

Does A Parent Peer Support Program Help Parents of Children Who Need Mental Health Services Support Their Child's Care?—The Family VOICE Study

Gloria M. Reeves, MD¹; Heidi J. Wehring, PharmD²; Kristin Bussell, MS¹; Deborah R. Medoff, PhD⁵;
Thomas Tsuji^{1,4}; Raymond C. Love, PharmD^{2,3}; Jason Schiffman, PhD⁴

Affiliations:

¹Child and Adolescent Psychiatry Division, Department of Psychiatry, University of Maryland School of Medicine, Baltimore, Maryland

²Maryland Psychiatric Research Center, University of Maryland School of Medicine, Baltimore, Maryland,
³University of Maryland, School of Pharmacy, Baltimore, Maryland

⁴Department of Psychology, University of Maryland, Baltimore County, Baltimore, Maryland

⁵Division of Services Research, Department of Psychiatry, University of Maryland School of Medicine, Baltimore, Maryland

Original Project Title: The Family VOICE Study: A Randomized Trial of Family Navigator Services Versus Usual Care for Young Children Treated with Antipsychotic Medication

PCORI ID: 997

HSRProj ID: 20143360

ClinicalTrials.gov ID: NCT01804582

To cite this document, please use: Reeves G, Wehring H, Bussell K, et al. 2019. *Does A Parent Peer Support Program Help Parents of Children Who Need Mental Health Services Support Their Child's Care?—The Family VOICE Study* Washington, DC: Patient-Centered Outcomes Research Institute (PCORI). <https://doi.org/10.25302/3.2019.CER.997>

Table of Contents

ABSTRACT	3
BACKGROUND	5
CONSUMER AND STAKEHOLDER PARTICIPATION IN THE DESIGN AND CONDUCT OF RESEARCH AND DISSEMINATION OF FINDINGS	7
METHODS	9
Study design and hypotheses	9
Participants	10
Study setting	10
Randomization	10
Interventions and follow-up	11
Safety/ethical considerations	12
Study outcomes and data collection	13
Data collection and sources.....	15
Analytic and Statistical Approaches.....	15
Conduct of the study	17
RESULTS	17
Participants	17
Outcomes and Estimation Results	22
Study Retention	26
Harms.....	27
DISCUSSION	27
Context for Study Results in context	27
Generalizability of study results	32
Sub-population considerations.....	33
Study limitations	33
Future studies	33
CONCLUSION	34
REFERENCES	36
APPENDIX.....	38

Abstract

Background: Family navigators (FNs), lay workers who utilize their *lived experience* of raising a child with special mental health needs, provide emotional and resource/referral support to other parents. Prior work suggests that parents who have a child with mental illness appear to value peer support services, but there is limited evidence about these types of interventions from large, rigorous trials. In this study, we assessed the impact of a family navigator program developed to increase child behavioral therapy service utilization on parent and child outcomes.

Objectives: The Family Value of Information, Community Support, and Experience study is an open-label, randomized controlled trial of FN services versus usual care for Medicaid-insured youth approved for antipsychotic medication treatment. The primary outcomes are parent-reported (1) empowerment, (2) social support, and (3) satisfaction with child mental health treatment, and the secondary outcomes are (1) parent report of child global behavioral functioning, (2) child utilization of behavioral therapy services, and (3) antipsychotic medication dose changes over the course of 90 days.

Methods: We randomized parents of Medicaid-insured youth <16 years old approved for antipsychotic medication treatment through a prior authorization program to family navigator services versus usual care. We provided family navigator services through flexible, telephone-only contact spanning 90 days.

Services included resource/referral information and support, and parents could also request assistance for any household family priorities (eg, assistance with housing). A research assistant, blinded to the study intervention, measured parent and child outcomes at baseline and at 90 days. We measured therapy service claims during the 90 days of prestudy and poststudy enrollment.

Results: The study enrolled 350 parents and 70% completed the 90-day follow-up. We assessed the primary outcome for 245 participants (128 FN, 117 treatment as usual). There were no

significant differences between the 2 groups in terms of changes in the 3 coprimary outcomes: (1) Family Empowerment Scale (FN pre mean [M] = 3.75, SD = 0.52, post M = 3.81, SD = 0.55; Treatment as Usual (TAU) pre M = 3.86, SD = 0.51, post M = 4.02, SD = 0.51; $p = 0.15$); (2) Social Support Scale (FN pre M = 2.58, SD = 1.10, post M = 2.48, SD = 1.10; TAU pre M = 2.46, SD = 1.07, post M = 2.45, SD = 1.06; $p = 0.53$); or (3) Youth Services Treatment Satisfaction Survey scores (FN pre M = 3.75, SD = 0.64, post M = 3.81, SD = 0.61; TAU pre M = 3.90, SD = 0.63, post M = 3.95, SD = 0.60; $p = 0.80$) from baseline to 90 days. We observed no significant differences between groups in terms of the secondary outcomes psychosocial services utilization (Wald χ^2 [1, N = 696] = 1.60; $p = 0.21$) or improvement in child behavioral functioning on the Brief Problem Monitor Scale (FN pre M = 69.51, SD = 5.69, post M = 67.63, SD = 6.03; TAU pre M = 69.19, SD = 5.62, post M = 66.73, SD = 6.83; $p = 0.33$) during the intervention. Of those who remained on the same antipsychotic medication (FN 110 out of 175; TAU 119 out of 173), 23.6% of youth whose parents received family navigator services had an increase in antipsychotic medication dose at 90 days compared with 41.2% of youth whose parents received usual care, marking a statistically significant difference between the groups (χ^2 [1, N = 229] = 7.99; $p = 0.005$).

Conclusions: Short-term family navigator services did not result in greater improvement in therapy service utilization or parent empowerment, social support, or satisfaction with child mental health services compared with usual care. Youth whose parents received family navigator services were less likely to have an antipsychotic dose increase compared with those who received usual care.

Limitations: Family navigator services did not provide any direct intervention for the child and we completed no long-term (beyond 90 days) follow-up assessments. As this study failed to detect benefits of short-term, phone-delivered family navigation, future work in this area may consider offering an intervention with more intensive and/or longer peer support services.

Background

Antipsychotic medications are prescribed to children and adolescents primarily for the management of nonpsychotic conditions. The most common diagnosis among antipsychotic treated youth is attention deficit hyperactivity disorder and target symptoms are often behavioral (eg, severe aggression).¹ These medications may help reduce safety concerns (eg, violence risk) and the need for crisis services (eg, inpatient care) but, unfortunately, this treatment is also associated with significant side effects. The newer antipsychotic medications, referred to as second-generation antipsychotic (SGA) medications, can cause metabolic-/obesity-related side effects including weight gain; increased blood sugar; abnormal cholesterol; and, rarely, new onset diabetes.²

Since SGA medications are largely used to target serious behavioral symptoms, practice guidelines emphasize the importance of concurrent treatment with psychosocial services (eg, behavioral therapy) to minimize the dose and duration of pharmacotherapy required. However, parents of youth with serious mental illness face significant treatment decision-making challenges and complex barriers to seeking comprehensive care that includes behavior therapy. In Koren et al⁸ Medicaid state program study, only 48% of Medicaid-insured youth had claims for psychosocial services during the 3 months prior to initiating antipsychotic treatment.³ Parents may have trouble identifying treatment programs that are appropriate for their child's unique needs (eg, behavioral services for youth who are nonverbal or have intellectual disability). In rural/underserved areas, there may also be long wait lists and transportation challenges associated with available services. Primary care providers may be accessible for psychiatric medication treatment but they often do not provide therapy services. Parents may feel uncomfortable seeking psychosocial services in specialty settings because of stigma about mental health treatment, so even if services are available they may not be utilized. There are also practical challenges. Psychosocial service appointments are usually longer and more frequent than medication appointments, so they may cause problems such as missed time from work, childcare issues, and conflict with other medical appointments. In addition to these logistical issues, underutilization of psychosocial services may be related to parents

experiencing emotional issues. Parents may feel overwhelmed or anxious/depressed caring for their child with significant mental health concerns. This common emotional response can impact parents' abilities to seek out services and make decisions about treatment options.

Most states have developed or are planning medication oversight programs to improve safe and appropriate antipsychotic treatment of children and adolescents. Approximately 31 states have an antipsychotic medication prior authorization program for Medicaid-insured youth.⁴ This type of health care system usually involves contact between a prescriber and a clinical or administrative reviewer to ensure there is an appropriate indication (eg, review diagnosis and target symptoms) and a safe plan (eg, review dosing and drug interactions) for medication treatment. This type of program generally does not involve routine contact with consumers (ie, patients or their parents). However, medication prior authorization programs do identify antipsychotic-treated youth across treatment programs so there is an opportunity to identify a statewide population of parents who are raising youth with serious and complex mental health illnesses. Parents are key stakeholders for improving effective, evidence-based treatment of children. They are the most familiar with their child's needs and are strong advocates for their child's care. However, they may lack information on resources and clinical standards to support their child's recovery. Strategies to directly engage and empower parents who have youth with serious illness are needed to support them in identifying optimal community services and addressing emotional (eg, parents feeling overwhelmed) and logistical (eg, transportation) barriers to utilizing them.

Peer support services to address unmet child/family needs in health care systems have several benefits. Parents view peers as highly credible sources of information, and peer support providers can use their personal experience to address practical concerns and identify community resources. A lay provider workforce can also provide resources that are often more flexible than traditional clinical services (eg, greater ad hoc and after-hours availability) without taxing an already overburdened child health system. The novel linkage of a parent peer support service with a medication prior authorization program has the added benefit of providing

universal outreach to families dealing with complex child health issues so it eliminates parent barriers to seeking out this type of resource (eg, parents may be too overwhelmed to look for support and may not know what support will be tailored to their family's needs). An antipsychotic medication program identifies a statewide population of youth with serious mental illness who have complex mental health service needs. Peer support strategies that offer emotional and resource support may improve child/family outcomes by empowering parents to seek out services they value, improving social support to overcome barriers to services and optimizing treatment satisfaction. Increased psychosocial service utilization may also have secondary effects on child medical treatment (eg, less need for increases in medication dosage to stabilize the child's condition if parents are able to learn effective behavioral strategies).

Consumer and Stakeholder Participation in the Design and Conduct of Research and Dissemination of Findings

We designed the Family Value of Information, Community Support, and Experience (VOICE) study in collaboration with (1) parent consumers, (2) community providers, and (3) child-serving agency leadership with members of the academic research team, as detailed in Reeves et al.⁵ The executive director of the Maryland Coalition Family Leadership Institute, the director of the Child Behavioral Health Administration, and 2 medical directors of large child mental health treatment programs, which have services throughout the state, met with the Psychopharmacology Institute (PI) and researchers to design the study. The study design was also presented and modified during advisory board meetings that also included 4 parent consumer representatives (from rural and urban settings) and community providers. We sought feedback on study design from the Maryland Coalition Family Leadership Institute attendees (32 parent consumers) as well as from the University of Maryland, Baltimore (UMB) Psychopharmacology Institute experts (leaders in community care, child serving agencies, academic research, and consumer advocacy). The PI received study updates twice a year. We achieved balance of stakeholder perspective at our advisory board meetings by providing structuring meetings so each stakeholder group was invited to present to the group on its

experiences and perspectives on gaps in services and the executive director of the Maryland Coalition and the PI cofacilitated the discussion groups. Advisory board members and family navigators (FNs) were corecruited by the executive director and the PI. The Maryland Coalition had a subcontract budget, so the FNs would be hired as employees of this organization and their cosupervision would be provided the PI and executive director. The 3 family navigators (parent consumers) who were hired implemented the study intervention.

The academic research team worked very closely with the family navigators during the course of the study. The initial family navigator training was 1 week. There were 2 ongoing weekly meetings to provide case supervision and training. Family navigators copresented with the PI at local, state, and national conferences on the study design. For example, all 3 family navigators copresented with 3 academic researcher team members at a workshop at a national Federation of Families conference. This workshop described the family navigator training protocol and provided specific training on strategies to employ trauma-informed family engagement as part of peer support interactions. Family navigators also cotaught several classes with the PI on principles of family-centered care for graduate trainees at the University of Maryland School of Medicine and School of Pharmacy. Finally, family navigators attended annual child mental health awareness activities, including legislative advocacy events to provide consumer perspectives on child mental health services.

Of note, family navigators were also involved in communication with PCORI. They volunteered to provide feedback on their experience participating in research, they attended progress calls with PCORI to present their perspective on the study, and one of our family navigators presented at the inaugural PCORI conference.

The aims and design of the study reflect the input we received from consumers/advocates during design discussion that (1) parent feedback is often overlooked in child mental health research outcomes—focus tends to be on child symptoms outcomes and clinician ratings (“*Why don’t researchers ask the parents how they are doing?*”); (2) parents may not seek out peer

support services when they need it the most, especially when they are overwhelmed with crisis concerns (“*We wish we could help more parents but a lot of them are too depressed or stressed out to seek help*”); and (3) parents value ad hoc and telephone availability because their schedule may be unpredictable when their child is not well (“*If you get that dreaded phone call from the school that your child is having a meltdown, you have to drop everything and go.*”). Peer support services appear to be highly valued by consumers but they are often implemented in community health systems without rigorous assessment in intervention studies. Data are needed to clarify the health impact of peer services and to improve peer service integration in health systems. There is also limited research to assess the impact of parent peer services on both child and parent outcomes.

Methods

Study design and hypotheses: The Family VOICE study is an open-label, randomized controlled trial of family navigator services versus usual care for Medicaid-insured youth (<16 years old) approved for antipsychotic medication treatment through a prior authorization program.

Our primary aim focused on parent-reported, family-centered measures. We hypothesized that parents who received family navigator services would have greater improvement in the coprimary aims of parent (1) empowerment, (2) social support, and (3) satisfaction in child mental health treatment at 90 days compared with parents of youth who received usual care. Our secondary aims focused on child outcomes. We hypothesized that youth whose parents received family navigator services would be less likely to have an increase in antipsychotic medication dose and less likely to have an increase in number of total psychiatric medications prescribed over the course of 90 days compared with youth whose parents received usual care. We also hypothesized that youth of parents who received family navigator services would have more therapy claims services and greater improvement in measure of global behavioral functioning over the intervention period compared with youth whose parents received usual care.

Participants: We enrolled parents of Medicaid-insured youth <16 years old who had been approved for antipsychotic medication treatment. We identified eligible families through the medication prior authorization program. We excluded parent participants who do not have legal guardianship of their child (eg, foster parents) because we were seeking to engage individuals who have authority to consent for treatment. We attempted to contact 100% of potentially eligible participants. We sent a letter to all eligible parents and gave the option of responding by phone or response card. We informed parents that they would be contacted by phone if we did not receive a response or if their response indicated they were interested in obtaining more information. We informed parents that their study participation would not interfere with their ability to continue using their child's current services. We completed the informed consent discussion by phone and we mailed a copy of the consent form to the home after the parent provided verbal consent for study participation. We completed all baseline assessments by phone and we then randomized parents to either family navigator services or usual care. Parent compensation for study participation was for baseline and follow-up assessments only (\$20 gift card or check mailed to the home after each of the assessment visits, for a possible total of \$40). Parents who were assigned family navigator services determined the frequency of the services during the 90-day intervention based on their interest and needs. We invited all parents to participate in the 90-day follow-up assessment regardless of whether they used the family navigator services during the intervention period. We tracked the number of family navigator contacts for each participant in the intervention arm.

Study setting: The research coordinators/assistants made initial recruitment calls in a private research office. Research assistants who were not involved in recruitment and were blinded to the assigned treatment made the 90-day follow-up calls. Family navigators primarily worked from their home office. They had a dedicated cell phone, encrypted, and password-protected laptop computer, and a locked file cabinet. Progress notes and call logs were submitted using secure electronic files, and the laptop computers were returned at the end of the study.

Randomization: We completed randomization using permuted blocks of random sizes to ensure equal numbers in the 2 study conditions. We randomly generated order of assignments

for each block using a computer program with a random number generator. The study statistician generated the allocation sequence and a research assistant who did not perform recruitment calls prepared randomization envelopes. Three study team members conducted the recruitment calls and baseline assessments. They assigned randomization groups based on the allocation concealment protocol after baseline assessments were completed.

Interventions and follow-up: We provided family navigator services for 90 days to assigned participants. The Family VOICE study developed a family navigator service for parents of antipsychotic-treated, Medicaid-insured youth in Maryland. Family navigators are parents with *lived experience* of raising a child with special mental health needs. The goal of this service was to provide parent peer support to improve psychosocial service utilization for antipsychotic-treated youth. We based the family navigator service implemented in this study on (1) a family navigator program developed by the Maryland Coalition of Families (Maryland Coalition; <http://www.mdcoalition.org>) and (2) the Parent Empowerment Program (PEP).⁶

The Maryland Coalition is a nonprofit family peer support and advocacy program. The Maryland Coalition offers a family navigator service by phone and in person to help parents with emotional support and referral and resource needs, as well as ongoing management of complex family needs. In this program, parents initiate contact with the Maryland Coalition for voluntary services. The program is not specific to antipsychotic-treated youth. Family navigators are located in regional offices throughout the state and they provide outreach on mental health concerns in addition to direct services to families.

PEP is a peer support program based on the Unified Theory of Behavior, which focuses on 2 main constructs required for action: (1) immediate determinants of behavior and (2) behavioral intention.⁷ Immediate determinants of behavior include factors such as knowledge and skills, salience, habits, and environmental constraints. Behavioral intention includes factors such as expectancies, attitudes, social norms, self-concept, emotions, and self-efficacy. According to the Unified Theory of Behavior, decisions to engage in behaviors are predicated on positive

valences related to intentional factors such as expecting a positive outcome or conforming to social norms. Behavioral intentions, however, can translate into action only if the foundations for behavior (immediate determinants such as the skills to perform the behavior) are in place.

These services were available only by telephone, with flexible scheduling (evenings, weekends), and ad hoc availability. We gave parents a consistent family navigator to work with during the intervention period. The initial contact focused on parent engagement and discussion of parent priorities/goals of how they might utilize the services. We gave parents a list of possible mental health resources, daily living/ancillary services, and parent support program resource information (outlined in Reeves et al)⁵ to stimulate discussion about priorities and goal setting. We asked all parent participants if they had internet access, since many programs had either online applications or websites to update on available services. If parents did not have internet access, information was provided on free or reduced home services for low-income families. Family navigator services could be used to address family/household needs rather than to focus only on the individual child. If the parent did not respond to the call from the family navigator, the assigned navigator made a weekly attempt to reach the parent. If the parent did contact the family navigator, the navigator offered to follow up with the parent weekly. However, the parent could decide on the frequency and duration of the contact, and no parent was discontinued from the intervention if he or she chose to not contact the family navigator. The family navigator did not provide any medical advice but did offer strategies on how to be an effective consumer of child mental health services (eg, organize and write down questions about medication or therapy options prior to the visit).

Participants who received usual care were not provided with any services from the study team during the 90-day intervention period. These parents all had access to medical care to support mental health referral/resource needs for their child since all were approved for antipsychotic medication.

Safety/ethical considerations: The PI and stakeholder team addressed safety/ethical

considerations with careful oversight. We provided all parent participants with the PI emergency contact cell phone number in their informed consent paperwork. A licensed clinician was always available for the family navigators to triage any urgent concerns, including issues that came up after hours and on weekends (eg, report of suspected child abuse). All family navigators participated in a 1-week training program prior to working with families. During the course of the study, the family navigators also attended weekly group supervision meetings by phone with clinician members of our team to discuss parent engagement challenges, review new community resources, and share successes/challenges with family navigation. All family navigators were trained in state-mandated child abuse reporting guidelines, and each case of suspected child abuse/neglect was required to be reviewed with the PI directly. Parent participants were encouraged to address any concerns about clinical services directly with their provider. We did not restrict access of parent participants to any peer support programs available in their community.

Study outcomes and data collection: Our primary outcomes (specific aim 1) were parent report measures of empowerment, social support, and satisfaction with child mental health treatment, as measured by. The Family Empowerment Scale⁸ is a 34-item, parent self-report scale that assesses parent empowerment related to their family (eg, “I make efforts to help my child grow and develop.”), service system (eg, “My opinion is as important as professionals who are providing services to my child.”), and community (eg, “I feel I can have a part in improving services for children in my community.”). The Family Empowerment Scale has demonstrated good reliability and validity and provides comprehensive information about empowerment, including attitudes, knowledge, and behaviors.

The Duke-UNC Functional Support Questionnaire⁹ is a 14-item, parent-report questionnaire that assesses confidant (eg, “I get chances to talk to someone I trust about family problems.”), effective (“People care what happens to me.”), and instrumental (“I can get help when I need transportation support.”) domains of support. In a validation sample, we found the measure to have good internal consistency and it correlated with related domains of psychosocial

functioning in expected directions. This measure has been widely used to assess social support among patients with somatic medical conditions as well as patients with mental illness.

The Youth Services Survey for Families¹⁰ is a 26-item questionnaire that specifically targets parents' satisfaction with children's mental health services. The measure assesses 5 domains of parent satisfaction: cultural sensitivity, access, treatment participation, appropriateness, and outcome. This measure has been adopted by several state mental health systems to evaluate parent satisfaction with child services.

The secondary aims outcomes included pharmacy and psychosocial service claims as well as a global measure of child functioning/behavior. For pharmacy claims, we assessed all psychiatric medication prescription fills. We assessed if a dose increase in antipsychotic medication had occurred at 90 days. We also assessed if the number of psychiatric medications (ie, a proxy for medication complexity) had changed at 90 days. Psychosocial service claims reviewed during the intervention period included individual, family, and group therapy. We were interested in dose outcomes since most pediatric antipsychotic treatment is for *off-label* conditions, so practice guidelines emphasize the importance of using the lowest effective dose given the potential side effects and limited evidence base to guide care. For psychosocial service claims, we assessed the number of claims during the 90-day timeframe prior to enrollment as well as at 90 days post-enrollment. We assessed behavior therapy claims because this model of treatment empowers parents to serve an active role in their child's recovery and therapy is recommended in practice guidelines as part of comprehensive treatment for youth with serious mental illness.

A global child behavioral measure called the Brief Problem Monitor-Parent Form¹¹ (abbreviated Child Behavior Checklist) was completed at baseline and 90 days. We opted to use a global specific clinical disorder (ie, only entry criterion is that all youth have antipsychotic treatment). This measure asks parents to rate items about behavioral and emotional problems on a 0- to 2-point scale (not true, somewhat true, or very true). The items include internalizing,

externalizing, attention, and total problem subscores.

Data collection and sources: We employed several strategies to complete follow-up contact with parent participants. We offered flexible time to complete parent interviews (weekends, evenings, early morning hours), all interviews were conducted by telephone, and we made several attempts to contact the parents at the 90-day follow-up. We were able to obtain medication and psychosocial therapy service claim data for all participants with permission from Medicaid. No parents requested to discontinue study participation. Participants who did not complete the 90-day follow-up assessment were lost to follow-up (ie, unreachable by phone after several attempts to contact them).

Analytic and Statistical Approaches

Preliminary Analyses. We screened all data for errors using frequency and contingency tables and univariate and bivariate plots before formal analysis was completed. We performed a chi-square test of independence between groups based on child ethnicity, parent ethnicity, child gender, and parent gender. We used independent sample *t* tests to test for differences between groups on child age, parent age, and baseline measures as a test of the success of the randomization. We assessed all participants at follow-up regardless of whether they engaged with the family navigator during the study period (intent to treat). Although we used all of the data collected, we assessed for the potential confounding effects of missing follow-up data by comparing the baseline characteristics of the participants who were lost to follow-up prior to completing the 3-month assessment with those participants who did complete the assessment using the same above-described procedures. Given the intent-to-treat approach, we used mixed models in order to include any participant with data at any single timepoint. In addition, we completed 2 sensitivity analyses. First, we ran our analyses for an *as treated* sample. In this case, we included only family members in the active condition who had at least 1 contact with the FN (N = 118). We also ran a *completers* analysis including only those participants with baseline and follow-up data (FN = 128, TAU = 117).

Hypothesis 1 (parent impact) **tested whether self-report measures of support, empowerment, and satisfaction significantly improved at 90 days for parents who received FN services compared with those parents who did not receive FN services.** We used a general linear mixed effects model with a random intercept to account for nonindependence due to the repeated measures with study condition, time, and study condition x time interaction as the independent variables. The test of the null hypothesis of no difference between intervention conditions from baseline to the 3-month follow-up assessment is the test of whether the coefficient for the study condition x time interaction term is 0.

Hypothesis 2 (child impact) tested whether **children whose parents received FN services had (1) greater improvement in a global measure of child functioning and (2) more claims for psychosocial services, and would be (3) less likely to have either a dose increase or psychiatric medication added over the course of 90 days compared with children of families that did not receive FN services.** Each of these child outcomes required a different statistical model. The test of the global measure of child functioning followed the same model as described above for hypothesis 1.

We collected a count variable—the psychosocial therapy claims—at both baseline and 90 days for the previous 3 months. The psychosocial claims count was 0, inflated and highly skewed to the right. Therefore, we recoded claims for psychosocial services into a yes/no variable after reviewing the claims distribution numbers. “Yes” indicates the child had at least 1 (but could be more) claim and “no” reflects no psychosocial claims during the 3-month time period prior to baseline and the 3 months prior to the follow-up date. Therefore, we used a generalized estimating equation (GEE) model to assess the dichotomous psychosocial claims variable over time between intervention groups using the same independent variables described above.

Medication change was either a dose increase in the originally prescribed antipsychotic or a psychiatric medication added during the 3 months following baseline. We measured medication changes as dichotomous outcomes. We created separate variables for dose increases (yes/no)

and additional psychotropic medication prescribed (yes/no). We also tested these outcomes with the GEE model. These variables are measured at only one timepoint, so intervention condition is the only independent variable. We conducted data analysis with SPSS 23 software.

Conduct of the study: The study was IRB approved by the University of Maryland and the Maryland State Department of Health and Mental Hygiene IRBs. Study enrollment occurred from August 5, 2013, to January 11, 2016.

We made 2 changes to the original study protocol from the original grant: (1) We increased the child age range for study eligibility from youth aged <10 to <16 years old and (2) we decreased the sample size from 450 to 350 participants. In the original grant application, the very large sample size of 450 parents allowed for the detection of a small effect size (0.25). We did not necessarily predict that the intervention would have such a small effect. Our recruitment in the first 17 months averaged 11 parents enrolled per month. We had not anticipated that we would not be able to reach approximately half of eligible parents (eg, disconnected numbers, no number available). Based on our initial recruitment rate and accounting for attrition, we anticipated our total sample size would be $n = 264$ after 30 months of recruitment. A reanalysis of the power with this sample size provides greater than 80% power to detect an effect of $d = 0.35$. This effect size is still in the small to medium range, as we suggested in our original application. We anticipated expansion of the child eligibility age range would allow us to enroll an additional 7 parents per month. The change in the child age eligibility criteria was possible because the antipsychotic prior authorization program expanded to include reviews of older children. The family navigators received additional training on services/resources specifically for adolescents prior to enrolling parents of adolescents. Our revised target sample size was 350. A reanalysis with this sample size provides greater than 80% power to detect an effect of $d = 0.30$. This effect size is similar to the original estimate (0.25-0.30).

Results

Participants: The study enrolled 350 parent participants and randomized participants to the family navigator ($n = 177$) and treatment as usual ($n = 173$) conditions (Figure 1). We

administratively excluded 2 parents after randomization to the family navigator condition because the family navigator became aware that the parent did not actually have guardianship of the child. We did not include these 2 participants in any analyses. The 90-day follow-up completion rate for the entire sample was 70% (N = 245) and by treatment group FN 73% (n = 128) and TAU 68% (n = 117) (Figure 1), and there was no difference in attrition between treatment groups (FN 73% [n = 128] and TAU 68% [n = 117]; [$\chi^2 = 1.27, p = 0.26$]). Parent participant demographics are detailed in Table 1. The sample was primarily female and Caucasian, with a mean age of 39.28, and there were no significant differences between groups on demographic variables. We enrolled parents from every county in Maryland (Figure 2).

The demographics of the children in treatment are presented in Table 2. The child sample included primarily boys of Caucasian race with a mean age of 9.92 and there were no significant differences between groups on demographic variables. Pediatric antipsychotic medication treatment at baseline (n = 348) was primarily with risperidone (40.5%), aripiprazole (34.5%), and quetiapine (10.3%). Additional medications prescribed included olanzapine (n = 8), lurasidone (n = 5), haloperidol (n = 2), ziprasidone (n = 2), perphenazine (n = 2), asenapine (n = 1), and paliperidone (n = 1). See Table 3 for antipsychotic medication by condition. Approximately 8.3% (N = 29) of youth had no pharmacy claims for any antipsychotic medication at baseline or 90-day follow-up, 18.1% (N = 63) had no antipsychotic medication at 90-day follow-up, 6.6% (N = 23) switched antipsychotic medication during the 90-day period, and 1.1% (N = 4) had multiple antipsychotic medications at baseline and 90-day follow-up. Therefore, analyses on medication changes were limited to N = 229.

Figure 1: The Family VOICE study CONSORT Flow Diagram

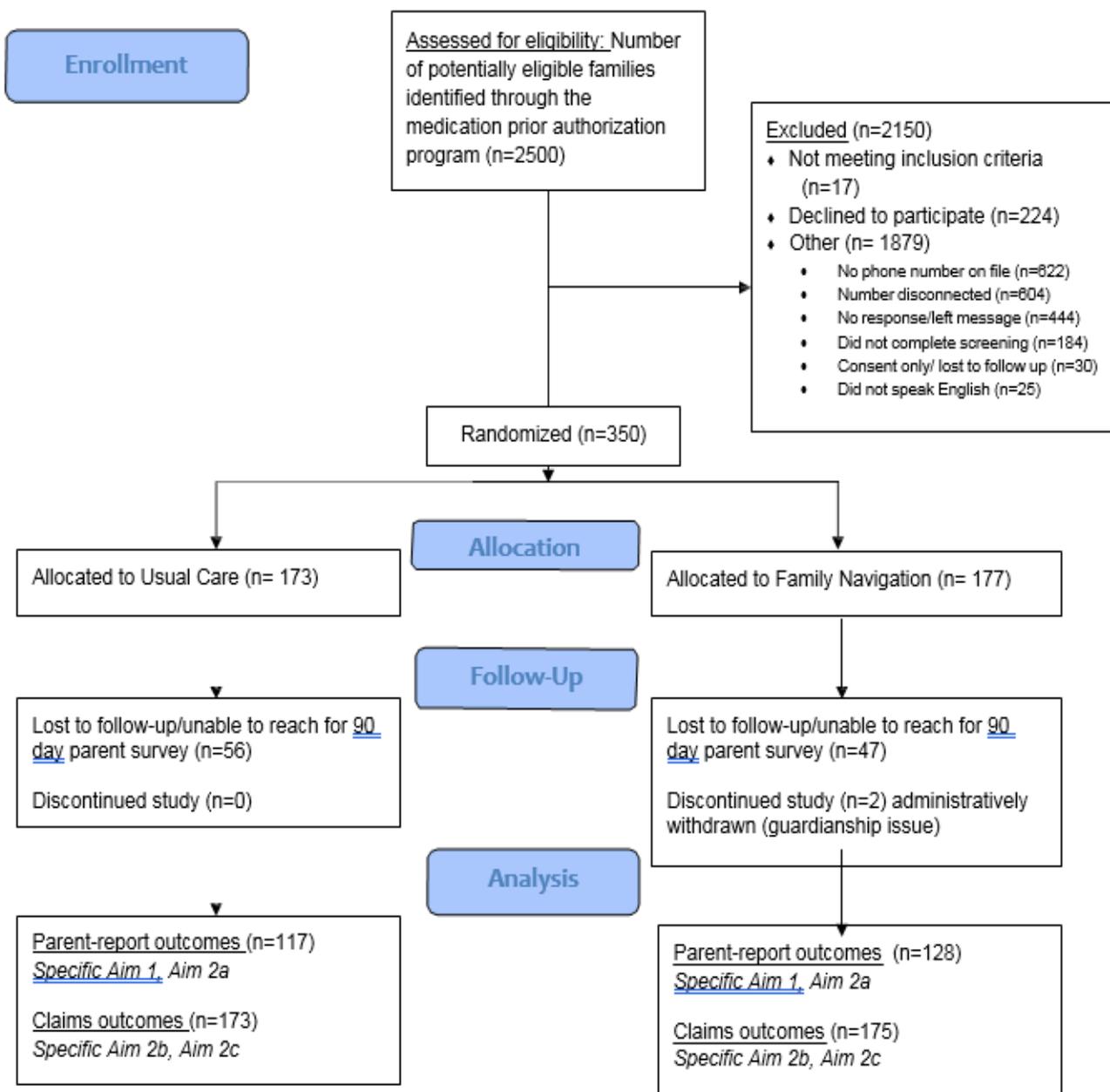


Figure 2: Peer review final report study enrollment map

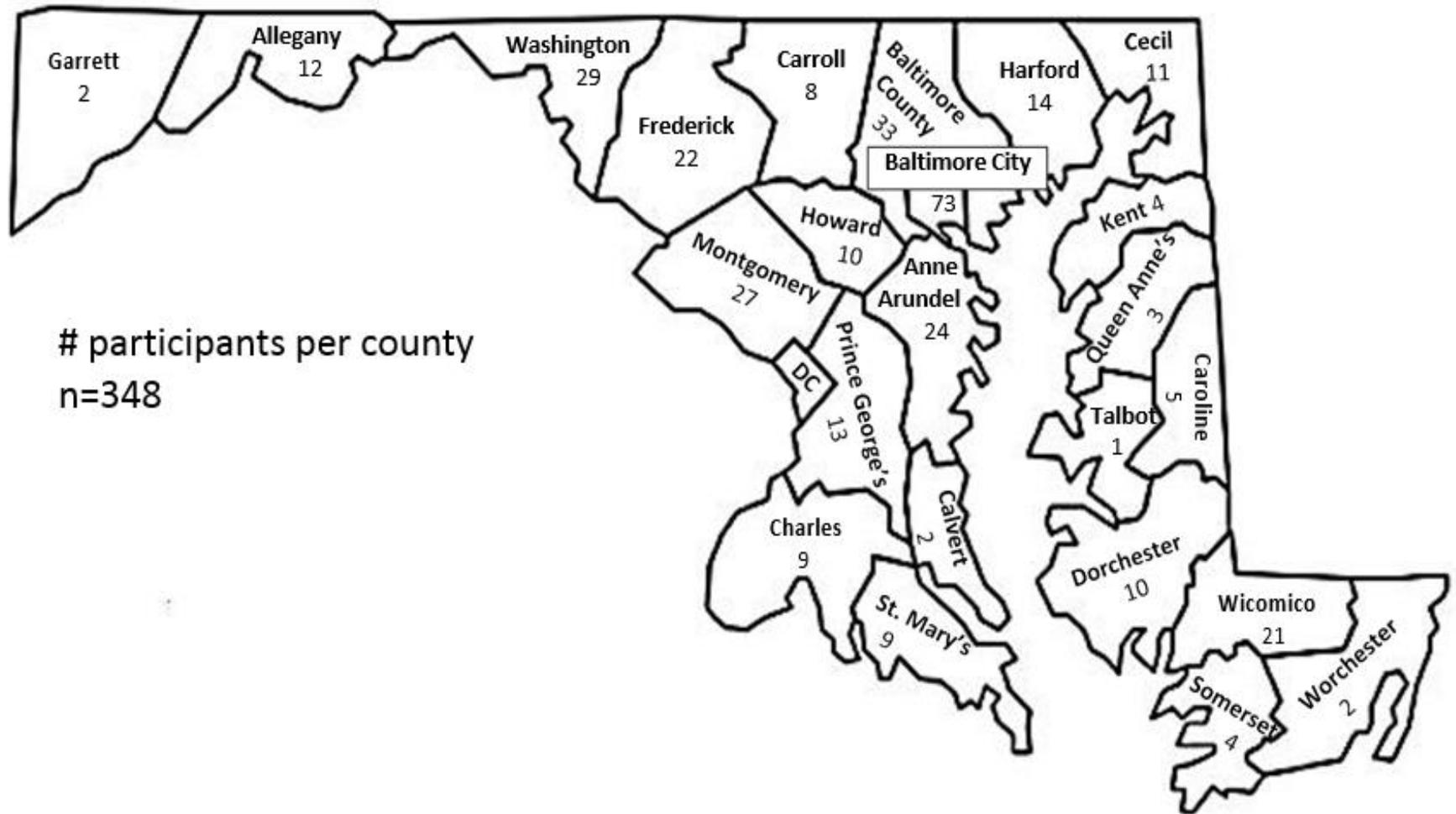


Table 1. Parent Demographics by Condition			
	Family Navigator N = 175	Treatment as Usual N = 173	Total N = 348
Gender			
Male	8 (4.6%)	15 (8.7%)	23 (6.6%)
Female	167 (95.4%)	158 (91.3%)	325 (93.4%)
Age (mean SD)	40.09 (10.06)	38.47 (10.00)	39.28 (10.05)
Race			
Asian	2 (1.1%)	2 (1.2%)	4 (1.1%)
African American	61 (34.9%)	57 (32.9%)	118 (33.9%)
Caucasian	95 (54.3%)	101 (58.4%)	196 (56.3%)
Mixed race	9 (5.1%)	4 (2.3%)	13 (3.7%)
Other	4 (2.3%)	7 (4.0%)	11 (3.2%)
Not reported	4 (2.3%)	2 (1.2%)	6 (1.7%)

^a Data were missing for parent race/ethnicity. There were no significant differences between groups based on gender ($\chi^2 [1, N = 348] = 2.37; p = 0.12$) or race ($\chi^2 [4, N = 342] = 3.06; p = 0.55$).

Table 2. Child Demographics by Condition

	Family Navigator N = 175	Treatment as Usual N = 173	Total N = 348
Gender			
Boys	107 (61.1%)	122 (70.5%)	229 (65.8%)
Girls	68 (38.9%)	51 (29.5%)	119 (34.2%)
Age (mean SD)	10.18 (2.85)	9.66 (2.71)	9.92 (2.79)
Race			
Asian	2 (1.1%)	2 (1.2%)	4 (1.1%)
African American	60 (34.3%)	55 (31.8%)	115 (33.0%)
Caucasian	76 (43.4%)	77 (44.5%)	153 (44.0%)
Mixed race	34 (19.4%)	30 (17.3%)	64 (18.4%)
Other	3 (1.7%)	8 (4.6%)	11 (3.2%)
Not reported	0 (0.0%)	1 (0.6%)	1 (0.3%)

^a Data were missing for child ethnicity. There were no significant differences between groups based on gender ($\chi^2 [1, N = 348] = 3.40; p = 0.065$) or race ($\chi^2 [4, N = 347] = 2.72; p = 0.61$).

Table 3. Baseline Antipsychotic Medication by Condition

Antipsychotic Medication	Family Navigator N = 175	Treatment as Usual N = 173	Total N = 348
Risperidone	68 (38.9%)	73 (42.2%)	141 (40.5%)
Aripiprazole	64 (36.6%)	56 (32.4%)	120 (34.5%)
Quetiapine	18 (10.3%)	18 (10.4%)	36 (10.3%)
Olanzapine	3 (1.7%)	5 (2.9%)	8 (2.3%)
Lurasidone	3 (1.7%)	2 (1.2%)	5 (1.4%)
Haloperidol	1 (0.6%)	1 (0.6%)	2 (0.6%)
Ziprasidone	2 (1.1%)	0 (0.0%)	2 (0.6%)
Perphenazine	1 (0.6%)	1 (0.6%)	2 (0.6%)
Asenapine	1 (0.6%)	0 (0.0%)	1 (0.3%)
Paliperidone	1 (0.6%)	0 (0.0%)	1 (0.3%)
No fill at baseline	13 (7.4%)	17 (9.8%)	30 (8.6%)

Outcomes and Estimation Results

Family navigator contact: Family navigators made contact with 118 parents for at least one session out of the 175 parents assigned to the intervention arm. The range of sessions was 0 to 21 (Figure 3), with a mean and standard deviation of 3.90 and 2.85, respectively. The median number of visits was 2. We were unable to contact 57 parents out of the 175 parents randomized to family navigator services for parent report 90-day assessments. We obtained service claims data on all participants in the study.

Hypothesis 1 was not supported. Family navigator services were not associated with significantly greater improvement over time in parent-rated empowerment, social support, or satisfaction with child services measures compared with TAU (Table 4).

Hypothesis 2a was not supported. Parents in the family navigator condition did not rate their child as showing *improvement in a global measure of child functioning* over time as compared with parents in the TAU condition (Table 4).

Hypothesis 2b was not supported. There were no significant changes in the probability of the child or family in the FN condition receiving at least 1 psychosocial therapy service after the intervention as compared with the TAU families (68.6% to 64.0% for FN and 62.4% to 62.4% for TAU; Table 5).

Figure 3. Number of FN Calls Completed by Participants Who Made at Least One Contact with an FN

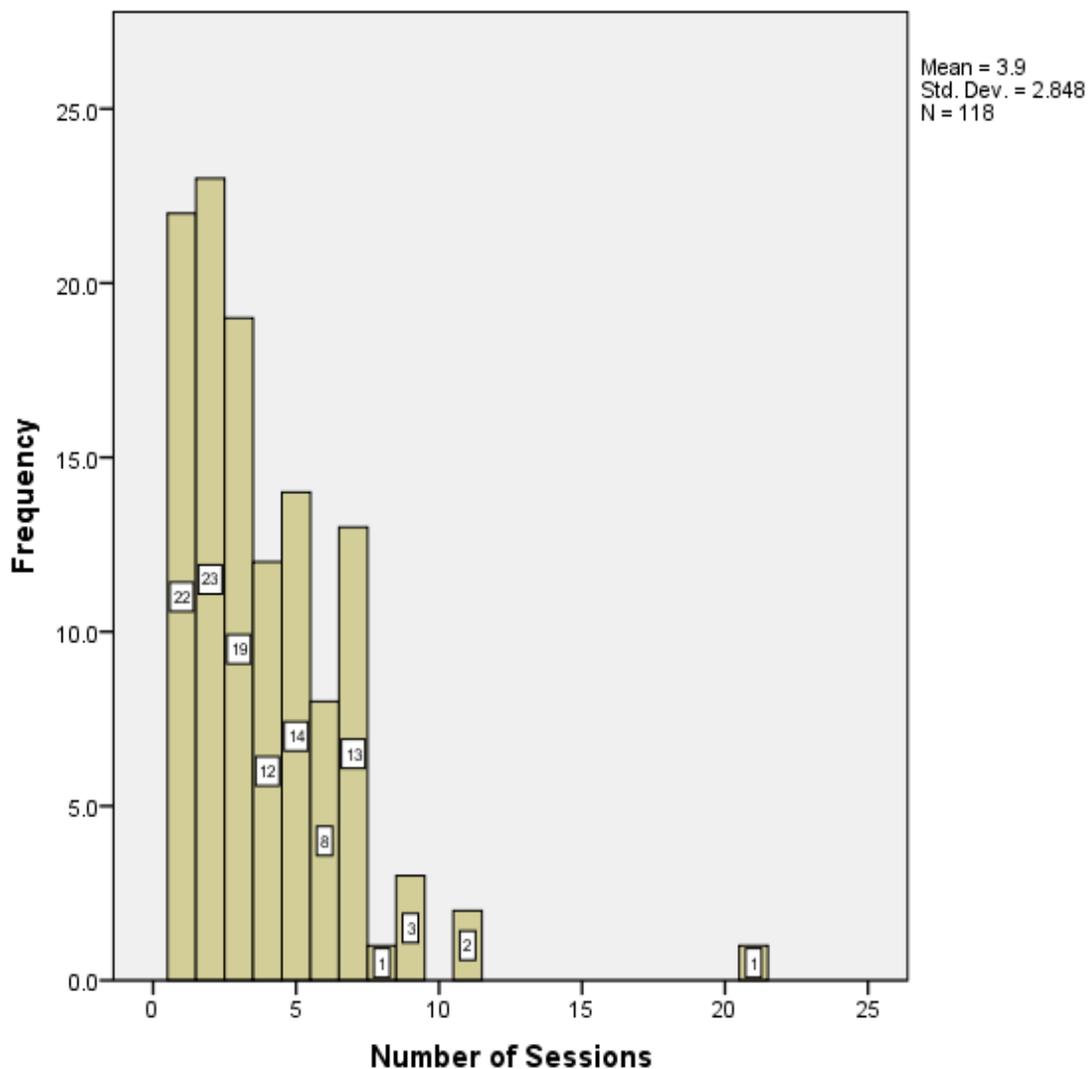


Table 4. Repeated Measures General Linear Mixed Model for Pre and Post by Condition

	Family Navigator				Treatment as Usual				Condi tion	<i>p</i>	<i>d</i>	Time	<i>p</i>	<i>d</i>	Condi tion*Ti me	<i>p</i>	<i>d</i>
	M	95% CI	SD	n	M	95% CI	SD	n									
Family Empowerme nt Baseline	3.75	3.67, 3.82	.52	175	3.86	3.79, 3.94	.51	173									
Post	3.81	3.74, 3.91	.55	128	4.02	3.93, 4.11	.51	117	8.47	<.01	.24	21.07	<.001	.23	2.14	.15	.19
Social Support Baseline	2.58	2.42, 2.75	1.1 0	175	2.46	2.30, 2.63	1.07	173									
Post	2.48	2.30, 2.65	1.1 0	128	2.45	2.24, 2.61	1.06	117	.62	.43	.06	1.68	.20	.07	.39	.53	.08
Youth Services Survey Baseline	3.75	3.65, 3.84	.64	175	3.90	3.80, 3.99	.63	173									
Post	3.81	3.72, 3.92	.61	128	3.95	3.85, 4.06	.60	117	5.31	.02	.19	3.41	.07	.11	.07	.80	.02
Brief Problem Monitor Baseline	69.51	68.67, 70.36	5.6 9	175	69.1 9	68.34, 70.03	5.62	173									
Post	67.63	66.54, 68.72	6.0 3	128	66.7 3	65.42, 67.68	6.83	117	1.42	.23	.10	34.15	<.001	.38	.96	.33	.11

Condition, Time, Condition*Time values represent F statistic

Hypothesis 2c was partially supported. There was no significant difference in the probability of receiving at least one coprescribed psychotropic medication (ie, other nonantipsychotic psychiatric medications) use between treatment groups (22.3% FN and 22.5% TAU; $\chi^2[1, n = 348] = 0.003$; $p = 0.95$; Table 6). To assess whether a dose change occurred for the originally prescribed antipsychotic, we could only use those children who had at least 2 prescriptions for the originally prescribed antipsychotic (N = 229). Results suggest that the percentage of youth of parents who were randomized to the family navigator condition were less likely (23.6%) to have an increase in antipsychotic dose at 90 days compared with youth of parents in the treatment as usual group (41.2% $\chi^2 [1, N = 229] = 7.99$; $p = 0.005$; Table 7).

Table 5. Therapy Claims (Yes/No) by Condition

	90 Days Prior to Enrollment	90 Days Post Enrollment
Family Navigator N = 175	120 (68.6%)	112 (64.0%)
TAU N = 173	108 (62.4%)	108 (62.4%)

Wald $\chi^2 (1, N = 696) = 1.60$; $p = 0.21$

^a Count represents number of families in each condition who had claims in the 90 days prior and 90 days post.

Table 6. Increase in Total Number of Coprescribed (Non-antipsychotic Psychiatric Medication) by Condition

	Family Navigator N = 175	Treatment as Usual N = 173
Concomitant increase	39 (22.3%)	39 (22.5%)
No concomitant increase	136 (77.7%)	134 (77.5%)

$\chi^2 (1, N = 348) = 0.003$; $p = .95$; $\phi = 0.003$

Includes all participants

Table 7. Same AP/Increase Dose by Condition

	Family Navigator N = 110	Treatment as Usual N = 119
Dosage increase	26 (23.6%)	49 (41.2%)
No dosage increase	84 (76.4%)	70 (58.8%)

$\chi^2 (1, N = 229) = 7.99; p = 0.005; \phi = 0.19$

^a Does not include youth with no AP claims (n = 29), no follow-up AP claims (n = 63), AP switch (n = 23), or AP polypharmacy (n = 4).

Although we designed the family navigator services to improve therapy service utilization, many parents used family navigator services to access services to support household daily living needs. In our entire sample at baseline, 123 (35%) parent participants requested assistance with food services, 101 (29%) requested information on housing programs, and 54 (16%) families needed assistance with both housing and food services. For parents who were receiving family navigator services, the most common intervention for daily living needs was referral for a local food pantry (most parents were already receiving Supplemental Nutrition Assistance Program benefits [ie, food stamps] but did not have adequate supply of food for their family during the entire month). The family navigator was also able to provide information on transportation, if needed, though most families had access to food pantries relatively close by (eg, available through a local church program).

Study Retention

Participant retention was higher than anticipated. Given the lack of any face-to-face visits during the course of the study and a study design in which parents did not initiate contact to request services, we expected study retention would be 60% during the course of the study. We included this retention rate in our original study proposal. However, our final retention rate was 70%. No parents requested to discontinue their study participation in either group.

Harms

We are not aware of any harms from study participation. We did make 4 Child Protective Services (CPS) reports for suspected abuse/neglect. All 4 reports were about children of parents in the family navigator condition. There were no CPS reports made about children of the treatment as usual condition. Parents were informed as part of the consent process that the study team members are mandated CPS reporters. The PI made all 4 reports.

Discussion

Context for study results: Contrary to our expectations, parents who received family navigator services did not have greater improvement in parent empowerment, social support, satisfaction with child services, or child global behavioral measures compared with parents who received usual care. Family navigator services may not be effective in improving these family-centered outcomes for several reasons. First, family navigator services as offered in our protocol involve contact with only the parent. Because there is no direct contact with the child or observation of the parent and child together, the family navigator has limited data to inform his or her recommendations for mental health services, which may be a barrier to improving child functioning and satisfaction with treatment. Second, family navigator services did not involve any face-to-face contact (virtually or in person) with the parent. The limited contact may have interfered with the parent's comfort or willingness to disclose information about personal issues, including his or her social relationships or feelings of stigma about mental health issues, which may be important to better address parent empowerment and social support. Additionally, family navigators are not clinicians. Their lived experience and training on child mental health issues may support families with referral/resource assistance but they do not have training to implement clinical interventions (eg, parenting skills training) that may impact child global functioning.

The outcomes selected in this study may not be effectively targeted by family navigator services or may not improve in the short timeframe assessed. A meta-analysis of *family centered help-giving practices* identified that one of the outcomes most strongly related to family-centered

help-giving was self-efficacy.¹² Parent self-efficacy—ie, a parent’s belief that he or she is able to help his or her child—may be more amenable to change over a short period than parent empowerment, which also includes beliefs about ability to influence larger systems (eg, community care for his or her child and other children). Further, outcomes that were more distal to the intervention (eg, child behavioral outcomes after a parent support intervention) were less impacted by family-centered support strategies. Regarding social support, parents may have increased awareness and intention for using social supports in their community (eg, parent support group; however, they may not be able to prioritize this type of support while their child is acutely ill (ie, recently started on an antipsychotic medication)).

Family navigator services also did not result in greater improvement in psychosocial service utilization compared with usual care. Family navigator services may have been too brief or not intensive enough to be effective in expanding psychosocial service utilization. The timing of family navigator services (ie, after the antipsychotic medication is approved) may not be optimal to increase psychosocial service utilization. Although speculation, it is possible that parents may be more motivated and interested in therapy services for their child after the child has adequate time to adjust to medication changes (eg, medication dose adjustments often occur in the first 90 days of treatment). Also, parents who utilized family navigator services may have opted to seek therapy services through their child’s school special education program or other community-based programs that might be associated with less stigma than traditional mental health services. These types of treatments are not reflected in the claims data since they are not paid for by Medicaid.

As hypothesized, youth of parents who received family navigator services were less likely than youth of parents in the treatment as usual group to have an antipsychotic medication dose increase over the course of 90 days. This finding should be considered in the context of the following study limitations and cautions. Lower antipsychotic dose does not necessarily mean better care. We did not assess claims for medication treatment appointments (ie, we looked at only claims that involved a psychosocial service) so it is possible that a medication may not have

increased in the timeframe studied because the child did not attend medication appointments consistently or the parent may have rejected provider dose recommendations. In our study design, the family navigator did not provide medication education or guidance to parents. It is possible that the dose finding is a false positive result since there was no impact of family navigator services on psychosocial service utilization, so it is unclear how family navigators would have impacted medication outcomes. One consideration is that family navigators did provide some coaching to parents on strategies to address treatment concerns with providers (eg, prepare for appointment with a list a questions). Also, family navigators did impact significant household needs (eg, access to food and housing), which may have generally reduced child/family stress levels. However, we did not systematically assess these possible factors for how family navigator services might indirectly impact medication outcomes. Future research is needed to study this possible relationship between family navigator services and dosage outcomes. Practice recommendations for off-label pediatric antipsychotic treatment (eg, treatment of maladaptive aggression) emphasize the importance of using the lowest effect dose to minimize side effect concerns¹³ so strategies that can be developed to support this type of outcome can have health benefits for the child.

A common theme that was identified anecdotally through ongoing supervision in the family navigator contact was that parents had significant needs for basic daily living support, namely food and housing services. Although all parents had a child enrolled and were seeing a Medicaid provider, many parents expressed that these daily living issues were not always addressed as part of their child's clinical care. A striking challenge for low-income families that already have inadequate food supply is that medication treatment can exacerbate the problem by increasing appetite ("My child is hungry all the time."). This challenge has implications for medication adherence and willingness to try the medication. In one example, a father of a child participant reported that his child missed school because she could no longer fit into her school uniform and the family could not afford to replace it. Thus, obesity-related side effects may tax limited parent resources in providing daily living needs for their child. Although not tested in

the current study, it is possible that peer support providers may be effective agents to screen and address daily living need concerns that can have a major impact on child health and functioning. Parents may not bring up these concerns consistently to clinical providers because of many competing priorities during appointments (eg, need to address recent school crisis episode), which may be even more challenging to address in the context of an appointment—which may be shorter than appointments for specialty care—in a primary care setting. Parents may also feel uncomfortable addressing household concerns with a clinician. The importance of basic daily living needs for children and adolescents is consistent with the growing scientific literature on the “social determinants of health” in pediatric development,¹⁴ and future studies on the role of peer support in addressing these needs may provide contributions to the literature.

The family navigator services implemented in this study required a medication prior authorization program to identify eligible families. An advantage of using this type of health care program to identify a population is that a complete list of eligible families can be obtained, and outreach to families is possible for a statewide population, regardless of the treatment setting (eg, primary care or specialty care) or location (eg, rural area). Although many do, not all states have an antipsychotic prior authorization program. An alternative strategy for identifying a complete, statewide population of youth might be to query Medicaid pharmacy claims. A strategic approach could focus on specific subgroups of youth (eg, youth who have claims for antipsychotic medication but no claims for psychosocial services).

These study results contribute to a limited literature of large randomized trials of family interventions to improve utilization of child mental health services. Ingoldsby¹⁵ identified only 17 randomized controlled trials published since 1980 of family engagement and retention strategies for child mental health services with clearly reported randomization data and outcomes. These studies largely employed clinician- (eg, motivational interviewing) and office staff- (eg, appointment reminder calls) delivered interventions rather than parent peer support

strategies. Ingoldsby identifies key elements of effective interventions as (1) individualized approach that addresses unique family needs, concerns, and barriers; (2) intensive strategies that assess engagement at multiple time points and with multiple family members; (3) intervention based on a strong theoretical framework; and (4) intervention integrated well within the treatment program. These findings suggest that redesign of family navigator services to improve behavioral service utilization might include increasing parent contact and possibly adding structured sessions as well as integrating parent peer support with treatment programs.

A 2013 review of parent peer support interventions for youth with chronic physical disabilities assessed studies that provided formal or informal support to parents of disabled or chronically or seriously ill children, excluding infants in neonatal intensive care or children receiving cancer treatment. Although the studies were not required to have a comparator condition, only 17 studies were identified (7 were randomized trials). As the children differed from our family navigator study sample in that they had chronic physical conditions, co-occurring mental health concerns were very common among youth and their parents. We identified important elements of positively received interventions including benefits of finding a shared identity, opportunity to learn practical information, support for personal growth, and opportunity/ability to support others. While we determined none of the interventions to be harmful, when parents do not express a need for or expectation of support, they are more likely to be perceived as unhelpful (eg, the parent perceives that he or she participating in a program because it was recommended by the clinical provider rather than out of personal interest). In our family navigator study, services were offered regardless of parent interest. In future designs of the family navigator intervention, greater attention to parent expectations/preferences for peer support at the initial contact may help improve retention in the program and also parent empowerment.

Other studies of parent peer support interventions for families dealing with child mental illness have studied parent-reported outcomes related to emotional well-being, including parent anger, depression, and distress. These outcomes may be more amenable to change in response

to a parent peer support intervention compared with one of our primary outcome measures, parent satisfaction with child services, since family navigator services may directly impact parent emotional status but the family navigators are not integrated in clinical care so they may not directly impact behavioral treatment outcomes.

Generalizability of study results: The results of this study are generalizable to families that have a Medicaid-insured youth treated with antipsychotic medication. Outcomes may be different for families with private insurance who may have greater resources for both mental health services as well as daily living needs. It is also important to note that results may not generalize to families with an older adolescent (ie, youth ≥ 16 years old).

Implementation of study: Of note, although not formally evaluated, the interaction of family navigators with clinicians and researchers on our team seemed to have bidirectional impact. Clinicians learned about alternative strategies to engage parents from hearing about family navigator lived experience as well as their work with other parents. For example, family navigators structured their initial discussions with parents to address household/family needs rather than focusing on the designated patient (ie, their child). The family navigators discussed in our team meetings how parents may not be able to focus on important child mental health service issues if they are dealing with more pressing challenges of unstable housing or inadequate access to food for their family. Also, researchers learned from our family navigators about the daily living needs of our target population. This information fundamentally changed the direction of our research and impacted the study design for our subsequent study. Thus, our experience would suggest that consumers, clinicians, and researchers benefit from ongoing contact/dialogue rather than traditional models of consumer support in which supervision and collaboration may be solely with other consumers. An issue that did come up in implementing our study was that the family navigators did not have prior research background or experience. We addressed this problem by adding training on conducting clinical research during our weekly call with the family navigators. For example, we discussed how outcomes are used to

assess an intervention, and the family navigators were able to develop a clearer understanding of how we would determine if the intervention was impactful and beneficial. Our family navigators learned about our outcomes questionnaire, which they reported was helpful in shaping what they discussed with parents.

Sub-population considerations: We were not powered to conduct subgroup analyses.

Study limitations: This study has limitations that warrant consideration for future study design. Our recruitment strategy allowed us to identify 100% of eligible parents to participate in the study and enroll 350 parents, but challenges with obtaining current telephone numbers and addresses made it difficult for us to contact nearly half of eligible parents. Parents from low-income families may have challenges such as unstable housing (ie, frequent changes in mailing address) and inadequate financial resources to maintain consistent telephone service (ie, disconnected number). We learned that most parents had internet access through multiple sources (eg, work, home, public library) even if they did not have a stable address or telephone number. Recruitment strategies that use some type of online contact or study advertisement through high-traffic websites (eg, websites that provide information on food and housing services) may increase likelihood of contacting parents of Medicaid-insured youth.

Additionally, the family navigator did not have any contact with members of the child's mental health treatment team. Communication and coordination with the treatment team could be beneficial for the family navigator to better understand what resources the family has already utilized and identify gaps in services. Our study retention rate was higher than we anticipated, but another limitation was that we were unable to contact 30% of the entire sample to obtain outcome measurements.

Future studies: Given the frequent daily living challenges experienced by families in our target population, future studies may be needed to improve access and utilization of food/housing services. Since antipsychotic medications cause increased appetite as a side effect, researchers

could study if interventions to improve food supply at home impact medication adherence. Parents may have concerns about continuing their child on a medication that increases appetite if they do not have adequate resources to feed their family. Strategies to improve housing stability may also impact psychosocial service utilization since frequent moves may make it difficult for parents to continue their child's treatment at a particular setting (eg, parents may not be able to afford the additional time and cost involved in transportation after they move).

Conclusions

In this study, family navigator services did not improve parent empowerment, social support, or satisfaction with child services. The limited contact of the parents with the family navigator during this brief intervention further suggests that this type of intervention may not be intensive enough to impact these parent-reported outcomes, especially since the intervention is delivered during a period of child instability (ie, child recently started on an antipsychotic medication after a psychiatric decompensation in functioning) when parents are under considerable duress.

The Family VOICE study is an example of a family-centered study with parent consumer collaboration during all phases of research, including design, implementation, and dissemination. Consumer feedback was very influential in designing the intervention to provide parents with flexible, ad hoc access to support and resources that serve the needs of a family rather than just focusing on a designated patient. Family navigator contact with families identified significant unmet daily living needs (eg, food access) that may not be adequately addressed through contact with health care systems.

We need future studies to more systematically assess the hypothesis that family navigator services may impact medication outcomes (eg, medication dose) during the time when youth are most likely to experience a dose increase (ie, during the first few months of treatment). Interventions that support use of the lowest effective dose are especially important for this patient population because treatment is largely for off-label indications and can result in

significant side effects. From a research process perspective, we need studies to investigate different strategies to improve collaboration between academic investigators and consumers, including training approaches before studies are implemented and strategies to retain consumer partners in the research workforce.

References

1. Olfson M, Blanco C, Liu SM, Wang S, Correll CU. National trends in the office-based treatment of children, adolescents, and adults with antipsychotics. *Arch Gen Psychiatry*. 2012;69(12):1247-1256.
2. De Hert M, Detraux J, Van Winkel R, Yu W, Correll CU. Metabolic and cardiovascular adverse effects associated with antipsychotic drugs. *Nat Rev Endocrinol*. 2012;8(2):114-126.
3. Finnerty M, Neese-Todd S, Pritam R, et al. Access to psychosocial services prior to starting antipsychotic treatment among Medicaid-insured youth. *J Am Acad Child Adolesc Psychiatry*. 2016;55(1):69-76.
4. Schmid I, Burcu M, Zito JM. Medicaid prior authorization policies for pediatric use of antipsychotic medications. *JAMA*. 2015;313(9):966-968.
5. Hoagwood K, Jensen P. *Parent Empowerment Training Manual*. New York, NY: Oxford University Press; 2007.
6. Olin SS, Hoagwood KE, Rodriguez J, et al. The application of behavior change theory to family based services: improving parent empowerment in children's mental health. *J Child Fam Stud*. 2010;19(4):462-470.
7. Reeves GM, Wehring HJ, Connors KM, et al. The family value of information, community support, and experience study: rationale, design, and methods of a "family centered" research study. *J Nerv Ment Dis*. 2015;203(12):896-900.
8. Koren PE, DeChillo N, Friesen BJ. Measuring empowerment in families whose children have emotional disabilities: a brief questionnaire. *Rehabil Psychol*. 1992;37(4):305.
9. Achenbach TM, McConaughy SH, Ivanova MY, Rescorla LA. Brief Problem Monitor—parent form for ages 6-18. *Man ASEBA Brief Prob Monit*. University of Vermont. 2011. Available at: <http://www.aseba.org/ASEBA%20Brief%20Problem%20Monitor%20Manual.pdf>
10. Broadhead WE, Gehlbach SH, De Gruy FV, Kaplan BH. The Duke-UNC functional social support questionnaire: measurement of social support in family medicine patients. *Med Care*. 1988;26(7):709-23
11. Riley SE, Stromberg AJ, Clark J. Assessing parental satisfaction with children's mental health services with the youth services survey for families. *J Child Fam Stud*. 2005;14(1):87-99.

12. Achenbach, TM, McConaughy, SH, Ivanova, MY, Rescorla, LA. Brief Problem Monitor—Parent form for ages 6-18. *Man ASEBA Brief Prob Monit*. University of Vermont.
13. Dunst CJ, Trivette CM, Hamby DW. Meta-analysis of family centered help giving practices research. *Dev Disabil Res Rev*. 2007;13(4):370-378.
14. Rosato NS, Correll CU, Pappadopulos E, et al; Treatment of Maladaptive Aggressive in Youth Steering Committee. Treatment of maladaptive aggression in youth: CERT guidelines II. Treatments and ongoing management. *Pediatr*. 2012;129(6):e1577-e1586.
15. Garg A, Toy S, Tripodis Y, Silverstein M, Freeman E. Addressing social determinants of health at well-child care visits: a cluster RCT. *Pediatr*. 2015;135(2):e296-e304.

Appendix: Sensitivity Analysis, Navigator Made Contact

Repeated Measures General Linear Mixed Model for Pre and Post by Condition

	Family Navigator				Treatment as Usual				Condition								
	M	95% CI	SD	n	M	95% CI	SD	n	Condition	<i>p</i>	<i>d</i>	Time	<i>p</i>	<i>d</i>	Condition x Time	<i>p</i>	<i>d</i>
Family Empowerment Scale baseline	3.71	3.62 -	0.53	118	3.86	3.79 -	.53	173									
		3.81				3.94											
Post	3.82	3.74 -	0.49	98	4.02	3.93 -	.49	117	9.02	<.01	.41	20.67	<.001	.63	0.87	.35	.13
		3.92				4.11											
Social Support Scale baseline	2.64	2.45 -	1.08	118	2.46	2.30 -	1.07	173									
		2.84				2.62											
Post	2.54	2.24 -	1.05	98	2.42	2.24 -	1.02	117	1.60	.20	.17	1.18	.28	.15	.22	.64	.07
		2.61				2.61											
Youth Services Treatment Satisfaction Survey baseline	3.70	3.58 -	.63	118	3.90	3.80 -	.63	173									
		3.81				3.99											
Post	3.80	3.68 -	.58	98	3.95	3.85 -	.57	117	7.21	<.01	.39	3.73	.06	.27	.26	.60	.07
		3.91				4.06											
Brief Problem Monitor Scale baseline	69.74	68.35 -	5.65	118	69.19	68.35 -	5.66	173									
		70.03				70.03											
Post	67.96	66.70 -	6.37	98	66.55	65.41 -	6.27	117	2.30	.13	.21	27.03	<.001	.71	1.03	.31	.14
		69.23				67.69											

Condition, Time, Condition x Time values represent *F* statistic

Appendix: Sensitivity Analysis, Completers Only

Repeated Measures General Linear Mixed Model for Pre and Post by Condition

	Family Navigator				Treatment as Usual				Condition								
	M	95% CI	SD	n	M	95% CI	SD	n	Condition	<i>p</i>	<i>d</i>	Time	<i>p</i>	<i>d</i>	Condition x Time	<i>p</i>	<i>d</i>
Family Empowerment Scale baseline	3.73	3.67 -	.53	128	3.86	3.77 -	.53	117									
Post	3.81	3.77 -	.53	128	4.02	3.82 -	.53	117	7.37	<.01	.35	21.04	<.001	.59	1.75	.19	.17
		3.96				3.91											
Social Support Scale baseline	2.59	2.30 -	1.09	128	2.50	2.30 -	1.09	117									
Post	2.48	2.25 -	1.08	128	2.45	2.25 -	1.08	117	.22	.64	.06	1.96	.16	.18	.25	.62	.06
		2.64				2.64											
Youth Services Treatment Satisfaction Survey baseline	3.73	3.62 -	.65	128	3.89	3.78 -	.65	117									
Post	3.81	3.71 -	.61	128	3.95	3.84 -	.61	117	4.50	.04	.27	3.53	.06	.24	.07	.11	.04
		3.92				4.06											
Brief Problem Monitor Scale baseline	69.59	68.63 -	5.51	128	69.51	68.51 -	5.51	117									
Post	67.67	66.55, 68.79	6.42	128	66.72	65.56, 67.90	6.42	117	0.60	.44	.10	35.36	<.001	.76	1.22	.27	.14

Condition, Time, Condition x Time values represent *F* statistic

Appendix: Sensitivity Analysis, Navigator Made Contact Same AP/Increase Dose by Condition

	Family Navigator N = 75	Treatment as Usual N = 119
Dosage increase	21 (28.0%)	49 (41.2%)
No dosage increase	54 (72.0%)	70 (58.8%)

$\chi^2 (1, N = 194) = 3.46; p = .06; \phi = 0.13$

Appendix: Sensitivity Analysis, Completers Only Same AP/Increase Dose by Condition

	Family Navigator N = 77	Treatment as Usual N = 85
Dosage increase	18 (23.4%)	37 (43.5%)
No dosage increase	59 (76.6%)	48 (56.5%)

$\chi^2 (1, N = 162) = 7.32; p = .007, \phi = 0.19$

Acknowledgment:

The authors wish to acknowledge the leadership and staff at the Maryland Coalition of Families for Children's Mental Health who have provided essential feedback in designing this study.

Copyright© 2019. University of Maryland Baltimore. All Rights Reserved.

Disclaimer:

The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

Acknowledgement:

Research reported in this report was [partially] funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Award (#997). Further information available at: <https://www.pcori.org/research-results/2012/does-parent-peer-support-program-help-parents-children-who-need-mental-health>