Title

Adaptation of an evidence-based parenting intervention for integration into maternal-child home-visiting programs: Challenges and solutions.

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Adaptation of an evidence-based parenting intervention for integration into maternal-child home-visiting programs: Challenges and solutions

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Abstract

Background

The objective of this study was to assess potential challenges, prioritize adaptations, and develop an implementation and research approach to integrate and study a parenting intervention for mothers in recovery from substance use disorders in community-based home-visiting programs.

Method

An explanatory mixed-methods design, guided by process mapping with Failure Modes and Effects Analysis tools, and an Advisory Panel of 15 community members, identified potential implementation challenges and recommended solutions for the proposed intervention within five pre-specified domains. Thematic content analysis identified themes from detailed field notes.

Results

The Advisory Panel identified 44 potential challenges across all domains. They determined that the recruitment domain was most likely to create challenges. Regarding the potential challenges, two cross-domain themes emerged: (1) development of mistrust in the community and (2) difficulty initiating and sustaining engagement. Potential solutions and adaptations to protocols are reported.

Conclusion

Mistrust in the community was cited as a potentially important challenge for the delivery and study of an evidence-based parenting intervention for mothers in recovery through home-visiting programs. Adaptations to research protocols and intervention delivery strategies are needed to prioritize the psychological safety of families, particularly for groups that have been historically stigmatized.

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Plain Language Summary: Effective evidence-based public health interventions for women and children face common implementation challenges in community-based settings, frequently yielding lower benefits to participants. Adaptation can improve the integration of interventions in these settings. In this study, implementation process mapping was a particularly effective approach to adapt a complex community-based intervention to a population that has been stigmatized. This tool may be useful for adapting other community-based interventions.

Introduction

Effective evidence-based public health interventions for women and children face common implementation challenges in community-based settings (Aarons & Palinkas, 2007; Feinberg et al., 2011; Worthington et al., 2011). Such interventions delivered in-home or through public sector systems frequently yield lower benefits in real-world settings, a phenomenon known as the "voltage drop" (Kilbourne et al., 2007). The use of systematic approaches to adaptation and implementation can help address these challenges by increasing acceptability and engagement (Chambers et al., 2013; Rathod et al., 2018). Additionally, adaptations that improve the match of the intervention to its practice setting and existing processes lead to longer-term sustainability (Scheirer & Dearing, 2011).

Maternal, infant, and early childhood home-visiting programs are examples of complex, multi-component, community-based services. While home-visiting programs select service delivery models that are evidence-based, a need to adapt programs to local contexts and specific populations remains. For example, sub-populations, such as women in recovery from substance use disorders (SUDs), may not receive the full benefit or exit programs prematurely (Suchman et al., 2006). Targeted interventions may support the greater promotion of recovery and improved parent–infant relationships (Suchman et al., 2006).

Mothering from the Inside Out (MIO) is an attachment-based intervention for mothers with SUDs tested in multiple randomized control trials with positive effects on maternal relapse and parent–child interactions (Suchman, 2016; Suchman et al., 2017). Adapting the implementation process of MIO for community-based home-visiting programs may help broaden its reach (Dennis & Chung-Lee, 2006). However, additional adaptation and evaluation of the implementation and research processes are needed to support acceptability and feasibility when integrated into community settings (Onken et al., 2014).

Intervention process mapping together with failure modes and effects analysis (FMEA) are tools that aid in intervention adaptation and are used within health services (Broder-Fingert et al., 2019; Lins et al., 2018; Tamene et al., 2020). The coupling of process mapping with FMEA aims to identify and reduce challenges inherent in complex interventions by gathering diverse perspectives of community members and addressing potential problems prior to implementation (Failure Modes and Effects Analysis (FMEA) Tool, 2017). Their utilization has produced more appropriate, effective, and sustainable systems with improved service delivery (Lins et al., 2018). This approach may be particularly useful in guiding the adaptation of interventions for inherently complex community-based delivery.

This article reports our team's work adapting the implementation process of MIO for delivery through home-visiting programs within a research context. Specifically, a process mapping and FMEA exercise conducted with an Advisory Panel of community members guided the systematic adaption of MIO for home-based delivery. The aim of the study was to identify the aspects of intervention implementation most likely to create challenges, prioritize the focus of adaptations within a research context, and develop an implementation approach most likely to support engagement and delivery of MIO for mothers in recovery through home-visiting programs.

Method

Study Design and Participants

We employed an explanatory sequential mixed-methods design (Figure 1) using process mapping and FMEA tools (Creswell & Clark, 2017). Both quantitative and qualitative analyses identified potential challenges within five specific domains of the research and intervention process and developed potential adaptations (Johnson & Onwuegbuzie, 2004). The FMEA was conducted in a group setting with an Advisory Panel. Participants were community service providers and members of the larger [Springfield, MA] community actively engaged in providing services to women in recovery. Potential participants were informed of the study via email and offered participation in-person or via video-conference. Verbal informed

Figure 1. Explanatory Sequential Mixed-Methods Process.
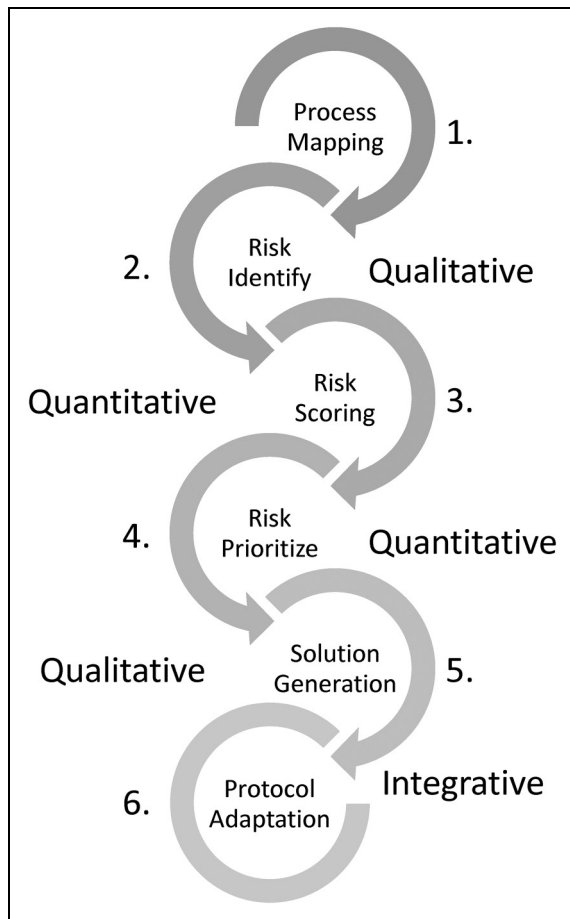
consent was obtained at the first meeting. Participants completed a demographic survey before beginning participation. The Institutional Review Board at [Baystate Medical Center] approved this study.

Development of a Preliminary Process Map

Two of the authors (EPC and MCC) worked together to create a preliminary process map with input from home-visiting directors, a behavioral health specialist and community partner (TMF), and the FMEA facilitator. Authors iteratively incorporated feedback and edited the map after sequential meetings. The map described the steps involved in the research and intervention implementation process. Qualitative data from prior studies of engagement in home-visiting services (Edwards et al., 2017; Lea, 2006; Magnusson et al., 2017; Peacock-Chambers et al., 2020) informed the map. The five domains of the preliminary implementation and research process map included: (1) recruitment, (2) screening, (3) enrollment, (4) matching, and (5) delivery (Figure 2). This served as the basis for FMEA discussions.

Advisory Panel Meetings

A total of 15 community members from a variety of disciplines and life experiences related to SUDs participated in two separate 2-hour Advisory Panel meetings focused on identifying the process domains most likely to present potential challenges. Maximal variation sampling was used to ensure the inclusion of a variety of professional and personal perspectives (Sandelowski, 2000). No other people were present.

FMEA

FMEA is a risk management tool and quality assurance process used to identify and address potential failures related to a particular process or intervention prior to implementation (Failure Modes and Effects Analysis (FMEA) Tool, 2017). The process follows specific steps led by a facilitator. It has been developed into an effective tool to guide the implementation of behavioral health interventions (Broder-Fingert et al., 2019). Note, we use the world "challenges" rather than "failures" to align with strengths-based language.

Identification of Potential Challenges

In the first meeting, the PI provided a brief overview of MIO and an experienced FMEA facilitator (SD, registered nurse, Division of Health Care Quality, with no prior relationship to participants) gave a detailed explanation of FMEA methodology. Participants reviewed the preliminary process map, asked questions, and suggested modifications before starting the FMEA.

To begin the FMEA, Advisory Panel participants collectively identified individual challenges that could contribute to performance gaps in the implementation of the intervention across the five process map domains within the context of a research study. They also identified possible causes and consequences of the potential problems. Participants came to a consensus on a number value (0–10 Likert-type scale) of the overall likelihood of the challenge occurring, detection, and severity, with 10 being the highest likelihood, for each of the domains in the process map. The Risk Profile Number represents the overall risk for potential challenges to occur in each of the process map domains.

Generation of Solutions to Address Potential Challenges

In the second meeting, the Advisory Panel focused on the process domain with the highest Risk Profile Number and developed strategies to reduce the specific challenges based on causes, likelihood of occurrence, detection, and severity. The Advisory Panel drew from their own lived and local experience as well as professional training to develop solutions through collective discussion.

Figure 2. Refined Process Map of MIO Implementation.
Note. HV = home visiting. MIO = Mothering from the Inside Out intervention.
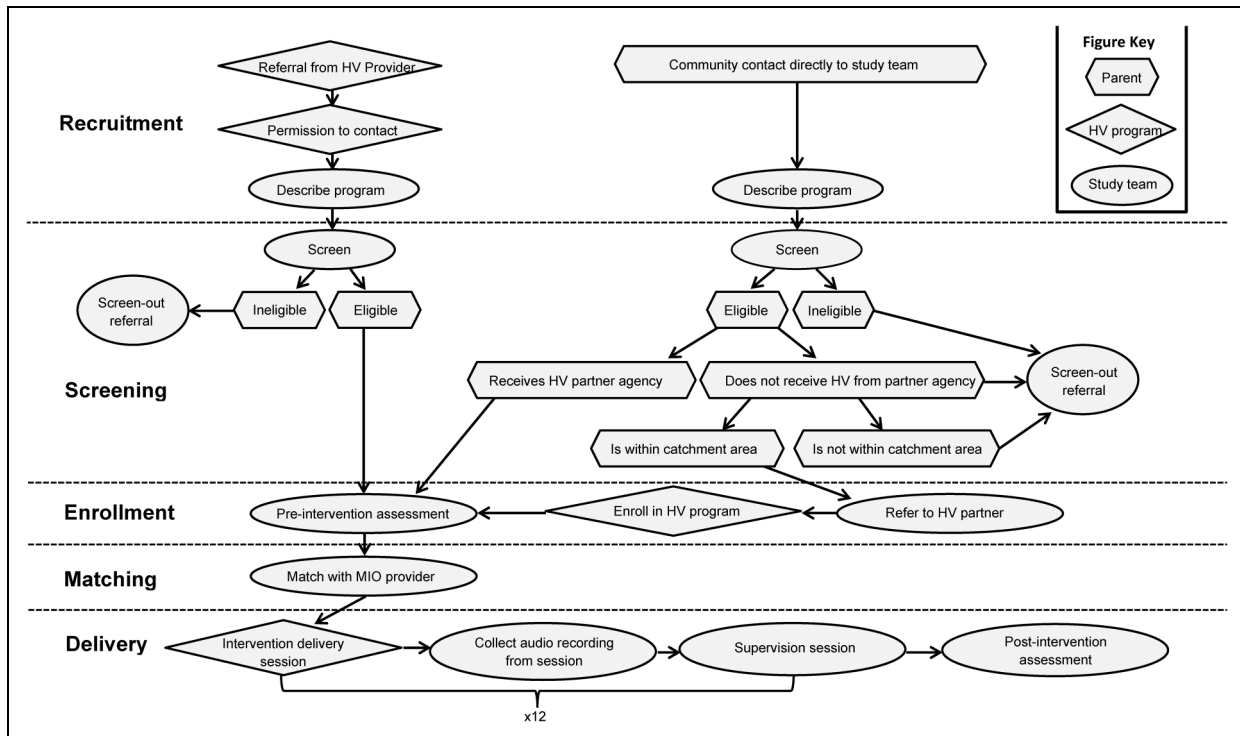
Data Analysis

Quantitative Data Analysis

The recommended standards (Failure Modes and Effects Analysis (FMEA) Tool, 2017) and input from an experienced facilitator (SD) guided the conduct of the FMEA. Risk priority numbers (RPNs) were calculated collectively for the potential challenges within each step of the intervention delivery process as the product of the likelihood of occurrence, detection, and severity values with the composite score ranging between 0 and 1,000 (RPN = Severity × Occurrence × Detection). Descriptive statistics summarize participant demographic data.

Qualitative Data Analysis

We conducted a qualitative analysis of detailed field notes collected during the FMEA to understand individual challenges and solutions across all the process domains. Content analysis identified emergent themes and sub-themes (Vaismoradi et al., 2013). Consistent with FMEA methodology (Broder-Fingert et al., 2019), the study team worked to review field notes systematically, reach consensus on key concepts, and organized concepts into principal themes and sub-themes.

Integration and Prioritization of Adaptation

The study team integrated qualitative and quantitative findings to inform protocol and process map adaptations.

Adaptions were focused on the highest risk domains, as well as the availability and feasibility of possible solutions recommended by the Advisory Panel, consistent with the Planned Adaptation Framework (Lee et al., 2008). Decisions were triangulated for feedback from the Advisory Panel and community members that did not participate in the panel.

Results

Advisory Panel Participants

Advisory panel participants included parents in recovery ($n = 2$), and providers working in the fields of substance use treatment services ($n = 8$), healthcare ($n = 2$), Early Intervention ($n = 3$), and others ($n = 1$). There were 14 females and one male. Race/ethnicity included American Indian/Alaska Native ($n = 1$), Black or African American ($n = 2$), Hispanic or Latino ($n = 2$), and White ($n = 10$) representation. The average age of participants was 48 years old.

Quantitative Analysis: Ratings Potential Challenges

The Advisory Panel identified 44 potential challenges across the research and intervention process: 13 within the recruitment domain, 10 within screening, six within enrollment, four within matching, and 11 within intervention delivery. RPNs were generated for each domain in the process

Table 1. *Challenges, Mean Risk Priority Numbers, and Solutions by Intervention Delivery Domains.*

Intervention delivery domains	Description	Potential challenges	Occurrence (1–10) mean	Detection (1–10) mean	Severity (1–10) mean	Risk priority number	Solutions to potential challenges
Recruitment	Outreach in the community; explanation of program; connections with referral sources	Use of stigmatizing language: lack of interest from parents or buy-in from providers; complexity of referral process	8	10	10	800	Partner with those in community trusted by eligible population; share findings on the effectiveness of the intervention; identify invested provider champions at referral sites
Screening	Determination of eligibility	Screening language; feelings of rejection from parents determined ineligible	5	3	7	105	Ensure the use of nonstigmatizing language; Establish a clear referral plan and warm handoff for ineligible parents
Enrollment	Referral to home visiting program; informed consent process; pre-intervention assessment	Eligibility changes post-screening	5	2	8	80	Expand inclusion criteria to mothers who do not have custody of child(ren)
Matching	Determination of parent and provider availability; pairing of parent and provider	Schedules do not align; parent does not like provider	7	10	7	490	Establish process to re-match parents and providers; focus on culturally, non-stigmatizing language in training
Delivery	Intervention sessions; supervision sessions	Parent privacy concerns with recording sessions; parent does not want sessions to take place at home; parent loses interest in intervention	4	2	10	80	Make clear audio-recording is for supervision of provider; offer private setting as alternative to home for sessions; use of non-stigmatizing language

(Table 1). The recruitment domain had the highest overall risk (RPN = 800), as well as the highest score for the likelihood of challenge occurrence and difficulty detecting the challenge. The intervention delivery domain received the highest severity rating (10), indicating this domain posed the greatest potential risk of harm to participants.

Qualitative Analysis: Potential Challenges, Causes, and Solutions

Two cross-domain themes emerged related to individual challenges and their causes, consequences, and solutions:

(1) development of mistrust in the community and (2) difficulty initiating and sustaining engagement. Themes, sub-themes, and potential consequences of challenges are provided in Table 2. Solutions to potential challenges were generated by the Advisory Panel in response to potentially high-risk challenges (Table 1).

Refined Process Map

Changes were made to the process map and study protocol in direct response to the recommendations from the

Table 2. *Potential Implementation Challenges: Cross-Domain Themes and Sub-Themes.*

Themes	Sub-themes	Potential consequences
Development of mistrust in the community	Unintentional use of stigmatizing, culturally insensitive, and "deficit-based language"	Creating a bad reputation for the program and study team in the community through peer-to-peer information sharing
	Difficult to detect due to the absence of engagement	Unable to mitigate development of mistrust if it develops
	Stimulate feelings of rejection among the most vulnerable due to study ineligibility (specifically parents without custody of their children)	Negatively affect parents and damage reputation of the program
	Privacy and confidentiality concerns (audio-recording, other family members present during sessions)	Failure to consent, withdrawal from program, unable to fully benefit from sessions
Difficulty initiating and sustaining engagement	Oversaturation of services for new mothers in recovery	Lack of interest in the MIO program
	Complexity of the referral process, "too many hands on the referral process"	Lack of understanding of procedures by referral sources, failure to make referral
	Fluidity of circumstances (e.g., changing residence, provider changing jobs, changing schedules)	Difficulty maintaining a parent-provider match

Advisory Panel. Examples include edits to the screening script, identification of champions in multiple community-based organizations, and improved channels of communication with collaborators. Overall, allowing parents greater choice was seen as critical to building trust in the community. The Advisory Panel emphasized that the population of parents in recovery are diverse and likely will need flexible pathways to the intervention. Protocols were modified to give participants greater choice in terms of meeting location, privacy, and method of recording to further protect confidentiality.

Furthermore, the panel identified parent–child relationships for mothers without custody as potentially fragile. Participants believed that noncustodial parents needed greater support around changes in custody and that this intervention could mitigate these stressors. The study team expanded the inclusion criteria to mothers without custody, working towards reunification. A referral resource guide was added for parents determined ineligible for the program. Changes were integrated into the final process map (Figure 1).

Discussion

This study identified potential challenges that could occur when integrating an evidence-based parenting intervention for mothers in recovery from SUDs into community-based home-visiting programs. These challenges were specific to intervention adaptation within a research context and related to working with mothers in recovery. Using quantitative method to identify the highest risk domains, and qualitative method to map themes across domains, we found that the recruitment domain in the research process was at the highest risk of presenting potential challenges. The

development of mistrust in the community emerged as a primary theme related to recruitment challenges. Overall, consideration of the psychological safety for parents with SUDs, in terms of empowerment through choice and consideration of the needs of individuals that have been highly stigmatized, arose as the optimal solution for mitigating these risks within the context of research and within the parenting intervention. Changes to the preliminary process map also reflect solutions identified by the Advisory Panel in response to logistical barriers to sustained engagement for parents and community collaborators.

Community-based behavioral interventions are inherently complex, particularly those engaging populations that have been marginalized (Aarons & Palinkas, 2007; Suchman et al., 2006). FMEA provides a systematic way to identify potential challenges prior to the implementation of the intervention and study procedures. We focused our adaptation on strategies that addressed the local and historical context when recruiting and working with mothers in recovery in a research study and new home-based setting.

Participant recruitment is a significant challenge across a range of research settings (Treweek et al., 2013). Equitable recruitment into community-based maternal-child health programs is also challenging (Feinberg et al., 2011), likely as a result of a combination of individual, environmental, and historical factors (UyBico et al., 2007). Although strategies for addressing barriers to research recruitment for people with SUDs have been identified (Jaffee et al., 2009), much less is known about the recruitment of mothers in recovery (Pinto et al., 2011; Winhusen et al., 2012). Our study adds to the existing literature by identifying the development of mistrust as a potential cause of recruitment challenges for these mothers.

Historical and present-day context outside of the intervention can contribute to mistrust of research and healthcare more broadly. People with SUDs often mistrust both research and medical systems because of perceived stigma, adverse prior experiences, and the intersection between criminal justice systems and SUDs (Hewell et al., 2017; Snoek & Horstkötter, 2018; Winkelman et al., 2018). For parents in recovery, the fear of custody loss of children for reasons related to substance use history can compound mistrust (Harp & Oser, 2018; Ondersma et al., 2010; Snoek & Horstkötter, 2018).

The Advisory Panel perceived that parents without active custody of their children would benefit most from the proposed parenting intervention. In [Massachusetts], parents working to reunite with their children should be involved in EI, though this is not common practice. Thus, the solution proposed by the panel to purposefully include this population could provide needed support and engagement while paying special attention to their unique risks (Holland et al., 2022). Although research guidelines and requirements help ensure the physical and psychological safety of research participants, protocols still need to be tailored to unique risks as the safety measures built into the research process may not be adequate or readily apparent to potential participants. The FMEA tool may be particularly useful in developing these strategies for other community-based intervention research involving similar groups that have been historically marginalized or disempowered.

This analytic approach moved our research protocol and intervention delivery strategies in the direction of greater prioritization of psychological safety for potential participants by highlighting the importance of providing options for *how* they engage in the study and allowing flexibility to meet specific needs. In addition, it raised our awareness that addressing the needs of ineligible participants, is an important advance beyond traditional physical and psychological protections for human research subjects (Hébert et al., 2015).

Strengths and Limitations

While our results were specific to a community and intervention delivered in the context of research, implementation process mapping and FMEA can be applied to a variety of settings. We expect that the findings of an FMEA conducted outside of the research context would differ. This FMEA study did not involve analysis at the level of individual challenges, rather it focused on five process domains supplemented by qualitative data. Other settings and processes may benefit from analysis at the level of individual challenges to optimize protocols. In addition, we utilized group consensus to determine the process domain at the highest risk of facing challenges. This approach may have caused our results to skew toward the opinions of more outspoken participants. A

skilled facilitator works to elicit opinions across the group when using this approach. Alternatively, one can perform the FMEA by collecting RPN scores from individuals and averaging the scores to mitigate this risk. Our Advisory Panel consisted primarily of service providers. Depending on the research question, different community members may be preferable.

Conclusion

Our study provides a novel approach to the adaptation of intervention for mothers in recovery from SUDs, delivered and studied in a community setting. This process may inform future community-based research serving populations facing similar social or economic disadvantages. Additional research is needed to understand whether this methodology accurately predicted potential challenges and effective solutions, whether it led to greater uptake of the intervention, and whether process mapping and FMEA tools can help provide additional protections to people receiving community-based behavioral interventions in research and practice.

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