

Cover Page

Expert Guiding Technology to Help Individuals With Developmental Challenges Build Life and Vocational Skills

NCT04518358

10/17/2019

1) Abstract of the study

Autism affects approximately 1% of the world's population. Applied Behavior Analysis (ABA) is the gold standard in treating autism. Up to 50% of young children with autism who undergo early, intensive ABA therapy may achieve normal IQs and developmentally typical language skills within 2 – 3 years. ABA therapy requires highly trained instructors who implement individually designed educational programs in 1:1 teaching sessions. The instructor role can be filled by therapists, paraprofessionals such as educational assistants and family members. These complex teaching sessions involve precise prompting, behavior shaping, error correction, and reinforcement strategies. ABA therapy programs are developed by highly trained clinicians who provide close supervision and monitoring of front-line ABA instructors to ensure student progress. There is a growing research base showing that ABA strategies are also highly effective for teaching important skills to adults with autism (Tincani & Bondy, 2014).

The purpose of this study is to evaluate the *Guidance, Assessment, and Information System (GAINS)*, a mobile, hands-free™ data-driven guidance and data collection system to augment ABA therapy. The GAINS interface consists of software run on a mobile device which is carried by the ABA instructor who wears a Blue Tooth headset with a microphone. GAINS allows the instructor to select a particular ABA therapy instructional program (e.g., teaching non-verbal imitation), and then provides step-by-step, speech-based guidance to the instructor on how to implement the program with fidelity. GAINS also collects data on individual responses from speech-based input of the instructor, and adjusts therapy procedures accordingly. In the proposed study, the principal investigators will implement GAINS with approximately 50 adults with autism served by the Chimes of Delaware (support letter attached) , and collect formal and informal data on usability and effectiveness of the system.

2) Protocol Title

Guidance, Assessment, and Information System (GAINS): Usability Testing in Applied Behavior Analysis Therapy

3) Investigator

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Collaborators: Matt Tincani, Ph.D., Department of Teaching and Learning, College of Education; Judy Stull, Ph.D., Senior Research Associate, Institute for Schools and Society, John Nosek, Computer Science, College of Science & technology.

4) Objectives

The purpose of this study is to evaluate the *Guidance, Assessment, and Information System (GAINS)*, a mobile, data-driven guidance and data collection system to augment ABA therapy. In the proposed study, the principal investigator and collaborators will implement GAINS with 50 adults with autism, and collect formal and informal data on usability and effectiveness of the system. The following research questions will be addressed:

1. Can ABA instructors successfully implement basic ABA therapy programs to teach skills such as non-verbal imitation, expressive language, and object-to-object matching, as guided by GAINS?
2. What are the opinions of ABA instructors, ABA program supervisors and other consumers about the goals of GAINS to increase the efficiency of ABA therapy, the ease with which GAINS can be used to guide therapy, and the outcomes of therapy when guided by GAINS?

5) Rationale and Significance

The success of ABA therapy programs depends heavily on the quality of the ABA intervention team, including the ABA instructors and ABA program supervisors (Drew et al, 2002; Sofronoff et al, 2004, Randolph et al, 2011). Traditional instructor training depends heavily on a didactic approach, in which supervisors provide a great deal of explanation, modeling, and feedback directly to the instructor (Granpeesheh et al. 2009). Although sometimes effective, this approach is time consuming and expensive as it requires significant face-to-face time between instructors and supervisors. Moreover, training by this traditional method can only occur if an expert supervisor is available, and instructors are prone to make many therapy mistakes without adequate supervision. In turn, individual progress can suffer.

There is a trend toward standardizing intervention via computerized information management systems in different health areas to optimize the quality of care a patient receives (Balust & Macario, 2009). Hand-held computer use by medical residents is found to provide educational, institutional and patient care benefit, and this may also be the case for other professionals, such as ABA instructors (Tempelhof, 2009). Interventions promoting such technological information management and communication have the potential to not only improve the quality of care, but also to contain costs (Gagnon, 2009).

It is hoped that GAINS will add to the existing knowledge base by improving ABA therapy in the following ways:

- 1. Reduce ABA therapy expense and increase availability.** The technology will reduce costs in ABA therapy by increasing the efficiency of therapy and reducing the need for direct supervision of front-line instructors. Lower costs of ABA therapy will stretch limited funding and provide opportunities for more

ABA therapy for more children and adults.

2. Improve effectiveness and quality of those who fulfill ABA therapist role.

Training those who fulfill the ABA therapist role, including parents, can improve ABA outcomes (Drew, 2002; Sofronoff et al, 2004, Strauss et al, 2012, Weinkauf et al, 2011, Sarokoff & Sturmey, 2004). Many functions of the senior therapist, for example, showing the trainee how to give instructions, prompt correct responses, correct errors, and deliver reinforcement, could be facilitated by the technology.

3. Improve guidance and support for ABA therapists. Appropriate guidance will increase the effectiveness and efficiency of instruction. The technology will guide the instructor in a way that offloads the burden of remembering what to do, while facilitating data collection and report generation. For example, during instructor training and therapy sessions, instead of the instructor remembering what to do, the software agent will guide the instructor on 1) what task to initiate; 2) how to initiate the task; 3) what prompts to use to prompt/assist the student in task completion; and 4) if reinforcers should be used, what reinforcers of what strength and duration to use.

4. Improve Program Fidelity. The technology will incorporate precise instructions to guide the instructor. This will motivate instructors to follow good practice insuring improved program fidelity.

5. Improve instructor-student interaction with improved interfaces. The support technology will be smoothly integrated into the instructional environment to reduce instructional distractions and limit the need for manual input.

6) Resources and Setting

The principal investigator for the study, Dr. Hantula, and collaborators, Drs. Tincani and Stull, will meet on an as needed basis to discuss the purpose of the study, the study's procedures, and data, in terms of their respective roles. Drs. Hantula and Tincani will collaborate in the usability and effectiveness testing of GAINS as described in this proposal. Dr. Stull will focus on program evaluation.

Approximately fifty adults with autism and their direct support staff who implement ABA programming will participate. A support letter from Chimes Delaware, the agency where the research will take place, including a contact person, is attached. If additional sites are added, support letters and the contact person at the site will be provided to the IRB prior to conducting trials.

7) Prior Approvals

Support letters from settings are provided as separate attachments.

8) Study Design

a) Recruitment Methods

Approximately fifty subjects will be recruited for the study. Initial potential subjects will be identified through discussions with the contact person at each setting, who will identify adults with autism who receive behavioral interventions from the therapy service provider. One member of the research team or supervisor at the therapy service provider will contact the parents of each potential subject by phone or in person, and will explain the purpose, procedures, benefits, and potential risks of the study in detail, and will provide a copy of the informed consent form. If additional sites are added to Appendix A, the person at the site who will help recruit subjects will be identified in a similar way and this information will be provided to the IRB with the contact information and letter of support.

b) Inclusion and Exclusion Criteria

Subjects in the study will be adults with autism who receive behavioral therapy for at least five hours per week. Individuals will not be excluded on the basis of gender, race, or ethnicity.

c) Study Timelines

Subject recruitment, as described above, will take approximately two weeks. The timeline for the study is expected to occur for up to a year; we anticipate 4-8 hours of participation per week for each subject during a total of 360 calendar days during normal therapy sessions. Approximately two sessions with each instructor may be observed. We anticipate that all data will be collected by August 31, 2020.

d) Study Procedures and Data Analysis

Each study session, lasting approximately 30 minutes, will occur as follows:

1. The subject's instructor will be provided with the GAINS interface, comprised of a mobile device equipped with GAINS software, and a Bluetooth headset.
2. For the first session, the instructor will be instructed on how to start and use the interface.
3. The instructor will run one of the adult's ABA instructional programs using the system, which provides speech-based guidance to the instructor on the specific steps of implementing the program. Each program implemented by the instructor will be part of the adult's normal habilitative

program, and will include such skills as non-verbal imitation, expressive language, and matching identical objects or identical pictures.

4. For observed sessions, a member of the research team will use a paper and pencil checklist which contains each of the steps of the program to record whether the instructor has implemented the steps accurately, as measured by a percentage of steps correctly implemented. For some observed sessions, the researcher may ask the instructor to first run one of the individual's ABA instructional programs without using GAINS, followed by the instructor using GAINS to run the individual's instructional program.
5. Following sessions at approximately the following schedule: first time, first month, quarterly, the instructor will complete a survey to assess his or her opinions about the usability of GAINS and usefulness of GAINS in increasing the efficacy of ABA therapy. For example, "What did you like about using GAINS?" "Did GAINS make delivering the X program easier? How?"
6. Data on accuracy of student responses will be collected by the GAINS system and stored on a secure, remote database server. Later these data will be analyzed to evaluate the extent to which students responded accurately to therapy augmented by GAINS. This analysis could include looking for patterns in data collected such as data mining.
7. Demographic data of instructors, such as their education level and number of years experience teaching individuals with autism will be collected. Investigators will be accessing clinical records for the following background information: a) demographic information on the individual (gender, educational background, etc.); b) results of previously given autism diagnostic Instruments; c) prescriptions and dosage.

e) Withdrawal of Subjects

There are no anticipated circumstances in which the subjects would be withdrawn from the study without their consent.

There will be no penalties or other consequences for subjects whose parents choose to withdraw them from the study. To withdraw an individual from the study, a parent or guardian may contact the principal investigator and request that his or her son or daughter be withdrawn.

f) Privacy & Confidentiality

The study will not use or disclose subjects' Protected Health Information (PHI).

All electronically collected research data will be transferred to a private, secure database. Any paper records of subjects' data or other confidential information will be kept in a locked filing cabinet. Only the research team will have access to the data. Any identifying information will be omitted from published or disseminated reports of the data to maintain confidentiality of subjects.

Results of the study may be shared through conference presentations or written reports disseminated in peer-reviewed journals or other formats (e.g., book chapters or grant proposals). In such cases, pseudonyms will be used and no identifying information (e.g., geographical location of subjects' residences) will be included when discussing results.

As the research procedures are part of normal educational procedures and settings for the individual, it is not anticipated that subjects will feel uneasy during the experiment.

9) Risks to Subjects

There are no foreseeable risks to the study other than loss of instructional time. Given that the research employs normal educational procedures, we anticipate loss of instructional time to be very minimal (i.e., a few minutes per day), even if that occurs. No aspect of the research will cause discomfort or physical danger to subjects. Subjects will not be inconvenienced, as the research will take place as part of their typical therapy sessions. The individuals with autism will not use or interact with the GAINS technology - only the instructor will do so, hence there is no additional risk for the individual.

10) Potential Benefits to Subjects

Potential benefits of the study to subjects include increased learning opportunities provided through GAINS augmented therapy sessions.

11) Costs to Subjects

There is no cost for participation in this research.

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12) Informed Consent

Informed consent will be obtained by a member of the research team or supervisory personnel of the therapy service provider. Following recruitment, a member of the research team or supervisory personnel of the therapy service provider will explain the purpose, procedures, benefits, and potential risks of the study in detail, and will provide a copy of the informed consent form.

Because subjects will be individuals with autism who have limited communication skills and/or cognitive deficits, it is highly unlikely that they will understand the

purpose, procedures, and benefits and risks of the study; therefore, assent will not be sought from the subjects.

13) Vulnerable Populations

The study will involve a vulnerable population, adults with autism. The study involves minimal risk to subjects as it uses normal educational procedures and settings and the benefits of the study in terms of enhanced learning outweigh the risks.

Appendix A – List of Settings for the Study

CHIMES, Newark, DE