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ORIGINAL RESEARCH

A randomized preference trial to inform personalization of a parent training program implemented in community mental health clinics

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Abstract

Incorporating participant preferences into intervention decision-making may optimize health outcomes by improving participant engagement. We describe the rationale for a preference-based approach to the personalization of community-based interventions. Compensating for the limitations of traditional randomized controlled trials (RCTs) and partially randomized preference trials (PRPTs), we employed a doubly randomized preference trial in the present study. Families (N=129) presenting to community mental health clinics for child conduct problems were randomized to choice or no-choice conditions. Within each condition, parents were again randomized, or offered choices between home- and clinic-based, individual and group versions of a parent training program or services-as-usual. Participants were assessed at baseline, and treatment retention data were gathered. Families assigned to the choice condition were significantly less likely to drop out of treatment than those in the no-choice condition. In the choice condition, in-home treatment was the preferred modality, and across conditions, families were less likely to be retained in group and clinic modalities. Research on preferences may boost participant engagement and inform shared decision-making.

Keywords

Preference, Personalization, Parent training, Treatment retention

Implications

Implication for researchers: Personalization studies aimed at tailoring treatment options to family preferences with the help of decision aids to promote informed choice are needed.

Implications for practitioners: Accommodating to parents' treatment preferences may be a good strategy for increasing engagement in children's mental health service particularly when viable equipoise options exist.

Implications for policymakers: Parents' participation in the delivery and design of children's mental health services (e.g., maximizing parents' choice) probably should be recommended as a matter of public policy.

INTRODUCTION

Low participant engagement represents a key barrier to the implementation and uptake of evidence-based prevention and treatment interventions in the community [1]. Addressing participant preferences in services may improve enrollment, engagement, and outcomes [2, 3]. Indeed, increasing focus has been paid to findings suggesting that the 'one size fits all' approach of most mental health interventions fails to meet the needs of many patients [4].

Research identifying tailoring variables–typically, moderators of intervention effectiveness–is used as the foundation for testing *personalized* approaches to intervention. Personalized (also known as adaptive) interventions use tailoring variables to determine what modalities, dosages, or sequences of interventions a participant is offered. While research on personalization has increased in recent years [5–7], much of this empirical literature focuses on titrating intervention *dosage* by participant need. Relatively less attention has been paid to participant preferences for intervention components or *modalities*, yet addressing preferences may remove a crucial barrier to poor mental health treatment outcomes: low participation rates.

This pilot study provides a rationale for research on a doubly randomized preference trial for personalization of interventions. Once identified, variables that predict families' engagement in interventions can be used to modify interventions (e.g., by providing guided decision-making, and/or preference models that fit family contexts). These data, in turn, enable program developers to develop tools for patients to make informed choices about effective and desired interventions (i.e., decision-aids). For instance, preferences and treatment engagement may be associated with participants' specific knowledge, beliefs, and opinions about various treatment options. Understanding that information in plain (non-technical) language with the help of a decision aid pamphlet, video, game, or other communication medium can assist parents to make effective decisions for choosing the treatment that is

appropriate for their children. For example, a decision aid might simply lay out treatment options and inform patients which types of patients tend to prefer which options, or it might take patients through an algorithm which assesses patients cognitions, beliefs, and opinions, and then make automated recommendations based upon the data provided by the patient ("your profile suggests that you might prefer x"). Decision aids have been tested with good success in the oncology field [8], but are relatively new to mental health. This research exemplifies a translational perspective such as the five-stage typology highlighted in this issue [9].

Based on this typology, our present work with personalized preference trials would illustrate research at stages 1 and 2. The identification of potential tailoring variables derived from theory would address etiological mechanisms underlying conduct disorder and implementation characteristics, which constitutes research at stage 1. This might involve an empirical test of the relationships of selected variables with various intervention modalities. At stage 2, intervention trials comparing interventions assigned randomly or by participant choice, would be conducted, and the effects of each would be examined in terms of rates of participation and health outcomes.

Attending to participant preferences

User participation in the delivery and design of health and mental health services (e.g., maximizing patient choice) is, increasingly, recommended as a matter of public policy [10–12]. For interventions involving children, responding to parent preferences in treatment planning decisions not only empowers parents to determine their children's care and address logistic barriers associated with engagement, but also provides families with preferred services thought to lead to improved intervention outcomes [13, 14]. Increasing parent autonomy in decisions about their children's health care needs should enhance parents' engagement in services that are consistent with their preferences. Nevertheless, no empirical literature has examined whether parents' preferences for children's mental health services are actually associated with their participation in community mental health treatment.

Experimental designs for examining preference

In the current study, preference refers to treatment modalities that patients favor or desire [15]. A variety of experimental designs have been utilized to examine participant preferences for interventions: traditional randomized controlled trials (RCTs), partially randomized preference trials (PRPTs) [16]; and doubly randomized preference trials (DRPTs) [17, 18], also known as parallel hybrid study designs [19]. In traditional RCTs, participants are asked to indicate their preferences before they are randomized to a treatment. Randomization occurs regardless of preference: participants may or may not be randomized to a treatment they had previously expressed a preference for. In the PRPT, participants with strong preferences are offered their treatment of choice, while those who agree with randomization are randomized as in any RCT. In the DRPT, participants are randomized into a choice, or no-choice condition. Respondents in the choice condition select their preferred option; those in the no-choice condition are randomized.

In traditional RCTs, some participants happen to receive a treatment they prefer and others do not. This design fails to consider that participants may drop out if they have strong preferences, which lead to the consequence that only participants with weak preferences (i.e., those for whom receiving a non-preferred treatment is acceptable) remain in the study. Moreover, the fact that participants are not randomized into a choice condition weakens internal validity [20].

Although PRPTs are advantageous in including participants with strong preferences, the internal validity and the reliability of the treatment effects from PRPT are compromised [21]. For example, if one treatment modality is strongly favored by participants, few will fall into the randomization condition. As a result, few participants receive a non-preferred treatment. Moreover, for individuals who do not indicate preferences, poor treatment outcomes may be ascribed to their lack of motivation for change [22].

DRPTs have several strengths: they increase the external validity of randomized studies by controlling for setting, participants, and cohort effects, but also enable researchers to examine whether providing choices to patients has an impact on their engagement and outcomes, because patients are randomized into a choice condition (and actually receive the treatment they choose), or a no-choice condition (where they are randomized to one of the treatments without being given a choice). The two-stage design (randomization to choice/no-choice, followed by randomization within the no-choice condition) is the only design that can provide unbiased estimates of selection effects (i.e., mean difference in outcomes between the choice and random arms (possibly specific to treatments); and preference effects (the conditional benefit that an individual participant experiences from receiving the preferred vs the non-preferred treatment), as well as outcomes (i.e., the effects of treatment) [23].

Evidence suggests that the research design in a preference study does appear to matter for the findings: a meta-analysis conducted by Swift, Callahan, and Vollmer indicated that research design (i.e., *how* participants are given choices) significantly moderated the effect of choice status on treatment outcomes [24]. The largest outcome differences between choice and no-choice conditions were found in studies randomizing patients to a treatment, while the smallest outcome differences were found in PRPTs; differences in DRPT studies were in-between.

Preferences and treatment engagement

Participants who receive their preferred treatment may be more likely to be engaged in and adhere to

the treatment [25, 26], thereby increasing the likelihood of positive outcomes [20]. A recent meta-analysis found that participants who were matched to their preferred treatment were half as likely to drop out of treatment compared to those participants who were not matched to their preferred treatment [20]. Using a traditional RCT design, Kwan, Dimidjian, and Rizvi found that participants who were randomized to their preferred treatment had significantly lower chances of dropping out of treatment, greater session attendance, and higher patient–therapist alliance compared to those randomized to their non-preferred treatment [27]. Furthermore, the effect of preference on session attendance did not differ across treatment modalities.

Examining preferences in community mental health settings

Few of the studies discussed above were conducted in routine care settings, yet settings such as community mental health clinics should be studied in order to extend the generalizability of research findings regarding preference. The differences in choices made in real-world care settings and those made in the context of highly controlled research trials are one of the challenges to be addressed by translational prevention research; yielding preference estimates from these settings is crucial to further research. Community mental health clinicians typically use their clinical judgment in order to advise patients into treatment, or more commonly, participants receive whatever services are available or have the shortest waitlist. Few clinics offer families a choice of treatment, and less is known about the patterns and dimensions of families' treatment preferences (e.g., parent training vs child therapy, group vs individual intervention). Indeed, our community partners reported being more systematic about matching families with treatment as a key reason for collaborating on this study.

Purpose of the current study

Prior data indicate a relationship between choice status (i.e., the ability to select a preferred treatment among several) and treatment engagement. However, to our knowledge, no prior studies have examined associations of *parents'* preferences for their child's treatment with retention in that treatment. Parents are key to the success of interventions for children's mental health. For treatment of child externalizing disorders, parenting is the treatment target [28]. Moreover, externalizing problems are the most common source of mental health referrals in pediatric settings [29]. Clearly, more research is needed to better understand how addressing parents' choices are associated with retention in children's mental health treatment. In addition, some uncertainty surrounds prior findings due to diverse study designs–few studies have used the doubly randomized preference trial design, the strongest empirical tool for examining preference.

The purpose of this pilot study, then, is to examine the feasibility of conducting a DRPT study in a community setting and to yield estimates of preference rates for the different intervention formats. An additional exploratory aim was to further understand associations between parental choice status (choice/no-choice), intervention modalities, and treatment compliance; i.e., how is choice and treatment modality associated with families' dropout?

METHOD

Research design

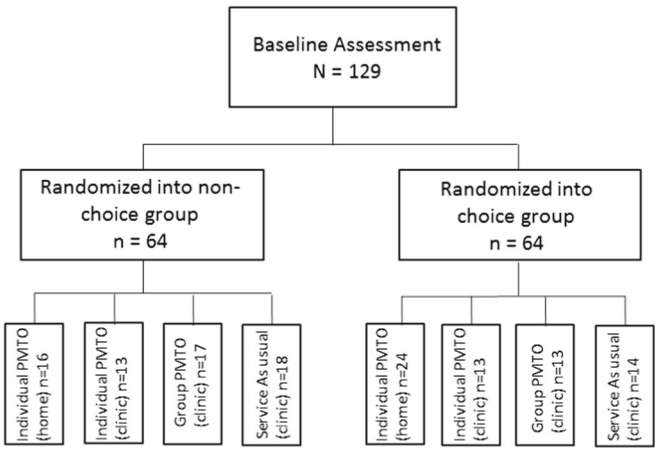
This pilot study adopted a doubly randomized preference trial (DRPT) design. Families presenting to outpatient clinics for child behavior problems were randomized to one of two conditions: no-choice, or choice. Parents randomized to the no-choice condition were further randomized into one of four treatment modalities: (i) home-based Parent Management-Training Oregon model (PMTO) treatment, (ii) individual, clinic-based PMTO, (iii) multi-family group (clinic-based) PMTO, or (iv) supportive child or family psychotherapy ('services-as-usual'). Parents randomized to the choice condition were offered their preferred treatment modality from the four options. Most families who either preferred or were randomized to the service-as-usual group received services immediately; for those assigned to other conditions, if no PMTO was available, the average wait time was 3.2 months. The average wait time was similar between modalities. Forty three families in the choice condition had to wait to receive treatment. That Fig. 1 is a consort diagram indicating flow of families to study conditions. In the larger study from which this dataset is drawn, data were gathered from parents and teachers at baseline, post-intervention, and 6 months post-intervention, and treatment participation data were gathered from clinics. The current study utilizes only baseline and treatment retention data.

Procedures

This ongoing study is being conducted in collaboration with three mental health clinics in Oakland County and the city of Detroit, Michigan. Families with a target child ages 4–12 years, presenting to three community mental health clinics for their child's behavior problems, were invited to participate in the study. Families were excluded from the study if they had previously received treatment for child behavior problems, if parents had psychosis or did not have custody of the target child, or if they were unwilling to be randomized. A research coordinator contacted those who agreed to participate, informing families that their participation in the study was voluntary, and their children's treatment at the clinic would not be influenced by study participation. Parents were given questionnaires to complete and mail back; families were compensated for each assessment.

Measures

Demographics–Parents reported their own, and their child's gender, date of birth, education, race, and the annual household income and household composition.



Note. One family's modality information in the choice group was missing.

Fig 1 | Consort diagram indicating flow of families to groups. One family's modality information in the choice group was missing

Family participation in treatment–Family's treatment participation was measured in two ways: (1) a dichotomous measure determining whether families completed or dropped out of treatment, as reported by clinics. Families were considered to have completed treatment if they attended at least 12 sessions of services-as-usual, or if they completed at least the encouragement and limit setting (i.e., core) components of PMTO; and (2) a continuous measure of the number of intervention sessions each family completed.

Treatment modalities–PMTO is a well-validated intervention that teaches parents to monitor and modify children's behaviors through strategies based on social interaction learning theory [30]. PMTO teaches five positive parenting skills which are spread out among the sessions: teaching through encouragement, limit setting, monitoring, problem solving, and positive involvement. Each of the clinics participating in this study had facilitators who were trained in PMTO and participated in the required fidelity supervision. PMTO has been implemented throughout the state of Michigan and requires rigorous, extensive training and certification to practice. All clinicians in the current study were certified in PMTO and were mental health (psychology, social work or marriage, and family therapy) providers at the clinics. Individual clinic- or home-based PMTO sessions last for 45–60 min, and group sessions last for 90 min; both are provided weekly. Individual treatment lasts 3–9 months; group lasts about 4 months (14 sessions), and 6–10 parents attend each group.

Families assigned to, or selecting services-as-usual were treated by therapists trained in modalities other than PMTO. Treatment typically was non-directive child psychotherapy (e.g., play therapy) or family therapy. Sessions lasted 45–60 min and continued until discharge.

Participants

At baseline, 191 eligible families were referred by clinics to the study. In total 134 families participated in the study, with approximately a 70 % response rate, but five families were found to have previously received services from the clinic and were excluded from analyses, leaving a final sample of 129 families. Sample household yearly income ranged from zero to $130,000 per year with a median of $12,662. Three-quarters of parents reported annual household incomes below $20,000. Parents were 21 to 63 years old (M=32.78), and reported their race as 61.5 % African American, 1.0 % Hispanic, 29.8 % White American, 1.0 % Native American, 5.8 % multiracial, and 1.0 % other races. Almost 36.5 % parents reported no college education and 50 % parents had some college education; 13.5 % parents had bachelor or masters degrees. Just 15.4 % of children were reported to be living with two biological or adoptive parents. Children's mean age was 7.59 years, with 65.1 % boys and 34.9 % girls, which is consistent with gender breakdowns for child mental health referrals [31].

RESULTS

Families were retained in the study regardless of participation in treatment; thus data are reported for the entire study sample of 129 families. Attrition from treatment was significant: almost two-thirds of the sample (65.9 %) either did not attend treatment at all (25.6 %), or left prior to discharge (i.e. no showed at least twice, or dropped out; 40.3 %). Just 34.1 % of the sample completed treatment. Median number of PMTO sessions and service-as-usual sessions across the entire sample was 3 (M=6.95, mode=0, range=0–40) and 11.50 (M=13.91, mode=0, range=0–52) respectively. Evidence-based treatments like PMTO typically are shorter (i.e., fewer sessions to completion) than supportive psychotherapy. Therefore, the number of PMTO sessions and service-as-usual sessions to completion of treatment were not identical.

The breakdown of preference by treatment modality, and average number of sessions completed by

Table 1 | Frequencies of participants who completed treatment and the median number of sessions attended by treatment modalities for choice and no-choice groups (N=129)

Modality/variable	Choice n=65	No-choice n=64
Group-based PMTO	n=13	n=17
No. completed	4	0
Median no. sessions (range)	2.5 (0–15)	0 (0–3)
Home-based PMTO	n=24	n=16
No. completed	11	7
Median no. sessions (range)	8.5 (0–40)	4 (0–20)
Clinic-based PMTO	n=13	n=13
No. completed	3	4
Median no. sessions (range)	3 (0–22)	1 (0–35)
Child therapy (SAU)	n=14	n=18
No. completed	9	6
Median no. sessions (range)	18 (0–52)	7.5 (0–24)

One family's modality information in the choice group was missing

families in each modality can be found in Table 1. Within the choice condition, the most preferred modality was home-based PMTO (40.7 % of the choice group selected this option). Table 2 provides a breakdown of treatment modality by demographics for those assigned to the choice condition. Hierarchical logistic regression was employed to explore whether demographic variables, clinic/site, modality, and choice status were associated with families' dropping out of treatment. Missing data were observed for 30 of the 129 cases (23.3 %); n=99 were included in the analysis.[1] A rule of thumb for determining minimum sample size for regression analysis is that the model includes at least ten participants for each predictor [32]. In our analysis we included eight variables estimating ten parameters with a total sample size of n=99. In the first block, demographic variables (child gender, parent age, race, and family income) and clinic did not significantly predict treatment dropout (χ^2=5.74, df=6, p=0.45). After adding service modality, the second block was statistically significant (χ^2=16.94, df=3, p=0.001). The coefficient on the modality variable had a Wald statistic equal to 13.29 which was significant at the 0.01 level (df=3). The Negalkerke R square of the model increased from 0.08 to 0.28. Parents in the PMTO group and individual clinic modalities were more likely to drop out of treatment than parents in services-as-usual (p=0.001; p=0.008, respectively). Entering choice status, the third block was statistically significant (χ^2=5.58, df=1, p=0.018), and the overall model was significant (p<0.01; see Table 3). Regarding model fit, the Negalkerke R square increased to 0.33 (the final model explained 33 % of the variance in dropout), and the Hosmer and Lemeshow test was not significant, suggesting good fit with the data [33]. The interaction between choice status and service modality was not significant, thus the interaction term was not included in the model. Families randomized to the no-choice condition were more likely to drop out of treatment than families in the choice group (p=0.022), regardless of service modality.

[1] The missing data (23 %) were due to missing values in demographics (family income, parent age, and ethnicity) from families who did not complete the demographics form. Therefore, methods to impute missing values were not used in the study.

DISCUSSION

These data indicate the feasibility–and the challenges–of using doubly randomized preference trials in order to understand parent preferences for child treatment for conduct problems. The study demonstrated that despite the significant barriers to care that exist in community mental health clinics (low dosage, high dropout, high-risk family contexts), it is feasible to use a DRPT to provide a preliminary window into the understanding of parents' preferences for their children's treatment. It is estimated that just 25 % of the children who need services actually have contact with the mental health system [34]. Populations at-risk were families living in poverty or the inner-city and single parent households, well-represented in the current study, are at higher risk for mental health problems and face more barriers to participating in mental health services [35, 36]. Moreover, as our data demonstrate, even presenting to a mental health clinic does not guarantee participation: almost two thirds of families in the current study either did not attend at all, or dropped out of treatment prior to completion. The high attrition was primarily due to 'no shows' (i.e., families failing to show up for treatment, and/or not responding to clinic calls) and this issue is exacerbated by stringent policies of managed care that do not reimburse providers for missed sessions. These policies and the fiscal realities of managed care place strong pressure on clinics to quickly move off their rolls patients who do not reliably show up. In most of the participating clinics, three missed sessions resulted in a family being discharged. Unfortunately, although there are empirical data to show that small and

Table 2 | Descriptives of treatment modality by demographics in the choice group (N=129)

Variable	Group-based PMTO	Home-based PMTO	Clinic-based PMTO	Child therapy (SAU)
Parent race (African American %)	53.3 %	35.0 %	46.2 %	68.8 %
Parent age (M/SD)	33.26 (7.87)	33.03 (8.19)	32.82 (7.42)	32 (9.38)
Child age (M/SD)	7.22 (2.07)	7.75 (1.98)	7.55 (2.72)	7.77 (1.99)
Child gender (male %)	63.30 %	67.50 %	53.80 %	71.90 %
Family income (median $)	11,500	16,200	10,824	11,964

inexpensive strategies (e.g., a phone call the day before the session, troubleshooting logistical barriers) [37] can significantly increase show rates, most clinics do not use such strategies to improve retention. Our findings resonate with the literature showing average length of treatment in community mental health clinics is just three to four sessions [38]. Families of children with conduct problems are at increased risk for dropping out of treatment [39], as are low-income families who may be uninsured or underinsured. The paradox here is that the low rates of participant engagement provide a compelling argument for research examining preferences–yet conducting such research in community settings is challenging for these very reasons.

Despite the very high attrition, this study reveals some promising trends with regard to preference. First, even with a small, underpowered sample, our data suggest that providing families with choices of intervention modality is associated with a lower likelihood of dropping out of treatment. Accommodating to parents' treatment preferences may be promising for increasing families' engagement in services to benefit children's mental health, particularly when viable equipoise options exist. For example, when both group and individual, home-based and clinic-based services are available, offering families the choice between these–and providing decision aids that include the parameters for each one (e.g., how soon the family can be seen, session length, treatment length, etc.) may increase participation in services. An effective decision aid might, for example, gather data via targeted questions for parents that enable calculation of an algorithm to determine–for example–parents' beliefs about interventions, the child's behavior, and their motivation to participate in treatment, as well as parents' preferences for specific treatment features [40] to ensure that families are helped to select the treatments that match their profiles (beliefs, motivational cognitions, etc.).

In order to match family choices, however, clinics must have the resources to offer not simply one, but multiple formats and/or types of evidence-based practices. Evidence-based practices are slowly being implemented on a wide scale in community settings, but relatively few clinics offer multiple options. In the current study, we were able to capitalize upon a natural laboratory: Michigan is one of the few states with widespread implementation of PMTO, and the only one to offer multiple formats of the intervention.

Within the choice group, the most popular treatment modality was home-based PMTO. Home-based treatment is convenient and saves families' time and money. Demographics (child and parent age, parent race, child gender, family income) were not associated with treatment selection within the choice group. However, the sample was highly skewed towards poverty. It is unknown whether home-based treatment would be this popular among a higher-income population or a population with a broader range of income.

Regardless of choice assignment/status, those in multi-family groups and clinic-based individual

Table 3 | Summary of logistic regression analysis predicting dropout: full model (*N*=99)

Variable	*B*	SE	Wald	OR	95 % CI
Clinic			4.77		
Clinic 1 (ES)	−1.91	0.88	4.77*	0.15	0.03–0.82
Clinic 2 (S)	−1.37	0.81	2.84	0.26	0.05–1.25
Clinic 3 (CC)[a]	–	–	–	–	–
Child gender (boys)	0.33	0.53	0.39	0.72	0.25–2.04
Parent race (African American)	0.64	0.57	1.26	0.53	0.17–1.61
Parent age	−0.02	0.03	0.68	0.98	0.93–1.04
Family income	−1.00	0.60	2.81	0.37	0.11–1.19
No-choice	1.14	0.50	5.22*	3.12	1.18–8.29
Modality			13.51**		
PMTO group	3.08	0.92	11.32***	21.75	3.62–130.85
PMTO clinic	2.36	0.83	7.93**	10.54	2.05–54.22
PMTO home	1.55	0.81	3.64	4.71	0.96–23.18
Child therapy[a]	–	–	–	–	–

OR odds ratio, *CI* confidence interval

*p<0.05; **p<0.01; ***p<0.001

[a] Clinic 3 (CC) and child therapy are the reference groups in each category

PMTO were more likely to *drop out* of treatment than families in home-based treatment or supportive psychotherapy. These data are preliminary and must be replicated with a larger sample. However, they are consistent with other research showing improved attendance in home-based vs. office-based therapy [41]. Interestingly, assignment to or selection of the 'services-as-usual' modality was not associated with higher dropout, even though that modality, too, was clinic-based. Evidence-based behavioral interventions tend to be much harder work than supportive psychotherapy, due to the focus on behavioral rehearsal. Moreover, for parents who view their child as the source of difficulties (rather than their own parenting behavior), child psychotherapy may be more palatable than parent training despite its unproven effectiveness in improving child behavior problems.

Further research is needed to examine whether factors not examined here (in particular, for example, expectations about therapy, attitudes towards child problems, and parental locus of control) may distinguish families selecting one format or type of therapy over another. Examining these data with a larger sample would allow for the analysis of interaction effects—which could address the question of whether families may select preferred options that match their attitudes and expectations. Our pilot data can guide future research in preferences by establishing estimates of cell sizes in the preference group (i.e., the approximate balance of preference for each treatment). That is, our data indicated that while approximately 40 % of families in the choice condition preferred home-based services, other options were equally represented among the remaining 60 % of families (20 % in each of the remaining three groups). It is important to note, however, that in this study, choices were offered without the help of a decision aid. Providing a decision aid may result in different proportions of preferred treatments. For example, it may be that when informed about the lack of evidence for supportive psychotherapy for conduct problems, families would be more likely to select among the other, evidence-based options. (Of course, this is related to supply: clinics, in some cases, had fewer therapists to deliver PMTO, resulting in a waitlist for PMTO but not for supportive psychotherapy).

A key limitation of this pilot study is the small sample size given the multiple cells. This may explain the relatively large odd ratios and confidence intervals observed in our results. Replication of this study using a larger sample is warranted to verify the findings. Moreover, we assumed equipoise (treatment equivalence), but–though both individual and group-based PMTO have been shown to be effective [28]–there are not yet any comparative effectiveness data. Such a study is underway [42]. Child outcomes are not yet available in this study, but other research has shown associations between treatment engagement and better outcomes [1, 43].

In conclusion, our results suggest that, despite being a complex and sometimes challenging undertaking, translational prevention science can be conducted in the context of community mental health. Offering patient choices may be both feasible and beneficial for increasing family engagement in services for children's mental health problems. These data pave the way for subsequent personalization studies aimed at tailoring treatment options to family preferences with the help of decision aids to promote informed choice [44].

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Compliance with ethical standards

Conflict of interest: Abigail Gewirtz is a consultant to Implementation Sciences International, which provides training in the PMTO model.

Adherence to ethical principles: This study was approved by the University of Minnesota IRB and the Human Subjects Research Protection Board of

the State of Michigan's Department of Community Health. Informed consent was obtained from all participants for being included in the study.

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