# Study Protocol and Statistical Analysis Plan

For

# Steps to Effective Problem-solving (R01HD086211)

NCT02855008

April 8, 2021

## B. RESEARCH STRATEGY

### B1. Significance

Intellectual disability (ID) affects 1%-3% of the 312 million U.S. population (3-10 million),[23,24] over 85% of whom have mild to moderate ID. Members of this population often have aggressive/challenging behaviors (A/CBs)[15]. A/CBs (including physically or verbally aggressive, destructive, socially offensive, or other behaviors) pose a risk to the health and safety or negatively affect the quality of life of individuals with ID or others and require management.[26] Epidemiologic studies show that, among individuals with ID, A/CBs are more of a problem among males. [27]A/CBs also may be an atypical feature of depression in this population.[28]Rates of depressive symptoms are as high as 28%-39% in individuals with ID,[29-31] and more common among females.[32] A/CBs are also associated with adverse life events common among residents of group homes such as the death of a parent, family member, or an individual important in one's life.[33-34] Despite their cognitive deficits, evidence indicates that A/CBs are modifiable for persons with this disability.

**B1a. Deficits in social problem solving.** Evidence suggests that individuals with ID are susceptible to A/CBs due to deficits in social problem solving (SPS).[7,27] SPS is the process of finding solutions to problems. It includes the cognitive and behavioral activities one uses to recognize, cope with, and find solutions to problems. SPS is made up of two independent but interrelated dimensions: attitude and style.[6] The dimension of attitude includes positive and negative attitudes. Positive attitude involves recognizing problems and their sources, and believing in one's ability to manage or solve problems. Negative attitude involves thinking of problems as a threat, inaccurately describing their sources, and believing that one is unable to solve or manage the problems.[6] Individuals with ID who have A/CBs tend to have a negative attitude; they are more likely to view interpersonal situations as hostile.[7,27]

The three SPS styles are rational, avoidant, and impulsive. Defining problems, generating and thinking through alternatives, and systematically carrying out and verifying solutions are part of the rational problem-solving style.[6] Inaction, dependence, and passivity toward problems are part of the avoidant style. Immediate emotional responses to problems are part of the incomplete, hurried, and careless impulsive style of SPS. Individuals without aggression problems use more assertive responses (rational style)[7,27]. Individuals with ID who have A/CBs respond to situations with hostile actions more frequently than non-aggressive individuals with ID,[7] and, in stressful situations, use more aggressive responses (impulsive style)[27]

**B1b. AC/Bs and the group home.** A/CBs of individuals with ID living in group homes represent an important public health issue in an under-researched and under-treated vulnerable population. A/CBs directed to self, other residents, and staff are reportedly common in group homes and a major concern for residential staff,[18,36] who report witnessing A/CBs at least several times a week.[18,36] Also, 20%-24.5% of individuals with ID in group homes report experiencing distress from other residents' A/CBs.[16,37] Such behaviors increase problematic interactions, perpetuating the problem.[16,37] Punitive means of handling A/CBs (e.g., physical and/or chemical restraints, timeouts) can be as dangerous and are unacceptable in terms of human rights.[38.39] To reduce and eliminate the use of such methods, agencies providing residential services for individuals with ID are encouraged to follow a system of positive behavioral support.[40] SPS interventions show effects in reducing problem behaviors, but have never been tested in a clinical trial as a preventive intervention in the community, including group homes and work settings. A critical need exists for evidence-based behavioral interventions that can be implemented as part of positive behavior support to reduce A/CBs.

**B1c. Lessons learned from SPS interventions.** Our pilot intervention used SPS training among individuals with ID and their residential staff as a preventive intervention to address A/CBs in a community setting. The intervention systematically involved support staff and the group environment to enhance the intervention. Our pilot was specifically designed to incorporate strengths found in previous research and to address gaps in previous efforts. (1) Over the past 25 years, almost all SPS studies were conducted in clinical and forensic settings and with individuals with ID referred for severe behavior and anger management problems, *necessitating delivery by highly trained psychologists and graduate students, making the interventions expensive*[41-47] Studies found improvement in SPS skills, including use of rational style (specifically generation and quality of alternative solutions) and a decrease in impulsive style and anger provocation.[41-47] Improved SPS was demonstrated by self-report and coded digital audio- and videotapes, and reduced A/CBs were demonstrated by self-report, caregiver report, and role-play measures.[41-47]Reductions were maintained for up to 12 months. Our pilot developed a SPS intervention specifically as a preventive intervention. (2) Two studies suggested that outcomes were better for individuals who had a staff member accompany them, but staff were not included as an integral part of the interventions. Our study systematically involved staff. (3) The support environment for SPS is an important consideration.[42,47] In addition to residential staff support, group training in SPS skills may encourage individuals with ID to think about the point of view of others and identify alternatives for problem solutions.[48] Research showed that when individuals with mild or moderate ID living in residential facilities made decisions as a group about common problems, the decision-making skills of the individuals improved.[49] Factors in the group environment, such as group cohesiveness, have been shown to affect outcomes.[50] Our pilot intervention specifically used the support environment of the

group home to help individuals with ID maintain and use social problem-solving skills and thus prevent problem behaviors. Previous studies did not provide a path to sustainability. Our interventionists have qualifications similar to qualified ID professionals (QIDPs), who currently provide services to individuals with ID in group homes. QIDPs have bachelor's degrees in a human services field (e.g., sociology, special education, rehabilitation counseling) and at least one year of experience with individuals with ID.[51] This will provide evidence about whether QIDPs could carry out the STEPS intervention in practice.

Additional gaps in the current literature were identified in a recent Cochrane review of randomized or quasi- randomized interventions for outwardly aggressive behavior among individuals with ID.[52] Only four studies met the review criteria; of these, three included SPS training.[42,44,45] The review concluded that previous studies all had a moderate risk of selection bias and lacked intent-to-treat analysis. The review recommended larger randomized trials with objective outcome measures of aggressive behavior and cost-effectiveness analysis.[52] Other gaps included that no studies assessed outcomes across community and work settings.

We will address prior gaps by conducting a randomized clinical trial in a community setting (group home) with objective outcome measures of A/CBs in the group homes and in work settings. *We also will conduct a cost-effectiveness analysis.* We will implement the STEPS intervention in group homes with residents with ID and residential staff and investigate the mediating effect of the support environment for SPS (residential staff SPS, group SPS, and group cohesiveness) on the intervention outcomes. We will use an intent-to-treat approach, will evaluate efficacy using multiple measures of A/CBs, *including objective measures.* By addressing these gaps, we will provide empirical data on the efficacy of SPS training and effects in the prevention of A/CBs in individuals with ID.[21,22]

**B1d. Conceptual framework**. We will use the STEPS Framework, developed in our pilot study[53,54] (B3a). The STEPS Framework (Figure 1) is based on the Interaction Model of Client Health Behavior[6] and the Relational/Social Problem-Solving Model.[55] These models are grounded in the broad philosophic construct of human agency that addresses the capacity of humans to adapt, change, make choices, and make things happen by their own actions. The STEPS Framework allows one to examine explanatory relationships among determinants of the A/CBs of individuals with ID, intervention strategies, the support environment for SPS, and subsequent outcomes (SPS skills and A/CBs). A/CB determinants are characterized by background characteristics (demographics, past life events, environment, and current health). A/CBs are associated with SPS attitude and style, specifically negative attitude and impulsive style. STEPS intervention strategies are targeted to SPS skills, specifically to increase positive attitude and rational SPS style. The STEPS intervention affects relationships between background characteristics and outcomes of SPS skills and A/CBs. Targeting SPS skills for improvement can reduce A/CB outcomes. The support environment for SPS mediates the relationship between the intervention and individuals with ID outcomes. The framework specifies that participant outcomes (i.e., SPS and A/CBs) are dynamically related: the greater the improvement of SPS skills, the greater the likelihood of decreased A/CBs.

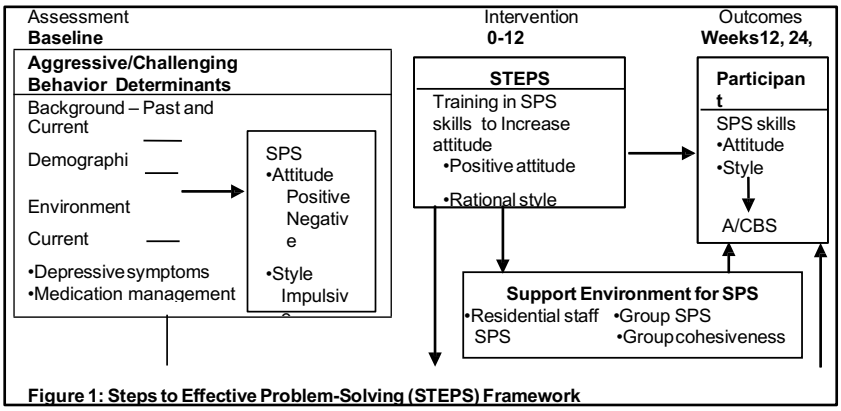

**Figure 1: Steps to Effective Problem-Solving (STEPS) Framework**

**B2.** ***Innovation***

The STEPS intervention is a prevention-oriented approach to reducing A/CBs for individuals with ID. We created a unique adaptation of an existing SPS skills-building program by translating it from the clinical setting to group homes in the community, an environment ideal for preventive interventions. Our proposed study takes this further by using interventionists with similar backgrounds to QIDPs who work providing residential services. We will conduct cost-effectiveness analysis providing a new means to quantify the costs of A/CBs to individuals with ID, their support systems, and society. We will provide a robust means to address the impact of the intervention on costs. If the intervention proves successful, next will be conducting implementation research to address whether QIDPs can conduct SPS training with individuals with ID and residential staff in group homes with the support of agency management. Doing so will demonstrate a mechanism for delivering STEPS in the community in a way that relies on staff usually in these settings rather than requiring additional professionals. If these innovations are successful, it will provide an innovative model of sustainable cost-effective care for this population.

***B3. Approach***

**B3a. Preliminary Studies**

**Developing a SPS program for the group-home environment (PI Ailey, S., Co-I Miller, A. Rush CON Pilot Funding, 2010-2011).**[21,22] The **purpose** of this study was: (1) Phase 1: modify and tailor Nezu and colleagues' Attitude, Define, Alternatives, Predict and Try-out (ADAPT) social problem-solving program[6] so that it was understandable and acceptable for individuals with ID in group homes and their residential staff,

and (2) Phase 2: pilot test feasibility of the newly adapted program (now called STEPS).[21]

**Methods Phase 1**: In previous work, we found the views of individuals with ID differed from those of their support staff and caregivers.[29,56,57] Also, translating clinical research to community settings includes obtaining input from community members on how they understand materials and how they would like interventions delivered.[58] Thus, in this study we used multiple sequential methods and sought input from four groups of important stakeholders. First, a panel of experts, including the PI, co-I (a counseling psychologist), and Dr. Nezu, made modifications to the ADAPT program manual. Second, an advisory committee of six agency program directors (responsible for developing behavioral programs for individuals with ID) from four agencies providing residential services met with the PI to review the revised manual and recommend additional changes. Third, the new program manual was reviewed with three individuals with ID who lived in group homes and had a history of A/CBs requiring behavior program plans. Cognitive interviewing was used.[59,60] Fourth, the program was reviewed with three group-home residential staff using cognitive interviewing. After all cognitive interviews were complete, the expert panel and a methodological consultant (Dr. Janet Melby) met again to edit and approve the program that was used during the pilot in Phase 2. Based on experience during the pilot and satisfaction interviews with residents and residential staff who participated, further modifications were made to the program. The same three individuals with ID who participated in the cognitive interviews reviewed the modifications. The STEPS program was then finalized.

**Results Phase 1:** Reviewing the initial modification of the ADAPT program manual, the Advisory Committee of agency program directors recommended reducing the number of sessions *from 12 in the original to 6.* They also suggested the need for interactive group materials and activities to build group cohesiveness. The cognitive interviews with individuals with ID provided examples of problems likely to lead to A/CBs and ways the individuals might respond, alternative wording, and ideas for the logistics of the program. Residential staff expressed confidence in working with the program, provided suggestions for interactive games, and suggested the use of narrated PowerPoint slides to reinforce the material in the manual. The expert panel, in consultation with the advisory committee, made modifications to the program throughout the process. *We distilled the program to the core elements (attitude, define, alternatives, predict, tryout). Further, we simplified language to be comprehended by persons with ID (aimed for 2nd grade comprehension level). Group members knew one another so time to build familiarity was reduced. Thus, we could reduce the modules from 12 to 6.*[22]

**Methods- Phase 2:** A pre-post design was used to test STEPS. One agency identified two group homes (one male, one female) with a history of A/CBs. Of the 14 residents in the two homes, 12 agreed to participate; of these, 9 required consent of a legal guardian. Six residential staff signed consents to participate, and four actually participated. A Data and Safety Monitoring Committee reviewed data and protocols during the pilot.

The psychiatric nurse interventionist and a research assistant were trained in the intervention. The six weekly sessions and one booster of the STEPS program were delivered over 12 weeks. Outcomes measured pre and post intervention were SPS skills of the individuals with ID and residential staff, group-level problem solving, and A/CBs of individuals with ID.[42,50,61-62]

**Results Phase 2:** The mean age of individuals with ID was 36.6 (SD 10.5). All 4 residential staff and 5 of the 12 individuals with ID were women. Half of residential staff (50%) and 25% of individuals with ID were minorities. Among residents, 33% had incident reports during the previous 12 weeks. On average, the individuals with ID attended 70% of the sessions and residential staff attended 67%. One individual with ID dropped out over the 12 weeks due to lack of interest, *one staff member went to a different home, and another staff member left the employ of the agency midway through the study*. Satisfaction was high among individuals with ID and residential staff (91% and 87% highly satisfied, respectively). The effect size for improvement in SPS skills was *d* = .60 for individuals with ID and residential staff. The effect size for decrease in A/CBs of individuals with ID was *d* = .60. Effect sizes for improvement were *d* = .51 in group-level problem solving and *d*= 1.43 in cohesiveness (first session to last).[22]

Residential staff indicated that training in breaking down problems and getting to know how individuals with ID related to each other were the most helpful aspects of the program. They suggested that because some issues are “touchy” for group discussion, sessions should start with “easier” issues and move to increasingly difficult topics. They wanted guidance on the program and more guidance for practice between sessions. Both individuals with ID and residential staff felt the best time to meet was a weekday evening.

**Implications for the proposed study**: We were successful in recruiting and retaining individuals with ID and their residential staff. Satisfaction was high for both. There was a medium-to-large effect size, indicating improved SPS skills and

decreased A/CBs in a videotaped interaction. Based on residential staff recommendations and review by residential staff involved in both Phase 1 and 2 and our field notes, we developed an orientation manual for residential staff. Orientation will be conducted before the start of the intervention in our proposed study, and we will guide residential staff during the program (see Appendices C and D). Also, we will space out the six content sessions over three months (1 every other week) to allow time to assimilate problem-solving skills, and have one booster session six weeks later (midway through the maintenance phase, at Week 18). In sum, our pilot work suggests that STEPS is likely to improve the SPS of individuals with ID and residential staff and likely to improve group-level SPS. Also, our pilot work shows that it is feasible to implement STEPS within the group home with high levels of satisfaction.

**B3b. Methods**

**B3b1. Design**. A cluster-randomized clinical trial design will be used in which 36 group homes (14 male, 14 female, and 8 co-ed) will be randomly assigned to either the STEPS intervention (n = 18; 7 male, 7 female, and 4 co-ed homes) or attention-control (n = 18; 7 male, 7 female, and 4 co-ed homes). We have worked with or are currently working with eight agencies, five of which were in the original nine that were randomly ordered for participation. Two more of the original nine requested to be contacted again in early 2019, related to absence of key staff for one and merger with another agency for the other. Within some agencies, we will be able to identify six homes (2 of each gender and 2 co-ed) that meet criteria. Within agencies with only 3 homes for any or all three genders (male, female, co-ed) we will randomize homes within gender. If recruitment rates render a randomized home ineligible, we will randomly select an alternative home from a different agency. For agencies with only 1 eligible home for any gender, we will draw additional homes from a different agency. Whenever possible, we will adjust ordering of agencies to allow all participating homes within an agency to participate within the same time frame so that they are part of the same cohort. In addition, we may need to recruit additional agencies in order to reach the required number of 36 homes for this research . We will inform the IRB of any new agencies and provide letters of support. Group homes (residents and staff) will be recruited after randomization to simplify the process of explaining the study to individuals with ID. If fewer than two residential staff and/or fewer than three residents are willing to consent to participation, that group home will be ineligible and the third group home serving the same gender within that agency will be approached for recruitment.

Group homes in both conditions will receive one session (STEPS or attention-control Food for Life) every other week for 12 weeks, for six total sessions, and a booster at 18 weeks. Data collection for both conditions will be at baseline (pre-intervention) and 12 weeks (post-intervention), to estimate intervention effects and at 24 and 36 weeks after the start of the intervention to estimate maintenance.

Prior to going on pause related to COVID 19 on March 12, 2020 We had already finished or begun the intervention at 25 homes homes (8 female and 15 male, and 2 co-ed). These include 17 homes with 24-week data collection, 5 with 12-week data collection, 4 that were part way through the intervention. There are an additional 2 homes where we had all consents and completed baseline data collection, but had not started the intervention (both co-ed), and 7 homes where we had started the consent process (3 female, 4 co-ed). Starting in study Week 204 (Month 11 of Year 4), we will again recruit two cohorts of five to six group homes (plan for two male, two female, and 1-2 co-ed home for each condition) , staggered to begin every 10-12 weeks over weeks 204-260. . There will be eight weeks of recruitment for each cohort of five- six homes (allowing time to contact guardians if needed). We plan to return to the homes where we had consents but had not completed the consent process or had not started the intervention and work to recruit these homes again. The COVID pandemic has led to efforts to improve online learning for this population http://project10.info/DPage.php?ID=428). Internet-based technology has been found to be feasible among persons with ID for more than 10 years (Lotan et al., 2009). We now will conduct the intervention virtually.Data will be collected using an intent-to-treat approach; thus, we will attempt to collect data from subjects even if they stop attending groups.

**Setting and subjects.** Agencies have on average 25 group homes, each serving 4-8 individuals with ID. The setting for the study will be group homes for individuals with mild to moderate ID located in the Chicago area. Individuals with mild to moderate ID have an IQ of 50-75 and basic reading and writing skills ranging from being able to write their names and addresses to writing simple sentences; hold jobs in work centers, supported employment of independent community employment; may take public transportation independently; and need support in instrumental activities of daily living such as budgeting, making appointments, and nutrition planning. The group homes accept only residents aged 18 or over. Each group home has two or more residential staff working an afternoon/evening shift when residents eat the evening meal and engage in afternoon/evening activities. Most group homes were formerly single-family homes (not specifically built to be group homes) and look like other homes in the neighborhoods. Homes typically have a living room, dining room, kitchen, bedrooms, and often a recreation room. Homes have laundry facilities, a common TV in the living room, and recreational materials. Residential staff and residents cook meals. Staff and residents do the regular cleaning, and agencies have

maintenance staff for heavier cleaning and repairs. Residents often have their own TVs in their bedrooms and usually share a bedroom with one roommate. Residential staff in Illinois are only required to have an 8th grade education, though most agencies require 12th grade.[63] They receive assistance from QIDPs who are required to have a Bachelor's degree in a human service field and at least one year of experience working with individuals with ID.[51]

**Group home inclusion/exclusion criteria** are: (1) serve individuals with mild to moderate ID; (2) have at least 10 A/CB incident reports in resident files over the prior six-month period, with at least 30% of residents in each home having incident reports in that period; (3) have 5 or more residents, with a minimum of 3 agreeing to participate; (4) individuals with ID and residential staff all speak English; and (5) have one residential staff member who agrees to participate. Group homes will be excluded if they serve individuals with ID who also have serious mental illness (e.g., severe autism, schizophrenia) or homes for forensic populations. Group homes that participated in the pilot study (B3a) will be excluded. Ten accredited agencies located across the Chicago area, managing over 225 group homes serving individuals with mild to moderate ID, have agreed to participate (see letters of support, Appendix A). . Generally, agencies do not have their homes located closer than 1.5 miles to one another (Figure 4); eight of ten are included on the map. This geographic separation reduces contamination across sites.

**Individuals with ID inclusion criteria** are: (1) mild to moderate ID (operationalized as IQ 50-75[64] per agency records) and mild to moderate limitations in adaptive functioning (measured by the Inventory for Client and Agency Planning[65] used in all residential agencies in Illinois, per agency record); (2) live in a chosen group home; and (3) verbal and speak English. Individuals who participated in the pilot study (B3a) will be excluded.

**Residential staff inclusion criteria** are: (1) employed as residential staff in the chosen group homes and (2) speak and read English. Residential staff who do not meet these criteria or who participated in the pilot study (B3a) will be excluded.

**Recruitment, consent, and retention**. We will use the successful recruitment and retention strategies tested in pilot study B3a,[21,22] modified to be virtual. Agencies will identify homes meeting the inclusion criteria. Though we do not anticipate unwillingness to participate, going forward we will randomize 6 group homes (2 male, 2 female, and 2 co-ed) from each of 4 agencies (where we had not yet completed the intervention or with which we had not yet worked with) for randomization. . Randomization steps are: (1) randomly order agencies for participation (2) within each agency, six homes will be randomly assigned to the STEPS or attention-control condition (1 male, 1 female, and 1 co-ed home per condition). Once randomized, agency personnel will distribute a recruitment flyer and a form to residential staff asking their agreement to be contacted by a research team member. Once the recruitment flyer is returned (scanned document via email, fax, USPS), A research team member will contact the residential staff member via phone or Webex and determine best means to send the consent form to the residential staff. Materials can be sent via email, fax, or USPS. Once the staff person has the consent, the research team member will again contact the residential staff, explain the study, read the consent form over with the residential staff, confirm eligibility, answer questions, and obtain consent and set up a means to have consent sent to research team. Materials can be sent via email, fax, or USPS. . The flyer and consent explicitly state: (1) participation is voluntary; (2) the agency does not require or expect participation; and (3) there are no consequences to any conditions of employment or performance evaluations if they do not participate. Once the residential staff are recruited (at least two), recruitment of individuals with ID will commence. If the residential staff or the residents decline participation, the home will be replaced by the extra home from that agency. We will recruit until we have 11 additional homes ( [3 male, 4 female, and

co-ed] in each condition). As we have already recruited 25 homes that completed all or some of the intervention, we do not expect to have as many co-ed homes as male and female in the study.

For individuals with ID who have a legal guardian, agencies will send the guardian a recruitment letter about the purpose of the study and eligibility. A research team member will call all legal guardians who express an interest to explain the study and answer questions. A consent form will be sent to the guardian. Guardian consent may be sent to us by mail, fax or email of scanned document. After guardian consent is obtained, a research team member will contact the potential participant by phone or Webex to explain the study, answer questions and explain that participation is voluntary. They will also answer questions and obtain assent from the individuals with ID. For individuals with ID who are their own guardians, an agency QIDP will read a flyer about the study and obtain agreement to be contacted. Once the recruitment flyer is returned (scanned document via email, fax, USPS), a research team member will contact the individual with ID via phone or Webex and determine best means to send the consent form. Materials can be brought by an agency staff person, sent via email, fax, or USPS. Once the individual with ID has the consent, the research team member will again contact the individual, explain the study, read the consent form over with the person, confirm eligibility, answer questions, and obtain consent and set up a means to have consent sent to research team. If the individual with ID prefers, a residential staff person can be

present for assistance. Participant consent may be sent to us by mail, fax or email of scanned document.. Based on previous experience, we will use Fisher and Cea's[68] recommendations to assess ability of individuals with ID to consent/assent (Appendix B). Those unable to consent/assent will not be accepted.

Participating individuals with ID and staff in STEPS and attention-control Food for Life conditions will receive $20 for each data collection assessment: baseline, 12, and 24 weeks. The interventionist or research assistant will contact participants who miss sessions to invite them to continue if they still wish.(see Human Subjects). We will maintain regular (at least every two weeks) contact with agency management staff to discuss progress and any concerns. (see Environment). Also, we have access to the Community Engagement Board of the Center for Clinical and Translational Science at the University of Illinois at Chicago for input on recruitment and retention (see Letters of Support).

**STEPS Intervention.** The STEPS intervention consists of a half-day residential staff orientation, which we will set up by phone or Webex at a convenient time; residential staff will be oriented to the STEPS intervention to improve SPS skills, and practice assignments will be explained. Following this, six sessions (every other week for 12 weeks) for residential staff and residents, plus one booster session (at week 18 during maintenance), will be led virtually by a research team interventionist. To match the qualifications of QIDPs, interventionists will have a bachelor's degree in a human services field such as sociology, special education, rehabilitation counseling, or psychology, and at least one year of experience with individuals with ID.[51]

The six one-hour group sessions follow the standardized STEPS manual. Each session has an interactive gameto build group cohesiveness. The games were developed during our pilot work (B3a). To standardize delivery, each session has a script to present the material, with visual representations of emotions and actions. These are used to prompt and reinforce discussion during the sessions. The presentations and associated worksheets for between sessions will be sent to the home prior to the session for both individuals with ID and residential staff to view before and after the session as desired. Based on our previous work,[69,70] we will provide highlights of the previous sessions that will be written by the project director in consultation with the interventionists using a standardized format developed during our pilot (See Appendices C and D). The highlights will be sent to the home before the following session (via scanned document, fax to agency staff, or mail0 to help with engagement and provide cues for retention of materials. The highlights are only for the residents and residential staff in the group home. At the end of each session, participants the worksheets to practice skills learned in the training will be explained. They will be asked to complete the worksheets they received prior to the next session. We will also have sent Residential staff additional materials with tips on how to help residents practice. Table 1 presents the STEPS sessions with the SPS concepts (attitude, define problem, identify alternatives, predict outcomes, and try out solutions) and corresponding content.

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|---|---|---|---|
| 1 | The W's: Who We Are, What Makes Us | Introduction to Attitude, Define, | Introductions, describe program, introduce selves<br>Content: Begin "Stop and slow down." Pick a name for group.<br>Practice worksheets: "What Is Special about Me" and "My Ways to Stop |
| 2 | Don't Get Mad; Stop and Slow | Attitude, Define | Interactive group exercise<br>Content: Think positive, Describe problems likely to lead to A/CBs. Describe immediate emotional responses ("triggers") likely to lead to A/CBs. Practice "Stop and Slow Down."<br>Practice worksheets: "I Stop and Slow Down" and "Top 10 Ways to |
| 3 | W e H a | Attitude, Define | Interactive group exercise.<br>Content: See problems as challenges; describe/break down problems. Describe problems likely to lead to "acting out." Describe problems likely to lead to avoidance |
| 4 | Things Happen | Alternatives, Predict | Interactive group exercise.<br>Content: Alternative solutions; consequences when dealing with problem well or "acting out." |
| 5 | Bright Alternative | Alternatives, Predict | Interactive group exercise.<br>Content: Practice "brainstorming" alternatives; predict what will |
| 6 | Sum mary | Try out<br>Review Sessions 1– | Interactive problem-solving game<br>Content: Trying out possible solutions to |
| 7 | Booster Session | Review Sessions 1–6 | Interactive problem-solving game with elements of Attitude, Define, Alternatives, Predict, and Try out |

**B3b4. Attention-control: Food for Life nutrition program**. This program is based on work by Dr. Heller (co-I) for an earlier NIH-funded program comparing a control to an exercise and nutrition program for both individuals with ID and their staff or family caregivers.[69-72] Dr. Ailey was a research staff member on the project and responsible for delivering the program. A nutrition intervention was chosen for the attention-control because nutrition is an issue among individuals with ID. A U.S. based population study found a combined rate of overweight and obesity among adults with ID to be 64%; thus, all participants will receive an intervention directed at needs. Previous research also indicated that carer training in health promotion and active support affects the nutritional intake of individuals with ID. Attention control Food for Life sessions will be led by an interventionist with the same qualifications as STEPS interventionists. They will follow the standardized Food for Life manual (Appendix D). As with the STEPS intervention, there will be six one-hour sessions every other week for 12 weeks and a booster in Week 18. As in STEPS, copies of the presentation for each session and associated worksheets for practice between session will be sent to the home prior to the sessions, and highlights will be sent prior to the following sessions to help with engagement and provide cues for retention of materials. The sessions and content of each session are shown in Table 2. Drs. Ailey and Moro will oversee the integrity of the Food for Life attention-control intervention.

| | | |
|---|---|---|
| 1 | The W's: Who We Are, What | Introductions, describe program, introduce selves. What foods do we like? Why is food |
| 2 | My Plate | Content: What should the plate have on it? My foods that make the plate. |
| 3 | Water | Content: What is good about water? Alternatives to soda. |
| 4 | Snacks | Content: Better vending- |
| 5 | Let's Go Out to | Content: What do we like when we go out to eat? Healthy choices. |
| 6 | Sum | Content: "Eat and be healthy"; |
| 7 | Booster | Content: "We make healthy choices." |

Questionnaires will be read to individuals with ID during virtual data collection visits. The Measures (Table 3) have been successfully used with individuals with ID. (See Table 3).

**Fidelity plan.** Treatment fidelity will be assessed using the Behavior Change Consortium model, which assesses design, training, delivery, receipt, and enactment.[80] **Design:** The intervention has been standardized with scheduled sessions and program manuals outlining all session activities and length. **Training:** Standardized training manuals have been developed for (1) interventionists and intervention research assistants; (2) data collectors; and (3) PST raters. Interventionists and intervention research assistants in both conditions will receive 10 hours training in delivering their respective interventions from the PI and Project Coordinator Dr. Moro. After the first cohort of four STEPS and attention-control group homes receive the interventions, we will provide two more hours of training to reinforce procedures. We will meet separately every other week with STEPS interventionists and with attention-control interventionists and their respective research assistants to review experiences and problems of the past session and prepare for the next intervention session. Additional maintenance training will be delivered yearly. Intervention research assistants will participate virtually in the STEPS or attention-control session, take notes during intervention to be used in highlights, assist with the intervention, andaudiotape the sessions using the record audio only function in Webex. As in our previous pilot study,[29,57,81] to ensure high-quality data, social workers, nurses, and persons with experience interviewing individuals with ID or other vulnerable populations were trained as data collectors. They received eight hours of training in the administration of questionnaires and videotaping procedures for the IFIRS. After completion of data collection for the first cohort of four group homes, we provided two more hours of training to reinforce procedures. Prior to the commencement of virtual data collection, they will receive training sessions on conducting virtual data collection and will conduct mock virtual data collection on Webex using other data collectors and research assistants. All training and supervision of data collectors will be conducted separately from that of intervention staff.

| Table 3: Concepts/Measures, Reliability/Validity, Participant Burden, Source, and Data Collection Time Point for Behaviors | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Concept/Measure | Reliability/Validity | Range | Mins | Participant | Source[a] | Schedule (weeks) | | | |
| **Individuals with ID (IWID) outcomes** | | | | | | 0 | 12 | 24 | 36 |
| SPS skills<br>○ IFIRS Individual-level Problem-solving scales (5 items *coded from videotaped interactions*)[62,73] | Predictive, *convergent, and discriminant validity*[73] | *5-45* | 30 | IWID | V | X | X | X | |
| ○ Problem-solving Task (PST) (5 problems, 20 items, 0-5 scale *coded from audiotape*)[42] | Alpha .88-.93<br>.83 interrater<br>.79 test-retest | *0-100* | 20-30 | IWID | A | X | X | X | |
| A/CBs<br>○ IFIRS Dyadic-interaction scales (22 items *coded from videotaped interactions)*[62,73] | Predictive, *convergent, and discriminant* validity[73] | *22-198* | N/A | IWID | V | X | X | X | |
| ○ GMI scale of ICAP GMI) (8 domains, 0-5 frequency, 0-4 severity)[65] | .80 interrater<br>.80 test-retest | *0-40*<br>*0-32* | N/A | IWID | R, W | X | X | X | X |
| ○ Behavior incident reports (collected weekly) | N/A | | N/A | IWID | R | X | X | X | X |
| **A/CB behavioral determinants** | | | | | | 0 | 12 | 24 | 36 |
| • Demographics: Age, gender, ethnicity, level of ID | N/A | | N/A | IWID | R, S | X | | | |
| • Life events : Life events section of Psychiatric Assessment Schedule for Adults with Developmental Disabilities (17 items 2-recent 1-event 0-never) | Convergent validity IWID[74-77] | *0-34* | 15-20 | IWID | S | X | X | X | |
| • *Environment: Agency characteristics (urban/suburban, # of clients ,types of services, # of homes), Home characteristics (agency, location, gender, # of residents)* | N/A | | N/A | | *R* | X | | | |
| • Current health<br>○ Depression -LD (20 items, 0-2 scale)[78] | Alpha .87-.90[28,78] | *0-40* | 15-20 | IWID | S | X | X | X | |
| ○ Medication management | N/A | | N/A | IWID | R | X | X | X | |
| **Nutrition**<br>○ Adapted Nutrition and Activity Knowledge Scale for Adults with ID<br>Weight and BMI | | | | | S<br><br>R | X<br><br>X | X<br><br>X | X<br><br>X | |
| **Support environment for SPS** | | | | | | 0 | 12 | 24 | 36 |
| • Residential staff SPS<br>○ SPSI-R SF (25 items, 0-5 scales)[61,79] | Alpha .88-.93[61,79] | *0-125* | 15-20 | Res staff | S | X | X | | |
| ○ IFIRS Individual-level Problem-solving scales (5 items *coded from videotaped interactions*)[62,73] | Predictive, *convergent, and discriminant validity*[73] | *5-45* | N/A | Res staff | V | X | X | X | |
| • Group SPS<br>○ IFIRS Group-level Problem-solving scales (4 items *coded from videotaped interactions*)[62,73] | Predictive, *convergent, and discriminant validity*[73] | *4-36* | N/A | Group | V | X | X | X | |
| • Group cohesiveness<br>○ Group Intervention Environment Scale (3 sessions 1 and 6)[50] | Alpha .87[50] | *6-32* | N/A | Group | A | X | X | | |
| Support for Nutrition | | | | | | | | | |
| ○ Residential staff nutrition knowledge<br>○ | | 7-28<br>9-36 | 5-10<br>5-10 | Res staff<br>Res staff | S<br>S | X<br>X | X<br>X | x<br>x<br>x | |

Sources: S= Self-Report; V = Videotape; A = Audiotape; R = Agency Records; W=Work Setting

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We will use the same data collectors for intervention and attention-control. Every attempt will be made to conceal from data collectors the allocation of homes to intervention or attention-control condition.[82] The PI and Project Coordinator Dr. Moro will train all interventionists, intervention research assistants, and data collectors on how to deal with adverse events and high depression scores .They will be trained on how to respond to suicidal intentions and how to defuse and/or manage A/CBs displayed during group sessions or data collection (See Appendix E). The protocols for suicidal ideation and A/CBs were written by the PI Dr. Ailey and Dr. Paun, a psychiatric nurse specialist). PST raters will be trained by the PI and Project Coordinator Dr. Moro to score the audiotapes of the Problem-Solving Task (see Measures).[42] We will keep and review notes of the training sessions and of research team meetings about training. **Delivery**: All sessions for STEPs and the Food for Life attention control will be digitally audiotaped. We modified Breitenstein's Fidelity Checklist[83] to assess adherence to the STEPS and attention-control interventions and competence in its delivery. We will randomly select 25% of session audiotapes to score with the Fidelity Checklist and will observe, via Webex, 10% of intervention sessions. This information will

be used to update training of staff and prevent drift. **Receipt** of the seven sessions, or dose, will be **Procedures.** Baseline data collection: The time needed for administration of questionnaires and videotape (baseline, 12 weeks, and 24 weeks) is estimated at 1 hour 40 minutes for individuals with ID, and 25-40 minutes for the residential staff. Based on our pilot study, the attention of individuals with ID can be held for approximately 50 minutes. Therefore, data collection for individuals with ID will be broken into two sessions. Also, participants will be given breaks as desired. During the first data collection session, For the data collection, research team members will work with residential staff to find a private, quiet place in the homes and to get assistance from staff if needed. All of the measures will be administered via Webex. Responses to the GDS will be recorded in REDCap. For the PST, the data collector will read the vignette to the resident being interviewed and record the response using the audio only function in Webex. Data collection for residential staff members will be conducted at their convenience over the phone or virtually. Answers will be entered into REDCap. 12- and 24-week data collection: will use the same procedures as at baseline data collection the questionnaires and audiotapes of the Problem-solving Task (PST)[42] will be completed. Self-report questionnaires will be read to each individual with ID and will be done over Webex with the participant in a private, quiet place in the homes. For the PST, the data collector will read the vignette to the resident being interviewed and audiotape the response using the audio only record function in Webex.. A second data collection visit will be arranged to obtain the digital recording of the entire group that will be used to score the IFIRS.[62,73] For the IFIRS, the data collector will meet with the group over Webex and help the group generate the topic for discussion. The group of individuals with ID and their staff will discuss the problem. The discussion with be recorded with the webcam video function in Webex. Data collection for residential staff members will be conducted at their convenience via phone or Webex. The Webex recorded videos will be made available for secure download by Dr. Melby's laboratory at Iowa State University (Ames, IA) to be scored by her specialists.

Intervention: Intervention sessions for STEPS and attention-control sessions will be conducted via Webex. The group of individuals with ID and their residential staff will be asked to use a dining room or kitchen table as a place to talk and look at materials. Based on our pilot study (B3a), sessions will be held from approximately 6:30–7:45 p.m. on a weeknight. The evening before the session, the interventionist will reconfirm the time. All sessions are audiotaped using the audio only record function in Webex for fidelity. Audiotapes from Sessions 1 and 6 will be used to score the IGES. Interventionists and research assistants will meet every other week with the PI and intervention coordinator over Webex

12- and 24-week data collection: The procedures will be the same as baseline. The GMI will be obtained from QIDPs at the agency.

Data collectors:

Videographer:

Interventionists: Daniel Reitsma, Kelly Flinkman, Sally Scheib, Deanna Ellis and Ella Swanson are contracted staff for the interventions. NIH Human Subjects training certificates are available for these staff. See documents below.

We are adding Virshauna Brown, Samantha Kreps; Camila Sanchez; Nicole Karabas; and Micala GIammarino as Research Assistants.

We are adding We are adding Horace Nowell III, Jaime Chang, Maura Benson, Margaret Czerwein as research assistants. All have Citi training.

We are adding Taylor White (English) as a Research Assistant. She is a Rush employee and has Citi training.

We are adding Rianna Bachan as a Research Assistant. She is a Rush nursing student who is work study. She has completed Citi training and compliance training. She will be doing data entry.

***A/CB determinants***. Demographics (age, gender, ethnicity, and level of ID) will be obtained from agency records. Life events are measured by staff- report with the Life Events section of the Psychiatric Assessment Schedule for Adults with Developmental Disabilities [75].It is used extensively in this population. It is predictive of emergency room visits for A/CBs, psychopathology, and psychiatric events.[75-77] Environment includes whether homes are urban/suburban and the number of people living in the homes. Current health includes depressive symptoms of

individuals with ID and medication management. The Glasgow Depression Scale for People with Learning Disabilities [GDS-LD][78])was developed for use among individuals with ID (called "learning disabilities" in the UK). It has sensitivity ranging 90-96% and specificity ranging 83.9–90%, with a score of 13.[39,78] Information on psychotropic medications will be gathered from agency records.

***Support environment for social problem solving.*** These include the residential staff SPS, group SPS, and group cohesiveness. The residential staff SPS will be measured in two ways. The IFIRS Individual-level Problem-solving Scales[62,73] are the same instrument used with individuals with ID. Also, a self-report measure, Social Problem Solving Inventory Revised – Short Form (SPSI-R SF), will be used.[61,79]The five dimensions of this measure are positive attitude, negative attitude, rational style, impulsive/careless style, and avoidant style. Group SPS will be will be measured with IFIRS Group-level Problem-solving Scales.[62,73] The scales include problem-solving enjoyment, agreement on problem description/solution, implementation, and problem difficulty for group, and are scored by Dr. Melby's staff. Group cohesiveness will be measured using the Intervention Group Environment Scale (IGES).[50]The IGES is a 25-item measure of group environments. The three subscales are implementation and preparedness, counterproductive activity, and cohesiveness.[50] In previous research, it related to health behavior outcomes.[50] The IGES will be scored using audiotapes from Sessions 1 and 6 by trained research assistants. In our pilot study, graduate nursing students were trained to do the rating of the IGES.[22]

***Individuals with ID Outcomes: Nutrition.*** Nutrition outcomes are measured in three ways, nutrition knowledge, weight and BMI. We will measure nutrition knowledge using the Adapted Nutrition and Knowledge Scale for Adults with Intellectual Disabilities[76,77] We will address the mediating effect of residential staff nutrition knowledge of residential staff on the nutrition knowledge, weight and BMI of participants with ID.[80]

**B3b6. Fidelity plan.** Treatment fidelity will be assessed using the Behavior Change Consortium model, which assesses design, training, delivery, receipt, and enactment. **Design:** The intervention has been standardized with scheduled sessions and program manuals outlining all session activities and length. **Training:** Standardized training manuals have been developed *for (1) interventionists and intervention research assistants; (2) data collectors; and (3) PST raters*. Interventionists and intervention research assistants in both conditions received 10 hours training in delivering their respective interventions from the PI Dr. Ailey and Research Coordinator Dr.Moro. After the first cohort of four STEPS and attention-control group homes received the interventions, we provided two more hours of training *to reinforce procedures*. We will meet separately every other week with STEPS interventionists and with attention-control interventionists and their respective research assistants to review experiences and problems of the past session and prepare for the next intervention session. Additional maintenance training will be delivered yearly. Intervention research assistants will be trained to , take notes during intervention to be used in highlights, and audiotape the sessions. Prior to the commencement of virtual interventions, interventionists and research assistants will receive training sessions on conducting virtual interventions and will conduct mock virtual interventions on Webex using other interventionists and research assistants. As in our previous pilot study,[29,57,81] to ensure high-quality data, social workers or nurses with experience interviewing individuals with ID were trained as data collectors. They received eight hours of training in the administration of questionnaires and videotaping procedures for the IFIRS. After completion of data collection for the first cohort of four group homes, we provided two more hours of training to reinforce procedures. All training and supervision of data collectors will be conducted separately from that of intervention staff. We will use the same data collectors for intervention and attention-control. Every attempt will be made to conceal from data collectors the allocation of homes to intervention or attention-control condition.[82] The PI and Co-I Dr. Paun, a psychiatric nurse specialist, will train all interventionists, intervention research assistants, and data collectors on how to deal with adverse events and high depression scores. They were or will be trained (if new) on how to respond to suicidal intentions and how to defuse and/or manage A/CBs displayed during group sessions or data collection (See Appendix E). Prior to the commencement of virtual data collection, they will receive training sessions on techniques and challenges in virtual data collection and will conduct mock virtual data collection on Webex using other data collectors and research assistants. PST *raters* will be trained by the PI Dr. Ailey and Research Coordinator Dr. Moro to score the audiotapes of the Problem-Solving Task (see Measures).[42] We will keep and review notes of the training sessions and of research team meetings about training. **Delivery**: All sessions for STEPs and the attention control will be digitally audiotaped using the audio only recording function in Webex.. We modified Breitenstein's Fidelity Checklist[83] to assess adherence to the STEPS and attention-control interventions and competence in its delivery. We will randomly select 25% of session audiotapes for research assistants under the directions of Drs. Ailey and Moro to score with the Fidelity Checklist and will observe in person 10% of intervention sessions. This information will be used to update training of staff and prevent drift. **Receipt** of the seven sessions, or dose, will be assessed by tracking attendance. We will use a web-based tracking system, Study360,[84] to monitor and calculate attendance rates. Attendance rates for individuals with ID and residential staff will be calculated as the number of sessions attended divided by total number of sessions. Reasons for not attending, if known, will be collected throughout the intervention from individuals with ID and residential staff, and a log will be kept. Using a checklist we developed in our pilot study, we will randomly select 25% of audiotaped sessions to determine the number of times each individual participated in discussion of a covered skill and whether the individual gave an example of

how he/she used or would use the skill. With these data, we can assess receipt of the intervention by participants. Satisfaction of the individuals with ID and residential staff will be measured at 12 weeks. **Enactment** will be assessed by counting the number of completed and returned practice worksheets (total = 8 per individual with ID).

**B3b7. Procedures.** Baseline data collection: The time needed for administration of questionnaires and videotape (baseline, 12 weeks, and 24 weeks) is estimated at 1 hour 50 minutes for individuals with ID, and 50 minutes for the residential staff. Based on our pilot study, the attention of individuals with ID can be held for approximately 50 minutes to one hour. Therefore, data collection for individuals with ID will be broken into two sessions. Also, participants will be given breaks as desired. During the first data collection session, the questionnaires and audiotapes of the Problem-solving Task (PST) will be completed. For the data collection, research team members will work with residential staff to find a private, quiet place in the homes and to get assistance from staff if needed. All of the measures will be administered via Webex. Responses to the GDS will be recorded in REDCap. For the PST, the data collector will read the vignette to the resident being interviewed and record the response using the audio only function in Webex. 12- and 24-week data collection: will use the same procedures as at baseline data collection A second data collection visit will be arranged to obtain the digital videotape of the entire group that will be used to score the IFIRS. For the IFIRS, the data collector will help the group generate the topic for discussion. Data collection for residential staff members will be conducted at their convenience over the phone or virtually. Answers will be entered into REDCap. . The videos will be made available for secure download by Dr. Melby's laboratory at Iowa State University (Ames, IA) to be scored by her specialists.

Intervention: Intervention sessions for STEPS and attention-control sessions will be held virtually. The interventionist and research assistant will conduct the session. They will ask the participants in the group to use a dining room or kitchen table as a place to talk and look at materials. Based on our pilot study (B3a), sessions will be held from approximately 6:30–7:45 p.m. on a weeknight. The evening before the session, the interventionist will reconfirm the time. All sessions are audiotaped for fidelity using the audio only record function in Webex.. Audiotapes from Sessions 1 and 6 will be used to score the IGES. Interventionists will bring audiotapes to the project office. Interventionists and research assistants will meet every other week with the PI and intervention coordinator.

12- and 24-week data collection:. The procedures will be the same as baseline. Participants (individuals with ID and residential staff) will be given a
$20 gift card after each data collection.

**B3b8. Data analysis.** All tracking of participants will follow CONSORT[85] and be entered into the RedCap database. SPSS for Windows (v. 23) and SAS (v. 9.3) will be used for data management and statistical analysis. Descriptive statistics for all variables will be obtained; *t* tests and chi-square analyses will be performed on demographics, baseline life events, environment, and current health (depression symptoms and medication management) to determine if intervention and control groups are comparable. Missing data will be imputed using SAS software and the multiple imputation strategy described by Rubin.[86] *To reduce Type-I error associated with multiple dependent variables, a .01* significance level will be used for all tests. From previous research, we expect all outcome measures to be close to normally distributed. We will use Tukey's[87] ladder of transformation to achieve normality, if needed. Outcome measures that cannot be successfully transformed to achieve normality will be analyzed separately using the rank-ordered multilevel analysis available in SAS.

**Specific Aim 1.** Because multiple dependent variables are being examined, a repeated-measures multivariate analysis of variance will be conducted to ensure control of experiment-wise $\alpha$, and to perform an initial assessment of intervention effects. We will then calculate intervention efficacy on individual measures of SPS skills and A/CBs of individuals with ID using a nested hierarchical model; the three levels will be group home, person within site, and time-point within person. All analyses will be performed on an intent-to-treat basis. Intervention condition will be dummy coded (treatment vs. control) at the level of the group home. To control for effects of background characteristics on the intervention, measures associated with background variables will be entered into the model as two propensity measures: one based on individual measures, the other based on group home measures. This is, in effect, a two-level propensity analysis. This two-level approach is a novel and innovative statistical method for conducting propensity analysis. Propensity analysis is a well-validated statistical approach useful in balancing groups on observed covariates so that analyses of treatment effects are more accurate.[88,89] If a propensity measure has a nonsignificant effect, it will be discarded; if significant, it will be included in the final model. Categorical covariates (e.g., gender, ethnicity) will be dummy-coded and entered into the model as a block. Propensity scores will be estimated using individual participant (e.g., age, length of residence) and group home level measures (e.g. location [urban/suburban], gender, and number of residents/home) that could influence outcomes. We also will check for differences in baseline SPS and A/CBs by agency and by interventionist; if found, we will enter these into the propensity score analysis. This final set of variables (the direct predictors) will constitute an optimal model for assessing each outcome measure.

**Specific Aim 2.** We expect the support environment for SPS (residential staff SPS, group SPS, and group cohesiveness) to mediate improvements that occur in the individuals with ID. To assess the mediating effects, we

will modify the regression models discussed in MacKinnon (p. 49). MacKinnon's models generate three regression equations and then examine the impact of a single mediator in terms of reduced variance explained in the outcome from the direct predictor variable when the mediator variable is included in the model. The same approach will be used[91,92] in this analysis, except that we will examine multilevel regression instead of simple regression models. With this modified approach, we will estimate three sets of regression equations for each of the three potential mediators making up the support environment for SPS, crossed with each of the measures of SPS skills and A/CBs of individuals with ID. Intervention condition will be included as predictor variables in these mediation models. The first set of regression equations estimates the simple effect of the intervention on the SPS skills and A/CBs of the individuals with ID (Aim 1). The second set estimates the effect of the intervention on the mediator variables (residential SPS, group SPS, or group cohesiveness). The third set estimates the combined effects of the intervention and mediators on the group measures of SPS skills and A/CBs of the individuals with ID. We will examine the impact of the change in the estimated coefficients associated with the introduction of each mediator. Significant mediators will be left out of subsequent models because of concerns about collinearity. Retention of a significant mediator may make it difficult to detect mediation effects in subsequent analyses.[90] Though several mediation models are being estimated in this aim, the analysis is based on the assumption that significance values are of limited use in analysis to find mediation effects. Our analyses should allow us to evaluate whether the support environment for SPS mediates the relation between the intervention and the outcomes and should give us information on which mediation variables are responsible for the effect. Identifying key mediators will contribute to enhancing the intervention, improving long-term cost-effectiveness, and designing future interventions. The same type of analysis will be conducted to determine the effects of the *Food for Life* nutrition intervention and the mediating effects of residential staff nutrition knowledge of the nutrition knowledge, weight and BMI of participants with ID.

***Specific Aim 3.*** *Evaluate the cost-effectiveness of STEPS relative to usual care.*

***Methods.*** *We will evaluate the cost-effectiveness of STEPS from the societal perspective, taking into account costs borne by the program, group home, health care system, public services, participant, and family. STEPS will be compared to usual care (control group costs of A/CBs excluding costs of the nutrition intervention). We will conduct additional analyses separately from the perspective of the program, group home, health care system, public services, and participant. For cost measurement, quantities of resources used and their associated prices will be collected for the program (either prices paid or value of staff time), group home (value of staff time) and participant (value of participant's time to participate in STEPS). For the effectiveness measurement, effectiveness will be measured using the number of A/CB incidents. We will also quantify the cost of each A/CB incident to calculate the net cost (or savings) of STEPS relative to standard of care. A/CB costs include for group home, participant and family members, public service (value of police officer time, ambulance), and health care system (cost per ED visit, urgent care or other physician visit, hospitalization) costs. To calculate total program-related costs, the program, group home, and participant costs will be summed to calculate total cost per participant. Similarly, total A/CB costs will be summed across the group home, participant and family, public service and health care system. All costs will be valued in 2016 dollars.*

*Data for the cost-effectiveness analysis will be drawn from study records, incident reports, and group home staff time logs (Table 4). Cost-effectiveness will be evaluated by combining the mean total program-related cost per participant with the number of A/CBs. We will calculate the incremental cost-effectiveness ratio (ICER) for STEPS relative to usual care, such that* $ICER = (C_1 - C_0)/(E_1 - E_0)$, *where C is program cost and E is effectiveness. Subscript 1 denotes STEPS and subscript 0 denotes usual care. 95% confidence intervals for the ICERs will be calculated to evaluate the uncertainty of these results. We will conduct one-way and multi-way sensitivity analyses for the key parameters to evaluate whether the ICERs are sensitive to plausible changes in their values. The sensitivity analysis is a check on the robustness and will determine the key parameters impacting the ICERs. We will also plot acceptability curves based on varying threshold (willingness to pay) values for a one-incident reduction in the number of A/CBs. Also, because A/CB incident costs will be collected, we will calculate the net cost (or net savings) associated with STEPS, such that the net cost = program-related cost – A/CB incident cost.*

**Specific Aim 4:** Evaluate the effect of the Food for Life intervention and the mediating effect of the nutrition knowledge of residential staff on nutrition knowledge, weight and BMI of participants with ID. We hypothesize that participants in the attention control Food for Life nutrition intervention will show greater improvement in nutrition knowledge and improvement in weight and BMI for overweight and obese individuals compared to the STEPS intervention.

**B3b9. Potential problems and alternative strategies:** (1) We have no assessment-only control, which may attenuate our findings. However, we are assessing the mediation effects of the support environment for SPS in our analysis. (2) The attention-control group may also be affected by being in a group intervention. We therefore minimized group process in our attention-control group. (3) The assessment process may affect the SPS skills of residents and residential staff and the A/CBs of residents. To minimize this possibility, no feedback will be given on responses to questionnaires about problem-solving or the problem-solving discussion used to code the IFIRS, and no practice of problem-solving is provided in the assessment process.

(4) Incident reports are filled out by residential staff who observe the incidents and reviewed by QIDPs. Bias in reporting by residential staff based on intervention condition is possible. The agencies, however, have protocols for reporting incidents, and, during orientation to the program, we will instruct residential staff to continue to use those protocols. Bias, if present, is more likely to impact reports of minor incidents (e.g., arguments) than reports of serious incidents (e.g., involving injury or property damage). By analyzing serious incidents separately, we will minimize bias in incident reports. We also have a second measure of behavior not dependent on residential staff report, the IFIRS Dyadic Interaction Scales. Finally, we are collecting data on A/CBs from work setting supervisors where informants will be naïve to study conditions. Though it is possible that IFIRS coders or work setting supervisors may become aware of study condition, this is expected to be rare and to have minimal impact on study results. (5) We have chosen to randomize prior to recruitment so that individuals with ID can be told specifics about the intervention to which they have been assigned. Although it would be ideal to randomize after recruitment and baseline data collection, trying to explain to individuals with ID that they may be assigned to either STEPS or a nutrition intervention would likely be confusing. (6). While we only have 3 measures related to nutrition among individuals with ID and one measure among residential staff, our study has a larger sample size participating in a nutrition intervention than previous studies, has a homogenous sample and defined randomization techniques. We expect to contribute to the body of research on nutrition interventions in this population.

| | | | |
|---|---|---|---|
| *Interventionist time to | Study payroll reports | Minutes per | Average hourly wage |
| *Residential staff | Attendance records | Minutes per | Average hourly wage |
| *Participant time to | Attendance records | Minutes per session | Minimum wage |
| Residential staff time to | Staff | Minutes per staff | Average hourly wage |
| Residential staff | Staff | Minutes per staff | Average hourly wage |
| QIDP time to review incident | Staff | Minutes per | Average hourly wage |
| Residential staff and QIDP | Staff | Minutes per | Average hourly wage |
| Repair/replacement costs | Staff self- | Actual cost | Actual cost |
| Participant time related to the | Incident report | Minutes per incident | Minimum wage |
| Family member(s) time related | Incident report | Minutes per incident | Average hourly wage |
| Police officer time to intervene | Incident report | Minutes per police | Average hourly wage |
| ED visits | Incident report | Occurrence of visit | National average cost for an ED visit with principal diagnosis of a behavioral health condition or |
| Hospitalizations | Incident report | Occurrence of hospital stay and length of hospital | National average cost for a hospital stay with a principal diagnosis of a behavioral health |
| Urgent care and other physician visits | Incident report | Occurrence of visit | National average cost for an ED visit with principal diagnosis of a behavioral health condition or |

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**B3b10. Timeline**. In the first three months of funding, we will hire staff, complete preparations for data collection and intervention, and work with partner agencies to finalize the identification and selection of eligible group homes. We will begin recruitment of participants in the first group homes in Month 4 and complete recruitment by Month 32. All group homes should have completed the intervention sessions (1-6) by Month 35 and 12-week data collection by Month 36. Booster sessions will be completed by Month 37 and 24-week data collection by Month 38. All incident reports will be collected by Month 40. We anticipate this timeline to be reasonable based on recruitment and data collection experience in our preliminary study.