Cluster Randomized Trial of a School Intervention for Children with Autism Spectrum Disorder

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Abstract

Objective. There are currently no empirically-supported, comprehensive school-based interventions (CSBIs) for children with autism spectrum disorder (ASD) without concomitant intellectual and language disability. This study compared outcomes for a CSBI (schoolMAX) to typical educational programming (services-as-usual [SAU]) for these children. Method. A total of 103 children (ages 6-12 years) with ASD (without intellectual and language disability) were randomly assigned by school buildings (clusters) to receive the CSBI (n=52 completed) or SAU (n=50 completed). The CSBI was implemented by trained school personnel and targeted social competence and ASD symptoms using social skills groups, emotion recognition instruction, therapeutic activities, behavioral reinforcement, and parent training. Outcome measures tested the effects of the CSBI on social competence and ASD symptoms, as well as potential collateral effects on academic achievement. Outcomes (baseline-to-follow-up) were assessed using tests of social-cognition and academic skills and behavioral observations (by masked evaluators) and parent-teacher ratings of ASD symptoms and social/social-communication skills (non-masked) [ClinicalTrials.gov, NCT03338530, https://www.clinicaltrials.gov/]. Results. The CSBI group improved significantly more than the SAU group on the test of emotion recognition skills and parent-teacher ratings of ASD symptoms (primary outcomes) and social/social-communication skills (secondary outcome). No differences between groups were detected for recess social interactions or academic skills. Conclusions. The CSBI improved several core areas of functioning for children with ASD compared to usual educational programming. Additional intervention elements may be needed to expand the efficacy of the CSBI so that the observed skills/symptom improvements generalize to recess social interactions and/or academic skills are enhanced. [*Keywords:* comprehensive school intervention, ASD]

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According to 2012 CDC estimates, children with ASD without concomitant intellectual disability comprise more than two-thirds of those diagnosed (Christensen et al., 2016). Despite relative cognitive and language strengths, their social impairments and circumscribed/repetitive behaviors/interests significantly interfere with adaptive functioning (American Psychiatric Association, 2013). For the purposes of this study, the term ASD will be used to refer to individuals with ASD without intellectual and language disability. Social impairments include deficits in both rudimentary social behaviors (e.g., initiating/responding to social bids) and more complex social-cognitive understanding, such as interpreting facial and vocal expressions and others' perspectives (Bellini, Gardner, & Markoff, 2014). Together, these negatively affect the way these children understand and respond to others (Scarpa, Reyes, & Attwood, 2013). Increased stereotyped and repetitive behaviors/interests have also been associated with lower adaptive and social performance (McDonald et al., 2015).

A common psychosocial treatment for children with ASD is social skills interventions which seek to increase social knowledge/understanding and skills/behaviors using structured environments, direct and explicit instruction, modeling, role-play/rehearsal, repeated practice, and performance feedback/reinforcement, and some include parent training (McMahon, Lerner, & Britton, 2013; Reichow, Steiner, & Volkmar, 2012). Social interventions, including social skills groups (SSGs) are especially applicable because they integrate cognitive and behavioral strategies that allow for targeting of characteristic impairments in social cognition/understanding and skills/behaviors (Scarpa et al., 2013). Cognitive and behavioral elements play critical roles in social performance (understanding social cues and enacting an appropriate response; Bauminger-Zviely, 2013) and development of social-cognitive skills is a prerequisite for

improvements in social performance of these children (McMahon, Vismara, & Solomon, 2013). Providing reinforcement for use of targeted skills strengthens acquisition and maintenance and maximizes practice trials (Reichow et al., 2012). Laugeson and colleagues completed several treatment studies that supported the efficacy of a university-/clinic-based SSG intervention for adolescents with ASD. For example, Laugeson, Frankel, Mogil, and Dillon (2009) and Laugeson, Frankel, Gantman, Dillon, and Mogil (2012) tested the efficacy a 12- and 14-week SSG intervention targeting social/social-communication skills using direct instruction, modeling, rehearsal, and feedback, along with parent education and coaching, for adolescents with ASD. Results indicated that adolescents with ASD that completed the intervention, compared to the waitlist group, showed significantly greater improvements in social knowledge and received significantly better parent ratings across several social indicators (e.g., hosted get-togethers, social skills, and/or ASD symptoms). Teacher ratings were inconsistent and suggested more limited effects but the response rates from teachers were very low (<50%). These studies supported the efficacy of the tested interventions however there was variability in the findings within each of the studies. Recent meta-analyses of SSG randomized trials in clinic/university settings for youth with ASD have also suggested that these interventions yield social improvements for youth with ASD, although the gains have not been consistent (Gates, Kang, & Lerner, 2017; Reichow et al., 2012). Both meta-analyses suggested low-to-moderate effects overall and significant variability in outcomes, and they highlighted the need for ongoing testing in rigorous randomized trials.

Although these reviews and studies suggested some promise, the effects rarely transfer to school environments leading to calls for development and testing of social interventions within schools (Kasari et al., 2016). These have the potential to increase the social and academic

performance of children with ASD (Kasari et al., 2016); however, questions have been raised about their feasibility and effectiveness in schools (Reichow & Volkmar, 2010). Bellini, Peters, Benner, and Hopf (2007) completed a widely-cited meta-analysis of single-subject studies and concluded that social skills interventions in schools yielded low-to-questionable treatment effects for students with ASD. The studies, however, included students with ASD of variable cognitive levels (not exclusively students with ASD without intellectual disability).

The current review revealed a paucity of randomized controlled trials (RCTs) of school social interventions for children with ASD and a range of methodological limitations in school studies including a lack of randomized designs, fidelity monitoring, and intervention manualization, and small and poorly characterized samples. Two notable exceptions were conducted by Kasari and colleagues. Kasari, Rotheram-Fuller, Locke, and Gulsrud (2012) compared the effectiveness of a 6-week (2 sessions per week) adult delivered (1:1) social intervention, peer mediated social intervention, combined adult delivered (1:1) and peer mediated intervention, and services-as-usual (SAU) control group. Significant improvements in social network salience, friendship nominations, teacher rated social skills, and isolation on the playground were found for children with ASD that received peer mediated interventions. The authors noted however that reciprocal friendships did not improve and that higher intensity might be needed. Kasari et al. (2016) compared the efficacy of an 8-week (2 sessions per week) adult directed social skills group intervention to a peer mediated intervention. In contrast to the prior study, results indicated no difference in social network salience or friendship nominations between conditions, but significantly more peer engagement and less isolation during recess for the adult directed group. The authors suggested that the direct instruction and practice opportunities with other children with ASD in the adult directed group sessions may have

increased friendship development and skills generalization. In both studies, the interventions were delivered by research staff so their feasibility and efficacy when delivered by school staff are unknown.

Although questions have been noted about the feasibility of school-based interventions for students with ASD (Reichow & Volkmar, 2010), several studies have utilized school staff to implement the interventions. Mandell et al. (2013) compared the effectiveness of two school-staff delivered interventions on the cognitive abilities of kindergarten-second grade students with ASD (*Mean* IQ=59). Fidelity was low across both intervention approaches (≤57%) which suggested some challenges with implementation accuracy and feasibility. Despite this, children in both intervention groups exhibited significant increases in cognitive skills. Kretzmann, Shih, and Kasari (2015) utilized school staff (paraprofessionals) to deliver a 10-week recess social intervention for elementary school students with ASD. The paraprofessionals received active daily coaching from research staff during the first two weeks of implementation, followed by an additional six-to-eight coaching and consultation sessions over the subsequent six weeks, and no consultation support during the final two weeks. Fidelity (accurate use of responsive and strategic behaviors) significantly improved from entry to the end of the intervention but did not reach 60% for either time-point for the intervention group. Children that received the recess intervention demonstrated significantly greater peer engagement than children with ASD in the waitlist group. Although this study yielded significant gains for the children in the intervention, the paraprofessionals received significant support (e.g., modeling and prompting) from the researchers which might have enhanced the intervention effects and the relatively low fidelity suggested some implementation challenges. Studies such as these highlight the implementation

challenges in school settings but also suggest that school staff may be viable interventionists for social skills interventions.

Another factor that can limit the effect of social skills interventions is that many are narrowly focused (targeted). In contrast, comprehensive interventions target multiple domains using multiple treatment components (Odom, Boyd, Hall, & Hume, 2010; Smith et al., 2007). These interventions are manualized, instituted intensively over an extended period, and target core ASD impairments, broader functioning, and the needs of individual children (Odom et al., 2010). There is currently a dearth of comprehensive school-based interventions (CSBIs) specifically for children with ASD (without intellectual and language disability; Odom, Boyd, Hall, & Hume, 2014); these interventions should target both social-cognition and specific skills/behaviors (Bellini et al., 2014). Given the recognition that multi-component interventions are more difficult to administer in schools due to competing demands and priorities (Kasari & Smith, 2013), it is useful to initially test their feasibility prior to conducting more expensive RCTs (Smith et al., 2007).

Lopata, Thomeer and colleagues adapted a multi-component summer treatment (summerMAX) found to improve the social performance and ASD symptoms of children with ASD in several RCTs (e.g., Lopata et al., 2010; Thomeer et al., 2012) into a CSBI for these students. The summerMAX program is a comprehensive 5-week manualized cognitive-behavioral treatment that targets social/social-communication, emotion recognition, and nonliteral language skills, and interest expansion. Intensive skills instruction groups and therapeutic activities using direct instruction, modeling, role-play/rehearsal, feedback/reinforcement, and repeated practice are delivered in small groups of children with ASD. The summer program also includes a reinforcement system (response-cost and individual

daily note) to increase skills development and reduce ASD symptoms and problem behaviors, as well as weekly parent training. A detailed description of the CSBI adaptation process was previously published in Thomeer (2012). Briefly, school staff and administrators and parents of children with ASD participated in a series of focus groups to discuss the perceived need for interventions and available resources for elementary school-age students with ASD. The group members then reviewed and discussed the summerMAX treatment manual and identified the instructional procedures, content, and schedule they considered feasible in the school setting. This collaborative process yielded the manualized CSBI that was tested for feasibility and initial outcomes in two year-long pilot studies (Lopata et al., 2012ab). The CSBI included SSGs, emotion recognition instruction, therapeutic activities, a behavioral reinforcement system, and parent training administered by school staff during the school year. The intervention utilized cognitive-behavioral techniques including direct instruction, modeling, role-play/rehearsal, repeated practice, performance feedback, and reinforcement. Results supported feasibility via high levels of implementation accuracy (fidelity $\geq$87% for all components) and parent and school staff acceptability and satisfaction. Baseline-to-follow-up improvements were found on child testing of social-cognitive emotion recognition skills (*d*s 0.94 and 1.64) and parent and/or teacher ratings of ASD-symptoms and social-communication skills (*d*s from 0.59-1.22). This study tested the efficacy of the manualized CSBI for a large sample of children with ASD in a cluster randomized trial.

Method

Participants

An *a priori* power analysis was conducted to determine the targeted sample size for the current study using the smaller of the two effect sizes for the primary measures from the CSBI

pilot studies (Lopata et al., 2012ab). Based on the smaller effect size (*d*=.99 [95% CI .39,1.6]) and school-level ICC (0.23) from the pooled data from those studies, and a Bonferroni-adjusted alpha of .025 (.05/2 primary measure comparisons), a sample size of 90 students (15 schools per group, average of 3 students per school) yielded 84% power to detect the prior effect. To protect statistical power, a 5% projected dropout rate was used to adjust the targeted sample size upward to 48 students per condition (total targeted sample of 96 students with ASD from 32 schools).

The sample was recruited from public elementary schools in suburban districts in the United States. A total of 17 school districts were approached and all agreed to participate and enrolled. Each district's director of special education sent parents of 1st-5th grade students in special education a letter describing the study and directing those interested to contact the study staff for additional information and to schedule a screening. The trial was approved by the Institutional Review Board, and written parental consent and child assent were obtained (prior to randomization). Eligibility criteria were a diagnosis of ASD (confirmed via the Autism Diagnostic Interview-Revised; Rutter, LeCouteur, & Lord, 2003), Wechsler Intelligence Scale for Children-Fourth Edition short-form IQ >70 (WISC-IV; and VCI or PRI $\geq$80; Wechsler, 2003), and short-form Comprehensive Assessment of Spoken Language (CASL; Carrow-Woolfolk, 1999) expressive or receptive language score $\geq$75. The short-form of the WISC-IV consisted of the Block Design, Similarities, Vocabulary, and Matrix Reasoning subtests and CASL consisted of the Antonyms, Synonyms, Syntax Construction, and Paragraph Comprehension subtests. An exclusionary criterion included a history of psychosis (per parent report or prior clinical report).

A total of 114 children were screened, with 103 children from 35 schools meeting inclusion criteria and enrolling (May 2013-August 2016; Figure 1). As such, the intent-to-treat

(ITT) sample included 103 children, ages 6-12 years (grades 1-5) with ASD attending public elementary schools. Given the group format of certain treatment elements, school buildings (clusters) were randomly assigned to receive the CSBI or the school's typical educational programming (services-as-usual [SAU]). Randomization was stratified by school economic level to insure balance between conditions. Individual buildings contained 1-5 students with ASD (*Mean*=3). The randomization sequence was generated independently by the biostatistician and transferred to the study personnel, resulting in 17 schools (52 children with ASD) assigned to the CSBI and 18 schools (51 children with ASD) to SAU. One child withdrew from the SAU condition without explanation. Demographic and outcome measure data for the sample are presented in Table 1. No significant differences were found between conditions on any child variable or parent education level, or on any baseline outcome measure (demonstrating baseline equivalence; see Table 1).

The participating schools were also similar in terms of their broader student population. To illustrate, the mean percentage of students with disabilities within the CSBI schools was 14% (range 10-24%) and SAU schools was 16% (range 11-29%). Similarly, the mean percentage of students receiving free-and-reduced lunch was 28% (range 7-61%) in the CSBI schools and 34% (range 5-66%) in the SAU schools. With the exception of one school in the CSBI condition (42% Caucasian), the majority of students in the participating schools were Caucasian (CSBI schools *Mean*=84% [range 56-96%] and SAU schools *Mean*=85% [range 64-93]).

[Figure 1]

[Table 1]

Procedures

The efficacy of the CSBI was tested in a cluster RCT. Baseline assessments were conducted six weeks into the school year (prior to initiation of the CSBI) and follow-up upon completion of the CSBI (two weeks prior to the end of the school year). Child testing and behavioral observations were conducted by evaluators masked to treatment condition; parent and teacher ratings were not masked. School staff from the CSBI buildings completed training during the summer and established fidelity with the protocol (see *School staff training and treatment integrity*). Children in the SAU condition were provided a 5-week psychosocial treatment during the summer following participation in the study as compensation and their teachers were provided training in the CSBI protocol the following year.

CSBI condition. The CSBI (aka schoolMAX) is a multi-component manualized intervention delivered by school staff consisting of social skills groups (SSGs), emotion recognition instruction (*Mind Reading*), therapeutic activities, a behavioral reinforcement system (individual daily note), and parent training. The SSGs, emotion recognition instruction, and therapeutic activities required a total of 160-210 minutes per week to administer, whereas the individual daily note was implemented across each school day and parent training was conducted for 60-90 minutes per month. To avoid over-burdening any individual, different school staff members were responsible for implementing different components (based on position/role, training, and/or experience). The researchers met with the educational team of each student and described the individual intervention components. Team members then identified the individual from the team that was best qualified and able to integrate the component into the student's programming and their schedule. This allowed all the components to be implemented during the school day with minimal disruption to the students' educational programming and school activities. Characteristics of the school staff that implemented the CSBI components are

presented in Table 2. These staff were predominantly female and Caucasian, with a range of educational backgrounds and years of experience. The intervention was coordinated at regular weekly meetings conducted by the students' educational teams, with consultation support from the research team. These 15-30 minute meetings were used to plan activities, discuss child progress, and review fidelity data to ensure implementation accuracy. They also fostered clear and ongoing communication among team members and a focus on the student's and intervention's goals. The following is a description of the intervention components.

[Table 2]

SSGs were conducted 2-3 times per week for a total of 60-90 minutes by a designated member of the school team (school psychologist, speech pathologist, or social worker). Groups contained up to 6 students with social impairments including 1-3 target students with ASD. Each manualized SSG began with a review of rules and was then conducted according to the framework of *Skillstreaming* which teaches interpersonal skills to children with social impairments using teaching, modeling, role-play, performance feedback, and transfer of learning (McGinnis & Goldstein, 1997). Twenty-six social skills were taught in a progression from basic to more-complex. Each session closed with a short discussion of how to use the skill in future classroom activities. To ensure awareness of the target skills, classroom teachers also displayed a list of the skills taught to date (and component steps of each) and parents were continually informed of the target skills through electronic communications and hardcopy updates, and during parent training.

Emotion recognition instruction (*Mind Reading*) was conducted 2-3 times per week for a total of 60 minutes by a designated member of the school team (classroom aide or teaching assistant). The interactive software teaches recognition of emotions in facial and vocal

expressions (Baron-Cohen, Golan, Wheelwright, & Hill, 2004) and studies have found it effective in improving emotion recognition skills and ASD-related impairments of children with ASD (e.g., LaCava, Golan, Baron-Cohen, & Myles, 2007; Thomeer et al., 2015). The program utilizes direct instruction and repeated practice exercises in various program formats (i.e., Emotions Library, Learning Center, and Games Zone) and it employs a token reinforcement system that allows participants to access the Rewards Zone using points earned for accurate completion of questions. One-hundred *Mind Reading* emotions (10 groups of 10 emotions per group) were included and students were taught one group of emotions each week. The sequence of emotion groups was repeated two more times during the school year for a total of three exposures to the 100 emotions. Children completed lessons independently on laptop computers and a school staff member monitored each session to ensure the children completed lessons in the prescribed program areas.

Therapeutic activities were conducted 2 times per week for a total of 40-60 minutes by a designated member of the school team (counselor and/or teacher). These cooperative group activities included general and/or special education peers and were conducted to practice and reinforce target social and emotion recognition skills, and promote interest expansion. At the outset the facilitator reviewed the rules and discussed the purpose of the activity and skill targeted. The facilitator also discussed with the target student how to use the target and previously taught skills during the activity. Throughout these activities, facilitators remained in proximity to the target students and provided verbal reinforcement when students exhibited targeted skills. Each activity closed with a brief discussion of how the students used the targeted skill during the activity and how to use it during the school day/week.

The individual daily note (behavioral reinforcement system) was managed by the classroom teacher and administered throughout the school day to practice and reinforce targeted skills, and reduce ASD symptoms/problem behaviors. It fostered school-home communication and ensured the student, school staff, and parents were focused on specific treatment targets and performance criteria. Each individual daily note utilized a standardized template and included 3-5 operationally-defined targets; to increase generalization ≥2 targets were skills taught in the CSBI. Base-rate data were collected for 5 days on each target skill/behavior to determine goal criteria. Then, the student's school day was divided into intervals (based on individual reinforcement needs). During each interval, the student received immediate verbal feedback and at the end of each interval the teacher/aide provided feedback on the student's performance during that interval and also prompted the student to work on the targets during the subsequent interval. The student was eligible to earn 1 point for each target per interval and was required to have earned ≥75% of her/his daily points to receive a home reward (reinforcer) provided by parents. To illustrate, for a student with a skills target of *asking a question* (twice per interval) the teacher would provide immediate verbal reinforcement for any and all demonstration(s) of the skill. At the end of the interval, if the student asked a question at least 2 times she/he was awarded a point on her/his individual daily note.

Parent training was conducted monthly, 60-90 minutes per session during the school year by at least 1 member of the school team (social worker and/or school psychologist). This served to increase parental understanding of the CSBI, home-school communication, and integration across settings, and ensured establishment of parent-provided home reinforcers for school-day performance on the individual daily note. Parent training sessions were manualized and facilitators delivered content using detailed lesson plans or showed a video recording of the

lesson(s) (which covered the same lesson plans). Each session included a brief update on the CSBI, delivery of session content, discussion of how to integrate content into the daily routine, and review of implementation procedures.

SAU condition. Children with ASD in the SAU schools received their typical educational program. Given randomization at the school level, contamination was unlikely however any school staff member that provided services across buildings was eliminated from participation. Each student's IEP was collected to document her/his legally-mandated support services; only 13 were receiving any social skills intervention (generally only 30-minutes per week) and only 14 had a behavior plan. Observations and interviews with school staff indicated that none of the social skills interventions were manualized or followed a curriculum and that their approach to social skills intervention generally involved discussion of friendship-making skills and use of informal games to foster social relationships. The observations and interviews also revealed that none of the behavior plans were standardized and included social skills targets. Lastly, observations conducted in the SAU schools revealed that the CSBI elements were rarely, if at all observed (see *School staff training and treatment integrity*).

School staff training and treatment integrity. School staff from the CSBI schools received the intervention manual and completed a 30-hour manualized training during the summer (each was provided $1,200 financial compensation). Training included approximately 10 hours of classroom-based didactic instruction and 20 hours of observations, practice, and planning. The classroom-based instruction provided detailed information on ASD and the CSBI protocol. Following completion of the classroom instruction, the school staff observed video recordings of exemplars modeling implementation of the CSBI components and participated in applied practice exercises to develop and demonstrate competency in the component. The staff

also spent time planning and preparing for the upcoming year. School staff were observed by research assistants during the applied exercises and rated for fidelity using standardized fidelity forms; each demonstrated ≥90% fidelity administering her/his component.

A comprehensive procedure was used to assess fidelity in the CSBI schools and monitor typical programming within the SAU schools. Fidelity was measured as adherence to the steps and sequence in the protocol for each component. Prior to each school year, research assistants were trained to use the fidelity forms and established inter-observer agreement (IOA; ≥90%). The research assistants were trained and established IOA using the fidelity forms by watching other research assistants implement the protocol and rating the accuracy of implementation. In the CSBI schools, research assistants observed >33% of sessions (randomly selected) each for the SSGs, emotion recognition lessons, therapeutic activities, and parent training and conducted two 60-minute classroom observations per week to monitor individual daily note implementation; fidelity was >92% for all components (SSGs =92.2%, emotion recognition lessons =98.6%, therapeutic activities =96.7%, individual daily note =93.6%, and parent training =98.9%). Within the SAU schools, the same fidelity forms (with sequencing requirements removed) were completed during two 60-minute observations per week; results indicated that the CSBI elements were rarely observed (elements of the SSGs =5.9%, emotion recognition lessons =0.0%, therapeutic activities =0.5%, individual daily note =8.4%, and parent training =0.0%). To ensure rater accuracy, 20% of all observations were conducted simultaneously by a second research assistant and IOA was >98%.

Primary Outcome Measures

Cambridge Mindreading Face-Voice Battery for Children (CAM-C; Administered to Child). The CAM-C (Golan & Baron-Cohen, 2006) measures cognitive understanding/skills

involving emotion recognition for 15 emotion concepts using facial expression video clips and speech audio clips. Children view/listen to each clip on a computer and select 1 of 4 emotion words that reflects the emotion of the person in the clip; higher total scores indicate greater accuracy (the number correct was used in the analyses). Test-retest reliability over a 10-15 week interval was 0.74-0.76. The CAM-C accurately differentiates children with ASD from typical children and its scores are negatively correlated with ASD symptoms (Golan, Sinai-Gavrilov, & Baron-Cohen, 2015).

Social Responsiveness Scale, 2nd Edition, School Age Form (SRS-2; Completed by Parents and Teachers). The SRS-2 (Constantino & Gruber, 2012) is a 65-item objective measure of ASD-related symptoms including social-communication deficits and circumscribed and repetitive behaviors/interests. Informants rate the frequency of behaviors on a scale of 1 (not true) to 4 (almost always true); higher total scores indicate greater symptoms/severity. The total score has internal consistency estimates of 0.92-0.97. Moderate-to-high correlations are reported between the SRS-2 and other ASD diagnostic measures, and the test accurately discriminates ASD and non-ASD samples. The mean of the parent-teacher ratings (*T*-scores) for each child was used in the analyses.

Secondary Outcome Measures

Adapted Skillstreaming Checklist (ASC; Completed by Parents and Teachers). The ASC (Lopata, Thomeer, Volker, Nida, & Lee, 2008) measures social/social-communication skills and behaviors of children with ASD. Each item measures a specific skill/behavior and is keyed to a clinical feature of ASD. Across the 38 items, 32 assess social/social-communication skills and 6 assess behavioral regulation and flexibility. Each item is rated from 1 (almost never) to 5 (almost always); higher total scores indicate greater use of the prosocial/adaptive skills. A

large-scale study of the ASC for children with ASD (Lopata et al., 2017) yielded good internal consistency (0.92) and test-retest reliability (6-week =0.81 and 9-month =0.63). Validity was supported in moderate-to-high inverse correlations with ratings of ASD symptoms and problem behaviors and positive correlations with prosocial/adaptive skills on established scales. The mean of the parent-teacher ratings (total item scores) for each child was used in the analyses.

Social Interaction Observation Scale (SIOS; Behavioral Observation). The SIOS (Bauminger, 2002) assesses social interactions of children during peer interactions. Raters observe the child interacting with peers for 15 minutes (50s observe-10s record) and record the occurrences of operationally-defined social behaviors (*positive, low-level,* and *negative interaction*). This study utilized interval sampling and, given the emphasis of the CSBI on development of social/social-communication and prosocial skills, the *positive interaction* scale only. The *positive interaction* scale consists of behaviors that reflect positive social engagement and interactions (e.g., "The child approaches another child with a social intention", "The child offers help to another child"). Observations were conducted during recess at each student's school by masked evaluators. Two 15-minute observations were conducted at baseline and two 15-minute observations at follow-up for each student (the total of the two baseline observations and the total of the two follow-up observations were used in the analyses). IOA $\geq$85% for the evaluators was established prior to observations. This was done by having the evaluators view video-taped game sessions from a prior study of children with ASD and code their interactions. IOA was also checked during 20% of baseline and follow-up observations and was 93%.

Woodcock-Johnson III Tests of Achievement (WJ-IIII Ach; Administered to Child). Academic achievement was assessed using five subtests including Letter Word Identification, Calculation, Spelling, Passage Comprehension, and Writing Samples (Woodcock, McGrew, &

Mather, 2001); higher subtest standard scores indicate greater academic skills (standard scores were used in the analyses). Median internal consistencies for these subscales (ages 6-12) ranged from 0.75-0.94. The WJ-III Ach is a respected norm-referenced measure of academic achievement. It was included to test whether improvements in social-communication skills and symptoms were associated with gains in academic skills/performance.

Data Analyses

Of the 103 children in the ITT sample 1 discontinued (from the SAU condition), leaving 102 completers in the analyses. Potential demographic and baseline measure differences were examined using *t*-tests and Fisher's exact tests. Family-wise Type I error rate was maintained at 5% for the primary outcomes (.025 per comparison); no adjustment was made for the secondary analyses. Given the hierarchical data structure caused by school clustering, data were analyzed by fitting a linear mixed effects model that included intervention group (CSBI vs. SAU) as a fixed effect, and school as a random effect to capture school-level variation, with an unstructured covariance matrix. Treatment effect was assessed by testing the mean change (baseline-to-follow-up) between-conditions. Linear mixed effects analyses were performed using STATA/IC 15.1. Effect size (*d*) estimates and 95% CIs were calculated via Hedges (2007) formulas for cluster randomized trials implemented in Comprehensive Meta-Analysis 3.0 (Borenstein, Hedges, Higgins, & Rothstein, 2017). Per the CONSORT extension for cluster randomized trials, cluster-based ICCs are reported. The clinical significance of each participant's change (baseline-to-follow-up) was also assessed via the reliable change index (RCI; with scores >1.96 considered significant and clinically meaningful; Jacobson & Truax, 1991). RCI results are reported for the measures that yielded significant between-groups differences.

Results

Primary Outcome Analyses

Primary analyses tested the efficacy of the CSBI on emotion recognition skills (CAM-C) and ASD symptoms (SRS-2). Results for the CAM-C revealed a significant treatment effect (F[1, 100]=33.16, p<.001, d=1.41 [CI .74, 2.09], school ICC=.28); children in the CSBI demonstrated a significantly greater increase compared to those in the SAU condition. A total of 20 CSBI children demonstrated reliable improvement (RCI >1.96) on the CAM-C compared to 1 SAU child (χ^2= 20.73, p<.001). Similarly, parent-teacher SRS-2 ratings showed that children in the CSBI had a significantly greater decrease in ASD symptoms compared to SAU children (F[1, 100]=23.51, p<.001, d=-1.15 [CI -1.77, -.53], school ICC=.22). A total of 30 CSBI children demonstrated reliable improvement (RCI >1.96) on the SRS-2 compared to 11 SAU children (χ^2= 13.51, p<.001).

Secondary Outcome Analyses

Secondary analyses examined the effect of the CSBI on social/social-communication skills ratings (ASC), social interactions (SIOS), and academic skills (WJ-III Ach). Results of the ASC parent-teacher ratings indicated a significantly greater increase for children in the CSBI compared to SAU (F[1, 100]=32.91, p=.001, d=1.29 [CI .60, 1.98], school ICC=.15). A total of 38 CSBI children demonstrated reliable improvement (RCI >1.96) on the ASC compared to 14 SAU children; (χ^2= 20.73, p<.001). No significant between-condition differences were found for the children's positive social interactions during recess (SIOS; F[1, 100]=.16, p=.692, d=.08 [CI -.33, .49], school ICC=.05) or for any of the academic subject areas (WJ-III Ach.; Letter Word Identification F[1, 100]=.03, p=.859, d=.03 [CI -.36, .43], school ICC=.02; Calculation F[1, 100]=.18, p=.673, d=.09 [CI -.33, .50], school ICC=.01; Spelling F[1, 100]=.38, p=.540, d=.08 [CI -.46, .63], school ICC=.00; Passage Comprehension F[1, 100]=.88, p=.349, d=.19 [CI -.73,

1.11], school ICC=.00; Writing Samples F[1, 100]=1.95, p=.166, d=.28 [CI -.21, .77], school ICC=.02).

Discussion

This was the first study to examine the efficacy of a cognitive-behavioral CSBI (schoolMAX) specifically for children with ASD (without intellectual and language disability). Relative to children in SAU schools, children that received the CSBI exhibited significantly greater improvements (large effects) in emotion recognition skills (social-cognition) and ratings of ASD symptoms and social/social-communication skills. The findings from the emotion recognition testing (CAM-C) were not surprising as the emotion recognition instruction in the CSBI directly addressed facial and vocal decoding skills. These gains were accompanied by improvements in ratings of ASD symptoms and social/social-communication skills which, taken together, reflect improvements in both proximal and more distal skills/symptoms. Overall, these results were considered promising as they reflect improvements in the defining features of ASD. The findings are similar to prior studies of the summer treatment from which the CSBI was adapted (Lopata et al., 2010; Thomeer et al., 2012), as well as the school-based study by Kasari et al. (2016). Those studies also used adult directed manualized interventions and direct instruction, modeling, role-play, reinforcement, and repeated practice; however the current study utilized school staff to deliver the intervention. School staff were able to deliver the multiple components with a high level of accuracy (>92%); this was a positive result given concerns over the feasibility of such interventions in schools (Reichow & Volkmar, 2010). Having different school team members implement different components likely made implementation more manageable and increased fidelity.

Despite the substantial improvements in core social impairments, no between-groups difference was found in the children's social interactions during recess. The reason(s) for this is unknown. The setting characteristics recorded by observers indicated significant variability in peer composition, environments, and activities within and across buildings; this lack of uniformity likely affected social opportunities. It is also possible that the children failed to generalize the skills/symptom improvements to the recess environment. Kasari et al. (2012) noted that specific instruction in the recess environment might be necessary to promote social engagement in that complex social setting. Another possibility is that the measure used (SIOS) lacked treatment sensitivity and another measure might better detect the improvements noted in parent-teacher ratings. Lastly, the discrepancy between results of the SIOS and parent-teacher ratings could have been associated with parent and teacher participation in the CSBI which could have biased their ratings.

This study also found no effects of the CSBI on academic skills. This was not necessarily surprising; although the individual daily note might have addressed some classroom behaviors, the CSBI did not target academic skills. A less obvious, but related positive result was that the time dedicated to implementing the multi-component CSBI did not negatively affect the students' academic skills. This is important given the potential perception by educational staff that non-academic interventions detract from academic priorities (competing time demands; Kasari & Smith, 2013).

Overall, results provided some support for the efficacy of the CSBI and use of specific techniques (direct instruction, modeling, role-play, reinforcement, repeated practice, and parent training) when delivered by school staff in school settings. This is promising as school interventions allow students with ASD to learn and practice skills in the settings they are

expected to use them (Kasari & Smith, 2013). In addition to the specific teaching techniques, the current findings may provide school staff with a broader framework to support students with ASD. For example, this study suggests that the feasibility of multi-component (comprehensive) interventions can be enhanced by including multiple team members to reduce implementation burden. Although this will require coordination among the team members, including multiple members can result in better integration of the intervention across the school day and increase and maximize opportunities for practice and reinforcement. Beyond the positive effects on several indicators of social skills and ASD symptoms, the current study suggests that specific instruction in recess environments might be needed so that the skills/symptom improvements generalize to recess social interactions. In addition, academic skills components might be needed to expand the effects of the CSBI and/or other psychosocial interventions to include academic skills.

Although this is one of the largest school-based intervention studies and the only test of a CSBI delivered by school staff for these students, and it had a number of strengths (e.g., randomized design, manualized intervention, comprehensive fidelity monitoring system, very low attrition, use of masked evaluators for several measures, statistical accounting for clusters and adjustments for the primary measures, etc.), there are several limitations. One involved the sample which was largely male and Caucasian, and the schools were from suburban districts which limits generalization of the findings. It is also possible that the findings are unique to the participating schools/districts so replication studies are warranted. Another limitation involved the multi-component nature of the CSBI which does not yield information on the most effective or necessary elements. The study also included some rating scale measures completed by non-masked raters (parents and teachers); as such, rater bias is a potential threat for those measures.

Additionally, fidelity was only assessed for adherence and no data were collected on other fidelity components (e.g., quality). This study also did not assess school staff and parent acceptability and satisfaction involving the CSBI which would provide information on the social validity of the intervention. Lastly, significant variability in recess environments hindered the use of those observations as an outcome measure. Given these limitations, future studies should test the CSBI in RCTs that utilize large diverse samples from different areas (urban and rural districts). These studies should also assess stakeholders' views of the CSBI (acceptability and satisfaction), as well as other aspects of fidelity (e.g., quality). Additional studies involving adaptive interventions testing individual and combinations of the CSBI components, as well as intensity levels would be informative. Studies might also consider testing an academic skills component and/or strategies to generalize skills to recess environments to expand the intervention effects. Finally, research is needed to identify outcome measures that can be completed by masked evaluators and that exhibit good treatment sensitivity and psychometric properties.

In summary, schools constitute important intervention environments and school staff are critically-important agents of delivery. This study suggested that school staff were able to implement the CSBI with a high degree of accuracy and the intervention yielded positive effects on core ASD symptoms and social-communication skills. The study also supported the applicability and efficacy of clinic-based cognitive-behavioral techniques in school settings; however additional adaptations may be needed to generalize skills to recess settings and/or enhance the academic impacts of the CSBI.

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Figure 1. CONSORT flow diagram

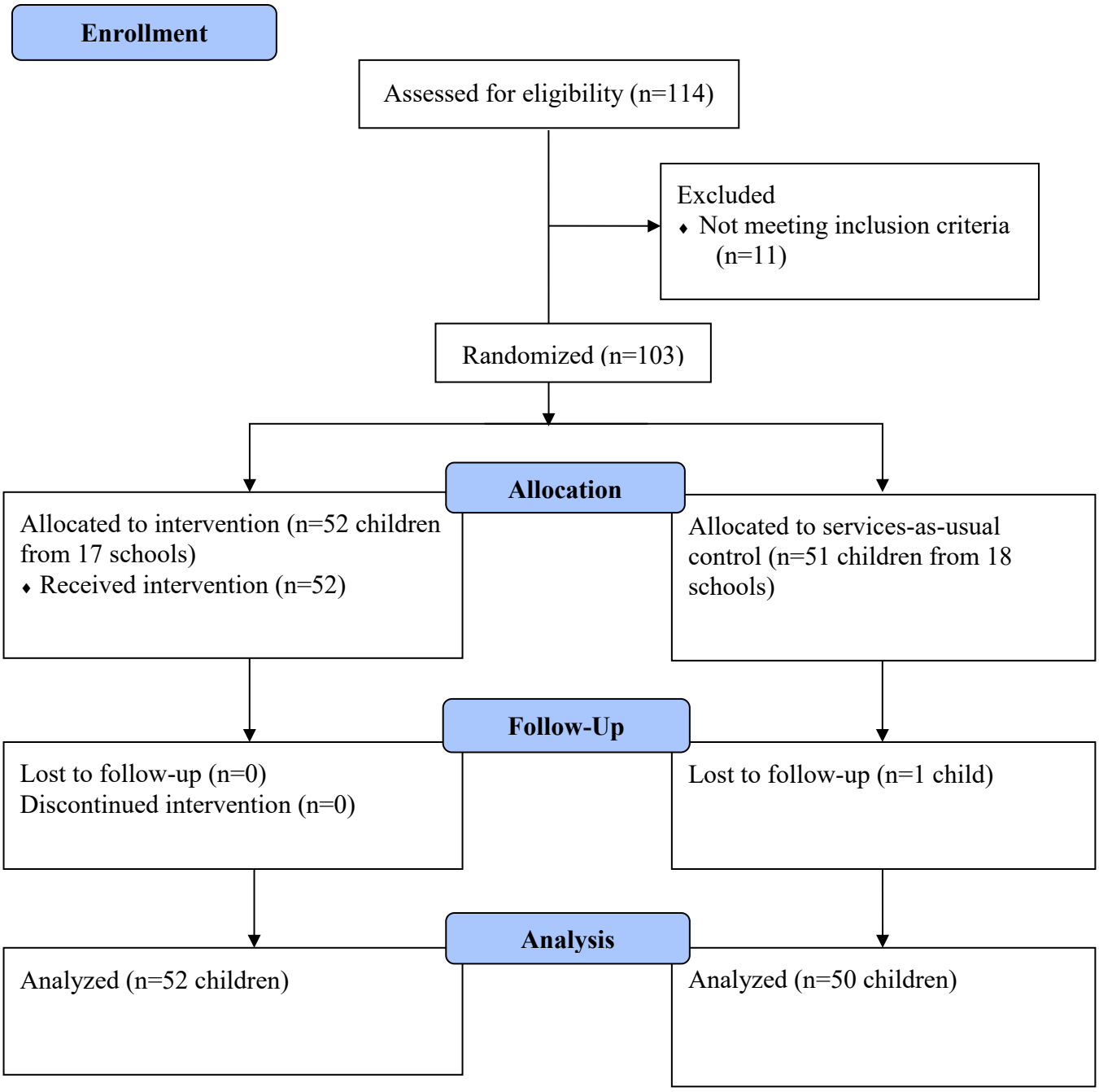

Table 1

Descriptive Statistics for Demographic, Baseline, and Follow-Up Measures

Characteristic	CSBI (*n*=52)	SAU Control (*n*=51)	*t* / Fisher's exact (*p*)	CSBI (*n*=52)	SAU Control (*n*=50)
Demographic					
Parent Education: Mean (*SD*)	15.76 (2.08)	15.41 (2.14)	.84 (.41)		
Child: Mean (*SD*)					
Age	8.65 (1.29)	9.01 (1.45)	1.32 (.19)		
WISC-IV IQ	103.82 (12.94)	100.94 (14.84)	1.05 (.30)		
WISC-IV VCI	103.04 (14.39)	100.21 (14.07)	1.01 (.32)		
WISC-IV PRI	103.82 (15.82)	101.50 (16.59)	.73 (.47)		
CASL Expressive Language	98.04 (15.10)	95.11 (14.52)	1.02 (.32)		
CASL Receptive Language	103.84 (17.49)	100.19 (16.22)	1.10 (.27)		
ADI-R Social Interactions	18.31 (5.91)	18.67 (5.72)	.31 (.76)		
ADI-R Communication	14.52 (3.91)	15.20 (5.43)	.73 (.47)		
ADI-R Repetitive Behavior	6.10 (1.72)	5.90 (2.24)	.50 (.62)		
Gender (male): *n* (%)	47 (90.4)	47 (92.2)	.10 (1.0)		

Ethnicity (Caucasian) *n* (%)	50 (96.2)	49 (96.1)	1.34 (1.0)		
Outcome: Mean (*SD*)	Baseline	Baseline		Follow-Up	Follow-Up
CAM-C	46.04 (12.92)	46.09 (11.70)	.03 (.98)	58.73 (14.60)	48.76 (12.94)
SRS-2 Parent-Teacher	71.93 (9.98)	71.48 (7.04)	.27 (.79)	64.84 (8.13)	69.72 (9.23)
ASC Parent-Teacher	104.73 (17.98)	107.40 (13.33)	.86 (.39)	112.20 (17.13)	108.71 (14.03)
SIOS	33.96 (20.03)	29.35 (18.00)	1.23 (.22)	37.58 (21.15)	35.04 (20.56)
WJ-III Ach					
Letter Word Identification	107.04 (14.93)	106.37 (13.77)	.24 (.82)	106.83 (11.36)	106.18 (12.32)
Calculation	102.77 (21.53)	98.94 (18.43)	.97 (.34)	107.19 (17.22)	102.80 (20.84)
Spelling	102.21 (15.91)	103.21 (19.81)	.28 (.78)	104.46 (15.61)	104.58 (20.76)
Passage Comprehension	94.54 (15.91)	94.84 (12.07)	.11 (.91)	97.10 (12.74)	93.84 (11.97)
Writing Samples	92.98 (15.53)	94.31 (16.71)	.42 (.68)	97.67 (10.49)	95.86 (17.80)

Note. CSBI=Comprehensive School-Based Intervention; SAU=Services-As-Usual; WISC-IV=Wechsler Intelligence Scale for Children-4th Edition; VCI=Verbal Comprehension Index; PRI=Perceptual Reasoning Index; CASL=Comprehensive Assessment of Spoken Language; ADI-R=Autism Diagnostic Interview-Revised; CAM-C=Cambridge Mindreading Face-Voice Battery for Children; SRS-2=Social Responsiveness Scale, 2nd Edition; ASC=Adapted Skillstreaming Checklist; SIOS=Social Interaction Observation Scale; WJ-III Ach=Woodcock-Johnson III Tests of Achievement.

Table 2

Characteristics of School Staff that Implemented the CSBI Components

Component	Position (*n*)	Gender (% female)	Race/Ethnicity (% Caucasian)	Degree (%)	Years of Experience Mean (range)
SSG					
	School Psychologist (7)	86%	100%	71% Masters, 29% Doctorate	11 (2-20)
	Speech Pathologist (20)	95%	100%	100% Masters	15 (2-30)
	Social Worker (14)	100%	93%	100% Masters	17 (3-26)
MR					
	Classroom Aide (20)	100%	100%	30% High School, 45% Some College, 15% Bachelors, 10% Masters	10 (1-28)
	Teaching Assistant (12)	100%	100%	17% High School, 8% Some College, 8% Bachelors, 67% Masters	14 (2-26)
TA					
	Counselor (15)	100%	93%	93% Masters, 7% Doctorate	17 (2-28)
	Teacher (52)	100%	100%	4% Bachelors, 96% Masters	15 (1-36)
IDN					
	Teacher (66)	100%	100%	100% Masters	14 (1-36)
PT					
	School Psychologist (11)	91%	100%	91% Masters, 9% Doctorate	15 (7-28)
	Social Worker (8)	100%	100%	100% Masters	19 (7-26)

Note. SSG=Social Skills Group; MR=Mind Reading (emotion recognition instruction), TA=Therapeutic Activity; IDN=Individual Daily Note; PT=Parent Training.