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Families in transition (FIT) study protocol: feasibility, acceptability and preliminary effects of a group-based parent training in parents of youth in psychiatric residential treatment

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ABSTRACT

Introduction Although adolescents make treatment gains in psychiatric residential treatment (RT), they experience significant difficulty adapting to the community and often do not sustain treatment gains long term. Their parents are often not provided with the necessary support or behaviour management skillset to bridge the gap between RT and home. Parent training, a gold standard behaviour management strategy, may be beneficial for parents of these youth and web-based parent training programmes may engage this difficult-to-reach population. This study focuses on a hybrid parent training programme that combines Parenting Wisely (PW), a web-based parent training with facilitated discussion groups (Parenting Wisely for Residential Treatment (PW^{RT})). This study aims to: (1) establish the feasibility and acceptability of PW^{RT}, (2) evaluate whether PW^{RT} engages target mechanisms (parental self-efficacy, parenting behaviours, social support, family function) and (3) determine the effects of PW^{RT} on adolescent outcomes (internalising and externalising behaviours, placement restrictiveness).

Methods and analysis In this randomised control trial, parents (n=60) will be randomly assigned to PW^{RT} or treatment as usual. Each week for 6 weeks, parents in the PW^{RT} condition will complete two PW modules (20 min each) and attend one discussion group via Zoom (90 min). Adolescents (n=60) will not receive intervention; however, we will evaluate the feasibility of adolescent data collection for future studies. Data from parents and adolescents will be collected at baseline, post intervention (6 weeks post baseline) and 6 months post baseline to allow for a robust understanding of the longer-term effects of PW^{RT} on treatment gain maintenance.

Ethics and dissemination The study has been approved by The Ohio State University Institutional Review Board (protocol number 2022B0315). The outcomes of the study will be shared through presentations at both local and national conferences, publications in peer-reviewed journals and disseminated to the families and organisations that helped to facilitate the project.

Trial registration number NCT05764369 (V.1, December 2022).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Pilot trials are not powered to test the efficacy of an intervention; however, the sample size is sufficient for assessing feasibility, acceptability and preliminary effects.
⇒ Data are collected from parent and youth allowing for a more robust understanding of intervention effects.
⇒ Assessing outcomes across a span of 6 months can provide insight into changes in youth placement.

INTRODUCTION

Psychiatric residential treatment (RT) settings are one of the most intensive, restrictive and expensive behavioural healthcare settings available to adolescents.[1–3] Although adolescents can make significant treatment gains, including reductions in internalising and externalising behaviours[4] and improvements in educational achievement[5] and social functioning,[6] they experience significant difficulty adapting to less restrictive placements and often do not sustain gains made in treatment.[7–12] Oftentimes, RT focuses mainly on the adolescent with little focus on the home environment, despite nearly 70% of adolescents return to their family and home environments at discharge.[13] Parents often report feeling unprepared for their adolescent's discharge and have reported that they need greater support, education and skills building before their adolescent is discharged.[14 15] One effective method of equipping parents with behaviour management skills is through parent training programmes.[16] While several barriers limit the provision of parent training in RT (eg, out-of-county placement),[17–20] web-based programmes may increase reach and engagement.

Parenting Wisely (PW) is a web-based parent training programme that is self-administered, developed initially for parents with court-involved adolescents aged 11–17 years with moderate externalising behaviours.[21] PW targets parenting practices to reduce adolescent externalising behaviours with small-to-medium effects (Cohen's d=0.20–0.46).[14 22–26] Our team previously tested the feasibility and acceptability of PW in a sample of parents (n=20) with adolescents transitioning from RT to the community.[27] PW was administered over 5 weeks with parents completing two individual interviews regarding programme perceptions and a satisfaction survey. Parents felt PW was user-friendly and the content was helpful and easy to understand. Parents were satisfied that the modules contained videos that served as examples of how to implement parenting skills. However, parents felt that they needed a way to differentiate and tailor the skills to their lives to implement them effectively. Furthermore, parents identified the need to build community and that their confidence in implementing the skills would be bolstered by learning from other parents.

Based on feedback from key stakeholders, we augmented PW with virtual facilitated discussion groups (referred to as Parenting Wisely for Residential Treatment (PW^{RT})). PW^{RT} is a 6-week intervention that includes weekly completion of two PW modules (~20 min each) and facilitated discussion groups via videoconference (90 min). The goal of the discussion groups in PW^{RT} are to support programme completion and parent engagement, provide a venue to discuss individualising PW strategies, reduce isolation and support parents by engaging in conversation about parenting in the RT context. PW^{RT} is strengths based and provides emotional support by creating a community where parents can develop relationships to reduce isolation and shame. Parents evaluate strengths and difficulties with the assistance of facilitators to develop a plan to incorporate PW skills into daily life more adequately. The facilitator provides individualised tailoring and coaching to troubleshoot strategies during the discussion group.

Study objectives

The primary aim of this study is to evaluate the feasibility and acceptability of PW^{RT}. The secondary aim of this study is to test the effects of PW^{RT} compared with treatment as usual (TAU) on target mechanisms including family function, parental self-efficacy, parenting practices and social support. We will also evaluate the effects of PW^{RT} compared with TAU on adolescent outcomes (eg, internalising and externalising behaviours) and placement restrictiveness (ie, level of autonomy and freedom of movement an adolescent has in their living location).[28] Parents (n=60) will be randomly assigned to the intervention (PW^{RT}) or TAU group. Adolescents (n=60) will not receive intervention; however, they will complete surveys, allowing us to evaluate the feasibility of adolescent data collection for future studies.

METHODS AND ANALYSIS

Design

This randomised controlled trial is designed to evaluate the feasibility, acceptability and preliminary effects of PW^{RT} in parents with adolescents transitioning from RT to the community. Parents (n=60) will be randomly assigned to the PW^{RT} or TAU conditions. Parent (n=60) and adolescent (n=60) data will be collected at three time points: baseline (T1), post intervention (6 weeks post baseline; T2) and 6 months post baseline (T3). The planned start date for the study is 1 December 2022 and the planned end date is 30 November 2025.

Eligibility criteria

The inclusion criteria for parents are that they are an adult caregiver (eg, biological, step, kin, foster, adoptive) to an adolescent aged 11–17 years who is admitted to RT. The parent must be allowed to have contact with the adolescent and the parent must have access to a device (eg, smartphone) with internet access. The inclusion criteria for adolescents are that they must understand and be willing to provide written assent and their legal guardian provides written consent. Adolescents must also be currently or previously admitted to RT and between the ages of 11–17 years at enrolment. Parents and adolescents are excluded if they are not able to speak English.

Sample size justification

We will recruit 60 parents (30 per condition) to account for an attrition rate of 20% at 6 months post baseline, resulting a final sample of 48 (24 per condition) for analysis. The sample size is sufficient for assessing feasibility and acceptability measures of targeted ≥50% within a width of ±21% for a two-sided 95% CI. The study was not designed to be adequately powered to detect efficacy. We conducted a power analysis using mixed effects linear modelling for repeated measures and a two-sided alpha level of 0.025 to adjust for multiple comparisons from two repeated post-treatment measures for the purpose of guiding result interpretation. A sample size of 48 parents 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 (eg, for parenting practices) to 0.46 (eg, for adolescent behaviours) for the intervention effect of PW.[14 23] We expect the intervention augmentation (ie, adding a group to PW) 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, but will report point estimates, precision (eg, 95% CI) and effect sizes. With our sample size and a two-sided 95% CI, we will have ±0.40σ precision to estimate group-specific means and ±0.58σ precision to estimate between-group mean differences.

Recruitment

We will recruit participants from US-based RT facilities with staff referral being the primary mode of recruitment in this study. Staff at the recruitment sites (eg, social workers) will have recruitment flyers in their offices and virtual copies of the flyers. When staff interact with families, the staff will read a short script about the study and provide parents with a flyer. The staff will ask parents if they are interested in learning more about the study. If so, a parent will provide verbal permission for the staff to provide the parent's contact information to the study team. The staff member or the parent will complete a referral form in REDCap that includes the parent's name, phone number and email address. Recruitment materials will also be displayed in waiting rooms, agency newsletters, social media and listservs to facilitate passive recruitment. Finally, more than one parent may participate, but each family will designate one parent as the primary parent for data analysis.

Study setting

While parents and adolescents are recruited from RT facilities, all research procedures will occur remotely including screening, consent, intervention delivery and data collection. This strategy offers greater convenience and efficiency while maintaining the same level of flexibility that has become commonplace since the start of the COVID-19 pandemic.

Randomisation and interventions

After completing the baseline assessment, the parents will be randomly assigned 1:1 to either the PW^{RT} (n=30) or the TAU (n=30) condition based on a computer-generated randomisation scheme using permuted block randomisation with varying block sizes of two and four. Randomisation will be implemented using REDCap randomisation module.

Parenting Wisely for Residential Treatment (PW^{RT})

Parents in the PW^{RT} condition will complete two assigned PW modules and attend one 90 min discussion group per week for 6 weeks. To reinforce effective parenting practices, parents view video vignettes in PW of common problems that families experience (eg, sibling conflict). After viewing the vignette, parents how they would respond to the scenario. The three behavioural responses range in behaviour management effectiveness. The selected response is portrayed in a second video vignette. Along with the vignette, there are interactive questions and answers to engage the parent in thinking about effective parenting practices. Each module takes approximately 20 min to complete. The final module is devoted to composite skills practice. Parents will attend a 90 min facilitated discussion group via Zoom each week. The discussion groups provide an opportunity for parents to share successes and challenges with applying the PW strategies to their lives, receive individualised feedback, pursue personal goal development and build community.

Treatment as usual

The TAU condition is the standard of care offered to parents during an RT admission and after discharge. Parents in the TAU condition will receive traditional programming, which may include family therapy. 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. After discharge, programmes frequently recommend follow-up with an outpatient provider for medication management and therapy.

Intervention fidelity

There will be a high level of consistency in intervention delivery as PW is web based and consistent across all users. To ensure the discussion groups are delivered with fidelity, the facilitator went through training that included viewing the PW modules, reviewing the discussion facilitator training guide and practising discussion groups. After each discussion group, the facilitator will complete a self-assessment to rate their adherence to the protocol. The assessment includes attendance tracking, individual and group engagement and group cohesion. The assessment also contains questions that are specific to each session based on the protocol (eg, in session 1, the facilitator describes how to log into PW). Discussion groups are conducted and recorded in Zoom and 15% will be audited by independent evaluators to evaluate fidelity and determine if there is additional facilitator training needed. Additional training would encompass the facilitator revisiting training materials and role playing with the Principal Investigator (PI).

Variables and measures

The primary outcomes in this study are feasibility and acceptability of PW^{RT}. To evaluate the feasibility of PW^{RT}, several metrics are tracked including, frequency, dose and duration. Frequency will be evaluated through tracking and averaging group attendance and the number of parent logins to PW. Frequency is feasible if parents attend at least 50% of discussion groups and attempt at least 50% of modules. Dose will be evaluated through tracking module completion rates in PW. Dose is considered feasible if at least 50% of modules are completed. Duration will be evaluated through tracking time spent completing PW modules and time spent in group. The study team will monitor and record the length of time for parents to complete modules. The study team will examine modules lasting <10 min or >40 min for relevance. The facilitators will monitor and record the length of time to complete the discussion groups. Discussion groups lasting <40 min or >90 min will be evaluated and modified. At the end of the intervention period, at the T2 data collection time point, parents complete a 13-item self-report satisfaction survey to evaluate acceptability. PW^{RT} will be considered acceptable if at least 50% of parents indicate they were satisfied.

Table 1 Study measures and data collection schedule

Measure	Administration timeline		
	T1	T2	T3
PW^{RT} Feasibility Metrics		P	
PW^{RT} Satisfaction Survey		P	
Brief Problem Monitor	PY	PY	PY
Restrictiveness Evaluation Measure	PY	PY	PY
Parenting Sense of Competence Scale	P	P	P
Adult-Adolescent Parenting Inventory	P	P	P
Medical Outcome Study Social Support	P	P	P
McMaster Family Assessment Device	P	P	P

P, parent; T1, baseline; T2, postintervention 6 weeks post baseline; T3, 6 months post baseline; Y, youth.

In addition to evaluating feasibility and acceptability, this study also examines preliminary effects on a myriad of secondary outcomes including adolescent internalising and externalising behaviours, placement restrictiveness, family function, social support, parenting practices and parental self-efficacy. These outcomes will be evaluated by examining change in the outcome from baseline to subsequent time points (ie, T2 or T3). See table 1 for the study measures and data collection schedule.

Adolescent internalising and externalising behaviours from the parent and adolescent perspective will be assessed using the Brief Problem Monitor (BPM) for ages 6–18 years.[29] The BPM consists of 19 items derived from the Child Behavior Checklist. The Restrictiveness Evaluation Measure will be administered to parents and adolescents to evaluate perceptions of adolescent placement restrictiveness and consists of 27 items.[28] There are two subscales; one scale identifies 25 placement settings varying in restrictiveness, and the second subscale consists of questions about the activity and lifestyle restrictions in such placements.[28]

The McMaster Family Assessment Device (FAD) will be administered to parents to evaluate changes in family function.[30] The FAD is 60 items that assesses problem-solving, family roles, communication, affective involvement, affective responsiveness, behavioural control and general functioning.[30] The Medical Outcomes Study Social Support Survey (MOS-SSS) will be administered to parents to evaluate changes in social support.[31] The MOS-SSS is 19 items that assess emotional support, informational support, tangible support, affectional support and positive social interactions.[31] Changes in parenting practices will be evaluated using the Adult-Adolescent Parenting Inventory is a parent self-report 40-item measure that consists of questions that ask about

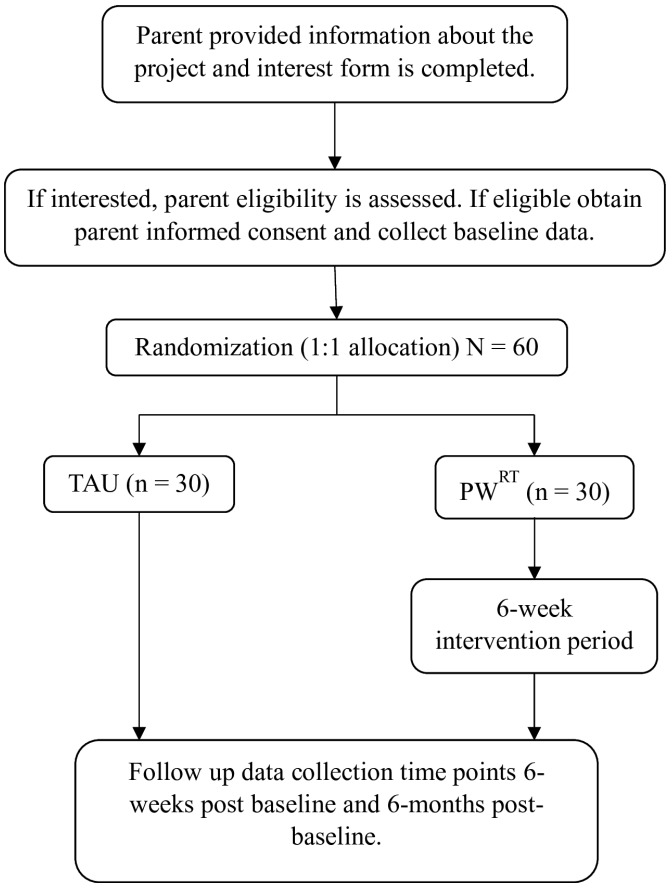

Figure 1 Study flow of parent participation. PW^{RT}, Parenting Wisely for Residential Treatment; TAU, treatment as usual.

parenting practices, parenting knowledge and attitudes towards parenting.[32] The Parenting Sense of Competence Scale (PSOC) will be administered to parents to evaluate changes in parental self-efficacy.[32] The PSOC is 17 items that measure satisfaction and parental self-efficacy.[33]

Data collection, management and analysis

Data collection and visits

See figure 1 for participant flow through the study. The study staff will be responsible for eligibility screening and answering study-related questions. Screening questions are self-report, require approximately 10 min 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 (see online supplemental material). In this study, parents will provide written informed consent and potentially parent permission, if the enrolled parent is the legal guardian of the adolescent. 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, compensation, potential benefits and risks and confidentiality. If interested in participating, the adolescent will be provided an assent form.

All surveys will be administered through REDCap with a member of the study team on phone or Zoom to answer any questions. At the completion of the baseline surveys, parents will be randomly assigned to PW^{RT} or TAU. After randomisation, parents are informed of their group assignment. Participants will be scheduled for T2 and T3 assessments several weeks before the assessment target dates. The administration procedures will be the same in T2 and T3 as baseline. Adolescents may have transitioned from RT to the community at the T2 and T3 data points. For adolescents living at home, the study team 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 (eg, 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. Parents receive a US$20 gift card at each time point with a total possible compensation of US$60. Parents only receive incentives for completing data collection appointments and do not receive incentives for completing the intervention. Adolescents receive a US$10 gift card at each time point with a total possible compensation of US$30.

Data management

REDCap will be used to manage recruitment, screening, consenting, data collection and tracking of participants throughout the study. Data stored in REDCap will be password protected and backed up automatically. Data exported from REDCap (using study ID variables) will be stored on secured servers for analysis. SAS V. 9.4 will be used for data cleaning, management and analysis. We will regularly monitor completeness of data collection, identify errors and outliers and make corrections to ensure maximum data quality.

Statistical methods

Descriptive statistics will be used to evaluate the feasibility of PW^{RT} by tracking frequency, dose and duration. For the exploratory aim (ie, feasibility of enrolling adolescents), we will use descriptive statistics to assess feasibility, including enrolment, retention and missing data. Analyses for study objectives 2 and 3 will use mixed effects linear regression modelling for repeated measures and will estimate the intervention effect on each target mechanism variable and adolescent placement restrictiveness. From the models we will (1) estimate the fixed effects of the intervention, time, interventions by interactions, (2) derive contrast estimates on the within-group 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. Analyses will use trend plots to determine whether parallel patterns exist across time in the changes of outcomes of interest. 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. 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.

Patient and public involvement

Patients or the public were not involved in the design of this clinical trial or in the plans for study conduct, reporting or dissemination.

ETHICS AND DISSEMINATION

The study protocol was approved by The Ohio State University Institutional Review Board who determined the study to pose minimal risk to participants. All participating parents are required to sign an informed consent for themselves. If adolescents enrol in the study, the legal guardian must sign a parent permission form and the adolescent must sign an assent form. All adolescents will be fully informed about the study before providing assent. Study participation is voluntary and does not replace clinical referrals or treatment options for the family. All potential study participants are encouraged to consider their participation and take time before proceeding with providing with consent. The study has a data safety monitoring board who convenes at least twice per year and as needed to review study progress and events, if applicable. The study was also enrolled in the National Institute of Mental Health's (NIMH) Clinical Research Education, Support, and Training programme that provides additional support and guidance to teams who work with vulnerable populations. The team has developed and practised extensive protocols in the event of suicidal or homicidal ideation, domestic violence, and suspected abuse or neglect. To maximise research dissemination, plans included sharing results through presentations at regional and national conferences, publications in peer-reviewed journals, as well as sharing findings with participating families and recruitment sites. Additionally, the data derived from this project will be deposited into the NIMH National Data Archive with participant consent.

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Contributors KH, SMB, AT and BMM designed the study and obtained funding. KH and SMB led the design of PWRT. ATT and SB refined the study procedures and protocols. All authors contributed to the writing and revising of the paper and approved the final submission.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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The Ohio State University Consent to Participate in Research

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

Protocol Number: 2022B0315

Researcher: Kayla Herbell, Ph.D., RN

Sponsor: National Institute of Mental Health

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary. Please consider the information carefully. Feel free to ask questions before deciding whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose: This study aims to test the outcomes of a web-based parent training program and discussion groups to support parenting and child behavior for parents of children admitted to residential treatment. We are interested in understanding how the program supports parents and children, especially during the transition from residential treatment to the community.

This study is open to any caregiver who cares for a child admitted to residential treatment. This includes grandparents, step-parents, adult siblings, foster parents, etc. If more than one parent of the child is interested in participating, we will separately consent each parent. However, for data collection and analysis purposes, each family will designate one parent as the "primary" parent. Data will be collected from the primary parent only, and the primary parent will be designated using a survey.

If you have multiple children in residential treatment that meet eligibility criteria, we will randomly select one of the children and you will answer questions about that child.

If you choose to participate in this study and you are the primary parent, you will:

Read this consent form and agree to participate. Complete all survey measures on a device with internet access. The research team will email you a link to access the surveys and be available to answer any questions you have regarding the surveys. The first visit (baseline) is at the time of enrollment and you will be asked to respond to survey questions about parenting and child behavior. The second set of questionnaires is six weeks after baseline and the third is six months after baseline. It will take approximately 1 hour each time you fill outthe surveys. Any data collected as part of the eligibility screening collected before you provided consent will be used for research purposes.

After completion of the baseline surveys, primary parents will be randomized into one of two groups: (1) intervention group or (2) the usual care group. If you are in the usual care group, you will continue the treatments and programming you normally engage in. For example, this may include regularly scheduled family therapy, case management, or other programming. If you are in the intervention group you will complete an online program and attend virtual parent groups. Activities will include completing two modules in a web-based program (takes approximately 20 minutes) and attending 90-minute discussion groups over Zoom. The research assistant will provide training on the assigned web-based program (e.g., logging in, how to begin using the program, and technical assistance). You will receive reminder text messages and phone calls throughout the 6-month study period. The study team will

Consent Form Version: 1 Date: 6/8/23

monitor how much you use the program. For example, we will collect whether you complete modules, how long modules take, and quiz scores.

If you participate in this study and are the non-primary parent you will:

Read this consent form and agree to participate. Complete a short set of questions about your background. Receive instruction regarding the primary parent intervention group assignment. If the primary parent is assigned to the usual care group, you will continue the treatments and programming you normally engage in. For example, this may include regularly scheduled family therapy, case management, or other programming. If the primary parent is assigned to the intervention group, the research assistant will provide standardized training on the assigned web-based intervention (e.g., logging in, how to begin using the program, and technical assistance). Surveys will be completed by the primary parent only. For parents attending group, the primary parent must attend (although you may participate). Both parents will have individual access to the assigned program content, and web-based program usage data will be collected from both parents.

Duration: The study lasts six months and the total time required for participating in the study varies depending on which group you are assigned. The total time commitment for parents in the intervention group is about 12.5 hours, while the total time commitment for parents in the usual care group is about 3.5 hours.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits: There are no known physical risks associated with participation in the proposed study or receiving the web-based program, parent groups, or the usual care conditions. There are no alternative treatments or procedures.

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 discomfortwith data collection in that participants may feel uncomfortable being recorded or answering some of the questionsasked, or their responses may reveal problems in child behavior or parenting. If you do not wish to answer a question, you may skip it and go to the next question.

Your participation is voluntary and you can leave the study at any time.

Portions of this study are recorded. For example, the parent groups will be recorded to ensure we follow the study protocol. Further, the parent groups have other parents in them, and while we ask others in the group to keep the discussion content confidential, we cannot guarantee this. Please remember this when choosing what to share in the group setting.

In any study that collects information, there is a risk that information, or data, would be seen by someone outsidethe study team who should not have access to the information. We will take several actions to keep your information safe and confidential. Although we will have records that will allow your name and identifying information to be associated with your data and recordings, your survey responses or other online data we collect will be kept secure and associated with your unique ID number. Your data will be stored in a password-protected database, and only approved research team members will have access to it. When storing your data, we will use a unique identification code

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to identify you whenever possible. In this way, your name or other identifying information will onlybe connected through a separate file that links your name and the code. Given all of these actions, it is unlikely that your information would be seen by someone not authorized to see it.

We are required by the agency funding this research to assess for suicidal ideation using a questionnaire. If you endorse suicidal intent, we will help you to seek further assistance through resources such as a warm line or the National Suicide Hotline. Per state law, all research team members are required to report child abuse or neglect as well as significantsafety concerns related to wanting to harm yourself or others.

There are no direct benefits to individual participants.

Confidentiality: We will work to make sure that no one sees your online responses without approval. But, because weare using the internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the riskthat other people can view the responses.

Again, participation is voluntary.

There may be circumstances where this information must be released. For example, personal informationregarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

Office for Human Research Protections or other federal, state, or international regulatory agencies; The Ohio StateUniversity Institutional Review Board or Office of Responsible Research Practices; The Sponsor, the National Instituteof Mental Health (NIMH), supporting the study.

Certificate of Confidentiality:
The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to the study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

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You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

Clinical Trials: A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Will my de-identified information be used or shared for future research? Data from this study can be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database that stores and manages de-identified study data from many NIH studies. Sharing your de-identified study data helps researchers learn new and important things more quickly than before.

De-identified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information to make that code number. The code number cannot be used to identify you, and the researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your de-identified data from each study. This data matching helps researchers who use NDA data to count you only once. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the researchers will send de-identified study data about your health and behavior to the NDA. Other researchers worldwide can request your de-identified study data for different research projects. Every researcher (and the institution to which they belong) who requests your de-identified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers worldwide learn more about how to better support families of children with mental illness. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

Do you consent to having your data deposited in the National Institute of Mental Health Data Archive? You may decide now or later that whether you want your study data added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the researcher before the end of the appointment. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available online at http://nda.nih.gov

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1, Yes, I consent to depositing my de-identified data into the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health.

2, No, I do not consent to depositing my de-identified data into the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health.

Incentives: Only the primary parent in the study will receive incentives. The primary parent will receive a $20 gift card at the first data collection appointment and $20 at the completion of surveys at the second and third time points. The total gift card amount is $60. If you choose to skip some questions because you are uncomfortable responding, you will still receive the incentive. By law, payments to participants are considered taxable income.

Participant Rights: You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

Contacts and Questions: For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Kayla Herbell, Ph.D., RN, 614-688-0959, herbell.3@osu.edu

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

Will you be contacted about participating in future research? If you agree, we may contact you after your participation in this study about participating in future research. Please check one of the following options.
1, Yes, I agree to be contacted about future research.
2, No, I do NOT agree to be contacted about future

As a condition of participation in this study, primary parents must be able to have contact with their child who is in residential treatment. This means primary parents can freely speak to their child and/or visit their child. This also means that there are no orders from child protective services or other parties that say that you may not have contact with your child. By clicking “I agree” you certify that you are allowed contact with your child and there are no orders in place that restrict your contact.
1, I agree

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Providing consent

I have read (or someone has read to me) this page and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by agreeing to participate.

To print or save a copy of this page, select the print button on your web browser.

Printed name of participant:

Signature of participant:

Date:

Time:

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent:

Signature of person obtaining consent:

Date:

Time:

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