Approved by WKU IRB 09/06/2022

Advancing the Effectiveness of Functional Communication Training for Children With Intellectual and Developmental Disabilities in Schools

NCT05445596

Primary Investigator: Jessica Torelli, Ph.D., BCBA-D
Western Kentucky University
270-745-4054

Sponsor:
KY INBRE

Title	Advancing the Effectiveness of Functional Communication Training for Children With Intellectual and Developmental Disabilities in Schools
Methodology	Single-case experimental design
Study Duration	Estimated duration is 3-6 months per participant
Study Center	School sites near Western Kentucky University, Bowling Green, KY
Objectives	Primary Objective: to evaluate the effects of functional communication training (FCT) with concurrent and chained schedules on rates of problem behavior
Number of Subjects	8
Diagnosis and Main Inclusion Criteria	Children will be eligible to participate if they are: (1) preschool or elementary school students between the ages of 3–11, (2) have an intellectual and/or developmental disability, (3) have a functional behavior assessment and behavior intervention plan or have been identified as needing a functional behavior assessment, and (4) exhibit problem behavior that occurs at least daily. Children will be excluded if they have excessive absences from school and if problem behavior occurs less frequently than daily.
Study Product, Dose, Route, Regimen	All participants will receive functional communication training with concurrent and chained schedules
Statistical Methodology	Visual analysis will be used due to use of single-case experimental design.

Purpose:

The primary purpose is to evaluate the effects of functional communication training (FCT) with concurrent and chained schedules on rates of problem behavior.

Methods:

Study Design.

The proposed project uses single case experimental design to address the research questions. In each of the three project aims, each participant will be a stand-alone experimental design in which they serve as their own control. Their behavior will be compared across conditions to determine the presence or absence of functional (causal) relations between independent and dependent variables. For example, researchers will collect data on the participant's problem behavior and prosocial communication during baseline and intervention conditions to evaluate whether there are systematic decreases in problem behavior and increases in prosocial communication when implementing the intervention relative to other conditions.

Because participants will serve as their own control, they will not be assigned to different study groups. However, the sequence of some intervention conditions will be counterbalanced across participants to control for threats to internal validity. When condition sequence is counterbalanced, participants will be randomly assigned to a sequence.

Study population and selection criteria.

Children will be eligible to participate if they are: (1) preschool or elementary school students between the ages of 3–11, (2) have an intellectual and/or developmental disability, (3) have a functional behavior assessment and behavior intervention plan or have been identified as needing a functional behavior assessment, and (4) exhibit problem behavior that occurs at

least daily. Children will be excluded if they have excessive absences from school and if problem behavior occurs less frequently than daily. Excessive absences would prevent the research team from being able to conduct treatment regularly, and infrequent problem behavior may preclude our ability to demonstrate an intervention effect (Type II errors would be likely). For each student participant, we will also recruit 1–2 school staff members who provide direct services to the student, such as teachers or paraprofessionals. In accordance with a consecutive controlled case series design, the first eight student participants nominated who meet inclusion criteria will be included. We will recruit a total of 8 student participants and 10–12 educators.

Study Procedures.

Procedure	**Duration**
Educator interview	Twice (beginning and end of study)
Educator social validity questionnaire	Twice (middle and end of study)
Student educational record review	One time (beginning of study)
Descriptive classroom observations	1–5 times per student
Assessment session implementation and observation	1–4 hours per student
Intervention session implementation and observation	3–6 hours per week for 3–6 months per student

Interviews, Questionnaires, and Record Reviews: At the beginning of the study, the research team will interview participating educators to gather information about the student's problem behavior and assessments and interventions the school team has previously used. The research team will also interview educators at the end of the study to gather data on their perceptions of the intervention as a measure of social validity. Educators will complete a social validity survey at the middle and end of the study informing the acceptability, feasibility, and utility of the study goals, procedures, and effects. At the beginning of the study, we will review the student's educational records to gather data on age, race and ethnicity, special education qualifying conditions, educational goals, present levels of academic and functional performance, functional behavior assessment results, and history with academic and behavioral intervention.

Behavioral Observations: For each participant, there will be three types of behavioral observations during the study: (1) descriptive classroom observations, (2) assessment session observations, and (3) intervention session observations. Because we will use single case experimental design to evaluate effects of the intervention on student behaviors, the total number of sessions will vary by participant based on the clarity of outcomes observed (i.e., additional sessions are conducted until clear patterns are established) (Ledford & Gast, 2018). However, on an individual basis and in collaboration with school staff, we will identify a maximum number of sessions to be conducted per study phase to avoid unnecessary extended periods of data collection. For example, we might decide that if we do not observe a treatment effect in 10 sessions, we will modify treatment.

Descriptive Classroom Observations: We will conduct between 1 and 5 descriptive classroom observations for each participating child. The purpose of these observations is to generate one or more hypotheses about why a child engages in problem behavior. During these observations, research staff will collect data (using electronic tablets or paper-and-pencil data collection forms) on child problem behaviors, academic behaviors, and social behaviors, as well as classroom variables potentially related to problem or appropriate behaviors (e.g., teacher attention, academic demands). Later in the study, we will conduct observations to evaluate the extent to which the child has generalized behaviors learned during intervention sessions to typical classroom routines. Observations may range in duration from 10–60 minutes and will be

conducted during the child's usual instructional routines. Observers will arrange themselves as unobtrusively as possible in the classroom.

Assessment Session Implementation and Observation: We will conduct assessment sessions over 1–2 school days for 1–2 hours per day. The purpose of these sessions is to directly test one or more hypotheses about why a child engages in problem behavior (Beavers et al., 2013; Hanley et al., 2003; Hanley, 2012). During these sessions, research staff will program one or more classroom variables (e.g., presentation and removal of academic tasks, delivery and restriction of adult attention) and research staff will collect data on student behavior and fidelity to programmed procedures. Each assessment session will last between 1 and 10 minutes. Assessment sessions will be completed in the child's usual classroom setting unless there is a compelling reason to complete the assessment in a separate setting, such as an empty classroom or office in the school building (e.g., the form of problem behavior poses a safety concern, such as aggression toward peers).

Intervention Session Implementation and Observation: We will conduct intervention sessions 1–3 times per week for 1–2 hours per day over a period of 3–6 months. Each intervention session will be between 5–20 minutes long. The purpose of these observations is to evaluate the effects of a behavioral intervention, functional communication training (**FCT**; Carr & Durand, 1985), on problem and alternative behaviors. FCT is a differential reinforcement of alternative behavior procedure in which the therapist reinforces an alternative behavior, a functional communicative response (**FCR**), as an alternative to problem behavior (Tiger et al., 2008). For example, a child who engages in self-injury to escape math instruction may be taught to exchange a "break, please" picture card to receive a brief break from the math task as an alternative to self-injury. Research staff will implement sessions and collect data on student behaviors and fidelity to programmed procedures. During the final phase of intervention, research staff will train participating educators to implement intervention sessions. Research staff will collect data on student and educator behaviors, including fidelity to programmed procedures. Each intervention session will last between 5 and 20 minutes. Intervention sessions will be completed in the student's usual classroom setting unless there is a compelling reason to conduct the sessions in a separate setting, such as an empty classroom or office in the school building (e.g., topography of problem behavior poses a safety concern). If intervention sessions are initially implemented in a separate setting, we will transfer intervention to the student's usual classroom after establishing efficacy in the separate setting.

The intervention will have three primary phases, each of which corresponds to a project aim. During the first phase, we will evaluate the effects of FCT with concurrent schedules. We will compare two different versions of FCT to evaluate the conditions under which FCT without extinction reduces problem behavior and establishes alternative behavior. In the first version, problem and alternative behaviors will result in the same consequence (e.g., 30-s break from academic demands). In the second version, alternative behavior will result in longer duration, higher quality reinforcement relative to problem behavior. For example, exchanging a break picture card may result in a 1-min break with a preferred activity, while problem behavior may result in a 20-s break. Replicating these two conditions across days (i.e., using a single case reversal design) will allow us to experimentally evaluate the effects of enhancing the quality and duration of reinforcement for alternative behavior relative to problem behavior, informing conditions under which FCT with concurrent schedules is effective.

The second phase of FCT intervention will be the treatment extension. During the treatment extension, we will address project aim 2, to evaluate the effects of a treatment package on obtaining stimulus control over FCRs and work completion, while maintaining reductions in problem behavior. The purpose of the treatment extension is to increase the practicality of the intervention by building tolerance for delays to reinforcement and teaching the child when high-quality reinforcement is and is not available. In other words, the student learns that after completing academic work requirements, requests for high-quality reinforcers will be

honored. The treatment extension package will include three components: chained schedules of reinforcement, demand fading, and choice. Chained schedules are a type of compound schedule with schedule-correlated stimuli in which completing one component schedule produces the next component schedule, and reinforcement becomes available contingent on successively completing all basic schedules (Ferster & Skinner, 1957). Demand fading is systematically increasing the number, duration, or difficulty of demands required to access reinforcement (Hagopian et al., 2011). These two components will be combined to teach the student when high-quality reinforcement is and is not available to acquire stimulus control over appropriate requests and academic work completion and to build the student's tolerance for delays to reinforcement. We will incorporate choice to help maintain reductions in problem behavior (Royer et al., 2017), promote self-determination (Shogren et al., 2004), and promote engagement and academic performance (Kern et al., 1998). The student will have choice opportunities within and between tasks and in choosing reinforcers. Specifically, we will teach the student multiple communicative responses to promote their ability to individualize reinforcement. They will also have choices over the order of activities or specific problems to complete (e.g., Dunlap et al., 1991, Moes, 1998). The treatment extension phase will continue until the student has met the tolerance goal set in collaboration with the student's educators related to the amount of work the student should be able to complete without engaging in problem behavior.

During treatment extension sessions, we will teach the student when high-quality reinforcement is and is not available using visual cues. For example, a red index card may signal breaks are unavailable, while a green index card signals breaks are available. When the red card is present, the student will need to complete an academic work requirement (e.g., write two letters). After completing the work requirement, the therapist will remove the red card and present the green card. When the green card is present, the student may request and access high-quality reinforcement (e.g., 1-min break with preferred activities). As the student demonstrates success with shorter, easier work requirements, the therapist will progressively increase the number or difficulty of academic tasks. For example, by the end of the treatment extension, the student might be required to complete a 10-min math activity without problem behavior. During treatment extension sessions, visual cues will be systematically programmed to be present or absent, depending on the session, to address experiment 3a toward project aim 3. In other words, during some sessions, the green and red cards will be present, and during other sessions, they will be absent. This will allow us to evaluate how visual cues impact communicative responses and academic work completion.

After meeting the terminal goal during treatment extension sessions, we will move to the third stage of intervention, generalization. The purpose of this phase is to transfer treatment effects to natural implementers and multiple relevant educational contexts. During this phase, we will conduct experiment 3b addressing project aim 3, examining the role of visual cues in the transfer treatment effects across educational contexts and implementers. All procedures will remain the same as during the treatment extension, except we will systematically introduce educators as interventionists, and we will begin conducting intervention sessions in up to two generalization contexts. We will train educators on how to implement intervention sessions prior to their implementation, and we will provide in vivo coaching during and in between sessions. Generalization contexts will be instructional activities during which the student typically engaged in problem behavior, such as small group reading instruction. Transferring implementation to educators and typical educational contexts will help promote the long-term success of treatment when research team support is removed after study completion.

Data Monitoring

The PI will assume responsibility for monitoring the trial (rather than establishing a board) due to the low-risk status of the project. The PI will monitor the project's risks by (a)

analyzing participant data following each appointment to monitor the appropriateness of the procedures and research design, (b) ensuring two research staff conduct independent checks of consent and maintain thorough records to ensure consent has been provided for each participating student and educator, and (c) seeking input regularly (weekly) from participating educators on study procedures.

The data sources are educator interviews, social validity questionnaires, educational record review, and behavioral observations. Only the PI and project manager will conduct educator interviews and administer social validity questionnaires. Data collectors for behavioral observations will be trained on data collection procedures and must meet a training criterion of at least 85% agreement on all dependent variables across three data collection attempts prior to collecting study data. Interobserver agreement will assessed on at least 25% of sessions across participants and conditions to monitor reliability throughout the study. Sessions will be randomly selected for interobserver agreement, and data collectors will not know which sessions will be selected prior to coding. The PI will conduct data analyses using Excel and GraphPad Prism. Data will be stored in a secure and encrypted server. Data will be identified only by the study ID of the participant. The document linking participant names and IDs will be kept confidential in a secured office on password protected computers.

Institutional Review Board

The protocol, informed consent forms, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

Consent Process

Parent Consent: We will seek parental consent for potential participants who meet inclusion criteria based on de-identified descriptions provided by educators. The consent form will include a description of the project purpose, procedures, and possible benefits and risks in everyday language. Parental consent and child assent forms will be sent home together by a school representative on behalf of the principal investigator (PI) and returned to the representative, who will then give it to the PI. Thus, informed consent for parents will be communicated by returning the printed form, and the PI will not be informed of any potential participants' names until written consent is obtained. We will ask school representatives to send an extra copy of the consent form for the parent/guardian to keep. The consent forms will explain to the parents/guardians that they are free to withdraw at any time.

Educator Consent: We will obtain informed consent from at least one educator per student. The consent form will include a description of the project purpose, the procedures, and possible benefits and risks in everyday language. The PI will offer to address any questions or concerns practitioners have about the consent form or study in general via phone or teleconference meeting. Moreover, the PI will emphasize the voluntary nature of participation, and that they are free to end their participation in the study at any time. School personnel will receive an extra copy of the consent form to keep.

Child Assent: We will obtain assent from any child (regardless of disability), who can provide it. However, we anticipate that the children who participate in this study may vary in terms of communication repertoires. On the parent/guardian consent form, parents will indicate whether their child can understand the information presented on the assent form. In child friendly language, the assent form will describe that the child's parents have given permission for the child to work with the PI and her team, what will happen during sessions, and that the child may stop participation at any time with no adverse consequences. If parents indicate their

child can understand the information presented on the assent form, we will ask them to indicate on the consent form whether their child can provide written assent (in the form of a signature). If they indicate yes, then the research team will obtain written assent from the child in the presence of school personnel as a witness. If they indicate no, then we will obtain verbal assent from the child in the presence of school personnel as a witness.

Protocol Deviation

A protocol deviation is any noncompliance with the clinical trial protocol or GCP requirements. The noncompliance may be either on the part of the participant, the Investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly. All protocol deviations/violations should be documented using the Protocol Deviations/Violations CRF and submitted to the IRB according to their reporting guidelines.

Laws and Regulations

This clinical study will be conducted in compliance with all national laws and regulations of the countries in which the clinical trial is performed, as well as any applicable guidelines. The trial will be registered on www.clintrials.gov and on other sites, as appropriate.

Publication and Data Sharing Policy

The preparation and submittal for publication of manuscripts containing the study results shall be in accordance with a process determined by mutual written agreement among the study Sponsor and participating institutions. The publication or presentation of any study results shall comply with all applicable privacy laws, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996.

Study Personnel and Roles

Jessica Torelli, Ph.D., BCBA-D	Principal Investigator	Responsible for all study related issues

Conflicts of Interest

No conflicts of interest have been reported.