at five time points: (1) Time 1: intake, (2) Time 2: after feedback session, pre-psychoeducation, (3) Time 3: post-psychoeducation (i.e., after the second psychoeducation session or equivalent time after feedback for PAU group), (4) Time 4: at 6-week follow-up from the end of psychoeducation, and (5) Time 5: at 6-months follow-up from the end of psychoeducation. Times 1-4 consisted of measures of caregiver empowerment and ASD knowledge; Time 1 included measures of current services; Times 2-5 included a measure of new additional services since the prior timepoint; and Time 3 also included a measure of satisfaction with the psychoeducation services.

Measures

Primary Outcome Measures

Primary outcomes include the assessment of feasibility and satisfaction.

Feasibility of the study will be assessed by tracking the number of parents who completed the psychoeducation sessions and the attrition from Time 2 to Time 3.

Caregiver satisfaction with our psychoeducation services will be collected at Time 3 (the end of the final psychoeducation session or after two weeks of materials for the PAU group). This survey includes 32 questions on a 5-point Likert Scale from 0 (Completely Disagree) to 4 (Completely Agree). This measure surveys areas of convenience, process, quality, interpersonal sensitivity, satisfaction with psychoeducation, and general satisfaction. Because scales have varying numbers of items, each subscale is calculated by adding the item scores and dividing by the number of items in that scale, for a mean score ranging from 0 to 4. For the current study, we will sum 5 items related specifically to the psychoeducation services, for a possible total of 20. Higher mean scores indicate greater satisfaction.

Secondary Outcome Measures

Family Empowerment Scale (FES; Koren et al., 1992) measures levels of perceived efficacy in areas such as community involvement and navigating services for the child and family. The FES is a 34-item questionnaire, providing a 5-point Likert scale for each item. The FES provides raw sums of the items within three domains of empowerment: Family (max = 60), Service System (max = 60), and Community/Political (max = 50). A higher raw score indicates greater empowerment in a given area. These factors are conceptually meaningful, congruence between them is high, and internal consistency is strong (.78-.89; Singh et al., 1995). In the current study, a sum total of all scales will be obtained, and a change score will be calculated between pre- and post-intervention. Positive scores indicate an increase in empowerment.

Caregivers also reported on their ASD knowledge and beliefs on the *Autism Stigma and Knowledge Questionnaire* (ASK-Q; Harrison et al., 2017). The ASK-Q consists of 49 True/False statements, which comprise four subscales of ASD knowledge: diagnosis, etiology, treatment,

and stigma, which results in a raw total score. The ASK-Q demonstrates strong internal consistency (.88). The knowledge subscales – diagnosis, etiology, and treatment – as well as the total score were used in this study. The items on this measure demonstrate strong face and construct validity, as well as cross-cultural utility. It also demonstrates strong discrimination between those who do and do not have adequate knowledge about ASD. In the current study, a sum total of all scales will be obtained, and a change score will be calculated between pre- and post-intervention. Positive scores indicate an increase in knowledge.

Parents will complete a *New Services Survey* to assess additional services they have received since the prior timepoint. In the current study, we will calculate the number of families in each condition (PE and PAU) that added any new service across all timepoints for the duration of the study up to 6 months post-psychoeducation.

Statistical Analysis Plan

For Aim 1, the feasibility aim of this study, primary analyses will include tracking completion and attrition with the psychoeducation services across both groups: PE and PAU. These analyses will be descriptive only. Additionally, we will compare each group on satisfaction with the psychoeducation services. Independent t-tests will compare total satisfaction scores between the PE and PAU groups.

For the second aim, we will assess the differential efficacy across the PE and PAU conditions on the measures of caregiver empowerment and ASD knowledge, as well as new services received. First, we will calculate the change score (Time 3 minus Time 2) for the FES total score and the ASK-Q total score to determine the change in empowerment and knowledge from pre- to post-psychoeducation. Independent t-tests will compare the PE and PAU conditions on FES change score and on ASK-Q change score. To assess new services received, we will calculate the percent of families in each condition (PE and PAU) that indicated receiving a new service at any timepoint over the course of the study up to the 6-month follow-up. This analysis will be descriptive only.