

Study Protocol

Resilience in Action: Building Resilience and Appropriate Independence in Young Adults with Autism

Sponsored by:

National Institute of Mental Health

Award Number:

1R21MH115375

Principal Investigator: Megumi J Okumura, MD MAS

Day Month Year

18 October 2018

Statement of Compliance

The study will be carried out in accordance with Good Clinical Practice (GCP) as required by the following

- *U.S. Code of Federal Regulations applicable to clinical studies (45 CFR 46)*
- *Completion of Human Subjects Protection Training*
- *NIH Clinical Terms of Award*

RIA Protocol:

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Site Investigator: Megumi J Okumura

Signed: 

Date: 10/18/2018

Megumi J Okumura, MD MAS
Professor of Pediatrics, Internal Medicine and Health
Policy

Table of Contents

	<u>page</u>
Statement of Compliance.....	i
Signature Page	ii
List of Abbreviations.....	iv
Protocol Summary	v
1 Key Roles.....	1
2 Background Information and Scientific Rationale	2
2.1 Background Information	2
2.2 Scientific Rationale.....	Error! Bookmark not defined.
2.3 Potential Risks and Benefits.....	4
2.3.1 Potential Risks.....	4
2.3.2 Known Potential Benefits.....	4
3 Objectives	6
4 Study Design.....	7
5 Study Population.....	7
5.1 Selection of the Study Population	10
5.2 Inclusion/Exclusion Criteria	10
6 STUDY PROCEDURES/EVALUATIONS	12
6.1 Study Procedures.....	12
7 Statistical Considerations.....	12
7.1 Study Outcome Measures.....	14
7.2 Sample Size Considerations	14
7.3 Participant Enrollment and Follow-Up.....	15
7.4 Analysis Plan.....	15
8 Subject Confidentiality	15
9 Informed Consent Process	18
9.1 Informed Consent/Assent Process (in Case of a Minor or Others Unable to Consent for Themselves)	18
10 Literature References	20

SUPPLEMENTS/APPENDICES

List of Abbreviations

AE	Adverse Event
GCP	Good Clinical Practice
ICF	Informed Consent Form
IDEA	Individuals with Disabilities Education Improvement Act of 2004
IRB	Institutional Review Board
ISM	Independent Safety Monitor
n	Number (typically refers to subjects)
NIMH	National Institute of Mental Health
NIH	National Institutes of Health
PI	Principal Investigator
RIA	Resilience in Action
SAE	Serious Adverse Event
SMC	Safety Monitoring Committee
YAASD	Young Adults with Autism Spectrum Disorder

Title: **Resilience in Action: Building Resilience and Appropriate Independence in Young Adults with Autism**

Population: **Qualitative study:** 30 (young adults, parents, community agency staff, teachers and those involved with the care of young adults with autism)
Pilot Study: 30 young adults ages 18-26 with autism.

Number of Sites *University of California, San Francisco*
The Arc, San Francisco
Golden Gate Regional Center

Study Duration: *2 years*

Subject Duration: *2 hours (qualitative study) and 9 months (intervention)*

Objectives:

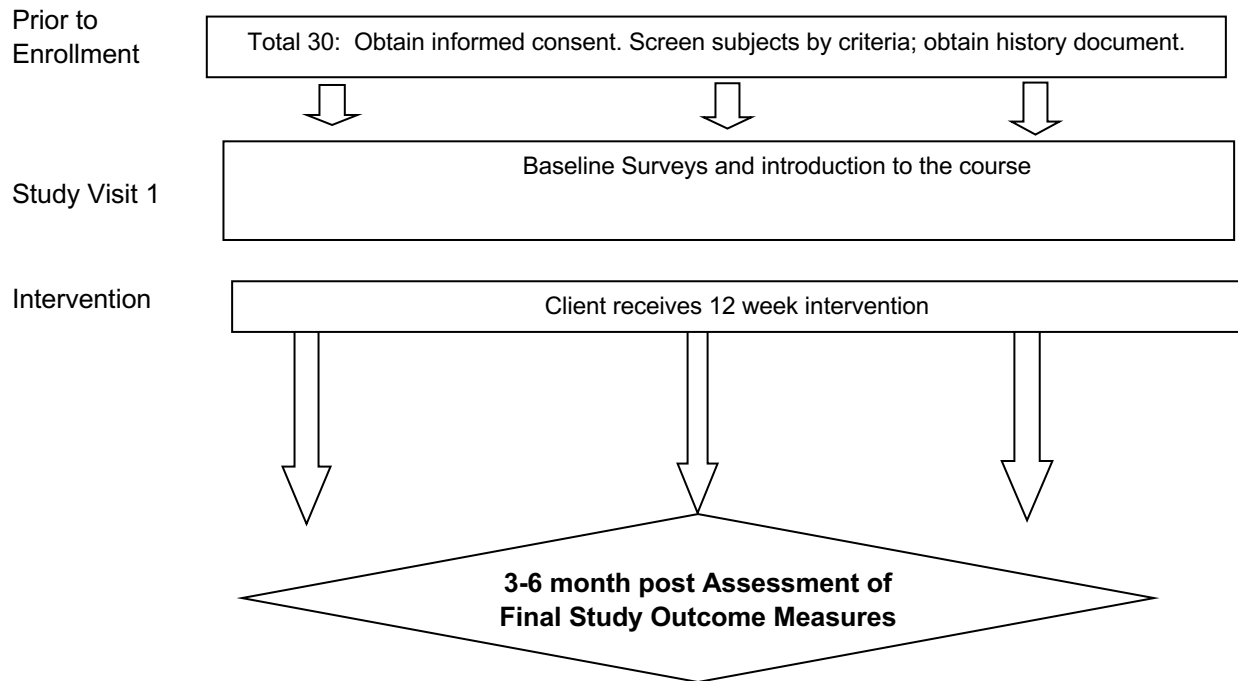
Primary:

- **Develop the RiA intervention protocol for YAASD. This protocol involves incorporating a resilience framework within a community life-skills program that assists YAASD.**

Secondary:

- **Identify the social and vocational barriers encountered by YAASD transitioning from high school to adult life, and address these barriers through a resilience framework.**
- **Pilot the Resilience in Action (RiA) program with a group of 30 YAASD, and measure outcomes of resiliency, demographics, skill/function, self-efficacy and quality of life.**

STUDY : Flow diagram



1 KEY ROLES

Individuals:

Principal Investigator:

Megumi Okumura, MD MAS

Professor of Pediatrics, Internal Medicine and Health Policy

Institutions: *University of California, San Francisco*

2 BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

As young adults with autism spectrum disorder (YAASD) transition out of the academic supports provided by school, these young adults experience a degradation of social skills over time. This has led to poor academic, educational and health outcomes. YAASD require continuous and ongoing skill development in order to maximize their potential; however, there are few services available to adults with autism to develop and maintain their skills. While interventions exist in early childhood, mid-childhood and adolescence, few programs have been focused on the young adult with autism. **Resilience in Action (RiA)**, is a research study, performed and delivered in the community setting, which seeks to develop supports to address the 'adult world' needs of young adults with autism exiting out of secondary education. We propose to develop this program through three specific aims. In our first aim, we propose in-depth interviews with adults with autism and/or their families and service providers to better understand barriers and facilitators to "adult living" after graduating out of the school system. In our second aim, we will use the information gained from Aim 1 to develop a 12-week curriculum integrating a resilience framework and methodologies into a community adult life skills program for persons with disabilities,. A trained transition curriculum expert who had developed transition curriculum for youth with autism spectrum disorder in our local school district will assist in this "adult" curriculum to fill gaps that exist in the school district curriculum. As part of the infrastructure and support for this pilot, we will generate a protocol for the participant's existing case manager to help support youth and families after the curriculum is completed. Our third aim is to then pilot test RiA on 45 young adults with autism who have recently graduated from the secondary education system. Through an iterative program evaluation, we will further hone the intervention and adapt the program to different levels of disability and learning styles. We will measure characteristics of those who were successfully engaged in the program and measure outcomes such as socialization, quality of life, vocational/social activities and self-efficacy. Through this research we will have developed a final protocol for a resiliency course to be tested in a larger clinical trial to see how this type of curriculum can improve longer term social and health outcomes.

2.1 Scientific Rationale

The number of children and young adults with autism spectrum disorder (YAASD) is increasing. It is imperative that we understand the best strategies for meeting the diverse

social and health needs of this high-risk population to improve their quality of life, particularly as they transition to adulthood.

Approximately 1 in 68 children born today in the United States is expected to develop autism spectrum disorder (ASD). ASD is a heterogeneous condition, which has a range of severity and may be accompanied by other developmental disabilities. The cognitive and/or social impairments experienced by some YAASD are barriers to being fully participatory in our society. YAASD may not fully engage in academic, vocational, health, or social services. In one study of YAASD, 75% reported needing social assistance and 46% reported poor outcomes in occupation, friendships and independent living.²⁵ During the time of transition from pediatric to adult programs, YAASD further lose access to care, social supports, and mechanisms to ensure social integration as there are fewer programs that support adults with ASD.¹ Consequently, YAASD often experience poorer social functioning and health outcomes compared to other young adults with chronic conditions. Despite these well-documented poor outcomes, few studies have investigated methods to improve social integration and overall wellness for YAASD, and as a result, there is a lack established best practices to support them in developing supports and skills to function more independently as adults. Programs nested exclusively in health care do not address the broader social issues YAASD face, such as education and vocational training and support, which are required to transition to adult roles. Social and community-based interventions are necessary to prevent institutionalization or marginalization of YAASD as they grow older; yet these supports are lacking.³⁶⁻³⁸ Drs. Okumura and Rehm's qualitative work with families of children with developmental disabilities has highlighted the need for coordination and advocacy skills to navigate between individuals' schools, work, and community agencies in order to address the future health needs of YAASD,

Current state of secondary education and pediatric health care systems do not provide YAASD with sufficient "adult life" preparedness skills– especially preparedness for life and health transitions. Few mechanisms exist which provide YAASD the ongoing support needed to foster the lifelong development and maintenance of social, medical and vocational skills.

The federal Individuals with Disabilities Education Improvement Act of 2004 (IDEA) mandates that school districts provide transition planning services for young adults with disabilities (ages 18-22). Some national programs have been developed to address the social support "cliff" that YAASD encounter after age 18 (the typical graduation age for the average population). These "transition programs" have emerged out of necessity in order to meet the continuing needs of those with developmental disabilities; however, these programs have not been systematic or unified within school systems. In addition, most of these programs have focused on vocational attainment and identification of problem areas, but do not address and promote skills important for community integration – factors such as the building and maintenance of strengths to promote the ongoing resiliency required to surmount social barriers encountered by transition-aged YAASDAs a result, nationally, YAASD have been found to lack life skills; this contributes to their relatively poor outcomes relating to employment, continuing education, social adjustment, health care, and independent living after high school. YAASD and their families largely depend on the public

school systems to accommodate their developmental needs. Although schools attempt to link students with appropriate community agencies for support, they have not adequately provided YAASD with tools to ensure self-management and self-advocacy skills. Thus, it is crucial that we develop evidence-based resources and supportive interventions to improve the quality of life and independent living skills of YAASD. The proposed curriculum aims to fill a significant void not currently filled by the school systems by providing YAASD with supports that will assist YAASD in the development and maintenance of the cognitive and social skills to improve social and health outcomes.

2.2 Potential Risks and Benefits

There are 2 parts to this study, the first is the qualitative interviews. The 2nd is participation in a life skills course with survey evaluations by participants and families. Both are considered behavioral/educational intervention low-risk studies

The interviews will help guide the coursework. The course is a life skills course that is meant to enhance resiliency in young adults. This life skills course is being adapted to focus on resiliency but contains topics as part of a standard life skills course. The benefit to the participant is a free class to help encourage vocational attainment and social engagement. The risks are potentially being upset with assignments or the coursework. The investigators think there is minimal risk to the participant, and the potential gain to assist young adults with social integration and employment outweighs any risk of discomfort.

2.2.1 Potential Risks

For the qualitative studies: Some of the interview questions may make the participant uncomfortable or upset, but the interviewee is free to decline to answer any questions the individual does not wish to answer, and the individual can stop the interview at any time. We will be asking questions about service delivery and barriers to a full social integration for adults with autism. We will not be asking about specific health conditions.

For the life course: This is a social services intervention aimed at improving the transition process for young adults with ASD and leading to better social, vocational and wellness outcomes. In particular, the researchers will work with the 45 young adults in after school sessions where using hard copy tools adapted for this population the youth will be engaged in identifying their strengths and values and make decisions about their post-secondary school lives.

The evaluation of the Resiliency in Action curriculum will be conducted through interviews, surveys, and observations by UCSF staff and the curriculum developer. Therefore neither this program nor its evaluation involves medical procedures or tests and the intervention and study design itself is low risk. However, loss of privacy may be a risk, as we will collect some information individuals might prefer to keep private, such as income, education, immigration status and presence of anxiety. Patients may feel uncomfortable working with a university study team, though our study design and partnership with families during the development is meant to address ways to partner with families in a culturally competent manner. Eligible participants who do not want to enroll in the study will receive usual care

and services. No families or patients will lose any standard services already available to them.

If there is any sign of abuse of the participant, we will notify the GGRC and appropriate social services.

2.2.2 Known Potential Benefits

The potential benefit is to gain life skills through a community life skills course.

3 OBJECTIVES

Aim 1. Identify the social and vocational barriers encountered by YAASD transitioning from high school to adult life, and address these barriers through a resilience framework. Using a community-engaged participatory approach, we will interview key stakeholders (e.g. YAASD, family members, employers, community agencies, and case managers) to identify barriers -- and investigate ways to attenuate barriers -- to "adult life" activities (including activities which promote and enhance vocational and social engagement). We will ascertain why available social and educational service supports may be underutilized, and we will develop a model of care -- using a resilience framework -- for YAASD and their families.¹⁴ Assumptions: Barriers faced by YAASD are the result of insufficient support, skills and low self-efficacy and self-advocacy.

Aim 2. Develop the RiA intervention protocol for YAASD. This protocol involves incorporating a resilience framework within a community life-skills program that assists YAASD.

We will develop an intervention protocol for a 12-week program to promote life-skills and protective factors that build resilience and address barriers to transitioning as identified in Aim 1. Because YAASD have various levels of function and learning styles (auditory, visual, etc.), the curriculum will include adaptations to various levels of disability. Hypothesis: Building resilience (as measured by problem solving, life skills, social competence, self-efficacy and autonomy) in YAASD will help them overcome barriers identified in Aim 1.

Aim 3. Pilot the Resilience in Action (RiA) program with a group of 30 YAASD. We will pilot the RiA intervention with thirty YAASD with a range of skills and learning styles. We will measure the feasibility and acceptability of implementation of this program for YAASD, their families, and program staff. We will measure process outcomes of the intervention targets and assess/pilot potential outcome measures. In addition, we will compare YAASD experiences, barriers, and potential outcome measures pre and post study.

4 STUDY DESIGN

Please note that young adults with autism will be involved in both Aims 1, 2 and 3, by giving input to the program through qualitative interviews as well as participating and giving feedback to the curriculum.

Study procedures as outlined from our grant:

C3a. Aim 1: Identify the social and vocational barriers encountered by young adults with autism spectrum disorder (YAASD) transitioning from high school to adult life, and address these barriers through a resilience framework. The research for Aim 1 will be used to investigate the reasons some young adults have and have not been successful with the transition process. In addition, we will also conduct follow up interviews of clients who complete the pilot intervention. The goal of these investigations is to identify potential target areas for the resiliency framework. While there is some literature on transition supports, few investigators have looked at community-based mechanisms to improve the success of persons with autism. Understanding these facilitators, barriers, and needs will inform the development of the pilot project. Part of this recursive design is to tailor the program for AYAASD of various skill levels.

C3b. Aim 2. Develop the RiA intervention for YAASD. This pilot involves incorporating a resilience framework into an existing community life-skills program which assists YAASD.

Resilience in Action (RiA) Intervention: The RiA intervention will be designed to incorporate lessons learned from Aim 1 and build upon young adults' strengths to support them with their specific life goals as they move into the community-based service sector. Also, the RiA helps mediate behaviors, which may impede achievement of specific goals. After completing the RiA program, long term support for participants will be provided by GGRC case managers who have existing relationships with study participants. The resilience curriculum is comprised of flexible components that can be tailored to meet the needs of the YAASD, and can be administered in individual or small group sessions. In order to function within the resiliency framework, the intervention will have 3 components: First, we will build a life skills curriculum to help YAASD adapt to adult life and societal expectations. This curriculum will integrate 4 distinct modules to cover resiliency areas as shown in Figure 1. Second, a support component will be provided through the GGRC case managers (who are also trained in the resilience framework) in order to ensure long-term continuous support. See Table 1 for comparison of intervention to "usual care."

Development of the life-skills resilience curriculum. The RiA curriculum will be integrated into twelve one-hour modules developed at the Arc of San Francisco to build life skills for people with developmental disabilities. The RiA components will be developed for moderate/high functioning persons with autism; therefore, the curriculum can be easily adapted for higher or lower functioning persons with autism during regular meetings between researchers and Arc personnel. By integrating a resiliency component into an established life-skills program, this framework can then be adapted to any community program that supports YAASD. Development of the curriculum will be done in conjunction with a special educational curriculum specialist, Heidi Seretan, of the San Francisco Unified School District. Ms. Seretan developed the transition curriculum for the San Francisco Unified School District transition programs for persons with developmental disabilities and

autism. Through a collaboration between developmental-behavioral pediatrics, special education, clinical psychology, resilience experts, and transitions researchers, we will devise a practical, “developmentally appropriate”, and age appropriate adult learning module for YAASD. Extending and building upon effective curriculum used in the high school transition program, the duration of each class will be one hour and include ten students per course to maximize interaction and learning.

Addressing Mental Health Needs of YAASD: Because concurrent mental health challenges often arise in YAASD, we will be working with Dr. Martin-Herz to address any potential needs that may arise in the program. For example, in one resilience program for school aged children, a component of cognitive behavioral therapy (CBT) was incorporated into the program. We have the capacity at the Arc to incorporate therapy into RiA if deemed appropriate. Our primary goal is to ensure all participants have the appropriate mental health and counseling support, and we will adapt RiA as necessary and refer participants/families to outside agencies/providers if needed.

Case management support: We will provide coaching to GGRC case manager(s) who work with the 30 participants. The GGRC case manager will provide continued support to these 30 YAASD after completion of the course and study period. The personnel implementing the RiA receive standardized training and fidelity of administration is monitored. Case managers will receive training on the resilience framework and motivational interviewing to build their capacity and skills to incorporate positive relationships and strength assessment into their interactions with YAASD. Case managers then work with the individual to identify goals, to help YAASD determine how to utilize strengths in order to achieve these goals, and to support the young adult in the achievement of self-generated goals after the study has ended.

C3c Pilot the Resilience in Action (RiA) program on YAASD.

Overall Study Design: This is a pilot project utilizing an intention to treat design to of 30 individuals who agree to participate in RiA. This design allows us to have a control group and be acceptable to our community partners during the pilot creation. This allows us to recruit a breadth of disability and client type and, thus, this method would be responsive to the expectations of our community partners. The pilot intervention will commence within six months of grant start (Table 2. Timeline). Families will be compensated \$50 per survey for participation in the study (pre-post curriculum).

Program evaluation

Table 2. Timeline: Activity in months	0-3	4-6	7-9	10-12	13-21	22-24
Enrollment for Aims 1 and 3 and IRB	X	X	X			
Aim 1. Qualitative interviews	X	X	X	X	X	X
Aim 1. Qualitative analyses	X	X	X	X	X	X
Aim 2. Program/course development	X	X		X	X	
Aim 3. Training of case manager	X	X				
Aim 3. Pilot resiliency 1 st group				X	X	
Aim 3. Pilot resiliency 2 nd group					X	

Aim 3. Pilot resiliency 3 rd group					X	
Aim 3. Data collection			X	X	X	X
Aim 3. Program evaluation				X	X	X
Dissemination/Manuscripts				X	X	X

The program evaluation, performed by the UCSF investigative team, will evaluate whether the intervention addresses the key resiliency targets and whether fidelity of the study design was executed. We will use a mixed methods design to monitor both qualitative and quantitative measures of key processes and outcomes of this pilot intervention as well as test potential outcomes for a larger, longitudinal study.

The Course: The course will be 1-1.5 hours long to be performed at the Arc of San Francisco. The course will follow the curriculum developed in Aims 1 and 2. The course will be taught by 1 staff member and have 2 assistants there to help lead small groups and help students.

5 Study Population

5.1 Selection of the Study Population

Study subjects and recruitment strategy: *Inclusion criteria for YAASD for Aims 1 & 3:*

The qualitative study and intervention will be described to case managers at GGRC and the Arc, they will be asked to identify YAASD who are completing the high school transition program, or who have exited the school system within the last three years and who may be interested in the program. We will ask to recruit from a diverse group of YAASD – a set which includes a range of moderate functioning and high functioning YAASD, as well as different learning styles for purposes of testing the curriculum. We define moderate to high functioning YAASD by the Social Responsiveness Scale, Second Edition (SRS-2) with a T score < 75). We will ask to have a mix that reflects the gender and racial mix representative of the client population (see recruitment section in appendix). The study team will then contact the YAASD or their guardians, with permission from the case manager, and inquire whether the YAASD wish to participate in Aim 1 and Aim 3 of the study. We will recruit YAASD until we have 30 YAASD for Aim 3. We will ask a sample of those 30 to participate in Aim 1 until we reach thematic saturation (~7 YAASD). Our interviews will adapt to account for both verbal and non-verbal communication (relying on parents for input for those with difficulty with verbal communication). *Inclusion criteria for stakeholders for Aim 1:* We will generate a purposive sample of key stakeholders including parents of YAASD, school district transition program staff, and public and private community service agencies that support YAASD as identified by case managers and YAASD/families. *Exclusion criteria:* We will exclude YAASD who are non-English speaking, unable to consent, wards of the state, or incarcerated.

5.2 Inclusion/Exclusion Criteria

Inclusion Criteria

(1) Moderate to high functioning persons with autism, ages 19-35 years, who have exited the school system. (SRS <70, ABAS >80, or can function within small working group). We will use the ABAS-3 to characterize functional status of participants in order to assess any functional group differences which would affect ability to participate in – and benefit from – the program. Since a floor effect may be anticipated in the social adaptive domain of the ABAS-3, the SRS-2, which is designed to assess social functioning/impairment specifically in individuals with ASD, will also be administered and will serve this purpose for the socioemotional domain.

(2) They must be able to participate in a one hour class with nine other participants and be able to interact with participants and the teacher without support.

If family members feel that their child does fit these two criteria, we will ask for the name of their GGRC case manager to evaluate the appropriateness of the client for this program. This will ensure that, while we ask screener questions for the parent/caregiver, the youth may be lower functioning than parental assessment. The case manager will use information from their Client Development Evaluation Report (CDER) and experience from the school

program to assess whether they are ineligible (for example require 1:1). The case manager will ensure that the client would be successful in the pilot class.

Exclusion Criteria

We will exclude YAASD who are non-English speaking, unable to consent, wards of the state, or incarcerated.

6 STUDY PROCEDURES/EVALUATIONS

6.1 Study Procedures

We will first solicit case managers to recommend individuals to the study team for the study. The study team, including Dr. Okumura and future research assistant will then screen for eligibility based on screening interview and GGRC case records for diagnosis of autism and level of severity. ABAS-3 may need to be administered by the study team in order to ensure that appropriate severity is categorized. Persons who are unable to participate in a classroom (follow basic instructions) would be excluded from this program. We will also ask the case managers to refer families for interviews. We will contact service providers of persons with autism via standard publically available contact information. For example, the special needs coordinator at Jewish Vocational Services.

For clarification of eligibility, we will first ask family members to identify whether their child meets both of the following criteria:

- (1) Moderate to high functioning persons with autism, ages 19-35 years, who have exited the school system.
- (2) They must be able to participate in a one hour class with nine other participants and be able to interact with participants and the teacher without support.

If family members feel that their child does fit these two criteria, we will ask for the name of their GGRC case manager to evaluate the appropriateness of the client for this program. This will ensure that, while we ask screener questions for the parent/caregiver, the youth may be lower functioning than parental assessment. The case manager will use information from their Client Development Evaluation Report (CDER) and experience from the school program to assess whether they are ineligible (for example require 1:1). The case manager will ensure that the client would be successful in the pilot class.

Interviews

Interview Plan: The interviews will identify targets that would best facilitate the transition toward appropriate independence and determine best practices for a resilience-based program to meet the long-term needs of YAASD. Drs. Okumura and Rehm will conduct approximately 30 semi-structured interviews with YAASD, family members, and staff providers (15 interviews in the development phase, 15 at the end of the intervention (Aim 3)).

Interview Procedures: Interviews will take between 45 and 60 minutes, and will be audio-recorded and transcribed for analyses. The investigators will review the first 3 interviews from each category of participant in order to analyze the interview process and to modify interview guides as necessary. Interviews will take place in a location of the participant's choosing: either in the home, school, at The Arc, or at UCSF. Participants in Aim 1 will receive a \$25 incentive.

Interview Guides: These have been designed to gather the participants' experiences and to capture respondents' interpretations, subjective understandings, and beliefs about

desired programmatic elements and their needs in adulthood. The context in which particular transition barriers and facilitators have been encountered will be discussed with the YAASD, their families and the other service participants. We will also discuss goals and strategies for life planning, vocational endeavors, or home placement. For non-verbal YAASD, the interviews will be done with family with YAASD present.

Course Development:

The curriculum will initially be developed with information gathered within Aim 1. The curriculum specialist will use this information – along with input from the study team – to modify and finalize the curriculum to meet the needs of participants across the ASD spectrum. This will be an iterative process with input from Arc and GGRC staff and UCSF investigators. The curriculum developer will then test the curriculum on the first class of ten students and get feedback from participants after each class. We will then take 1-2 months to redesign the curriculum in order to address issues that arose during the first course; this redesign will take into account input from students, families, and case managers. The revised curriculum will be vetted again with further facilitator guide development. Another round of feedback by the UCSF staff and curriculum developer will be performed and the third and final class will be taught by another staff member in order to test the usability and clarity of the protocol with community agency staff; after this course is completed, further refinement of the curriculum will yield the finalized resiliency protocol which will be used in a future larger trial.

Pilot Course participation:

Once enrolled participants have agreed to participate; they will be sent a packet to their homes that contain all the baseline surveys and informed consent. An orientation will be given on the first day of the class for the family members and participants will be introduced to the course. On the first day of the course, there will be an orientation; the participants will also have an opportunity to finish the surveys and complete the informed consent before the class starts. Participants will receive \$50 for returning the baseline survey.

The participants will then meet once a week for 1.5 hours for a total of 12 sessions. The course offering and structure will be developed as part of Aim 2. After the completion of the course they will receive \$150 for completing the course. Participants are allowed to miss 3 sessions of the course and still receive full remuneration.

Once the course is completed, the participants will receive a packet in the mail with the follow up surveys 3 months after course completion. Participants will be contacted by email and phone to confirm their addresses. Once completed, the participant will receive \$50 for returning the follow-up survey.

7 STATISTICAL CONSIDERATIONS

7.1 Study Outcome Measures

Measures: We will be performing a qualitative analysis for our evaluation (Aim 1). In addition we will be using various survey instruments to measure potential mediators and outcomes listed in our framework. We will also measure demographics, skill/function, resiliency, self-efficacy and quality of life as those are major targets of our intervention. We will measure levels of satisfaction with social roles which are key outcomes to resiliency program. We will also measure post-school outcomes, such as entry into day programs and vocational status post intervention and self-efficacy in engaging health care. Table 1 shows all measures being collected as part of the study.

Measures	What it measures	Level of measure	Frequency of measure
ABAS®-3 Adaptive Behavior Assessment System® Second Edition	Skills Areas: Conceptual Practical, Community Use Home Living, Self-Care Social Functional, Academics Social, Community, Leisure Health and Safety, Self-Direction, Work	Parent/ Primary Caregiver Form	Baseline & post- intervention
Demographic information	Sex, race, family structure, income, education level and community participation	Parent/ Primary Caregiver Form	Baseline
McMaster Family Assessment Device (General Functioning Subscale)	12-60 item scale to look at stress and impact on family Problem Solving; Communication, Roles, Affective Responsiveness, Affective Involvement, Behavior Control, General Functioning.	Parent/ Primary Caregiver Form	Baseline & post intervention
Pediatric Quality of Life Scale	Validated quality of life measure that has been developed across different developmental ages and adults	Parent or young adult	Baseline & post intervention
Resilience Scale ⁷⁴	Personal competence and acceptance of self and life, which measures the construct of resilience. Adapted for 2 nd and 5 th grade reading level.	Young adult	Baseline & post intervention
PROMIS: Satisfaction with Social Roles and Activities (v2.0)	Satisfaction with performing one's usual social roles and activities (e.g., "I am satisfied with my ability to participate in family activities").	Young adult	Baseline & post intervention
PROMIS: Self Efficacy	A person's belief in his/her capacity to manage functioning and have control over meaningful events.	Young adult	Baseline & post intervention
Vocational measures and community measures	Employment, school, home activities, volunteering. Time at home, time outside of home	Young adult/client level or caretaker	Baseline & post intervention

7.2 Sample Size Considerations

To reach thematic saturation for our study, we think that having about 7 youth and 15 family members/stakeholders in caring for young adults will be sufficient.

Our class is being tested for 10 students per class for 3 cycles.

In this pilot, for our outcome of resiliency, we have the ability to pick up a 12-16 point difference between pre and post-intervention (resiliency scale range 25-175) with a 2-tailed α of 0.5 and β of 0.2.

7.3 Participant Enrollment and Follow-Up

30 patients will be enrolled in the study and participate in a 12-week life skills course. After the course ends, they will be contacted between 3-6 months to complete a follow-up survey.

7.4 Analysis Plan

For the qualitative analysis:

Interview Analysis: Every two weeks during the study period, the research team will meet to review transcripts. This will provide investigator triangulation. Data will be entered into Atlas Ti, a computer software analysis program that provides a means for storing, organizing, and manipulating large quantities of qualitative data. Specific steps in the analysis include: 1) Review of each transcription, and construction of a participant summary; 2) Open coding of each transcript to identify salient issues; 3) Analysis of major categories built from step 2; 4) Identification and description of unifying themes that capture contextual factors affecting barriers and facilitators to transitioning for YAASD. The end product will be an in-depth description of major themes and their contexts. This description will include the various ways in which YAASD and their parents and community providers experience the transition stage. These findings will then be used develop the RiA curriculum and pilot in Aim 2. Interviews completed after the pilot will be part of the program evaluation in Aim 3.

Interview Guides

Interviews for the proposed study will be semi-structured and result in an in-depth look at barriers and facilitators to vocational and social success in young adults with autism spectrum disorder (ASD). Data collected in this manner is based on the individual life experiences of informants and reflects their interpretations, subjective understandings, and beliefs about their own lives, rather than the preexisting conceptions of the researcher. The context in which particular barriers and facilitators have been encountered will be discussed with the participants. Initial versions of semi-structured, open-ended interview guides have been developed to address the objectives listed under the Specific Aims and the gaps in the literature discussed in Background and Significance. After the initial interview, transcripts will be reviewed and subsequent follow-up interview guides will be constructed, with guidance of the study team, to follow-up issues of importance to the overall sample. The community provider interview covers related topics, from the providers' viewpoint, including goals for adult living and plans to accomplish them, barriers and facilitators to accomplishing these goals, strategies for working with young adults and their caregivers to

also maintain high quality chronic illness care, and communications with other health care providers and community agencies, along their vocational and social needs. A copy of the interview guide has been attached.

For the quantitative analysis:

This is a pre-post design with 30 students (3 classes, 10 students each). We will conduct pre-post analysis of intervention participants on our survey measures and resiliency outcomes using appropriate bivariate analyses given the small sample size.

8 SUBJECT CONFIDENTIALITY

The research material will consist of qualitative interviews and reviewing drafts of tailored modules to assess client and family understanding of the materials. Dr. Okumura (PI) will have access to protected health information, as will the project manager and the research assistants at UCSF. All identifiable private information will be maintained on a password-protected server maintained by UCSF's RedCAP or Qualtrix server. We will also be surveying transition aged persons with Autism from the Regional Center. These persons will be identified through the regional center registry and case managers. Those persons at the regional center will not receive the intervention, but should the pilot be successful, they will be the target of the randomized control trial of the developed intervention. All data collected will be confidential and will be used only for research purposes. In addition we will perform the following data management procedures to minimize the risks of breaching confidentiality: 1) storing all data in locked file cabinets; 2) using only pre-assigned ID numbers with no other identifying information on all and qualitative analysis; 3) storing the master list with ID codes and names separately in a locked drawer, and 4) storing consent forms in separate lockable file cabinet. All electronic data file will be password protected limiting to project staff's access only. As all the coding will be de-identified, and study results reported in aggregate means, there will be minimal risk to all participants. All secondary data analysis in this proposal contains de-identified data, so no individual would be at risk for breach of confidentiality. Any personal information will be kept in locked storage with personally-identifying information only accessible by the study team.

9 INFORMED CONSENT PROCESS

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continuing throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation in this study will be provided to the subjects and their families. Consent forms describing in detail the study procedures and risks are given to the subject and written documentation of informed consent is required prior to enrolling in the study. Consent forms will be IRB approved and the subject will be asked to read and review the document. Upon reviewing the document, the investigator will explain the research study to the subject and answer any questions that may arise. The subjects will sign the informed consent document prior to being enrolled in the study. The subjects should have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. The subjects may withdraw consent at any time throughout the course of the study. A copy of the informed consent document will be given to the subjects for their records. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

9.1 Informed Consent/Assent Process (in Case of a Minor or Others Unable to Consent for Themselves)

The primary investigator, who is a health services trained physician and has performed numerous studies with persons with developmental disabilities and special health care needs, will determine whether the individual is able to comprehend the risks and benefits of the study and understands the purpose of the study. In addition, all other study members have behavioral and developmental backgrounds, or have performed studies on children with developmental disabilities (Tebb, Rehm and Martin-Herz). Capacity for informed consent will be determined by whether the individual can: 1.) Articulate to the investigator the purpose of the study once they study is explained to the participant by asking "So could you tell me the purpose of this study as you understand it?" and 2.) Articulate to the investigator the potential risks and benefits of the study after explanation of the study by asking "So can you tell me what some of possible good and bad that could happen to you by participating in this study, based on your understanding of this study?". They must also 3.) be able to voice understanding of their own rights and understanding that they do not have to participate and 4.) be able to voice whether or not they wish to participate in the study. If the potential participant is unable to articulate understanding and answers to these 4 questions/points, or they are non-verbal, the informed consent process will be conducted with the parent or guardian. Information about the study will be shared with the parent or legal guardian and the study team will ask them the parent or guardian to partake in the study. We will also evaluate whether the parent or legal guardian

understands the information. If the parent or legal guardian cannot voice understanding of the study, and the risks and benefits of the study, we will then stop the study process with that participant. If they understand the purposes of the study, we will then proceed with the informed consent process with the parent or guardian asking about the said child's health care. If at any time, the participant gives any indication that they do not want to participate, no further action will be taken and they will be withdrawn from any further participation without any consequence. The research assistant is TBA and will be trained to assess capacity. We will use the UCSF IRB capacity form which goes over each of the steps described above.

10 LITERATURE REFERENCES

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