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SURVIVING AND THRIVING IN THE REAL WORLD: A DAILY LIVING SKILLS INTERVENTION FOR ADOLESCENTS WITH ASD

ABSTRACT:

Despite Daily Living Skills (DLS) being an area of significant impairment for the majority of adolescents with high functioning Autism Spectrum Disorder (ASD), there are no intervention packages that target the acquisition of DLS to the population who may benefit the most[1-8]. The current study will be the first to develop and pilot test an intervention package based on evidence-based strategies to directly target DLS, which appear to be critical to high functioning youth with ASD leading independent lives, attending and graduating from college, and obtaining and maintaining a job. Specifically, the current intervention (i.e., Surviving and Thriving in the Real World – STRW) was developed to fill a gap in the literature by targeting complex, age-appropriate DLS through direct instruction to adolescents and their parents in order to increase acquisition and maintenance of skills in an efficient and time-limited manner. The group format of the STRW intervention allows for parents to share how to implement effective strategies and build motivation, and it also increases social opportunities and highlights the importance of DLS for adolescents with ASD. The STRW intervention is also unique in that it will be utilizing the expertise of the fields of psychology and occupational therapy in order to more effectively address skill acquisition. While several interventions have been developed for high functioning adolescents with ASD and proven effective in using evidence-based strategies to target specific symptoms [9-11] (e.g., social skill deficits) or comorbid disorders[9,12,13] (e.g., anxiety), [none have addressed DLS. An intervention package that utilizes evidence-based strategies (e.g., contract to reinforce skill development, technology, video modeling) to teach critical DLS could have a significant impact on both current functioning and future adult outcome for high functioning adolescents with ASD.

PURPOSE OF STUDY:

The current study seeks to develop the first DLS intervention package for high functioning adolescents with ASD and evaluate its effectiveness. We hope to further refine the STRW intervention by conducting an ORBIT (Obesity-Related Behavioral Intervention Trial) Phase 2b feasibility RCT (Randomized Clinical Trial). This RCT will test the preliminary effectiveness of STRW in 56 adolescents (14-21 years) with high functioning ASD as compared to a robust evidence-based social skills intervention (Program for the Evaluation and Enrichment of Relational Skills - PEERS[14]). The current proposal represents a critical step toward improving the adult outcome of individuals with ASD.

Aim 1: Examine the preliminary effectiveness of STRW in a feasibility RCT. Participants randomized to STRW will demonstrate improvement on targeted DLS on the Vineland-3, pre- to post-treatment as compared to PEERS (control). The secondary outcome measure will be goal attainment scaling. Exploratory outcome measures (i.e., daily phone diaries, direct behavioral observations, and self-report of DLS) will be examined.
Aim 2: Assess maintenance of treatment gains at 6-month follow-up. Participants in STRW will maintain greater DLS as compared to PEERS (control).
Aim 3 (Exploratory): Explore how social skills, executive functioning, psychopathology, and parenting factors, which have been linked to DLS, are affected by participation in STRW.

BACKGROUND:

Individuals with high functioning ASD are not developing the skills necessary to successfully transition from adolescence to college, employment, and independent living. Recent studies[15-17] have found that nearly 50% of individuals with ASD can be classified as high functioning (IQ $\geq$70), and 25% have IQs in at least the average range (IQ $\geq$85). Despite their cognitive abilities, the outcomes of attending college, living independently, and being employed for adults with high functioning ASD are extremely bleak[18] as they are less likely to be engaged in any vocational or educational activities after high school even as compared to individuals with ASD and a comorbid ID[19]. A recent review of adult outcomes found that 50% of adults with high functioning ASD are living with their parents and require significant supports with everyday activities[20]. Individuals with high functioning ASD are uniquely at risk for struggling with attending and graduating from college and obtaining and maintaining a job even when compared to youth with intellectual disability (ID)[21]. One study found that only 12% of individuals with high functioning ASD attended a 4-year college[21]. Further, only 50-55% of adults with high functioning ASD are employed in full or part-time jobs[22,23] and little is known about factors that prevent them from obtaining employment or being underemployed[24]. These poor outcomes

are startling because parents and professionals often expect individuals with high functioning ASD to successfully transition to the adult world because of their intact cognitive abilities and less severe profile of ASD symptomatology. Thus, it is critical to develop interventions that may lead to acquisition of skills necessary to succeed in college, employment, and independent living[25].

DLS have been linked to positive adult outcome in individuals with ASD. Studies have consistently found that adults with high functioning ASD who have better developed DLS were more likely to attend college, be employed, have more meaningful social relationships, and have an increased quality of life as compared to those with poor DLS[21,23,26-28]. DLS are tasks or activities that are required for everyday independence at home and in the community, college, and workplace. DLS do not typically require an understanding of complex and nuanced social-communication skills that may be particularly difficult for individuals with ASD. Rather, DLS often require specific instruction, practice, and feedback from others and include skills in the areas of personal (e.g., brushing teeth, taking medication), domestic (e.g., laundry, cooking, cleaning), and community (e.g., budgeting money, managing time). The acquisition and mastery of DLS are critical for achieving certain adult milestones including maintaining a job and living independently. For example, basic DLS such as showering, wearing deodorant, and changing one's clothes are expected and essential when interacting with co-workers.

Despite the importance of DLS to adult outcome, adolescents with high functioning ASD have impaired DLS. Individuals with high functioning ASD gain DLS at a significantly slower rate compared to peers with typical development and even compared to peers with developmental disabilities[29-32]. Adolescents with high functioning ASD have impaired DLS that fall far below what would be expected based on their cognitive abilities and chronological age[1,5,6,31,33]. Duncan and Bishop[5] found that in a sample of 417 adolescents with high functioning ASD over 50% had DLS that were at least one standard deviation below their full scale IQ, as measured by the Vineland-II[34]. Another study found that among individuals with ASD who had IQs above 70, there was an average difference of 34 points between DLS and full scale IQ[1]. Thus, a high percentage of individuals with high functioning ASD have DLS that are 6-8 years below their chronological age[31]. Duncan and Bishop[5] also found that neither IQ nor the social-communication difficulties and repetitive behaviors that are associated with a diagnosis of ASD had a significant impact on whether individuals had impaired DLS. Duncan and colleagues[35] completed a microanalysis of DLS on the Vineland-II in adolescents with ASD and found strengths in skills that are typically acquired in preschool-aged children (e.g., eating, dressing, toileting), but deficits in skills critical for independent functioning such as household tasks, managing time and money, and traveling in the community. These DLS deficits likely contribute to difficulties in college, employment, independent living, and socialization for high functioning adults with ASD[27,28,36,37].

A complex set of environmental, individual, and family factors likely affect the ability of adolescents with high functioning ASD to acquire critical DLS. It appears that adolescents with typical development acquire DLS somewhat automatically through instruction, experiences at home, school, and the community, and via interactions with adults and peers[34]. However, there are barriers that may prevent adolescents with high functioning ASD from implicitly acquiring DLS including: (1) impaired social-communication skills (e.g., understanding expectations, asking for help, fewer peer interactions) and restricted and repetitive behaviors (e.g., resistance to change) associated with their ASD diagnosis[2,38-41]; (2) executive functioning difficulties[2,42-44] (e.g., self-monitoring, planning, following multi-step directions); (3) parenting factors[45-49] (e.g., expectations, decreased fostering of independence); (4) being overly dependent on others[2,37]; (5) comorbid psychopathology (i.e., anxiety, depression, and ADHD); and (6) lack of quality, affordable services for adolescents with ASD and their families[20,40,50,51]. These factors may contribute to DLS deficits and undoubtedly make the transition to adulthood particularly challenging. Thus, adolescents with high functioning ASD and their parents need additional supports to learn DLS.

There are currently no evidence-based DLS intervention packages for adolescents with high functioning ASD that would prepare them for independence in adulthood. Despite the strong and clearly documented link between DLS and adult outcome, there are no intervention packages that target the acquisition of DLS[1,6-8,52,53]. A 2016 Government Accountability Office (GAO) report on Youth with Autism[54] identified life skills education and experience as one of 14 critical services that needs to be targeted during the transition to adulthood. The

report further specified that DLS interventions would address and support all 5 goals of transitioning youth with ASD in the areas of (1) postsecondary education (e.g., handling social demands and living on campus); (2) employment (e.g., handling the work environment); (3) independent living (e.g., performing tasks of daily life); (4) health and safety (e.g., managing aspects of both physical and mental health); and (5) community integration (e.g., building skills to increase social interactions and community participation). Despite the clear need for interventions for youth with ASD, a 2017 Congressional report found that only 2% of all autism funded research is focused on transition and adult issues[55]. Recent literature reviews and studies have identified evidence-based teaching strategies (e.g., direct instruction, task analysis, visual supports, technology, video modeling, and behavioral based strategies such as reinforcement and prompting) that have been effective in teaching adaptive behavior skills, including DLS, to adolescents with ASD[7,53,56-61]. Other evidence-based strategies such as parent-implemented intervention, social narratives, and visual supports have been shown to lead to adaptive behavior skill acquisition for children and younger adolescents with ASD[57,58,60-62]. Interestingly, while several studies have demonstrated successful acquisition of DLS in adolescents with ASD using evidence-based strategies, these studies are often designed for individuals with ASD and a comorbid ID, focus on simplistic DLS (e.g., counting money, making a clay pot), and/or take place in the classroom with minimal parental involvement to promote generalization to the real world[56-58]. These studies often lack the rigor of an RCT as they have been conducted with fewer than 5 participants or are case studies or single subject design studies. What is lacking is an intervention package that (1) targets adolescents with high functioning ASD, (2) addresses multiple DLS required for independent functioning, (3) uses evidence-based strategies to teach skill acquisition, maintenance, and generalization, and (4) provides parents with education and skills to facilitate increased independence, decision making, and promote generalization through practice in the home and community when targeting DLS[1-8,37]. A DLS intervention package for adolescents with high functioning ASD that uses evidence-based strategies for teaching DLS and incorporates parental involvement has the potential to directly affect current functioning and future adult outcomes by increasing capabilities for skills that are needed to succeed in college, work, and independent living.

PRELIMINARY STUDIES:

ORBIT Phase 1 Studies. After receiving a competitive internal grant in 2014, I conducted a series of single subject case studies of adolescents with high functioning ASD in the school setting (N=3), followed by refinement to the clinic setting (N = 2) in order to identify essential features of a DLS intervention (ORBIT Phase 1a). Adolescents were taught skills identified as critical by their parents (e.g., developing a morning hygiene routine, cooking on the stove, and doing laundry). Through these early studies, it became clear that a parent component was needed to promote practice of skills outside of the sessions. I then incorporated parents into the intervention and utilized behavioral contracting between the adolescent and parent to increase motivation to practice and master targeted DLS between sessions. This initial work allowed me to identify core intervention components, refine strategies used to target DLS, and identify what motivates adolescents with ASD and their parents to participate. It was perhaps most surprising that parents needed such intensive instruction, oversight, and peer support from other parents to promote the development of DLS (e.g., difficulties identifying appropriate and motivating reinforcers). Parents reported that they struggled to prioritize the development of DLS and were often more focused on academic success or social skills. Thus, as a result of the initial ORBIT Phase 1a case studies, I found that the intervention will be best delivered in a clinic setting in order to: (1) effectively support parents with the acquisition of their adolescent's skills using evidence-based strategies; (2) allow for adolescents with ASD to practice critical DLS in realistic settings (e.g., doing laundry with an actual washer and dryer which is available in our clinic setting but not in most schools); and (3) provide a group setting that will allow for adolescent and parent participants to learn from one another.

ORBIT Phase 2a Pre-Post Trial and Pilot Study. The lessons from the initial ORBIT Phase 1 studies were incorporated into the design of a pre-post trial (ORBIT Phase 2a) designed to refine the treatment and examine the initial feasibility of Surviving and Thriving in the Real World (STRW). Specifically, we examined effectiveness of recruitment strategies, relevance of content, specific teaching strategies, and acceptable number of treatment sessions. In addition, we piloted GAS as a way to measure baseline skills and individual progress on the targeted DLS goals. Data was collected after each session to evaluate acceptability, feasibility, and parent and adolescent satisfaction. We successfully recruited and retained 7 adolescents with ASD and

their families with high rates of attendance. Satisfaction ratings following each of the 12 sessions were high for both adolescents and parent participants. Results indicated that adolescents made clinically significant improvements on both the Vineland-II Domestic subdomain and Daily Living Skills domain from baseline to post-treatment (i.e., mean age equivalence scores on the Domestic subdomain were measured as 8.6 years at baseline and improved to 10.9 years at post-treatment). Thus, adolescents gained over 2 years of skills over the course of a 12-week group intervention[32]. The adolescents maintained improvement and in some areas (e.g., Community subdomain) show further gains at the 6-month follow-up. GAS was used to provide a more individualized assessment of change in DLS in the areas of Morning Routine, Laundry, Kitchen/Cooking, and Money Management, and parents reported statistically significant changes in all of the 4 areas assessed at both baseline to post-treatment and baseline to follow-up. These findings are particularly promising because they demonstrate that while DLS are deficient in individuals with high functioning ASD, we may be able to significantly close the gap between their actual skill level and the skill level that is expected based on their chronological age. Focus groups were held with adolescent and parent participants and overall satisfaction rates with the intervention content were high. The STRW manual was revised based on feedback from the focus groups (e.g., adding additional sessions and content to more thoroughly cover topics such as money management, grocery shopping, and managing worry and stress related to growing up). Since the last submission, under the support provided by the CT2 Scholar program, we conducted a second ORBIT Phase 2a pilot study in which 10 participants were randomized to either the STRW treatment group or a waitlist control group to examine the revised STRW treatment manual on acceptability, feasibility, satisfaction, and proof-of-concept relative to a waitlist control. These results replicated our pre-post trial as adolescent participants in the STRW group gained 2 years of DLS on the Vineland-3 Domestic subdomain (e.g., safe kitchen practices, cooking snacks and meals, doing laundry). In addition, with the expanded sessions on money management the adolescent participants now showed a gain of 2.5 years on the Vineland-3 Community subdomain (e.g., budgeting, using a checking account, comparing prices) from baseline to post-treatment. Adolescents in the waitlist control group did not show improvements in their DLS. Acceptability, satisfaction, and value were rated highly, and session attendance (77%) and intervention completion rates (100%) were high even with the expanded number of sessions. Relevant to the current proposal, 3 waitlist participants dropped out. Offering an alternative, clinically relevant control intervention will help address uneven dropout in the control group. In preparation for the Phase 2b Feasibility RCT being proposed in the current K23, the STRW intervention materials (i.e., manual, acceptability and satisfaction forms, and treatment adherence checklist[63]) will be refined and finalized based on feedback from OTs in TKOC at CCHMC and my mentoring team by July, 2018. I will also attend the official clinical training for the PEERS intervention (the control group) in July, 2018.

STUDY DESIGN:

The current study involving human subjects consists of a feasibility RCT to test the feasibility and effectiveness of the STRW intervention as compared to a social skills intervention. A total of 56 adolescents with ASD between the ages of 14-21 will be randomized to STRW (n=28) or a social skills group (n=28). Outcome measures will be assessed at baseline, post-treatment, and 6-month follow-up. 2 outcome measures (i.e., DPDs and behavioral observation measures of targeted DLS) that have been previously piloted will be used as well.

SELECTION AND RECRUITMENT OF PARTICIPANTS:

Inclusion Criteria

The inclusion criteria: between 14-21 years of age and attending high school; a diagnosis of ASD (based on meeting the cut-off score on the Autism Diagnostic Observation Schedule, 2nd Edition - ADOS-2 administered by a research reliable ADOS-2 assessor at the eligibility assessment or at CCHMC within the previous 2 years)[64]; a full scale IQ of 70 or above as measured by the Stanford Binet Intelligence Scales, 5th Edition (SB-5)[65] administered by a psychologist at the eligibility assessment or at CCHMC within the last 2 years; and deficient DLS as assessed by the Vineland-3[66].

Exclusion Criteria

Participants with psychosis or other major psychiatric disorder requiring intensive treatment will be excluded, but children will be eligible to participate if they have a condition commonly comorbid with ASD (e.g., ADHD, mild anxiety, and mild secondary depression) that does not require intensive treatment and is not considered to be the primary driver of their symptoms and impairment. The decision of whether the comorbid disorder requires treatment will be made by a child psychologist during the screening interview. Also, if the adolescent has already completed the social skills group (PEERS), either at Cincinnati Children's or in another setting, they will not be eligible for the study unless it has been a significant amount of time since they did the PEERS group (2-3 years, or up to the discretion of the PI). In these cases, the parent must give verbal understanding that their child may be randomized to the social skills group.

Recruitment

Participants will be recruited from TKOC at CCHMC and identified through a variety of resources including (1) an existing database of over 100 adolescents who were previously assessed and diagnosed with an ASD at TKOC; (2) Dr. Duncan's existing research database of 150 adolescents with ASD who have participated in her previous studies; (3) Dr. Erickson's existing research databases; (4) treatment referrals from clinicians at TKOC and community providers; (5) fliers that will be distributed and/or posted in TKOC and CCHMC; and (6) fliers that will be distributed and/or posted at schools, community events, and organizations (i.e., Autism Society of Greater Cincinnati). Families will be sent a letter describing the study along with a "Do not contact further" postcard. Families not returning the postcards and self-referred families will be called by research staff to share more about the study and invite participation. Families who agree will then complete the phone screening. Families self-referring from community referrals/fliers will receive the same information and screening when they call.

Via Chart Review: Potential participants will be identified via a systematic electronic medical chart review using EPIC in which research personnel will identify adolescents who meet the inclusion criteria. Specifically, participants will be identified through a search of relevant provider schedules in TKOC and the Department of Psychiatry at CCHMC. Chart reviews will be conducted on adolescents enrolled in CCHMC clinical programs (i.e., individual therapy, group therapy, re-evaluations, yearly follow-up visits) through TKOC and the Department of Psychiatry at CCHMC. Families of adolescents meeting criteria for the initial screening will be contacted after confirming with their provider that this is acceptable. If they do not express interest in the study, they will be removed from the potential subjects. We may also request to see the teen's Individualized Education Plan (IEP) in order to confirm eligibility. If the parent does not provide the IEP or does not agree to give us access, it will not be a determining factor in their eligibility.

All families that express an interest in participating will undergo a phone screening to ensure that they meet general study inclusion/exclusion criteria. These inclusion/exclusion criteria include that the child is in the selected age range, has a diagnosis of ASD, has IQ within the average range, and has decreased DLS. If the child appears to meet inclusion criteria and does not meet any of the exclusionary criteria, an eligibility assessment will be scheduled. If the eligibility assessment confirms that all inclusion criteria have been, a baseline assessment will then be conducted.

PROCESS OF OBTAINING CONSENT:

At the eligibility assessment, the adolescent and their parent will be informed about the study in detail by study personnel. Research staff will go over the consent forms (with parents and adolescents over the age of 18 who are their own legal guardian), assent forms (with adolescents under 18 and adolescents over the age of 18 who are not their own legal guardian), answer questions, and inform participants of the study procedures, risks, and benefits, voluntariness, confidentiality issues, and other aspects of informed consent/assent. Participants and their parents will be informed of their right to refuse to participate in the study or any part of the data collection, and will be given the phone numbers of the Principal Investigator as well as the Institutional Review Board of CCHMC in the event that they desire further information or would like to issue a formal complaint. Families will be explicitly told that their medical care will not be affected by participating or not participating in the study. No assessment procedures will occur until after parent consent and adolescent consent or assent are obtained. The Institutional Review Board of CCHMC will be responsible for monitoring risks to human

participants and assessment of ethical issues related to this study, and will have approved the consent form and protocol prior to initiation of the study. Participants may be consented using eConsent, or written consent.

eConsent: Electronic informed consent will be developed and implemented using REDCap. The CCHMC REDCap team has templates available for research use for eConsenting which includes Consent to be a Research Subject and Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study (HIPAA). The REDCap electronic consent format does not accommodate the current CCHMC formatting which includes headers with logos and stamps on each page and will therefore require some modifications.

Participants may be consented either in person or via telehealth (phone or video). Subjects presenting to clinic will be screened for COVID-19 using the questions on Centerlink. They will be given an electronic tablet with the preloaded IRB approved and HIPAA documents for the specific study. Subjects consented via telehealth will be sent the consent via redcap and consented over the phone or streaming video. Subjects will be given time to read through the consent form(s) and then the study coordinator (or designee) will review the consent, and any study handouts with the participant. Once the consenting process has been completed and all questions have been answered, the study and HIPPA consents will be signed and dated by the subject and witness and submitted via the REDCap database. Subjects will elect either a printed or electronic copy of the ICF documents and will receive documents as per preference. Signed and submitted documents will be available as a PDF in REDCap's File Repository. A PDF of the eConsent document will be sent to CCHMC HIM per requirements and long-term storage will be at the CCHMC approved vendor, LabArchives, which is 21CFRPart11 compliant.

For the Consent, the IRB approved consent document will be uploaded into the database instrument. The IRB approved consent will be modified to an electronic format that includes all the same elements found on the paper document (i.e. IRB number, approval dates, and CCHMC logo, etc.). The elements of the consent requiring a signature has been added as a generate field. The instrument includes fields to capture full name, signature, and date and time of the signature for the consenter, and witness and conditional text that states that all signatures are associated with the Subject ID# registered in the database. Participants and Witnesses will type their first and last name into a text box, sign their name in the signature field with a stylus or finger and then click “Now” by the date field to automatically enter the date and time. A copy will be printed or sent electronically to the subject per their preference. When completed REDCap will generate a footer that contains the long date and time the document was submitted and “Confidential” listed in the header as an added precaution to preserve the research participant’s confidentiality. REDCap's 'Auto-Archiver + eConsent Framework' will be used. The 'Auto-Archiver + e-Consent Framework' survey option adds two things to the typical survey-taking process. 1) Before a participant completes the survey, an extra certification page is added to end of the survey that displays an in-line PDF copy of their survey responses in which they will be asked to confirm that all information in the document is correct. Once they confirm all is correct, the survey will then be marked as complete. The survey will not be considered complete until they fulfill the certification step. 2) Upon completion of the survey, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's File Repository. The consent-specific PDF may have the values of the e-Consent Framework Options inserted at the bottom of each page in the PDF. These values (i.e., name, date of birth, etc.) are added to the PDF as extra documentation of the identity of the person who is consenting.
In order to ensure that each adolescent comprehends his/her rights as a volunteer in the study and the study procedures, a simplified consent form will be used. Although some of the adolescents will be able to provide consent, some may have difficulties (e.g., due to reading comprehension difficulties, due to language deficits). Study staff will ask the adolescent participants specifically whether they understand what we are going to do in the study, and if they understand that they are volunteers and don’t have to participate if they don’t want to. Potential participants will only be asked to participate and consent if the research staff believes they are able to understand that to which they are agreeing.

PROCEDURES:

SURVIVING AND THRIVING IN THE REAL WORLD: A DAILY LIVING SKILLS INTERVENTION FOR ADOLESCENTS WITH ASD

Procedures will consist of running 4 cohorts of 14 high functioning adolescents with ASD (IQ≥70) and their parents in the STRW group or a social skills group (i.e., Program for the Evaluation and Enrichment of Relational Skills –PEERS [14]). Approximately 7 adolescents with ASD and their parents will participate in each STRW and PEERS group. Thus, across 4 cohorts, the goal will be to enroll 28 adolescents in both the STRW and PEERS groups during Years 1-4.

The parent will complete the Vineland-3 and the adolescent will be administered the SB-5 and the ADOS-2 if they do not have one that has been completed at CCHMC within the past 2 years. If the eligibility assessment indicates that inclusion criteria has been met, the adolescent and parent participants will complete the baseline assessment. At the baseline assessment, parents will complete an in-depth clinical interview to assess the DLS that will be targeted in the intervention and a questionnaire packet. Adolescent participants will complete activities to directly assess their DLS and a questionnaire packet. All procedures for the baseline visit except for the ADOS, IQ test, and Behavioral Observation may be conducted via telehealth. Adolescent and parent participants will also complete 3 DPDs (two weekdays and one weekend) after completing the baseline assessment visit. Once an eligible cohort of 14 adolescents with ASD has been obtained and completed measures at the baseline assessment visit, adolescents will be randomly assigned to either the STRW or PEERS intervention using a stratified randomized block design with IQ (≥85 and <85) and age (≥17 and <17) as strata variables to ensure balanced group assignment for each cohort. Thus, across 4 cohorts, the goal will be to enroll up to 28 adolescents in both the STRW and PEERS groups during Years 1-4.

Randomization: Once an eligible cohort of 14 adolescents with ASD has been enrolled and completed measures at the baseline assessment, adolescents will be randomly assigned to either STRW or PEERS using stratified random sampling. The stratification is based on IQ (IQ<85 and IQ≥85) and age (≥17 years and <17 years) and will be used to ensure balanced group assignment for each cohort. A simple randomization within the strata will be generated and subjects will be assigned to one of the two groups. The randomization will be conducted by an individual independent of the study in order to reduce any potential biases. The clinical research coordinator who will conduct the daily phone diaries with adolescents and parents, DLS GAS interview with parents, and direct behavioral observation measures with adolescents will be blinded to study arm.

The STRW Intervention consists of 14 weekly (90 minute) concurrent sessions that both adolescents with ASD and their parents attend. The main daily living skills (DLS) targeted including Morning Routine, Laundry, Kitchen/Cooking, and Money Management. These skills are taught to adolescents using evidence-based strategies such as video modeling, task analysis, technology, and direct instruction. Parents are taught to facilitate practice and generalization of these DLS to the home. Sessions are flexible and can be individualized to address the specific needs of adolescents with ASD and their parents. Due to COVID-19, an undetermined number of sessions will be conducted via telehealth using a HIPAA compliant version of Zoom.

STRW Intervention Group:

STRW In-Person Sessions:

Adolescent Group Sessions.

Each week one DLS will be targeted. Through didactics, demonstration, role plays, small group activities, and direct teaching, therapists will discuss how to break down a target DLS into manageable steps and then work towards acquiring the DLS using effective evidence-based strategies for adolescents with ASD[2,58,67]. Adolescents will work with therapists in small groups to learn and practice the skill in session. While not directly targeted, appropriate social skills will be modeled (e.g., listening to others, respecting others' opinions) and discussed when relevant (e.g., tips for interacting with cashiers when grocery shopping, effectively negotiating with parents using the behavior contract). The importance of acquiring DLS will be discussed in each session to increase understanding and foster motivation.

Parent Group Sessions. Each week parents will receive instruction and detailed information (e.g., handouts, online and print resources) and have an opportunity to practice strategies or approaches to promote skill acquisition, maintenance, and generalization of targeted DLS for adolescents with ASD[2,58,67]. The content and activities of the adolescent sessions will be discussed in detail. Parents will be taught to use a behavior contract to increase adolescent motivation to engage in skill acquisition of targeted DLS in the home or community. The behavior contract, as it applies to each targeted DLS, will be reviewed each week and will be the primary method in which parents will motivate adolescents to work towards their DLS goals. Techniques to encourage independence will be discussed (e.g., fading prompts and rewards). The therapist in the parent group sessions will discuss the content of adolescent sessions in detail and also assist in problem solving any barriers (e.g., addressing decreased motivation from adolescent to work on DLS, developing parental skills to foster independence, cultural issues). Parents' skill acquisition and implementation will be further facilitated by the group process of sharing successes and problem-solving with each other.

STRW Telehealth Sessions:
The STRW parent sessions will be facilitated via video, using the HIPAA compliant version of Zoom. The format will be similar to the in-person sessions.
The STRW teen sessions will be scheduled and run by a psychology post-doctoral fellow or graduate student trainee. The sessions will be scheduled for 1 hour, and both parent and teen will participate. Targeted daily living skills will be practiced using the participant's home appliances and materials.

PEERS Control Group:
PEERS In-Person Sessions: PEERS is the control group and consists of 14 weekly (90 minute) concurrent sessions that both adolescents with ASD and their parents attend. Social-communication and interaction skills such as building friendships, handling arguments, dealing with teasing, arranging and attending outings with peers are targeted through direct instruction, modeling, and practice in adolescent sessions. Parents are taught how to build and reinforce social skills outside of sessions.

PEERS Telehealth Sessions: The PEERS parent and teen sessions will be run simultaneously using the HIPAA compliant version of Zoom. This will require families to have two devices so both parent and teen can attend sessions at the same time.

STRW and PEERS Follow-up visits: All randomized participants in the feasibility RCT will complete post-treatment and 6-month follow-up visits. Adolescent participants will complete a questionnaire packet and direct behavioral observation measures of their DLS. Parent participants will complete a questionnaire packet and clinical interview. All procedures for the post-treatment and 6 month follow up visits except for the Behavioral Observation may be conducted via telehealth. Both parent and adolescent participants will complete daily phone diaries (two weekdays and one weekend) after their post-treatment and 6-month follow-up assessment.

Follow Up Outcomes Survey
Parents may complete a one-time 15-20 minute outcomes survey to assess their child's current status in education, work, independent living, social connectedness, and daily living skills after completing the intervention in the last 18-42 months. This will provide us with feedback for the interview we are developing to look at longer-term outcomes after completing the daily living skills intervention.

MEASURES:
Baseline only:
The Background History Form will collect demographics including race, ethnicity, maternal education, household income, and current treatments and services. Information obtained from the Background History form will be utilized to describe the sample and as covariates in statistical analyses.

The Autism Diagnostic Observation Schedule, 2nd Edition (ADOS-2)[64] is a well-established clinician-administered diagnostic assessment. Either Module 3 or Module 4 of the ADOS-2 will be administered to all

adolescents at the baseline assessment to confirm ASD diagnosis. A previous ADOS may be used to confirm eligibility if was done less than 2 years ago or up to the discretion of the P.I. Dr. Duncan is research reliable and a certified trainer of the ADOS-2. In addition to being suited to screen for eligibility, the ADOS-2 will be used to describe the sample and as a predictor in statistical analyses.

The Stanford Binet Intelligence Scales, 5th Edition (SB5)[65] will be used to assess verbal, nonverbal, and overall cognitive abilities and will be administered at the baseline assessment. The SB5 will be used to confirm that the adolescent participant meets the inclusion criteria of a full-scale IQ >70 and will also be used as a predictor in statistical analyses.

Baseline, Post-Treatment, and 6-Month Follow-Up:
The Vineland Adaptive Behavior Scales, 3rd Edition (Vineland-3)[66] is a well-established standardized measure of adaptive behavior that assesses skills in the Communication, Daily Living Skills, and Socialization domains. The DLS domain is comprised of the Personal, Domestic, and Community subdomains and has items that directly correspond to goals being targeted in the STRW intervention. The Vineland-3 will be used at screening to confirm that the adolescent has deficient DLS (i.e., at least 1 of the 3 DLS subdomain standard scores is at least 15 points or more below full scale IQ). Raw scores and age equivalent scores on the DLS domain and subdomains will be used as a primary outcome measure.

Daily Phone Diaries (DPDs)[68,69]
The Daily Phone Diary uses a cued recall procedure to track adolescents with ASD and their parents through their activities over the past 24-hours and provides a fine-grained analysis of activity patterns, companions, level of prompting for activities, and mood [70,71]. For all activities lasting five minutes or longer, a parent and their teen reports the type of activity, duration, and who was present. The interviewer assists the parent and teen in reconstructing his/her day as accurately as possible by providing prompts, such as the time of day or information about the previous activity ("after you finished dinner, what did you do next?"). Each activity is recorded by the interviewer on a computer with the time, a set of activities, companions, level of prompting/assistance, and a rating scale for mood ranging from 1 (Extremely Negative) to 5 (Extremely Positive). After completing each DPD, parents and teens will also be asked about their level of satisfaction with completing the DPDs. A set of 3 DPDs (2 weekdays and 1 weekend day) will be conducted by phone. The 24-hour recall procedure was adapted for use with parents of children with asthma. The DPD has yielded reliable stability coefficients over a 3-week period (rs = .61-.71, p < .01) and high levels of interrater reliability (> 90%) in a cystic fibrosis population [70]. Furthermore, strong convergent validity was found for parental differential treatment between the DPD and both home interview and nightly rating scale measures for parents of toddlers [71]. Similarly, strong convergence (77-80% (Quittner et al., 1992)) was found for daily routines between the DPD and Self Observation Report Technique [72]. Activity codes for the DPD are presented in Table 1. Both parents and adolescents will complete 1 set of 3-day diaries at each time point.

Table 1. Activity Code Definitions

Activity	Definition
Basic Child Care	Meeting the basic physical needs of the child (e.g., putting to bed, dressing) and facilitating child activities (e.g., driving to activities/school)
Medical Care	Caring for the child's health, including disease-specific treatment regimens (e.g. AED therapy, attending physician/clinic visits, and general health concerns (e.g., well visits, immunizations)
Household Tasks	Engaging in general household chores, including cleaning, yard work, laundry, and grocery shopping

Meals	Preparing and consuming food (e.g., making dinner, fixing snacks, eating lunch)
Recreation at home	Engaging in leisure, relaxation, or social activities inside the home (e.g., reading, watching TV/movie, having friends over)
Recreation outside the home	Engaging in leisure, relaxation, or social activities outside of the home (e.g., going to mall, movie theater, visiting friends and family)
Work/Attending School	Engaging in paid employment in or outside of the home (e.g., driving to and from work, time at work)
Self-care	Caring for one's own physical needs, including bathing, dressing, and personal hygiene
Sleeping/Resting	Engaging in naps or sleeping at bedtime
Other	Includes all activities not encompassed in above categories, including time spent doing the DPD or one-time activities (e.g., wrapping gifts for a party)

Direct Behavioral Observations will be developed and piloted through task analyses of targeted DLS (e.g., separating clothing and loading a washing machine, using cash to purchase an item at the store, making macaroni and cheese in the microwave, etc.) to obtain an objective measure of DLS in adolescents with ASD. The direct behavioral observations will be completed by the adolescent performing several specific DLS in the kitchen or life skills room at CCHMC. For example, the adolescent will be given all necessary materials (e.g., eggs, butter, milk, salt, pepper, bowl, whisk, pan, etc.) and told to "Make scrambled eggs on the stovetop." The assessor will utilize a task analysis that includes all of the steps for the target DLS to record the number of incorrect and correct steps performed by the adolescent. After the activity is completed, a percentage of steps performed independently will be calculated for each targeted DLS[59].]
The direct behavioral observations will be obtained at the baseline, post-treatment, and 6-month follow-up assessments.

The Daily Living Skills Goal Attainment Scale (DLS-GAS)[73] will be created for each adolescent based on an in-depth clinical interview completed with the parent that assesses specific skills in all of the goals that will be targeted in the STRW intervention. The DLS targeted in STRW will be explicitly defined for each participant using GAS based on their current skill level. For example, for the targeted skill of laundry, parents will be asked to describe their adolescent's ability to independently separate clothes, use the washing machine and dryer, and fold and put clothes away. An independent clinical research coordinator who will not participate in any aspect of the STRW intervention will develop the DLS-GAS for each adolescent participant and evaluate change in goals on the DLS-GAS at post-treatment and 6-month follow-up assessments. The therapists facilitating the STRW intervention will not have access to the DLS-GAS. The DLS-GAS will be utilized as a primary outcome measure.

The ***Adaptive Behavior Assessment System, 3rd Edition (ABAS-III)[74]*** is a parent and self-report measure that assesses adaptive behavior in the conceptual, practical, and social domains. The raw scores and T-scores will be utilized to compare parent and adolescent ratings of DLS.

The ***Behavior Rating Inventory for Executive Function, 2nd Edition (BRIEF-2)***[75] is a parent and self-report measure that assesses executive functioning across 8 scales including initiate, emotional control, shift, inhibit, organize/plan, organization of materials, and working memory. Raw scores for the scales and indices will be utilized to explore the relationship between executive function and participation in the intervention.

The ***Social Responsiveness Scale, 2nd Edition (SRS-2)***[76] is a 65-item parent-report measure that assesses social functioning in the areas of social awareness, social cognition, social communication, social motivation, and restricted interests and repetitive behavior. Raw scores and T-scores will be utilized to explore the relationship between social skills and participation in the intervention.

The ***Behavior Assessment Scale for Children, 3rd Edition - Parenting Relationship Questionnaire (BASC-3 PRQ)***[77]***, Parent Rating Scales (BASC-3 PRS), Self-Report of Personality (BASC-3 SRP)***, the BASC-3 PRQ is a parent-report measure that assesses aspects of the parent-child relationship including attachment, communication, involvement, parenting confidence, and relational frustration. The PRS measures both adaptive and problem behaviors in the community and home setting. The SRP provides insight into a child's or adult's thoughts and feelings. Raw scores will be utilized to explore the relationship between parenting factors and participation in the intervention.

The ***Helicopter Parenting Questionnaire***[78] will be completed by adolescents and their parents and was adapted from another questionnaire. Five items, rated on a 5-point scale, assess parental involvement in making important decisions (e.g., solves any problem, intervenes in settling disputes with teachers). The raw score will explore the relationship between parental expectations and participation in the intervention.

The ***Parental Expectations Questionnaire***[79] will be completed by adolescents and their parents and was developed from the National Longitudinal Transition Study-2 to assess parental expectations in the areas of education, postsecondary school completion, and independence. Each item is scored on a 4-point Likert scale and the raw score will explore the relationship between expectations and participation in the intervention.

The **Family Quality of Life (FQOL) scale**[80] will be completed by parents and has 5 domains that assess family interaction, parenting, emotional well-being, physical/material well-being, and disability related support. Each of the 25 items is scored on a 5-point Likert scale and the raw score on each domain will explore the relationship between family quality of life and participation in the intervention.

The **Social Skills Improvement System (SSIS)**[81]
The SSIS (Gresham, 2008) is a parent and self-report measure that assesses social skills (i.e., communication, responsibility, self-control, cooperation), competing problem behaviors (e.g., externalizing, internalizing, bullying), and academic competence (e.g., motivation to learn). Raw scores and standard scores will be utilized to explore the relationship between social skills and participation in the intervention.
It will be completed by parents and adolescents at the baseline, post-treatment, and 6-month follow-up assessment visits.

Friendship Qualities Scale (FQS)[82]**.** The Friendship Qualities Scale is a teen self-report measure that assesses the quality of best friendships. It uses a Likert scale on each of the 23 items, from 1 to 5. Teens are instructed to identify their best friend and keep this friendship in mind when completing this measure. It has 5 subscales: companionship, closeness, help, security, and conflict.

Test of Adolescent Social Skills Knowledge (TASSK)[83]**.** The Test of Adolescent Social Skills Knowledge is a 26-item criterion-referenced test developed for PEERS to assess the teen's knowledge about the specific social skills taught during the intervention. Teens are presented with sentence stems and asked to choose the best option from two possible answers.

Quality of Socialization Questionnaire (QSQA and QSQP)[84]**.** The Quality of Socialization Questionnaire consists of 12 items, both teen and parent versions, to assess the frequency of get-togethers with peers over the previous month. It also assesses the level of conflict during these get togethers.

The Community Integration Scale is a 33-item measure that documents a person's involvement in their community. There is a parent version for their child, and a self-report version.

Child Concentration Inventory, Second Edition (CCI-2). The CCI-2 [85] is a child-report measure of SCT symptoms. The CCI-2 consists of 16 items that are rated on a four-point scale (0 = never, 1 = sometimes, 2 = often, 3 = always). There is evidence supporting the reliability and validity of the CCI-2 in children and adolescence [86].

Child and Adolescent Behavior Inventory (CABI). The CABI SCT module was derived from a meta-analysis which examined the stability and reliability of SCT items derived from various measures[87]. Parents will complete the CABI [88] SCT module. Recent studies support the reliability and validity of the CABI [89,90].

Outcomes Survey. This survey, completed by parents via Redcap survey, assesses their child's current status in education, work, independent living, social connectedness, and daily living skills.

DURATION:

Recruitment will begin in month 10 of Year 1. We will recruit 4 cohorts of 14 adolescents with ASD and their parents that will then be randomized to Surviving and Thriving in the Real World (STRW) or Program for the Evaluation and Enrichment of Relational Skills (PEERS). We plan on recruiting a total of 56 adolescent and parent participants during Years 1-4. All participants will complete an eligibility assessment, baseline assessment, 14-week intervention (STRW or PEERS), post-treatment assessment, and a 6-month follow-up assessment. The 3 DPDS (two weekdays and one weekend day) will be completed by both adolescent and parent participants within a week of the baseline, post-treatment, and 6-month follow-up assessment visits.

DATA ANALYSIS/METHODS:

Data Entry Procedures

Physical data, including test protocols that are collected at CCHMC will be housed in locked file cabinets in the PI's lab space. This space will be locked at all times. Only the principal investigator or other IRB approved members of the CCHMC research team will have access to the physical data.

All data for each participant will be labeled with a unique ID number. Source documents and protocols may be scanned to a PDF and stored as an electronic file in the secured CCHMC server. Data will be entered into REDCap, a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

After a family has completed participation, the physical files will be stored in locked cabinets at CCHMC. Audio and video recordings will be uploaded to a secure CCHMC server or external hard drive which only IRB approved staff will have access to. The hard drive will remain locked in a cabinet in staff office. Data in the electronic database are available indefinitely to qualified researchers who have access to the database. Thus, unless a participant indicates that they no longer consent to making their data available for analysis, de-identified electronic data will remain available for research in the database indefinitely. Audio recordings of parent interviews, video recordings of assessments, and video recordings of group sessions will be destroyed after data analysis has been completed and the study is closed. Physical data obtained from participants will also be housed by the PI indefinitely given that data collection has concluded. There may be reason to move the hard copy files to a different storage location at some point (e.g., P.I. change/move) either during or after the study. This will be approved through the IRB and all protected health information will remain secure. If at any time during or after the conclusion of the study, a participant requests that their data not be used, the PI will immediately destroy all physical data and also ensure that all electronic data connected to that participant be removed from the database.

Analyses

Power Analyses: The feasibility RCT is being conducted with the intent of examining the differences in DLS to be expected. Few studies have examined the trajectory of DLS in individuals with ASD[31,50,91], and no studies have examined how DLS develop during adolescence. Power calculations focused on the anticipated increase or improvement in the age equivalence scores of each of the Vineland-3 DLS subdomains for the STRW group and control group. We used conservative estimates of change in DLS subdomain age equivalence scores for our sample size estimation, even though a recent pre-post trial and pilot RCT on STRW found a mean improvement of 2.3 to 2.6 years across the 3 subdomains[32] from baseline to post-treatment.

Aim 1: For each Vineland-3 DLS subdomain, we anticipate that adolescents in the STRW group will have a mean improvement of 11 months (a mean gain in age equivalence of 11 months) at post-treatment compared to a mean improvement of 4 months in the control group. Assuming a conservative pooled standard deviation of 8.4, we will have 80% power to detect the above effect size (of 0.8) with 24 participants per group. Accounting for a potential 15% drop out rate, the effective sample size is 28 per group. Based on our past studies[32], we would expect the mean improvement in the STRW group to be 16 months, but we wanted to be conservative and estimate the sample size based on detecting a mean improvement as small as 11 months in the STRW group.

Aim 2: For each DLS subdomain, we anticipate that all participants who receive the STRW treatment will maintain treatment gains from post-treatment to 6-month follow-up.

A secure REDCap[92] database has been built and will be maintained for all measures administered in the current study. The primary DLS outcome measure for Aims 1 and 2 at post-treatment and 6-month follow-up is change in Vineland-3 DLS domain and subdomain raw scores and age equivalent scores. The secondary DLS outcome measure is change in score on the goals targeted on the DLS-GAS. The expectation is that the STRW group will have an increased change in score on both the Vineland-3 and DLS-GAS as compared to the control group (PEERS). The exploratory DLS outcome measures are (1) Daily phone diaries that assess the daily behaviors/experiences of adolescents with ASD (e.g., number of DLS completed for adolescents with ASD over a 24-hour period); (2) number of incorrect and correct steps for the task analysis of specific DLS as assessed by the direct behavioral observation measure; and (3) parent report and self-report of DLS as assessed by the ABAS-3. All analyses will be done using SPSS Version 20.0. Univariate statistics such as means, medians, and standard deviations will be computed for each variable to allow for examination of any outliers, variables that are not normally distributed, and heterogeneous variance between groups. The comparability of the STRW group and control group (PEERS) prior to treatment will be assessed using chi-square tests for categorical variables and t-tests for continuous variables.

FACILITIES and PERFORMANCE SITES:

The Division of Behavioral Medicine and ClinicalPsychology (BMCP) at Cincinnati Children's Hospital Medical Center (CCHMC) will serve as the project site for the recruitment and assessment of participants for the study. Assessment rooms (approximately 225 sq. ft.) within DDBP will be used for the assessments. The video and audio recording equipment needed for the project will be housed in this space for the duration of the project.

The in-person STRW treatment group and PEERS group meetings will be held in the Schubert Research Clinic through the Clinical Translational Research Center (CTRC) in the T building on CCHMC's campus. We will be using the Metabolic kitchen for the cooking portion of the group, as well as 2 other conference rooms for the parent and adolescent weekly meetings.

DATA SAFETY MONITORING PLAN:

The subject pool is a vulnerable population (i.e., adolescents with ASD) and there is the potential for adverse events. Therefore, we recognize the need for a careful data and safety monitoring plan to ensure the well-being of the adolescents in this study and scientific integrity of the project. The PI and her primary mentor will review and evaluate the accumulated data for participant safety, adverse events, study conduct and progress [as part of their weekly meetings. They will make recommendations to the appropriate regulatory agencies (i.e., IRBs, NIH) concerning continuation, modification, or termination of the study. In addition, provision will be made for an emergency meeting should any serious adverse events occur. The PI will prepare reports to be reviewed with her primary mentor and statistician at each quarterly meeting. Further, an independent safety

monitoring committee has been established to ensure the well-being of participants in the study and maintain the scientific integrity of the project. Dr. Anna Esbensen is a developmental psychologist and Dr. Julia Anixt is a developmental pediatrician. These individuals are not associated with this research project and work independently of the PI. They are not part of the key personnel involved in this grant. No member of the Committee has collaborated or co-published with the PI within the past three years. They are qualified to review the patient safety data generated by this study because of their unique expertise in research with (Dr. Esbensen) and clinical care (Dr. Anixt) of youth with ASD and other developmental disabilities. The PI and Mentor will meet with the independent safety monitoring committee every six months and review all reports listed below throughout Years 1-4 when participants are being actively seen or followed.

The reports will include a summary of the following topics: Performance Monitoring: A report of subject recruitment, comparison with targeted recruitment, retention, protocol adherence, and quality of data collection procedures. Safety Monitoring: A review of safety of the subjects, including confidentiality, any adverse events or side effects related to the treatment or study participation. Treatment Monitoring: A report of treatment integrity and compliance, which will include attendance to assessment and treatment visits. This will also include the data from the personnel who will be reviewing videotapes for the behavioral intervention. Stopping Rules: If a serious adverse event as a result of participation in the study occurs, participant accrual will discontinue until the PI and her primary mentor have reviewed the information with the independent safety monitoring committee and the subject has received adequate care. Participant recruitment will commence again only after the PI has been given permission to continue. In addition, if the subjects in the treatment group are not showing beneficial response to treatment (i.e., no significant change in skills), the PI and her primary mentor will meet with the independent safety monitoring committee and may make the determination that the study be modified or discontinued. Finally, if during the course of the trial, new information becomes available about the effects of behavioral intervention or other major advances in the treatment of DLS for adolescents with ASD that significantly impacts treatment approaches, the PI and her primary mentor will review the evidence with the independent safety monitoring committee to make a decision about discontinuing the trial.

POTENTIAL BENEFITS:
The potential benefits of this study to individual participants are many. Participants will receive a full diagnostic evaluation for ASD and will receive cognitive and adaptive behavior assessments. Thus, parents and adolescents who complete the eligibility assessment will receive a written report detailing 1) ASD diagnosis and profile of strengths and difficulties and 2) SB-5 and Vineland-3 scores. Further potential benefits for those enrolled in the feasibility RCT include the possibility that the STRW intervention will improve the participant's DLS and that the PEERS intervention will improve the participant's social skills.

A DLS intervention for adolescents with high functioning ASD has the potential to directly impact current functioning and future adult outcomes by increasing capabilities for skills that are needed for independent living, employment, post-secondary education, community participation, and socialization with peers. However, little research has been conducted on the development, implementation, and effectiveness of interventions targeting DLS in this population. The results of the current study may provide critical insight into how to target acquisition of DLS in adolescents with ASD via a group treatment model that utilizes components including evidence-based strategies, parent involvement, and targeted practice of newly learned skills in the clinic, home, and community settings.

POTENTIAL RISKS, DISCOMFORTS, INCONVENIENCES AND PRECAUTIONS:
While this study does include vulnerable subjects as described above, our research team has extensive experience with the unique needs of this population, thus we feel that this study does not present significantly increased risk to subjects beyond what is encountered in everyday life. The assessments (e.g., cognitive, adaptive behavior) they will be completing are similar to tasks conducted in our outpatient clinics to assess developmental skill levels with individuals with ASD. The treatment sessions will utilize evidence-based strategies and supports that are similar to those conducted clinically in our outpatient clinics. We will manage increased risks (i.e. inconvenience, time, and confidentiality) as described above to ensure a positive experience for participating adolescents with ASD and their families.

Cognitive/Behavioral assessments, DPDs, and direct behavioral observations of DLS: The assessments are somewhat time consuming (60 to 90 minutes) and may possibly lead to emotional distress or boredom when families are asked about their children's behavior or report on their experiences and behaviors during the DPDs. Further, adolescent participants may experience emotional distress or boredom when completing self-report assessments, reporting on their experiences/behaviors during the DPDs, or completing tasks that directly assess their DLS. One potential risk for adolescent and parent participants include fear or embarrassment resulting from clinical interviews or psychological testing. The questions and measures used in the study are standard for psychological evaluations and therefore have minimal risk associated with them. Adolescent and parent participants are free to not answer any questions to which they object.

Intervention*:* During the STRW and PEERS treatment groups, adolescent and parent participants may possibly experience emotional distress or embarrassment during group sessions in which specific skills and behaviors are targeted. The teaching strategies and format of group sessions are standard practice of care for adolescents with ASD and their parents. All therapists have significant experience working with adolescents with ASD and their families and will take precautions to minimize any emotional distress experienced.

The population of the study does include women capable of bearing children; however the study poses no additional risk to pregnant women. Also, this population is unlikely to engage in sexual behavior due to their mental disorder, therefore the risk of any participant becoming pregnant is extremely low.

Confidentiality*:* The potential for a breach in confidentiality always exists, specifically with the written research data and study databases.

PRIVACY & CONFIDENTIALITY:
Participants who indicate that they no longer wish to participate will not be contacted again for any reason.

Participants will be informed that all information they provide will be kept confidential unless there is a risk of harm to the participant or others (e.g., abuse, suicide, homicide), and/or if a clinician is required by law to make a report. Appropriate referrals will be provided in situations where follow-up clinical services are required.

Staff members will be trained on the importance of confidentiality and techniques to maintain confidentiality of all information reported by research participants. Detailed information related to data entry and storage procedures is detailed above in the Data Analysis/Methods section.

COST OF PARTICIPATION:
All procedures related to this study are for research purposes only. Families or third party payers will not be charged or billed for any part of the study procedures.

PAYMENT FOR PARTICIPATION:
Adolescent participants can receive up to a total of $190, and parent participants can receive up to a total of $265 as compensation for participating in the assessments (i.e., eligibility, baseline, post-treatment, and 6-month follow-up) and completing the DPDs at the baseline, post-treatment, and 6-month follow-up assessment visits. Specifically, parent and adolescent participants will each receive $25 as compensation at the eligibility assessments. Parent and adolescent participants who proceed to the baseline assessment will each receive an additional $25 as compensation. The parent and adolescent participants will each receive $40 as compensation at both the post-treatment and 6-month follow-up assessments. Parent and adolescent participants will also each receive $10 for each completed DPD (2 weekdays and 1 weekend day) completed at baseline, post-treatment, and 6-month follow-up assessment visits. Participants will receive up to $90 for completing 3 sets of 3 DPDs. Parents will receive $25 for the outcomes survey.

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