

Title: Pilot RCT of a Daily Living Skills Intervention for Adolescents with Autism Spectrum Disorder in the Last 2 Years of High School

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ABSTRACT:

Adolescents with high functioning ASD are not developing the skills necessary to successfully transition to the adult world in the areas of college, employment, independent living, and social interaction. Studies have consistently found that adults with high functioning ASD who have better developed daily living skills (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 (Farley et al., 2009; Shattuck et al., 2012). DLS are skills that allow individuals to function independently such as being able to cook, do laundry, and use a debit card to make purchases. Adolescents with high functioning ASD have impaired DLS that often fall 6-8 years below what would be expected based on their cognitive abilities and age (Duncan & Bishop, 2015; N L Matthews, Pollard, et al., 2015) and are most proficient in DLS that are typically acquired in preschool-aged children (e.g., eating, dressing, toileting) (Duncan et al., 2014). Thus, it is especially critical to develop DLS interventions for adolescents with ASD to facilitate a more successful transition to the adult world. Despite the strong and clearly documented link between DLS and adult outcome, there are no intervention packages that help adolescents develop age-appropriate DLS (N L Matthews, Pollard, et al., 2015; Palmen, Didden, & Lang, 2012). A DLS intervention package for adolescents with high functioning ASD that uses evidence-based strategies for teaching DLS and incorporates parents in the intervention has the potential to directly affect adult outcome by increasing capabilities for skills that are needed to succeed in college, employment, and independent living (Duncan & Bishop, 2015; Hume, Boyd, Hamm, & Kucharczyk, 2014; N L Matthews, Pollard, et al., 2015; Palmen et al., 2012; Taylor, Smith, & Mailick, 2014).

In the current study, we will examine how the *Surviving and Thriving in the Real World (STRW)* intervention improves the DLS of 72 adolescents with ASD in their last 2 years of high school. Our previous work has found that STRW can increase the DLS of adolescents with ASD by 2-2.5 years over the course of the intervention, which has significant and practical implications for both current functioning (e.g., maintaining a part-time job while in high school, managing a checking and savings account, cooking meals for oneself) and future adult outcomes (e.g., budgeting for monthly expenses, keeping one's apartment clean, making routine medical appointments, planning for meals for an entire week and then going grocery shopping). The current study will examine these outcomes and also explore how factors such as social-communication skills (e.g., understanding expectations, taking others' perspectives), executive functioning abilities (e.g., getting started on tasks, organizing, managing time), and parenting and family factors (e.g., parental stress, over-involvement in daily routines) may affect one's ability to acquire DLS.

PURPOSE OF STUDY:

The main objective of the current proposal is to conduct a pilot RCT (i.e., treatment group and social skills control group) to examine how participation in STRW affects proximal outcomes with a larger sample size ($n = 70$). As social skills, executive functioning, and parenting factors have been linked to the acquisition of DLS, the current study will also explore how these are linked to participation in STRW. Lastly, goal attainment scaling (GAS) will be utilized, along with gold standard parent report and adolescent self-report measures, to assess DLS.

Aim 1: Examine the effectiveness of Surviving and Thriving in the Real World (STRW) in a pilot RCT. Participants will be randomized to STRW or a social skills control group (Program for the Evaluation and Enrichment of Relational Skills-PEERS). The STRW group will show significant improvement on the Vineland Adaptive Behavior Scales, 3rd Edition (Vineland-3) and progress on targeted DLS using goal attainment scaling (GAS), baseline to post-treatment, as compared to the control group.

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Aim 2: Assess the maintenance of treatment gains 6-months after completion of STRW.

Participants in the STRW group will continue to show significant improvement on the Vineland-3 and progress on targeted DLS using GAS, baseline to 6-month follow-up, as compared to the control group.

Aim 3 (Exploratory): Examine how social skills, executive functioning, and parenting and family factors, which have all been linked to DLS, are affected by participation in STRW.

BACKGROUND:

Individuals with high functioning autism spectrum disorder (ASD) are not developing the skills necessary to successfully transition from adolescence to college, employment, and independent living. Recent studies (Centers for Disease Control and Prevention, 2014; Charman et al., 2011; Christensen et al., 2016) have found that nearly 50% of individuals with ASD can be classified as high functioning (i.e., IQ ≥ 70), and 25% have IQs in at least the average range (i.e., IQ ≥ 85). Despite their cognitive abilities, the outcomes of living independently, attending college, and being employed for adults with high functioning ASD are extremely bleak (Henninger & Taylor, 2013) 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 intellectual disability (Taylor & Seltzer, 2011). 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 (Magiati, Tay, & Howlin, 2014). 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 disabilities (Shattuck et al., 2012). One study found that only 12% of individuals with high functioning ASD attended a 4-year college (Shattuck et al., 2012). Further, only 50-55% of adults with high functioning ASD are employed in full or part-time jobs (Barneveld, Swaab, van Engeland, & de Sonnevile, 2014; Farley et al., 2009) and little is known about factors that prevent them from obtaining employment or being underemployed (Walsh, Lydon, & Healy, 2014). A study that examined the outcomes of adults with ASD within 4 years of graduating high school found that nearly one quarter of adults with high functioning ASD were not participating in any vocational, postsecondary, or community activities during the day, a rate 3 times higher than those with ASD and a comorbid intellectual disability (Taylor & Seltzer, 2011). 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 will lead to success in college, employment, and independent living (Chakrabarti & Fombonne, 2001).

Daily living skills 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 daily living skills (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 (Farley et al., 2009; Klinger, Klinger, Mussey, Thomas, & Powell, 2015; Orsmond, Shattuck, Cooper, Sterzing, & Anderson, 2013; Shattuck et al., 2012; Wei, Yu, Shattuck, McCracken, & Blackorby, 2013). 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 areas such as personal (e.g., brushing teeth, showering, putting on deodorant, taking medication, managing health care appointments), domestic (e.g., doing laundry, cooking snacks and meals, cleaning rooms), and community (e.g., managing a checking and savings account, budgeting money, managing time, using public transportation). The acquisition and mastery of DLS are critical for achieving certain milestones in adulthood including maintaining a job, attending and graduating from

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college, and living independently. For example, basic DLS such as taking a shower, wearing deodorant, and changing one's clothes are expected and essential when interacting with co-workers or classmates.

Despite the importance of daily living skills to adult outcome, adolescents with high functioning ASD have impaired daily living skills. Individuals with high functioning ASD gain DLS at a significantly slower rate compared to peers with typical development and even compared to peers with other developmental disabilities (Bal, Kim, Cheong, & Lord, 2015; Levy & Perry, 2011; N L Matthews, Smith, et al., 2015). Adolescents with high functioning ASD have impaired DLS that fall far below what would be expected based on their cognitive abilities and chronological age (Bal et al., 2015; Duncan & Bishop, 2015; Kanne et al., 2011; Klin et al., 2007; N L Matthews, Pollard, et al., 2015). *Duncan* and Bishop (Duncan & Bishop, 2015) 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 Adaptive Behavior Scales, 2nd Edition (Vineland-II) (S. S. Sparrow, Cicchetti, & Balla, 2005). 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 (N L Matthews, Pollard, et al., 2015). Thus, a high percentage of adolescents with high functioning ASD have DLS that are 6-8 years below their chronological age (Bal et al., 2015). *Duncan* and Bishop (Duncan & Bishop, 2015) 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 (Duncan et al., 2014) 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, getting dressed, toileting), but deficits in skills critical for independent functioning such as engaging in regular hygiene routines, completing household tasks such as laundry and cooking, managing time and money, and traveling in the community. Another recent study confirmed DLS deficits in both adolescents and young adults with ASD in areas such as taking medications, preparing basic foods, preparing complex recipes, planning meals, counting change from a purchase, using a checking or savings account, and budgeting money (Nicole L Matthews, Malligo, & Smith, 2017). These studies highlight the dire need for interventions that target commonly impaired DLS, especially before adolescents with ASD exit high school. These DLS deficits likely contribute to difficulties in college, employment, independent living, socialization, and overall quality of life for high functioning adults with ASD (Orsmond et al., 2013; Wei et al., 2014; Wei et al., 2013).

A complex set of environmental, individual, and family factors likely affect the ability of adolescents with high functioning ASD to acquire critical daily living skills. 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 (S. S. Sparrow et al., 2005). However, there are barriers that 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, black and white thinking) associated with their ASD diagnosis (Hume et al., 2014; Kapp, Gantman, & Laugeson, 2011; Shattuck et al., 2007; Tantam, 2003; Taylor & Seltzer, 2010); (2) executive function difficulties (Hume et al., 2014; Pugliese et al., 2015; Pugliese et al., 2016; Wallace et al., 2016) (e.g., self-monitoring, initiating tasks, planning and organizing, following multi-step directions); (3) parenting factors (Drahotá, Wood, Sze, & Van Dyke, 2011; Green & Carter, 2014; Hall & Graff, 2011; Kirby, 2016; Tomanik, Harris, & Hawkins, 2004) (e.g., setting appropriate expectations for current and future behaviors, decreased fostering of independence); (4) family quality of life (Gardiner & Iarocci, 2015) (e.g., stress, cohesiveness); (5) being overly dependent on others at school and home (Hume et al., 2014); and (6) lack of quality, affordable services to support adolescents with ASD and their families (Baghdadli et al., 2012; H. Chiang, Ni, & Lee, 2017; Magiati

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et al., 2014; Tantam, 2003). The above factors likely contribute to DLS deficits and undoubtedly contribute to making the transition to adulthood particularly challenging. Thus, adolescents with high functioning ASD and their parents require additional supports to learn DLS that factor in their unique profile of strengths and difficulties.

There are currently no evidence-based daily living skills 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 (Duncan & Bishop, 2012; Kanne et al., 2011; Matson, Hattier, & Belva, 2012; N L Matthews, Pollard, et al., 2015; Palmen et al., 2012; Smith, Maenner, & Seltzer, 2012). A 2016 Government Accountability Office (GAO) report (US Government Accountability Office (GAO), 2016) on Youth with Autism 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). The report also noted that family training and support is integral for teaching DLS so that it can generalize from the clinic setting to home and community settings. 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 DLS to adolescents with ASD (Bennett & Dukes, 2014; Flynn & Healy, 2012; Hume & Reynolds, 2010; Matson et al., 2012; Mechling, Gast, & Seid, 2009; National Autism Center, 2015; Palmen et al., 2012; Wong et al., 2015). Other evidence-based strategies such as parent-implemented intervention, social narratives, and visual supports have been shown to lead to acquisition of DLS for children and younger adolescents with ASD (Flynn & Healy, 2012; Hong et al., 2015; Hume & Reynolds, 2010; National Autism Center, 2015; Wong et al., 2015). The few studies that have demonstrated successful acquisition of DLS in adolescents with ASD using evidence-based strategies are often designed for individuals with ASD and a comorbid intellectual disability and/or focus on simplistic DLS (e.g., counting money, cooking a specific recipe in the microwave, making a clay pot). Further, many of the DLS treatment studies lack parental involvement because they take place in the classroom or clinic setting (Bennett & Dukes, 2014; National Autism Center, 2015; Wong et al., 2015). Integration of parents into an intervention targeting DLS is critical to its success because DLS need to be taught, mastered, and generalized in the adolescent's natural environment (e.g., at home, while out in the community, etc.). Lastly, the few DLS studies that have been conducted often lack the rigor of a randomized clinical trial (RCT) as they have been conducted with fewer than 5 participants or are case studies or single subject design studies. Thus, a sophisticated 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 practice in the home when targeting DLS (Drahotka, Sterling, Hwang, & Wood, 2013; Duncan & Bishop, 2015; Hume et al., 2014; Kanne et al., 2011; N L Matthews, Pollard, et al., 2015; Palmen et al., 2012; Smith et al., 2012; Taylor et al., 2014) is lacking. *A DLS intervention package that incorporates that above 4 components has the potential to directly affect current functioning and future adult outcomes by increasing capabilities for skills that are needed to succeed in college, employment, and independent living.*

STUDY DESIGN:

Pilot RCT of Surviving and Thriving in the Real World (STRW): The pilot RCT will consist of running 5 cohorts of 16-20 high functioning adolescents with ASD ($IQ \geq 70$) and their parents in a

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STRW treatment group or social skills control group. Once an eligible cohort of 16-20 adolescents with ASD has been recruited, adolescents will be randomly assigned to either the STRW group or control group using a stratified randomized block design with IQ as a strata variable (IQ<85 and IQ≥85) to ensure balanced group assignment for each cohort. Approximately 8-10 adolescents with ASD and their parents will participate in each STRW group. Thus, across 5 cohorts, the goal will be to enroll at least a total of 70 adolescents in the study, 35 in the STRW group and 35 in the control group across Years 1-3.

SELECTION AND RECRUITMENT OF PARTICIPANTS:

Inclusion Criteria

The inclusion criteria for the 70 adolescent participants include the following: between the ages of 15-22, in the last 2 years of high school (i.e., in the 11th or 12th grade or has deferred their high school graduation); a diagnosis of ASD (based on clinical judgement and/or meeting the cut-off score on the Autism Diagnostic Observation Schedule, 2nd Edition; ADOS-2)(Lord et al., 2012); a full scale IQ of 70 or above as measured by the Stanford Binet Intelligence Scales, 5th Edition (SB-5)(Roid, 2003); and deficient DLS as assessed by the Vineland Adaptive Behavior Scales, 3rd Edition(S. Sparrow, Cicchetti, & Saulnier, 2016) (Vineland-3; i.e., at least 1 of the 3 Daily Living Skills subdomains is at least 15 points below their full scale IQ).

Exclusion Criteria

Exclusion criteria include significant aggressive behaviors or mental health issues that require treatment out of the scope of the current intervention. Information about medication usage and services/therapies received at home, school, or community will be collected at each assessment. 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

Via Flier: Participants will be recruited from The Kelly O'Leary Center for ASD (TKOC) at Cincinnati Children's Hospital Medical Center (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 Dr. Duncan's Autism Adolescent Assessment Clinic in TKOC; (2) Dr. Duncan's existing research database of 150 adolescents with ASD who have participated in her previous studies; (3) existing research database of adolescents with ASD who have participated in various research studies at TKOC; (4) fliers that will be distributed and/or posted in TKOC and CCHMC; (5) fliers that will be distributed and/or posted at schools, community events, and organizations (i.e., Autism Society of Greater Cincinnati); (6) fliers that will be distributed to community providers (e.g., psychologists, social workers, etc.); and (7) previous research participants through the Department of Child Psychiatry. We will also recruit military families in the area by partnering with the Exceptional Family Member Program located at Wright Patterson Air Force Base in Dayton, Ohio through research fliers. Families of adolescents meeting criteria for the initial screening will be sent (via postal service) a letter describing the study along with a "Do not contact" return addressed, stamped postcard (see Appendix A and Appendix B). Families who do not return the "Do not contact" postcard within 10 days will then be contacted by study staff via phone call and/or email to provide additional information about the study, address any questions the guardian/parent and adolescent may have about the project, and complete the phone screening for inclusion/exclusion criteria. Families who meet initial screening criteria and express interest will be scheduled for a baseline visit where final eligibility will be determined. Families of adolescents who contact the study staff in

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response to fliers posted in the community will receive the same information, screening, and invitation to a baseline visit as described above.

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 (i.e., between the ages of 15-22, diagnosis of ASD, and $IQ \geq 70$). 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 sent (via postal service) a letter describing the study along with a “Do not contact” return addressed, stamped postcard (see Appendix A and Appendix B). Families who do not return the “Do not contact” postcard within 10 days will then be contacted by study staff via phone call and/or email to provide additional information about the study, address any questions the guardian/parent and adolescent may have about the project, and complete the phone screening for inclusion/exclusion criteria. Families who meet initial screening criteria and express interest will be scheduled for a baseline visit where final eligibility will be determined. 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.

PROCESS OF OBTAINING CONSENT:

Participation in the study will be completely voluntary and solely for research purposes. Participation or lack of participation in the study will not affect any services the patients receive from CCHMC. For adolescents enrolled in CCHMC clinical programs a chart review will be conducted to screen for eligibility followed by a phone screening to determine if they meet initial eligibility criteria. Families of adolescents responding to community fliers will receive the phone screening. If initial eligibility criteria is met during the phone screen, adolescent and parent participants will complete a baseline pre-assessment that will formally assess inclusion criteria using standardized assessments and research personnel will also obtain informed consent from the parent/caregiver. 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 HIPAA 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.

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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.

During the pre-assessment prior to any data collection, the study objectives and procedures will be explained to the participant by one of the members of the study staff. If they wish to participate, parental permission will be obtained from the parents, and assent will be obtained from the participant if they are under 18 years of age. Informed consent will be obtained from participants 18 and over who are their own guardian or parents will sign on the LAR line for their adult child if they are not their own guardian. When a child that was under 18 years old at the time they were enrolled in the study becomes of legal age while participating in the study, we will have them sign the Informed Consent document if they are their own guardian.

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:

Phone Screening. When talking to interested participants, the research team will assess whether they meet initial criteria (e.g., age, diagnosis of autism, at least average cognitive abilities based on previous cognitive testing, and deficient daily living skills based on parent report) prior to scheduling the baseline pre-assessment.

Baseline Pre-Assessment. Adolescent participants will be assessed using the SB-5 to confirm that their full scale IQ is greater than or equal to 70 and the ADOS-2 to measure their level of autism symptomatology. Both clinical impressions and the ADOS-2 cutoff score will be used to determine if the adolescent meets criteria for a diagnosis of ASD. If a subject has previously completed IQ testing

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or the ADOS-2, either clinically or for a previous study, record of this exam including scoring may be utilized in this project if the results are considered acceptable for use by the Principal Investigator (i.e., completed within the last 2 years, completed by a psychologist who is research reliable on the ADOS-2). The parent participants will complete the Vineland-3 to confirm that their adolescent has deficient daily living skills (i.e., 15 points below their full scale IQ in 1 of the 3 Daily Living Skills subdomains) and a clinical interview that assesses specific daily living skills that will be targeted in the STRW intervention. The baseline assessment will include parent questionnaires, a parent interview, and an adolescent assessment (in which they will also complete questionnaires) and will take approximately 2-3 hours for both parent and adolescent participants to complete. All procedures for the baseline visit except for the ADOS and the IQ test may be conducted via telehealth. Information about medication usage and services/therapies received at home, school, or community will be collected at each assessment. The parent interview will be audio or video taped to assist in the development of goals using the method of goal attainment scaling (GAS). If inclusion criteria is met, participants will then be randomized to either the STRW group or the social skills group.

Post-Treatment and 6-Month Follow-up.

The post-treatment and 6-month follow-up assessments will include parent questionnaires, a parent interview, and adolescent questionnaires and will take approximately 60-90 minutes for both parent and adolescent participants to complete. All procedures for the post-treatment and 6 month follow up visits may be conducted via telehealth. Information about medication usage and services/therapies received at home, school, or community will be collected at each assessment. The parent interview will be audio or video taped to assist in the development of goals using the method of goal attainment scaling (GAS).

The STRW treatment group and the PEERS control group will complete 3 research assessments (baseline, post treatment, and 6 month follow up).

12-Month, 18-Month, and 24-Month Parent Follow-Up

We will conduct a phone interview with the parent at 12, 18, and 24 months from the end of the group. We will complete the Vineland-3 Interview, and a short follow-up survey to get current information about the young adult participant. The 12, 18, and 24 month data may or may not be collected based on when a participant completed the intervention. Therefore, Cohort 1 will only do the 24 month visit, Cohort 2 will do 18 and 24 month visit, Cohorts 3-5 will do the 12, 18, and 24 month visit. We will re-consent any family who both 1.) Agrees to complete these time points, and 2.) Signed a previous version of the consent.

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

Electronic administration and scoring will be used when possible for all measures excluding the ADOS-2 and the Stanford Binet 5. The ADOS-2 may be video recorded for training and reliability purposes.

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

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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)***(Lord et al., 2012) is a well-established clinician-administered diagnostic assessment. Module 4 of the ADOS-2 will be administered to all adolescents at the baseline assessment to confirm ASD diagnosis. 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. As noted, this will only be collected at the first baseline time point for both groups.

The ***Stanford Binet Intelligence Scales, 5th Edition (SB-5)***(Roid, 2003) 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. As noted, this will only be collected at the first baseline time point for both groups.

Baseline, Post-Treatment, and 6-Month Follow-Up:

The ***Vineland Adaptive Behavior Scales, 3rd Edition (Vineland-3)***(S. Sparrow et al., 2016) 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.

The ***Daily Living Skills Goal Attainment Scale (DLS-GAS)***(Ruble, McGrew, & Toland, 2012) 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)***(Harrison & Oakland, 2015) 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)*** (Giola, Isquith, Guy, & Kenworthy, 2000) 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)***(Constantino, 2012) is a 65-item parent-report measure that assesses social functioning in the areas of social awareness, social cognition,

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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 (BASC-3)***(Kamphaus & Reynolds, 2015), is a comprehensive set of rating scales and forms including the Teacher Rating Scales (TRS), Parent Rating Scales (PRS), Self-Report of Personality (SRP), Student Observation System (SOS), and Structured Developmental History (SDH). Together, they help you understand the behaviors and emotions of children and adolescents. This study will utilize the Parent Rating Scales (BASC-3 PRS Adolescent), the Self-Report of Personality (BASC-3 SRP Adolescent), and the Parent Relationship Questionnaire (BASC-3 PRQ Child/Adolescent).

The ***Helicopter Parenting Questionnaire***(Padilla-Walker & Nelson, 2012) 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***(H. M. Chiang, Cheung, Hickson, Xiang, & Tsai, 2012) will be completed by 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***(Hoffman, Marquis, Poston, Summers, & Turnbull, 2006) 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 ***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 (Becker, 2015) 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 (Sáez, Servera, Burns, & Becker, under review).

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(Becker et al., 2016). Parents will complete the CABI (Burns, Lee, Servera, McBurnett, & Becke, 2015) SCT module. Recent studies support the reliability and validity of the CABI (Becker, Burns, Schmitt, Epstein, & Tamm, 2017; Sáez, Servera, Becker, & Burns, 2018).

The Social Skills Improvement System (SSIS). 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.

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Friendship Qualities Scale (FQS). The Friendship Qualities Scale (Bukowski, Hoza, & Boivin, 1994) 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). The Test of Adolescent Social Skills Knowledge (Laugeson, Frankel, Mogil, & Dillon, 2009) 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 Play Questionnaire (QPQ). The Quality of Play Questionnaire (Frankel & Mintz, 2008) 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.

Follow Up Young Adult Survey Questions. This survey was created by the study P.I. and is conducted interview-style by study staff. It is compilation of questions obtained from the NLTS-2 WAVE 5 Parent and Young Adult Forms, which are free to the public. The purpose of the measure is to examine how participation in Surviving and Thriving in the Real World daily living skills intervention affects future outcomes.

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.

STRW Intervention Group:

The STRW intervention consists of 14 weekly concurrent adolescent and parent group sessions. The DLS to be targeted in the intervention include: *Morning Routine* (i.e., completing a morning personal hygiene routine); *Laundry* (i.e., sorting clothing, using a washing machine and dryer, and folding and putting clothes away); *Kitchen/Cooking* (i.e., cooking items in the microwave, oven, and stove, safe kitchen practices, cleaning up the kitchen after cooking, and grocery shopping); *Self-Management* (i.e., managing worry and stress related to learning DLS and transitioning to adulthood); and *Money Management* (i.e., using money to purchase items, evaluating the quality and price of items, understanding and using a checking and savings account, and budgeting money to cover expenses). The above targeted skills are based on the preliminary studies conducted by Dr. Duncan on common DLS deficits in high functioning adolescents with ASD (Duncan, Ruble, Meinzen-Derr, Thomas, & Stark, in press; Duncan et al., 2014). Several evidence-based strategies will be utilized to help adolescents acquire specific DLS in session and then generalize these skills to the home and the community. Specifically, in adolescent group sessions, visual strategies such as creating a task analysis and checklist of steps (e.g., the steps involved in doing laundry) are used to increase skill acquisition. Technology such as video modeling (e.g., creating a movie of one completing their personal hygiene routine that can be watched on their computer or phone) or apps for smart phones (e.g., money management app, grocery store app, cooking app with videos of recipes) are also used because these have been shown to be an effective way to understand and learn targeted skills in other areas of functioning and increase motivation for learning new skills (Burton, Anderson, Prater, & Dyches, 2013; Satriale, Chance, & Nepo, 2009) in individuals with ASD. Parent participants will receive instruction on how to utilize evidence-based strategies to teach and generalize DLS for adolescents with ASD including a behavior contract, task analysis, chaining, modeling, reinforcement, rewarding reasonable attempts, prompting, prompt fading, generalization, incorporating special interests, visual strategies, self-management, video modeling, and technology (Hume et al., 2014;

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National Autism Center, 2009; Wong et al., 2015). Due to COVID-19, an undetermined number of sessions will be conducted via telehealth using a HIPAA compliant version of Zoom.

STRW In-Person Sessions: The STRW parent sessions will be facilitated by the PI. The STRW adolescent sessions will be facilitated by a psychology post-doctoral fellow and graduate student trainees (e.g., in the fields of psychology and occupational therapy) recruited from the Leadership Education in Neurodevelopmental Disabilities (LEND) training program at CCHMC (see letter of support for additional information).

Group Sessions. Each group session lasts 90 minutes and consists of four main components: (1) Overview of session activities; (2) Updates from group members on progress towards DLS goals being targeted and weekly homework assignments; (3) Divide into separate parent and adolescent groups to work on session-specific content; and (4) Reconvene as a group to summarize and share the activities that were done during the session and discuss homework assignments targeting the DLS goals for the week. Weekly homework assignments will be given to the adolescent to encourage acquisition, maintenance, and generalization of skills to the home and/or community (e.g., do laundry at home, purchase items at a grocery store using a pre-defined budget). Completion of homework assignments will be tracked at each session via parent and adolescent report. In addition, parents will be contacted by email or text message (parent preference) each day to track completion of homework assignments. Throughout each session, the therapists will facilitate the development of a behavior contract that specifies when the newly taught DLS will be practiced and the contingent reward that the parent will provide (see Figure 3 for an example of a completed behavior contract). At the end of each session, parent and adolescent pairs will complete feasibility, acceptability, and satisfaction surveys.

Adolescent Group Sessions.

Each week one DLS will be targeted. Through didactics and demonstration, therapists will teach and model how to break down a target skill into manageable steps and then work towards completing each step using evidence-based strategies that have been shown to be effective for adolescents with ASD (Hume et al., 2014; National Autism Center, 2009; Wong et al., 2015). For example, for the session targeting cooking on the stovetop, therapists will utilize visual strategies (e.g., following a recipe with both written directions and pictures of each step), technology (e.g., viewing a video of how to cook scrambled eggs using a phone app that has both recipes and accompanying videos that demonstrate how to cook the recipe), and direct instruction and feedback as each adolescent participant prepares, cooks 1-2 items, and cleans up the kitchen area. Adolescents will work with therapists as a group to learn and practice the skills in each session. While not directly targeted, appropriate social skills will be modeled (e.g., listening to others, respecting others' opinions, offering appropriate advice to other teens) and discussed when relevant (e.g., tips for interacting with cashiers when grocery shopping, how to effectively negotiate 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 direct instruction on skills that have been found to be established strategies or approaches to promote skill acquisition, maintenance, and generalization for adolescents with ASD (Hume et al., 2014; National Autism Center, 2009; Wong et al., 2015). Direct instruction will be combined with practice utilizing these skills through role play. Parents will be taught to use a behavior contract (see Figure 3 for an example of a completed behavior contract) to target the adolescent practicing the specific DLS that are addressed in the intervention. The behavior contract, as it applies to each skill, will be reviewed each week and will be the primary method in which parents will hold adolescents accountable for working towards their DLS goals. The therapist in the parent group sessions will also discuss barriers (e.g., addressing

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decreased motivation from teen to work on DLS, developing parental skills to foster independence with DLS, identifying rewards to increase the likelihood of continued skill development) and assist in problem-solving these barriers.

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.

The PI will provide weekly supervision to all fellows and trainees that facilitate the STRW adolescent sessions. Both in-person and telehealth sessions will be videotaped and coded for treatment adherence and fidelity. A blinded coder will complete a treatment adherence and fidelity checklist on 25% of the sessions chosen at random.

PEERS Control Group:

Due to COVID-19, an undetermined number of sessions will be conducted via telehealth using a HIPAA approved version of Zoom.

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. The purpose of the control group is to allow us to assess change in daily living skills in a group of high functioning adolescents with ASD who have deficient daily living skills but do not receive systematic behavioral treatment targeting specific skills using evidence based strategies.

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.

DURATION:

The entire study will last from October 2018 through December 2022. Participant recruitment and randomization will begin in October 2018. The duration of the study per participant randomized to either STRW or the control group is approximately 12 months. Data collection will be completed by Dr. Duncan and approved research personnel. Data analysis and reporting of results pertaining to the primary aims of the current study are expected to continue through December 2022.

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.

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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

A secure REDCap⁸⁰ database has been built and will be maintained for all measures administered in the current study. The primary analysis will be conducted with an intent-to-treat approach. The primary outcome measures for Objectives 1 and 2 at post-treatment and 6-month follow-up are (1) change in Vineland-3 DLS domain raw score and age equivalent score and (2) change in score on the goals targeted on the DLS-GAS. We will also evaluate the Vineland-3 subdomain raw scores and age equivalent scores. 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. 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 two groups in some measured baseline covariates prior to treatment will be assessed using chi-square tests for categorical variables and t-tests for continuous variables. Variables found to be non-normal will be transformed using appropriate functions to confirm with the normality assumptions.

To test Aim 1: Initially a two-sample t-test will be used to test the difference on the change scores in the Vineland-3 DLS domain and GAS (post-treatment and baseline) between the STRW and control groups. Although this is a randomized study it is possible that some of the demographic variables might be differentially distributed between the groups. In this case, the initial analysis will be followed by a general linear regression analysis where cohort will be treated as the main effect and other differentially distributed variables will be added to the model as possible confounders in order to investigate the independent effect of the intervention group on outcome.

To test Aim 2: The within-subject change between post-treatment and 6-month follow-up for each individual receiving the intervention will be calculated and a paired t-test will be conducted to evaluate this change (post-treatment and 6-month follow-up).

To test Aim 3: Exploratory analyses will be conducted to examine the relationship between progress in DLS and executive functioning, social skills, and parenting and family factors. A regression analysis will be used to estimate and examine this potential relationship. In this model the change score (post-treatment and baseline) will be modeled as a function of each of the measures of executive function, social skills and parenting and family factors. This will allow us to characterize the response profile.

Missing data methods

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All missing data will be discussed and every effort will occur to ensure all data are accounted for. Parents will be given multiple opportunities to fill out parent-report forms. To minimize possible loss to follow up, we will stay in close contact with families and identify any potential barriers to successful completion. Despite these efforts, missing data may occur. We will first examine the missing pattern to determine if missingness occurs systematically and differentially for each group, and tabulate the reason for missingness. Assuming at random, we will use multiple imputation technique to generate multiple datasets and systematically combine the estimates obtained from each dataset and associated variability. We will also investigate the potential that the missingness is not at random by performing sensitivity analysis recommended for clinical studies. Suspected biases will be taken into account in the interpretation of results.

Sample Size and Power Calculations

The pilot 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 (Baghdadli et al., 2012; Bal et al., 2015; Szatmari et al., 2009), 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 on STRW with 7 participants found a mean improvement of 2.3 to 2.6 years across the 3 subdomains (Duncan et al., in press) from baseline to post-treatment.

Aim 1: For each DLS subdomain, we anticipate that adolescents in the STRW group will have a mean improvement of 9 months (a mean gain in age equivalence of 9 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 0.71) with 32 participants per group. We will have 90% power to detect an effect size of 0.82 (a 9.9-month difference in the change of age equivalents between groups).

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

FACILITIES and PERFORMANCE SITES:

The Division of Behavioral Medicine and Clinical Psychology (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 and control group sessions 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 use 2 conference rooms for the parent and adolescent weekly meetings. We will be using the Metabolic kitchen for the cooking portion of the STRW group.

POTENTIAL BENEFITS:

We hope that all participants in the intervention group will benefit greatly from the individualized intervention in daily living skills provided in this study. We also hope it may increase skills in other areas and by incorporating parental involvement, potentially directly affect current functioning and future adult outcomes by increasing capabilities for skills that are needed to succeed in college, employment, and independent living. Further potential benefits for those enrolled in the PEERS intervention include hopefully improving the participant's social skills. However, it is important to

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emphasize that this study is being conducted for research purposes and does not ensure better or safer treatment nor guarantee individual benefits to the participant. Participants will receive monetary compensation for their time spent completing the study protocol.

A possible indirect benefit of this research is the knowledge that results from this project might positively impact the ability of researchers to obtain a better understanding of issues related to the postsecondary education, employment, and the overall transition to adulthood for individuals with DD. Further, this may lead to an increase in better services and supports as they make the transition to adulthood.

POTENTIAL RISKS, DISCOMFORTS, INCONVENIENCES AND PRECAUTIONS:

The risks associated with participating in the study are considered to be minimal and are commensurate with everyday risks. All of the measures used in this study have been used in previous research. Participants may experience transient emotional distress upon completing some of the interviews and questionnaires, which ask about their child's development or affective state. The clinicians and researchers who will be conducting the assessments are trained to assess and minimize any discomfort that results from the interviews or questionnaires. In the event that a participant finds the psychological evaluation mildly anxiety provoking, interviewers will express empathy and test-appropriate encouragement and reassurance. All participants will be informed that their participation is completely voluntary, and that they are free to withdraw from the study at any time.

The population of the study does include women capable of bearing children; however the study poses no additional risk to pregnant women.

RISK/BENEFIT ANALYSIS:

Based on the stated potential benefits and potential risk, we believe the study is considered "Minimal Risk", without potential direct benefit to the participants. Based on this assessment, we believe there is no need for a Data Safety Monitoring Board. The P.I. will be responsible for monitoring the study data through consistent communication with the coordinator during each phase. We will report any unanticipated problems and unexpected adverse events per CCHMC policy R-18.

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:

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Both adolescent and parent participants will each receive \$50 as compensation for the baseline assessment prior to randomization. For both the post-group and 6-month follow-up assessments, parent participants will receive \$50 for compensation. For both the post-group and 6-month follow-up assessments, adolescents will receive \$25 for compensation. Parents will also receive another \$25 for each of the 12 month, 18 month, and 24 month calls, if they complete them. Parents will receive \$25 for the outcomes survey. Thus, adolescents will receive a total of \$100 and parent participants can receive a total of up to \$250 as compensation for participating in the assessment visits. Screen fails will receive \$25 for parent and teen for coming to the pre-assessment but not completing all the measures.

Participants will not be compensated for attending the daily living skills treatment sessions or the PEERS group sessions.

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Appendix A – Recruitment Flier



Dear Parent,

You are receiving this letter because your child has been a patient or research participant at Cincinnati Children's Hospital Medical Center (CCHMC), and/or you have an upcoming appointment in the Division of Developmental and Behavioral Pediatrics (DDBP) or Psychiatry.

Researchers in DDBP are conducting a study designed to help adolescents with an autism spectrum disorder learn different daily activities (e.g., cooking, doing laundry, managing money, morning and evening hygiene routines) by participating with their parents in a 14-week group intervention. Participants will be randomized to the daily living skills group or a social skills group called PEERS (Program for the Evaluation and Enrichment of Relational Skills). Currently, we are inviting families of adolescents who have at least average IQ (i.e., full scale IQ >70), are in their last two years of high school (i.e., are in 11th or 12th grade, or have deferred graduation), and have an autism spectrum disorder to participate. You cannot have participated in the PEERS group previously through CCHMC.

If you are eligible and decide to participate in this study, you will be asked to participate in a baseline pre-assessment which will include parent questionnaires, a parent interview, and an adolescent assessment and will take approximately 2-3 hours for both parent and adolescent participants to complete. The intervention will be 1.5 hours long for 14 weeks. The intervention is not billed to insurance. There will also be a post-group assessment and 6 month follow up for parent participants that will last approximately 1-2 hours. Your child will receive \$100 and you will receive \$150 as compensation for participating in the intervention and assessment visits.

If you would like to learn more about participating in this study and complete a brief prescreening interview to see if your family is eligible, please contact Meera Patel at (513) 803-8901 or meera.patel2@cchmc.org.

If you would NOT like to be contacted about this research study, please drop the "Do Not Contact" postcard in the mail, and we will not contact you.

Sincerely,

Amie Duncan, Ph.D.
Assistant Professor
Division of Developmental and Behavioral Pediatrics
Cincinnati Children's Hospital Medical Center

Meera Patel
Clinical Research Coordinator II
Division of Developmental and Behavioral Pediatrics
Cincinnati Children's Hospital Medical Center

v.3, 12/5/18

**Pilot RCT of a Daily Living Skills Intervention for Adolescents with Autism Spectrum Disorder
in the Last 2 Years of High School**

**Pilot RCT of a Daily Living Skills Intervention for Adolescents with Autism Spectrum Disorder
in the Last 2 Years of High School**

Appendix B – Post Cards (front and back)

Postcard ID#: _____

“STRW”

(Surviving and Thriving in the Real World (STRW): A Daily Living Skills Intervention)

By returning this postcard, I am indicating that I have received and read the information regarding the STRW study for adolescents in their last 2 years of high school. I am also indicating that I do not want to receive further contact regarding the study and do not wish to participate. (needs stamp)

v.1 4/18/18



Cincinnati Children's Hospital
3430 Burnet Ave, MLC 4002
Cincinnati, OH 45229
Attn: Amie Duncan

Pilot RCT of a Daily Living Skills Intervention for Adolescents with Autism Spectrum Disorder in the Last 2 Years of High School