Optimizing a Paraprofessional, Family Partner Navigation Model for Children

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1. List of Abbreviations

Abbreviation	Abbreviation definition
FN	Family Navigation
FP	Family Partners
ACO	Accountable Care Organization
MOST	Multiphase Optimization Strategy
OCHIN	Oregon Community Health Information Network
CCM	Chronic Care Model
PPSC	Preschool Pediatric Symptom Checklist
PSC-17	Pediatric Symptom Checklist-17
SWYC	The Survey of Wellbeing of Young Children
CBCL	Child Behavior Checklist
PSN-I	Interpersonal Relationship with Navigator
PHQ-2	Patient Health Questionnaire
FRS	Family Resource Scale
EHR	Electronic Health Record
RE-AIM	Reach Effectiveness Adoption Implementation Maintenance
TAU	Treatment as Usual

2. Protocol Summary

Title:	Optimizing a Paraprofessional, Family Partner Navigation Model for Children
Population:	The study will include 715 participants which include parent/legal guardian, a child and eligible siblings who will be enrolled from DotHouse Health, a Federally Qualified Community Health Center in Boston. We will enroll children ages 3-12 years who screen positive on behavioral health screening tools, - the Preschool Pediatric Symptom Checklist (PPSC) (3-5 years), which is included in the Survey of Wellbeing of Young Children (SWYC) or Pediatric Symptom Checklist-17 (PSC-17) (6-12 years) OR whose parents indicate a behavioral health concern during any pediatric visit. These screening tools are administered as standard of care (SOC). The study enrollment is expected to be 84% ethnic-racial minority families (i.e. primarily Asian, Latino, and African American).
Intervention:	This is a pragmatic optimization trial of Family Navigation (FN), an evidence-based care management strategy which is a promising intervention to help low income and minority families access timely mental health services. Despite significant evidence supporting the effectiveness of FN, concerns exist about the ability to disseminate FN to a broad population due to inefficiency and cost. The current proposal is designed to develop an optimized, efficient, effective, and equitable version of FN to be delivered by trained Family Partners (FP), the goal being to improve access to, and engagement in, diagnostic and treatment services for children with mental health disorders. Specifically, families who participate in the study (includes parent/legal guardian, child and if applicable, additional siblings) will work with one of the trained study Family Partners (FPs) and will be randomized to one of 16 possible strategies to

	deliver FN. FPs will then work with families based on the condition to which they were randomized.
Objectives:	Our primary objective is to identify which of the FN delivery strategies: (A) use of enhanced technology for care coordination vs. usual care; (B) community and home-based delivery vs. clinic-based delivery only; (C) intensive symptom tracking vs. low level symptom tracking; and (d) individually tailored vs standardized, schedule-based visits with families contribute meaningfully to improvement in the primary outcome - access to child mental health services. We will estimate impact of the 4 delivery strategies and the combinations of these strategies on the study's primary outcome. Based on our findings we will determine the best combination of FN components for evaluation in future randomized trial. Our secondary objectives are to evaluate which components of FN are most effective for whom and the mechanisms related to effectiveness.
Design/Methodology:	We will be using a highly efficient experimental design to identify which of the FN components contribute meaningfully to improvement in the primary outcome - access to child mental health services. We will concurrently gather information on FN's mechanisms of effectiveness. The study will take place in the real world context of a community health care center. Children will be enrolled if they have a positive behavioral health screen on one of the age appropriate screening measures (PSC or PPSC) which are universally used in the clinic OR parent report of a behavioral health concern. If agreeable, families will be referred to a FP who will inform families about the study. Families who consent to study participation will be randomized to one of 16 combinations of strategies to deliver FN and will work with the study FP. Families who decline participation in the study will have the option to work with health center care managers (instead of the study FPs) who also offer care coordination. Those families will not be randomized or followed as part of the study. Delivery of FN will be systematically varied across four components, each of which is represented by a separate factor in our 2x2x2x2 factorial study design (See figure 1). Specifically, each family (includes parent/legal guardian, child and if applicable, additional siblings) will be randomly assigned to one of two conditions within each of 4 factors or delivery strategies, defining 16 separate experimental conditions. Strategies include: (A) technology-assisted delivery of care coordination using an innovative, web-based platform called Act.MD (compared to usual care); (B) clinic based FN + community-based (compared to clinic-based only); (C) enhanced symptom tracking using more frequent behavioral symptom tracking by the FP (compared to standard pediatric surveillance); and (d)) individually tailored vs standardized, schedule-based visits with families. All children will be followed through the EHR for 12 months, for outcomes in services access and symptom tracking.

	We will estimate main effects of the 4 experimental factors and the effects of combinations of the delivery strategies on the study's primary outcome – family engagement in child mental health services. We will also include a "watchful waiting" group for families of children who are referred to the study but who decide that they are not interested in accessing child behavioral services when the FP speaks to them about study enrollment . The FP will ask parents if she can reach out to them in 3 months to see if they desire services for the child at that time. If upon recontacting the family, they would like services and would like to work with the FP, the family will have the opportunity to enroll in the study and be randomized to a study condition.
Total Study Duration:	4.5 years (6 month start up period)
Subject Participation Duration:	12 months

3. Background/Rationale & Purpose

3.1 Background Information

Description of the health issue and research question. Significant disparities exist in access to mental health services for low income and ethnically diverse children. On average, low income and minority children are diagnosed later than their white, higher income peers, and experience substantial delays in initiating treatment – even after diagnosis.[1,2] Obtaining a diagnosis and engaging with treatment involves a number of complex steps, including: visits to primary care for screening, visits to a subspecialist for diagnosis, receipt of an individually-tailored treatment plan, and ongoing specialty support. Common barriers include availability of services, miscommunication, complex payment systems, and cultural bias. In addition, because children require coordination of the entire family unit across many systems (school, medical, community), unique challenges (e.g., parent stress, parent-provider communication) also exist for this population. Therefore, an individually tailored intervention, based on principles of engagement in mental health and family dynamics, is necessary to alleviate disparities for this population.

Research Question. Which FN components contribute meaningfully to improvement in access to child mental health services, defined as engagement in mental health service within 90 days after randomization.

Brief description of the study intervention: A paraprofessional model of family navigation for child behavioral health. FN is an evidence-based care management strategy designed to reduce disparities in care, and thus, represents a promising strategy to help low income and minority families access timely mental health services. Traditional navigation models utilize trained community health workers who assist families in overcoming systems and patient-specific barriers to a defined set of services over a time-limited period. Navigators - in the proposed study called "Family Partners" (FPs) – are paraprofessionals who share key attributes (cultural, language, lived experience) with the population served. FN is rooted in the Chronic Care Model [3] and has evidence in diseases such as cancer and HIV as a means to reduce disparities by shortening the interval between a positive screen (e.g., a mammogram for breast cancer) and definitive diagnosis. [4,5] Data from our group and others demonstrate that a

paraprofessional model of FN can reduce the time from screening to diagnosis and improve access to, and retention in, treatment services for a variety of child mental health disorders.[6-11]

Delivery of family navigation: *who*, *how*, *what,* and *why* does it matter? Despite the promise of FN to reduce disparities in access and engagement in services, studies demonstrate varying success or diminution of impact of FN upon implementation in real-world practice. [12-14] These findings suggest that a set of fundamental questions about FN still need to be answered. FN is a complex, multi-component intervention that incorporates motivational interviewing (MI), problem-solving, patient education, and care coordination. [5,15] Components can be delivered through a range of strategies, including: clinic-based meetings, home visits, telehealth, web technologies or mobile technologies. In this study, all participants will receive the same core FN intervention which will be delivered by one of two FPs. FPs will be trained in MI and problem solving techniques, child mental health conditions, community resources, and care coordination (see page 13 for a detailed description of core FN components). Families will be randomized to one of 16 combination of delivery strategies: Strategies include: (A) technology-assisted delivery of care coordination using an innovative, web-based platform called Act.MD that allows multiple users (parents, primary care clinicians, and schools, for example) to develop, communicate, and execute shared care plans (compared to usual care); (B) clinic based FN + community-based (compared to clinic-based only); (C) enhanced symptom tracking using more frequent behavioral symptom tracking by the FP (compared to standard pediatric surveillance) and (d)) individually tailored vs standardized, schedule-based visits with families (see Figure 3).

Understanding how to best deliver FN, which delivery components are most critical (and for whom), and what strategy to employ for implementation is essential for future dissemination. FN delivery can be costly and time-consuming, even in the best of circumstances. Learning how to optimize FN by determining which components are most effective is critical to its scalability and sustainability—and ultimately its success as a public health intervention. At the same time, understanding FN's cost as well as who benefits most is critical to decisions about how to optimally deploy available resources and generate the most equitable benefit. Answering these questions is a necessary step toward creating an optimized version of FN, one that aligns with the "triple aim"[31] of producing the greatest population impact at the lowest cost.

Pertinent prior experience with the intervention. From 2010 to 2017, our group implemented and tested multiple comprehensive care management systems for urban children and families with behavioral and mental health concerns (e.g., ADHD, ASD, maternal depression).[7,10,11,16-19] These studies used rigorous designs (e.g., comparative effectiveness, hybrid implementation-effectiveness) to test paraprofessional interventions (e.g., navigators, care managers) to assist patients beginning at the earliest detection of risk. Families were navigated from primary care, early intervention, and Head Start to specialty behavioral and developmental services. The goals of these intervention studies were to address person and systems-level barriers to accessing services among low income and minority children, and are similar to those of the proposed study (albeit targeted to a different condition). For example, in an NIMH R21, Drs. Feinberg and Silverstein piloted FN to help mothers with depression access mental healthcare.[20] In an NIMH R01, Drs. Feinberg and Broder-Fingert are conducting a hybrid implementation-effectiveness trial of FN to enhance access to services for children who screened positive for ASD in primary care.[21] Dr. Feinberg is currently directing TEAM UP, a multi-site pediatric behavioral health integration project in three federally qualified community health centers utilizing paraprofessional community health workers to improve engagement in services. These examples demonstrate the team's success in developing and testing strategies to improve early identification, treatment, and engagement for young children with behavioral concerns.

Importance of the study. Health service delivery reforms focused on primary care transformation - where primary care networks are promoted as the 'hub' of care coordination – are growing, and

financial incentives created under the Affordable Care Act are spawning new systems that link primary care and specialty services within integrated networks. For example, Accountable Care Organizations (ACOs)[32] are groups of doctors, hospitals, and other healthcare providers, who join together to give coordinated, high quality care. Developing Family Navigation (FN) within the setting of a newly formed ACO (Boston Accountable Care Organization) links this innovation to the broader policy context and maximizes scale-up potential within emerging delivery systems. Understanding implementation within this new context is critical to FN's ultimate success as a public health intervention and effectively and efficiently assisting families iin accessing behavioral health interentions..

Known risks and potential benefits. The proposed study offers minimal risk. It has the potential to assist participating families with access to child behavioral health services. The primary risk is breach of confideniality; therefore, we have planned for protections of confidentiality throughout study procedures.

This study will be conducted in compliance with the protocol, applicable regulatory requirements, and BMC/ BU Medical Campus Human Research Protection policies and procedures.

3.2 Rationale and Purpose

Importance and value of the information to be gained. Despite significant evidence supporting the effectiveness of FN, concerns exist about the ability to disseminate this intervention to a broad population due to inefficiency and cost. The current proposal is designed to test which FN components are most efficient and effective. This information then guides assembly of an optimized FN model, tailored to low income and racial-ethnic minority families, seen in primary care and in accessing mental health services that achieves the primary outcomes with least resource consumption and participant burden .

Innovating FN delivery through new methods and technologies. Our principal innovation involves use of a Multiphase Optimization Strategy (MOST) to identify the most effective FN delivery approaches. Although FN has been previously used successfully across a variety of mental and behavioral health conditions (e.g., ASD and ADHD), we are proposing to use a methodology—one that is conceptually rooted in engineering and that emphasizes efficiency and careful management of resources—to systematically study FN delivery and guide the development of an optimized intervention model of FN for child behavioral health services. At the same time, to promote future spread, we are deliberately testing FN within the Oregon Community Health Information Network (OCHIN), embedded in the HER, OCHIN is a healthcare innovation center designed to promote the dissemination of quality care for all. Use of these methodologies and technologies within the study population offers the opportunity to develop an optimized FN delivery strategy, grounded in empirical data, that can be disseminated and provide a solution for barriers to behavioral health care engagement for traditionally undeserved children and families.

4. Objectives

4.1 Study Objectives

Primary Objective: To identify which of the FN delivery strategies: (A) use of enhanced technology for care coordination vs. usual care; (B) community and home-based delivery vs. clinic-based delivery only; (C) intensive symptom tracking vs. low level symptom tracking; and (d)) individually tailored vs standardized, schedule-based visits with families contribute meaningfully to improvement in the primary outcome - access to child mental health services.
Secondary Objective: To evaluate the mechanisms of FN effectiveness and for whom it is effective.

4.2 Study Outcome Measures (See Table 1)

4.2.1 Primary Outcome Measures

Objective 1: To identify the most effective strategy to deliver FN

Our primary outcome measure is receipt of behavioral health services within 90 days (yes/no) will be defined as first encounter with behavioral health services within 90 days of randomization obtained from the electronic health record including Family Partner's template documentation.

Related to this primary objective, we will evaluate *time-to-receipt of behavioral health services* defined as time from randomization to first behavioral health service encounter obtained from the electronic health record, including family partner's template documentation. Dates will be obtained from administrative and billing data (electronic health records) for services within DotHouse, and FP documentation for services outside the health center.

A second primary outcome includes change in child symptoms over time.

- Pediatric Symptom Checklist-17 (PSC-17). A 17-item psychosocial screen designed to recognize cognitive, emotional, and behavioral problems. Three subscale Internalizing, Attention, and Externalizing have specific cutoffs and provide additional guidance regarding need for further follow-up. PSC-17 is embedded in the Epic (electronic health record) as a self-scoring form. It is widely used and has been validated in diverse populations.[23-26]
- The Survey of Wellbeing of Young Children (SWYC). The SWYC screens for cognitive, motor, language, and social-emotional development among children up to 5½ years of age. We will track behavioral symptoms using the SWYC's Preschool Pediatric Symptom Checklist (PPSC), an 18-item questionnaire that has demonstrated strong concurrent validity with the Child Behavior Checklist (CBCL) and parents' reports of socio-emotional diagnoses as well as acceptability in diverse populations. Translations are available in a range of languages and the SWYC is currently being incorporated into the Epic system used at DotHouse.

4.2.2 Secondary Outcome Measures

Objective 2a: To evaluate for whom the FN delivery strategy is most effective

Related secondary outcome measures include retention in services and satisfaction with FN

- Retention in services will be defined as ≥4 visits within 90 days after randomization, or resolution of service need, for children receiving psychotherapeutic or psychopharmacological services.[22]
- Satisfaction with Hospital Care Questionnaire (HCQ). The SHCQ addresses aspects of care including information, patient autonomy, and emotional support.
- Interpersonal Relationship with Navigator (PSN-I) is a validated 9-item scale with strong psychometric properties in samples of culturally diverse, underserved patients.
- Qualitative Parent Interviews: We will explore how cultural and linguistic concordance affects family engagement with mental health services and achievement of families' service goals. We will address this question qualitatively through hour long interviews with families about their experiences and perspectives working with a FP. We will purposively sample families for whom there was and was not cultural and/or linguistic concordance with the FP. These interviews are optional. Parents will have the option to consent to the qualitative interview at the time of enrollment. Parents may choose not to participate in the interview and still participate in the study. Families who agree to the qualitative interview will be contacted by our research staff at 6 months to schedule the interview. The interview will be done via BMC Zoom but will be audio recorded with a separate audio recording device. We will

conduct interviews in English, Spanish, and Vietnamese. Vietnamese interviews will be done using a phone interpreter who will interpret the questions and answers. After families complete the interviews they will receive a $20 Clincard to thank them for their time.

- Qualitative DotHouse Staff Interviews: We will interview different DotHouse clinic staff (providers, nurses, case managers, etc) to gather their perspective on the implementation of Family Navigation. These interviews will last approximately 30-40 minutes and will gather information on work flow changes for example. We will gain an understanding of the implementation of FN in a clinic setting. We will present the opportunity for these interviews during the clinic's all staff meetings and will contact providers by email to invite them to participate to the study. We will attach an exempt information sheet to the email. We will schedule interviews with interested providers and obtain verbal permission to participate and be audio recorded. Interviews will be done exclusively in English.

Table 1. Primary and Secondary Outcomes

	Outcome	Description	Measurement Source	Timing
Primary	*Time to services*	Time from randomization to first behavioral health service encounter	Electronic health record including FP's template documentation	90 days
	Access to services	1st encounter with behavioral health services within 90 days of randomization	Electronic health record including FP's template documentation	90 days
	Child symptoms	Score on PSC-17 and SWYC	Measures will be sent to families via Epic's mobile app MyChart or administered by Zoom/telephone in REDCap or sent to the parent by mail	Baseline 3, 6, 9, & 12 mo
Secondary	*Retention in services*	≥4 visits or resolution of service need for families receiving psychotherapeutic or psychopharmacological services	Electronic health record including FP's template documentation	90 days
	Patient Satisfaction	HCQ & PSN-I	Measures will be sent to families via Epic's mobile app MyChart or administered by Zoom/ telephone in REDCap or sent by mail	6 mo
	Qualitative Parent Interviews	Parent interviews to describe the effect of cultural and linguistic concordance between patients and FN.	Interview completed through Zoom/phone and audio recorded, stored in HIPPA compliant BOX drive.	6 mo
	Qualitative DotHouse Staff Interviews	DotHouse staff interviews to understand their perspective in the implementation of family navigation (work flow changes etc).	Interview completed through Zoom/phone and audio recorded, stored in HIPPA compliant BOX drive.	ongoing

Note: The PSC-17 is currently administered to children at pediatric well visits at DotHouse as part of usual care. Plans are to implement the SWYC in summer/fall of 2018. Both tools have been used extensively and research supports use for symptom monitoring.[27]

Objective 2b. To evaluate the mechanisms of FN effectiveness (assessment of mediators and moderators):

Consistent with a pragmatic design, we will use brief measures that align with standard clinical processes. Measures include:

Improve Parent Capacity:[28-31]

- The Parental Attitudes Towards Psychological Services Inventory—21-item validated questionnaire to assess help-seeking attitudes, help-seeking intentions, and mental health stigma. We hypothesize FN will improve attitudes and reduce stigma, leading to improved *parent capacity* to pursue services.
- Patient Health Questionnaire-2 (PHQ-2)—validated 2-question depression screening tool. We hypothesize that FPs will improve parent mental health by providing support and connection to resources, in turn improving *parent capacity*.

Increase Access to Resources:

- Family Resource Scale (FRS)—30-item scale assesses family concerns regarding adequacy of resources. We hypothesize that FN will improve *access to resources* over time.

Overcome Structural Barriers:

- Professional contact data. Using FN logs on contacts with others on the care team we will measure level of care coordination (number and frequency of contacts between care providers) and existence of barriers (as delineated in logs). We hypothesize that care coordination by the FP will mitigate structural barriers.

Table 2. Theory-based Mechanisms and Measures

Domain	Target	Theoretical	Instrument	Description	Timing
Person	*Parent capacity*	Improved parental attitudes about mental health increases capacity to engage in services	Parental Attitudes Towards Psychological Services Inventory	26-item questionnaire to assesses mental health attitudes and stigma	Baseline, 6, 12 months
	Parent capacity	Improved parent mental health increases capacity to engage in services	Patient Health Questionnaire-2	Validated 2-question depression screener	Baseline, 3, 6, 9, 12 months
Systems	*Access to resources*	Improving social determinants increases access to resources	Family Resource Scale	30 items assess adequacy of resources	Baseline, 6, 12 months
	Overcome barriers	Coordination decreases structural barriers	Electronic Health Record FP Templates	Contains resource use and care coordination activities	Monthly data reports

5. Study Design

Type of study design. Our design is a factorial experiment utilizing a multiphase optimization strategy (MOST). We will test the effectiveness of 4 FN delivery strategies using a randomized (2x2x2x2) full factorial design.

Study population and setting. This study will be conducted at DotHouse Health (DotHouse), a federally qualified community health center in one of Boston's most diverse neighborhoods. DotHouse serves >3,000 children in our target age range, of which >85% are racial/ethnic minority and report incomes ≤200% of the federal poverty level. In addition to medical services, the health center provides comprehensive child behavioral health services. Multilingual, multicultural social workers, licensed mental health clinicians, and a psychiatrist provide behavioral care in an onsite behavioral health department, behavioral health clinicians integrated within the pediatric primary care clinic provide assessment and brief intervention. DotHouse participates in Boston HealthNet, an integrated safety-net care delivery system that includes 13 health centers and Boston Medical Center, which provides primary and specialty care in Boston's urban, low income neighborhoods. In 2018, Boston HealthNet will become part of Boston Accountable Care Organization, a model of care designed to address the "triple aim" of improving patient experience, health, and reducing cost.

Rationale for study design and features. Specifically, we will use *Multiphase Optimization Strategy (MOST)*, a research method borrowed from the field of engineering, which relies on a randomized, multi-factorial design, and therefore facilitates our ability to simultaneously test the effectiveness of three novel strategies and combinations for delivering FN components. The design will also allow us to test varying combinations of FN factors, ranging from what we propose is the least innovative (core FN) to the most innovative (enhanced technology +community visits +enhanced monitoring). We will then evaluate which combinations of factors are most effective and efficient in regards to achieving the primary outcome (engagement in child mental health services). *This is also a pragmatic experiment.* Similar to pragmatic trials, FN will be integrated into routine clinic workflow and supported by standardized visit templates within the electronic health record which will assist with studying implementation and next steps for dissemination into other primary care and community health centers in the future.

Figure 3. Full factorial experimental design (3^2: 2x2x2)

Group	Experimental conditions			Effects of interest				Notes
	Factor A	Factor B	Factor C	A	B	C	A*B	
1	Standard FN	Standard FN	Standard FN	-1	-1	-1	+1	Least innovative model (standard FN)
2	Standard FN	Standard FN	Enhanced monitoring	-1	-1	+1	+1	
3	Standard FN	Community visits	Standard FN	-1	+1	-1	-1	
4	Standard FN	Community visits	Enhanced monitoring	-1	+1	+1	-1	
5	Enhanced technology	Standard FN	Standard FN	+1	-1	-1	-1	
6	Enhanced technology	Standard FN	Enhanced monitoring	+1	-1	+1	-1	
7	Enhanced technology	Community visits	Standard FN	+1	+1	-1	+1	
8	Enhanced technology	Community visits	Enhanced monitoring	+1	+1	+1	+1	Most innovative model

"Standard FN" = primary care based FN; "Enhanced technology" = additional use web portal ACT-MD; "Community visits" = visits at home or in the community; "Enhanced monitoring" = additional screening conducted by FPs between pediatric visits.

Randomization Process. Before initiation of FN and after obtaining parent consent, FPs will randomly assign each family an experimental condition using a computer program. The computer program will use both a randomly-generated number and "minimization procedures" to minimize imbalances across conditions with respect to target variables, including family/child characteristics (e.g., education,

gender, race/ethnicity, screening score). In this procedure, the first participant is assigned at random. Subsequent participants have a p chance of being randomly assigned and a 1-p chance of being automatically assigned to the condition that would most reduce imbalance based on selected sample characteristics. Minimization procedures are considered best practices for sequential assignment.[32-35] Families with more than one child enrolled will participate in the same random condition for all children.

Number of study groups/ arms and descriptions. Randomization across 4 binary factors results in 16 possible combinations of the 4FN delivery strategies (see **Figure 3**). In total, we plan to enroll 304 families: n=19 for each of the 8 cells. 304 families represent around 715 unique human subjects with 304 parent/legal guardian, 304 index children, 107 additional siblings for families with more than one child enrolled.

Planned variation in intervention strategy. As seen in figure 3 above, study participants will be assigned to varying combinations of intervention delivery strategies or factorials:
Strategy A - Care Coordination (Usual care v. Enhanced: Technology assisted);
Strategy B - Mode of Delivery (Clinic-based v. Clinic + Community); and
Strategy C - Symptom Tracking (Pediatric Surveillance at annual well-child visit v. Enhanced: Tracking at 3, 6, 9, and 12 months).
Strategy D: Visit structure (individually tailored vs standardized, schedule-based visits with families)

Methods for collecting data for assessment of study objectives. As seen in **Table 1**, data regarding use of services will be collected and obtained for analysis using the EHR. This EHR data will include FP's template documentation of FN activities, and service use measures (engagement in services measures). Clinical Measures will be sent to families via Epic's mobile app MyChart program, REDCap, administered via telephone or HIPAA compliant Zoom by the study RA or sent to the parent by mail with a return stamped envelope. Once the measures are received by mail, the responses will be manually entered into our RedCap database and the paper copies stored in a locked filing cabinet in a locked office. In cases where families are unable to use MyChart due to limited access to a computer or limited computer literacy and the FP will contact them and enter responses to measures into the appropriate EHR form or mail the parent a copy.

Assessment of fidelity to the Family Navigation core model and delivery strategies.
An important component of the procedures includes training of the family partners and assurance of fidelity. After completing a manualized training curriculum, we will assess fidelity to the Family Navigation model using methods employed in our ongoing navigation study (as well as two additional prior FN studies) and adapted for the current study. To assess content fidelity, we will adapt our Navigation Fidelity Checklist (NFC) to rate adherence to the 6 key components of the Family Navigation intervention outlined in our proposal: identification of family preferences for behavioral health services; support for access to behavioral health services, promoting engagement in evidence-based treatment; monitoring of family goals; family strengthening, and connection to concrete resources.

Adherence to the core components and the assigned FN delivery condition will be evaluated through review of structured navigation visit templates integrated into the electronic health record, FP contact logs, and via review of a randomly selected session between the FP and each patient that will be audio recorded for fidelity purposes . A random sample of 2 visits per month for each FP will be reviewed using the Navigation Checklist. In addition, the project manager will review reports of data abstracted from the electronic health record and the FP contact logs monthly to monitor possible contamination among study conditions. The integration of MI techniques into interactions between FPs and participating families will be assessed using audio recordings of sessions between the FP and parent. The interactions will be scored using the Motivational Interviewing Treatment Integrity (MITI), a measure validated for use in training

and supervision in implementing MI.[48-54] In order to support ongoing fidelity, FPs will meet bi-weekly with their supervisor and Dr. Rubin (a co-investigator and child psychiatrist at DotHouse) to review cases. If a FP is not meeting fidelity criteria, they will be provided with retraining and additional support. Once per year, FP will participate in an MI booster training session to maintain their MI skills.

6. Potential Risks and Benefits

6.1 Risks

The principle potential risk to participants is the **breach of confidentiality**. Although we will make every effort to store data in a secure and confidential manner, and to use de-identified data, breaches of confidentiality may occur accidentally. In order to protect participant confidentiality:

- All data collection from families will be conducted either using HIPAA compliant or encrypted technology (i.e. EHR, EPIC patient portal, MyChart patient communication tool embedded in Epic, REDCap, and Act.MD) or through direct administration of measures per family preference.
- Only coded data will be sent by DotHouse to the study investigators. The investigators will keep a mastercode/ cross walk for all enrolled participants which will be kept separately from the coded data.

Additionally, because the research covers the topic of mental health and potential psychosocial stressors participation may be **emotionally distressing** to individuals in the study. Although we will strive to maximize the cultural sensitivity in delivery of the proposed intervention, it is possible that, among parents, their explanatory models of their child's condition will be incompatible with our proposed intervention and even assessments. There is also the possibility that a concern of child abuse or neglect and the identification of suicidal or homicidal risk may be disclosed. Although we do not believe that these are direct risk or adverse events related to the intervention, we believe that they are important to anticipate and address. This has the potential to upset study participants. In order to address the potential for upsetting events potentially related to participation:

- We will make every effort to hire bicultural and bilingual (Spanish and Vietnamese) family partners in order to ensure that all families receive clear information about FN, their referral plan options and can adequately share their preferences and explanatory models of their child's needs.
- FP and all staff will be fully trained by the PIs and FN supervisor on how to work with children and families, including working with the families of children with behavioral health care needs, as well as the protocol for managing mandated reporting procedures for concerns of child abuse and management of emergency situations including suicidal or homicidal Ideation (see page 11, Section 10.2 Concerns about Abuse, Neglect, and Suicidality). In these situations the FP and staff will let the mandated reporters (PIs and responsible clinical staff at the health center) if such a concern is identified at the health center during routine encounter) know of these concerns/ emergencies in order to allow for appropriate management.
- Families will clearly be informed that they have the right to decline receiving FN services and still be able to continue their other clinical services at DotHouse without negative consequence.

6.2 Potential Benefits

The potential long-term benefits of this study plan outweigh its risks. All children who demonstrate behavioral health symptoms during screening OR whose parents express a concern will have the opportunity to receive services that exceed those currently provided. The FN support, which will be available to all participants, will likely assist the child and their family in coordinating and accessing appropriate behavioral health services. Specifically, children receiving FN services could benefit from screening and early identification of symptoms, working with the family partner and through the FN

supports, psycho-education, care coordination, access to and engagement with behavioral health services.

6.3 Analysis of Risks in Relation to Benefits

Subjects could directly benefit from FN and accessing behavioral health services. We believe the potential benefit outweighs the individual risk in this study.

7. Study Subject Selection

7.1 Subject Inclusion Criteria

We will be enrolling parent-child dyads and in the cases where more than one child is eligible parents can enroll all eligible children. Eligibility criteria are defined as:

- Children ages 3-12 years who screen positive on the Survey of Wellbeing of Young Children (SWYC) (3-5 years) OR Pediatric Symptom Checklist-17 (PSC-17) (6-12 years) OR whose parents indicate a behavioral health concern during any pediatric visit. These screens are conducted at every well-child visit as standard practice. They are embedded in EPIC and results recorded in the child's EHR. We include concern because data from minority and low income populations has shown that parental concern in combination with a screening tool can provide critical information about a child's mental health.[38]
- We will enroll children and parents regardless of language. Both the PSC-17 and SWYC are available in multiple languages including Spanish and Vietnamese. As we have in previous studies, we will use telephonic translation services as needed (for languages other than English, Spanish or Vietnamese). We have selected this specific age range (3-12 years) because we believe our FPs are well qualified to work with this group for two reasons: 1) our FPs have experience interacting with the school systems and children in this age range are served by the school systems (as opposed to children <3 who may be served by Early Intervention).

7.2 Subject Exclusion Criteria

Parent-child dyads in which the child meets any of the following criteria will be excluded from participation in this study:

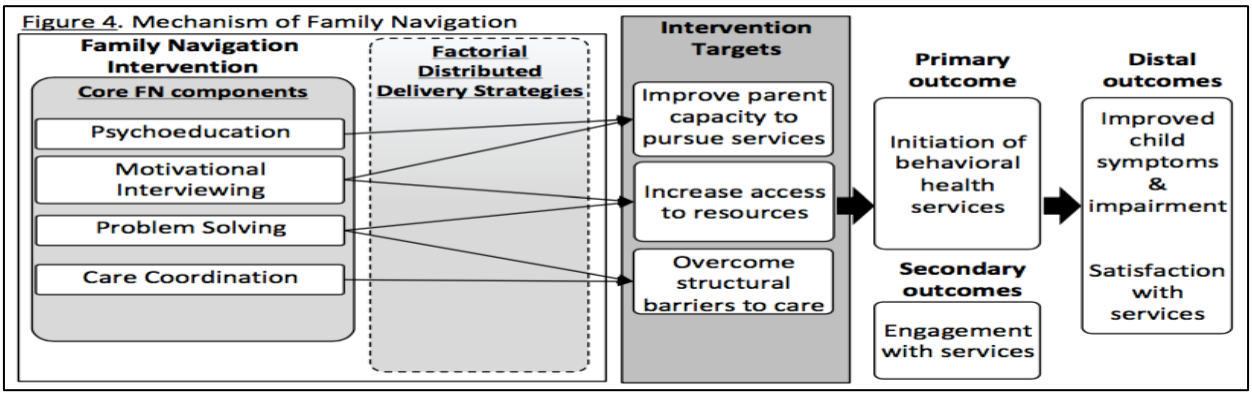
- Children who are already actively engaged in behavioral health specialty care services for which they are being referred, (e.g. a family may not be referred for behavioral health therapy if they are actively engaged in these services in the past 30 days) , children with active psychosis, or children with safety concerns requiring emergency mental health services. They *may* be referred if they are in need of *additional, new services* like school services.

8. Study Intervention: Family Navigation

Family navigation (FN) is care management designed to address barriers to services – in our study, behavioral health services. In this study, the core FN intervention will be delivered to all participants by study Family Partners (FP), a paraprofessional community member who is trained to support families of children with behavioral health. FN strategies to be tested will be delivered. Literature strongly supports the hypothesis that initiation of behavioral health services is directly influenced by several key domains, including: parents' motivation and capacity to pursue services (e.g., health literacy, mental health), families' resources and competing demands on their time, and healthcare system factors, such as difficulties scheduling timely appointments and barriers to communication.[28,39-43] Core FN components (see Figure 4) are designed to address these domains. For example, motivational interviewing is included

to increased parents' motivation to pursue services. Problem-solving strategies are introduced to improve parents' capacity to pursue services, and education addresses health literacy. Assistance with social determinants of health is essential for reducing competing demands on families' time (e.g., help with housing, benefits). Care coordination is focused on healthcare system factors and is designed to promote an activated care team. The components of the core navigation intervention, which all participants will receive, are described below.

Of note, the core FN intervention exceeds the current standard of care at the health center. Dothouse



employs care managers who assist families access behavioral health services and meet concrete resource needs. However, care managers are not routinely involved with all children with behavioral health concerns and they do not support engagement longitudinally.

- Universal Screening and Behavioral Health Referral**.** As described above, The FN intervention begins with a family-centered response to a positive behavioral health screening or parent report of a concern. The FP will provide psychoeducation and use MI to explore family preferences regarding further evaluation, and referral to behavioral health services.
- Support for Access to Behavioral Health Services. The FP will work with the family after referral from the pediatric clinician to access recommended services, support family preferences, and engagement in treatment through the creation of a Family Plan. FPs will employ problem solving strategies to assist families to resolve logistical barriers, MI to address hesitancy to engage in services, and provide care coordination including with schools and other providers.
- Engagement in evidence-based treatment. FN aims to support family adherence to the recommendation for further behavioral healthcare. The FP, who is trained in motivational interviewing and collaborative decision making, will use these skills to explore parental response to any identified concerns, with the goal of supporting parental engagement in the referral process and behavioral health treatment plan.
- Monitoring to achieve family goals. Active FN will continue until the goals articulated in the Family Plan have been achieved, at which point the FP will be available on as needed basis for up to 12 months.
- Family strengthening. FNs will refer families to local support groups and parent mental health services if needed.
- Connection to concrete resources: FPs, who will receive extensive training on available local resources and entitlements, will connect families to community-based resources (e.g., disability insurance, utility discounts).

We will test 4 **FN delivery components** in a highly efficient experimental design. Families will be randomized to one of eight combinations of components that will be delivered by FPs. The following is a description of the specific components.

Strategy A: Core FN v. Enhanced: Technology assisted. In core FN, FPs keep records and communicate with families using standard information technology, including telephones, electronic medical records, and standard desktop software. In the enhanced condition, FPs will also have access to Act.MD, a cloud-based care coordination and communication tool that offers the potential to improve communication with families, schools, and the primary care site through administration of online questions, videoconferencing, and common portals that can be used by parents and multiple providers (e.g., FP, pediatrician, teacher). Families randomized to have access to Act.MD will work with the FP to become familiar with the features of this technology. The FP will demonstrate how to set up the program on a SMART phone and a computer. She will obtain permission to reach out to school personnel in accordance with FERPA guidelines to introduce this technology to relevant school staff – e.g. the child's teacher or counselor. The FP will work collaboratively with the child's family and care team to determine how to utilize Act.MD to support the child and the family's goals. These features will incur additional costs for licensing fees and staff time, but we hypothesize it will also improvement cross system collaboration and engagement with services.

Strategy B: Clinic-based v. Enhanced: Clinic + Community. In core FN (i.e. Clinic-based), FPs will be restricted to working at the primary care clinic - communication will be restricted to telephone, text, and clinic visits. In the enhanced condition, FPs will be available to meet families in their home and community, and accompany families to community-based meetings at school or childcare (IEP meetings, parent-teacher conferences, meetings with in-home behavioral health providers) . While out-of-clinic visit may substantially increase costs due to the FP's travel (time and mileage), we hypothesize it will also improve engagement with services.

Strategy C: Pediatric Surveillance v. Enhanced: Tracking at 3, 6, 9, and 12 months. In core FN (i.e. Pediatric Surveillance at well-child visits), monitoring is determined by standard pediatric practice. In Massachusetts, behavioral screening is mandated at every pediatric visit, which for children in the target population (ages 3-12 years) is annually. In experimental conditions with "enhanced monitoring," FPs will screen children using validated instruments quarterly (SWYC, PSC-17 based on age) and communicate results to the child's care team. The screening tools will be deployed through MyChart , the EPIC EHR patient portal. Results feed directly into the child's record. Screening tools may also be deployed through REDCap or mailed to the parent in a sealed envelope with a stamped and addressed return envelope inside. Once the mailed parent measures are received by research staff at Boston Medical Center, they will be manually entered into RedCap and the paper copies will be stored in a locked filing cabinet in a locked office. The FP will be responsible for initiating and tracking the screening. She will message the child's PCP when new screening results are available and communicate with the PCP and care team regarding any changes in symptoms. We expect additional costs of increased monitoring to be modest, and that the additional information will allow care to be better aligned with children's symptomatology and, thus, lead to improved engagement with services.

Strategy D: tailored vs standardized, schedule-based visits with families. Families who receive tailored visits, will work with their FN on addressing issues as they arise. They will not have any pre-specified schedule for visits or contacts. Families who received standardized scheduled visits, will have a pre-specified schedule of visits. This will include monthly contacts with families for 6 months. Each contact will have a specified agenda which includes review of family goals, and a topic (e.g. what is an individualized education plan) to review.

Regardless of the combination of delivery components to which families are randomized (core or enhanced strategies), families will core FN elements.

9. Study Procedures

Study procedures are designed to align with existing health center workflow as much as possible.

Behavioral health screening. All children are screened for behavioral health concerns at all well child visits or episodic visits during which parents raise behavioral concerns. Behavioral health screening is part of routine care at the health center.

Referral to FP. If agreeable, families of children who are identified with a behavioral health concern during a primary care visit - either through a positive behavioral screen or parental concern - will be referred to the study.

Referral and consent can occur through two different pathways. For both pathways the member of the child's care team will provide a brief description of the study and ask permission for the FP to contact the family. [**SEE ATTACHED SCRIPT**] The member of the care team will explain that if the FP is available at the time of the visit, the FP will come in to meet with the family in-person. If the FP is not available, she will reach out to the family via phone. In both cases the referral and permission to contact will be documented through the health center's internal referral mechanism, which is utilized to refer families to health center-based ancillary services, including behavioral health and case management. The overall goal is to align referral and consent as closely as possible with existing workflows to reduce staff burden and support sustainability
Prior to beginning study enrollment, we educate the healthcare team about the study goals and procedures to refer families to the study. This education will be done at a pediatric team meeting. Study investigators will reach out to members of the healthcare team individually who are not present at the meeting to ensure all pediatric clinicians are aware of relevant study procedures.

Pathway 1 Warm handoff: This pathway will be utilized when the FP is available to meet with the family at the time that the concern is identified. The FP will meet in-person with the family.

Pathway 2 Telephone outreach: If the FP is not available to meet with the family, she will reach out to the family by telephone within 48 hours of receiving an internal referral.

Because some families will be referred for a behavioral health visit without referral to a FP, but may in fact benefit from a visit with an FP based on assessment by the behavioral health clinician, we will allow for the behavioral health provider at DotHouse to refer to the study. This provider will also be able to follow either Pathway 1 or Pathway 2 as described above. Any member of the child's care team may refer to the FP

Initial contact with FP. As much as feasible, the FP will meet with the child and family during the visit. If the FP is not available (e.g. evening/weekend visits,) the initial contact will be via telephone. During this visit/contact, the FP will describe this research study, including randomization to different study conditions, and obtain consent. The FP will obtain written consent and HIPAA authorization for all in-person meeting. The FP will obtain verbal consent for both study participation and HIPAA authorization when the initial contact is by telephone. (See INSPIR for further detailed description of recruitment, consenting, and randomization procedures.)

Families who decline participation in the study will have the option to work with health center care managers (instead of the study FPs) who also offer care coordination. Those families will not be randomized or followed as part of the study.

If during the discussion with the FP, the parent states that s/he is interested in the study but not interested in seeking behavioral services at this time, the FP will ask the parent if she can reach out to them in ~ 3 months to see if services for the child are desired at a later date. If upon recontacting the

family, they would like services and would like to work with the FP, the family will have the opportunity to enroll in the study and be randomized to a study condition. This group of parents will be called the "watchful waiting" group. The watchful waiting group will NOT be consented at the time of initial contact. If they are interested in pursuing services for their child at the time of recontact, the parent and child will be offered study participation at that time and will have the opportunity to consent to or decline participation. We have included this group based on our clinical experience. We find that many families wish to delay services for a number of reasons including life events (family moving, expecting a new baby) and timing (child going away for the summer, want services through school and school ending or not in session). We would like to make study participation available for such families.

The FP will administer the baseline assessment measures and then the family will be randomized (on an individual basis through a randomization generator centralized with the study statistician) to a study condition. If the family declines participation, the FP will refer the family to health center care managers and have no further contact with the family.

Randomization Procedures. Before initiation of FN, FPs will assign each family an experimental condition using a computer program. The computer program will use both a randomly-generated number and "minimization procedures" to minimize imbalances across conditions with respect to target variables, including family/child characteristics (e.g., education, gender, race/ethnicity, screening score). In this procedure, the first participant is assigned at random. Subsequent participants have a p chance of being randomly assigned and a 1-p chance of being automatically assigned to the condition that would most reduce imbalance based on selected sample characteristics. Minimization procedures are considered best practices for sequential assignment.[32-35] Families with more than one child enrolled will participate in the same random condition for all children.

Development of a service plan. In consultation with the primary care team and the pediatric integrated behavioral health clinician, the family partner will work with the family to collaboratively choose from a selection of referral options: onsite integrated behavioral health services with a clinician embedded in primary care pediatrics; onsite behavioral health services provided in the behavioral health department; school based services; and/or referral to an external behavioral health clinician or agency.

Ensuring linkage with service. The family will receive assistance with referral and coordination of care based on the child's needs and the family's interest. The FP will ensure that a referral is made, an appointment scheduled, support family engagement in services through such activities as text reminders and assistance with transportation.

Ongoing engagement with FP. Families' ongoing engagement with the FP will be guided by the core components of FN described above, family needs, and the study condition to which they were assigned. For example, some families will meet with the FP in the community, others will only do so by phone or in the clinic; some may use Act.MD to assist with care coordination with school or conduct remote visits, others will not have access to this technology. Based on our previous experience, we expect considerable variation in the intensity of engagement among families. The FP will have a manualized intervention workbook that will help guide their interaction with families. The FP will document all FN activities and contacts in a FN log within the EHR. We expect that the range of ongoing activities might include assistance in obtain school evaluations and necessary accommodations (504B plan, IEP); linkage to community-based supports such as parent groups and recreational activities; trouble shooting challenges to accessing services; and coordinating services between primary care, school, and specialty services. The Family Partner will also complete a Family Needs worksheet that will used to summarize the amount of support required by a family. This worksheet will not be administered to participants but may be used as process data by the research team.

Collection of research measures. Families will complete research measures based on the schedule outlined in Table 1. Measures that currently exist in OCHIN EPIC (for example PSC, SWYC, PHQ-2) will be administered through MY CHART, with default to telephone administration or mailed to the parent. Measures not available in OCHIN EPIC will be administered by telephone or through Zoom by a RA blinded to study condition or via REDCap or mailed to the parent with a stamped and addressed envelope to return to research staff at Boston Medical Center. Once the measures are received we will manually input the responses into RedCap and store the paper copies in a locked filing cabinet in a locked office. We expect that the full battery of measures will take less than 15 minutes to administer. Research measures include follow-up PSC -17 and SWYC measures; Parent PHQ2, Satisfaction with Hospital Care Questionnaire, Client Satisfaction with Navigator, Family Resources Tracking.

Participant Timeline. (See Appendix A).

COVID-19. During COVID 19, the initial encounter (consent conversation) and subsequent contacts with enrolled families may be done over HIPAA compliant Zoom. Follow-up measures administered by an RA may also be done over HIPAA compliant Zoom. The conversations will not be recorded.

Optional Qualitative Interviews:

- Qualitative Parent Interviews: Families will have the option to consent to the optional qualitative interviews at the time of consent. They will be contacted by research staff at 6 months to schedule the interview. Interviews will be an hour long and ask about cultural and linguistic concordance. They will be audio recorded and stored in BOX, a HIPAA compliant web storage. We will conduct interviews in English, Spanish and Vietnamese, the Viet interviews will be done using a phone interpreter. After families complete the interview they will receive a $20 Clincard to thank them for their time.
- Qualitative DotHouse Staff Interviews: We will interview different DotHouse clinic staff (providers, nurses, case managers, etc) to gather their perspective on the implementation of Family Navigation. These interviews will last approximately 30-40 minutes and will gather information on work flow changes for example. We will present the opportunity for these interviews during the clinic's all staff meetings and will contact providers by email to invite them to participate to the study. We will attach an exempt information sheet to the email. We will schedule interviews with interested providers and obtain verbal permission to participate and be audio recorded. These interviews will be done exclusively in English.

10. Assessment of Safety and Data Safety Monitoring Plan (DSMP)

10.1 Definitions

This is a non-medical study and so not all of the following definitions will be as applicable in the assessment of safety.

Adverse Event (AE) is any untoward or unfavorable occurrence in a human subject, including any symptom, disease or event, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Life-threatening means that the event places the subject at immediate risk of death from the event as it occurred.

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:

- is unexpected; AND

- is related or possibly related to participation in the research; AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures (or interventions) involved in the research.

Unexpected means the nature, severity, or frequency of the event is not consistent with either:
- the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
- the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

For the current study, the most important adverse events to monitor are:

- Breach of confidentiality.
- Psychiatric hospitalizations which have the potential to increase through participation in the study, however this may be a result of improved screening, identification and engagement in clinical services.

10.2 Safety Review

Both the risks listed in Section 4.1 and unknown risks will be monitored as follows:

DATA AND SAFETY MONITORING PLAN

Because this project is a clinical trial, includes a clinical intervention, Family Navigation, and aims to enroll a vulnerable population, the inclusion of a Data and Safety Monitoring Plan and Board is appropriate and required by the funder, NIMH. The Data and Safety Monitoring Board (DSMB) will include an independent group of experts on child behavioral health, clinical trials, and biostatistics, who will advise and monitor the project with the study principal investigator (Feinberg). None of the members will directly supervise, report to, or directly collaborate with the PIs. The DSMB will meet every six months. Its primary responsibilities will be to: 1) review and evaluate the accumulated study data for participant safety, study conduct and progress, and efficacy; and 2) make recommendations concerning the continuation, modification, or termination of the trial. In this proposed project the DSMB will consider: study-specific data and any concerns for poor clinical outcomes among patients in a particular randomization condition.

As part of their responsibility, DSMB members will ensure the timeliness, completeness, and accuracy of the data submitted to them for review. Members will ensure submitted data are sufficient for evaluation of the safety and welfare of study participants. The DSMB will also assess the performance of overall study operations and any other relevant issues, as necessary.
Specific items to be reviewed by the DSMB will include:
- Interim/cumulative data for evidence of study-related adverse events;
- Interim/cumulative data for evidence of efficacy according to pre-established statistical guidelines;
- Data quality, completeness, and timeliness;
- Adequacy of compliance with goals for recruitment and retention, including those related to the participation of women and minorities;

- Adherence to the protocol;
- Factors that might affect the study outcome or compromise the confidentiality of the trial data; and
- Factors external to the study such as scientific or therapeutic developments that may impact participant safety or the ethics of the study.

After each meeting of the DSMB, members will meet without the study PIs and provide them with a written letter of recommendations. (See Appendix C for DSMB charter)

Additional Protections for Children. Children between the ages of 3 and 12 of age and a parent will be recruited and enrolled in this study. All parents, even those considered minors, have the right, according to state law in the jurisdictions where the study will be implemented, to consent to treatment for themselves and their child. We have enrolled such parents in our previous studies, which have been reviewed and approved by the Boston University Medical Center IRB and without any adverse events. Given that the study poses minimal risk and has the potential to benefit this vulnerable populations we would include them in the current study. To provide additional protections, we will assure that the investigative team has the appropriate expertise to deal with children and parents. All of the investigators are licensed clinicians. The family partners will be parents themselves; thus, they will be experienced working with children. The study facility will be appropriate to children, as these facilities will be either families' homes or pediatric healthcare sites. We will make sure that all psycho-educational materials, treatment plans are written in a straightforward manner, at the appropriate literacy level and language to ensure parents can understand any referral or care recommended for their children. We will use translators/language line as needed to further ensure parents can fully understand study procedures and communicate any concerns about their child's care.

Because our focus is on children with early symptoms of behavioral health problems, we have targeted children in an age range when they are likely to have symptoms newly identified and diagnosed. All parents, even those considered minors, have the right, according to state law in the jurisdictions where the study will be implemented, to consent to treatment for themselves and their child. Therefore, parents between the ages of 16 and 18, who are the legal guardians of the child referred for assessment, will not be excluded based on age; thus, it is possible that we will enroll parents who are under 18. Young parents often face additional barriers accessing health services for their children. For this reason, we plan to enroll parents in this age group in the study. Of note, we have enrolled such parents in our previous studies, which have been approved by the Boston University Medical Center IRB and without any adverse events. Therefore, we are confident that protocols for the proposed research will be ethical, lawful, and will be approved by the institution's IRB.

All of the investigators are licensed clinicians and are mandated reporters of child abuse and neglect. Family Partners will be parents themselves; thus, they will have extensive experience working with children. As part of family partner training, Dr. Fortuna and Dr. Rubin (Dr. Rubin is a child psychiatrist at DotHouse and a co/investigator on this project) will provide training on working with the families of children with behavioral healthcare needs, as well as mandated reporting procedures and management of emergency situation. All facilities used in the study will be appropriate for children, as these facilities will be either families' homes or pediatric healthcare sites. We will make sure that all study materials are written in a straightforward manner, at the appropriate literacy level. All patient-facing materials describing the project will be designed to ensure they are culturally responsive.

Concerns about Abuse, Neglect, and Suicidality. We do not expect child abuse and neglect or suicidality to be a risk of the interventions of the study. However, since children and families with behavioral issues may be at greater risk for abuse or suicide, we will ensure that our a research staff will all be trained on signs of abuse, neglect, and suicide risk and the emergency procedures to follow in the event that research staff have concerns about abuse or neglect or a study participant discloses suicidal or homicidal thoughts or plans. In the proposed study, children and families may be seen either in the

health center or in the community therefore the safety plan will include procedures for both settings. At the health center, we will follow the health center's emergency protocol, which involves contacting the clinician on-call for mental health emergencies. The clinician is available during all health center hours to conduct emergency assessment and determine appropriate next steps. For mental health emergencies identified outside of the health center, study staff be trained to contact Dr. Rubin, who will assess for imminent risk and develop a plan for referral. Dr. Rubin is available by pager. In the event that clinicians are not available or cannot be contacted, the staff will be trained to call the Boston Emergency Services Team or the Department of Children and Families hotline, both of which is available 24 hours a day to evaluate the mental health and child protection emergencies and intervene immediately. Dr. Rubin will be contacted by research staff regarding all such events to review the handling of such events and provide additional guidance and support to the study staff.

10.3 Reporting Plans

The Principal Investigator at BMC/BU Medical Campus will report Unanticipated Problems, safety monitors' reports, and Adverse Events to the BMC/BU Medical Center IRB in accordance with IRB policies:

- Unanticipated Problems occurring at BMC/BU Medical Campus involving a fatal or life-threatening event will be reported to the IRB within 2 days of the investigator learning of the event.
- Unanticipated Problems occurring at BMC/BU Medical Campus not involving a fatal or life-threatening event will be reported to the IRB within 7 days of the investigator learning of the event.
- Reports from safety monitors with recommended changes will be reported to the IRB within 7 days of the investigator receiving the report.
- Adverse Events (including Serious Adverse Events) will be reported in summary at the time of continuing review, along with a statement that the pattern of adverse events, in total, does not suggest that the research places subjects or others at a greater risk of harm than was previously known.
- Reports from safety monitors with no recommended changes will be reported to the IRB at the time of continuing review.
- The Principal Investigators will report Unanticipated Problems and Adverse Events to the safety monitoring board Data Safety Monitoring Board which will meet every 6 months (see attached DSMB Charter, Appendix C).

10.4 Stopping Rules

The study has no stopping rules, but will follow the rules and guidelines of the funding entity, National Institute of Mental Health, and the rules and guidelines of each research ethics entity involved in this study.

11. Data Handling and Record Keeping

11.1 Confidentiality

Data collection, management, and protection. All participants will be assigned a unique study code. This study code will be used to link data from the EHR, billing records, and Act.MD. The crosswalk that links study codes to participant names will be held by the PIs of the study and separate from the data. It will be kept in a locked office. This crosswalk will be kept for the duration of the study and kept for at least 7 years before being destroyed. The study PIs will be responsible for ensuring that it is shredded or otherwise destroyed. Any paper surveys and consent forms will be transferred the same day that they are completed to a locked file cabinet in the locked office of Dr. Feinberg, one of the study PIs.

All data obtained from DotHouse will be stored on a HIPAA compliant, password protected, secure hard maintained by Boston Medical Center.

Mailed Questionnaires: We will address the return envelope of the participant measures with our BMC office address in both the sender and return address. This would prevent parents from writing in their names or personal addresses as well. We will also instruct families not to write their names nor their child's name in any of the surveys. We will pre-label all questionnaires with their unique study ID. During the phone call where we confirm with families that they would like a mailed option, we will ensure to make it clear that there is no need to any other information aside from the answers to the questions. As mentioned before study staff will collect the questionnaires that are mailed in the office and will enter the data in RedCap. Once that is complete we will store the paper documents in Dr. Emily Feinberg's locked office in a locked filing cabinet.

Access to individually identified private information. Only the PI and study staff who have been trained in HIPAA regulations and human subjects protections will have access to individually identifiable information about study participants. This information will only be available after participants have consented to study participation. For all sources of data described above, all personal identifiers will be removed (e.g. name, DOB, address, SS#) and names replaced by ID codes at DotHouse prior to being released to the investigators. Furthermore, identifying information will not be shared with others outside this research study. FPs will have access to the DotHouse EHR in order to document their work with families. In addition to completing HIPAA and human subjects training, FPs will also adhere to any additional DotHouse confidentiality procedures and FERPA guidelines in any interactions with schools.

For all study data, the following safety procedures will be used:

- All hard copies of data will be kept in a locked file in a locked office
- All electronic data will stored on HIPAA complaint, password protected cloud storage system

The study protocol will be registered and updated on ClinicalTrials.gov.

The study monitor or other authorized representatives of the sponsor may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the subjects in this study. The clinical study site will permit access to such records.

Study staff will work with BMC IT to ensure that all technology devices used to communicate with patients (for example, cell phones) or that contain PHI are encrypted and compliant with institutional privacy policies. New and current staff will review confidentiality and privacy measures on a quarterly basis with the research team and ongoing as needed.

11.2 Source Documents

This study includes data collection and management tools that also meet HIPAA security rules to protect confidentiality and security of protected health information.

Electronic Health Record (EHR): Data will be abstracted from the EHR of children including diagnoses (from the child's problem list), basic demographic data, and information on scheduled appointments, missed appointments, screening tools administered, screening results, referrals made, referrals completed, billing codes, and surveys collected through MyChart, the EHR's patient portal. MyChart is an interactive system integrated into the patient EHR (Epic/ OCHIN) and offers patients personalized and secure on-line access to portions of their medical records and also allows providers to send messages and to communicate with patients. MyChart will be used to communicate with families, conduct screening, and monitor symptoms, and track study outcomes / measures. Epic/OCHIN is a fully encrypted, HIPAA compliant system. EHR records at the health center are further protected by firewall

technology. The study investigators will only receive de-identified, ID coded MyChart collected data from DotHouse.

All data will be provided by DotHouse to the study investigators in ID coded form.

FP visit templates**:** FPs will document in the EHR the details of the eight tasks outlined in protocol manuals: 1) initial encounter, 2) assessment of barriers, 3) plan to address barriers, 4) referrals to service (type and location) 5) confirming appointments scheduled, 6) confirming appointments attended, 7) post-assessment follow-up, and 8) connecting with treatment services. De-identified logs will be scored by study staff to measure the number and nature of completed tasks by the FP.

BACO billing data: We will triangulate BACO billing data with EHR data documenting service use. BACO data will allow us to capture behavioral health services provided outside of DotHouse. BACO billing data will be de-identified by staff at DotHouse who are responsible for maintaining the cross walk between patient name and study ID.

Data from Act.MD: ACT.md allows for data capture and reporting, including patient demographics and assessment data. Dynamic patient-centered care plans and project management functionality allow care teams to track goals, activities, events and referrals. Act.MD also offers panel management capabilities, event notification and tracking, and appointment management capabilities. Data will be abstracted from the Act.MD on care coordination information, frequency of parent and care team use. Act.MD is not part of the EHR and uses patient names. A cross-walk that links study IDs to participants' names will be kept locked at DotHouse and used to link data from Act.MD to data obtained from EHR and billing data prior to releasing these data to the study investigators. Only after obtaining parental release of information, will the FP use Act.MD to coordinate with schools and other care providers outside of DotHouse. Confidential data transmitted outside of DotHouse networks will be encrypted. Transmission of confidential data to an entity outside the DotHouse networks is permitted if the sender has determined that all the following conditions are met: the receiving entity has been authenticated; the receiving entity is aware of the transmission and is ready to receive the transmission; and the sender and the receiver are able to implement a compatible encryption and decryption mechanism. All Act.MD data are encrypted at rest. Because it is possible that we may obtain data from schools, we will ensure that all data collection and data sharing comply with FERPA guidelines.

Procedures will ensure that source data meet the “ALCOA” standards: Attributable, Legible, Contemporaneous, Original, and Accurate.

REDCap: We will be using a web-based database to track upcoming tasks and remind the family partners of tasks they need to complete with each family, such as sending questionnaires to families and upcoming visits. The database application, called REDCap, uses MS SQL Server as the back end relational database. The program can support one or more research studies, is presently being used at dozens of major academic research centers to support numerous NIH funded projects and is available commercially. The HIPAA privacy rules and HIPAA security rules mandate that covered entities have in place appropriate policies and procedures to protect the confidentiality and security of protected health information. In compliance with these regulations, the database security features of REDCap target multiple levels including the data element (e.g. restricted access to fields), user (e.g. password authentication access), application (e.g. role-based access to features, access audit trails), and hosting services (e.g. firewall, secure sockets layer). Taken together, these features ensure access control, audit control, data integrity, user authentication, and transmission security.

BOX: Interview transcripts and recordings will be stored in BOX, a HIPAA compliant cloud storage platform. Once interviews are transcribed and de-identified, the recordings will be destroyed.

11.3 Study Records Retention

All study records will be retained for seven years after completion of the study. Documentation of informed consent of subjects will be retained for at least three years after the study is closed. Such records are preserved as a combination of hardcopy, and electronic form and will be accessible for inspection and copying by authorized individuals.

12. Statistical Plan

12.1 Study Hypotheses

Within each factor, we hypothesize that one condition will be more effective in assisting families in accessing mental health services than the other (Enhanced: Technology assisted > usual care; Clinic + Community > Clinic-based; Enhanced: Tracking > Pediatric Surveillance).

12.2 Sample Size Determination

Sample Size and Power.

Of the three measures to operationalize engagement, we powered our study on the dichotomous variable "receipt of BH services within 90 days" - the most conservative estimate. We base our power calculation on the number needed to detect the smallest differences in primary outcomes that are of clinical importance. Our formative work with staff at DotHouse and other community health centers indicates that a relative risk of approximately 25% would be considered clinically significant. Therefore, if 60% of families in the core navigation condition engage in mental health services (estimates based on our prior work), to detect a 25% difference (i.e. 75% of families in any of the FN delivery conditions engage in services), and assuming 2-tailed tests and a type 1 error rate of 5%, approximately 304 participants are required to detect this effect (n=38 in each of 8 cells). Although 304 participants are required for our power analysis, we will be enrolling 715 human subjects which include 304 parent/legal guardian, 304 index children for primary analysis and around 107 siblings for families with more than one eligible child. Additional sibling analysis will be done to explore differences in service goals etc.

We expect strong effects of study mediators, in particular fidelity variables and variables that are central to our theoretical model, such as increased parent capacity. Following published guidance based on an empirical review,[44] we estimate that our design will have at least 80% power to detect mediation effects where the paths from independent variable to mediator and from mediator to outcome are of at least small-to-medium effect (ES=.26). Given that our mediation analyses are designed to support decisions regarding intermediate outcomes to be tracked for quality control and assurance, effect sizes less than this magnitude are not considered to be clinically important. In contrast, analyses of patient-level treatment moderators are exploratory as we have no evidence to support hypotheses of any effect.

12.3 Statistical Methods

Overview. All statistical analyses will be done in SAS (v9.4) and Mplus (v8). Baseline characteristics of parents and children will be compared across experimental conditions to assess balanced randomization. Characteristics include: race/ethnicity, insurance status, primary language, and child characteristics (e.g., screening scores). Because of the minimization procedures we propose to assign participants to experimental conditions, we expect no significant differences on these variables; nevertheless, we will test for differences in baseline characteristics across conditions. Plots and histograms will be used to explore any non-linear relationships in the distributions of these variables across conditions.

Objective 1: Effectiveness of FN delivery strategies.

Following an intent-to-treat model, multiple regression models will be used to test hypotheses regarding the main effects of the three delivery strategies and their combined effects on the study's primary outcome, engagement in appropriate mental health services. A series of increasingly complex models will be constructed to address each specific index of outcome. For example, a logistic regression analysis will test receipt of behavioral health services within 90 days. Cox regression (proportional hazards) analyses will then be used to test the effect of each factor on time-to-scheduling date, and then on time-to-receipt of behavioral health services (with *time to third-next-available appointment* included as a covariate). Given that children may be referred to behavioral health services beyond those designated as primary in their initial visit, multi-level models will then be constructed with time-to-receipt of each behavioral health service as an outcome and with services clustered within child. Similarly, engagement in services will first be analyzed with logistic regression using our definition of engagement in care as a binary outcome, with subsequent multilevel models to analyze engagement in multiple services.

For outcomes involving engagement with services, sensitivity analyses will be conducted in which missing data from the EHR is interpreted as failure to engage in services. While we do not hypothesize interactions among the delivery strategies, these will also be explored. Following recommendations for factorial designs, effect coding (not dummy coding) will be used for experimental conditions to assess for interaction. In addition to evaluating effects "at the margins" using all available cells, results for each individual cell will also be reported,[45] as will simple main effects.

Objective 2: Mediator/Moderator Analyses.

Examination of intervention mechanism. Consistent with our theoretical model and based on our prior studies and literature review, we hypothesize that FN intervention effects will be mediated by parents' capacity to pursue services, access to services, and structural barriers. We will examine meditational effects using two different, but related, methods: the approach of Baron and Kenny and the use of path analysis models. Each approach can be used to differentiate between direct and indirect intervention effects. In the path analysis models (which have greater statistical power), we will create a series of nested models based on our theoretical model in which we will systematically vary model parameters and constraints to test the effect of each potential mediator. Nested models will be compared using difference tests and other standard indices (Akaike's Information Criterion, the comparative fit index (optimal value > 0.95), the Tucker-Lewis index (optimal value > 0.95), and the root mean square error of approximation (optimal values < 0.06)). We will fit these models with MPlus software, which allows for the modeling of continuous and dichotomous, endogenous, and exogenous variables. While our study design only allows for direct testing of the causal effects of primary delivery strategies A, B, C, the causal effect of mediating variables can be analyzed by treating factors as instrumental variables in the path analysis.[46,47] Results will directly inform choice of final variables for statistical process control charts to be refined in Aim 3 and investigated in future studies as a quality control method.

Moderator analyses. We will evaluate the extent to which each delivery strategy, race/ethnicity, primary language, and symptom severity moderate FN effects using stratified analysis. Previous studies have found no effect of such demographic variables on the effect of FN. We hypothesize that any effects will be small and clinically non-significant yet will perform these analyses as evaluation of moderators is important to ensure equity.

Approach to missing data. Given our reliance on EHR and billing records rather than self-report to assess primary outcomes, we anticipate relatively little incomplete data in primary analytic variables. Nevertheless, initial analyses will also compare participants with complete data with those who are missing outcome data. We will explore and summarize the extent of incomplete data and use multiple imputations if they are deemed appropriate. Such methods allow for the calculation of unbiased estimates despite many types of missing data.

13. Ethics/Protection of Human Subjects

This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines).

Consent Process

If agreeable, families of children who are identified with a behavioral health concerns during a primary care visit - either through a positive behavioral screen or parental concern - will be referred to the study. Referral and consent can occur through two different pathways:

Pathway 1 Warm handoff: This pathway will be utilized when the FP is available to meet with the family in a private space at the time that the concern is identified. The FP will meet with the family, explain the study, and obtain written consent, child assent (with explanation of the study offered to children ages 2 and older in an age appropriate manner) and obtain HIPAA authorization.

Pathway 2 Telephone outreach: If the FP is not available to meet with the family, she will reach out to the family within 24 hours of receiving an internal referral. For these families, we are requesting approval for verbal consent for study participation and a waiver of child assent. We will obtain written HIPAA authorization when families are seen later in person and prior to obtaining additional PHI.

In both cases The PCP (or integrated behavioral health clinician) will complete an internal referral form using the health center's internal referral mechanism in EPIC (electronic medical record). This mechanism, which is accessed through EPIC's orders module is already utilized to refer families to health center-based ancillary services, including behavioral health and case management. We will work with DotHouse Health IT to develop a new referral form, similar to one that we have used in our autism study, Project Early. [SEE SAMPLE TEXT] for the current study. The completed form will be routed to the FP, as a record of permission to contact.

SAMPLE INTERNAL TEXT
This is an internal referral that will enable your patient to be referred to the Navigation research study and connected one of the Navigation Project's Family Partners.

Eligibility: Children ages 3-12 years who have a positive behavioral health screen or parental concern about their child's behavior or mental health

Purpose: To test different ways to support engagement in behavioral health services

Benefits: Family will be provided assistance to connect with behavioral health services

Compensation: None

Child's Name:
Child DOB
Parent/Guardian Name:
Phone Number:
Best time to call:
Language Preference:

Reason for referral:

As a pragmatic trial, the overall goal is to align referral and consent as closely as possible with existing workflows to reduce staff burden and support sustainability. Therefore, PCP will complete the internal referral form in EPIC for any patient who 1) the PCP thinks would be eligible for the study based on inclusion criteria, and 2) family agrees to have their information shared with the FP (research staff). To ensure that the rights of families are honored, we will educate pediatric clinician about referral procedures, emphasizing the need for families to give permission for the FP to contact them.

We are requesting a HIPAA waiver for the use of the internal referral form for contacting potentially eligible families. It would be impractical to obtain a signed HIPAA consent from all eligible families given the busy CHC clinical work flow and the pragmatic nature of this trial. However, research staff will need to access a limited number of identifiers in order to later contact the referred families. Specifically, the following identifiers are needed: MRN (to access chart), name, DOB (to confirm age eligibility) and phone number. All identifiable information associated with the internal referral form will be transmitted, stored, analyzed, or otherwise exist only in EPIC, a HIPAA-compliant electronic system that meet the standards for protection of PHI at DotHouse. The referral form and the associated PHI will remain in EPIC and in the child's medical record. If identifiers are in any case taken from the referral form, printed or recorded on paper, it will be destroyed as soon as eligibility has been determined for potential subjects.

If during the discussion with the FP, the parent states that s/he is not interested in seeking behavioral services at this time, the FP will ask the parent if she can reach out to them in ~ 3 months to see if services for the child are desired at a later date. If upon recontacting the family, they would like services and would like to work with the FP, the family will have the opportunity to enroll in the study and be randomized to a study condition. This group of parents will be called the "watchful waiting" group. We have included this group based on our clinical experience. We find that many families wish to delay services for a number of reasons including life events (family moving, expecting a new baby) and timing (child going away for the summer, want services through school and school ending or not in session). We would like to make study participation available for such families.

Only after the consent process is complete will the child and family be randomized. For parents who have more than one eligible child that participants, all children will be assigned to the same random condition.

We will use the parent consent form version which includes both parent and child as subjects of the study. We will conduct verbal consent if patient is contacted by phone (See Consent Form--Verbal) or written consent and assent if the initial visit with the parent is in person. For parents who have more than one eligible child they would like to participate, we will obtain a consent form for each unique child.

The study will recruit children between 3 and 12 years of age and a designated parent/ guardian for each child. One parent may consent more than one child into the study. It will not involve prisoners or institutionalized individuals. The study could involve two populations considered to be vulnerable: pregnant women and children.

Pregnant women. Although the study will not specifically target pregnant women, given that the study enrolls young children and their families, it is possible that a mother could be pregnant. Such women will not be excluded. Women of childbearing potential will be entitled the same protections as listed above. We foresee no extra risk of the study for a woman of child bearing potential than it is to anyone else.

Children. This research targets children, and their caregiver/legal guardian, who are being offered FN supports for accessing behavioral health services. Parents between the ages of 16-21, who are the legal guardians of the child referred for assessment, will not be excluded based on age; thus, it is possible that we will enroll parents who are under 21. Young parents often face additional barriers accessing health services for their children. For this reason and according to state law in the jurisdictions where the study will be implemented, we plan to enroll parents in this age group in the study. We have enrolled such parents in previous studies, which were reviewed and approved by the Boston University Medical Center IRB, without any adverse events. Therefore, we are confident that protocols for the proposed research will be ethical and lawful, and will be approved by the participating institutions' IRB.

For children who are enrolled in the study as participants, we will assure that the investigative team has the appropriate expertise to conduct research with children. All of the investigators are licensed clinicians and are mandated reporters of child abuse and neglect. Family Partners will be parents themselves; thus, they will have extensive experience working with children. As part of family partner training, Dr. Fortuna and Dr. Rubin will provide training on working with the families of children with behavioral healthcare needs, as well as mandated reporting procedures and management of emergency situation. All facilities used in the study will be appropriate for children, as these facilities will be either families' homes or pediatric healthcare sites.

In addition, we will obtain formal assent from children for whom the study consenting process is done in-person during a clinic visit based on their cognitive ability to understand that their parent is seeking assistance to find services to help address their behavioral or emotional concerns.

For the children for whom assent is appropriate, we will explain the study in simple terms appropriate for child's developmental level. We expect that the detail of this explanation will vary given the age range of eligible children. The primary points that we will make sure all children understand are:

1. this research study involves helping their parent(s) find behavioral or mental health services that they believe will be helpful for their child;
2. families will get different combinations of assistance; the exact combination will be decided randomly - like flipping a coin;
3. the FP will assist their parent connect to services but will not be providing any direct services to the child;
4. participation is voluntary and their parent can decide to stop at any time without any negative consequence.

We will not obtain assent from children for whom the study consenting process is done via telephone. As a pragmatic trial, we believe that it is not practical to do obtain child assent when the consenting process is done via phone. It is very likely that the child will not be present at the time of parental consent - e.g. child is at school; child is playing elsewhere; parent and child are not in same location. In addition, parents routinely make final decisions about what is in the best interest of their child's health, thus the rights and welfare of the child are sufficiently protected by only having the parent consent.

This protocol and any amendments will be submitted to the Boston Medical Center and Boston University Medical Campus IRB, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator. A copy of the initial IRB approval letter will be provided to the sponsor before commencement of this study.

Protecting right of withdrawal

The study team will stress that participation in the study is entirely voluntary, that participants will be permitted to withdraw consent and leave the study at any time without incurring any negative effect on their care. Potential participants will be also told that they are free to take breaks and/or terminate the consent process. If at any time the potential participant is not interested in the study, the team will thank them for taking the time to hear about the study and then record information about why they were not interested in participating.

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Appendices

Appendix A. Schedule of Events/Timeline for Child and Patient during Intervention

Months	*Baseline*	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*
Behavioral Health Screening	x	x											
Index Visit with FP	x	x											
Randomization	x	x											
Referral to behavioral health	x												
First appointment with behavioral health (target within 90 days)													
Retention in Services measured ≥4 visits or resolution				x									
Intervention delivery including coordination and meeting with FP based on needs/ plan and by randomized strategies													
Family Resources Tracking	x						x						x
Child Symptoms Tracking TAU	x						x						x
Child Symptom Tracking Enhanced	x			x			x			x			x
Parent Capacity (PHQ2)	x			x			x			x			x
Tracking Resources Use and Care coordination Activities (EHR FP Template)		x	x	x	x	x	x	x	x	x	x	x	x
Client Satisfaction Questionnaire							x						x
Satisfaction with Navigator							x						

Appendix B. Schedule of Events/Timeline.

Table 4. Timeline	**YEAR 1**				**YEAR 2**				**YEAR 3**			
QUARTER	*1*	*2*	*3*	*4*	*1*	*2*	*3*	*4*	*1*	*2*	*3*	*4*
Hire and train FPs and research staff	x	x										
Work with clinic EHR to create reports, templates, integrate surveys	x	x										
Finalize procedures, manuals, and protocols	x	x										
Participant enrollment			**N= 50**		**N= 152**				**N= 202**			
Intervention delivery			x	x	x	x	x	x	x	x	x	x
Follow-up assessments						x	x	x	x	x	x	x
Outcomes analysis												
Implementation analysis					x	x	x	x	x	x	x	x

The first 6 months will include start-up activities—setting up workflow for baseline screening and data collection protocol; hiring/training FPs and study staff; and protocols for mitigating contamination between conditions. We will also work with IT staff at DotHouse, with input from our consultant (Dr. Daftary), to modify the EHR as needed. We will begin participant enrollment at 6-months, continue with 12 months of follow-up for all study participants, and end with the last 6 months dedicated to data analysis and manuscript preparation.

Appendix C. DSMB Charter

Study: Optimizing a Paraprofessional, Family Partner Navigation Model for Children

PIs: Dr. Emily Feinberg

1. Introduction

This Charter is for the Data and Safety Monitoring Board (DSMB) for the study titled: **Optimizing a Paraprofessional, Family Partner Navigation Model for Children**

The National Institute of Mental Health (NIMH) requires that all clinical trials include a DSMB Charter. Furthermore. Because this project includes a clinical intervention, a vulnerable population, and a verbal consent, the inclusion of a Data and Safety Monitoring Plan and Board is appropriate. The DSMB will include an independent group of experts on child and family behavioral health, clinical trials, and biostatistics, who will advise and monitor the project with the study principal investigator (Feinberg). None of the members will directly supervise, report to, or directly collaborate with the PIs. The DSMB will meet every six months. Its primary responsibilities will be to: 1) review and evaluate the accumulated study data for participant safety, study conduct and progress, and efficacy; and 2) make recommendations concerning the continuation, modification, or termination of the trial. In this proposed project the DSMB will consider: study-specific data and any concerns for poor clinical outcomes among patients in a particular randomization condition.

The Charter is intended to be a living document. The DSMB may wish to review it at regular intervals to determine whether any changes in procedure are needed.

2. Responsibilities of the DSMB

The DSMB is responsible for safeguarding the interests of study participants, assessing the safety and efficacy of study procedures, and for monitoring the overall conduct of the study.The DSMB is an independent group advisory to the investigators of the study, and is required to provide recommendations about starting, continuing, and stopping the study. In addition, the DSMB is asked to make recommendations, as appropriate, to the NIEHS about:

- Efficacy of the study intervention
- Benefit/risk ratio of procedures and participant burden
- Selection, recruitment, and retention of participants
- Adherence to protocol requirements
- Completeness, quality, and analysis of measurements
- Amendments to the study protocol and consent forms
- Participant safety, and
- Notification of and referral for abnormal findings

3. Organization and Interactions

The following illustrates the relationship between the DSMB and the study investigators.

Communication with DSMB members will be primarily through the principal investigator (PI), Dr Feinberg. It is expected that other study investigators will not communicate with DSMB members about the study directly, except when making presentations or responding to questions at DSMB meetings or during conference calls.

4. DSMB Members

DSMB members and their expertise are listed in Appendix A. Program Staff involved in the study, and their responsibilities are listed in Appendix B. The Project Manager (PM) will provide an unbiased staff interface for the DSMB, especially during executive sessions. The PM is responsible for assuring the accuracy and timely transmission of the final recommendations and DSMB minutes.

5. Scheduling, Timing, and Organization of Meetings

DSMB meetings are usually held by remote connections. The purpose of the first meeting is to review and discuss this Charter, to provide an overview of study activities, to review and make recommendations about the protocol(s), and to determine the frequency of interim analyses and whether data will or will not be masked to identity of randomized groups. Enrollment in a study cannot begin until the DSMB's Charter has been accepted, and IRB approval has been obtained.

Meetings will be approximately twice a year, with additional meetings or conference calls scheduled as needed.

- For this DSMB, meetings and calls will be held: every 6 months, with the first at the beginning of the study and prior to the first randomization of study participants.
- Review of interim data analyses will occur: every 6 months

The agenda for DSMB meetings and calls may be drafted by the study Project Manager (PM). The PM will finalize the agenda after consultation with the DSMB Chair. The agenda and meeting materials should be distributed by the PM 2 week**[s]** before each meeting or call.

Before each meeting, when the agenda is sent out, the PM will ask all DSMB members to state whether they have developed any new conflicts of interest since the last formal annual report. If a new conflict is reported, the Chair and other members will determine if the conflict limits the ability of the DSMB member to participate in the discussion, and whether further evaluation of the BMC ethics officer for intramural studies, is warranted. The DSMB also will review adverse event data, other safety data, enrollment data, and quality and completeness of study data at each meeting to ensure proper trial

conduct. At intervals, as noted above, the DSMB will also review formal interim analyses of the primary end point.

It is expected that all DSMB members will attend every meeting and call. However, it is recognized that this may not always be possible. Quorum for voting is considered to be half the number of standing members plus one. The Board may wish to decide if particular expertise is needed within the quorum for the meeting to be valid. All standing Monitoring Board members are voting members. The Board may also wish to decide in advance whether *ad hoc* members can vote.

6. Discussion of Confidential Material

DSMB meetings and calls will be organized into open, closed, and executive sessions.

- During the **open sessions**, information will be presented to the DSMB by the PIs and PM as appropriate, with time for discussion.
- During the **closed sessions**, the DSMB, PIs, PMs, if appropriate and approved by the Chair, will discuss confidential data from the study, including information on efficacy and safety. The DSMB will decide whether to remain masked to the treatment assignments at each meeting.
- The DSMB may elect to hold an **executive session** in which generally only the DSMB members are present in order to discuss study issues independently.

If the **closed or executive session** occurs on a conference call or video connection, steps will be taken to ensure that only the appropriate participants are on the call, and to invite others to re-join the call only at the conclusion of the executive session.

At the conclusion of the **closed or executive** sessions, the participants will be re-convened so that the DSMB Chair can provide a summary of the DSMB's recommendations. This provides an opportunity for study investigators to ask questions to clarify the recommendations. The meeting is then adjourned.

7. Reports of DSMB Deliberations

- Formal minutes: The PM is responsible for the accuracy and transmission of the formal DSMB minutes. These minutes are prepared to summarize the key points of the discussion and debate, requests for additional information, response of the investigators to previous recommendations, and the recommendations from the current meeting. If concerns are identified, the report will outline the concerns, the board's discussion of the concerns, and the basis for any recommendations that the DSMB has made in response to the concerns.
- The DSMB Chair may sign the minutes or indicate approval electronically via email. If there are no concerns or major issues raised, signed minutes will be sent to the PI within 7 days of each meeting or call. If concerns or major issues are raised during the meeting, signed minutes will be sent to the BMC Director and PI within 2 days of the meeting or call. The PI will forward the minutes to the IRB as soon as possible. Subsequently, minutes are included in the materials for

the subsequent DSMB meeting to be approved by voice vote at that meeting. Once they have been voted and approved by the Board, they are considered final.

8. Reports to the DSMB

For each meeting, the PM will prepare summary reports and tables to facilitate the oversight role of the DSMB. The DSMB should discuss at the first or subsequent meetings what data they wish to review and how it should be presented.

9. Statistical Monitoring Guidelines

At the first meeting, review of the protocol will include review of the statistical analysis plan. The DSMB should discuss the adequacy of that plan. The DSMB should discuss the statistical monitoring procedures they propose to follow to guide their recommendations about termination or continuation of the trial. These procedures could include guidelines for early termination for benefit, termination for futility, and termination for safety reasons.

DSMB members and their expertise

DSMB Member	**Department/Title**	**Expertise**
Kate Guastaferro, PhD	Assistant research professor at the Methodology Center at Pennsylvania State University	MOST framework; prevention of child maltreatment; advanced research methods
Christina Borba, PhD, MPH	Director of Research for Department of Psychiatry, BMC	Mixed method research and statistical analysis in the field of behavioral sciences; development and management of randomized clinical trials
Veronika Shabanova, PhD	Faculty in the department of Pediatrics at Yale University	Biostatistician with expertise in statistical and epidemiological methods
Molly Brighman, LICSW	Mental health clinician at Codman Square Community Health Center.	specializes in Attention Deficit Disorders (ADHD), Counseling, Counseling - Children and Adolescents, Grief and Bereavement, Post-Traumatic Stress Disorder (PTSD), Social Work. She is also a site champion for TEAM UP, a behavioral

		health integration initiative led by Emily Feinberg at Codman Square that also utilizes a Family Partner Model.

Appendix B – Program Staff and Responsibilities

Emily Feinberg	PI
Sarabeth Broder-Finger,	Co-I
Chris Sheldrick	Co-I
Megan Jordan	Co-I
Dana Rubin	Co-I
Andrea Chu	Project Coordinator
Data Analyst	Data Analyst