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TITLE: Feasibility and Initial Efficacy of an After-School Social Intervention Delivered by Paraprofessionals in School Settings for Children with ASD

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14. ABSTRACT

This pilot RCT is testing the feasibility and initial efficacy of an after-school social intervention delivered by paraprofessionals in school settings for children with ASD (without intellectual disability). The intervention targets a range of social skills and these are taught, practiced, and reinforced using social skills groups, social recreational games, and a behavioral reinforcement system. The program is delivered 4 days/wk., 90 mins./session, over 8 wks. in group format by paraprofessionals to groups of 12-15 children including 2 children with ASD. Feasibility is assessed via fidelity, satisfaction ratings, and attendance and attrition rates. Outcomes test the intervention effect on a child test of social-cognition, parent ratings of social skills and ASD symptoms, and behavioral coding of social competence during game play. Efficacy is assessed immediately following the 8-week intervention (and again at 3-month follow-up for the treatment group only). Following year 1, significant progress has been made in regard to the major activities/objectives which included: (1) completing the regulatory review; (2) enrollment of sampling waves 1 and 2; (3) recruitment and training of research assistants; (4) implementation of the intervention for the treatment group followed by waitlist control group; and (5) completion of outcome testing. All of these were completed in year 1.

15. SUBJECT TERMS
Children with ASD, after-school social intervention, paraprofessionals, schools

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1. INTRODUCTION

This pilot RCT is testing the feasibility and initial efficacy of an after-school social intervention delivered by paraprofessionals in school settings for children with ASD (without intellectual disability). The intervention targets a range of social skills and these are taught, practiced, and reinforced using social skills groups and social recreational games, as well as a behavioral reinforcement system. Groups are conducted using direct instruction, modeling, role-play, feedback, reinforcement, and repeated practice. The program is delivered 4 days per week, 90 minutes per session, over 8 weeks in group format by paraprofessionals to groups of 12-15 children including 2 children with ASD (the remaining children consist of typically-developing peers). Feasibility is assessed via fidelity, satisfaction ratings, and attendance and attrition rates. Outcomes test the intervention effect on a child test of social-cognition, parent ratings of social skills and ASD symptoms, and behavioral coding of social competence during game play. Efficacy is assessed immediately following the 8-week intervention (and again at 3-month follow-up for the treatment group only).

2. KEYWORDS

Children with ASD, after-school social intervention, paraprofessionals, schools

3. ACCOMPLISHMENTS

Major goals of the project

Per the approved SOW, this pilot RCT will test the feasibility and initial efficacy of an after-school social intervention delivered by paraprofessionals in school settings for children with ASD (without intellectual disability). Feasibility will be assessed via implementation fidelity, satisfaction ratings, and attendance and attrition rates. Outcomes will test the intervention effect on a child test of social-cognition, parent ratings of social skills and ASD symptoms, and behavioral coding of social competence by naïve raters during unstructured game play.

Tasks	Timeline (month)	% Complete	Date Completed
Subtask 1: IRB and regulatory review			
Finalize consent form and human subjects protocol	1	100%	1/21/22
Local IRB protocol submission and approval	1	100%	2/1/22 (approved)
Submit and secure approval from OHRO	1	100%	2/22/22 (approved)
Submit amendments as needed	As needed	100%	2/20/23 (submitted local IRB) 2/27/23 (approved local IRB) 3/7/23 (OHRO determined that the

			amendment did not require OHRO review and approval)
Complete IRB report and secure IRB renewal annually	Annually	100%	2/1/23 (approved local IRB) 2/2/23 (approved OHRO)
Subtask 2: Conduct study			
Wave 1			
Recruit, screen, and consent/assent participants (wave 1; n=4)	2-3	100%	2/10/23
Randomly assign participants to treatment or waitlist control groups	3	100%	2/10/23
Recruit, train, and establish reliability of research assistants and evaluators/coders	2-3	100%	10/1/22
Implement 8-week treatment	4-5	100%	4/20/23
Assess participants at baseline, posttest, and follow-up (follow-up for treatment group only)	3-9	100%	6/23/23
Wave 2			
Recruit, screen, and consent/assent participants (wave 2; n=8)	4-6	100%	2/10/23
Randomly assign participants to treatment or waitlist control groups	6	100%	2/10/23
Implement 8-week treatment	7-8	100%	4/20/23
Assess participants at baseline, posttest, and follow-up (follow-up for treatment group only)	6-12	100%	6/23/23
Implement 8-week treatment for waitlist and test outcomes after completion	10-12	100%	6/20/23

Accomplishments under these goals

Regulatory review

The local IRB protocol was developed and submitted during the months leading up to the start date of the grant. Local IRB approval was received on February 1, 2022; this approved protocol was then submitted to the OHRO and approved on February 22, 2022. One amendment was subsequently submitted to the local IRB and was approved on February 27, 2023. The approved amendment was submitted to the OHRO but was determined by the OHRO to be a non-substantive amendment and to not require approval by the OHRO (per email on March 7, 2023). In addition, the local IRB renewal was approved on February 1, 2023 and subsequently approved by the OHRO on February 2, 2023. **Per the SOW for year 1, all regulatory tasks were completed as proposed.**

Recruitment, enrollment, and randomization of sampling wave 1

The target sample size for wave 1 was *n* = 4 children with ASD. Recruitment, enrollment, and randomization of wave 1 was delayed due to the length of time needed to establish the

program protocols in the schools including procedures for securing time to train paraprofessional after-school staff. This process allowed the research team to learn and better prepare for program preparation and establishment in schools for subsequent sampling waves. Although accrual and enrollment was delayed for wave 1 due to slower start-up in the schools, we successfully recruited, screened, enrolled, and randomized the 4 children with ASD targeted for wave 1 as part of the wave 2 process (see subsequent *Recruitment, enrollment, and randomization of sampling wave 2* section). As such, **the recruitment, enrollment, and randomization of sampling wave 1 was completed but later than proposed in the SOW.** Demographic data on the participants from year 1 (sampling waves 1 and 2) are presented in Table 1 (see Appendix).

Recruitment and training of research assistants and evaluators/coders

As proposed, we successfully recruited and trained the research assistants and evaluators/coders for year 1. The recruitment and training of research assistants and evaluators/coders occurred slightly later than proposed in the SOW (i.e., in month 4 instead of months 2-3). In preparation for conducting fidelity assessments during the study, the research assistants were required to pass the same exam (100% required) as the paraprofessionals and demonstrate fidelity (implementation accuracy $\geq$90%) during practice exercises prior to the study. They also received instruction on completing the fidelity checklists and established IOA ≥90% with the assessment coordinator prior to the study. The masked (blinded) evaluators/coders completed separate training on administration of the outcome measures and were required to demonstrate accuracy in test administration and reliability conducting observations prior to conducting measures as part of the study. Overall, **the recruitment and training of research assistants and evaluators/coders was completed** and all research assistants and evaluators/coders met the training requirements**.**

Implement 8-week treatment (for the active treatment group in wave 1)

As noted, wave 1 and wave 2 received the treatment during the same time period (for those randomized to the active treatment condition) due to the delay in program start-up in the schools. Although delayed, wave 1 participants randomized to the active treatment condition received the intervention in months 8-10 (see subsequent *Implement 8-week treatment* section for a more detailed description of the intervention and procedures). In addition, fidelity (implementation accuracy) was monitored throughout implementation (see subsequent *Implement 8-week treatment* section covering wave 2). Although delayed, **all tasks involved in implementing the 8-week treatment for sampling wave 1 were completed.**

Assess participants at baseline, posttest, and follow-up (follow-up for treatment group only; wave 1)

As noted, wave 1 and wave 2 received the treatment during the same time period (for those randomized to the active treatment condition) due to the delay in program start-up in the schools. As such, the outcomes assessments were also conducted during the same time period for both waves 1 and 2. Because of this, wave 1 completed their outcome assessments later than originally proposed. Despite the delay, **sampling wave 1 outcome assessments were completed** by the end of month 12 (see subsequent *Assess participants at baseline, posttest,*

and follow-up (follow-up for treatment group only) section for additional details on the outcome assessments).

Recruitment, enrollment, and randomization of sampling wave 2

The target sample size for wave 2 was *n* = 8 children with ASD. As noted, recruitment for both sampling waves was conducted simultaneously. Recruitment, enrollment, and randomization for wave 2 (as well as wave 1) was completed in month 8 (slightly later than the proposed completion date of month 6 for wave 2). A total of 13 children with ASD completed screening across the 2 waves, with 12 meeting eligibility criteria, enrolling and completing the study (1 child did not meet ASD criteria on the ADI-R). Written parental consent and written child assent were obtained for all participants who completed screening (screening consent/assent), as well as for those who qualified and were enrolled in the treatment trial (treatment consent/assent). The 12 enrolled children with ASD were randomly assigned to the treatment or waitlist control groups (i.e., *n* = 6 children with ASD in the treatment group and *n* = 6 children with ASD in the waitlist control group). Although delayed for both waves 1 and 2, **recruitment, enrollment, and randomization of the total targeted sample for year 1 (*n* = 12) was successfully completed.**

Implement 8-week treatment (for the active treatment group in wave 2)

As previously described, wave 1 and wave 2 received the treatment during the same time period (for those randomized to the active treatment condition) due to the delay in program start-up in schools. Wave 2 participants randomized to the active treatment condition received the intervention in months 8-10 (slightly later than the originally proposed months 7-8 for wave 2). The after-school social intervention targets a range of social skills and these are taught, practiced, and reinforced using social skills groups and social recreational games, as well as a behavioral reinforcement system. Groups are conducted using direct instruction, modeling, role-play, feedback, reinforcement, and repeated practice. The program is delivered 4 days per week, 90 minutes per session, over 8 weeks in group format by paraprofessionals to groups of 12-15 children including 2 children with ASD (the remaining children are typically-developing peers). Fidelity (implementation accuracy) was also monitored in approximately 40% of all intervention sessions (randomly selected) by research assistants (for waves 1 and 2). All children randomized to the active treatment condition in year 1 completed the intervention (no attrition) and fidelity (implementation accuracy) was high across sites (i.e., schools >90%). Overall, **all tasks involved in implementing the 8-week treatment for the full year 1 sample (wave 1 and wave 2) were completed.**

Assess participants at baseline, posttest, and follow-up (follow-up for treatment group only; wave 2)

As noted, wave 1 and wave 2 received the treatment during the same time period (for those randomized to the active treatment condition) due to the delay in program start-up in the schools. As such, the outcomes assessments were also conducted during the same time period for both waves 1 and 2. Outcome assessments included an objective child test of social knowledge (administered by blinded evaluators), parent ratings of social skills and ASD-symptom severity, and an objective observation measure (completed by blinded observers)

assessing the children's social performance during unstructured free-play sessions. Both the social knowledge testing and the observations of the children's unstructured free-play performance were done at their school sites. All outcome assessments/measures were completed for the children who participated in year 1 (*n* = 12 total from waves 1 and 2). Given the timing of the completion of the outcome testing, scoring of those protocols is not yet complete and outcome data are not available (that information will be summarized in the year 2 annual report). Despite the slight delay in treatment initiation, **all sampling wave 2 outcome assessments were completed** by the end of month 12 as proposed in the SOW (**all sampling wave 1 outcome assessments were also completed** by the end of month 12).

Implement 8-week treatment for waitlist children and test outcomes after completion

Because wave 1 and wave 2 received the treatment during the same time period (for those randomized to the active treatment condition) due to the delay in program start-up in the schools, the waitlist children from both waves (*n* = 6 total) also subsequently received the 8-week treatment during the same time period. Implementation accuracy (fidelity) was also tracked and was >90% for the waitlist group. All of the **waitlist children completed the treatment, as well as their post-treatment outcome assessments** by the end of month 12.

Summary and enrollment data

Overall, despite the slower than anticipated initial start-up in the schools all major activities and objectives for year 1 were completed by the end of month 12 and the project is on schedule. The initial delay was due to the length of time needed to establish the program protocols in the schools including procedures for securing time to train paraprofessional after-school staff. This process was very informative and allowed the research team to develop procedures to make the start-up more efficient for the subsequent sampling waves. In addition, the relationships we established during the initial start-up with district and after-school administrators will be advantageous as these districts also have other after-school sites interested in participating in years 2 and/or 3. We have already initiated contact with districts and after-school sites to execute the recruitment plan in July-September 2023 (this is consistent with the original SOW timeline). We consider the original timeline delineated in the SOW for years 2 and 3 to be feasible and we anticipate that the project will proceed without significant disruptions. The target enrollment for year 1 was *n* = 12 children with ASD. We screened 13 children with ASD, and 12 qualified, enrolled, and completed the study. As such, our enrollment goal for year 1 was met and there was no attrition.

Opportunities for training and professional development provided by project

Although this project is not intended to provide training and professional development opportunities, a number of opportunities are inherent in the project activities including the enhancement of knowledge, skills, and proficiency of paraprofessional staff, as well as undergraduate and graduate students. These opportunities are afforded to these individuals as a function of their involvement in the project.

In this study, paraprofessional after-school staff deliver the after-school program. These individuals complete a 20-hour training that includes classroom didactic instruction, passing an exam on the protocol (≥90% required), and applied practice exercises during which each is required to demonstrate implementation accuracy (≥90%). In addition to the paraprofessional after-school staff, graduate and undergraduate students serve as research assistants and evaluators/coders in this project. The research assistants complete training that requires passing an exam on the protocol and each is required to demonstrate implementation accuracy. They are also trained on completing the fidelity checklists and are required to establish reliability using the checklists. The masked evaluators/coders complete separate training on administration of the outcome measures and are required to demonstrate accuracy in test administration and reliability when conducting the observations. These training opportunities are unique for paraprofessional staff and graduate and undergraduate students.

Dissemination of results to communities of interest

Nothing to report involving dissemination of results (i.e., outcomes). To date, outreach activities have been undertaken mainly to share information about the project with school and after-school administrators/staff who would not ordinarily be aware of such research activities. The College's Office of Communications also issued a press release regarding the project and grant. Sharing this information about the project has increased public knowledge of the project, as well as assisted with recruitment of participants.

Plans for accomplishing project goals in next reporting period

For the next reporting period, we anticipate accomplishing all goals/objectives according to the SOW. As noted, we have already initiated contact with districts and after-school sites to begin recruitment and planning for implementation during the upcoming year.

4. IMPACT

Impact of the project on development of the principal discipline(s). Nothing to report (year 1 just completed).

Impact on other disciplines. Nothing to report

Impact on technology transfer. Nothing to report

Impact on society beyond science and technology

No conclusions on feasibility or efficacy are yet available. If the after-school social intervention delivered by paraprofessionals is found to be feasible and effective, it will improve the social performance of children with ASD (without ID) and clinical skills of the paraprofessionals, and provide school districts with a viable manualized intervention that can be done without over-

burdening school staff (professionals and paraprofessionals) during the school day (i.e., improve social and environmental conditions, and the clinical services/practices provided by schools).

5. CHANGES/PROBLEMS

Changes in approach and reasons for change. Nothing to report

Problems or delays and actions or plans to resolve them.

As described earlier in this report, the start of the study was delayed which was due to the length of time needed to inform/educate school and after-school program administrators on the study and methodology, and establish the program protocols in the schools. This process helped us identify common questions and misconceptions of administrators and allowed us to more clearly provide relevant information in our early discussions with school and after-school program administrators. We have already utilized this information in our discussions with district administrators to help facilitate a more rapid start-up for year 2 and the process has proceeded without difficulty so far.

Changes that significantly impacted expenditures. Nothing to report

Significant changes in use or care of human subjects. Nothing to report

6. PRODUCTS

Publications (journal articles, books), conference papers, and presentations. Nothing to report

Website(s) or other internet site(s). Nothing to report

Technologies or techniques. Nothing to report

Inventions, patent applications, and/or licenses. Nothing to report

Other products. Nothing to report

7. PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS

Individuals who have worked on project

Name:	Christopher Lopata
Project role:	PD/PI

Nearest person month worked: 3

Contribution to project: Responsible for all research and project implementation oversight, recruitment, and training of research staff. Conduct regular meetings of the senior research team, continually monitor study progress, and collaborate with the other investigators to coordinate assessments and supervision. Secure approval from the local IRB and OHRO, and share data and resources generated from the project. Assist in data interpretation and lead all writing of reports and manuscripts. Responsible for the budget and all grant-related/-required reports.

Funding support:

Name: Marcus L Thomeer

Project role: Co-PI (recruitment and clinical coordinator)

Nearest person month worked: 3

Contribution to project: Lead all recruitment efforts and execute the recruitment plan, lead the training and supervision of paraprofessional staff, establish staff fidelity to the protocol during training, monitor staff fidelity to the protocol during treatment, establish each child's performance goals, and monitor home-based reinforcement systems. Work closely with the principal investigator, attend research team meetings every two weeks, and assist with interpretation of data and writing of reports and manuscripts resulting from the study.

Funding support:

Name: James P Donnelly

Project role: Co-PI (data coordinator and statistician)

Nearest person month worked: 3

Contribution to project: Responsible for setting up procedures to maintain the quality of all data collection and processing, oversight of data collection, management, and entry, and fidelity of

	protocol scoring and data entry. Monitor and provide monthly status updates on assessments and data entry, and attend research team meetings every two weeks. Conduct quarterly reviews of the hard copy and electronic data to monitor and ensure its safety, conduct all data analyses, assist with interpretation, and contribute to report and manuscript preparation.
Funding support:	

Name:	Jonathan D Rodgers
Project role:	Co-PI (study and assessment coordinator)
Nearest person month worked:	3
Contribution to project:	Coordinate implementation of the intervention, conduct diagnostic screening and testing, assist with paraprofessional training, monitor treatment fidelity, and assist with supervision of paraprofessionals. Schedule screening and outcome testing sessions, and maintain contact with parents in order to ensure parents and children attend sessions and submit appropriate paperwork. Recruit, train, and supervise all research assistants and behavioral coders, coordinate protocol scoring, provide regular updates to the data coordinator and principal investigator, attend team meetings every two weeks, and assist with data interpretation and manuscript preparation.
Funding support:	

Name:	Kaitlyn Fellows
Project role:	Research Assistant (student)
Nearest person month worked:	2
Contribution to project:	Assist with preparation of assessment materials and assessments, complete training and establish fidelity with the protocol and reliability using fidelity checklists, conduct fidelity checks, monitor the status of protocol returns and follow-up

on missing protocols/items, check and score protocols, load data, and conduct checks for data accuracy.

Funding support:

Name: Jules Jones
Project role: Research Assistant (student)
Nearest person month worked: 2
Contribution to project: Assist with preparation of assessment materials and assessments, complete training and establish fidelity with the protocol and reliability using fidelity checklists, conduct fidelity checks, monitor the status of protocol returns and follow-up on missing protocols/items, check and score protocols, load data, and conduct checks for data accuracy.

Funding support:

Name: Rylee Campeau
Project role: Research Assistant (student)
Nearest person month worked: 2
Contribution to project: Assist with preparation of assessment materials and assessments, complete training and establish fidelity with the protocol and reliability using fidelity checklists, conduct fidelity checks, monitor the status of protocol returns and follow-up on missing protocols/items, check and score protocols, load data, and conduct checks for data accuracy.

Funding support:

Name: Jonathan Sandstrom
Project role: Research Assistant (student)
Nearest person month worked: 2
Contribution to project: Assist with preparation of assessment materials and assessments, complete training and establish fidelity with the protocol and reliability using fidelity checklists, conduct fidelity checks, monitor

	the status of protocol returns and follow-up on missing protocols/items, check and score protocols, load data, and conduct checks for data accuracy.
Funding support:	

Name:	Kylie McMahon
Project role:	Research Assistant (student)
Nearest person month worked:	2
Contribution to project:	Assist with preparation of assessment materials and assessments, complete training and establish fidelity with the protocol and reliability using fidelity checklists, conduct fidelity checks, monitor the status of protocol returns and follow-up on missing protocols/items, check and score protocols, load data, and conduct checks for data accuracy.
Funding support:	

Name:	Leanne Hanlon
Project role:	Blinded (Masked) Evaluator/Coder (student)
Nearest person month worked:	2
Contribution to project:	Complete training, demonstrate competency administering the social-cognitive test, establish inter-observer agreement prior to and during actual coding/rating, code the children's behaviors/skills according to the operational definitions, and assist with management of de-identified data.
Funding support:	

Name:	Aubrey Smith
Project role:	Blinded (Masked) Evaluator/Coder (student)
Nearest person month worked:	2
Contribution to project:	Complete training, demonstrate competency administering the social-cognitive test, establish inter-observer agreement prior to and during actual coding/rating, code the children's

behaviors/skills according to the operational definitions, and assist with management of de-identified data.

Funding support:

Changes in active other support of the PD/PI(s) or senior/key personnel since last reporting period. Nothing to report

Other organizations involved as partners

Organization name:	West Seneca Central School District
Location of organization:	West Seneca, NY
Partner's contribution to the project:	Facilities (domestic), collaboration

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Organization name:	Amherst Central School District
Location of organization:	Amherst, NY
Partner's contribution to the project:	Facilities (domestic), collaboration

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8. SPECIAL REPORTING REQUIREMENTS

None

9. APPENDIX

Table 1. Demographic Characteristics of Participants from Year 1 (Waves 1 and 2)

Table 1. *Demographic Characteristics of Participants from Year 1 (Waves 1 and 2)*

Characteristic	Treatment (*n* = 6)	Waitlist (*n* = 6)
	Mean (*SD*)	Mean (*SD*)
Age (years)	10.29 (0.68)	9.31 (1.02)
Parent Education (years)	16.33 (2.61)	16.50 (2.36)
ADI-R		
Social	16.17 (3.98)	19.67 (2.49)
Communication	15.83 (2.54)	14.50 (3.73)
Restricted and Repetitive Behavior	5.17 (1.67)	5.67 (1.70)
WASI-II		
Full-Scale	101.33 (14.37)	99.00 (18.47)
	n (% of total)	*n* (% of total)
Sex		
Male	6 (100%)	6 (100%)
Female	0 (0%)	0 (0%)
Race/Ethnicity		
White	3 (50%)	3 (50%)
Black/African-American	1 (17%)	0 (0%)
Asian-American	1 (17%)	0 (0%)
Other	1 (17%)	3 (50%)

Note. ADI-R = Autism Diagnostic Interview-Revised; WASI-II = Wechsler Abbreviated Scale of Intelligence-Second Edition.