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Developing Feasible and Effective School-Based Interventions for Children With ASD: A Case Study of the Iterative Development Process

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Abstract

Despite an emphasis on identifying evidence-based practices among researchers and using evidence-based practices among professionals in the field of education, there are still problems with uptake and implementation in real-world settings. This lack of diffusion of practices is evident in educational programming for children with autism spectrum disorder (ASD). One solution is to use an iterative process to develop interventions in which researchers work in collaboration with the end users to test and refine interventions. However, there are very few guidelines for developing feasible and effective interventions through these iterative processes. This article provides a description of the iterative process used to develop the Advancing Social-Communication and Play (ASAP) intervention, a supplemental program designed for public preschool classrooms serving students with ASD, and examples of how data from the sequence of iterative design studies shaped the intervention development. The research team offers guidelines for other researchers looking to engage in intervention development using an iterative process in the context of partnerships with end users, including suggestions for planning and executing an intervention development grant.

Keywords: autism spectrum disorder, classroom-based services, preschool, intervention development, translational research

Introduction

There is an increased awareness of the gaps between research and practice across various clinical disciplines (Kessler & Glasgow, 2011; Proctor et al., 2009), as well as education (Vanderlinde &van Braak, 2010). In response to this challenge, the Institute of Education Sciences (IES) in 2004 altered their goal structure for grant requests for applications (RFAs) to promote the movement of interventions into authentic education practice. Presently, four of their five funding goals are structured as steps in the research process to establish and empirically validate interventions, ranging from identifying malleable factors (Goal 1) to development (Goal 2) to efficacy and replication (Goal 3) to evaluation of effectiveness in everyday educational settings (Goal 4). Since 2004, approximately 45% of funded IES studies have been Goal 2 Development and Innovation grants. Yet, there is limited guidance for research teams developing interventions on how to facilitate the eventual "uptake" of those interventions by community partners. Thus, researchers in education and related fields can benefit from discussions of the intervention development process and how to meaningfully and effectively involve community stakeholders (e.g., practitioners, policy makers, families) in the development and dissemination of school-based interventions.

In the field of education, attempts to seek out more effective ways to engage with stakeholders in the research process to produce real and meaningful outcomes have been met with various challenges (Hoagwood & Johnson, 2003; Maggin, Robertson, Oliver, Hollo, & Moore Partin, 2010). With the growth of the evidence-based practice movement, stakeholders widely assumed that the results of high quality research on effective educational strategies would be infused into practices and policies and lead to positive changes in student outcomes. However, despite enormous efforts, these attempts have often been met with resistance and some failure (Cook & Schirmer, 2003; Maggin et al., 2010; Odom, 2009). The transportability, or "the movement of efficacious interventions into usual-care settings" (Schoenwald & Hoagwood, 2001, p. 1192), appears to be problematic in education. It has become increasingly evident that stakeholders across education research, policy, and practice must work together to genuinely tackle this problem (Maggin et al., 2010).

Research in the area of autism spectrum disorder (ASD) also has not been immune to these issues of transportability (Dingfelder & Mandell, 2011). Growing concern about the gap is reflected in the strategic plans for the Interagency Autism Coordinating Committee (2011) and Autism Speaks™ (2013), with values, strategies, and goals that directly address the disconnect among research, practice, and policy. Given the rising prevalence (Centers for Disease Control and Prevention, 2014) and the four to fivefold increase in children with ASD served under the Individuals With Disabilities Education Act (IDEA) in public schools from 1996 to 2006 (U.S. Department of Education, 2011), the need for effective, classroom-based approaches for intervention is a pressing concern. However, evidence of successful implementation of interventions for individuals with ASD in educational settings is lacking due to factors such as a perceived mismatch between research-validated interventions and educator or setting characteristics (Dingfelder & Mandell, 2011); for example, interventions may be designed to be implemented exclusively in intensive one-to-one settings, rather than incorporating group settings. This discrepancy highlights the importance of including end users (e.g., teachers, teaching assistants, related service professionals) and other stakeholders (e.g., administrators, policy makers, families) in the intervention development process to maximize eventual buy-in, use, and overall effectiveness.

In this article, we describe how our research team designed a classroom-based intervention intended for use in public school classrooms serving preschoolers with ASD. In response to specifications in the IES RFA related to Goal 2 Development and Innovation grants, we proposed to implement an "iterative development process" (IES, National Center for Special Education Research, 2006, p. 38) to adapt an intervention for school settings. Within this iterative process, recent IES RFAs charge researchers to measure the "usability, feasibility, fidelity of implementation, and final student outcomes and expected intermediate outcomes" (IES, National Center for Special Education Research, 2012, p. 44). These expectations encourage researchers to move away from more traditional research in which interventions are developed without plans for implementation in real-world settings. These specifications also challenge researchers to prioritize consideration of external validity in the formative development process, with the goal of developing interventions that will be usable and effective in the authentic settings for which they are ultimately intended.

Although high quality methodological standards have been specified (and debated) for studies of intervention *efficacy* (e.g., Odom et al., 2005; Schulz, Altman, & Moher, 2010; What Works Clearinghouse, 2013), no widely disseminated or accepted standards for high quality intervention *development* research are available. Our Goal 2 development grant yielded sufficiently convincing evidence of the usability and feasibility of the intervention and its promise for promoting student change to lead to a successful application for Goal 3 funding from IES. In retrospect, we recognize that we learned many lessons throughout the process that we wished we had known when first embarking on intervention development research. The goal of this article is to provide guidance for and promote discussion among educational researchers pursuing similar intervention development efforts. We seek to achieve this goal by summarizing the iterative design and study activities executed during our Goal 2 grant, and describing the types of data collected and how the data informed both the study design and the intervention. An iterative process necessarily involves a sequence of studies; our grant included four planned phases and a fifth phase that was added in response to the data. This article is intended to be a methodological case study in which we provide an in-depth description and evaluation of one effort to use an iterative process to successfully design a school-based intervention; our focus on conveying the integration of information across successive iterations in the intervention development precludes detailed descriptions of each of the component studies in our project. More comprehensive reports of results for two of these studies are published elsewhere (Dykstra, Boyd, Watson, Crais, & Baranek, 2012; Wilson, Dykstra, Watson, Boyd, & Crais, 2012).

Overview of the Advancing Social-Communication and Play (ASAP) Project

Our proposed development process integrated data from many stakeholders using a multiphased, iterative approach. We developed and adapted the intervention at each subsequent phase based on qualitative (e.g., focus group data, interventionist feedback, coaching logs) and quantitative data (e.g., child outcomes, fidelity measures). Through this iterative process, we combined knowledge and expertise from teachers, teaching assistants, related service providers, school administrators (referred to collectively as *educators* throughout the remainder of the article), and researchers. In addition, we collected data from children, educators, and parents in an effort to maximize both the utility and the potential efficacy of the intervention.

The intervention that resulted from this evidence-based and iterative development

process is titled Advancing Social-Communication and Play (ASAP). The original idea for development of the ASAP intervention was inspired by a clinic-based efficacy study by Kasari, Freeman, and Paparella (2006) that showed preschool children with ASD receiving a 30-hr-a-week applied behavior analysis (ABA) therapy and supplemental interventions targeting joint attention or symbolic play skills improved targeted skills compared with a control group in which children received only 30 hr of ABA intervention. In consultation with Dr. Kasari, the ASAP research team set out to adapt this intervention for implementation in authentic environments, specifically for public preschool classrooms serving students with ASD.

As part of the grant application process, the research team created a conceptual model of change for the ASAP intervention (see Figure 1) based on evidence from previous research. The team then used an iterative design process to develop the intervention based on the proposed conceptual model. The ASAP model posits that improved social-communication and play is expected to lead to enhanced child engagement with objects, peers, and adults and to have sub- sequent effects on other areas of development (e.g., language, social interaction, adaptive functioning). This model starts with the core skills of social-communication and play at the center as key or "pivotal" behaviors for young children with ASD (Kasari et al., 2006). Using the work of Kasari and colleagues, we adapted their hierarchies of social-communication and play objectives to support acquisition and generalization of these core skills. The initial draft of the manual focused on strategies and activities for promoting mastery of these sequential objectives in the two skills areas in a one-to-one intervention context (primarily provided in a push-in model), with an expansion to group contexts in a later draft of the manual. We compiled existing evidence-based practices, including dynamic assessment, data-driven decision making, and teaching strategies (e.g., prompting, reinforcement, naturalistic instruction), into a cohesive process for assessment and instruction across the two content areas (social-communication and play) and two contexts (one-to-one and group).

Case Study of an Iterative Approach for Intervention Development

To develop the ASAP intervention, the team executed a five-phase process, with each phase including stakeholder input and evaluation. The activities for each phase included the following: focus groups, classroom observations, an initial one-to-one intervention trial, manual development, and consumer reviews (Phase 1); a small randomized controlled trial (RCT) of the one-to- one context and manual/intervention elaboration for the group context (Phase 2); a single-case design (SCD) study assessing the two context (i.e., one-to-one, group) components (Phase 3); a quasi-experimental study of the full intervention (Phase 4); and a pilot study of the coaching model (Phase 5). The following section provides an overview of the multiphased approach with

details about the study design and activities, the types of data collected, and a sample of data- based decisions made during each phase of the study. We provide additional details about the phases of the project in Table 1.

Phase 1: Focus Groups, Consumer Reviews, and Classroom Observations

The purpose of Phase 1 was to inform the development of the content and style of the ASAP intervention and manual. To achieve this purpose, we used focus groups, observations in pre- school classrooms, and consumer reviews after educators reviewed

or tried out the one-to-one context portion of the ASAP intervention. The types of data included qualitative data from focus groups, observations, and consumer reviews, and quantitative data from reviewer ratings.

Study design and activities. For the focus groups, the team recruited public school teachers, teaching assistants, and related service providers (e.g., speech-language pathologists, occupational therapists) serving preschool children with ASD. The participants represented six school districts from one southeastern state, reflecting some variability across districts in the ways services for preschoolers with ASD were delivered. In addition, we conducted observations in local pre-school classrooms serving children with ASD to ascertain the contexts in which children naturally engage in social-communication and play, and strategies educators used to facilitate those skills. Based on the literature, the focus group results (Flippin, Watson, Boyd, McGuinn Dun-combe, & Lenhardt, 2008), and the team's observations of classrooms, we developed an initial draft of the ASAP manual.

We then sought feedback from intended end users of the ASAP intervention, specifically, related service providers as a group of educators likely to implement an intervention such as ASAP in one-to-one contexts. Overall, 24 school-based related service providers reviewed the manual and completed a survey to evaluate positive and negative aspects of the intervention. Then, 5 of these providers (without guidance from the research team) tried out the intervention with preschoolers with ASD in their schools in a one-to-one context and provided feedback through semi structured phone interviews with research staff.

Data and decisions. Overall, the data collected in Phase 1 focused primarily on usability, addressing end users' ability and willingness to implement the intervention. Focus group themes related to usability of the ASAP intervention included that (a) play is not valued by schools or parents and may be difficult to target, especially in Individualized Education Plans; (b) joint attention, though valued, may be misinterpreted as "paying attention" in the classroom environment; and (c) service intensity and delivery are driven more by parent advocacy and school practices than by individual child needs. One example of the limited value placed on play was this speech-language pathologist's comment:

> We are not supposed to write play skills into their IEPs. If the therapists from certain districts do decide to include goals with play components, they have to find a way around the rules by masking the goals with alternate wording like "interacts with materials," or "functionally using classroom materials such as toys and objects."

Furthermore, some of the reviewers noted they were not very familiar with developmental hierarchies of play, in general, and hierarchies of symbolic play with objects, in particular. By hearing about these key issues, we recognized the need not only to lay out clear hierarchies for both social-communication and play goals in the manual but also to provide a strong rationale and research evidence for why targeting higher-level object play explicitly could lead to improved language and social skills. Without this key information gained from stakeholders, we might have planned a play intervention that educators did not use or perceive as valuable and could not justify to administrators or parents. The initial draft of the manual we developed was aligned conceptually with our initial model of change, but it also included many enhancements

to our original ideas that reflected the qualitative data gathered from the focus groups.

In addition, the related service provider reviews of the initial draft of the manual, which covered general information about ASAP and specific information on the one-to-one context, were positive overall with 3.3 average scores across items on a 4-point rating scale. The quantitative review data along with explanatory comments also indicated clear areas for improvement. For example, there were notably lower scores (i.e., 3.0 and below) for items related to the usability and understandability of the structured assessments and the usability of the self-monitoring forms. The strengths and concerns that emerged from the manual ratings were echoed in inter- views with the five providers who briefly implemented the one-to-one component of the intervention. These findings led the research team to make modifications to the existing assessments and forms. Thus, the qualitative and quantitative data collected from stakeholders during Phase 1 were instrumental in shaping the intervention and the manual for subsequent phases.

Phase 2: Pilot RCT Study and Consumer Reviews

Phase 2 focused on the following three aims: (a) determining the feasibility of implementing the combined content components (i.e., social-communication and play) in one-to-one contexts with a larger sample size; (b) determining whether the ASAP intervention would show promise for promoting changes in child outcomes, even when implemented in a single context (one-to-one only without the group context) and for an abbreviated duration (i.e., 12 weeks rather than across a school year); and (c) creating and reviewing the group context portion of the ASAP intervention manual. The first two aims were achieved through a small-scale RCT study, with speech-language pathology (SLP) graduate clinicians implementing the one-to-one component with children with ASD in public preschool classrooms. The quantitative data related to these aims included pre and post intervention child data collected by blind observers and fidelity of intervention implementation data. The qualitative data collected were comprised of coaching logs, graduate student clinician notes, and implementer interviews. The third aim was achieved by consumer reviews of the expanded intervention in the form of quantitative ratings and qualitative feedback through written comments and semi-structured interviews.

Study design and activities. The small-scale RCT included 11 classrooms, with two to three child participants with ASD in each classroom (ASAP group $n = 18$; control group $n = 13$). The graduate students were trained in the ASAP intervention and coached by a certified SLP doctoral student with over 8 years of experience instructing children with ASD. This process also included the initial development of a professional development and coaching component of ASAP and the development and piloting of a fidelity measure. The graduate clinicians implemented the one-to- one component of the ASAP intervention with children for 12 weeks. Trained staff who were blind to the random assignment assessed the children before and after the 12-week intervention. At the end of the 12-week intervention, ASAP research staff interviewed the graduate clinicians.

Concurrent with the RCT, the team extended the manual to include a draft of the group context component, using data from Phase 1 focus groups and classroom observations. Then, 15 pre- school teachers reviewed the second draft of the manual, and a subset of 4 of these teachers implemented the group component in their own classrooms. As in Phase 1, these educators pro- vided data through questionnaires and semi-structured interviews.

Data and decisions. Overall, the data collected during Phase 2 addressed usability, feasibility, fidelity, and child outcomes; these data shaped both the intervention and future aspects of the study. For example, qualitative data from the SLP graduate clinician interviews suggested ASAP was feasible in the one-to-one context but that the number of target goals for a given session should be limited. Data from both the graduate clinician interviews and educator reviews showed that another need was for easier-to-use semistructured assessments. As a result, additional modifications were made to the intervention and manual. Fidelity data from Phase 2 showed overall high scores (averages with a range of 3.39-3.94 for graduate clinicians), suggesting that the ASAP intervention could be implemented with high fidelity by SLP graduate clinicians in the classroom. However, a major insight from the fidelity data during this phase was that scores could be impacted drastically by the child's behavior in any given session. Therefore, for Phase 3, we revised several of the questions on the fidelity checklist to focus on the efforts of the educator to engage the child in appropriate learning opportunities related to the ASAP goals.

Child outcomes in Phase 2 were measured with two assessments used in previous research: the Structured Play Assessment (SPA; adapted from Ungerer & Sigman, 1981) and the Early Social Communication Scales (ESCS; Mundy et al., 2003). Results suggested that the ASAP intervention showed promise in improving play skills, with a marginally significant group difference of moderate effect size, $F = 4.8$, Hedges's $g = .49$, $p = .06$. There was a significant group effect of moderate to large size on one type of social-communication behavior, responding to social interaction bids, $F = 7.8$, Hedges's $g = .79$, $p = .01$. An examination of results on other types of social-communication behaviors showed no group differences or time-related changes in either group; also, for initiating joint attention and responding to joint attention, the pre and posttest scores were not significantly correlated with one another. These quantitative findings related to child outcomes from this phase thus made two important contributions to the ASAP development process. First, they provided support for the promise of the ASAP one-to-one intervention component in promoting child change even over a relatively abbreviated length of time. Second, the findings suggested that our proximal measure of social-communication was not satisfactory in terms of its reliability and sensitivity to change for our targeted population. As a result, we replaced this assessment with an alternative method based on coding social-communication behaviors that occurred during repeated administrations of the Autism Diagnostic Observation Schedule (ADOS; Lord, Rutter, DiLavore, & Risi, 1999), a semi-structured play- based assessment that includes "presses" for social-communication. This unplanned activity of developing and validating a new social-communication outcome measure required a considerable amount of time during the remainder of the project.

Reviewer ratings for the revised draft of the ASAP manual (now including both the one-to-one and group contexts) remained generally positive and improved to a mean of 3.5 on a 4-point scale. Only 2 of 50 items had mean ratings suggesting significant concerns: items related to the feasibility of completing self-monitoring or child performance forms in the classroom context. These findings informed the planning for coaching ASAP in later phases, including the develop- ment of classroom-specific strategies for self-evaluation and child performance monitoring.

Phase 3: SCD Study With School Staff

The primary purpose of Phase 3 was to examine the implementation of the

ASAP intervention with school-based personnel. This was achieved by conducting a single-case multiple baseline design study with replication across three participants. The quantitative data collected in this phase consisted of observation of student behaviors, implementer fidelity, and social validity. The qualitative data collected included implementer interviews and coaching logs.

Study design and activities. During this phase, school-based teams implemented ASAP using staggered starts for the two context components of the intervention (i.e., group and one-to-one) to ascertain the additive value of the one-to-one component. The design of the SCD study was sequenced such that the group component was implemented first by the teacher and teaching assistants and then the one-to-one component was implemented by the school-based SLPs (see Dykstra et al., 2012, for more information). We assessed changes in child behavior across the intervention, as well as intervention fidelity when implemented by school-based teams. Also, the educators participated in semistructured interviews to gather feedback regarding the ASAP manual, intervention, and training and coaching supports. In addition, the researchers collected social validity data related to the changes in child behaviors from the participating educators and a group of educational professionals unfamiliar with the children or teachers. The research team also collected video-recordings at participating schools to create an ASAP training DVD, consistent with the recommendation from our school-based partners that video examples would enhance the likelihood of successful implementation.

Data and decisions. The data in this phase addressed usability, feasibility, fidelity, and child out- comes, and also impacted both the methodology and the intervention. Interestingly, the order of the contexts of ASAP (i.e., group, one-to-one) in the multiple baseline design for the SCD study reflected a change from the originally proposed study design, because educators in prior focus groups indicated that one-to-one intervention was not valued or provided in many preschool set- tings. Thus, a research question generated from the educators' insights was whether the one-to- one context was necessary for children to progress in developing the skills targeted in ASAP. The SCD study conducted in the public schools in Phase 3 offered a controlled demonstration of intervention effects and affirmed the importance of the one-to-one context of the intervention (see Dykstra et al., 2012, for full results). These data led the team to focus on supporting educators in providing ASAP in the one-to-one context early and intensively in the training and coaching process of subsequent phases. The fidelity data from Phase 3 showed overall adequate to high scores (averages ranged from 3.08-4.00 on a 4-point scale across educators), demonstrating that educators could implement the ASAP intervention with good fidelity. Interviews with educators during Phase 3 highlighted the need for materials to improve feasibility in busy classrooms, such as "quick glance" sheets, a wider variety of data collection forms, and the addition of a wall poster to visually display the skill hierarchies. Based on the study results and feedback, the manual was once again revised, retaining and refining both context components.

Phase 4: Quasi-Experimental Group Study of "Packaged" Intervention

The purpose of Phase 4 was to examine the fully (but not final) packaged ASAP intervention in public school settings. The aims were (a) to determine the impact of the intervention (fidelity and child outcomes) and (b) to continue to gather data about

usability and feasibility across a broader range of classrooms. The research team used a quasi-experimental study comparing the ASAP intervention with a business-as-usual (BAU) comparison group in public preschool classrooms. The quantitative data collected included measures of child outcomes, fidelity, and social validity. The qualitative data collected were coaching logs and implementer interviews.

Study design and activities. The quasi-experimental study examined the short- and long-term out- comes of children who received ASAP compared with children in a BAU comparison group. Following participation in a standardized training protocol (i.e., specified training presentation, materials, and activities), school-based teams (i.e., teachers, teaching assistants, related service providers) implemented the intervention over the course of a school year with coaching support from ASAP research staff. Coaching support was semi-structured through the use of a coaching meeting guide. Intervention fidelity was measured throughout the school year. Child outcome data were captured pre, post, and 6 months following intervention. Social validity of the out-comes was examined through parents' and teachers' ratings of their perceptions of the children's social-communication and play skills relative to a standard video of a typically developing preschooler at the pre and post intervention time points. Additional feedback related to social validity of the ASAP procedures and goals was gathered through interviews with school-based team members, which informed continued development of the manual, intervention, and training and coaching model. The research team also added video-recordings of classroom intervention to the training DVD.

Data and decisions. As with Phases 2 and 3, Phase 4 addressed usability, feasibility, fidelity, and child outcomes. These data affected study design (as the team prepared for a Goal 3 grant sub- mission) and the intervention. For example, we adapted the fidelity measure to differentiate between ASAP and non-ASAP classrooms, a task that was more difficult than we expected. The items were divided into general administration and intervention, to differentiate between items that reflected more general teaching practices (e.g., securing child's attention, using behavior management strategies) and items that reflected core features of the ASAP intervention (e.g., engagement, dosage, hierarchy of target skills). This new fidelity measure showed clearer differentiation between the ASAP and non-ASAP classrooms by the middle of the school year. At this time point, the ASAP and non-ASAP classrooms were comparable in their use of general teaching practices with average scores of 3.95 and 3.89, respectively, but different in their intervention usage with average scores of 3.42 and 2.78, respectively. Despite this improvement in measuring fidelity, the research team still struggled to determine how the fidelity measure would be utilized in future studies when fidelity assessors would be blind to classroom assignment, and how a fidelity measure could capture the less readily observable aspects of the intervention such as the process for goal selection and data-based decision making. This led the team to adapt the fidelity measure again in the previously unplanned Phase 5 to prepare for the larger efficacy study.

The child outcome data from Phase 4, an underpowered, quasi-experimental study, were more difficult to interpret due to striking baseline differences between the two groups. The children in the comparison group had significantly higher expressive language abilities than the ASAP group on the Expressive Language Scale of the Mullen Scales of Early Learning (Mullen, 1995), as well as showing significantly higher pre-test scores on our proximal measures of play and social- communication, suggesting that

the two groups may already have been on different developmental trajectories for the areas of interest in this study. Levene's test for equality of variances further indicated that the groups had unequal variances, thereby violating one of the assumptions for comparing the groups in a parametric model. Thus, we first compared the groups using the non- parametric Mann–Whitney U test and found no evidence for group differences in change from pre to posttest on play ($p = .589$) or on social-communication skills ($p = .164$). We then analyzed the growth of the students in the ASAP and comparison groups separately using single-group repeated measures ANOVAs; Cohen's d, corrected for the dependence of scores across time points, reflects the magnitude of the within-group change from pre to posttest. The results demonstrated significant growth in play, $F(1,18) = 21.6$, $p < .001$, $d = 1.24$, and social-communication, $F(1,18) = 6.2$, $p = .023$, $d = .58$, across the school year for the ASAP group. The growth in the comparison group was significant for play, $F(1,11) = 10.3$, $p = .008$, $d = .92$, but not for social-communication, $F(1,11) = 0.8$, $p = .404$, $d = .24$. Parent ratings on a social validity measure offered additional support for the intervention with significant changes for the ASAP group, $F(1,14) = 14.9$, $p = .002$, and no significant changes for the comparison group, $F(1,6) = 0.7$, $p = .735$. Overall, the data from this study, although not supporting a clear causal inference, indicated that ASAP was promising as an intervention that could positively affect social-communication and play skills in preschoolers with ASD, even when those skills are assessed by blind, unfamiliar examiners outside of the classroom setting or assessed more globally by parent ratings. Evidence of promise is one prerequisite for IES Goal 3 funding to test intervention efficacy. The 6-month follow-up results indicated that the children in both groups maintained their posttest levels of play skills with negligible changes. The ASAP group showed a nonsignificant decline in their social-communication scores compared with posttest ($F = 1.45$, $p = .231$, $d = -.30$), whereas the comparison group showed a nonsignificant gain ($F = 1.84$, $p = .203$, $d = .39$). What is most noteworthy, however, is that the trends for the two groups were in opposite directions. It appeared that even though the ASAP group had made substantial and significant gains during the active intervention phase of the study, their growth was not sustained during follow-up. In contrast, the pretest score of the comparison group ($M = 52.3$, $SD = 24.7$) exceeded the *posttest score* attained by the ASAP group ($M = 39.8$, $SD = 22.1$, $t = 1.46$, $p = .078$), leading us to hypothesize that the ASAP group never reached the level of social-communication skills necessary for these to become "self-maintaining" in the absence of active instructional support. The assumption that there is a point at which both play and social-communication skills will become self-maintaining and also lead to the incidental learning of other skills is a key element in our model of change; these results suggest that identifying that point is an important aim for future research.

Phase 5: Coaching Pilot Study on ASAP Professional Development Support

Phase 5 was added to the development process due to the increasingly clear need for a focus on professional education that came from our interactions with and observations of the professionals who were implementing ASAP. The goals of Phase 5 were (a) to assess and adapt the ASAP training and coaching supports and (b) adapt and test a revised ASAP fidelity tool (vital to our efficacy study plans). The goals were achieved through the development of coaching and training materials, and the execution of a small quasi-experimental study. The quantitative data collected in this phase included fidelity and social validity; the qualitative data collected included implementer interviews and coaching logs.

Study design and activities. For the small study, the researchers compared six preschool teams who received varying levels of implementation support (i.e., no support, manual and training support, or manual, training, and coaching support) from the ASAP team (Wilson et al., 2012). The ASAP manual, training protocol, coaching manual, and intervention fidelity procedures were further revised in preparation for an upcoming efficacy study. In addition, we developed fidelity mea- sures and procedures (e.g., trainers sent tapes of practice training sessions for review prior to training participants) to assess the adherence of trainers and coaches to the specific professional education protocols designed for use in the upcoming efficacy study.

Data and decisions. In addition to the fidelity measure, we also used coaching observations and logs to assess the fidelity of implementation. In Phases 2 and 3, the qualitative notes were relatively unstructured, but by Phase 4, we had developed a coaching meeting form to note specific challenges, strengths, and concerns observed and discussed in the coaching process. By Phase 5, the observation forms and coaching meetings were more fully developed to be used as supple- mental data. The observation logs had ratings and detailed notes. The new fidelity measure was developed to capture five aspects of fidelity for the ASAP intervention: content (via teacher knowledge), quality of implementation, dosage of implementation, process (via planning and teaming), and progress monitoring. The fidelity measure included teacher interview (dosage, process, and progress monitoring) and videotaped observation with follow-up questions (content and quality). In addition, the measure allowed for blind ratings of fidelity via audiotaped interviews and videotaped classroom sessions, which was important for the Goal 3 study. The small study that was completed as part of Phase 5 provided preliminary evidence for the impact of the ASAP coaching model (see Wilson et al., 2012, for full results). Descriptively, the quantitative fidelity data indicated that educators who participated in both ASAP training and coaching attained higher fidelity scores and reported a greater increase in collaborative practices than those who participated in ASAP training only, who in turn had higher scores than educators who were not exposed to the ASAP intervention. The small size of this trial did not permit statistical comparisons.

Summary

Over the five phases of the ASAP development project, our interdisciplinary research team worked closely with school-based educational teams to create and adapt the ASAP intervention. We strove to develop a user-friendly and informative manual and training DVD, and to hone the procedures of our intervention to enhance feasibility and buy-in of school professionals. In addition, we worked to identify or adapt measures to accurately assess fidelity and outcomes. We also established models of training and coaching to boost team motivation and intervention fidelity. Ultimately, the iterative study design resulted in an intervention that showed enough promise to obtain Goal 3 funding.

Discussion

The purpose of this article is to use our data and experiences to offer guidance for researchers engaging in iterative design studies and to encourage dialogue among researchers on this emerging method of intervention design. First, we evaluate the

iterative design process used in the ASAP study by summarizing the features and methods that were incorporated in the design and identifying challenges and recommendations based on our experiences adapting an intervention for public school programs. Second, we highlight important issues to consider in iterative design and suggest next steps for the field of educational research related to this type of intervention development.

Evaluation of an Iterative Design

The ASAP project started during the early years of IES and other agencies' focus on translational research. As such, funding agencies offered few specific guidelines at the time of our grant sub- mission. We discovered that the development and evaluation of interventions in partnership with real-world end users is arduous but also necessary and extremely valuable. These challenges are amplified in the field of ASD due to the heterogeneity of the children, as well as the complexity of their learning needs and the uniqueness of the disorder. In the following section, we discuss what we have learned from planning and executing a development grant that examines four major areas: usability, feasibility, fidelity of implementation, and student outcomes. See Table 2 for a summary of the data collection methods used during the five phases of the study across the four areas.

Usability. Usability focuses on the end users, specifically their ability to understand and implement the intervention, and their willingness to do so. One of the key ways we found to enhance usability was to have both former and current end users on the research team. The research team included individuals who had served as teachers, SLPs, occupational therapists, psychologists, and administrators in school settings. We also incorporated current end users to review and try out the manual and intervention (Phases 1-5), as well as interviewed them after implementation in each phase of the study. Within the focus groups (Phase 1), we asked questions about educators' current beliefs and practices. In developing our surveys and interviews (Phases 2-5), we designed questions to gather usability information about the key components of the intervention (e.g., manual and materials, assessments, intervention procedures, professional development). Based on interview data, the educators were very positive about the overall usability of the intervention, and many reported they would continue to use the intervention after the study.

Challenges and recommendations for usability. Despite success in improving usability across the phases of the study, the process of attaining and assessing usability information was not without its challenges. Feedback in this area is most often attained through qualitative research methods, including surveys and interviews. A lesson learned at this phase was that our team lacked expertise in mixed methods research, which would have been invaluable in designing and executing the entire development process. We also found that given the time-intensive nature of qualitative analysis, we were not able to fully analyze our qualitative data while also conforming to the rapid turnaround time required by our iterative design. Thus, in hindsight and with greater skill in mixed methods design, we may have better sequenced our activities (and subsequent analyses) to allow for more complete data to inform subsequent phases. Finally, we also realized belatedly that it would have been useful to engage a product design expert early in the process to specifically address the usability of the manual.

Feasibility. Feasibility focuses on the use of the intervention given the available supports and resource constraints in the targeted setting. We discovered it is critical to consider the issue of feasibility from the outset of developing or adapting an intervention. Our research team gained information about the available resources in public preschool classrooms directly from professionals working in those settings. It was helpful to obtain information in the focus groups from a variety of schools and districts to get a broader picture of potential supports and constraints (Phase 1). In addition, we recruited professionals from more distant regions of the state to pro- vide consumer reviews (Phases 1 and 2), allowing us to gather information from higher- and lower-resourced, urban and rural school districts. Our research team also included an autism services administrator (from one of the local school districts) who was paid on the grant and was extremely helpful in guiding us in district practices and policies that could affect feasibility. The research staff who served as coaches (Phases 2-5) also proved to be indispensable informants regarding feasibility, as they saw and heard the successes and struggles of the school-based teams firsthand.

Challenges and recommendations for feasibility. Although we made consistent efforts to gather feasibility information, some challenges emerged, as well as some broader tensions in considering feasibility. One concern was that all of the information was gathered from professionals within a single state. As researchers move toward more multisite studies and as technology improves, gathering information across states and sites with varied resources and limitations is becoming a more achievable goal. Another issue we neglected was to actively include more top-level administrators in the research process. Although we consulted administrators during the recruitment process (and had one district-level special education administrator on our team), new interventions cannot be successfully scaled up unless administrators fully understand the intervention and support the resources necessary for its implementation (Klingner, Ahwee, Pilonieta, & Menen- dez, 2003; Taylor, Nelson, & Adelman, 1999). For example, although we demonstrated that coaching improves the fidelity of implementation, the cost and feasibility of supporting a coaching model within school systems are unknown and would certainly require administrative support.

An additional issue is the tension between developing interventions that can be embedded within existing systems with little additional support versus those requiring more substantial sup- ports. A major issue when designing ASAP was considering the range of models of ASD intervention used within the state and across the country. Our intent was that ASAP could be used with many types of interventions or classroom curricula, particularly as a supplement to address specific goals important for preschoolers with ASD. In this way, we hoped that it could be easily embedded within existing systems, without entailing a great deal of extra support or resources. However, the flexibility of the ASAP intervention does not ameliorate tensions related to broader issues such as staff-to-student ratios or the hours of preschool programming available to students with ASD. For example, many of the education teams found providing the one-to-one component of the intervention to be challenging, despite the relatively low recommended intensity of 40 min per week. Our empirical data, however, supported its essential role in promoting gains, and therefore, the one-to-one component appears necessary to the intervention. These kinds of feasibility issues are important, and continued exploration by researcher–practitioner partnerships can potentially create interventions that are feasible within existing models and structures while still advocating for system change that reflects evidence-based practices.

Fidelity of implementation. Fidelity of implementation focuses on the delivery of the intervention by the end users in the way that it is intended to be used within the setting (Gresham, MacMillan, Beebe-Frankenberger, & Bocian, 2000). Our team collected fidelity data using a researcher- designed measure during each phase of implementation. During Phase 4 (quasi-experimental study of whole intervention), we used the fidelity measure not only to assess ASAP implementation in the treatment classrooms but also to assess whether key ASAP features (e.g., skill hierarchy, individual and group intervention, data-based decision making) were being used in the control classrooms. One initial complication was that some of the control classrooms received relatively high fidelity scores despite not receiving any ASAP training. As a result, the research team started to differentiate between generally "good classroom practices" and the essential ingredients of the ASAP intervention. With additional feedback, the fidelity measure continued to evolve during Phase 5, with attempts to measure intervention content and process, as well as the quality and quantity of ASAP intervention.

Challenges and recommendations for fidelity. Despite many discussions and changes surrounding fidelity, we have struggled with both assessing fidelity and establishing reasonable expectations related to fidelity in real-world settings. To ensure its feasibility in a variety of classrooms, the ASAP intervention was designed to be a supplemental intervention model. Thus, it was expected that there would be some variations in how it was delivered. For example, some teams might use more structured, adult-directed strategies whereas others use more naturalistic, child-directed strategies. This orientation is different from many other comprehensive (e.g., TEACCH®, Mesibov, Shea, & Schopler, 2004; Pivotal Response Training, Koegel, Koegel, Harrower, & Carter, 1999) and supplemental (e.g., Picture Exchange Communication System, Frost & Bondy, 2002) programs that focus on a defined set of strategies. The ASAP intervention is heavily process- based (e.g., recommended strategies for planning, data collection, and review) and content-based (e.g., skill hierarchies), which are often not transparent during classroom observations. In an attempt to capture these aspects of fidelity, an implementer interview was introduced as part of the fidelity measure in Phase 5, and questions were developed to elicit consistent and accurate responses from the teachers. However, this made blind assessment of fidelity difficult as teachers in the intervention group often used terminology related to the ASAP goals and intervention. Overall, we found that developing a fidelity measure is challenging work, but it ultimately forces researchers to identify core features and mechanisms for change.

Another interesting tension for research teams to be aware of is the difference between how fidelity is conceptualized for efficacy studies and how fidelity might be most useful to research teams. In efficacy studies, funders expect that fidelity is used to differentiate between treatment for intervention and control groups, and to be considered as a potential mediator of intervention effects. However, research teams may not always feel that fidelity is the actual or sole mechanism for change. Thus, it is important that research teams planning for studies consider how to assess the proposed mechanisms for change, even if they are beyond adherence to the intervention (e.g., overall changes in classroom quality). Researchers should also consider that fidelity might be used for multiple purposes. Fidelity measures not only serve a purpose in research (e.g., differentiator, mediator) but also support implementation of an intervention, for example, use of fidelity measures in the coaching process.

Final student outcomes and expected intermediate outcomes. The final outcomes for any classroom intervention should focus on the changes that are expected in the students, whereas the intermediate outcomes may be the behavior changes seen in the implementers. In the current project, aligned with the expectations of IES Goal 2 projects, we used both SCD (Phase 3) and underpowered group studies (Phases 2 and 4) to provide input to and assess the promise of the ASAP intervention. The SCD allowed for immediate data interpretation and for us to examine the relative impact of the one-to-one and group components. In contrast, the group designs utilized a broader array of students and classroom teams with whom to test the intervention and a larger and more diverse group of informants. Another benefit in our multiphased intervention development was the selection, refinement, and validation of measures of the proximal skills targeted in ASAP: social-communication and play. Finally, the use of multiple informants (teachers, assistant teachers, related service providers, and parents) and various types of measures (e.g., standardized assessments, coding systems for samples of play and social-communication behaviors, educator reports of progress, social validity ratings) provided a depth and richness of data that helped us assess the promise of the intervention.

Challenges and recommendations for outcomes. Finding and creating measures that were reliable and sensitive to change on the expected final proximal outcomes for the students receiving the ASAP intervention, however, proved to be a difficult process, a problem that has been noted in a recent review (Bolte & Diehl, 2013). Over the phases of this study, we relied heavily on resource- intensive coding systems, resulting in less efficient feedback loops for evaluating the data. One potential solution to this issue is to utilize live coding systems to gather data more immediately. In addition, we also recognized that it was challenging to assess the hypothesized distal outcomes of our ASAP model, the more generalized social, cognitive, and adaptive student factors expected to change downstream as a result of the more proximal intervention effects of ASAP. There were logistical difficulties (e.g., finding students who moved across classrooms or schools in subsequent school years) and methodological difficulties (e.g., accounting for potentially different exposures to ASAP as some children remained in a classroom with ASAP-trained teams across the years, while others moved to new classrooms). Indeed, given the confines of the time and resources, it may be too ambitious to look at more distal outcomes in any intervention development study. Finally, we collected only minimal data on changes in educator behavior, an expected intermediate outcome. However, it would be wise to collect more frequent data (e.g., regular coach or self-report ratings on progress) as well as more objective data on educator changes during the development phase. Such measures would also yield more nuanced insights into usability and feasibility, and potentially aid in developing guidelines on when coaching support can be reduced or withdrawn for a team.

Summary. In our ongoing efficacy study of ASAP, we are continuing to focus not only on questions related to student outcomes but also on questions related to the uptake of ASAP by educators across school districts and classroom models in four different geographic states. We believe the iterative model used to develop the ASAP intervention may be of use to others who similarly are interested in developing new interventions. This description of the barriers we encountered and the solutions we generated relative to examining usability, feasibility, fidelity, and final outcomes may be of help in guiding others. Table 3 provides a summary of the recommendations we make to others who are invested in using a translational process to engage end users in

intervention development and implementation. Although the specific decisions of research teams will vary based on aspects of the intervention being developed (e.g., setting, target population, characteristics of the intervention), it is important for the research community to develop guiding principles for teams engaging in researcher–practitioner partnerships.

Considerations and Next Steps for Iterative Design Studies

Given that intervention development grants are being funded at high rates and there is limited guidance on engaging in an iterative development process, it is critical for researchers to engage in ongoing discussions related to intervention development research. There are three key goals that we feel are important for the field to address to advance the state of the research for iterative design studies: (a) evaluating the impact of iterative design processes, (b) developing guidelines for the evaluation of iterative design studies, and (c) developing methods to identify and address system-level variables (barriers to and/or facilitators of successful implementation) during the initial development of an intervention.

First, although the process of including end users in intervention development has been heralded as a method for developing authentic interventions for school settings, there is limited evidence on whether these efforts actually result in interventions that are feasible, effective, sustainable, and scalable. As more IES Goal 2 grants move into Goal 3 funding, the field will have opportunities to evaluate whether interventions developed via an iterative process embedded in authentic educational settings are proving to be feasible and efficacious in these larger trials. Follow-up studies of educators who were involved in successful Goal 3 studies can provide information on sustainability of these interventions, prior to testing their scalability in Goal 4 grants. At each step of testing, a retrospective comparison of the iterative development processes used for "successful" (i.e., feasible, effective, sustainable, scalable) versus "unsuccessful" interventions may provide insights into quality indicators for iterative development designs.

A second, related issue is that no clear standards are currently available for evaluating the strength of an iterative development study. Educational researchers have identified guidelines for examining the rigor of randomized control trials and SCD studies (e.g., What Works Clearinghouse, 2013), so grant reviewers, as well as journal reviewers, have a clear idea of what to look for in those types of studies. However, iterative designs add a new layer of nuance and complexity as the studies consist of multiple phases of studies within studies, often include a wide range of types of data, and seek to measure many aspects of an intervention (e.g., usability, feasibility, fidelity, and outcomes). To incorporate the fluidity needed in iterative design and value the collaboration with end users, these studies may require a different balance of internal and external validity than efficacy studies. As noted earlier, funders are often looking for the promise of an intervention, but it would be premature to test the efficacy of the intervention in the context of these studies. It is important that both grant reviewers and journal reviewers acknowledge the differences of this type of research from more traditional research designs. If every aspect of intervention development needs to be subjected to a rigorous trial based on the current standards for efficacy studies, it will be difficult, if not impossible, to deliver an intervention ready for efficacy testing in a timely manner. Design experimentation (sometimes called educational design research) is a promising method that has been used in educational research (Burkhardt & Schoenfeld, 2003; Cobb, Confrey, diSessa, Lehrer, &

Schauble, 2003; McKenney & Reeves, 2012), but the guidelines that have been provided in the literature are varied and, at times, ambiguous, and the guidelines are not specific to special education. It will be important for researchers to identify methodologies, measures, and analyses that offer sufficient rigor for developing and piloting an intervention within budget and time constraints of intervention development grants.

Finally, the success of an intervention is dependent on many factors. In iterative development designs to date, researchers have focused largely on engagement with classroom personnel, students, and sometimes parents. System level factors have received limited attention prior to the time that interventions are being scaled up; yet these factors can affect implementation of the intervention in authentic settings during efficacy studies as well as in scaled up studies of effectiveness. Considering these factors at the time of intervention development may ultimately result in interventions that are more scalable. Thus, operationalizing the application principles of implementation science (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005) within iterative development designs may advance our efforts to develop interventions that can and will be used to effect change in authentic educational settings.

Conclusion

It is important for researchers to continue to consider the processes and methods for developing interventions to improve the likelihood that the interventions are feasible and effective in the set- tings and for the populations for whom they are designed. The challenges and successes that we experienced during the iterative process were integral in the development of the ASAP intervention and also in our development as researchers working in researcher–practitioner partnerships. We recognize there are additional steps that need to be taken to make research "truly translational," as suggested by Justice (2010), and we hope that our case study will spark additional discussion of intervention development research and ultimately improve the quality of iterative development designs.

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Table 1. Research Activities for Each Phase of Development.

Phase	Activity (timeline)	Informants/participants	Data	Decisions
1	Focus groups (summer 2007) teachers/TAs and	2 groups of 2 groups of related service providers 13 teachers, 2 TAs, 6 SLPs, 6 OTs	Focus group transcripts Identified themes	Include sections on research-based rationale for targeting play Ensure hierarchies for social-communication and play have clear definitions Adapt Phase 3 study to gather data for important of one-to-one instruction
	Consumer reviews of initial intervention manual (fall 2007/ spring 2008)	24 related service providers	Survey ($n = 24$) Phone interview ($n = 5$)	Revise the structured assessments to clarify process and improve usability Revise self-monitoring forms
	Classroom observations (fall 2008) 6 classrooms	2 research staff	Observation notes	Update manual to include group activities to fit within common classroom centers
2	Pilot randomized controlled trial (fall 2008—12 weeks)	4 Quasi-experimental group study (fall 2009/spring 2010—full school year plus fall 2011 6-month follow-up assessments)	5 Coaching pilot study (fall 2010 to spring 2011—full school year)	6 SLP graduate clinicians 30 children with ASD in public preschools (18 intervention, 12 control) 1 coach from research team 15 teachers 9 parents 3 teaching teams (each included a teacher, TA, and SLP) 3 students with ASD 1 coach from research team 10 teaching teams (6 intervention, 4 control)
	Consumer reviews of revised intervention manual (fall 2008)			
3	Single-case design studies (spring 2009 for three teams— 20 weeks)			

32 students with ASD (20 intervention, 12 control) 2 coaches from research team	Child outcome data Implementer report of child progress Fidelity of implementation Implementer's and coach's logs Interventionist interviews	logs Implementer interviews Fidelity of implementation Coaching logs Implementer interviews	Limit number of goals addressed per session Additional revisions to structured assessments Adapt fidelity measure to capture teacher effort more than child behavior Change assessment battery to capture pre and post social- communication skills ~~Target creation of data collection forms as~~ part of coaching process
6 teaching teams (2 manual + training + coaching, 2 manual + training only, 2 control) 2 coaches from research team			Increase support and coaching related to one-to-one context Add materials to manual to improve feasibility in classrooms (e.g., quick glance sheets, wall poster) Develop specific guidelines for coaching procedures
	Survey ($n = 15$) Phone interview ($n = 4$) Child observational data Implementer report of child progress Social validity (teachers, parents, adults unfamiliar to child) Fidelity of implementation Coaching logs Implementer interviews Child outcome data Implementer report of child progress Fidelity of implementation Social validity (teachers and parents) Coaching		Adapt fidelity measure to differentiate between core features of ASAP and quality teaching Manualize the coaching process Reorder small set of skills within hierarchies to better reflect order of development seen in participants
			Revise the fidelity measure to capture more aspects of ASAP process

Note. TA = teaching assistant; SLP = speech-language pathologist; OT = occupational therapist; ASD = autism spectrum disorder; ASAP = Advancing Social-Communication and Play.

Table 2. Data Collection Methods to Inform Intervention Development.

Measures	Usability	Feasibilit	Fidelity	Outcom	1: Focus	2: Pilot RCT	3: SCD study	4: Quasi-experiment	5: Coac
Child assessments									
Developmental				☐		☐		☐	
Play				☐		☐		☐	
Social-communication				☐		☐		☐	
Child observational coding				☐			☐		
Classroom observation notes	☐				☐				
Coaching logs		☐	☐			☐	☐	☐	☐
Consumer reviews									
Surveys	☐	☐			☐	☐			
Interviews	☐	☐			☐	☐			
Fidelity									
Observations			☐			☐	☐	☐	☐
Interviews			☐						☐
Focus group transcripts	☐	☐			☐				
Implementer interviews	☐	☐				☐	☐	☐	☐
Implementer logs	☐	☐	☐			☐			
Implementer reports of child progress				☐		☐	☐	☐	
Parent report									
Adaptive behavior				☐				☐	
Autism severity				☐				☐	
Social validity									
Parents				☐			☐	☐	
Implementers				☐			☐	☐	
Unfamiliar adults (educators)				☐			☐		

Note. RCT = randomized controlled trial; SCD = single-case design.

Table 3. Key Recommendations for Intervention Development Grants.

Usability

Build interdisciplinary research team including a variety of end users, administrators, and parents Gather usability information from end users across multiple contexts and geographic areas if possible Consider and plan for professional development needs

Engage a product design expert early in the development process

Feasibility

Recruit diverse participants and multiple school districts

Include multiple opportunities to gain feedback from implementers

Include administrators in data gathering

Negotiate with administrators for "teaming" time for implementers

Gather social validity data across

informants Engage policy makers in the

development process Fidelity

Recognize need to adapt or develop fidelity measures to fit targeted intervention, use established tools to guide scaling of measures when possible

Recognize and measure the different aspects of fidelity—e.g., process, content, strategies, quality, dosage

Consider a fidelity tool and qualitative data in fidelity measurement

Measure fidelity of training, implementation, and coaching

Plan to provide sufficient time for implementers to achieve fidelity

Outcomes

Use multiple informants and variety of methods to measure outcomes

Find efficient child measures that will highlight the child changes resulting from the intervention, develop new measures as last resort

Consider live measurement systems to speed data collection

Measure both implementer and child changes

Plan to include a variety of study designs as appropriate—e.g., single-case designs, quasi-experimental designs, etc.

Focus primarily on proximal outcomes

General

Establish rapport with research partners

Sequence activities to take into account time-consuming data analysis methods

Include an expert in mixed methods in the planning and execution of the development process

Consider different aspects of social validity (e.g., usability, perceived outcomes)

Remain flexible in modifying intervention features that are not essential to promoting desired outcomes, engage with partners to design feasible options for implementing essential features

Emphasize the value of research partners' feedback in the development process, highlight intervention features that resulted from that feedback

Establish systematic data collection methods for coaches (e.g., coaching log notes)
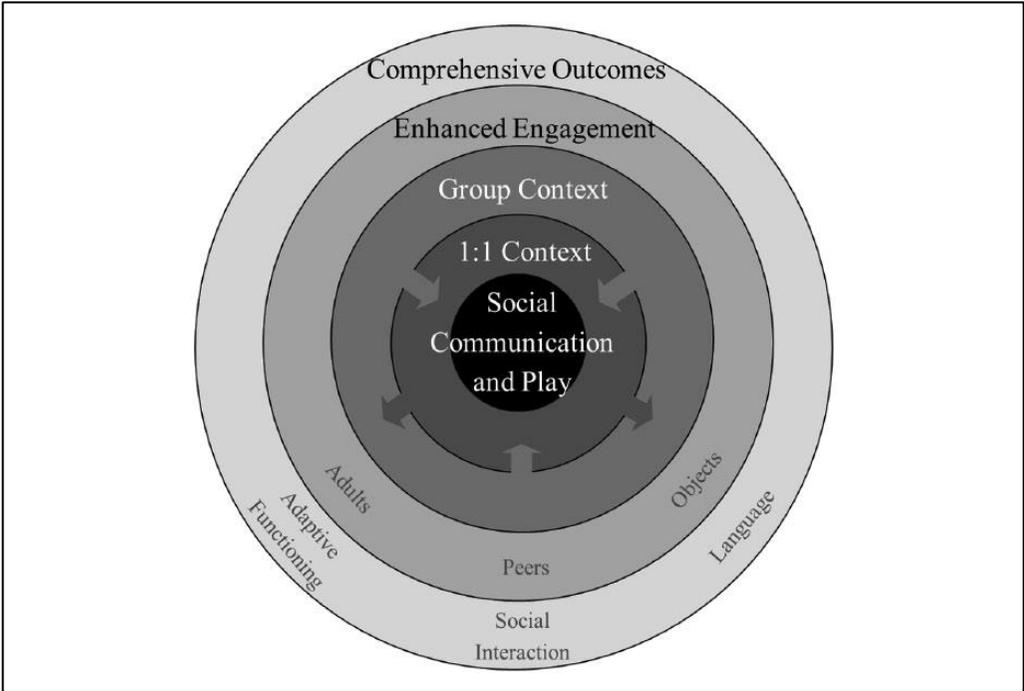
Figure 1. Advancing Social-Communication and Play intervention model