

Protocol ID: ^ 849995

ClinicalTrials.gov ID: NCT05207956

Title: App for Strengthening Services In Specialized Therapeutic Support (ASSISTS)

1. Description of theory, methodology, intent of study

Philadelphia's Department of Behavioral Health and Intellectual disAbility Services (DBHIDS) is about to make substantial investments in establishing and enforcing standards for autism intervention. Data collection will be an important part of these new standards. The objective of the proposed study is to learn about the barriers and facilitators of support staff's data collection in their work with children with autism. The main objective of the clinical trial is to test the refined app with 30 support staff from three agencies. Successful completion of the proposed study will lay the foundation to develop an intervention to increase data collection using behavioral economic principles.

BACKGROUND

Elementary school children with autism often need intensive support throughout the day. Concerns about safety, behavioral challenges, and need for a highly structured environment have resulted in an increased use of one-to-one aides at home, school and in the community. These aides, referred to as 'behavioral health technicians (BHTs)' in Philadelphia, usually have a bachelor's or associate's degree and receive limited training and supervision. (Please note that the terminology used to refer to these aides has changed from 'therapeutic support staff' [TSS]; all subsequent references to these aides in the document will be as BHTs.) Some BHTs have received additional training and are referred to as 'registered behavior technicians (RBT)'. Ideally, aides would use evidence-based interventions in the family of applied behavior analysis (ABA) to help children reduce problem behaviors and increase adaptive behaviors.

Philadelphia's Medicaid system spends ~\$80 million a year on BHTs, about a third of the children's mental health services budget. While children with autism comprise 7% of all children served through this system, they account for 40% of BHT services. Administrators, advocates and parents have decried the poor or unknown quality of care and outcomes associated with it; yet the very nature of the work they do makes it difficult to monitor. Our structured observations of BHTs in the community, combined with our interviews with administrators and clinicians suggest that BHTs are not supported in providing high-quality, evidence-based care, in large part because of the isolating nature of their work and limited opportunity for feedback and acknowledgement.

This project builds on our preliminary work to develop and test strategies to increase support staff's self-efficacy, supervision, and sense of belonging to a professional community, with opportunities for peer comparison and supervisor recognition as mechanisms to increase the use of evidence-based practice. The target practice for this study is data collection. We chose data collection because: 1) it is a component of every evidence-based intervention for children with autism and is common to many mental health interventions for other children as well; 2) this foundational practice is essential to measuring and monitoring outcomes and has been associated with more positive outcomes in and of itself; and 3) it makes possible objective assessment of the effectiveness of implementation strategies and supports iteration and improvement.

Our clinician-focused implementation strategy is based on three psychological principles that inform behavioral economics. The first is bounded rationality, defined as limited information, cognitive capacity and willpower. Support staff may find data collection difficult because they are not sure what information to collect or how to collect it easily. The second is perceptions of social norms. Based on typical practice, support staff may believe that their supervisors do not expect them to collect data and that none of their peers collect data. The third is hyperbolic discounting, in which people prefer more immediate gratification (not expending effort to collect data) at the expense of long-term outcomes (data ultimately used to show child progress and inform future interventions).

STUDY SAMPLE AND DATA SOURCE

The study will begin human subject activities in summer 2019 (pending full approval from the City of Philadelphia IRB as the IRB of record, and signature of a reliance agreement from the School District of Philadelphia Research Review Committee and the Penn IRB). We will continue enrolling human subjects until 2021.

Sample. Participants will include 30 BHTs who provide individual support to children with autism in Philadelphia preschools, schools, daycares, or homes.

Data Source.

Data in this objective will come from:

- 1. In-person observations (up to two hours each), or if infeasible due to COVID-19 restrictions, one-hour interviews by phone or video conference** to compare BHTs' data collection with data collected by an observer from the research team. Observations that take place via videoconference or phone will not be recorded in any form.
- 2. Two 10-minute follow-up questionnaires** about demographic information, perceptions of app usability and information regarding their intentions to collect data on their students.
- 3. Qualitative interviews (in person, by video conference, or by phone; 30-60 minutes)** to elicit contextual information about BHTs' experiences using the app and collecting data. The researcher will take notes during these interviews and they will be audio-recorded.
- 4. Data collection consistency, completeness and timeliness of BHT's** to understand the acceptability and utility of a mobile app developed in a partnership between study leads and the Mozzaz Corporation.

The study team will not collect any identifiable student data. The study team will not share data collected through this study with BHTs' supervisors.

PROCEDURES

We continue to partner with the Mozzaz Corporation, a digital health software company, to create two versions of a mobile application to help BHTs who work with students with autism collect data. The first version comprises a basic electronic platform for data collection. The second version has the same basic electronic platform for data collection, plus additional features designed to increase motivation to collect data and ease the burden of data collection. We will randomize BHTs (n = 30) to use one of the two app versions to evaluate the effect of including these additional

features on BHTs' rates of data collection. In the event that participants are recruited from different types of settings, we will work with the study statistician to implement appropriate stratified sampling strategies.

We will recruit BHTs from agencies whose leadership have agreed to allow BHTs to participate in this project. Research staff will contact leadership at community agencies with an overview of the study and confirm a plan to distribute information about the study in the following ways 1) leaders will email their team describing the study and inviting them to participate and/or, 2) agency leaders and participating BHT's will share BHT emails with research staff who will email BHT's directly to invite them to participate. The email will contain an electronic link to an electronic consent to be contacted form in REDCap.

After BHTs consent to participate in the trial, we will randomize them in pairs to one of the two study arms. Members of the research team will teach BHTs how to use the app during a brief individual meeting that will occur at the school where the BHT works, at their agency, or remotely, depending on BHTs' preference and possible COVID-19 restrictions. BHTs also will complete baseline questionnaires on REDCap on their demographic information, intentions to collect data, and the determinants of intention: attitudes, norms, and self-efficacy. BHTs will be compensated \$25 for these baseline activities, which we anticipate will take approximately 30-60 minutes.

We then will ask BHTs to use their assigned app to collect data daily for 3 weeks, or up to 15 sessions. All data collection will occur via the BHT's smartphone, or if preferred, through the research team's iPad. The Mozzaz app and associated server is HIPAA compliant. BHTs will only record de-identified data in the mobile app; neither the app nor study staff will collect identifiable information about the students with whom the BHTs work. As originally written, this project included research staff conducting in-person observations of BHTs' use of the app to verify BHTs' self-report data. Given COVID-19 restrictions, we propose multiple options to replace in-person observations:

1. *In the event that the BHT is working in person and in-person observation is possible:* Research staff will coordinate with the BHT to facilitate in-person observations over the course of approximately three weeks. Research staff would complete up to observations over the course of approximately three weeks (each up to two hours long.)
2. *In the event that the BHT is working in person but in-person observation is not possible:* In lieu of in-person observations, research staff will administer weekly one-hour interviews with the BHT about their experience using the app. Research staff would complete up to three one-hour interviews over the course of approximately three weeks.
3. *In the event that the BHT is working remotely:* Research staff will coordinate with the BHT to facilitate remote observations through their video conferencing platform. Research staff would complete up to three one-hour observations over the course of approximately three weeks.

In each scenario, BHTs will be compensated \$25/hour per observation or interview (up to six hours, up to \$150) and \$10 per ten-minute follow-up questionnaire (\$20).

After the three-week trial period concludes, BHTs will return their iPad to the study team if they were loaned one. Participants will complete ten-minute questionnaires about perceptions of app usability, their intentions to collect data, and determinants of their intentions to collect data (attitudes, norms, and self-efficacy) via REDCap. We also invite all participants to participate in an additional qualitative phone interview to probe deeper into the user experience and intentions to collect data. This optional interview will take about 30 to 60 minutes and BHTs will be compensated \$25 for completion.

In total, participants will be compensated up to \$220 for their participation in the study. Specifically, they will be paid:

- \$25 for the initial training and baseline questionnaires (about 30-60 minutes)
- \$25 for each set of observations or interviews (up to six hours, up to \$150)
- \$10 for two ~10 minute follow-up questionnaires (\$20)
- \$25 for qualitative interview about experience using the app (30-60 minutes)

Timeline	Measures
Baseline	<ul style="list-style-type: none"> • Demographic questionnaire • Intentions and determinants questionnaire
Trial Period	Mobile application analytics
Post-Trial Period	<ul style="list-style-type: none"> • Intentions and determinants questionnaire • System Usability Scale (SUS) • ASSISTS app feedback form <ul style="list-style-type: none"> ○ Basic app arm ○ Behavioral economics-informed app arm • Post-trial qualitative interview guide

ANALYSIS PLAN

There are three data collection quality metrics of interest: data collection consistency, timeliness, and completeness. Consistency was the percentage of intervals in which aides entered data per session. Timeliness was the delta (time difference in minutes) between behavior occurrences and the aides' data entry related to those behavior occurrences. Completeness was the percentage of metrics such as frequency, duration, severity, or accuracy that aides logged on behavior form entries out of the total number of metrics for that behavior. These metrics were captured via web analytics in partnership with our digital health company. The research team will also conduct two ten-minute follow-up questionnaires with BHTs.

The secondary outcomes of interest are: 1) the change in intentions to collect data and the determinants of intention (attitudes, norms, and self-efficacy), and 2) the usability of the app. We will calculate the change in intentions and determinants of intention by comparing the questionnaires distributed at baseline and after the trial. We will assess usability using the System Usability Scale (SUS) post-observation and by conducting qualitative interviews.

We will analyze outcomes as continuous variables at the BHT level across time points. Initially,

all outcomes will be described and compared between groups using summary statistics (means, medians, and estimates of variance). For each measure, the analysis data set will contain one

observation with each participant's outcome measure at baseline and post-trial. To determine the preliminary efficacy of our implementation strategy, the behavioral economics enhanced app, we will compare the two study arms (basic app vs. enhanced app) on the primary outcome (proportion of time intervals BHTs take data) and the secondary measures (change in intentions to collect data and the determinants of intention [attitudes, norms, and self-efficacy], and app usability), using linear regression with random effects for BHT and time (baseline, post-trial period). The regression will include treatment arm, time (baseline and endpoint), and the interaction between group and time. The coefficient associated with the interaction will indicate the effect of one treatment arm versus the other on data collection.

We also will examine appropriateness, acceptability and feasibility through qualitative analysis of the interviews conducted with all participating BHTs. Audio recordings of interviews will be transcribed and all transcripts will be loaded into qualitative analysis software for data management and analysis. Thematic analysis will be guided by an integrated approach that includes identification of the three priori attributes of interest (i.e., appropriateness, acceptability and feasibility), and grounded theory, which provides a systematic approach to identifying emergent themes and is used to generate robust theoretical models of social behavior in healthcare settings. This integrated approach uses an inductive process of iterative coding to identify recurrent themes, categories, and relationships in qualitative data. After exploring the data, a comprehensive coding scheme will be developed and applied to produce a fine-grained descriptive analysis. Study team members will separately code the transcripts and compare the results to assess the reliability of the coding scheme. Any disagreements in coding will be resolved through team discussion. After the coding scheme is finalized, coders will be required to code two transcripts in a row at high level of agreement ($\kappa > .8$) with the lead coder before independent coding of the rest of the transcripts. A subset of transcripts will be double-coded for the reporting of inter-rater reliability.

Data analysis will inform future refinements needed to optimize the development of the app and provide the basis for a peer-reviewed publication on the outcomes of the randomized controlled trial, as well as a subsequent grant application to test the effects of our implementation strategy in a fully-powered trial.

2. Description of Philadelphia Department of Public Health, Department of Behavioral Health or Risk Management involvement

This project is investigator-initiated. However, it is a result of many conversations with community stakeholders, including DBHIDS leadership. DBHIDS is not formally involved with this project and will not receive any identified data; however, we will share study findings to ensure that policy is shaped by the research, as consistent with best practices (e.g., present at Research Grand Rounds).

3. Duration of Study

The study plans to begin human subjects activities in Summer 2019 and run until May 2022. The end date has been amended in response to a pause in recruitment in schools caused by COVID- 19, .

4. Aspects of research

Potential Benefits. There are no direct benefits to the participant; however, participants may find satisfaction in sharing their ideas and experiences with research staff as their feedback may be utilized to inform future funding. The benefit to the community is that the results may ultimately help enhance the implementation of EBP. The ratio of risks to benefit is positive, considering that we do not think that the study poses considerable risks and that the scientific yield from the study could be greatly beneficial.

Dissemination. The findings from the research will be reported to the City of Philadelphia DBHIDS through Research Grand Rounds, agencies that provide child mental health services, and to the BHRS system that provides support to children with autism in schools so that the stakeholders will have the opportunity to review and discuss this information. Further, we will prepare findings for publication.

5. Risks to subjects

SUBJECT RISKS

There are no known physical or legal risks to participating in the study. Participants will be asked to answer questions about their practice and will also be observed. Self-report, brief observation, and semi-structured interviews could lead participants to feel some temporary emotional discomfort. The investigator or a member of our clinically trained team will be available to speak with any participants who feel unduly distressed, and appropriate referrals will be made. Participants will not be required to participate and lack of participation will not impact their employment. Our experience in similar previous research is that support staff who are not interested in participating in the research will leave after hearing about the study. This does not impact their employment because we ask managers/leadership to leave the room after introducing us during the consenting process, so leadership is not aware if any staff declined participation.

In the event that child abuse/neglect or suicidality/homicidality is identified upon observation, a member of our clinically trained team at the Penn Center for Mental Health (CMH) will follow-up with the support staff to ensure that a safety plan is in place to ensure that any information about child abuse/neglect or intent to harm self or others has been reported to the authorities, as required by law. In the event that staff misconduct is identified during observation, a member of our clinically trained team will follow-up with the support staff and/or his/her supervisor to determine whether the event is reportable and to ensure that the report is filed if deemed appropriate.

All research staff at CMH will be trained by a member of our clinically trained team on mandated reporting requirements. In the event of any of the above circumstances, research staff will report events to a member of our clinically trained team and they will follow-up with the support staff within 2 business days of becoming aware of any event to ensure that any necessary safety and/or reporting measures have been taken and that the child's support staff is knowledgeable about the occurrence and has taken action to address it.

SUBJECT CONFIDENTIALITY

As part of informed consent and assent, participants will be informed that all information they provide will be kept confidential (unless it is determined that it must be reported as required by law), within the personnel of the CMH. No information gathered as part of this research will be shared with agency executive directors, supervisors, or DBHIDS (unless it is determined that certain information must be reported as required by law). Participants will be asked to sign a consent form that thoroughly describes the procedures to be followed in the study and the type of assessments involved. The Philadelphia Department of Public Health Institutional Review Board will have approved the protocol and consent prior to the initiation of the study. The University of Pennsylvania and the School District of Philadelphia Research Review Committee will sign authorization agreements so that the Philadelphia Department of Public Health Institutional Review Board can serve as the IRB of record. We will submit these signed authorization agreements as a modification. Participants will be provided with copies of the signed consent forms while original copies of the signed consent forms will be kept in locked files at the CMH which no one will have access to other than Dr. Mandell and the research team. All data will be coded with a subject identification number. The names that correlate to those numbers will be kept separate, such that any identifying information will be stored in one file, while experimental data will be kept in a separate file. Only Dr. Mandell and the research team will have access to these files. All project staff will complete training on confidentiality through the Collaborative IRB Training Initiative (CITI) course.

All data, including the master list linking identifiers to the ID number and recordings will be destroyed in 2027. NIH policy requires that data be retained for a period of 3 years from the date of the final Federal Financial Report. The award period is from 2019-2021. That means that we must retain all study data until 2027, thus 8 years following study start. Assuming that data collection begins as planned in 2019, that means that the data of a participant who consented in 2019 will be kept until 2027 (8 years later).

Privacy and confidentiality is of the utmost importance given that a breach in privacy and/or confidentiality could result in serious consequences for participating clinicians (e.g., employment implications). Thus, breach of privacy and/or confidentiality are the biggest risk of participating in this study.

To ensure privacy, self-report measures will be completed either by hand in the classroom or using a HIPAA compliant web-based survey platform, e.g., REDCap or Qualtrics, hosted by the University of Pennsylvania. Participants will have the option of completing measures using paper-and-pencil or via web given our previous experiences that support staff prefer different options. Paper-and-pencil measures, only identified with ID numbers, will be sealed in a manila envelope and transported to Penn in a locked briefcase. Semi-structured interviews will be conducted in a private location of the participant's preference. In our previous studies, this has typically been over the phone or in-person in an open office in the school or agency where the support staff works. The participant interviews with the research staff and the content of the interview is recorded and then later transcribed and de-identified by individuals who are trained in human subjects protection.

To ensure confidentiality, we will use the following methods: (a) all self-report data, rating scales, observations, and interviews will be kept in a locked filing cabinet and/or on password-protected

servers, that can only be accessed by study personnel; (b) subject identity will be masked using numeric codes and password-protected master list which only Dr. Mandell and the research team will have access to; (c) data will be entered directly into password-protected files which only Dr. Mandell and the research team will know, and (d) files kept on the computer will only be identified with subject numbers and will not contain identifying information.

DATA DISCLOSURE

The proposed research will include data from support staff and supervisors who work in school settings in the City of Philadelphia. The final dataset will include quantitative and qualitative data for each support staff and supervisor who participated. The final dataset will be stripped of identifiers prior to sharing. Release of data for data sharing will occur after publication of the main findings from the dataset. We will make the data and associated documentation available to users under our own auspices by mailing an encrypted hard-drive to users. A data-sharing agreement must be signed that accounts for (1) commitment to using the data only for research; (2) IRB approval at the host institution, (3) a plan for securing the data using appropriate technology, and (4) an agreed upon plan to destroy or return the data upon completion.

6. Numbers of participants

30 BHTs will be enrolled in the RCT

7. Contact information for Principal Investigator

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8. Notation if requesting exemption from or alteration of written consent documentation and/or waiver of HIPAA authorization

We are requesting a ***waiver of written documentation of consent*** from the PDPH IRB for supervisors and BHTs who participate in the qualitative interview over the phone part of this research project. Because these interviews will be done over the phone, we will not have an opportunity to collect a signed copy of the consent form. Before the scheduled interview takes place, research staff will send a copy of the consent form to the participant via email. During the call but before the interview begins, the research staff will go through the required elements of informed consent and answer any questions the supervisor or BHT might have. If they agree to participate, then the member of the research team conducting the call will note the participant's name and the date the individual consented to participate on a consent form.

This research component presents ***no more than minimal risk*** of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. The primary risk related to study participation is the breach of confidentiality of the audio recording. We

minimize this risk by immediately transferring all data from the interview to a HIPAA-compliant platform (REDCap) and a HIPAA-compliant drive. The waiver of documentation of consent will ***not adversely affect the rights and welfare of the subjects***, since we will still go through all required elements of informed consent over the phone and send the consent form to the participant via email prior to the phone call.