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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

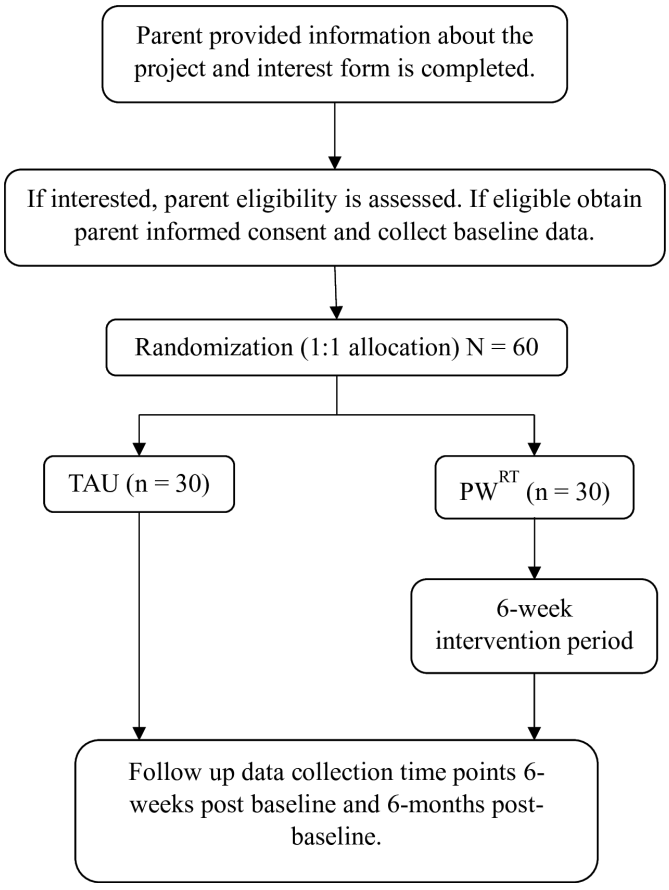

Figure 1 Study flow of parent participation. PW^{RT}, Parenting Wisely for Residential Treatment; TAU, treatment as usual.

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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Competing interests None declared.

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