

Using the Multiphase Optimization Strategy (MOST) Framework to Test Intervention Delivery Strategies: A Study Protocol

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Abstract

Background Delivery of behavioral interventions is complex, as the majority of interventions consist of multiple components used either simultaneously, sequentially, or both. The importance of clearly delineating delivery strategies within these complex interventions - and furthermore understanding the impact of each strategy on effectiveness - has recently emerged as an important facet of intervention research. Yet, few methodologies exist to prospectively test the effectiveness of delivery strategies and how they impact implementation. In the current paper, we describe a study protocol for a large randomized controlled trial in which we will use the Multiphase Optimization Strategy (MOST) – a novel framework developed to optimize interventions - to test the effectiveness of intervention delivery strategies using a factorial design. We apply this framework to delivery of Family Navigation (FN), an evidence-based care management strategy designed to reduce disparities and improve access to behavioral health services, and test four components related to its implementation. Methods/Design The MOST framework contains three distinct phases: Preparation, Optimization, and Evaluation. The preparation phase for this study occurred previously. The current study consists of the optimization and evaluation phases. Children ages three-to-twelve years-old who are detected as “at-risk” for behavioral health disorders (n=304) at a large, urban federally qualified community health center will be referred to a Family Partner – a bi-cultural, bi-lingual member of the community with training in behavioral health and systems navigation – who will perform FN. Families will then be randomized to one of 16 possible combinations of FN delivery strategies (2x2x2x2 factorial design). The primary outcome measure will be achieving a family-centered goal related to behavioral health services within 90 days of randomization. Implementation data on fidelity, acceptability, feasibility, and cost of each strategy will also be collected. Results from the primary and secondary outcomes will be reviewed by our team of stakeholders to optimize FN delivery for implementation and dissemination based on effectiveness, efficiency, and cost. Discussion In this protocol paper, we describe how the MOST Framework can be used to improve intervention delivery. These methods will be useful for future studies testing intervention delivery strategies and their impact on implementation.

Contributions To The Literature

- Traditional two-arm randomized controlled trials are limited in that they provide information about the general effectiveness of a packaged intervention. In contrast, the MOST framework requires analysis of components and determines the optimized version of an intervention.
- The MOST framework is particularly relevant to scaled implementation of Family Navigation interventions because of overall concerns related to cost, efficiency, and effectiveness of this intervention across contexts.
- This study protocol offers an innovative application of the MOST framework to improve the delivery of Family Navigation, which is an intervention that aims to improve accessibility of health services to historically underserved populations.

Background

Intervention Optimization

Delivery of behavioral interventions can be complex, as the majority of interventions consist of multiple components that can differ by order (e.g., simultaneously, sequentially, or both), locations (e.g., home, medical setting), method (e.g., in-person, remote), or individual (i.e., teacher, therapist). The importance of developing and testing efficient, effective delivery strategies for complex interventions has recently emerged as an important facet of intervention research (1). Yet, few methodologies allow for both the rigor of a randomized clinical trial and the flexibility and adaptability of designing and testing delivery for scale. This mismatch (i.e. narrow focus of randomized trial in which one or two strategies can be compared with the need for testing multiple delivery strategies) has contributed to a catalog of interventions that are “evidence-based”, yet without efficient strategies for delivery.

In 2005, Collins and colleagues developed the Multiphase Optimization Strategy (MOST) Framework (2), a guide for intervention developers that draws heavily from the fields of engineering, statistics, biostatistics, and behavioral science (3). MOST involves three phases: Preparation, Optimization, and Evaluation. The Preparation phase consists of: developing a conceptual model for the intervention; pilot testing; identifying “core components”; and determining what outcomes to optimize on (e.g. effectiveness, efficiency, cost). The Optimization phase uses a multifactorial design to conduct a randomized factorial experiment of specific components identified during the Preparation phase. Finally, the Evaluation phase consists of reviewing results of the trial and developing consensus regarding intervention components. Since its initial publication (4) multiple studies have utilized MOST to develop and test intervention components (5–10) with a primary focus on effectiveness (4,10,11).

Optimizing Intervention Delivery for Scale: Family Navigation as an Exemplar

Another promising use of the MOST Framework is optimizing intervention delivery. Many interventions—particularly complex interventions - have components that are fixed, but require a variety of delivery strategies for patients or clients that are efficient and effective (1). Family Navigation (FN) is an example of a complex, evidence-based intervention. FN is a care management strategy designed to reduce disparities in care (12). Traditional models utilize trained community health workers who assist families in overcoming systems and patient barriers to services over a time-limited period. FN is rooted in the Chronic Care Model (13) and has evidence in multiple diseases as a means to reduce disparities by shortening the interval between discovery of risk (e.g., a positive screening mammogram for breast cancer) and diagnostic ascertainment (14–25).

Despite the promise of FN, studies demonstrate varying success upon translation from controlled research to real-world practice (26–30). FN is a complex, multi-component intervention which

incorporates motivational interviewing (MI), problem-solving, education, and care coordination.(29,31) FN can be delivered through a range of strategies: clinic-based meetings, home visits, or telehealth. FN delivery can be costly and time-consuming (32). Learning how to optimize FN delivery by determining which strategies are most effective and efficient is critical to scalability and sustainability. 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 cost-effective, equitable benefit.

Frameworks

This study will rely on two frameworks, MOST and the Consolidated Framework for Implementation Research (CFIR) (33). MOST was created as a means for developing “better interventions” by comparing components with the goal of optimization. In the current paper, we describe our protocol in which we use MOST to identify the most effective delivery package of FN. Use of this novel framework and study design offers the opportunity to optimize FN delivery, using empirical data, to support dissemination. Our primary objective is to compare how four different FN delivery strategies impact FN's ability to enhance access to behavioral health services. Strategies we will compare include: (A) enhanced care coordination technology vs. usual care; (B) community/home-based delivery vs. clinic-based delivery; (C) intensive symptom tracking vs. usual symptom tracking; and (D) individually-tailored vs. structured, schedule-based visits. Outcomes of interest are access to behavioral health services. We will estimate the impact of the four delivery strategies on this primary outcome, and perform exploratory analyses regarding interactions between delivery conditions and interactions with patient characteristics. We will also assess implementation outcomes of fidelity, feasibility, acceptability, and cost quantitatively. Then, we will conduct semi-structured qualitative interviews based on the CFIR to further explore these implementation constructs. Finally, using consensus methods, we will combine data to develop an optimized delivery strategy.

Trial Status

This is protocol version number 2, updated June 26, 2019. Recruitment began on July 17, 2019. Recruitment is expected to be completed on July 16, 2023.

Methodology/design

Overview

We will use a randomized, multi-factorial design to simultaneously test four FN delivery strategies, as well as combinations of the strategies ranging from the most basic (core FN) to the most intensive (enhanced care coordination technology +community visits +enhanced symptom monitoring+structured schedule-based visits). We will evaluate which combinations of delivery strategies are most effective and efficient in regard to the primary outcome (accessing behavioral health services). Stakeholders will then evaluate

data to develop an optimized model of FN delivery. The study received approval from the Boston University Institutional Review Board (Protocol Number: H-37634; Clinical trial Number: NCT0356944).

Setting

The study setting is a federally qualified community health center in a diverse, urban neighborhood in Boston, Massachusetts that serves >3,000 children per year in the study's target age of 3–12 years old. Approximately 85% of patients are from a racial/ethnic minority group with >80% using Medicaid. In addition to medical services, the health center provides comprehensive child behavioral health services. Multilingual social workers, licensed mental health clinicians, and a psychiatrist provide behavioral care in an onsite behavioral health department and behavioral health clinicians integrated within primary care provide assessment and brief intervention.

Participants

We will enroll 304 children and their families to be randomized to a combination of four delivery strategies (Figure 1). All children seen at the study site are screened for behavioral health concerns at all well child visits or when parents raise behavioral concerns. For children aged 3 to 5 years, the Preschool Pediatric Symptom Checklist (PPSC) (34), which is part of the Survey of Wellbeing of Young Children (SWYC) (35) will be used. For those aged 6-to 12-years-old, the Pediatric Symptom Checklist–17 (PSC–17) (36–39) will be administered. If agreeable, families of children identified with a behavioral health concern will be referred to the study.

To promote enrollment and retention of participants, we will enroll families regardless of language and provide bicultural and bilingual services in Spanish and Vietnamese. Our Navigators - in this study called “Family Partners” (FPs) are bilingual in either English/Spanish or English/Vietnamese—the most commonly spoken languages at the health center. Both the PSC–17 and SWYC are available in multiple languages. We will use telephonic translation services as needed. To promote collection of data across all study timepoints, FPs will be available to help families complete questionnaires in person, over the phone, or electronically. Families will receive weekly reminders when questionnaires are due.

We will also include a “watchful waiting” group for families of referred children who are not interested in accessing child behavioral services. The FP will ask parents if she can reach out again after 3 months to see if they desire services for the child at that time. Upon re-contacting the family, the family will have the opportunity to enroll in the study if they would like services and to work with the FP.

[Insert Figure 1: Recruitment Process Map]

Core Family Navigation Intervention

The core components of FN (12) will be delivered by an FP, a paraprofessional community member trained to support families of children with behavioral health needs. Study procedures are designed to align with existing health center workflows. All families receive the following:

- Universal screening and behavioral health referral. FN begins with a response to a positive behavioral health screening or parent concern for behavioral health issues. The FP will provide psychoeducation and use MI to explore family preferences regarding further evaluation, and referral to behavioral health services. =
- Supporting access to behavioral health services. The FP will work with the family to access recommended services, support family preferences, and engage in treatment through the creation of a Family Plan, which includes setting family-centered goals.
- Engagement in evidence-based treatment. FN aims to support adherence to recommendation for behavioral healthcare. The FP, who is trained in MI and collaborative decision making, will use these skills to support parental engagement in the behavioral health treatment plan.
- Monitoring to achieve family goals. FP continue until the goals articulated in the Family Plan are achieved, at which point the FP will be available as needed for up to 6 months.
- Family strengthening. FPs will refer families to local support groups and parent mental health services if needed.
- Connection to concrete resources. FPs receive extensive training on available local resources and connect families to community-based resources (e.g., disability insurance).

[Insert Figure 2: Mechanisms of Family Navigation]

Family contact with FP

First contact. Initial contact with the FP will occur either in-person or by phone within 48 hours of referral. The FP will describe the study, obtain consent, administer baseline assessments, and determine a primary family-centered goal. The family will then be randomized to a study condition through a centralized randomization generator.

Development of a service plan. In consultation with the primary care team and the behavioral health clinician, the FP will work with the family to develop a plan for services which may include: onsite integrated behavioral health services; school-based services; and/or referral to an external behavioral health clinician or agency.

Linkage with services. The family will receive assistance with referral and care coordination based on the child's needs and family interest. The FP will ensure referrals are made, scheduled, and barriers are explored through activities such as text reminders and transportation assistance.

Engagement with FP. Families' ongoing FP engagement will be guided by the core components of FN. The FP will document all activities and contacts within the electronic health record (EHR). We expect that the range of activities might include assistance in obtaining school evaluations; linkage to community-based supports such as parent groups; troubleshooting challenges to accessing services; and coordinating services between primary care, school, and specialty services.

Study Conditions: Family Navigation Delivery Components

We will test four delivery strategies using a factorial design (Figure 3). Families will be randomized to one of sixteen combinations of delivery strategies (i.e., factors): Strategy A *Care Coordination* (i.e., usual care v. enhanced: technology assisted); Strategy B *Location* (i.e., Clinic-based v. Clinic + Community); Strategy C *Symptom Tracking* (i.e., Pediatric Surveillance at annual well-child visit v. Enhanced: Tracking at 3, 6, 9, and 12 months); Strategy D *Visit Structure* (i.e., individually tailored visits v. standardized, schedule-based visits). Descriptions of the specific FN delivery components are below. Regardless of the combination of delivery strategies to (core or enhanced strategies), families will all be provided the core FN intervention.

[Insert Figure 3. Full factorial experimental design testing four delivery strategies (4^2 : 2x2x2x2)]

Strategy A: Standard FN v. Enhanced: Technology assisted. In core FN, FPs keep records and communicate with families using telephones and EHR. In the enhanced condition, FPs will also have access to a cloud-based care coordination and communication software that offers administration of online questions, videoconferencing, and portals that can be used by parents and providers (e.g., FP, pediatrician, teacher). Families randomized to have access to care coordination software will work with the FP to become familiar with features. The FP will introduce this technology to relevant school staff—e.g. the child's teacher.

Strategy B: Clinic-based v. Enhanced: Clinic + Community. In core FN (i.e. Clinic-based), FPs are restricted to working at the clinic. Interactions will occur in-person at the clinic and remotely via phone, text-message, or other communication software. In the enhanced condition, FPs will be available to meet families in their home and community, in addition to clinic visits, and accompany families to community-based meetings. 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: Standard Pediatric Symptom Surveillance v. Enhanced Symptom Tracking at 3, 6, 9, and 12 months. In core FN (i.e. Surveillance at well-child visits), monitoring is determined by standard pediatric practice (annually). In experimental conditions with "enhanced monitoring," FPs will monitor symptoms using validated instruments quarterly (tool differs based on age) and communicate results to the child's care team.

Strategy D: Schedule-Based v. Flexible Meeting Schedule. In core FN, FPs provide content at their own discretion based on perceived family needs, there is no pre-determined structure for meetings, and FPs

may meet with families on an as-needed basis. In experimental conditions with scheduled visits, FPs will be expected to follow a curriculum that includes monthly meetings covering relevant topics.

Subject Allocation 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., gender, race/ethnicity, language). 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 (40–43). Randomization across four binary factors results in sixteen possible combinations (see Figure 3). We plan to enroll 304 families: $n = 38$ for each cell. Outcome assessors and data analysts will be blind to condition assignments.

Outcomes

All children will be followed for 12 months after enrollment. Measures will be collected at 3, 6, 9 and 12 months. See Figure 4 for a timetable of the study’s enrollment schedule, interventions, assessments, and visits for participants.

[Insert Figure 4: Study Timetable]

Primary measures. The study’s primary objective, access to behavioral health services, will be measured as completion of the primary family-centered goal outlined in the Family Plan within 90 days (yes/no). For example, for families who set a goal related to engaging in behavioral health treatment, completing the primary goal will be defined as attending a behavioral health appointment within 90 days of randomization. Related to this primary objective, we will evaluate *time-to-receipt of behavioral health services* defined as time from randomization to receipt of primary behavioral health service. Dates will be obtained from administrative and billing data (EHR) for services within the recruitment health center site, and FP documentation for services outside the health center. Additional engagement and child-level outcomes are described below.

Engagement in care, will be defined as ≥ 4 visits with a behavioral health provider within 90 days of first FP visit, or resolution of service need as determined by behavioral health provider (44).

Pediatric Symptom Checklist–17 (PSC–17). The PSC–17 is a 17-item psychosocial screen designed to recognize cognitive, emotional, and behavioral problems. Three subscales, Internalizing, Attention, and Externalizing, have specific cutoffs and provide additional guidance regarding need for further follow-up.

PSC-17 is embedded in the Epic (EHR) as a self-scoring form. It is widely used and has been validated in diverse populations (36–39).

The Survey of Wellbeing of Young Children (SWYC). The SWYC (35) screens for cognitive, motor, language, and social-emotional development among children up to 5½ years of age. We will track symptoms using the SWYC's Preschool Pediatric Symptom Checklist (PPSC) (34), an 18-item questionnaire that has demonstrated strong validity and acceptability in diverse populations. Translations are available in a range of languages.

Secondary measures. Secondary patient experience outcomes will be measured at baseline, 3, 6, 9 and/or 12 months. Secondary outcome measures will be used to evaluate the theory-based mechanisms of FN effectiveness and indicate for whom the FN delivery strategy is most effective (i.e., assessment of mediators and moderators). Theory-based mechanisms were both related to the *person* (e.g, attitudes) and the *system* (i.e., access to resources, overcome barriers). See Table 1 for the specific intervention targets, theoretical foundations, and instruments administered.

Client Satisfaction Questionnaire 8. This measure has established psychometric properties with ethnically diverse populations and will assess family satisfaction with care (45–47).

Interpersonal Relationship with Navigator (PSN-I). This measure is a validated 9-item scale with strong psychometric properties in samples of culturally diverse, underserved patients (48).

Parent Attitudes. To assess parental attitudes, we will use The Parental Attitudes Toward Psychological Services Inventory (PATPSI): The measure consists of 21 Likert-type items, assessing help-seeking attitudes, help-seeking intentions, and mental health stigma (49).

Parental Mental Health. To assess parental mental health the *Patient Health Questionnaire-2 (PHQ-2)* (50,51) will be administered. The PHQ-2 is a validated 2-question depression screener.

Access to community resources. We will measure families' access to resources with the *Family Resource Scale (FRS)* (52,53), which is a 30-item scale that assesses family concerns regarding adequacy of resources. We hypothesize that FN will improve *access to resources* over time.

Structural Barriers. Monthly *professional contact data* will be collected 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 the logs.

Service Use. Service use data will be collected through the EHR, which include FP's documentation, and appointments scheduled and completed.

[Insert Table 1: Theory-based Mechanisms and Measures]

Implementation Measures. For each delivery strategy, we will collect data on fidelity, acceptability, feasibility, and cost.

Fidelity to the FN Core Model and Delivery Strategies. We will use multiple data sources to assess fidelity, used in prior studies (16–19,25–27,29). We will review structured navigation visit templates integrated into the EHR and FP contact logs monthly. A random sample of 2 visits per month will be reviewed using a Navigation Checklist we developed for “real-time” monitoring. MI will be assessed quarterly using audiotaped standardized patient interactions, which will be scored using the Motivational Interviewing Supervision and Training Scale (MISTS) (54,55). We will assess both fidelity to the core model, and fidelity to the delivery strategies—for example, are FPs administering symptom monitoring, and how frequently, in the “symptom tracking” condition. 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.

Acceptability and Feasibility. We will use qualitative methods to assess acceptability of each delivery strategy. We will use purposeful sampling to interview five subjects from each of the 16 strategies (n = 80). Interview questions will be based on CFIR. Because the goal of the study is delivery optimization, we will specifically focus our questions on the eight domains that comprise the “Intervention Characteristics” construct within CFIR: source, evidence strength and quality, relative advantage, adaptability, trialability, complexity, design quality and packaging, and cost.

Cost. We will use *time driven activity based costing (TDABC)* to develop cost estimates for each delivery strategy (56). TDABC’s goal is to develop valid estimates of service costs while minimizing expenditures on research (56). It accomplishes this goal by requiring only two key sets of estimates: *capacity cost* rate and *demand for resource capacity*. Because the explicit goal of using TDABC in our project is to support process optimization and enhance scalability, we will not calculate costs over the entire care delivery value chain (57). Instead, we focus only on specific FN activities, consistent with use of TDABC in studies of healthcare processes (58).

We will first calculate the *capacity cost rate* for the FP as a function of total annual compensation divided by the time available for FN activities. Next, we will estimate the *demand for resource capacity* resulting from each FN delivery strategy. Assumptions regarding FN activities that create demand for resource capacity will be based on process maps (58). Process maps developed during a previous study of FN will be adapted and refined to reflect FN procedures in the current project (59). Based on these process maps, staff reports, and direct observations, we will develop time equations for each FN delivery strategy. Such time equations closely resemble linear regression equations in that they include an intercept that reflects a baseline time estimate, as well as coefficients and dummy variables that reflect additional time required to account for variations. For example, a time equation for an FN phone call to a patient might include an intercept of 2 minutes to look up a phone number and make a call, a coefficient that adds 5 minutes if the patient answers, and an additional 10 minutes if a survey is administered.

Data Management

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 kept in a locked office and separate from data. This crosswalk will be kept for the duration of the study and then destroyed. Any paper surveys utilized will be transferred the same day that they are completed to a locked file cabinet in the locked office of a study PIs.

All collected data will be stored on a HIPAA compliant, password protected, secure drive maintained by the institutions sponsoring the study. The study utilizes data collection and management tools that meet HIPAA security rules to protect confidentiality and security of protected health information.

Statistical Analyses

Overview. All statistical analyses will be done in SAS (v9.4) and Mplus (v8). Baseline characteristics of parents and children will be compared across conditions to assess balanced randomization. Characteristics include: race/ethnicity, insurance status, primary language, and child characteristics (e.g., age).

Main effects. Following an intent-to-treat model, multiple regression models will be used to test hypotheses regarding the main effects of the four delivery strategies and their combined effects on the study's primary outcome. 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-receipt of services. 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, 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 (60), as will simple main effects.

Mediator/Moderator analyses to examine 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 mediational 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 (61,62).

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.

Sample Size and Power

Of the three measures to operationalize engagement, we powered our study on the dichotomous variable "achieved goal related to receipt of mental health services within 90 days" - the most conservative estimate. We based 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 the recruitment health center and other community health centers indicated that a relative risk of approximately 25% would be considered clinically significant. Therefore, if 60% of families in the core FN 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 = 19 in each of 16 cells).

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. 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.

Qualitative Data Analysis

Each interview will be independently coded using the CFIR codebook by two members of the research team and then collectively reviewed to ensure coding consensus and reconcile discrepancies. A review of all of the codes for each interview will be conducted until members of the research team reach consensus as to which codes should be applied to specific segments of text. After consensus is achieved among coders, interview transcripts will then be entered, coded, and analyzed in QSR-NVivo.

Final Evaluation

The final stage of the MOST Framework—Evaluation—will be conducted after completing data analysis. We will convene key stakeholders in behavioral health, FN, and policy, to develop consensus recommendations regarding FN delivery. Data on effectiveness of each component both in isolation and in combination, secondary outcomes, and implementation will be presented to our stakeholder panel. Then, a modified Delphi approach (63) will be used to select components for inclusion in the final intervention package.

Discussion

The current study we use the MOST Framework to optimize FN delivery. Using a factorial design, we will develop an optimized, efficient, effective version of FN. The goal of the intervention is to improve access to, and engagement in, diagnostic and treatment services for children with behavioral health disorders. This approach represents important advances in the field of implementation science for several reasons.

First, we are using the MOST framework to optimize intervention delivery. While MOST is a framework for optimization, it is important to note that what one optimizes on (e.g., clinical outcomes, implementation, cost) is determined by the key stakeholders involved in the study. Thus, in this study we are specifically using MOST as a framework for *delivery*. This study protocol can serve as a guide for others working to optimize intervention delivery. The framework holds a unique benefit in that the majority of methodologies used for optimization do not include the rigor of randomization. Thus, understanding these methods can be of great value to the field.

Second, these methods can help inform others looking to optimize an intervention designed to alleviate disparities in access to services. Low income and ethnically diverse children with mental/behavioral health concerns often experience delays in obtaining a diagnosis and appropriate evidence-based treatments (64,65). Solutions to mitigate these disparities, such as FN, must be delivered in an efficient and effective manner to increase the likelihood of sustainable, wide-spread adoption. Furthermore, FN has been implemented in real-world practice with different strategies, and with varying success (26–28). The current study will advance our understanding of which delivery strategies are the most effective, and for whom. Given that some delivery strategies are more labor- and resource-intensive than others, to be efficient, FN programs understand “active ingredients” that lead to the most positive outcomes while leaving out potentially expensive and time-consuming strategies with lesser impact.

Finally, current health service delivery reforms are promoting primary care networks as the ‘hub’ of care coordination. 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) (66) are groups of doctors, hospitals, and other healthcare providers, who join together to give coordinated, high quality care. Implementation of 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 delivery within this new context is important to FN’s ultimate success.

Challenges and potential solutions

Two challenges we anticipate relate to complexity of subject assignment and pragmatic nature of the study. Specifically, because we are using a factorial design, we will be randomizing families to one of 16 conditions. There is therefore a large burden to the study team to prevent contamination across conditions, and monitoring for fidelity of each condition. Contamination a universal concern for studies using the MOST framework (67). We have implemented several strategies to prevent contamination. First, we are using an electronic randomization protocol that allows the navigators to directly randomize to a condition in real-time. This allows navigators to know, at the time of enrollment, which of the 16 conditions a family is randomized to. This program also allows us to input which condition the family is assigned into the medical record. Keeping this data within the medical record helps ensure that whenever a FP is working with the family, they are immediately alerted as to which condition the family is in. Finally, each condition is given a “code name” to support accurate categorization of each family into their correct condition. This code name is documented in the medical record as well.

The second challenge relates to the fact that this is a pragmatic trial embedded within usual care of a large, federally qualified health center, we lose the ability to tightly control the use of each condition. For example, if a navigator or families chooses not to use the web-based care coordination software, we will not have the ability to ensure use. Although this may make assessment of outcome data (i.e. effectiveness of a condition that is insufficiently used) it does allow us to better understand how conditions may be used in the “real-world”.

Conclusions

This study uses the MOST Framework to optimize FN delivery. We are comparing a specific delivery package against the aggregate effect of all the other delivery strategies—this framework offers a more efficient strategy for testing multiple delivery strategies over a traditional multi-arm trial. These methods will be useful for future investigators working to optimize interventions for implementation and dissemination.

List Of Abbreviations

ACO—Accountable Care Organization

ASD—Autism Spectrum Disorder

ADHD—Attention Deficit/Hyperactivity Disorder

EHR—Electronic Health Record

FN—Family Navigation

FP—Family Partner

FRS—Family Resource Scale

MI—Motivational Interviewing

MISTS—Motivational Interviewing Supervision and Training Scale

MOST—Multiphase Optimization Strategy

PHQ-2 —Patient Health Questionnaire-2

PPSC—Preschool Pediatric Symptom Checklist

PSC-17—Pediatric Symptom Checklist-17

PSN-I—Interpersonal Relationship with Navigator

SWYC—Survey of Wellbeing of Young Children (SWYC)

Declarations

- Ethics approval and consent to participate: This study received approval from the Boston University Institutional Review Board (IRB Protocol Number: H-37634; Clinical trial Number: NCT0356944). Informed consent will be obtained from all study participants.
- Consent for publication: Not applicable.
- Availability of data and material: Not applicable.
- Competing interests: The authors declare that they have no competing interests
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Tables

Table 1. Theory-based Mechanisms and Measures

Domain	Target	Theoretical Mechanism	Instrument	Timing
Person	Parent experience	Improved parental attitudes about mental health increases capacity to engage in services	PATPSI	Baseline, 6, 12 mo
	Parent experience	Improved mental health increases capacity to engage in services	Patient Health Questionnaire-2	Baseline, 12 mo
System	Access to resources	Improving social determinants increases access to resources	Family Resource Scale	Baseline, 6, 12 mo
	Structural barriers	Coordination decreases structural barriers	EHR FP Templates	Monthly reports

Figures

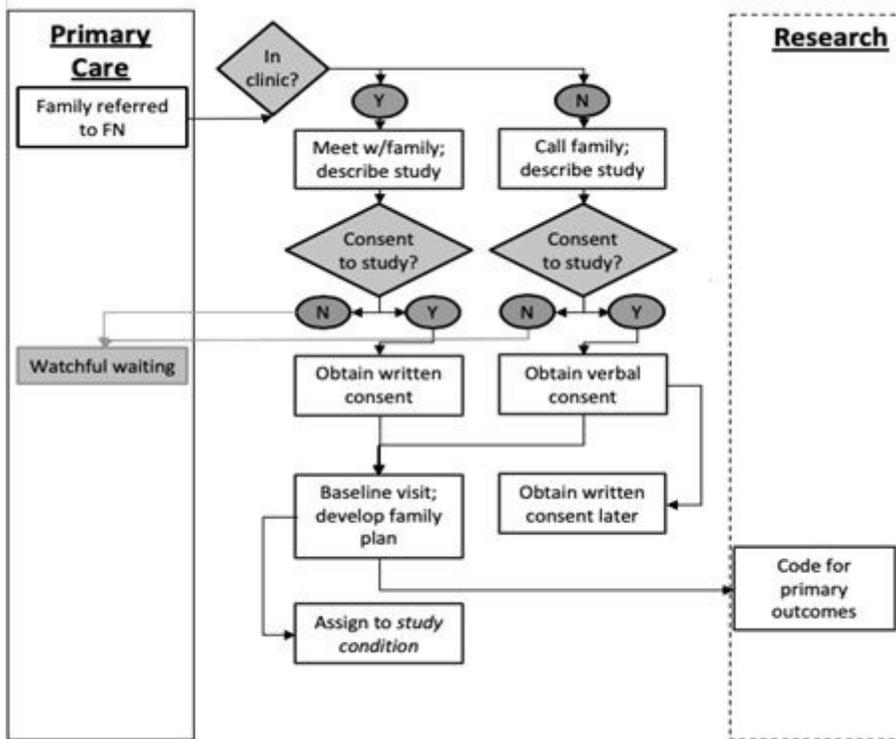


Figure 1

Figure 1. Recruitment Process Map

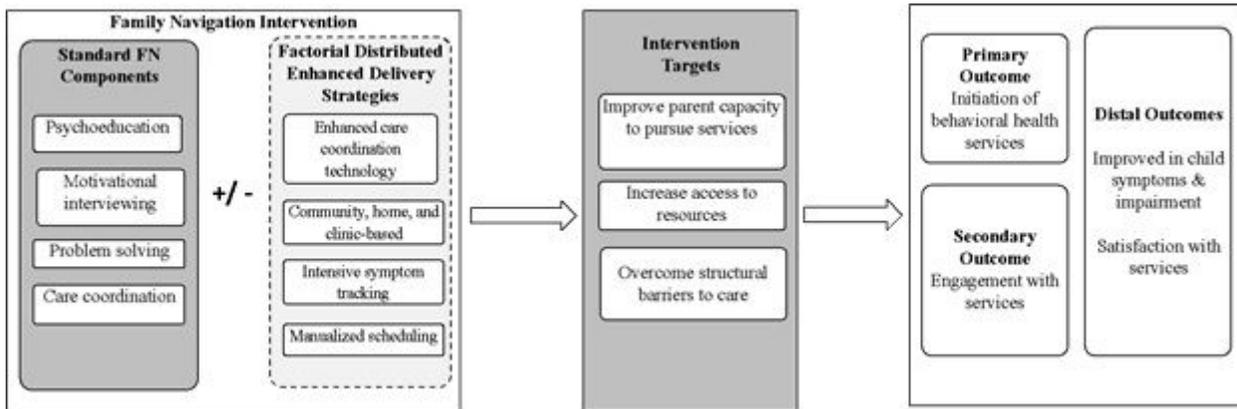


Figure 2

Figure 2. Mechanisms of Family Navigation

Group	Experimental conditions			
	Factor A	Factor B	Factor C	Factor D
1	Standard FN	Standard FN	Standard FN	Standard FN
2	Standard FN	Standard FN	Enhanced monitoring	Standard FN
3	Standard FN	Clinic-based	Standard FN	Standard FN
4	Standard FN	Standard FN	Standard FN	Schedule-Based
5	Standard FN	Clinic-based	Enhanced monitoring	Standard FN
6	Standard FN	Clinic-based	Enhanced monitoring	Schedule-Based
7	Standard FN	Clinic-based	Standard FN	Schedule-Based
8	Standard FN	Standard FN	Enhanced monitoring	Schedule-Based
9	Enhanced technology	Standard FN	Standard FN	Standard FN
10	Enhanced technology	Standard FN	Enhanced monitoring	Standard FN
11	Enhanced technology	Clinic-based	Standard FN	Standard FN
12	Enhanced technology	Standard FN	Standard FN	Schedule-Based
13	Enhanced technology	Clinic-based	Enhanced monitoring	Standard FN
14	Enhanced technology	Clinic-based	Standard FN	Schedule-Based
15	Enhanced technology	Standard FN	Enhanced Monitoring	Schedule-Based
16	Enhanced technology	Clinic-based	Enhanced monitoring	Schedule-Based

Figure 3

Figure 3. Full factorial experimental design testing four delivery strategies (42: 2x2x2x2) Note. Factor A: “Standard FN” refers to the standard family navigation (FN); “Enhanced technology” refers to additional use of electronic systems; Factor B: “Standard FN” refers to face-to-face meetings; “Clinic-based” limits meetings to the clinic or via phone; Factor C: “Enhanced monitoring” refers to additional screening

between visits; "Standard FN" refers to annual screening. Factor D: "Schedule-Based" refers to the use of a curriculum with predetermined content.

Timepoint	STUDY PERIOD					
	Enrollment	Allocation				
	-T ₁	0	T ₁	T ₂	T ₃	T ₄
Enrollment:						
	X					
Eligibility Screen	X					
Informed consent	X					
Baseline Visit	X					
Allocation		X				
Interventions:						
Standard FN			↔			
Standard FN + Enhanced monitoring			↔			
Standard FN + Clinic-based			↔			
Standard FN + Curriculum-based			↔			
Standard FN + Clinic-based + Enhanced monitoring			↔			
Standard FN + Clinic-based + Enhanced monitoring + Curriculum-based			↔			
Standard FN + Clinic-based + Curriculum-based			↔			
Standard FN + Enhanced monitoring + Curriculum-based			↔			
Enhanced Technology + Standard FN			↔			
Enhanced Technology + Standard FN + Enhanced Monitoring			↔			
Enhanced Technology + Clinic-based + Standard FN			↔			
Enhanced Technology + Standard FN + Curriculum-based			↔			
Enhanced Technology + Clinic-based + Enhanced Monitoring + Standard FN			↔			
Enhanced Technology + Clinic-based + Standard FN + Curriculum-based			↔			
Enhanced Technology + Standard FN + Enhanced Monitoring + Curriculum-based			↔			
Enhanced Technology + Clinic-based + Enhanced Monitoring + Curriculum-based			↔			
Assessments:						
Demographics	X					
Pediatric Symptom Checklist-17	X		X	X	X	X
The Survey of Wellbeing of Young Children (SWYC)	X		X	X	X	X
Client Satisfaction Questionnaire 8 (CSQ-8)				X		
Interpersonal Relationship with Navigator (PSN-I)				X		
The Parental Attitudes Towards Psychological Services Inventory (PATPSI)	X			X		X
Family Resource Scale (FRS)	X			X		X

Figure 4

Figure 4. Study Timetable

Supplementary Files

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