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Research Protocol

Optimizing residential treatment gains for adolescents through tailored behavioral parent training: An RCT

I. Objectives

The purpose of this study is to conduct a randomized controlled trial testing PW+ (Parenting Wisely augmented with facilitated discussion groups) vs TAU (treatment as usual) on target mechanisms and adolescent outcomes with parents and adolescents transitioning out of residential treatment (RT).

Aim 1: Evaluate the feasibility and acceptability of PW+. **1a.** Evaluate the feasibility of PW+ by tracking the frequency (discussion group attendance, PW logins), dose (module and practice exercise completion), and duration (time spent in PW and discussion groups). **1b.** Evaluate the acceptability of PW+ for parents with adolescents in RT via a satisfaction survey.

Aim 2: Determine the effects of PW+ on the target mechanisms compared to the TAU condition from baseline to 6-weeks and 6-months post-baseline.

Aim 3: Determine the effects of PW+ on adolescent outcomes compared to the TAU condition from baseline to 6-weeks and 6-months post-baseline. **3a.** Determine if changes in the target mechanisms are associated with adolescent outcomes at six weeks and six months post-baseline.

Exploratory Aim: Explore the feasibility of collecting data from adolescents in an RT facility by tracking frequency (recruitment, enrollment, retention rates), duration (time between parent consent and assent; survey duration), and barriers to data collection.

II. Background and Rationale

The High Costs of Residential Treatment (RT).¹⁷ RT serves approximately 14% of the pediatric psychiatric population,¹ is the most restrictive setting for emotional and behavioral health care, is viewed as a *last resort*^{26,27} with average lengths of stay of eight months²⁸ and accounts for 25% of the pediatric Medicaid budget.^{28–30} Unfortunately, the return on investment for such expensive and intensive treatment is often absent.^{4,31–35} Although adolescents make significant treatment gains, including reductions in internalizing and externalizing behaviors,³⁶ and improvements in educational achievement³⁸ and social functioning,³⁹ they experience significant difficulty adapting to less restrictive placements (e.g., home) and do not sustain treatment gains.^{4,31–35} Within one-month post-discharge,¹⁹ adolescents begin to engage in the same behaviors they were admitted to RT for, including aggression and delinquency.^{2,4,41} In the long term, 78% of adolescents return to restrictive placements, including readmission to RT, hospitalizations, or incarceration.^{4,5,12}

Family Function and Parenting Challenges Underpin Adolescent Outcomes. Parents are overwhelmed with the severity and chronicity of their adolescent's behaviors, which affects family dynamics (i.e., family function), their parenting (i.e., parental self-efficacy, parenting practices), and support network (i.e., social support).^{7,9,11,42,43} Nearly 70% of adolescents

discharge to a home-like environment under the care of a parent;⁹ however, the return home is often fraught with family dysfunction^{7,44} that may not support the maintenance treatment gains. Family function is among the most robust and complex familial risk factors and is defined as the extent to which the family unit is adaptable, flexible, and cohesive.⁴⁵ Family function in the RT context has been studied for decades highlighting that parents are vulnerable due to the family disruption and low resources in which these parents have access.^{39,46–48} Approximately 72% of families fall >100% below the federal poverty level, many are single-parent households, and encounter significant barriers (e.g., transportation, childcare, out of county placement) to engaging in care.^{1,7,17} Consistently, adolescents in RT score above the clinical cutoff^{44,49} on the McMaster Family Assessment Device,⁵⁰ indicating severe family dysfunction.⁵⁰ In a state-wide study (N=18,046 children discharged from RT), adolescents from low-functioning families had more severe behavior problems from admission to discharge and were less likely to be discharged to the community than adolescents from intermediate or high-functioning families.⁴⁷

Parenting an adolescent with severe behavioral health needs resulting in RT is challenging, and the parent-child relationship can be fragmented due to the placement out of the home.^{8,47} Parents have been described as disorganized,^{31,32,51} burnt out,⁵² highly stressed,^{7,53,54} and isolated.^{7,11,55} Parental self-efficacy comprises motivation, knowledge, and ability and is defined as the degree to which parents expect to manage their adolescent's behaviors effectively.^{56–58} Parental self-efficacy in parents with adolescents in RT is critically low,^{59–62} and these parents often have low levels of effective parenting practices.^{35,41,42} Specific challenges include lack of consistent and effective limit setting and the use of coercion.^{53,63} Because of the severity and chronicity of the adolescent's behaviors coupled with parental stress, parents withdraw demands, give into the adolescent's negative behaviors, and resort to coercing the adolescent to cease unwanted behaviors.⁶⁶ While these negative reinforcement strategies result in the adolescent ceasing unwanted behavior, the result is often temporary.⁶⁶ Parents with low self-efficacy tend to expect poor rather than positive outcomes when utilizing behavior management strategies.⁶⁷ Our prior work with parents with adolescents in RT suggests parental self-efficacy diminishes in lockstep with the adolescent's treatment trajectory.¹⁷ Along the trajectory, parents perceive "treatment failures" (i.e., suboptimal treatment effects) that condition parents to expect negative rather than positive outcomes.¹⁷ Treatment failures are difficult for parents to process because they experience uncertainty and lack knowledge about services, diagnoses, and treatments. They may have also had negative mental health care experiences or perceived stigma.^{11,17} Low social support levels are pervasive in RT as parents commonly report inadvertently sacrificing their mental health, employment, and interpersonal relationships to better care for their adolescent.¹⁷ Parent training, the gold standard for the treatment of adolescent behavior problems, is an appropriate intervention for adolescents in RT because skilled and effective parenting is a critical protective factor in the maintenance of RT-treatment gains and parenting-related issues in this population are severe, ongoing, and unaddressed

Description of Parenting Wisely. Parenting Wisely (PW) is a self-administered, web-based parent training with established efficacy developed initially for parents with court-involved adolescents aged 11-17 with moderate externalizing behaviors.⁶⁸ Donald Gordon, the developer of PW, will serve as a consultant on the proposed study. PW consists of ten modules, including managing housework, schoolwork, curfew, criticizing/step-parenting, monitoring (school, homework, friends), loud music/chores, sharing technology, sibling conflict, getting up on time, and finding drugs. PW is guided by a social-learning perspective in which parents are viewed as change agents and parenting practices mediate adolescent behavior problems.^{69,70} The objective of PW is to attenuate adolescent behavior problems by replacing coercive parenting practices with effective parenting practices such as warmth, praise, effective modeling of

behavior, supervision, and consistent boundaries.^{71,72} PW targets parenting practices by employing the social learning theory principles, modeling, and mastery experience.¹² PW uses modeling in videos depicting different parenting practices and corresponding consequences. Mastery is reinforced as parents are encouraged to practice skills daily.

PW has been tested in racially, ethnically, and socioeconomically diverse samples using multiple study designs, including open trials,^{19,23,73} quasi-experimental,^{22,74} and three RCTs.^{20,24,25} PW targets parenting practices to reduce adolescent externalizing behaviors with small to medium effects (Cohen's $d = .20-.46$).^{20,22,24,25,74,75} PW was one of three interventions implemented in North Carolina to reduce adolescent violence.²² Compared to no treatment, parents who received PW ($n=347$) reported increases in parenting confidence and parental self-efficacy and decreases in parent-adolescent conflict, adolescent aggression, and violent behaviors ($\beta = 0.22-0.30$, $p = 0.001-0.08$) between baseline and six months follow-up.²² Becker and colleagues (2021) augmented PW with individual telehealth coaching sessions for parents ($N=60$) with teens in substance use treatment. The augmentation was feasible (90% retention at 6-weeks follow-up, 86% completed PW modules, 87% protocol adherence) and acceptable (3% withdrawal, 88% satisfaction rate).²⁴ Parents who received the intervention showed positive effects in monitoring, parent-adolescent communication, and limit setting ($\beta = 0.32-0.53$, $p = 0.002-0.02$)⁷⁶ and their adolescents showed declines in cannabis use, drug use, and externalizing behaviors ($\beta = 0.14-0.17$, $p = 0.002-0.03$).²⁴ Our study is the first to augment PW with discussion groups to meet the needs of parents with adolescents in RT.

Description of PW+: Parenting Wisely Augmented with Facilitated Discussion Groups. In partnership with an advisory board of parents (who we will engage in this study) and RT staff, we augmented PW with virtual facilitated discussion groups (referred to as PW+) because there is compelling evidence that parents face persistent parenting challenges and require a higher level of support during the transition from RT.^{4,7,11,14,15,55} PW+ is a 6-week intervention that includes weekly completion of two PW modules (~20 minutes each) and facilitated discussion groups via videoconference (90-minutes) or 1:1 coaching calls with a member of the study team if the parents schedule cannot accommodate groups. The discussion groups in PW+ support program completion and parent engagement, provide a venue to discuss individualizing PW strategies, reduce isolation, and support parents by engaging in conversation about parenting in the RT context. PW+ is strengths-based and provides emotional support by creating a community where parents can develop relationships to reduce isolation and shame. Instrumental support is enhanced through role-playing, where parents share different scenarios and apply the PW skills. Parents evaluate strengths and difficulties with the assistance of the facilitators developing a plan to incorporate the PW skills into daily life more effectively. The facilitators provide individualized tailoring and coaching to troubleshoot strategies during the discussion group.

Prior Parent Training Programs in RT. Although parent training has been regarded as a promising strengths-based approach to engaging families in RT;^{77,78} few have tested parent training programs with parents in the RT setting. Those that have, described delivering in-person parent training to staff rather than parents.⁷⁹⁻⁸¹ Perhaps the most well-studied intervention with parent training components in the RT setting is On the Way Home.³⁸ This year-long aftercare program consists of: Check & Connect,⁸² Common Sense Parenting,⁸³ and homework support.⁸⁴ In the pilot RCT ($N=82$ families), there were significant differences in placement stability, caregiver empowerment, and self-efficacy in parents who received the intervention compared to parents in the TAU condition.⁸⁵ However, in confirmatory efficacy testing, there were no significant differences in home or school involvement or placement

stability between conditions.⁸⁵ Study limitations included contamination between conditions and a high attrition rate (32% post-intervention), introducing bias into the estimate of treatment effectiveness.⁸⁵ Further, 99% of the sample came from one RT facility (i.e., Boystown) that implements a distinct care model (i.e., Teaching Family Home), limiting the generalizability of findings to other RT facilities.⁸⁵ In addition to generalizability issues, there are challenges with access and sustainability. For example, On the Way Home does not begin until after discharge and is delivered in-person to parents within 60 miles of the RT facility. This delivery model poses barriers that may have affected enrollment, attendance, and engagement.^{86–88}

PW+ Increases Reach, Engagement, and Accessibility. While there are numerous efficacious parent training programs,⁸⁹ we selected PW for augmentation for several reasons. The most important factor in selecting a parent training program was the delivery because promoting parent engagement in RT is a best practice.^{77,78,90} Low parent engagement is associated with a myriad of negative treatment and discharge outcomes.⁹⁰ Parent training programs currently delivered in the RT setting are primarily in-person, which may pose significant barriers to parent participation, including low engagement, high cost, and geographic constraints. Participation and attendance are essential to the success of parent training,⁷⁹ yet,

Table 1. Integration of Residential Care Consortium's Recommendation into PW ^{RT}	
Residential Care Consortium Recommendation	PW ^{RT} and Study Elements
Involve parents in their child's active delivery of care	PW ^{RT} supports parents in developing effective behavior management strategies during their adolescent's admission
Focus attention on the transition to the community	Parents begin PW ^{RT} before the adolescent transitions to the community to promote continuity in care
Utilize assessments that identify family-level factors that may alter the interventions' effect on outcomes	We use a target mechanism approach with valid and reliable assessments to evaluate the effectiveness of PW ^{RT} on parent and family processes
Implement evidence-based strategies that reduce initial barriers to engagement	Technology and low-intensity programming reduce barriers to engagement; We partner with an advisory board to problem-solve engagement issues
Offer parenting education to the greatest extent possible	We augment an evidence-based parent training based on parents' needs
Integrate parent mentors into practice settings	Offer opportunities for parents who have faced similar challenges to build community

there is often a high level of attrition with in-person parent training,⁶² some of which is attributed to the inconvenience of scheduling weekly appointments when parents have several competing demands.⁸⁰ The attrition may also be attributed to a lack

of necessary resources such as transportation, time, or childcare to attend in-person parent training. Specific to RT, parents frequently reside significant distances from facilities (sometimes counties or even states or away), which immensely reduces the parents' ability to be involved in their adolescents' care.⁴⁷ In response to low parent engagement, The Residential Care Consortium proposes six recommendations to improve parent engagement.⁹¹ The proposed study and PW+ address each of the recommendations (see Table 1), including that PW+ is web-based which overcomes some of these barriers and is cost-effective, adaptable, and reliably delivered.⁹² Web-based parent training programs produce similar effects to in-person programs.^{93–95} They are increasingly more accessible given that 75% of the US population now owns a smartphone, desktop, laptop, or tablet,⁹⁶ with this prevalent use extending to minority⁹⁷ and low-income populations.⁹⁶ We address scheduling by encouraging parents to complete their PW modules at their convenience as parents have access to PW 24/7. We also offer two virtual discussion group time slots to choose from each week. Overall, web-based delivery allows the intervention to move outside traditional delivery settings and into the home, increasing access and reducing stigma.⁹⁸

The second most important factor in selecting a parent training program for augmentation was the child's age that the program was designed. Our selection of parent training programs was limited to programs designed for adolescents because adolescents aged 11 to 17 comprise over 75% of the RT population.²⁸ PW was designed for a population of court-involved adolescents with similarities (e.g., delinquency, aggression) to the RT population.²¹ Third, we consulted with

our parent advisory board, a partner in the proposed study, about the appropriate level of intervention intensity. While the parent advisory board endorsed a need for high-intensity programming (e.g., Wraparound), they prioritized engaging and accessible (i.e., web-based, non-clinical, strengths-based, community-building) programming that provides support during the adolescents' transition to the community. PW+ is not intended to take the place of high-intensity programming. Instead, PW+ will be integrated into the RT setting and act as adjuvant support to standard programming. In the proposed study, parents begin PW+ while the adolescent is in RT and continue PW+ after discharge. This design allows for care continuity and uninterrupted support for parents as they navigate the adolescent's transition home. Finally, we were interested in a program that could be readily tailored because parent training will soon be a required component of RT care and is newly reimbursable with recently enacted legislation (i.e., Family First Prevention Services Act; FFPSA).¹⁸

III. Procedures

A. Research Design

We employ a randomized controlled trial (RCT) design to evaluate the feasibility, acceptability, target mechanism engagement, and preliminary effects of PW+ in parents with adolescents transitioning from RT to the community. Parents (n=70) will be randomly assigned to the PW+ or TAU conditions. Comparing PW+ to TAU will determine how well PW+ works relative to routine clinical practice or care (TAU) and increases the chances of finding a signal¹⁰⁵ that target mechanisms (i.e., parental self-efficacy, parenting practices, social support, and family function) are engaged and underpin the intervention effects (i.e., internalizing and externalizing behaviors and placement restrictiveness). We anticipate that most adolescents will transition to the community during the study, meaning baseline data will be collected in the RT setting, and follow-up data will likely be collected in the community (i.e., home). While adolescents will not directly receive the intervention, they will be participants (n=70). Parents and adolescents will complete baseline (T1) and follow-up assessments at 6-weeks post-baseline (T2) and 6-months post-baseline (T3).

B. Sample

The target population includes parents of adolescents in RT because adolescents aged 11 to 17 represent 75% of the RT population,²⁸ and PW was designed for parents of adolescents.²¹ Parent inclusion criteria are:

1. adult over the age of 18
2. caregiver (e.g., biological, step, kin, foster, adoptive) to an adolescent aged 11-17 years old
3. adolescent is currently admitted to RT or adolescent has been discharged in the past month from RT
4. caregiver has unrestricted contact with adolescent
5. caregiver able to speak English
6. caregiver has access to a device (e.g., smartphone) with internet access.

Parent exclusion criteria:

1. Parent is not allowed contact with the adolescent

Adolescent inclusion criteria:

1. Youth's primary parent is enrolled in the study

2. The parent/guardian who is enrolled in the study is their legal guardian
3. The parent/guardian who is enrolled in the study has custody
4. Parent/guardian signs the parent permission form
5. Youth wants to participate/signs assent form
6. Youth is aged 11 to 17 at enrollment
7. Youth was admitted to a partner RT facility
8. Youth able to speak English
9. Youth has access to a device such as smartphone, tablet, computer OR phone to make calls

Exclusion Criteria

1. Primary parent is NOT the legal guardian
2. Primary parent DOES NOT have custody

Sample Size Justification. The target recruitment is 70 parent-adolescent dyads (35 per condition), leaving a final sample of 56 (28 per condition) after accounting for an expected attrition rate of 20% at six months post-baseline.^{106,107} The power analysis used mixed-effects linear modeling for repeated measures and a two-sided alpha level of 0.025 to adjust for multiple comparisons from two repeated post-treatment measures. This sample size has sufficient power (80%) to detect a large effect size (Cohen's $d = 0.9$) for between-group differences. Published studies reported small to medium effect sizes of 0.2 (e.g., for parenting practices) to 0.46 (e.g., for adolescent behaviors) for the intervention effect of PW.^{22,24} We expect the intervention augmentation will result in additional improvement in the outcomes with small to medium effect sizes of 0.2 to 0.5. The corresponding statistical power is 6% - 29%. Due to this study's pilot nature, we will not rely on statistical power for analyzing Aims 2 and 3. Instead, we will report point estimates, precision (e.g., 95% confidence interval), and effect sizes. These estimates, along with practical and clinical significance, will guide results interpretation and inform sample size calculation for larger trials. With our sample size and a two-sided 95% confidence interval, we will have $\pm 0.40\sigma$ precision to estimate group-specific means and $\pm 0.58\sigma$ precision to estimate between-group mean differences.

Recruitment. We will recruit parents and adolescents from RT facilities in Ohio: Genacross Family and Youth Services, NewPath Child & Family Solutions, Belmont Pines, The Village Network, Necco, and Safely Home. Cumulatively, these facilities treat over 700 youth in their RT programs per year. The proposed study has the support and buy-in of senior leadership from the recruitment sites (see Letters of Support). We expect an average of seven to nine discharges per week. With a conservative recruitment rate of 15%, we expect to recruit between four to six primary parents per month for 15 months. The study team will direct recruitment efforts towards parents, as adolescents will not be approached until the legal guardian provides consent. PI Herbell and the project manager will visit the recruitment sites several months before the start of recruitment to build rapport with staff.

RT staff referral is the primary mode of recruitment in this study. Staff at the recruitment sites (e.g., social workers) will have recruitment flyers in their offices. When parents visit the facility, the staff will read a short script about the study and provide the parent with a flyer. The staff will then ask the parent if they are interested in learning more about the study. If so, the parent will provide verbal permission for the staff providing the parent's contact information to the study team. The RT staff member will complete a referral form in REDcap including the parents name, phone number, email address, and preference for call/text/email. Alternatively, the recruitment

flyer will have a QR code on it and therefore, the parent can also complete the referral form themselves. Once the REDcap referral form is completed, the research team will receive an alert to contact the parent. The research team will then attempt to contact the parent up to five times and will track contact in the referral form.

Recruitment materials will also be displayed in waiting rooms, agency newsletters, social media, and listservs to facilitate passive recruitment. Recruitment flyers will be included in each admission and discharge packet from the RT facility. Families with youth currently admitted or recently discharged (past month) will also receive email and/or mail about the study. Email/mail communications will be sent to families once per month up to 5 times.

If recruitment slows, the research team will also engage organizations such as the Public Children Services Association of Ohio, the Ohio Children's Alliance, and child welfare agencies. The research team will ask these agencies to engage in the same recruitment methods as the RT facilities including: displaying recruitment flyers, sending flyers to families, adding information to newsletters or listserves, and social media posts.

Advisory board involvement. This study will also include an advisory board who the study team will meet with quarterly over the life of the project. Advisory board members are not participants in this study. The advisory board will be comprised of up to ten key stakeholders including parents with lived RT experience, RT staff, and mental health advocates. Advisory board members will be selected from a previous community-based participatory project (IRB 2021B0399). The PI will personally invite advisory board members to participate in the project. At quarterly meetings, the advisory board will be presented de-identified data on recruitment and retention and overall study progress. The key component of the advisory board is to assist in problem solving with the study team as challenges arise.

C. Measurement / Instrumentation

Data from parents and adolescents will be collected at baseline (T1), 6-weeks post-baseline (T2), and 6-months post-baseline (T3) to allow for a robust understanding of the longer-term effects of PW+ on treatment gain maintenance. Non-primary parents may enroll in the study; however, they only complete the demographic questionnaire at T1. Below is a summary of measures including a description and a timeline for administration.

Demographics Questionnaire: Asks about economic stability, physical environment, education, community and social context, health care access and treatment history. The full questionnaire is administered to primary parent, non-primary parent, and adolescent at T1. Selected questions are administered to primary parents and adolescents at T2 and T3.

Parenting Skills Use Diary: A brief assessment of parenting practice change over time. The assessment asks parents to review a list of positive/negative behaviors that a child did in the past week. The parent then selects which parenting strategies they used in response to the child's behaviors. The Parenting Skills Use Diary is administered to parents at T1, T2, and T3.

Reasons for Admission to Residential Treatment: This is an investigator-developed brief assessment derived from the Brief Problem Monitor. The assessment consists of 22 items. The assessment asks parents to reflect on before their child was admitted to residential treatment and rate how often each behavior occurred. This assessment is administered to parents at T1.

Patient Health Questionnaire-9: The PHQ-9 is the major depressive disorder module of the full PHQ. Participants are asked to rate their behavior during the past two weeks on a scale from 0 = not at all to 4 = nearly every day. The PHQ-9 will be administered to parents and adolescents at T1, T2, and T3. Please see sections below on protection for human subjects regarding this instrument.

Columbia Suicide Assessment Screen: The C-SSRS Screen Version is a validated tool that measures suicidal ideation over the past month and provides a classification of low, moderate, or high risk based on participant responses. The C-SSRS will be administered to parents and adolescents at T1, T2, and T3. Please see sections below on protection for human subjects should a positive screen be detected regarding this instrument.

Generalized Anxiety Disorder-7: The GAD-7 is a screener to measure anxiety in participants. The questions in the instrument ask participants to consider their behavior in the past two weeks. Parents will complete the GAD-7 at T1.

The Perceived Stress Scale-4: The PSS-4 is the short form of the full PSS. It is a brief measure of participants general stress level. Parents will complete the PSS-4 at T1, T2, T3.

Brief Problem Monitor: The BPM consists of 19 items derived from the Child Behavior Checklist. The subscales include internalizing, externalizing, and attention subscales. The BPM demonstrates construct validity, $\alpha=.91$, and elevated scores are correlated with an ADHD diagnosis. There are different forms for parent and child report. The BPM will be administered to parents and adolescents at T1, T2, and T3.

The Restrictiveness Evaluation Measure: The REM is 27-items assessing the level of restrictiveness in a placement setting. The REM demonstrates convergent validity between parent-child versions and $\alpha=.91$. There are different forms for parent and child report. The REM will be administered to parents and adolescents at T1, T2, and T3.

Parenting Sense of Competence Scale: The PSOC is 17-items that measures satisfaction and parental self-efficacy. Total PSOC scores are correlated with externalizing behaviors and family function, $\alpha=.80$. The PSOC will be administered to parents at T1, T2, and T3.

Adult-Adolescent Parenting Inventory: The AAPI is 40-items and consists of questions that ask about parenting practices, parenting knowledge, and attitudes towards parenting. The AAPI has strong predictive validity for child abuse, $\alpha=.80$. The AAPI will be administered to parents at T1, T2, and T3.

Medical Outcomes Study Social Support Survey: The MOS-SSS is 19-items that assesses emotional support, informational support, tangible support, affectional support, and positive social interactions. It demonstrates construct validity and has good internal consistency $\alpha=.91-.97$. The MOS-SSS will be administered to parents at T1, T2, and T3.

McMaster Family Assessment Device: The FAD is 60-items that assesses problem solving, family roles, communication, affective involvement, affective responsiveness, behavioral control, and general functioning. The FAD demonstrates convergent and discriminant validity in non-clinical and clinical samples, $\alpha=.78$. The FAD will be administered to parents at T1, T2, and T3.

The Confusion, Hubbub, and Order Scale: The CHAOS is 14-items and assessed the frequency of home environment chaos. The CHAOS is highly correlated with observer reported household chaos, $\alpha=.79$. The CHAOS will be administered to parents and adolescents at T1, T2, and T3.

Treatment as Usual Assessment: This is an investigator-developed questionnaire that attempts to capture the frequency and type of other interventions and services that parents and youth access during the course of the study. The questionnaire will be administered to parents at T1, T2, T3.

Intervention Satisfaction Questionnaire: Acceptability of PW+ will be determined with the Intervention Satisfaction Questionnaire completed by parents at T2. The Questionnaire consists of 14-items that assess satisfaction with PW+ by asking questions about what elements of PW+ they value most and if they would recommend PW+ to another parent.

WHODAS 2.0: This 12-item questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs. This is a NIMH common data element that will be administered to parents at T3.

Substance use screening: This is a brief measure administered to adolescents that asks about past month usage of alcohol and other drugs. It is administered to youth at T1, T2, and T3.

RCADS-25 Youth Self Assessment: The Revised Children's Anxiety and Depression Scale-25 (RCADS-25) is a 25-item scale that measures levels of anxiety (e.g. "I worry when I think I have done poorly at something") and low mood (e.g. "I feel sad or empty"). The scale has two subscales (Total Anxiety and Total Depression) and an overall score. The RCADS is a NIMH common data element that will be administered to youth at T3.

DSM 5 Cross Cutting Assessment: a self- or informant-rated measure that assesses mental health domains that are important across psychiatric diagnoses. The DSM 5 Cross Cutting Assessment is a NIMH common data element that will be administered to youth at T2.

Feasibility of PW+ Metrics: The feasibility of PW+ will be determined by tracking the frequency (attendance, PW logins), dose (module and practice exercise completion), and duration (time spent in PW and discussion groups/1:1 coaching calls). Frequency: The facilitators will take attendance at each discussion group or coaching call. The facilitators will also verify that parents logged into PW each week and attempted the modules. Dose: The facilitators will verify that parents completed the modules which require a passing quiz grade (80%). During group, parents are asked to describe how they practiced the skills with their adolescents. Duration: We will monitor and record the length of time for parents to complete modules. The facilitators will monitor and record the length of time to complete the discussion groups using the protocol. At the end of a cohort, the study staff with access usage data within Parenting Wisely to collect these metrics.

D. Detailed study procedures

Screening and Enrollment: Parents will be enrolled into cohorts with 4 to 5 parents in each cohort. The study staff will be responsible for eligibility screening and answering study-related questions. Screening questions are self-report, require approximately 15 minutes, and occur via Redcap and answers are confirmed with participants over the phone. Parents meeting criteria for participation will be provided with an informed consent document that outlines the study procedures, data collection timing, compensation, potential benefits and risks, and confidentiality.

Informed Consent, Parent Permission, and Assent: In this study, parents will be asked to provide written informed consent and potentially parent permission (if the adolescent is interested in participating in the study). Adolescents will be asked to provide written informed assent. In this study, we will obtain a formal and authorized written signature obtained electronically via REDCap. REDCap can be used to collect signatures remotely online when configured with a password for participants. All consent, permission, and assent procedures will take place over the phone/zoom with the RA. After participants have reviewed the consent, permission, or assent forms, the RA will direct them to establish a password to electronically sign the consent/assent/permission form in REDCap. The RA will then enter the passcode in the potential participant's REDCap record. Potential participants are sent a link to sign the consent/permission/assent form in REDCap via email, which does not include the password. Potential participants are then asked for the password which is cross referenced with the password already on file in the REDCap project. REDCap has the ability to save a PDF copy of the signed document (this feature will be enabled).

Parents will also be asked if they wish to provide permission for their adolescent to participate in the study. Only parents who are legal guardians will be asked about providing permission for their adolescent to participate. Interested parents will be emailed a REDCap link with the parent permission form will be sent to them. If the individual wishes to consider participation, the RA will provide with the study team's contact information. For adolescent assent, the study team will call the adolescent and their legal guardian together to discuss the study. The adolescent will be provided with a description of the study procedures. If interested in participating, the REDCap link with the assent form will be sent. Adolescents will be encouraged to ask questions or think about their decision to participate.

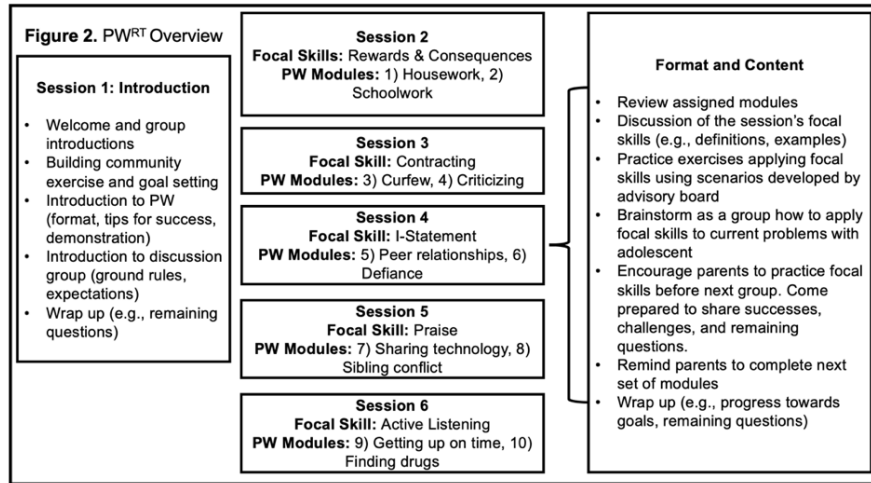
Enrolling More than One Parent: The effects of parent training are improved if more than one caregiver participates.^{109,110} If more than one parent is interested in participating, the RAs will consent the parents separately. A primary parent (i.e., person who has the greatest responsibility for the adolescent's daily care when at home) will be designated. Both parents will have individual access to PW, but only data from the primary parent will be collected and analyzed. The primary parent must be present during the discussion group (although the other parent may participate). The non-primary parent will be asked to complete a demographic questionnaire; however, they will not complete other assessments nor will they receive incentives.

Randomization: Parents (n=70) will be randomly assigned to the PW+ (n=35) or the TAU (n=35) condition. After completing the baseline assessment, the project manager will randomize and notify parents of their study assignment. For each condition, parents will be randomly allocated 1:1 to either of the two study conditions (PW+ vs. TAU) based on a computer-

generated randomization scheme using permuted block randomization with varying block sizes of two and four.

Adolescent Enrollment Considerations: When parents enroll, they will be asked if they would like to enroll the adolescent (if they are the legal guardian). While we propose to collect data from the adolescents, legal guardians may not consent for their adolescent to participate, or the adolescents may not assent. Eligible parents may still participate in the study even if they do not consent to enroll their adolescent or if their adolescent chooses not to participate. After the legal guardian's consent is received, the study team will make an appointment with the RT facility to speak (i.e., videoconference or phone) with the adolescent and the legal guardian to describe the study and complete the assent process if the adolescent chooses to participate. We will conduct all study visits for parents and adolescents remotely for efficiency, convenience, and safety. All conversations with adolescents will use developmentally appropriate terms.

PW+: Parents in the PW+ condition will complete two assigned PW modules and attend one 90-minute discussion group per week for six weeks. To reinforce effective parenting practices, parents view video vignettes of common problems families experience (e.g., sibling conflict). After viewing the vignette, parents select one of three responses based on how they would respond to the scenario. The three behavioral responses range in behavior management effectiveness. The selected response is portrayed in a second video vignette. Along with the vignette are interactive questions and answers with critiques that explain how effective parenting practices can solve family problems. Each module takes approximately 20 minutes to complete, with parents viewing videos, answering questions, and completing a short quiz. The final module is devoted to composite skills practice. Parents will attend a 90-minute discussion group via Zoom facilitated by a clinician with RT experience each week. The discussion groups provide an opportunity for parents to share successes and challenges with applying the PW strategies to their lives, receive individualized feedback, pursue personal goal development, and build community. Parents will receive text or email reminders to complete modules and attend their scheduled discussion group. During the first session, parents will receive login information for PW and be informed that they will have access to PW anytime on a device (e.g., tablet, smartphone) with internet. After the first session, parents will be emailed instructions for PW, including a manual with supplemental information and contact information (phone number, email) for technical issues or questions. Each discussion group is centered around focal skills (e.g., praise; see Figure 2). The discussion groups are not meant to cover each of the skills in PW. Rather, focal skills were selected based on advisory board input into which skills were most useful for parents. While each week's discussion group has a set of focal skills, other skills may come up in conversation. For example, we expect that parents will require ongoing support with contracting, which is a complex skill, and therefore anticipate working with parents on contracting beyond the third session. If a parent is unable to attend the groups because of their schedule or they miss a group, parents will be offered 1:1 coaching calls. The coaching calls will last approximately 20 minutes and be conducted with a member of the study team using a protocol (see attachments).



TAU: The TAU condition is the standard of care offered to parents at the partner RT recruitment sites. Parents in the TAU condition will receive traditional programming, including family therapy offered weekly during the RT admission. Parents will attend discharge planning meetings with caseworkers (if assigned) to discuss the adolescent's progress, continued treatment

needs, safety plans, upcoming appointments, and medication needs. There are no formal services provided following discharge, though programs frequently recommend follow-up with an outpatient provider for medication management and therapy for the adolescent.

Baseline Procedures (T1). Parents: After enrolling in the study, the RA will schedule a baseline data collection appointment. Before the data collection appointment, the RA will send parents a web link to REDCap, consisting of all baseline measures. Parents will receive up to three auto-reminders through REDcap to complete the assessments. During the baseline assessment (occurs over phone or Zoom), the RA will review responses and clarify missing or illogical responses. After completing the baseline assessment, parents will receive a \$20 e-gift card. Adolescents: Baseline data will be collected from adolescents over the phone during a scheduled appointment with the RT facility. The estimated time commitment is approximately 30 minutes and adolescents (or their parent) will receive a \$10 e-gift card after completing the baseline assessment.

Procedures for Six Weeks Post-Baseline (T2) and Six Months Post-Baseline (T3). Parents will be scheduled for T2 and T3 assessments two weeks before the assessment target dates. The administration procedures will be the same in T2 and T3 as baseline. The RA will send reminders by phone, text, or email. The estimated time commitment for T2 and T3 assessments is approximately 60 minutes. Parents will receive a \$20 e-gift card after completion of T2 and T3. Total compensation is \$60. Adolescents: Adolescents may have transitioned from RT to the community at the T2 and T3 data points. For adolescents living at home, we will coordinate with parents to schedule a data collection appointment over the phone with adolescents. Furthermore, as this is a population with a high rate of readmission and placement mobility, adolescents may be residing in alternative placements (e.g., hospital, juvenile detention) at the T2 and T3 data collection time points. We will track adolescents' placement at the T2 and T3 time points and coordinate with parents to collect data. The estimated time commitment for T2 and T3 assessments is approximately 30 minutes and adolescents will receive a \$10 e-gift card after completion of T2 and T3. Total adolescent compensation is \$30. The study team will attempt to collect data from participants up to 5 weeks past their scheduled data collection appointment.

Study Retention Procedures: To promote study retention, we will use brief, periodic check-ins (e.g., text, email) with parents to maintain contact throughout the study. At baseline, we will collect locator information (phone number, email address) and contact information from friends and family who may have the parent's contact information if research staff has lost touch. Parents and RT staff will be instrumental in tracking adolescents as they are the gatekeepers to this population. Contact information will be reviewed and updated at each study time point. We will schedule all follow-up assessments by phone, text, or email two weeks before the target date and send reminders according to preference. Recruitment and retention will be discussed in weekly study team meetings. These meetings will be integral in discussing methods for securing study enrollment and retention.

Potential Risks. All of the research related procedures, surveys, and questionnaires are to be reviewed by the IRB under §45 CFR 46.404, unless deemed otherwise by the IRB. Study staff are committed to minimizing risks even when though risks are minimal. Potential risks related to the proposed study include coercion, the actual or perceived loss of confidentiality, participant burden, and a risk related to data collection in that participants may feel uncomfortable being recorded or answering some of the questions asked or their responses may reveal problems either in child behavior or parenting. There are no known physical risks associated with participating in the proposed study, receiving PW, or participating in the discussion groups. PW+ aims to support and develop effective parental behavior management techniques to maintain adolescent RT gains in the community. As a component of regular care, participants in both conditions will receive services as determined by each adolescent's case plan; this will likely include individual and family therapy. Therefore, the overall risk level for parent and adolescent participation in this study, including data collection and intervention receipt, is minimal. There are no alternative treatments or procedures.

Protection Against Risks: Potential risks will be minimized by strictly adhering to the guidelines for research outlined by the IRB, state law, HIPAA, and the DHHS Federal Policy for the Protection of Human Subjects (45 CFR Part 46 Subpart D). Potential risks related to the proposed study include coercion, the actual or perceived loss of confidentiality, participant burden, and risk related to data collection (participants may feel uncomfortable being recorded or answering some of the questions asked, or their responses may reveal problems either in child behavior or parenting). There are no risks of incidental findings, as the proposed study only includes self-report data and does not include research imaging, disease or disorder screening, or paternity tests.

Coercion. For parents, the consent forms will state that participation in the project will not impact their ability or their adolescent's ability to access services or receive care. We will minimize the risk of adolescent coercion by assuring adolescents that participation is voluntary and that their care will not be influenced by participating or not participating. The assent forms will explicitly state that participation in the project will not impact participants' ability to access services. Adolescents are only able to participate if their legal guardian provides consent. Even if the legal guardian provides consent, the adolescent can choose not to participate.

Participant Burden. All participants (i.e., parents, adolescents) will be assured that they are free to withdraw from the research at any time. The study team was sensitive to participant burden in selecting the study measures. We selected short forms of measures whenever possible and kept assessments under one hour to minimize participant burden. Adolescent assessments are expected to take no longer than 30 minutes, and parents' assessments are expected to take no longer than one hour.

Confidentiality: Audio Recordings. Participants will be informed at enrollment and before beginning the study that portions of their participation may be audio recorded. For example, the PW+ discussion groups will be audio recorded for fidelity monitoring. The discussion groups will be hosted and recorded in Zoom, a secure, user-friendly, cloud-based enterprise videoconferencing service that Ohio State University implemented in 2018. The meeting host controls all meeting features, including mute/unmute participants, screen sharing, recording options, video sharing, remote screen control, and participant annotation. Audio recordings will be de-identified by transcribing the data and removing any names or titles that could link the comments with an identifiable person. Zoom is accessed via Ohio State's single sign-on solution, which provides an environment in which users can authenticate/log in at one time to a central server and connect with web-based services. Security best practices such as a waiting lobby, passwords to enter rooms, inability to join before host, disabling of sharing for participants, and disabling annotation by participants by default have been implemented. Only first names will be used in Zoom, and no medical information will be shared. Participants will be informed that they can decline to answer any questions and may discontinue participation at any point. As a component of the data analysis plan, any identifying information (e.g., name, facility) will be redacted from transcripts.

Confidentiality: Data Collection. All study assessments will be administered electronically via REDCap. The research team members will have a REDCap account and use REDCap to collect survey data and update participant contact information. The encryption used by REDCap to protect respondents includes hashed passwords and SSL certificates between client and server using the secure HTTPS protocol. REDCap allows for personalized hashed study ID links for each parent and adolescent. Further, we will use family IDs so that we can link parents and adolescents during the data analysis phase. Primary parent, non-primary parent, and adolescent data will be linked by the study team and individual participants will not have access to the answers of members of their family.

REDCap offers a Data Export Utility, which enables researchers to export their data in an automated manner into formats that are compatible with commonly used statistical analysis packages, such as SAS, SPSS, Stata, and R. All protected health information can be flagged and excluded on export to statistical analysis software. Each REDCap project has the ability to delete collected data in a single request.

Confidentiality: Data Storage. There will be no hard copies of data in this study. All data (e.g., audio recordings, surveys) will be housed in the Ohio State University College of Nursing's R-drive. Data will also be deposited in the NIMH NDA if a participant provides consent. Only research personnel (i.e., RA, study investigators) will have access to the R-drive. The R-drive runs Windows Server 2012R2 and is only used to host research files. The Windows operating system is kept up to date by weekly, automatic updates from Microsoft. The physical server is housed in a secure room within Newton Hall. Only pertinent IT staff and the building coordinator have keys to access this room. Electronic access to the research server is restricted to the college LAN or VPN by a Cisco ASA 5510 firewall. Access from the internet without VPN is not allowed. Electronic access is further restricted by the on-host Windows Firewall. User access is tightly controlled, by request only. New users must be cleared by the College of Nursing Associate Dean for Research. Permissions to individual folders and subfolders are managed individually. Users only have access to folders of projects in which they are directly involved. All changes are submitted in writing. Permissions are audited annually by IT in collaboration with the folder/study owner. The administrator account for the server has a non-standard password and has been disabled. All user accounts connecting to the server are domain accounts and are authenticated through a domain controller. Accounts are automatically locked out for 30 minutes

after 5 invalid attempts. User access and system information is logged and exported to a central event logging server.

Data will only be presented in aggregate with no disclosure of individual cases at scientific conferences or in publications. Data will only be transferred to others for analysis when the data is completely de-identified. Five years after the last follow up assessment is completed; any identifying information will be destroyed. Per the American Psychological Association guidelines, the de-identified data will be kept seven years after the final publication of these data.

Discomfort with Questions. There is a possibility that participants may feel uncomfortable answering questions. Any distress will be minimized by assurances that participants can skip questions they do not feel comfortable answering and withdraw from the study at any time without penalty. Participants will be encouraged to let the study team know if they feel distressed while completing questionnaires.

Procedures for Suspected Child Abuse. All consent and assent forms will include a statement that if a member of the research team has concerns about the safety of the participant, members of the household, or community, that all study team members are mandated reporters and are required to notify the proper authorities. In the case of suspected abuse or neglect, study team members are required by law to report the concern to child protective services. Ohio State law mandates that workers in certain professions (e.g., RNs and assistants working under the direct supervision of these professionals) report if they have reasonable cause to suspect abuse or neglect. Although we do not ask about child abuse or neglect, if something triggers the concern of anyone on the research team during the study related to child abuse or neglect, we will institute procedures for mandated reporting. The Ohio Department of Job and Family Services has an automated telephone directory that links callers to a child welfare office in the county. Study staff will call this number who may initiate an investigation. These calls will be made after consultation with Drs. Herbell, Breitenstein, and/or Melnyk. These procedures will satisfy all legal requirements.

Procedures for Homicidal thoughts/behavior In this study, we do not ask about homicidal intent or ideation. However, we have protocols in place should a parent or adolescent reveal homicidal intent or ideation. In the case of homicidal intent, we will report the information to both the police and the intended victim.

Procedures for elevated depressive symptoms and suicidal ideation:

In compliance with NIMH's policy regarding suicide risk assessment and intervention, we have developed a tiered suicide risk assessment and intervention plan that applies to parents and adolescents. We have added the Patient Health Questionnaire-9 (PHQ-9), a validated tool consisting of the Major Depressive Disorder modules of the full PHQ. We have also added the Columbia Suicide Severity Rating Scale (C-SSRS) Screen Version, a validated tool that measures suicidal ideation over the past month and provides a classification of low, moderate, or high risk based on participant responses. All participants will complete the PHQ-9 at baseline, (T2), and (T3). These time points represent major assessment points within the study design. Furthermore, these time points could potentially take place during major transitions that may be stressful for the parent and adolescent (e.g., newly admitted to RT; impending discharge; recent discharge to the community).

The PHQ-9 and C-SSRS will be administered by a member of the study team. threshold for a positive PHQ-9 screen occurs when there is a total score of 10 or above or a participant indicates any response greater than “never” on the item that asks “over the last two weeks, how often have you been bothered by thoughts that you would be better off dead or hurting yourself in some way.” If a positive PHQ-9 is detected, the RA will then administer the C-SSRS. The C-SSRS consists of six yes/no questions that are coded based on risk.

Intervening with youth

We have developed distinct procedures for adolescents that are dependent on where they are living at the time of data collection. Distinct procedures are necessary in this study because youth are expected to be enrolled in the study during a residential treatment admission and subsequent data collection time points are expected to take place in the community.

As part of our data collection protocol of working with high-risk adolescents, data are collected from youth when there is another adult such as a parent or RT staff that accompanies them. We will respect privacy of the adolescents by asking the adult to leave the data collection area. However, in certain scenarios (i.e., moderate and high risk for suicide), we will ask the adult to privately meet with the study team to discuss concerns and co-create a plan.

Low risk youth residing in RT will be encouraged to discuss these concerns with another adult such as a parent, caregiver, or therapist. No follow up is needed for low risk participants. Youth residing in the community will be provided a list of resources (e.g., 988, warmline).

Moderate risk: Youth are recruited from different RT facilities that have different policies and procedures for suicide prevention. Should there be an adolescent at moderate risk for suicide, study staff will notify the adult that accompanied the adolescent to the data collection appointment and site-specific protocols will be instituted at the RT facility. Such protocols facilitated by local RT staff may include 1:1, contracting for safety, or making an emergency appointment with a therapist. Should there be an adolescent at moderate risk for suicide and they are residing in the community, study staff will notify the adult that accompanied the adolescent to the data collection appointment of the elevated risk. Study staff will assist the adult with creating a plan for intervention which may include the adult and adolescents staying on the phone with the study staff to be transferred to a warmline (e.g., Cincinnati warmline, Boystown hotline).

High risk: Should there be an adolescent at high risk for suicide, study staff will notify the adult that accompanied the adolescent and site-specific protocols will be instituted at the RT facility. Such protocols facilitated by local RT staff may include 1:1, contracting for safety, making an emergency appointment with a therapist, or calling the crisis team. High risk youth residing in the community need prompt intervention in the form of helping them call the National Suicide Hotline or 988. If the participant refuses or hangs up, the study team will call 911 who will help determine further action and potentially accompany the participant to the emergency department.

Given the population (i.e., adolescents admitted to RT), it is likely that adolescents will be considered moderate or high risk for depression and/or suicide. Adolescents in this study do not receive intervention and only complete study assessments. As with all study participants, youth can withdraw from the study at any time; however, a moderate or high risk determination will not impact the youth's continued participation. Should a youth be deemed moderate or high risk, the study team will ask the youth if the study is too much of a burden and whether they want to continue.

Intervening with parents

Low risk parents will be provided a list of resources (e.g., 988, warmline).

Moderate risk participants will be provided a list of resources (e.g., 988, warmline). Moderate risk participants are encouraged to stay on the phone with the study team member to be transferred to a warmline (e.g., Cincinnati warmline, Boystown hotline).

High risk parents need prompt intervention in the form of helping them call the National Suicide Hotline or 988. If the participant refuses or hangs up, the study team will call 911 who will help determine further action and potentially accompany the participant to the emergency department.

Data Safety Monitoring Board

This study is required by the sponsor, NIMH, to have a data safety monitoring board. The board will meet approximately two times per year (or more frequent if necessary). Board member will not have access to identifiable participant information; rather, they will review aggregate data.

E. Data Analysis

Preliminary analyses will include descriptive statistics to summarize sample characteristics, check data accuracy, and examine variable distribution. All data anomalies identified will be thoroughly investigated and remedial strategies will be considered as appropriate. Descriptive analysis will be used for **Aim 1** and the **Exploratory aim**. We will perform intent-to-treat analysis for **Aim 2** and **Aim 3** using mixed-effects linear modeling as the primary analytical strategy. **Aim 1:** Using descriptive statistics, we will evaluate feasibility by tracking frequency (discussion group attendance, PW logins), dose (module and practice exercise completion), and duration (time spent in PW and discussion groups). Feasibility metrics will be monitored weekly, compared to the pre-defined benchmarks, and discussed in team meetings and the advisory board. Acceptability of PW+ will be determined by scores on the Consumer Satisfaction Questionnaire¹¹² and comparing scores to the pre-defined benchmarks. Descriptive statistics will be used for the quantitative measures of feasibility and acceptability. **Exploratory aim:** We will use descriptive statistics to assess feasibility, including enrollment, retention, and missing data.

Aim 2 and Aim 3: Descriptive statistics will be used to compare the two conditions (PW+ vs. TAU) on participant characteristics and baseline assessments. Mixed-effects linear regression modeling for repeated measures will be used to estimate intervention effect on each target mechanism variable (i.e., parental self-efficacy, parenting practices, family function, social support [**Aim 2**]) and adolescent outcomes (i.e., externalizing, internalizing) and adolescent placement restrictiveness [**Aim 3**]). From the models, we will 1) estimate the fixed effects of the intervention (PW+ vs. TAU), time (baseline, six weeks and six months post-baseline),

intervention by time interaction; 2) derive contrast estimates on the within- and between-group comparisons on change of outcome measure from baseline at each post-baseline time point; and 3) adjust for within-subject data dependency from repeated measures.

Aim 3a: We will first use trend plots to determine whether parallel patterns exist across time in the changes of outcomes of interest (e.g., social support and adolescent externalizing behaviors). Pearson correlation will be used to examine the unadjusted associations of the changes of the two outcomes of interest at each follow-up time point. Mixed-effect linear regression will be used to model adolescent outcomes (internalizing and externalizing behaviors; placement restiveness as a function of the mechanism factor (e.g., social support, intervention, time, and their two-way and three-way interactions). From the model, we can derive contrast estimates on the effects of change of the mechanism factor on the change of outcome, adjusting for covariates and within-subjects clustering from repeated measures. In the models for **Aims 2 and 3**, we will control for covariates and unbalanced baseline characteristics, if any. We will also explore the effects of **biological sex and age** of the parent and adolescent by including them and their interactions with intervention and time as fixed-effects covariates in the mixed-effects linear model. As emphasized in the power analysis section, we will report point estimates, precisions, and effect sizes. These estimates, along with practical/clinical significance, will guide results interpretation for this pilot study and sample size determination for our full-scale R01 trial.

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