Advocating for Supports to Improve Service Transitions (ASSIST)
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PROTOCOL

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Project ASSIST: Advocating for SupportS to Improve Service Transitions

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1. Background

In this background section, we explain the risk factors at play when youth with autism spectrum disorder (ASD) transition into adulthood; the problems and societal costs associated with this transition; and, the lack of feasible interventions to address this challenging period in the life of youth with ASD. With a prevalence rate of one in 59 (Centers for Disease Control and Prevention, 2018); over 500,000 youth with autism spectrum disorder (ASD) exit high school each year (Roux et al., 2015). The years immediately after high school exit are a critical time that either makes or breaks a successful transition to adulthood. If they don't go well, disengagement from post-secondary education (PSE), work, and social isolation can persist throughout adulthood, leading to significant societal costs. Despite the pressing need to better support youth with ASD during this turbulent time, few interventions for these youth have been developed and even fewer tested.

The transition to adulthood is a time of significant risk for youth with ASD. Youth with ASD almost universally encounter difficult experiences in their educational, vocational and social lives. Difficulties become particularly apparent during the transition to adulthood, when youth are expected to be gaining independence and actively engaging in young adult life. Yet, even the most able individuals with ASD struggle during this time. Employment and PSE are difficult to obtain, and are rarely maintained over time. Compared to typically-developing youth, youth with ASD are more socially isolated and have greater difficulty making friends. Although many youth may struggle during the transition to adulthood, youth with ASD are at even greater risk across multiple domains of daily life. These risks lead to significant societal costs: when considering both service use and lost productivity, lifetime costs for one individual with ASD in the U.S. ranges from $1.43 to $2.44 million (Buescher et al., 2014).

The transition years are a critical turning point that set the stage for positive or negative trajectories throughout adulthood, and are thus an optimal time for intervention. Although autism symptoms and behavior problems tend to improve while youth with ASD are in high school, that improvement slows or even stops after high school exit. Daily living skills (which improve while youth are in high school) plateau after high school exit, and then begin to decline in early adulthood. Social isolation increases during this time. Further, our study of 10-year change in vocational activities suggests that the level of independence that youth achieve during the years after high school set an upper limit for what they will achieve throughout adulthood; although we saw many examples of adults who either maintained or declined in their level of independence in vocational activities over time, only 5% were upwardly mobile (Taylor & Mailick, 2014). Thus, the transition years are a critical time for intervention.

These challenges during transition and beyond are partly caused by problems accessing adult services. Because of the Individuals with Disabilities Education Act (IDEA), youth with disabilities (including ASD) are eligible for mandated services through the school system until the age of 22 years or until they exit high school. However, after high school exit, these youth encounter an adult service system that is inadequately funded, fragmented, and difficult to navigate. Across the U.S., approximately 2.0 to 2.5 million

individuals are currently on waiting lists for adult disability services (National Council on Disability, 2005). Even when one is granted eligibility, the system only offers unconnected locations for services. Families must contact separate departments for services related to employment, home and community, and PSE. Along with identifying, accessing, and speaking with various agencies, families must understand each agency's eligibility scheme, funding mechanism, and programming. Parents must then advocate in order that the program meets the unique needs of their offspring with ASD. As many young adults with ASD require assistance in employment and activities of daily living, failure to access these needed services leads to serious ramifications.

Moreover, few interventions have been shown effective in smoothly transitioning young adults with ASD from secondary school to adulthood. Most programs focus on individual-based approaches such as teaching social skills or "soft job skills" such as arriving on time, being polite, and accepting criticism. Yet, few rigorous studies exist to document effectiveness. Similarly, while it undoubtedly helps to increase the capacity of state and local adult-disability service systems, political and economic barriers persist.

Proposed Methods and ASSIST Development

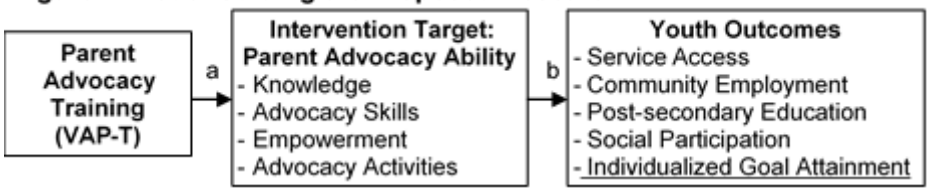
Instead of emphasizing the traditional individual or larger system-based approaches, the proposed research adopts a complementary approach, focusing on the middle-level of parents. We essentially teach parents of youth with ASD to become better advocates. Improving parents' ability to advocate on behalf of their son or daughter is a promising avenue to improve service access and youth outcomes. Already in most cases, parents serve as the main advocates for their offspring with ASD, and close and frequent contacts with the adult service system continue throughout adulthood. The mental health field increasingly recognizes the importance of focusing on parent needs as parents search for services for their children (Hoagwood et al., 2010). In providing supports to families, then, mental health workers have shifted from viewing the parent as a patient, to the parent as a partner. Parents, too, see family-focused interventions as highly valuable, and such interventions can potentially be delivered at low cost, with a high impact. Parent advocacy training is one type of family-focused support, and it has the potential to improve service access for youth with ASD, as well as improve youth outcomes. Our goal in this project is to equip parents with the knowledge, skills, and empowerment necessary to effectively access whatever services or resources are available to them.

To train these advocacy skills, we have developed and pilot-tested a parent advocacy training, called the Volunteer Advocacy Program-Transition (or VAP-T). The VAP-T aims to improve service access and youth outcomes during the transition to adulthood by providing parents the knowledge, skills, comfort, and expertise to support their son or daughter with ASD in securing a variety of post-high school vocational, community, and social activities (supported by R34 MH104428). For this project, we will be tested a national adaptation of the VAP-T, which is called ASSIST (Advocating for SupportS to Improve Service Transitions).

Drawing from the Vanderbilt Family Empowerment model, we propose a 2-step model for how the ASSIST program will improve transition outcomes for youth with ASD (see Figure

1 below). Our model holds that advocacy training will increase parents' advocacy knowledge, comfort, behaviors, and skills (path a). Such increases will lead to improved service access, particularly more effective dealings with service providers, and better understandings of service location, workings, access, eligibility, and receipt (path b). These increases will also lead to better employment, PSE, social outcomes, and enhanced goal attainment for offspring with ASD (path b) - positive transition outcomes may occur as a result of improved service access or independent of services (e.g., parents connect to informal supports during ASSIST, leading to employment opportunities).

Figure 1. Model Guiding the Proposed Research



Our pilot work testing the efficacy of this intervention is promising. Using a randomized-controlled trial (RCT) design with families of transition-aged youth with ASD, youth whose parents took the VAP-T (vs. a wait-list control) were twice as likely to be employed or in PSE after high school exit. Youth from the treatment group, on average, had an increase of 1.5 services from baseline to 6-month follow-up, compared to a 0.5 service increase in the control group (Taylor et al., under review).

Despite its promise, our preliminary work has a number of important limitations that will be addressed in the proposed research (see Table 1 below). The pilot work used a small sample size of 45 families. This sample was sufficient to demonstrate feasibility and gather initial evidence for efficacy, but insufficient to examine moderators of treatment response or mechanisms of action. Hypotheses regarding mechanisms can be postulated from our pilot work; the proposed project provides the sample size to make more definitive statements about why ASSIST participation leads to improved service access and youth outcomes, who is most likely to benefit, and what modifications might be made for families unable to access or benefit from the content.

Table 1. Limitations of Pilot Work and Solutions

Limitation	Proposed Solution
Small sample	Sample adequately powered to test mediators and moderators
State-specific curriculum	Nationally-relevant curriculum delivered at multiple sites
Data only collected from parents	Data collected from parents and youth with ASD

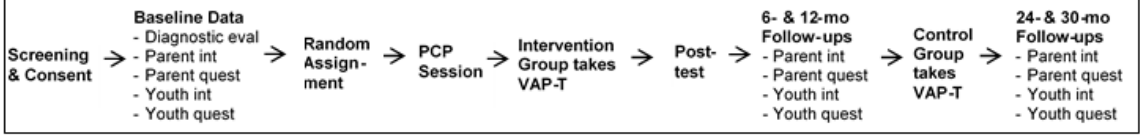
Next, the program was developed to reflect the availability and eligibility of services in one state (Tennessee); this decision was made because the adult service landscape differs from state to state. In the proposed project, we revise the curriculum to be nationally-relevant, by presenting aspects of each topic that are applicable across states and bringing in local experts to present information relative to their region. We also improve upon our study design by replacing a wait-list control with an active, materials-only control. The control group will receive the same written materials as the treatment group, but will not

receive the group-based training (they will have the option to participate in the training at the end of the study) This design improves upon our pilot work in two ways: (1) it will allow us to test whether receiving written information, without training, has similar benefits as the group-based program; and (2) it is more acceptable to participants. Though participants were not blinded, research staff facilitating completion of the surveys were blinded to experimental conditions.

2. Rationale and Specific Aims

An overview of the current study design is presented here (see Figure 2 below). We propose a multi-site (Nashville, TN; Chicagoland, IL; Madison/Milwaukee, WI) RCT of 180 families to test the effectiveness of ASSIST. Participants will be recruited in two cohorts and randomly assigned to either a treatment or materials-only control condition.

Figure 2. Study Design (eval = evaluation; int = interview; quest = questionnaire)



By randomly assigning participants to conditions, we reduce the likelihood of confounders that obscure treatment effects. Recruiting across three sites with diversity in community size, racial/ethnic make-up, and adult service systems will reduce bias due to unrepresentative samples.

We will also examine mechanisms of action and explore moderators of treatment response and barriers to participation. Our sample is sufficient to test our research questions (based on out statistical Power analysis). We will collect data from youth with ASD and their parents, to reduce informant bias. Post-randomization data collection will be conducted by personnel blinded to study condition. Based on existing research, we would expect that parents who receive the written materials might have some increase in knowledge about adult services, but likely not empowerment nor would we expect change in youth outcomes.

The ASSIST program is a 12-week advocacy training to educate parents of youth with ASD about the adult service system. It is a group training, comprised of didactic instruction, family-sharing activities, case studies, and group discussions. Due to social distancing restrictions during the COVID-19 pandemic, the intervention will be conducted via web-conferencing. The ASSIST program for the proposed study will be directed at each site by an experienced Program Facilitator from the community with knowledge about group processes, person-centered planning, and adult service systems, who will be coached by a member of the study team. The ASSIST program will be delivered in full partnership with the local disability community. In most sessions, the Program Facilitator will be aided by community content experts who present the specifics of each topic. Experts will include representatives from the Parent Training and Information Centers, The Arc, the University Centers for Excellence in Developmental Disabilities, various

government agencies, attorneys, and parents of individuals with ASD. We have tentatively identified (and partially recruited) most of these community experts at each project site.

Finally, we take further steps to ensure that parental advocacy reflects the goals of the youth with ASD by: having a semi-structured discussion with the youth with ASD and their supporters about that youth's hopes, dreams, and goals prior to their parent taking the ASSIST program; developing individualized goals for transition outcomes from those discussions that will be used as an outcome measure; and including the youth with ASD in follow-up data collection to incorporate their perspective.

Specific Aims

Specific Aim 1. To use a multi-site RCT to examine whether ASSIST participation increases the intervention target of parent advocacy ability (defined by parental knowledge about adult service systems, advocacy skills, empowerment, and advocacy activities).
Hypothesis. Relative to a materials-only control group, ASSIST participation will lead to improvements in parental knowledge about adult services, advocacy skills, empowerment, and advocacy activities.

Specific Aim 2. To test whether participating in ASSIST leads to increases in employment, PSE, social participation, and access to services that facilitate these activities (number of services, unmet service needs, barriers), for youth with ASD transitioning from high school to young adulthood.
Hypothesis. Relative to the materials-only control group, youth whose parents participate in ASSIST will have increased access to services and higher rates of employment, PSE, and social participation at 6-months and 12-months post-intervention.

Exploratory Aim 2a. We will examine whether ASSIST participation leads to enhanced goal attainment (as assessed by parents and youth with ASD), as well as better youth-reported quality of life and fit of employment/educational activities to the youth's skills and interests.

Exploratory Aim 2b. Using data collected 24-months and 30-months after intervention, we will examine whether treatment effects are maintained, strengthen, or wane.

Specific Aim 3. To examine which intervention targets (parent knowledge, advocacy skills, empowerment, advocacy activities) mediate the relations between ASSIST participation and youth outcomes of employment, PSE, social participation, service access, and goal attainment.
Hypothesis. In contrast to other intervention targets changed by ASSIST, parental empowerment will be the mechanism by which ASSIST participation leads to improvements in youth employment, PSE, social participation, service access, and goal attainment.

Exploratory Aim 4. To guide further adaptations of ASSIST, we will explore moderators of treatment response and barriers to participation in the intervention. We will explore factors that could relate to parents' ability to complete the ASSIST program and treatment

response, including: youth's intellectual functioning, pre- vs. post-high school exit, attendance at ASSIST sessions, socio-economic status, parental education, community size, family stress, and number of children with ASD in the family. We will also analyze qualitative data to inform future efforts to increase the accessibility of the ASSIST program for individuals with ASD.

If the aims of the study are achieved, the ASSIST program has the potential to be rapidly adopted and broadly implemented. Already we have received interest in providing the ASSIST program from multiple research groups and organizations across the country. Yet, a roadblock to dissemination is ASSIST's regional specificity. If a nationally relevant program is developed and shown to be effective, it can be incorporated into parent training services offered through national advocacy organizations and state/local governments. Further, because we train parents to advocate for both formal and informal supports, the ASSIST program will be broadly relevant to families of transition-aged youth regardless of the availability of adult services in their area. Given the high prevalence of ASD and of poor adult outcomes, as well as the geographic variability in services, it is critical to investigate an intervention such as the ASSIST program, which can be delivered through state or local agencies and can operate across an array of adult support landscapes. The proposed research is thus highly significant and has the potential for tremendous impact on both research and practice.

Innovation

This project features five major innovations:

1. **Life Stage.** While of monumental concern to families, the transition to adulthood has been relatively ignored by researchers. By testing a parent advocacy intervention to improve youth outcomes, this project will make substantial contributions to knowledge of how to improve the transition years for youth with ASD.
2. **Parent-Centered.** Traditional approaches to improving outcomes for transition-aged youth with ASD target individual skills or changing systems. Instead, the VAP-T focuses on parents. This approach allows for the development of programs for youth across the spectrum of functioning, including those with low cognitive abilities who often are excluded from interventions. If we demonstrate that parent-focused programs improve youth outcomes, similar strategies can be applied to interventions for people with ASD across the lifespan (from early intervention through adulthood), opening up new treatment opportunities.
3. **Expanded Outcomes.** In the VAP-T, we move beyond an emphasis on competitive employment, and instead focus on an expanded list of outcomes. These include access to needed services in PSE, health, financial support, housing, employment, and self-determination, which in turn foster fulfilling day-to-day activities and greater community engagement. Such an expanded – but specific – sense of adult success is rarely if ever included in intervention studies.
4. **Formal and Informal Supports.** We adopt a larger sense of services and resources, including but going beyond formal service systems. In most states, adult services are under-funded and fragmented. Thus, while we provide knowledge about various services, agencies, eligibility requirements, and other

issues, we also provide parents with information about additional resources – everything from disability-related call lines and parent groups, to names of local businesses amenable to hiring young adults with ASD. By expanding the focus to both formal and informal resources, we increase the likelihood that ASSIST can be broadly implemented, to areas with and without abundant adult services.

5. **More Nuanced Understandings of Treatment Effects.** The service needs of adults with ASD differ based on their personal characteristics and other factors such as stage of life. In keeping with the recommendation of Hoagwood et al., we will examine a limited number of targeted moderators of treatment response. We will assess the degree to which parents of offspring with different intellectual abilities benefit from ASSIST, and whether benefits depend on if the youth is in or out of high school. This will provide important evidence to suggest who might benefit most from the ASSIST program, as well as insight into how the program might be adapted to better serve those who are less responsive to ASSIST.

3. Inclusion/Exclusion Criteria

The goal of this study is to arrive at a sample of 180 families (one parent and one youth with ASD per family). We will recruit 2 cohorts of 90 families per cohort. Each of the three sites will recruit and test participants over the course of the study:

- Vanderbilt University Medical Center: n=60 (cohort 1 n=30, cohort 2 n=30)
- University of Wisconsin-Madison: n=60 (cohort 1 n=30, cohort 2 n=30)
- University of Illinois at Urbana-Champaign: n=60 (cohort 1 n=30, cohort 2 n=30)

The to-be recruited participants for the ASSIST study will be parents of youth with ASD in the transition years, and the youth with ASD themselves.

Families **must meet the following criteria** according to the parent/legally authorized representative (LAR) (of the youth with ASD) to be eligible for the ASSIST study:

- Parents willing to participate in the ASSIST 12-week intervention, who have an **offspring** with ASD between the **ages of 16 and 26 years**; There is no minimum or maximum age restrictions for the parent.
- **Parents** are **willing to be randomized** to the treatment or control condition;
- Parents are able to travel weekly to one of the project sites (Nashville, TN; Chicagoland; IL; Madison/Milwaukee, WI) to participate in the group ASSIST sessions (12 weekly sessions). The responding parent and his/her son/daughter with ASD must also be able to travel to a project site once if social distancing restrictions allow (for a diagnostic evaluation and baseline data collection visit);
- **Family lives in** one of the three states that will test ASSIST (**TN, IL or WI**), as the ASSIST curriculum will be state specific.

- The son/daughter has a **previous diagnosis of ASD** from an educational or health care provider, and meets lifetime cut-offs for ASD in a telephone screening of the Social Communication Questionnaire (**SCQ score >=15**[1]); and
- The participating parent is **proficient** with the **English** language, as all ASSIST presentations and data collection materials are in English.

If both parents in a family want to attend the ASSIST training, we will allow it but will designate one parent as the study's primary respondent.

4. Enrollment/Randomization

Given our need to ascertain whether participants meet the study eligibility requirements prior to arranging for families to enroll in the study, we will obtain oral agreement to talk with the parent/caregiver/LAR/legal guardian about the details of the study and proceed with the eligibility phone-screening interview in order to determine whether the project is a good fit for the prospective participant/family.

After families are screened and determined potentially eligible, if they decide to enroll in the project, they will be invited to complete the baseline data collection visit. At each site, written/electronic and oral consent will be provided by caregivers/LARs. Verbal and (whenever possible) written/electronic assent will be obtained from all minors and youth who have a LAR, prior to data collection (during their first visit). Youth with ASD who are able to consent for themselves will provide written/electronic and oral consent for participation in the study.

The consenting procedure will be as follows:

1. The study team member (hereafter STM) who completed the screening phone interview with the parent / LAR, will make initial determinations about the son/daughter's ability to consent based on: a) his/her age at the time of the baseline data collection visit; and 2) if over 18, whether the parent is the legally authorized representative of the son/daughter or whether he/she is his/her own representative.

2. Consent forms will be sent to research participants via email ahead of time so that they have an opportunity to become familiar with them prior to the study visit.

[1] Please note that in rare cases, a youth with a previous diagnosis of ASD may score between 10 and 14 in the SCQ (due to limitations to all psychometric measures). In these situations, the PI will review the responses provided by the parent during the phone screening interview, and determine if the family may still be a good fit for the study. If after careful consideration, the PI determines that the family is eligible to participate, that family will be enrolled in the study. This is by no means a general rule, and study key personnel will be instructed to follow the proposed inclusion / exclusion criteria, and review with the PI any "borderline cases" (e.g. someone who was given an ASD diagnosis that does not seem appropriate based on parent responses and SCQ score; someone who has a previous ASD diagnosis but the parent is not a good reporter of that youth's behaviors as a child, thus, obtaining a SCQ score that falls below the threshold, etc.).

3. At the baseline study visit, research staff members will review the consent forms with the parent and the son/daughter in person or through teleconference. The research team member will address all questions or concerns the participants may have during the informed consent process. The research team member will also minimize coercion and/or undue influence by: (1) assuring potential subjects (and withdrawing subjects) that their decision not to participate or decision to withdraw from the study will not affect other services they or the son/daughter with ASD are currently receiving (2) refraining from providing any unjustifiable assurances about benefits, risks or inconveniences of the research. If the parent agrees to participate, he/she will sign the written/electronic consent form. If the son/daughter consents or assents to participate, the research team member will make sure that the young participant understands what the study involves, that this is a voluntary study and that he/she can withdraw from the study at any point.

4. Participants who consent to participate will sign a hard-copy/electronic copy of the consent form. Each site will keep the original signed copy and participants will receive a copy of the signed consent form. During the informed consent process, participants will be reminded that participation in the study is voluntary and that they can decide to withdraw from participating at any time without penalties or negative consequences.

Note: When a STM is consenting a youth who is over 18 (and who does not have a legally authorized representative), the STM will stop after each section of the consent form, and ask a comprehension question. If the youth is unable to answer the questions, or if it is unclear whether he/she is fully comprehending the consent form, the STM will shift to the assent script with the youth, and ask the LAR/parent to provide consent for the son/daughter's participation.

Randomization

After eligibility is determined and baseline data are collected, parents will be randomized, in two cohorts, to the treatment or materials-only control condition. Given the relatively small sample size in each cohort at each site (n = 30 at each of three sites), simple randomization is not recommended as it might result in unequal group sizes. We will use 1:1 block randomization within each site to give an equal number of subjects in each group. To ensure balance of important covariates, we will block on our key moderators: whether the youth has an intellectual disability (ID) and is in high school. Co-occurring ID and being in vs. out of high school impact service eligibility, and ID impacts the likelihood of PSE and community employment. By balancing moderators, we maximize our power to detect effect modification of the treatment effect; and we minimize the chance of having a very extreme distribution of important (moderating) covariates.

1.0 Study Procedures

All data collection will occur in years 2019-2023 as explained below:

- Enrollment for the project is expected to occur in years 1-2.
- Cohort 1 (C1) Intervention group will take ASSIST from February-August 2020 (IL and TN sites; includes COVID break) and August-November 2020 (WI sites)

  - C1 Control group will take ASSIST September-November 2021 (TN and IL Sites) and January-March 2022 (WI Site)
- Cohort 2 (C2) Intervention group will take ASSIST from August-Nov 2020 (TN and IL Sites) and November 2020-Feburary 2021 (WI site)
  - C2 control group will take ASSIST from February-April 2022 (TN and IL) and March-May 2022 (WI sites).

Note: Due to social distancing restrictions, the in-person intervention series that began in February 2020 was paused between Spring 2020 to Summer 2020 for Cohort 1 intervention groups (TN and IL). In response to continued pandemic regulations, ASSIST was moved to synchronous web-conferencing in Summer 2020, and this method was the mode of delivery for all remaining sessions and series at all sites (TN, IL, WI)

A comprehensive characterization of each participant's circumstances and family context will be completed by administering a battery of direct assessments and informant report measures during the baseline visit. This visit will include structured observations, psychological testing, structured interviews, and questionnaires/surveys. Note that some of the survey measures will be offered to participants as web-links to be filled out at home or at the lab if social distancing restrictions allow. Paper copies of all surveys will be available based on participant preference.

Follow-up data collection points (post-intervention, 6, 12, 18, 24, and 30 months) may take place online or over the phone, depending on participants' preference and the included measures to be collected for that time-point. We will also make alternate methods of data collection available to youth with ASD for the interview, including video/text/online chat, as some participants with ASD may be more comfortable answering questions via chat than over the phone or web conference. The table of measures included in the *Procedures for Enrolled Families* section of this protocol, shows the longitudinal measures follow-up schedule for parent and youth participants.

5. Procedures

Eligibility Screening Procedures: Staff at each site will inform potential participants of the study, when subjects contact the site (via email, phone and/or interest form survey) in response to recruitment efforts. As soon as the potential parent participant is available, staff at each site (depending on the state of residence of the subject) will conduct a telephone screening interview with the subject's verbal permission. All screening phone interviews will be completed with parents (never with a youth with ASD) using the phone script electronically and/or in paper/pencil. During the eligibility screening phone call, the study team member will administer the Social Communication Questionnaire (SCQ – Rutter, Bailey, Kazak, Lord & Pickles, 2003) to the parent / LAR (as one of the eligibility inclusion criteria for the study is that the score on the SCQ Lifetime Questionnaire is 15 or higher; although in rare circumstances, a score between 10-14 may not prevent a family from participating in the study – this will be evaluated by the PI on a case by case basis). The SCQ offers a quick and easy way to screen for autism spectrum disorders by asking caregivers 40 yes/no question about the child's communication skills and social functioning.

If after the telephone screening, the STM determines that the family is not eligible to participate in the study, we will explain this to the parent. We will destroy any record of the parents' responses to the screening phone call questions, unless the family says they would like to be contacted for future studies. For reporting purposes only, we will document the reason for ineligibility of the screened family (e.g. the son/daughter never received a diagnosis of an ASD) in a "recruitment tracking document" that will not include any of the screened subject's PHI or responses.

Procedures for enrolled families: For each participating family, the testing battery at baseline will be the most extensive one. After that, the number of administered instruments will vary depending on the specific follow-up data collection time. Similarly, depending on the number and type of instruments to be collected during the follow-up data collection times; study staff at each site will collect the data via: phone interview or teleconference, REDcap survey, and/or paper protocols; depending on the family's preference.

Youth measures

Test / Procedure	Baseline (T0)	12-m FU (T3)	30-m FU (T6)
Youth (Baseline)	T0	T3	T6
Autism Diagnostic Observation Schedule: (ADOS-2; Lord et al., 2012) A semi-structured standardized observational assessment of social interaction and communicative skills that was designed as a diagnostic tool for identifying the presence of autism. It is organized into four modules, which are distinguished by their appropriateness for use with individuals functioning at different developmental levels, ranging from nonverbal children to highly fluent adults. Each module provides a set of behavioral ratings in five domains: Language and Communication, Reciprocal Social Interaction, Play or Imagination/Creativity, Stereotyped Behaviors and Restricted Interests, and Other Abnormal Behaviors. We will mainly use Module 3 and 4 (dedicated to verbally fluent teenagers and adults), and Module 1 and 2 (that can be used for non-verbal adults or less verbal adults). The scoring algorithm provides cutoffs that can be used to discriminate between a diagnosis of autism, autism spectrum, or non-spectrum. The ADOS will be administered to participants with ASD. It will be administered by trained research staff. All ADOS-2 administrations will be video-recorded with the participant's explicit consent. Note: After data collection was moved online due to social distancing restrictions, the ADOS-2 was no longer required as a diagnostic measure for remaining participants.)	X		

Wechsler Abbreviated Scale of Intelligence (WASI-II, Wechsler, 2011): Provides a brief, reliable measure of cognitive ability for use in clinical, educational, and research settings. It is comprised of 4 subtests that yield a verbal intelligence quotient, a performance quotient, and an overall intelligence quotient. (Note: After data collection was moved online due to social distancing restrictions, the research staff used 2 of the subtests which were able to be administered virtually. The other 2 subtests were not administered to remaining participants.)	X		
Youth Measures (Longitudinal)	T0	T3	T6
Vocational - educational activities interview: (Taylor & Seltzer, 2012) this instrument gathers information on vocational, educational, and other daytime activities. A trained research staff member will deliver this brief interview to gather information on current and previous high school employment, secondary education and post-high school vocational placements.	X	X	
Goal identification (baseline) / Goal Attainment (FUs): Our team developed a goal bank that includes goals that fall into 5 categories: Employment & Post-Secondary Education, Daily living, Social and Spirituality, Healthy Living, and Safety & Security. This goal bank is a start point to help families think about a vision for how their family member will live their life as an adult. The parent will select 5 potential goals from the goal bank, and work with a study team member to customize the selected goals during the baseline visit. After that, the youth will review the customized goals and/or select three of them that he/she is interested in (or create new customized goals if none of the goals the parent customized are of the youth's interest). Goals that are specified during this identification session will be scaled using Goal Attainment Scaling (GAS). GAS is an individualized outcome measure to calculate the extent to which specific goals are met by an individual. Goal selection will vary from participant to participant, but the goal scale will be standardized to measure goal attainment consistently across	X	X	

participants. During FUs, study staff will reach out to the youth participant and check in on goal progress status.			
Self-Determination Inventory System Adult (SDIS – ADULT): The SDIS (Shogren et al., 2017) is a 22-item survey that asks adults how they feel about their ability to be self-determined; make choices, set and go after goals, and make decisions. Participants use a sliding scale to indicate their level of agreement with various statements related to self-determination.	X	X	X
Transition Empowerment Scale (TES): Adapted from the Family Empowerment Scale (FES; Koren, DeChillo, & Friesen, 1992) to measure adolescents and young adults with disabilities' perceived empowerment during transition planning. This modified 31-item instrument enables young adults to self-report how empowered they feel to manage their day-to-day life, understand the services available to them, and advocate for themselves and for other adolescents with disabilities. The young adult rates statements from 1 (Not True) to 5 (Very True) to indicate how much each one applies to him/her. The scale captures the young adult's view of their own empowerment at one point in time by measuring both the level of empowerment and how it is expressed.	X	X	X
Satisfaction with Life Scale (SLS): the SLS (Diener et al., 1985) is a short 5-item measure of an individual's subjective quality of life. Participants rate their agreement with 5 statements on a 7-point scale, from 1 (Strongly Disagree) to 7 (Strongly Agree).	X	X	X
Open-Ended Questions: Participants give their opinions on future intervention programs for people with ASD			X

Parent measures

Test/ procedure	Baseline (T0)	Post-test (T1)	6-m CI (T2)	12-m FU (T3)	18-m CI (T4)	24-m CI (T5)	30-m FU (T6)
Youth /Parent Characterization (Baseline)	T0	T1	T2	T3	T4	T5	T6
Demographics and medical history: Demographic information for NIH reporting, as well as diagnostic and treatment information.	X						
Vineland 3- Comprehensive Interview form: (Sparrow, Cicchetti & Saulnier, 2016) a measure of adaptive behavior functioning. It is administered as a brief interview to parents or caregivers, and yields standard scores and age equivalents in the domains of communication, social, daily living skills and overall adaptive functioning.	X						
Social Responsiveness Scale, Second Edition: (SRS-2, Constantino & Gruber, 2012) A 65 item parent-report scale measuring the presence and severity of social impairment as it relates to Autism Spectrum Disorder. The measure is sensitive enough to quantify severity within the spectrum and differentiate between ASD and other disorders. The SRS-2 generates a total score as well as scores for each of its five subscales: social awareness, social cognition, social communication, social motivation, and restricted interests and repetitive behavior. The SRS-2 parent-report will be given to parents of all participants with ASD.	X						
Participants will complete the ABCL or the CBCL, depending	X						

on their youth's age. Parents of youth ages 16-17 will complete the CBCL, and parents of youth age 18 and over, the ABCL. **Child Behavior Checklist 6-18** (CBCL; Achenback & Rescorla, 2001) A 113-item scale designed to be rated by parents of children aged 6-18. The questions are scored on a three-point Likert scale (0=absent, 1=occurs sometimes, 2=occurs often). The time frame for item response is in the past six months. **Achenbach Adult Behavior Checklist 18-59:** (ABCL; Achenbach & Rescorla, 2003) A 118-item scale designed to be rated by parents of adult children aged 18 to 59. The ABCL is based on a multi-factor model, for which domains of withdrawn, somatic problems, and anxious depressed are indicators of a more general "Internalizing" factor, while delinquency and aggression domains are indicators of the "Externalizing" factor (Tenneij & Koot, 2007).							
Coping Orientation to Problems Experienced (COPE) Inventory: (Carver, Scheier, & Weintraub, 1989) multidimensional coping inventory to assess the different ways in which people respond to stress. Participants rate 60 items with potential responses to stress on a scale from 1 (I usually don't do this at all) to 4 (I usually do this a lot).	X						

Parent Repeated measures (Longitudinal)	T0	T1	T2	T3	T4	T5	T6
Family Empowerment Scale: (FES; Koren, DeChillo, & Friesen, 1992) developed specifically to assess empowerment in families with children with emotional disorders. The FES consists of 34 items with responses on a Likert scale ranging from 1 (Not true at all) to 5 (very true).	X	X^T		X^T	X		X
Parent Advocacy Skills and Comfort (ASC) & Knowledge measure: Both of these measures were developed by the ASSIST team. The Advocacy Skills and Comfort (ASC) measures the degree to which parents feel comfortable and skilled in advocating for their son/daughter with ASD. The assessment comprises 10 items, on which participants respond on a 5-point Likert scale (1 = not at all; 2 = below average; 3 = average; 4 = good; 5 = excellent). The Knowledge measure serves to examine the extent of parents' knowledge about the adult service system through a scale developed for this project (based on a measure developed to evaluate the VAP-T; Burke, Goldman, Hart, & Hodapp, 2016). Each response will be coded as either "correct" (1) or "incorrect" (0), with potential scores ranging from 0 to 22 and higher scores equaling greater knowledge of the adult disability service	X	X^T		X^T	X		

system. This measure was piloted among a group of parents of older sons and daughters with ASD to ensure that floor and ceiling effects were avoided.							
Vocational - educational activities interview: (Taylor & Seltzer, 2012) A trained research staff member will deliver this brief interview to gather information on current and previous high school employment, secondary education and vocational placements that the son/daughter is/was involved in.	X		X[P]	X[P]		X	X
Service Access questions Interview (NLTS2 questions and team-developed questions): The National Longitudinal Transition Study-2 (NLTS2) collected data over 10 years from parents, youth, and schools and provided a national picture of the experiences and achievements of young people as they transition into early adulthood. For the proposed research, we will use some of the questions developed for the NLTS2 concerning service access for youth with ASD, and will supplement them with questions developed for our research about specific types of services (e.g., Medicaid, etc.). These questions will be answered by parents using a semi- structured interview format	X		X[P]	X[P]		X	X
Parent Advocacy Activities Measure: (Taylor et al., 2017) this instrument has 16 items that measures how frequently	X			X[P]			X

parents spend time in advocacy activities for their son/daughter with ASD.							
Goal identification (baseline) / Goal Attainment (FUs): Our team developed a goal bank that includes goals that fall into 5 categories: Employment & Post-Secondary Education, Daily living, Social and Spirituality, Healthy Living, and Safety & Security. This goal bank is a start point to help parents think about a vision for how their family member will live their life as an adult. The parent will select 5 potential goals from the goal bank, and work with a study team member to customize the selected goals during the baseline visit. After that, the youth will review the customized goals and/or select three of them that he/she is interested in (or create new customized goals if none of the goals the parent customized are of the youth's interest). Goals that are specified during this identification session will be scaled using Goal Attainment Scaling (GAS). GAS is an individualized outcome measure to calculate the extent to which specific goals are met by an individual. Goal selection will vary from participant to participant, but the goal scale will be standardized to measure goal attainment consistently across participants. During FUs, study staff will reach out to the parent participant and check in on the youth's goals' progress status.	X			X^S			

Social Participation and employment correlates: The National Longitudinal Transition Study-2 (NLTS2) collected data over 10 years from parents, youth, and schools and provided a national picture of the experiences and achievements of young people as they transition into early adulthood. For the proposed research, we will use some of the questions developed for the NLTS2 concerning parent's social participation. In addition, we are including some questions developed to measure employment and social participation (Taylor, Adams, Bishop, 2017).	X			X[S]			X
Satisfaction with Life Scale (SLS) - proxy report regarding son/daughter: the SLS (Diener et al., 1985) is a short 5-item measure of an individual's subjective quality of life. The SLS scale allows participants to integrate and weigh these domains in whatever way they choose. Participants rate their agreement with the 5 statements on a 7-point scale, from 1 (Strongly Disagree) to 7 (Strongly Agree).	X			X[S]			X
Depression, Anxiety, Stress Scales – 21 items (DASS-21): (Lovibond & Lovibond, 1995) set of three self-report scales designed to measure the emotional states of depression, anxiety and stress. Each of the three DASS-21 scales contains 7 items, divided into subscales with similar content. The depression scale assesses dysphoria, hopelessness,	X			X			X

devaluation of life, self-deprecation, lack of interest / involvement, anhedonia and inertia. The anxiety scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. The stress scale is sensitive to levels of chronic nonspecific arousal. This scale assesses difficulty relaxing, nervous arousal, and being easily upset/agitated, irritable/over-reactive and impatient.							
General Life Events: assesses milestones, changes, and challenges that may have occurred in an individual's life within the past year. The parent participant indicates whether he/she, his/her spouse, and his/her children have experienced any of the 22 listed life events (e.g. marriage, divorce, moving to a new home, etc.) or other (item 23).	X			X			
Disability Connectedness: This measure assesses the extent to which a participant relates to his/her local disability community. The instrument consists of 10 items. Participants respond on a 5-point Likert scale (1 = not at all; 2 = slightly; 3 = to some extent; 4 = quite a bit; 5 = very much so).	X			X			X
Parent-Child Relationship: this 10-item instrument (Bengtson & Schrader; 1982) measures a parent's perceptions of how positive his/her relationship is with his/her child. Responses range	X			X			

from 1 (Not at all) to 6 (Extremely).							
Parent expectation questions from NLTS-2 (same for all): The National Longitudinal Transition Study-2 (NLTS-2; Sanford et al., 2011) documented the experiences of students nation-wide as they made their transition to adulthood. The NLTS-2 provides insight into the involvement of families in the educational development of high school-aged youth with disabilities. The present study uses a modification of the parent expectations questions from the NLTS-2, Parent Expectations, which asks parents to speculate about their youth's future at the end of and after high school. This measure includes items about the youth's potential employment, living situation, and postsecondary education.	X			X			X
Self-Determination Inventory System - Parent version (SDIS): (Shogren et al., 2017) measures a parent/family member's perception of a young person's self-determination. This survey includes questions about goal-setting, decision-making, and choice-making skills. Parent participants use a sliding scale to indicate their level of agreement with various statements related to self-determination of their youth.The assessment comprises 22 items.	X			X			X

Open Ended Questions: Participants give their opinions on the intervention program and feedback for future changes.							X

- Notes: CI: Check-in FU: Comprehensive Follow-Up
- Outcome Key: ^{T}(=Intervention Target) ^{P}(=Primary) ^{S}(=Secondary)

6. Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Adverse events at any of the sites will be relayed immediately (within 24 hours of occurrence) to the VUMC PI and/or VUMC study coordinator by study staff at all sites. Dr. Julie Lounds Taylor (VUMC PI) will be responsible for reporting any adverse event to the IRB within 7 calendar days from the day of report. If additional risks to participants are identified, then, Dr. Taylor will disseminate information and guidelines to follow to the other participating sites. In addition, if data safety is compromised, the VUMC study coordinator will communicate with the other participating sites to provide guidance on what steps to follow to resolve or prevent the issue.

7. Study Withdrawal/Discontinuation

Participants may ask to withdraw from the study at any time with no penalty. If participants opt to withdraw for any reason at any point in the study, no further data collection will be conducted for that participant. Although the project is longitudinal, some of the analyses proposed involve data from only one time point; thus, early termination of a participant does not necessarily mean that his/her data cannot be included in the analyses. Records will be retained in instances of the early termination of a participant.

8. Statistical Considerations

Effects of the Intervention (Aims 1 and 2): Generalized linear models accounting for repeated measurements over time will be used to estimate the effect of treatment group assignment on each of the outcomes. In modeling, outcomes will be considered at their key time-points with treatment group and the interaction of treatment with time serving as the main explanatory variables. Such a model will allow us to test for differences between treatment and control groups over time while accounting for heterogeneity among subjects at baseline. While the randomized block design should minimize confounding, we will adjust for site and sex to improve precision. Regarding the choice of statistical model, we will use ordinary multiple regression for truly continuous responses, logistic regression for binary responses, and for outcome scales that are not truly continuous or have heavy ties in some of their values, the proportional odds ordinal logistic model. The error structure of the model is assumed to be compound symmetric, and the validity of this assumption will be examined by computing Akaike Information Criteria against other common structures. **Mediation (Aim 3):** To assess direct and indirect effects of potential mediator variables, we will follow steps outlined by MacKinnon and

colleagues to establish mediation. Mediation models will be estimated using the "mediation" package in R. **Moderation (Exploratory Aim 4):** Modifiers of treatment effect over time will be considered by introducing interactions between modifiers and the treatment by time interaction. The model building and validation strategy will otherwise be the same as for Aims 1 and 2.

Power/Sample Size: We plan to recruit 180 subjects and expect to retain 152 through the 12-month follow-up (76 per cohort). For power calculations, we consider baseline to post-test changes. For continuous outcomes, the size of effect that we will have 80% power to detect will be impacted by the correlation between the pre and post measurement of the outcome. At worst (r=0), we will have 80% power to detect a 0.46 sd difference in continuous outcomes. If the correlation is 0.2 or 0.4 we will be able to detect a 0.29 or 0.17 sd difference, respectively. We believe these estimates are conservative because, from our pilot work, correlations between baseline and post-test scores of intervention targets were 0.56 (empowerment), 0.39 (advocacy skills), and 0.57 (knowledge). For binary outcomes, the probability of being employed or in PSE was about 0.5 in pilot data; under this assumption we will have 80% power to detect a relative risk of 1.44. For Aim 4, we will have 80% power to detect a 0.42 sd modification of the treatment effect assuming a r=0.2. All calculations assume a two-sided significance level of 0.05. The power to detect **mediation effects** were made using the MedPow package in R. For the power calculation, we considered moderate associations between (1) VAP-T and the mediator (rX,M=0.3), (2) Mediator and outcome, controlling for VAP-T (rM,Y|X=0.25), (3) VAP-T and outcome controlling for the mediator ((rX,Y|M=0.1) using a fixed sample size of 152 (α=0.05). Under these assumptions, we have 83% power to detect the indirect effect of VAP-T on the outcome through the mediator.

9. Privacy/Confidentiality Issues

IRB approval will be obtained prior to the initiation of the project. All project staff will be highly experienced in working with these populations, will have completed University mandated Human Subject Research Ethics training, and will be instructed in procedures for ensuring participant rights and confidentiality.

To protect confidentiality of participants, we will separate names and contact information from all other data. Participant codes, rather than names, will be used to index all data. Contact information, including names, must be maintained during this longitudinal study as participants must be scheduled for follow-up visits and all data files must be linked. Consent, contact information, and information linking participant identity with participant codes will be stored separately from all coded data.

Hard copies of data protocols will be stored in locked and secure cabinets accessible only to project staff. Electronic records with identifiers will be stored in a password-protected database. All lab personnel will be instructed as to the nature and confidentiality principles and procedures. The link between participant ID numbers and participant names will be destroyed when the project has been closed out with the IRB.

We will also video-/audio-record all the ADOS-2 administrations in their entirety (for visits before COVID-19 restrictions were established). This will allow us to perform fidelity checks and testing calibration. Parent and youth interviews completed during the baseline visit (Vineland 3, Vocational Index, Service Access Interview, and Goal identification) will be audio-recorded for reliability purposes. In addition, such recordings of sessions will allow us to re-score protocols that may need to be checked or that were difficult to score while they were being administered, and to complete the transcription and coding needed for the present project. As lead site for the project, the recordings will be centralized at VUMC. A secure cloud storage service such as Box/SharePoint/OneDrive will be used to safely transfer data in transit to the cloud with secure connections. Once stored on the cloud, data will be secured using file encryption. As an additional layer of security, users will receive a unique username and password to log into the service. Every effort will be made to ensure that the data is kept confidential.

A REDCap project created and managed by the VUMC research team will be used as a central location for data management. Vanderbilt University, with collaboration from a consortium of institutional partners, has developed a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. REDCap (Research Electronic Data Capture) data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the VUMC PI and research coordinator. The iterative development and testing process result in a well-planned data collection strategy for individual studies. The REDCap system provides secure, web-based applications that are flexible enough to be used for a variety of types of research, provide an intuitive interface for users to enter data and have real time validation rules (with automated data type and range checks) at the time of entry. These systems offer easy data manipulation with audit trails for reporting, monitoring and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap servers are housed in a local data center at VUMC and all web-based information transmission is encrypted. REDCap was developed specifically around HIPAA-Security guidelines. REDCap has been disseminated for use locally at other institutions and currently supports 240+ academic/non-profit consortium partners on six continents and over 26,000 research end-users (www.project-redcap.org).

10. Follow-up and Record Retention

Data will be collected in Years 1-4 of the project. Hard copy materials with identifying information will be maintained (at each site) for 6 years after the closure of the study, then destroyed. All electronic files (de-identified data, video and audio recordings) will be kept indefinitely.