PROTOCOL TITLE:

Integrating Text Messages into the Mothers and Babies Course to Address Depression in Low-Income Women and their Partners

PRINCIPAL INVESTIGATOR:

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1.0 Purpose of the Study:

Despite the well-established negative effects of postpartum depression on mother and child, most efforts have been directed at treating women already exhibiting depressive episodes rather than prevention. Emphasis on treatment neglects the large number of women with mild to moderate depressive symptoms, in high psychosocial risk contexts, who are at risk for developing postpartum depression. Interventions exist that are efficacious in preventing the onset and worsening of depression among perinatal women. In particular, the PI and colleagues have demonstrated that the Mothers and Babies Course (MB) prevents the worsening of depressive symptoms and onset of new major depressive episodes.

Enhancements to MB are warranted in two main areas. First, prior MB trials suggest the intervention is less successful for women who exhibit smaller changes in hypothesized intervention mechanisms and less fully engage in homework completion between sessions—a core component of cognitive-behavioral therapy (CBT) interventions like MB. Second, previous postpartum depression preventive interventions—including MB—have neglected to intervene with partners of pregnant women, despite the growing recognition that paternal depression also exerts influence on children's social-emotional development[6] and occurs in a similar timeframe.[7] Thus, in an otherwise successful intervention, these limitations—mixed success in improving hypothesized intervention mechanisms and limited engagement of fathers—may mitigate intervention efficacy. We hypothesize that core MB modules will prevent onset of major depressive episodes and worsening of depressive symptoms. We also conceptualize that relationships between MB modules and maternal mental health outcomes will be mediated by mechanisms that are the direct focus of MB content. Paternal depression is also hypothesized to mediate the relationship between MB modules and maternal mental health outcomes.

This study addresses these limitations. We will collaborate with 10-12 home visiting (HV) programs serving primarily low-income women. HV is an ideal setting for this study given the large numbers of perinatal women they serve and will build on the PI's existing relationships with HV programs in Illinois. In Phase 1, we will recruit 108 pregnant women for a RCT in which half the participants will receive MB and half will receive MB with a text message enhancement (MB-TXT). MB-TXT will provide reinforcement of key MB skills that are linked to hypothesized mechanisms of change, promote completion of MB personal projects (homework), and facilitate self-monitoring of one's mood. In Phase 2, we will recruit 36 mother-father dyads for an uncontrolled pilot in which mothers will receive MB-TXT and fathers will receive a Fathers and Babies (FAB) *(previously referred to as MB DAD)* pilot curriculum developed using existing materials and data collected via qualitative research with HV clients, their partners, and HV staff.

Aim 1. To determine the feasibility and acceptability of conducting the MB-TXT intervention protocol across three HV programs in preparation for a larger fully powered RCT. Using MB text messages already developed by Co-I Barrera, we will collect data on home visitor adherence to delivering text messages at specified intervals, percentage of clients responding to text messages, and client comprehension of text messages as well as perceptions of text messages' utility.

Aim 2. To calculate a preliminary effect size that could be used, along with other relevant data, to calculate sample size for a future fully powered RCT.
H1. Women receiving MB-TXT will exhibit greater reductions in depressive symptoms, compared to women receiving MB.
H2. Women receiving MB-TXT will experience greater changes in hypothesized intervention mechanisms compared to women receiving MB—specifically, fewer negative cognitions and increased behavioral activation, use of social support networks, and mood regulation.
H3. Women who participate in MB-TXT will report greater completion of personal projects.

Aim 3. To develop and determine the feasibility and acceptability of a) conducting the FAB intervention protocol and b) assessing paternal and dyadic outcomes across two HV

programs. Focus groups with RCT participants, their male partners, and HV staff will generate information on a) intervention content, b) frequency of contact, and c) relationship to MB materials received by their partner. These data will be used, in conjunction with materials already developed by Co-I Garfield, to create the FAB curriculum and protocol.

2.0 Background / Literature Review / Rationale for the study:

Postpartum depression is a serious mental illness that poses significant health and mental health risks for families.[8-15] Prevalence of postpartum depression is estimated at 10-22%, disproportionately affecting low-income women with 30-45% prevalence of depressive symptoms. [16-21] The strongest risk factors include a prior history of depression and depression during pregnancy, with a 25-50% risk of recurrence.[18,,22-27] Postpartum depression is associated with suicide risk,[28-32] and is a risk factor for poor parenting practices. [33-35] Children of depressed mothers are more likely to have poor attachment with caregivers, emotional and behavioral dysregulation, attention and memory problems, and are at greater risk for childhood psychiatric disorders. Depression occurs in 5-7% of new fathers with similar negative outcomes for children of depressed fathers.[36-39]

Despite calls for increased detection of postpartum depression, with the U.S. Preventive Services Task Force recommending universal prenatal and postpartum screening,[40] perinatal women are less likely to receive mental health services than women in the general population[41,42,46-51] due to factors such as stigma, lack of knowledge about treatment options, limited access to mental health providers, and childcare and family responsibilities.[42-44] Interventions specifically targeting women with elevated depressive symptoms are crucial to prevent the worsening of depressive symptoms and onset of major depression during the perinatal period.

Fathers are a missing yet important component of perinatal interventions. Depressed fathers (5-10% prevalence) [37,65] exhibit poorer parenting behaviors and greater likelihood of child neglect than non-depressed fathers,[39,66] and their children are at-risk for later psychiatric disorders,[37] poorer language and reading development[67] and increased behavior problems.[36,38] These findings suggest that interventions in the perinatal period focused exclusively on maternal mental health may be limited in their effectiveness. Nevertheless, according to recent Cochrane Reviews on perinatal depression prevention and treatment interventions, [51,68] no interventions explicitly address fathers' psychosocial wellbeing.[69]

Home Visiting (HV) programs offer services in every state [70] and typically enroll women prenatally with services continuing until a child reaches 2-4 years. Many HV models exist, with 14 evidence-based models showing favorable impacts on multiple maternal and child health outcomes.[71] Addressing maternal depression has been identified by federal agencies,[72,73] HV model developers,[74] and HV researchers[75] as a critically needed and highly impactful HV enhancement given high rates of women experiencing depressive symptoms in HV programs.[76-78]

Text messaging via a mobile device is low cost and accessible to the majority of people regardless of race, ethnicity, and socioeconomic status, [56,57] making texting an ideal tool to deliver health information and interventions, especially to communities where barriers to mental health care exist. A systematic review of studies using texts to deliver health information showed increased use of health services, dissemination of educational information, and utilization of disease management skills.[58,59] Although text messaging interventions are increasing in popularity, few have focused on perinatal depression. Several studies have examined feasibility and acceptability of implementing text message interventions among perinatal women without examining health outcomes.[60-63] A 2015 review [64] found 48 studies evaluated effects on knowledge, attitudes, or behaviors among pregnant women, women of reproductive age, or women with young children: of these, none focused on postpartum depression.

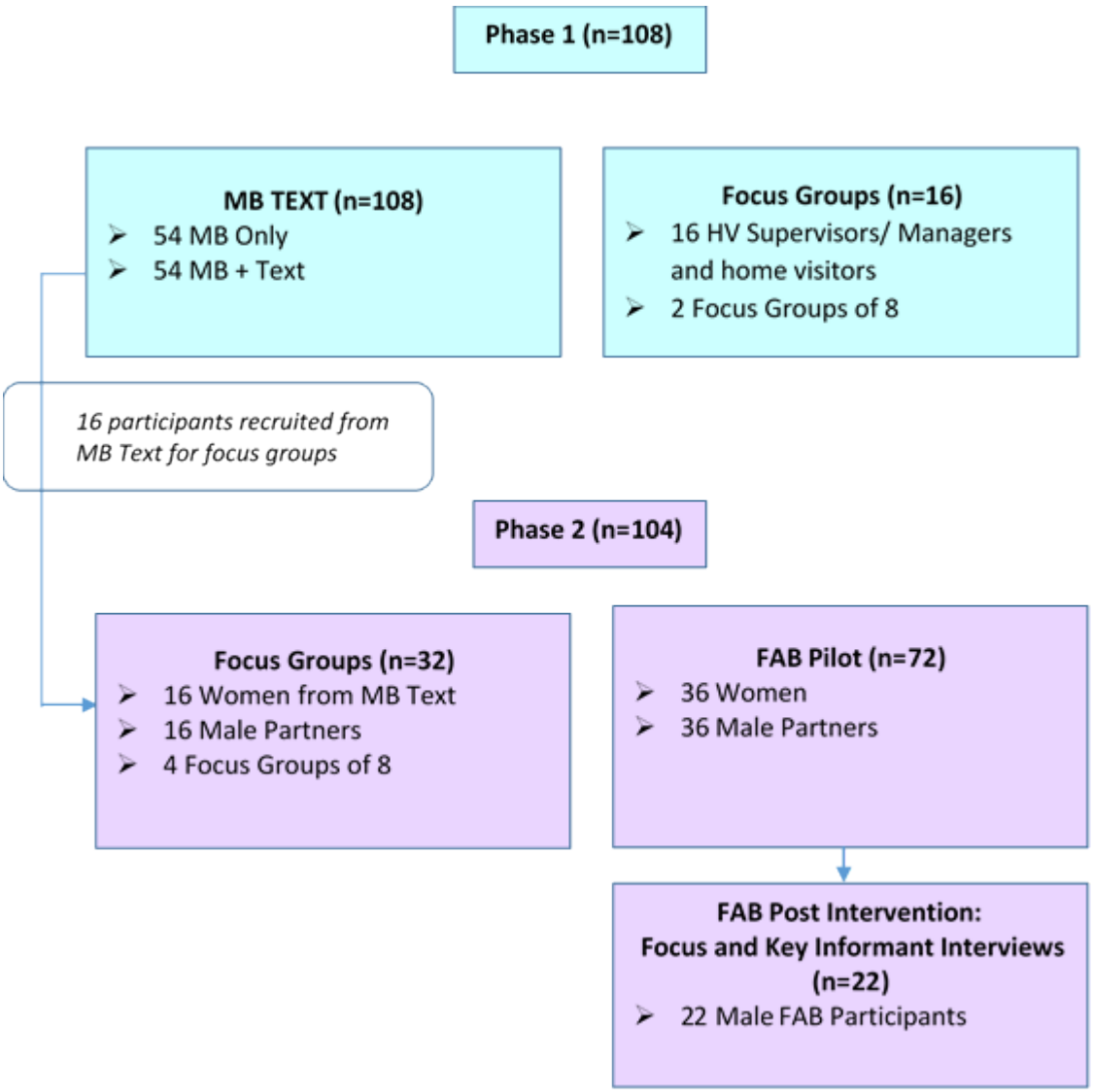
RCTs have demonstrated the association of the Mothers and Babies curriculum with prevention of new cases of major depression and reduction of depressive symptoms among perinatal women receiving MB.[13,14,16,17,55] Enhancements to MB are warranted in two main areas. First, prior MB trials

suggest the intervention is less successful for women who exhibit smaller changes in hypothesized intervention mechanisms and less fully engage in homework completion between sessions—a core component of CBT interventions like MB. Second, previous postpartum depression preventive interventions—including MB—have neglected to intervene with partners of pregnant women, despite the growing recognition that paternal depression also exerts influence on children's social-emotional development[18] and occurs in a similar timeframe.[19] Thus, in an otherwise successful intervention, these limitations—mixed success in improving hypothesized intervention mechanisms and limited engagement of fathers—may mitigate intervention efficacy.

3.0 Inclusion and exclusion criteria:

The study population will consist 212 study participants. During phase 1,108 participants will be HV clients and 16 will be Home Visiting supervisors/managers and home visitors. We will enroll 108 HV clients at 10-12 HV programs: 54 women will receive Mothers and Babies 1-on-1 without text message enhancements and 54 women will receive Mothers and Babies 1-on-1 with text message enhancements. Of the 108 women, 16 will be recruited for focus group participation in phase 2 of the study. The 16 HV supervisors/managers and home visitors will participate in two groups of 8 focus group participants. All focus groups will only be held in English.

During phase 2 of the study we will conduct focus groups with the identified 16 women from phase 1 of the study. We will also include their male partners (n=16) in two focus groups of 8 participants. All focus groups will only be held in English. Additionally we will recruit 36 women and their male partners (36 dyads from 10-12 HV programs) to participate in an uncontrolled pilot of the FAB intervention at two HV programs not participating in the Phase 1 RCT. We will conduct additional, qualitative data from 22 male partners after receiving FAB. Our informed consent from includes an option to be contacted for future research studies, we will only contact participants who indicate "yes" to this option for qualitative data collection activities (focus groups and key informant Interviews) after completing FAB.



Study Participants

Phase 1 (MB-TXT RCT)

We will recruit 108 study participants from 10-12 Home Visiting programs. English or Spanish-speaking women ≥16 years old enrolled in HV programs who are in their 1st or 2nd trimester (≤ 26 weeks) will be eligible for enrollment; across the 10-12 HV programs ~80% of women meet these criteria.

Phase 2 (FAB Development and Pilot)

(A) Focus Groups for FAB Development

We will recruit a total of 48 focus group participants, consisting of 16 female clients who participated in MB-TXT in Phase 1, 16 male partners of the female focus group participants, and 16 Home Visiting supervisors/managers and home visitors from the HV programs. The focus groups with the Home Visiting supervisors/managers and home visitors will be conducted during Phase 1 and 2 of the study. The focus groups will consist of 16 Home Visiting supervisors/managers and home visitors from the HV programs. The focus groups in phase 2 will consist of 16 female clients who participated in MB-TXT in Phase 1 and 16 male partners of the female focus group participants. All focus groups will only be held in English.

(B) FAB Pilot Study

We will recruit 36 women and their male partners (36 dyads from 8-10 HV programs).Eligible women (n=36) may be English speaking, ≥18 years old and enrolled in HV programs who are pregnant or

have a young child or children. Eligible men (n=36) may be English speaking, ≥18 years old, partners of female participants. We will recruit a total of 22 male partners who have received FAB (post-intervention) for focus group and key informant interviews.

Home Visiting Programs
The 10-12 HV programs that use either the Healthy Families America (HFA) or Parents as Teachers (PAT) model. HFA and PAT are evidence-based[71] paraprofessional HV models that enroll women prenatally and continue services until a child's second birthday (HFA) or entry into kindergarten (PAT). Both HFA and PAT recruit women at high risk for poor pregnancy and/or parenting outcomes via referrals from prenatal care clinics, community outreach, and current program participants. Both the HFA and PAT models call for weekly or bi-weekly home visits during pregnancy and the first six months postpartum. English or Spanish-speaking women ≥16 years old enrolled in HV programs who are pregnant will be eligible for enrollment in Phase 1 of the study. English speaking dyads; women ≥18 years old enrolled in HV programs and their male partners ≥18 years will be eligible for enrollment in Phase 2 of the study. Across the HV programs ~80% of women meet these criteria.

Vulnerable Populations
We will enroll pregnant women in both studies given that the Mothers and Babies Course can delivered prenatally as a postpartum depression prevention intervention. In Phase 1, we will offer participation to pregnant women, ages 16 and older, knowing that the client population of HV programs is younger, on average, than the general population. In Phase 2, we will offer participation to pregnant women or have a young child or children who are enrolled in HV, ages 18 and older. Mothers and Babies has been used in similar HV settings in the state of Illinois and nationally, with high ratings of acceptability and usefulness and no ill effects of participation detected.

4.0 Procedures Involved:

Phase 1 (MB-TXT RCT)
Study Activities Include:

- Recruitment of participants for MB / MB + Text RCT
- Focus Groups with Home Visiting supervisors/managers and home visitors (2 Groups of 8, n=16)

Program Implementation (MB-TXT RCT)
We will conduct a cluster RCT to determine the feasibility and acceptability of the MB-TXT intervention and calculate a preliminary effect size to determine a sample size for a future RCT. This RCT will also allow us to examine MB-TXT effects on proposed mechanisms underlying intervention efficacy. Cluster allocation by HV program minimizes contamination between study groups. We will work with 10-12 HV programs that have been trained on MB 1-on-1 and have working relationships with the PI. These programs provide a geographically, racially, and ethnically diverse set of recruitment sites. These programs are part of a network of Illinois HV programs overseen by the Illinois Governor's Office of Early Childhood Development which has supported scaling MB throughout Illinois and is enthusiastic about using text messaging to enhance intervention effectiveness. We will use a stepped wedge design—a form of RCT that involves sequential, but random, rollout of the intervention over multiple time periods. We have created two HV program clusters. Both clusters will initially implement MB 1-on-1 and will recruit MB participants for one quarter (i.e., three months) before crossing over to recruit MB-TXT participants for one quarter. MB-TXT's core curriculum is identical to MB 1-on-1 and adds a series of text messages throughout the curriculum.

Study Conditions:
MB 1-on-1. Half of our study participants (n=54) will receive MB 1-on-1. MB 1-on-1 is a manualized 12-session intervention divided into five modules. An introductory 2-session module establishes key

concepts related to stress, monitoring of one's mood, and ways in which one's mood influences one's internal thoughts and external environment; three 3-session modules correspond with key cognitive-behavioral elements: pleasant activities, thoughts, and social support/contact with others; a 1-session summary reviews content and identifies areas for future use of MB skills. Throughout MB, mood management skills are integrated using psycho-educational activities that encourage participants to understand connections between their mood and their activities, thoughts, and contacts with others. Content is tailored to specific needs and issues of pregnancy and the postpartum periods. Each MB session lasts 15-20 minutes and is delivered as part of a regularly scheduled home visit.

MB-TXT. Half of our study participants (n=54) will receive MB 1-on-1 along with text enhancements. Co-Investigator Barrera has developed text messages to complement MB content, both in English and Spanish. These texts focus on: a) skill reinforcement (e.g., Some thoughts just come to us, but we can make a conscious effort to think of positive thoughts.); b) homework reminders (e.g., What pleasant activity will you try today?), and c) self-monitoring (e.g., On a scale of 1-9, how would you rate your mood?).We will append the MB 1-on-1 Instructor Manual with instructions on how and when to integrate these 36 texts into the existing curriculum. These texts will be linked with the 12 MB sessions. Specifically, after completing each in-person session, 3 texts will be sent *by a home visitor* to her client; one text will focus on skill reinforcement, one will be a homework reminder, and one will focus on self-monitoring. We anticipate that texts will be sent within one week of the completion of a session to ensure standardization and minimize the likelihood that home visitors will forget to send messages. All texts will be sent through the HealthySMS platform used in Co-I Barrera's pilot study. To increase participant engagement (i.e., reading texts), messages will be sent at different times of the day, per the study participant's preference.[64] The Instructor Manual will specify the order in which the texts should be sent. Some messages will ask for a response from the client. This will allow investigators to determine whether a message is read and obtain data related to usefulness of a text message and/or client behavior. For example, in response to a text asking the client to rate her mood (i.e., self-monitoring), the client can enter 1 (worst mood ever) through 9 (best mood ever); these data will be sent to the HealthySMS platform which can be accessed by the home visitor. Additional open-ended responses can also be provided by clients. Each text and related response are linked and stored in HealthySMS for immediate access and review or future download and analysis. Home visitors will be trained by Co-I Barrera and PI Tandon on MB-TXT implementation. We have budgeted for participants to receive a monthly stipend to cover the costs text messaging until the 12 MB sessions are completed or up to six months post baseline. In phase 1 (MB-TEXT) this is available to only participants receiving texts. If participants do not cell phones with unlimited texting to ensure access to necessary technology.

Phase 1 Focus Groups
We will also recruit and conduct two focus groups with 16 HV supervisors/managers and home visitors beginning in phase one and into phase 2 of the study.

Training and Supervision of HV programs. The majority of participating All HV programs have been trained on MB 1-on-1 and are currently implementing the curriculum. Programs new to the MB Course will receive in-person training from the PI and/or study team. All programs will receive a half-day refresher training on MB along with guidelines on implementing MB-TXT conducted by Co-I Barrera and PI Tandon. All programs will receive supervision from PI Tandon after the first implementation of the intervention begins at the HV programs

Participant Screening: Participants will initially be screened for eligibility criteria by their home visiting program sites. Upon permission from the potential study participant, program sites will fill out a referral form, which will include the potential study participants name and contact information, and send it to the research team. The HV will explain the study and provide a brochure with study details during the referral process. Once the program sites refer potential study participants, a member of the study team will call the participant using the "Phone Script for Referrals" to screen the potential study

participant for eligibility criteria and move forward with the consent process either via telephone or a REDCap survey link.

Participant Outcomes Surveys:
Clients MB TEXT: Participant outcomes will be collected at three time points—baseline and 6 months post-intervention. Participants will receive $20 remuneration at the baseline and 6-months, assessments. $20 remuneration will be in the form of a Northwestern PNC stored-value card (Visa Gift-Card).

Home Visitors: Home visitors will be asked to respond to a REDCap survey items after completing each MB session to assess if clients came to the session having completed their personal project, implemented session, and next scheduled session date. Home visitors will measure clients' perceived utility and comprehension of text messages by asking clients to rate the extent to which each of the 3 text messages received between sessions was a) useful and b) easy to understand. Questions will be on a 4-point Likert Scale and will be asked of clients at the end of each MB session. These data will be inputted into the HealthySMS system.

Focus Groups: There will be six focus groups during the study. Two focus groups with HV supervisors, managers, and home visitors will take place during phase 1 and 2. Four focus groups with clients and their partners will take phase during phase 2. All focus group participants will receive $30 remuneration in the form of a Northwestern PNC stored-value card (Visa Gift-Card).

Related to Aim 1, MB-TXT feasibility and acceptability data will be collected from clients and home visitors. Similar to previous SMS studies, we will use percentage of text responses as an indicator of "read" messages. We will assess home visitor adherence to the MB-TXT protocol by using archived data from HealthySMS to calculate percentage of texts sent at appropriate intervals, as stated in the MB Instructor Manual. Home visitors will complete a brief web-based REDCap survey after completing each MB session to assess if clients came to the session having completed their personal project. Using a 4-point Likert Scale, home visitors will also ask clients to rate the extent to which each of the 3 intersession texts was a) useful and b) easy to understand; these data will be entered into REDCap. Related to Aim 2, participant outcomes will be collected via survey at baseline and 6 months. Data will be collected and managed using REDCap electronic data capture tools hosted at Northwestern. Participants will receive $20 remuneration for each assessment. At each assessment, a link to REDCap will be sent to study participants who can complete the assessment on any web platform (smartphone, tablet, and computer). The Project Manager or Research Assistant will complete assessments by phone for participants who prefer not to use REDCap. Depressive symptoms, as measured by the the Beck Depression Inventory-II (BDI)[100] a 21-item self-report measure is our primary outcome. Secondary outcomes, which map onto the hypothesized mechanisms for influence on depressive symptoms are: cognitive structuring (Experiences Questionnaire),[85] behavioral activation (Behavioral Activation Depression Scale),[86-88] social support (MOS Social Support Survey),[89] and mood regulation (Negative Mood Regulation Scale).[90,91] We estimate 15% attrition at 6months, resulting in 46 participants per arm; previous MB trials conducted by PI Tandon had 12 month attrition rates <10% and we will use similar procedures for minimizing attrition.

Analysis for Aim 2 is limited to the fact that this is a pilot study. As such, we will compare MB and MB-TXT groups at the individual level (not adjusting for potential clustering effect of either home visitor or HV program). The data will also provide key insights for future studies on how correlated the BDI scores will be over time, as longitudinal data during this postpartum period is not readily available. To address hypothesis 2, the first step in mediation is to determine the mediator's association with the criterion (group), as well as the outcome. The sample provides 80% power to detect effect sizes of 0.59 using two sided Mann Whitney tests at a type I error rate of 5% (for the between group comparison of potential mediators: negative cognitions, behavioral activation, use of support systems, mood regulation), as well as 80% power to detect correlations as small as 0.287 (comparing BDI to

the potential mediators). Pilot data will allow us to examine potential ranges of Intraclass Correlation Coefficients (ICC), which we need to account for in a larger RCT. These data will allow us to explore whether randomization should be done at HV program level, or the home visitor level. This sample provides 80% power to detect ICCs of 0.179 (13-14 observations at 10-12 HV programs), or of 0.261 (3 observations in 36 home visitors).

Phase 2 (FAB Development and Pilot)
Study Activities Include:

- Focus Groups with HV Clients (n=16) and their male partners (n=16)
- Development of FAB
- Pilot FAB
- Note: The research team submitted a modification to add/update details about the focus groups for phase 2 of the study. Focus group guide for these groups was submitted a modification for versions 7 of the protocol.
- Note: The research team submitted a modification to add/update details for the FAB intervention pilot in phase 2 of the study including recruitment materials. Modifications are included in version 8 of the protocol.
- FAB Post Intervention Focus Groups and Key Informant Interviews
- Note: The research team will submit a modification to add/update details about the FAB post intervention focus groups and key informant interviews. The modification will include focus and key informant consents, the focus group guide and the key informant interview guide.
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Overview of Phase 2 (FAB Development and Pilot). For Phase 2, we will conduct an uncontrolled pilot of FAB—an intervention for fathers that aims to a) support fathers' mental health and b) support their partners' mental health, as they become parents. This pilot will determine the feasibility and acceptability of conducting the FAB intervention with women enrolled in HV, and their male partners. It will also provide guidance on the appropriateness of measures to assess fathers' mental health and dyadic relationships and generate preliminary data from those measures that can guide a subsequent RCT.

Program Implementation (FAB Development and Pilot)
To develop the FAB curriculum and protocol we will conduct a series of focus groups with key stakeholders along with using materials already developed by Co-I Garfield (see C2). We will conduct a total of six focus groups, each comprised of 8 individuals per focus group (total 54 focus group participants). Two focus groups will be conducted with female clients who participated in MB-TXT in Phase 1; one focus group will be with predominately low-income African American women from a Chicago-area HV program while the other will be with predominately low-income white women from suburban Chicago. Two focus groups will be held with the male partners of the female focus group participants and two focus groups will be conducted with HV supervisors/managers and home visitors from the HV programs. The focus groups with the HV supervisors/managers and home visitors will begin in Phase I. At each HV program, 18 women will take part in MB-TXT, thereby making 8 women with their male partners a reasonable enrollment target.

Focus group questions will emphasize four domains: 1) content appropriate for fathers to support their own mental health, 2) content appropriate for fathers to support their female partner's mental health, 3) recommendations for frequency and duration of FAB text intervention, and 4) relationship/ synergy of MB-TXT and FAB content and delivery. Focus groups will be moderated by Co-I Garfield and the Project Manager. Notes will be recorded by the Project Manager. All focus groups will be audio recorded and transcribed verbatim. PI Tandon and Co-I Garfield have expertise with qualitative analysis[79,91-95] and will independently code the focus groups along with the Project Manager to identify key concepts and themes related to each of the four domains. These data will be used to develop a series of texts for the FAB intervention and the protocol for delivering those texts. This process will be

led by PI Tandon and Co-Garfield as well as three focus group participants—one female HV client, one male partner, and one home visitor—who will meet with the investigators in person (as needed) and by phone. Both PI Tandon and Co-I Garfield have experience developing and adapting intervention curricula while engaging stakeholders in the development process.[79,96] Once the series of texts and protocol is drafted, two additional focus groups will be conducted to refine the FAB protocol and content. These focus groups will be mixed-gender—i.e., women and their male partners can attend—and will consist of individuals who participated in the initial set of focus groups.

We will conduct an uncontrolled pilot of the FAB intervention at 10-12 HV programs. Programs from the TEXT phase will be included in the pilot and additional programs will be recruited. The additional programs will have been previously been trained in MB and are currently implementing the 1-on-1 modality. . HV programs will serve predominately low-income African American women and predominately low-income white women. We will recruit 36 women and their male partners. Eligibility criteria will be different from Phase 1 RCT. English speaking dyads; women ≥18 years old enrolled in HV programs who are pregnant or have a young child or children and their male partners ≥18 years will be eligible. Recruitment processes will be identical to the Phase 1 RCT. Male partners will also provide informed consent. Female clients will receive the MB-TXT curriculum (i.e., MB 1-on-1 plus MB-TXT) and their male partners will receive the FAB text based curriculum. Home visitors will be responsible for sending texts to both their female clients and the clients' male partners. Participant outcomes will be assessed at baseline and post-intervention at 3, and 6 months. All measures used in Phase 2 (see Table 2) will be administered to both female and male participants; these measures all have been widely used with both genders in prior research. Additional measures will be administered to both female and male clients on their relationship status,[97] father involvement with child,[98] and perceived social support from partner[99].

We will recruit a total of 22 male partners who have received FAB (post-intervention) for focus group and key informant interviews, to inform which aspects of FAB content and delivery are working well and which require modification. We will develop focus group guides and semi-structured interviews that prompt discussion about the following topics: (1) satisfaction with the existing FAB Course, identifying the most and least enjoyable, understandable, and useful content; (2) effectiveness of content delivery (e.g., web-based links to content, text-messages); (3) additional topics that should be included to meet the needs of new fathers and families; and, (4) methods to best engage fathers in the FAB intervention. Focus groups and key informant interviews will be audio-recorded, transcribed, and then analyzed to identify common themes to guide FAB Course revisions. In keeping with a collaborative approach that our research team has undertaken throughout our MB and FAB work, during our focus group and key informant interviews we will identify 2-3 fathers from different cultural backgrounds to serve as consultants, who will remain engaged in an iterative process of review and feedback about FAB revisions.

Study Conditions:

MB 1-on-1 plus MB-TXT. The female study participants (n=36) will receive MB 1-on-1 along with text enhancements. Co-Investigator Barrera has developed text messages to complement MB content. These texts focus on: a) skill reinforcement (e.g., Some thoughts just come to us, but we can make a conscious effort to think of positive thoughts.); b) homework reminders (e.g., What pleasant activity will you try today?), and c) self-monitoring (e.g., On a scale of 1-9, how would you rate your mood?). These texts will be linked with the 12 MB sessions. Specifically, after completing each in-person session, 3 texts will be sent by a home visitor to her client; one text will focus on skill reinforcement, one will be a homework reminder, and one will focus on self-monitoring.

FAB. The male study participants (n=36) will receive FAB a text based intervention/curriculum. PI Tandon, Co-Investigator Garfield, and the Research Project Manager have developed a curriculum that aligns and is complimentary to MB 1-on-1 plus MB-TXT. The first FAB session can be delivered in person with the dyad (female and male client) during a home visit, or separately. If the male client cannot be present for the first session, the Home Visitor or Project Manager will deliver the session over the phone. After the first session is initiated with the dyad, the female client will receive MB 1-on-1 and MB-TXT and the male client will receive FAB texts (9-15 per module). The HV will have flexibility to deliver additional sessions in to the male client but is not required. Text messages to complement MB content (English Only). These texts focus on: a) skill reinforcement b) practice reminders (c) self-monitoring. These texts will be linked with the 12 MB sessions that the female client is receiving but the male partner will receive additional texts to deliver the content in a text-based sessions. He will receive 3-6 text messages per session while his partner will receive 3 messages after each session. Specifically, after completing each in-person session, texts will be sent by a home visitor to both her female client (Total # of Txts = 36) and her partner (Total # of Txts = 51).

We anticipate that texts will be sent within one week of the completion of a session to ensure standardization and minimize the likelihood that home visitors will forget to send messages. All texts will be sent through the HealthySMS platform used in Co-I Barrera's pilot study. To increase participant engagement (i.e., reading texts), messages will be sent at different times of the day, per the study participant's preference.[64] Each text and related response are linked and stored in HealthySMS for immediate access and review or future download and analysis.

We have budgeted for each dyad to receive a monthly stipend to cover the costs of text messaging until the 12 MB sessions are completed or up to six months post baseline. In phase 1 (MB-TEXT) this is available to only participants receiving texts. If participants do not cell phones with unlimited texting to ensure access to necessary technology.

Training and Supervision of HV programs. All the participating HV programs have been trained on MB 1-on-1 and are currently implementing the curriculum. All programs will receive a two-hour training on implementing FAB and MB-TXT conducted by the Research Project Manager. All programs will receive supervision after the first implementation of the intervention begins at the HV programs.

Participant Screening: Participants will initially be screened for eligibility criteria by their home visiting program sites. Upon permission from the potential study participant, program sites will fill out a referral form, which will include the potential study participants name and contact information, and send it to the research team (e-mail or fax). The HV will explain the study and provide brochures for both the female client and male partner with study details during the referral process. Once the program sites refer potential study participants, a member of the study team will call the participants using the "Phone Script for Referrals" to screen the potential study participants for eligibility criteria and move forward with the consent process either via telephone or a REDCap survey link. The female client and male partner will be contacted and consented separately. The female and male client will both have to agree to participate in the study to be eligible to participate. If there is discordance, (female client or male partner does not agree) to participate the dyad will be ineligible. Our informed consent from includes an option to be contacted for future research studies, we will only contact participants who indicate "yes" to this option for qualitative data collection activities (focus groups and key informant Interviews) after completing FAB.

Participant Outcomes Surveys:

Clients FAB: Participant outcomes will be collected at three time points—baseline and 3 and 6 months post- intervention. Participants will receive $20 remuneration and will be in the form of a Northwestern PNC stored-value card (Visa Gift-Card).

We will measure male clients' perceived utility and comprehension of text messages by asking clients to rate the extent to which the text messages were a) useful, b) enjoyable, and c) easy to understand. Questions will be on a 4-point Likert Scale and will be asked of clients at the end of each MB module (Introduction, Pleasant Activities, Thoughts, Contact with Others and Review/Conclusion). We will measure male and female clients' perceived feasibility and acceptability post intervention. These data will be collected via REDCap.

Home Visitors: Home visitors will be asked to respond to a REDCap survey items after completing each MB session to assess if female clients came to the session having completed their personal project, implemented session, and next scheduled session date. Home visitors will measure female clients' perceived utility and comprehension of text messages by asking clients to rate the extent to which each of the 3 text messages received between sessions was a) useful and b) easy to understand. Questions will be on a 4-point Likert Scale and will be asked of clients at the end of each MB session. These data will be inputted into the HealthySMS system. We will assess home visitors' perceived feasibility and acceptability post intervention after all 12 session of MB-TXT and FAB are completed.. These data will be collected via REDCap.

Focus Groups: There will be three focus groups and 4 key informant interviews during the study and will take place during phase 2 after participants have completed FAB. All focus group and key informant participants will receive $35 remuneration in the form of a Northwestern PNC stored-value card (Visa Gift-Card).

Table 1: Detailed Description of Study Measures for Phase1

Text messages read by HV clients will be measured by calculating the percentage of text messages responded to by clients.
Home Visitor Adherence to MB-TXT protocol will be measured by using the archived data from HealthySMS to calculate the percentage of texts sent at the appropriate intervals, as stated in the MB Instructor Manual
Client completion of personal projects will be measured by asking home visitors to respond to a REDCap survey item after completing each MB session to assess if clients came to the session having completed their personal project.
Client perceived utility and comprehension of text messages will be measured by asking home visitors to rate the extent to which each of the 3 text messages received between sessions was a) useful and b) easy to understand. Questions will be on a 4-point Likert Scale and will be asked of clients at the end of each MB session. These data will be inputted into REDCap.
Depressive Symptoms will be assessed using the Beck Depression Inventory-II (BDI),[100] a 21-item self-report measure of depressive symptoms to assess severity of depressive symptoms consistent with DSM-IV symptom criteria. The BDI has excellent internal reliability for outpatient samples and its construct validity has been established.
Cognitive Structuring will be measures using the Experiences Questionnaire[85] a 20-item self-report scale measuring decentering and rumination, which has demonstrated strong internal consistency in studies examining effects of interventions that incorporate cognitive restructuring.
Behavioral Activation will be measured using the Behavioral Activation Depression Scale,[86] a 25-item, four subscale self-report with strong psychometric properties.[86,87] The four subscales assess activation, avoidance/rumination, work/school impairment, and social impairment. We will also use a brief checklist adapted from the Pleasant Events Schedule, a psychometrically strong questionnaire.[88] This 25 item self-report contains a list of pleasant events relevant to low-income pregnant women and assesses the extent to which subject's engaged in, and experienced pleasure from, these activities.

Social Support using the 19-item Medical Outcomes Study Social Support Survey.[89] This self-administered survey includes an overall functional social support index, as well as four functional support subscales: affectionate, emotional/informational, tangible, and positive social interaction.
Mood regulation will be measured using the Negative Mood Regulation Scale (NMRS).[90] The NMRS assesses an individual's expectancy that some behavior or cognition will alleviate a negative mood state. For each question, respondents use a five-point scale from "very much disagree" to "very much agree" to indicate what they believe they can do when they are disappointed or experiencing a negative mood. The scale has demonstrated excellent internal consistency, good test-retest reliability, and correlational evidence of both convergent and discriminant validity with constructs such as depressive symptoms and locus of control, respectively.[91]
Mothers and Babies Skill Utilization will be assessed using items developed the study investigators.
Client demographics will be assessed using items developed by the study investigators. Baseline Demographics –17 items 3 & 6 month Follow-up Demographics – 8 items
Prenatal Behavior and Service Utilization. - will be assessed using items developed by the study investigators.

Table 2: Detailed Description of Study Measures for Phase 2

Text messages read by HV clients will be measured by calculating the percentage of text messages responded to by female and male study participants.
Home Visitor Adherence to MB-TXT protocol will be measured by using the archived data from HealthySMS to calculate the percentage of texts sent at the appropriate intervals, as stated in the MB Instructor Manual.
HV Post Intervention Survey will be assessed using questions developed by the study investigators. Questions will be on a 4-point Likert Scale and will be asked of home visitors at the end of the 12 MB sessions.
Female Client perceived utility and comprehension of text messages will be measured by asking home visitors to rate the extent to which each of the 3 text messages received between sessions was a) useful and b) easy to understand. Questions will be on a 4-point Likert Scale and will be asked of clients at the end of each MB session. These data will be inputted into HealthySMS.
Female Client Post Intervention Survey will be assessed using questions developed by the study investigators. Questions will be on a 4-point Likert Scale and will be asked of the female clients at the end of the 12 MB sessions.
Male Partner perceived utility and comprehension of text messages will be measured by a survey to rate the extent to which the text messages received were a) useful and b) easy to understand. Questions will be on a 4-point Likert Scale and will be asked of clients at the end of each MB module.
Male Partner Post Intervention Survey will be assessed using questions developed by the study investigators. Questions will be on a 4-point Likert Scale and will be asked of male partners at the end of the 12 MB sessions.
Depressive Symptoms will be assessed using the Beck Depression Inventory-II (BDI),[100] a 21-item self-report measure of depressive symptoms to assess severity of depressive symptoms consistent with DSM-IV symptom criteria. The BDI has excellent internal reliability for outpatient samples and its construct validity has been established.
Anxiety symptoms will be assessed using the GAD-7- To assess anxiety, we will administer the Generalized Anxiety Disorder 7-item scale (GAD-7; Spitzer et al., 2006), which is a widely used self-report measure of anxiety symptoms.
Perceived stress will be assessed using the Perceived Stress Scale 10-item version. We will use the 10-item Perceived Stress Scale (PSS-10; Cohen & Williamson, 1988; Remor et al., 2006) to assess the level to which an individual considers their life stressful and how controllable a

person appraises her life.
Social Support will be assessed using the NIH Toolbox Instrumental Support and Emotional Support measures. Each measure asks 8 questions and asks respondents to indicate the extent to which they have received support for each area in the last month.
Mothers and Babies Skill Utilization will be assessed using items developed the study investigators.
Client demographics will be assessed using items developed by the study investigators. Female Client Baseline Demographics- 18 items Female Client 3 & 6 Follow-Up Demographics- 10 items Male Partner Baseline Demographics – 14 items Male Partner 3 & 6 Follow-Up Demographics- 8 items
Prenatal Behavior and Service Utilization. - will be assessed using items developed by the study investigators.
Relationship with partner will be measured using the Revised Dyadic Adjustment Scale (RDAS) cohesion subscale. The RDAS cohesion subscale is most relevant to this study and measures items such as engaging in activities together. The cohesion subscale consists of 4 items, each of which asks respondents to rate certain aspects of his/her relationship on a 5- or 6- point scale. Higher scores indicate greater relationship satisfaction. The RDAS has demonstrated excellent internal consistency.[97]
Fathers' involvement with child will be measured using the 10-item Father Engagement Scale (Dyer et al., 2015) which measures the number of times per month fathers engage in different types of activities with their child.
Perceived social support from partner will be measured using the Social Support Effectiveness-Questionnaire (SSE-Q) a 25-item version (Rini et al., 2011, J Consult Clin Psychol).

Participant Outreach and Contact: Study participants will be contacted at the following time points throughout the study:

1. Upon referral into the study. This contact will be from a member of the research team in order to conduct eligibility screening and review the study and next steps for consent and assessments
2. To schedule and/or conduct assessments by phone or REDCap survey link at baseline, post intervention, 3 and 6 months.
3. Text Messages after each session (MB +Text Only and FAB)
4. To check in with the study participants to make sure the study team has up to date contact information for the participant, as well as to stay engaged and build a rapport with the participant.
5. If the study participant is selected to participate in a focus group, research staff will call and coordinate focus group logistics.
6. Congratulation cards will be sent to each study participant after the birth of their baby
7. An information sheet will be mailed to notify participants who were previously consented and currently enrolled about the study being included in ClinicalTrials.gov and the change to the follow-up time points. We will only be following up at 6 months post-intervention and not at 9 month post-intervention.

5.0 Multiple sites:

Alinne Barrera is a CO-I on this grant. CO-I Barrera is the developer of the text messages and HealthySMS platform. Since she will be overseeing the implementation of the text message platform she will have access to participant information. She will not be involved in the consent or follow-up procedures and will not be directly interacting with participants. Alinne Barrera's

Institution is Palo Alto University. Palo Alto's IRB is ceding IRB review to Northwestern and signed an IRB Authorization Agreement (IAA).

6.0 Incomplete Disclosure or Deception: N/A

7.0 Recruitment:

Study Participants: During phase 1, we will recruit 108 study participants from each of the participating HV programs. We will enroll 108 HV clients at 10-12 HV programs, 54 women will receive Mothers and Babies 1-on-1 without text message enhancements and 54 women will receive Mothers and Babies 1-on-1 with text message enhancements. Of the 108 women, 16 will be recruited for focus groups phase 2 of the study.

During phase 2 of the study we will conduct focus groups with the identified 16 women from the 108 group that participated in phase 1 of the study. We will also include their male partners (n=16) in two focus groups of 8 participants. Additionally we will recruit 36 women and their male partners to participate in the FAB Pilot Study.

Home Visitors: We will recruit approximately 36 home visitors from 10-12 participating HV programs throughout the state of Illinois. All HV programs recruit women at high risk for poor pregnancy and/or parenting outcomes via referrals from prenatal care clinics, community outreach, and current program participation. All of the home-visitors who are being recruited through the participating home-visiting sites have been previous trained and are currently implementing Mothers and Babies 1-on-1. Home visitors that have not been trained will receive an in-person training (see training section for more detail). Each home-visitor will identify 1-4 client that will participate in study activities, of these clients 1-2 will receive MB without Text and 1-2 will receive MB with Text. All home-visitors will implement MB without text and MB with text. Programs will initially implement MB 1-on-1 and will recruit MB participants for six months before crossing over to recruit MB-TXT participants for 6 months. To pilot FAB 1-3 home-visitors from each program will identify 1-4 client dyads that will participate in FAB pilot study activities; Home-visitors who will implement FAB will recruit dyads.

We anticipate 16 home-visitors will participate in focus groups during phase 1 and 2 of the study. 10-12 HV programs will be recruited to implement the FAB pilot.

Recruitment Procedures/Attrition: Recruitment procedures will be identical to those used in a previous RCT of MB in HV programs conducted by Dr. Tandon. A postcard and/or flyer will be provided to the participating HV sites and the potential eligible study participants prior to NU research staff calling the study participants. The postcard/flyer will explain the purpose and overview of the study. Prior to beginning program implementation, potential study participants contact information will be obtained by the participating trained HV sites. The HV programs will fill out the referral form for eligible and interested participates, the form will be faxed or e-mailed to the Project Manager. The Project Manager and Research Assistant will share responsibility for calling each woman receiving HV services to tell them more about the recruitment and consenting process. A recruitment letter will be sent to the participants by the RA asking them to participate in the research study if the research team is unable to reach them by phone or email. The NU research team will also email the survey link to the study participants using email addresses provided by the HV sites, the link on NU REDCap database to be able to consent to participate in the program and complete a baseline assessment. The surveys will be available in both English and Spanish.

We will obtain names, phone numbers, and addresses of women and their partners. Individuals who meet our criteria for study eligibility but who are not interested in participating in our research activities will still be able to participate in the MB intervention. Based on previous research, we expect that fewer than 5% of eligible participants will opt out of research activities.

Phase 1 (MB-TXT RCT)
Each program will send contact information for an eligible participant to the Project Manager. The Research Assistant or Project Manager will contact these women to introduce women to the study, answer questions about participation, and ascertain interest in study participation. For women expressing interest, the Research Assistant will send an email link to the REDCap data collection portal to conduct the baseline assessment. Before completing the assessment, participants will provide informed consent via the REDCap system. Informed consent and surveys will be conducted by telephone with participants who do not have consistent internet access. These recruitment procedures have been used successfully in Dr. Tandon's current HV research in Illinois.

Phase 2 (FAB Development and Pilot)
Focus Groups
Informed consent forms will indicate that women participating in the MB-TXT intervention may be approached to participate in a focus group upon completion of the intervention. We anticipate recruiting women from the HV programs participating in MB-TXT. Should we have difficulty recruiting study participants from these programs, we will recruit from programs that have been previously trained in MB 1-on-1. .

To recruit male partners for the focus groups, we will use recruitment procedures used by Co-I Garfield in his previous research. We will first check with the female client that she agrees that her male partner should be invited to participate; this is an important consideration given the multitude of reasons female partners may not want their partner to engage in this project (e.g., domestic violence). If the female client agrees and provides contact information for their partners, we will directly contact fathers to inform them about the focus groups and gage their interest in participating. This may either occur through attempts at in-person or phone exchanges between the Project Manager/Research Assistant and fathers.

HV programs participating in this project understand that one goal is to develop intervention materials for fathers of HV clients, and are aware that home visitors from programs implementing MB-TXT will be recruited for focus group participation. Recruitment of home visitors for focus groups will be done by the Project Manager. We anticipate that home visitor focus groups will be conducted during a regularly scheduled supervision meeting among HV staff—a recruitment method that has proven effective in previous studies conducted by Dr. Tandon.

FAB Pilot
We anticipate recruiting women from the HV programs participating in MB-TXT and 2-3 new programs. We will take a three-pronged approach to recruitment and engagement of fathers in the pilot of FAB intervention. First, rather than take a maternal-gatekeeping approach to recruitment, we will take a father-centric approach where we directly contact fathers to inform them about this study. The home visitor will explain the pilot to her client and her partner during a regularly scheduled visit. The home visitor will leave brochures for both the mothers and fathers. Father-specific recruitment materials left for fathers who are not present at the time of recruitment by the HV staff. Second, all study materials will include father-specific language, images, and content supporting their role and importance to the family and the study. If the dyad is interested the HV will fill out the referral form and fax or e-mail it to the Project Manager. The Research Assistant or Project Manager will contact the female client and her partner separately and explain the study. For the uncontrolled pilot, recruitment procedures for females will be similar to those described earlier for Phase 1 (MB TEXT RCT). Recruitment procedures for male partners will use the same strategies as listed above. Male partners will also be sent an email link to the REDCap data collection portal to conduct baseline assessments and will be asked to provide informed consent via REDCap prior to completing this assessment. Informed consent and surveys will be conducted by telephone with participants who do not have consistent internet access. These recruitment procedures have been used successfully in Dr.Tandon's current HV research in Illinois.

Informed consent forms will indicate that male partners participating in the FAB intervention may be approached to participate in a focus group or key informant upon completion of the intervention.

8.0 Consent Process

All recruitment and consent procedures will be performed in accordance with guidelines of the Northwestern University Institutional Review Board. Women enrolling in home visiting programs during recruitment periods will complete the screening administered by phone by the Project Manager or Research Assistant. We request a waiver of written documentation of consent in order to administer this study online, or over the telephone if client participants do not have easy access to web-based resources. Online study implementation will decrease the time required to complete study assessments, and is more feasible to implement given that home visiting programs and clients across the State of Illinois and adjacent states will be participating, and our resources are limited.

Regardless of whether or not the study participant consents to the study online or over the phone, NU Research staff will offer the participant a copy of the consent form. If the study participant would like a copy of the consent, Research staff will either email or mail a copy of the consent form to the participant per their preferred method of contact.

Informed consent from home visiting participants and male partners will be collected primarily via a web-based survey using REDCap. For study participants who do not complete informed consent via REDCap, informed consent will be obtained by phone. Because in-person written consent will not take place, we will seek a waiver of documentation of consent from Northwestern University's Institutional Review Board. This protocol has been used successfully in prior HV studies conducted by Dr. Tandon.

If the enrollee meets eligibility criteria and is interested in participating in the study, the Project Manager or RA will indicate that a web-link with instruction on completing the baseline assessment via REDCap will be emailed or texted to them within the next two weeks. Consent will be conducted using online administration at the time of the first web-based survey. A brief questionnaire will follow the consent form in order to ensure the participant understands that (1) their participation is voluntary, and (2) they may withdraw or refuse participation at any time without consequence to their home visiting services. Both the online consent form and the study surveys for home visiting clients will be available in English and Spanish. Each time a study participant fills out a survey, the survey will include a prompt to the participant asking if they wish to continue their participation by completing the next survey.

For phase 1, we are requesting a waiver of parent permission in order to wave the signature of parents of children who are participants (Pregnant women >16years old; < 18 years old). This research involves minimal risk to the participants by only requiring the administration of online surveys and/or telephone interviews in order to collect data. Guidance from the U.S. Department of Health and Human Services Office of Research Protections (OHRP) indicates that individuals < 18 years of age can consent to study participation without parental consent if the study procedures for which they are consenting are such that they could provide consent outside of the research context. The waiver of parent permission will not adversely affect the rights and welfare of the minor subjects. This is a low-risk study. We will assess the Minor's ability to consent to participate by asking them a series of questions at the end of the informed consent process to ensure they understand 1) the main points of the study, including the research requirements, 2) the main risks of the study (in our case, feeling uncomfortable about some of the mental health questions, and 3) understanding that they can refuse to answer any questions on assessments and/or opt out of the study at any time w/o adversely affecting their relationship with their HV program. This research could not practically be carried out without the waiver of parent permission. Home- Visiting Program protocol is that parent/guardian consent is not required for a client under 18 to be able to enroll in a home-visiting program. The minors who we anticipate enrolling into the study may have fractured relationships with their parents

given the predominance of unplanned pregnancies may often cause family discord and even relocation of pregnant teens.

The study RA is bilingual and, therefore, will be able to communicate with both English- and Spanish-speaking participants. All of the surveys and assessments provided to the participants will be in either English or Spanish and administered either orally or written in the language in which the participants are most comfortable speaking.

The Co-PI (Garfield), Research Project Manager will conduct the focus groups. All focus group participants will be asked to provide informed consent prior to participating in the focus groups. Consent forms will clearly indicate that some study participants will be asked to participate in this additional data collection activity.

For Phase 1, we will enroll only pregnant women, given that our Mothers and Babies Course is delivered prenatally as a postpartum depression prevention intervention. We will offer participation to pregnant women, ages 16 and older. Each HV program will send contact information for an eligible participant to the Program Manager. The Manager or Research Assistant will contact these women to introduce women to the study, answer questions about participation, and ascertain interest in study participation. For women expressing interest, the Manager or Research Assistant will send an link to the REDCap data collection portal via email or text message, or Facebook message to conduct the baseline assessment. Participants that do not have access to online resources will be consented verbally and the baseline assessment will be conducted over the phone. Second, we will enroll HV supervisors/managers to participate in two focus groups. Consent will also be conducted in person by the Program Manager on the day the focus groups take place (prior to the focus groups).

For Phase 2, we will enroll two sets of study participants. First, we will enroll HV clients and their male partners of women participating in MB-TXT during Phase 1 to participate in four focus groups. Two focus groups will consist of 8-6 HV clients. Two separate focus groups will consist of 6-8 of their male partners. The Program Manager will administer the focus group consent in person on the day the focus groups take place (prior to the focus groups). We will enroll who are pregnant or have a young child or children and their male partners enrolled in HV and their male partners 18 years and older for our uncontrolled pilot of the FAB intervention. We will use processes similar to the ones described above to consent these individuals via REDCap prior to their baseline assessments. Again, for those individuals who choose not to consent via REDCap, phone consent will be conducted by the Program Manager or Research Assistant.

9.0 Process to Document Consent:

We request a waiver of written documentation of consent in order to administer this study online, or over the telephone. Online consenting will take place in Northwestern University's secure REDCap Database. There will be a continuous prompt to participants when filling out surveys regarding their current willingness to continue participation. Instructions to the REDCap assessments will provide rationale for the use of certain survey questions. Research team members administering assessments via phone or in person will be instructed to make sure this rationale is provided to study participants who do not see this rationale on the web-based REDCap system. Participants will be informed via informed consent and during all assessments that they may choose to not answer any question at any time for any reason and that not answering questions will not affect their relationship with their HV programs or ability to keep receiving the MB intervention (for those enrolled in the two intervention arms). Research assistants will consult with the Research Manager and PI, Dr. Tandon, if necessary, to resolve any questions they are unsure how to handle.

Because the majority of consents will be conducted online, we are asking for a waiver of written documentation of consent. For study participants who consent via REDCap, consent will be conducted prior to completion of the first web-based survey. The full consent form is provided in

REDCap and participants will be asked to indicate whether they agree to participate via a signature line for them to type in their name, which is their electronic signature. Participants who provide online informed consent to participate will be able to print the screen to retain the consent form for their records. If consent is being obtained over the phone, verbal consent will be used. The person obtaining consent will sign and the date the verbal consent form. A copy of the consent form will be mailed to the participant with their compensation. For study participants who consent prior to focus groups, a hard copy of the consent form will be signed at the time of consent. Regardless of how consent is obtained, all respondents will be asked 2-3 questions to ascertain understanding of the informed consent process—in particular, that their participation is voluntary, and they may withdraw or refuse participation at any time without consequence to their relationship to their home visiting program. All client consent forms are available in both English and Spanish.

10.0 Risks to Participants:

Potential Risks

There are no major risks to study participation. A participant in the study may experience some psychological discomfort while answering questions that may be considered of a sensitive nature about oneself or one's family. The Project Manager and Research Assistant are trained in a protocol for responding to participants' questions on the rationale for, and use of, certain survey questions. The Project Manager and Research Assistant will consult with the PI, Dr. Tandon, if necessary; to resolve any questions they are unsure how to handle. Study participants may also experience some discomfort discussing stressful life events during the MB intervention. Home visitors delivering MB materials will be specifically trained on protocols to handle such situations. Should a female participant wish to withdraw from the study for any reason, at any time, there will be no consequences to her access to home visiting and her relationship with her home visitor. Similarly, if a male participant chooses to withdraw from the study, this will not have an adverse effect on his partner's receipt of HV services. Given that all female study participants, to be eligible, will have some mild to moderate depression symptoms at study entry, it is within reason to expect there may be participants who experience and endorse some level of suicidality during the study. We have a safety protocol in place (please refer to Protection Against Risks) for such occasions and will ensure the Project Manager and home visitors are trained and prepared to implement any safety measures.

Protection against risks

Only the research team will have access to individually identifiable private information about human subjects, for the purpose of tracking recruitment and retention, as well as participation payments. All data will be deidentified in study databases. To safeguard confidentiality and anonymity, all data collection instruments will identify participants only by study ID number. Logs linking information to study numbers will be kept locked in a file cabinet in the Project Manager's office. Data analysis staff will not have access to identifying information. We will inform participants of the areas to be covered in the surveys and focus groups prior to their administration. Study participants will be told that if they experience any discomfort while participating in the data collection procedures they can ask to be removed from the study. Also, participants will be told that they do not have to respond to any questions that make them feel uncomfortable. Individuals will be told that their refusal to answer any question will not jeopardize their relationship with their HV program (female clients), their partner's relationship with their HV program (male clients), or their HV colleagues (home visiting supervisors and staff).

Consent forms for female HV clients and their male partners will include a statement that the privacy of family members will be respected and information not shared with anyone else, with the exception of concerns about risk of harm (e.g., suspected child abuse or suicidality). All staff will be certified in online State of Illinois mandated reporter training provided by the Illinois Department of Child and Family Services. Families will be explicitly informed during the consent process that they will be informed if confidentiality must be broken due to mandatory reporting guidelines designed to keep children and families safe. Participants will be invited to be present should the mandated reporting occur.

Mental health referrals and mandated reporting. There are several types of concerns that may arise that will require review and possible referral: (1) imminent risk of harm and/or potential abuse; (2) observed or reported extreme distress by the parent and/or by the parent in relation to the child; and (3) non-reportable concerns about practices during pregnancy that could be harmful to the fetus. All potential concerns will be overseen by the PI, Dr. Tandon. We will use procedures developed by the PI to respond to concerns about imminent harm and/or potential abuse. It is possible that some study participants will discuss suicidal ideation or having a suicide plan while discussing MB content. In these cases, home visitors will be directed to call their program supervisor for consultation, or, in extreme cases, 911. Home visitors will remain with participants until an action plan is implemented. While it is unlikely, some study participants may text home visitors with thoughts of harming oneself or another individual. In these cases, home visitors will similarly contact their program supervisor or 911. Home visitors will also be instructed to remain in electronic contact with the study participant. We believe the most likely imminent risk will be study participants who endorse suicidal ideation on research assessments. In these cases, the protocol will be to refer the study participant to a licensed clinical social worker at each HV program (typically the program manager), who will make a determination regarding whether the study participant is in danger of harming herself and will determine necessary steps to ensure the safety of the study participant. In addition, the study team will provide the participant with contact information (telephone and text) for 24-hour suicide and mental health crisis hotlines. Non-imminent concerns will be flagged and discussed in weekly team meetings and shared with providers as necessary. Since survey instruments will be asking about sensitive subjects such as family relationships, life stress, and mental health, it is possible that participants may become distressed. We will train all research staff how to identify distress during assessment procedures, identify flagged items indicating imminent risk (e.g., suicidality), as well as safety protocols to follow in different scenarios.

Phase 1 and 2 of this study will be registered as separate studies on ClinicalTrials.gov.

11.0 Potential Benefits to Participants:

Potential Benefits of the Proposed Research to the Subjects and Others

There may be no direct and immediate benefits for individuals participating in the research component of this study. We believe that women receiving the MB Course (Phase 1) will exhibit greater reductions in depression symptoms and improvements in hypothesized intervention mechanisms (e.g., behavioral activation). We also believe that partners of HV clients receiving the FAB intervention (Phase 2) will receiving useful information on how to improve their own mental health and be supportive of their partners' mental health. Findings from this study will be made available to researchers and the general public as soon as possible.

12.0 Financial Compensation:

Participant remuneration will be paid at the completion of each research activity. We will be using the *STORED VALUE (VISA) CARD PROGRAM* pre-paid PNC Stored-Value Cards (Visa Gift Cards). There are no fees associated with these cards. All gift cards come with full use instructions and will have a sticker on the front of the gift card with the following information:

- Can withdraw at any other ATM but fees may apply. No fees at PNC bank.
- Do not use at a Pump at a Gas station
- Use within 6 months to avoid fees

Participant remuneration is as follows:

<u>Study Phase 1 (MB-TXT)</u>

- $20 per assessment (n=108) x 3 surveys (baseline, and 6-months)
- $30 per focus group participant (n=16)

- $10 monthly stipend to cover monthly text messaging costs while receiving the MB text message up to six months (per participant)

Study Phase 2 (FAB)

- $20 per assessment (n = 72; 36 females, 36 males) x 2 surveys
- $30 per focus group participant (n=32)
- $10 monthly stipend to cover monthly text messaging costs while receiving the MB text message up to six months (per dyad)
- $35 per focus group or key informant participant (Post FAB Intervention) (n=22; 18 focus group participants and 4 key informants)

There is no cost to participate in any of the research activities. To ensure all participants in MB-TXT and FAB have access to the required technology for study participation, we have budgeted to purchase and provide no-contract cell phones with 6 months of service and text messaging capability for 25% of the study sample. Prior work with home visiting programs shows that between 70-75% of clients use cell phones as their primary contact with home visitors. We have budgeted to provide cell phones for the 54 participants who will participate in the text message intervention. We will rely on the discretion of the HV to indicate if the HV client will need assistance with minutes. During the referral process we will ask the HV clients if they have a cell phone to be able to participate in the study. There could be a cost to participating if participants have to pay for text messages. However, most people have unlimited text messaging plans included in their mobile phone service. If they incur additional costs, participants may choose not to participate. Participants can opt out at any time by sending the word “STOP.”

13.0 Provisions to Protect the Privacy Interests of Participants:

All data records will be identified using an ID number and e-mail only and will not contain other personally identifying information. All data will be collected electronically using (REDCap). The PI and project staff will have minimal contact with clients since all recruitment is being done through the service providers and data collection is being done electronically through a web-based survey. Only authorized persons will be granted access to study data. Passwords and system ID’s for the REDCap system will not be shared with other team members. Identifying information (e.g. personal and/or contact information) will be kept separate from the other data. All subject information collected will be kept in secure, password protected files on Northwestern University servers with access restricted to authorized personnel only. Redcap data will be periodically exported to a SPSS database (Statistical Package for Social Sciences) that will only be accessible to study personnel on a password-protected shared project drive.

14.0 Confidentiality and Data Management:

We will use several procedures to secure data to maintain its confidentiality. Only authorized study personnel will be granted access to study data. Only authorized persons will be allowed to enter and view study data. Passwords and system ID’s for the REDCap system will not be shared with other team members. Additionally, the physical security of the workstations and files where REDCap data are stored will be maintained by study personnel. All data collected will be de-identified using a study ID. The only document with identifying information is the consent form. We believe that the use of the Redcap data collection system will allow us to collect high quality data from all study participants and will not require the need for additional procedures to monitor data quality.

Related to Aim 1, MB-TXT feasibility and acceptability data will be collected from clients and home visitors. Similar to previous SMS studies, we will use percentage of text responses as an indicator of “read” messages. We will assess home visitor adherence to the MB-TXT protocol by using archived data from HealthySMS to calculate percentage of texts sent at appropriate intervals, as stated in the MB Instructor Manual. Home visitors will complete a brief web-based REDCap survey after completing each MB session to assess if clients came to the session having completed their personal

project. Using a 4-point Likert Scale, home visitors will also ask clients to rate the extent to which each of the 3 intersession texts was a) useful and b) easy to understand; these data will be entered into REDCap. Related to Aim 2, participant outcomes will be collected via survey at baseline, 6 months, and 9 months. Data will be collected and managed using REDCap electronic data capture tools hosted at Northwestern. Participants will receive $20 remuneration for each assessment. At each assessment, a link to REDCap will be sent to study participants who can complete the assessment on any web platform (smartphone, tablet, computer). The Project Manager will complete assessments by phone for participants who prefer not to use REDCap. Depressive symptoms, as measured by the the Beck Depression Inventory-II (BDI)[100] a 21-item self-report measure is our primary outcome. Secondary outcomes, which map onto the hypothesized mechanisms for influence on depressive symptoms are: cognitive structuring (Experiences Questionnaire),[85] behavioral activation (Behavioral Activation Depression Scale),[86-88] social support (MOS Social Support Survey),[89] mood regulation (Negative Mood Regulation Scale), and skills utilization.[90,91] We estimate 15% attrition at 6 months, resulting in 46 participants per arm; previous MB trials conducted by PI Tandon had 12 month attrition rates <10% and we will use similar procedures for minimizing attrition.

Analysis for Aim 2 is limited to the fact that this is a pilot study. As such, we will compare MB and MB-TXT groups at the individual level (not adjusting for potential clustering effect of either home visitor or HV program). As such, the analytic sample size of 46 per arm provides > 80% power to detect effect sizes of 0.59 or 0.52 using two or one-sided (respectively) t-tests at a type I error rate of 5% for the primary outcome, the BDI.

15.0 Data Monitoring Plan to Ensure the Safety of Participants:

Data and Safety Monitoring Plan and Board. In the collection of information about depressive symptoms, the research team has the ethical responsibility to appropriately respond to clinical information obtained in this study. Oversight of the data and safety monitoring plan will be the responsibility of the PI, Dr. Darius Tandon, with support from Co-Investigator Dr. Mary Kwasny for data monitoring. Dr. Tandon has conducted multiple trials of the MB Course with perinatal women in a variety of community settings. Dr. Kwasny has extensive experience as lead biostatistician in numerous behavioral health research projects over the past decade, including those focusing on depression and perinatal populations.

Online Survey:
Any study participant who endorses thoughts of self-harm will be referred to the supervisor at the home visiting program, by the Project Manager. The supervisor, who is trained in responding to and addressing suicidal ideation, will use their agency's protocol to make a determination regarding whether the study participant is in danger of harming herself or others and will determine necessary steps to ensure the safety of the study participant. The Principal Investigator will be notified immediately of any such referrals made by study staff. In addition, should administration of depression scale indicate the participant is experiencing severe depressive symptoms, the supervisor at the home visiting program will be notified in order to provide appropriate referrals for their client's mental health treatment linkage.

During any of the research assessments, if the participant endorses current thoughts of harming herself or others, the following protocol should be followed, and documented on an Incident Report.

Beck Depression Inventory-II (BDI) Question 9
→ In the past few days, subject selects answer #1, 2, or 3 (I have thoughts of killing myself, but I would not carry them out, I would like to kill myself, or I would kill myself if I had the chance).

When assessments are completed over the phone or online during regular business hours the following protocol will be completed within 24 hours.

Within 24 hours of the study participant's completion of their assessments a member of the Research team will call the study participant and will let the participant know that he/she will be contacting their home visiting program to let them know about the difficulties they are having with thoughts about death/suicide/hurting yourself/others, so they can reach out and offer support. The research team member will ask the study participant the following questions:

- "Are you thinking about killing yourself?"
- "Have you ever tried to hurt yourself before?"
- "Have you thought of ways that you might hurt yourself?"
- "Do you have pills/weapons in the house?"
- "Do you think you might try to hurt yourself today?"
    - *If her response is Yes, then call 911 and stay on the phone with her until help arrives*

All individuals that complete the above surveys will receive the following resources immediately upon answering the above answer choices on the noted assessments

- ✓ Home Visiting Program Office phone number
- ✓ National Suicide Prevention Hotline (24/7)
    - 1-800-273-8255 (1-800-273-TALK)
    - http://www.suicidepreventionlifeline.org/ (online chat available 24/7: "Lifeline Chat")
- ✓ Postpartum Support International (outside of Illinois)
    - 1-800-944-4773
- ✓ NorthShore Perinatal Support, 24-hour Crisis Hotline (in Illinois)
    - 1-866-364-MOMS (866-364-6667)

All of these resources (except the home visiting program office number) will also be shared with all study participants, regardless of answers to assessment questions, at the end of each assessment. The research team member will stay on the phone with those individuals who endorse the possibility of imminent self-harm. After the research team member ends the call with the study participant, they will call the Program Manager with relevant details, reporting what the client said and endorsed, as well as the information they gathered during the assessment and call with the participant. The research team member will then follow up with an email to the home visitor, supervisor, Project Manager, as well as the PI with relevant details.

If the survey is completed outside of regular business hours (i.e. weekends/holidays) the research team will follow-up with the participant within 24 hours. As noted above, the risk would be acknowledged in real time as the participant would still receive resources immediately following their answer selection to the above survey questions.

Text Message Reponses:
There are none to minimal physical, social, or legal risks to the participants associated with the text messages. Some messages may cause some discomfort among participants because they deal with issues of mood and depression, however, the goal of these text messages is to provide coping strategies. Participants who indicate that that they currently are experiencing increased thoughts of death or pose a risk to themselves or someone else will be given automated information for a suicide hotline. More specifically, participants will be referred to 1-800-944-4PPD which is a hotline that provides resources for perinatal mood and anxiety disorders and community resources. The hotline is sponsored by Postpartum Support International and includes a Spanish-language option. The researchers will be notified if a keyword is sent (to the system phone number) such as "die," "kill" and we will respond accordingly. However, participants will be clearly notified that the system is automated and that it does not constitute direct communication with a provider or therapist. The Research Manager's phone number is also listed at the bottom of the recruitment flyer.

All of our text messages are sent by an automated system. That means that there is not a live person sending, receiving, or monitoring the content of messages. Although we will review the content of the messages received by participants, we cannot respond to individual messages.
If participant responds to the sent text with the potential following responses:

- Or types a keyword (to the system phone number) such as “die,” “kill”

A text message will be automatically sent to the participant with the following messages:

- ✓ Based on your responses to a recent text, we would like to remind you that to talk to someone or find resources in your community for support, call 1-800-944-4PPD (4773).

- ✓ *If at any point you feel that you are in danger of harming yourself, please visit the nearest hospital or call your doctor. You can contact 1-800-273-TALK (8255) if you need someone to talk to for support at this time.*

REDCap will be programmed to notify the Research Manager if a participant indicates self-harm on a survey response. In addition, the Research Manager will review all text message responses no later than 24 hours from the time the text message response is sent. If a participant indicates self-harm on a survey response or a response to a text message, they will automatically receive resource messages listed above. In addition, the Research Manager will contact the participant’s Program Manager to notify them of their client’s response within this 24 hour period. HV programs have their own safety protocols they will follow. HV Program Managers are typically licensed clinical social workers who have the necessary skills to assess the extent to which clients need further response to their mental health needs. Moreover, they have established relationships with their clients. If a text message is received outside of regular business hours (i.e. weekends/holidays) the research team will follow-up with the participant’s Program Manager within 24 hours. As noted above, the risk would be acknowledged in real time as the participant would still receive resources immediately following their answer selection to the above survey questions.

We believe this to be a reasonable expectation in regards to protecting human subjects and the role of the research team. Previous Mothers and Babies studies conducted by the PI, as well as other nationally representative studies of perinatal women have shown that less than 1% of study participants will endorse the most “severe” response choice on survey items related to suicidality. As such, we anticipate that the number of study participants who endorse the most severe response related to suicidality outside of regular business hours over the course of this study will likely be < 1 individuals. As such, we believe our approach to handling this potential risk to study participants—i.e., immediate provision of 24/7 resources and follow-up by the study team no later than 24 hours —is reasonable given its likelihood of occurrence. Moreover, women receiving the Mothers and Babies intervention (100% of the sample) will be receiving information on modifying harmful thought patterns that may contribute to decreased thoughts about self-harm.

16.0 Data and if applicable, Specimen Banking:

All data collection will be conducted through web-based survey links via REDCap. Participants will click on a survey link in a direct email from the Mothers and Babies Research Team. Web-based survey data completed by participants are directly linked to our REDCap project. The Project Manager is responsible for regularly exporting REDCap data into SPSS databases, which are stored on our FSM/IPHAM/Mothers and Babies Project Folder on the shared drive, which is accessible only to authorized research team members via Net ID login.

17.0 Qualifications to Conduct Research and Resources Available:

Darius Tandon, PhD (Principal Investigator). Through my professional training as a community psychologist and prevention scientist and my subsequent career, I have developed skills and expertise that will be crucial for this application. My research has been devoted to the study of

psychological outcomes among low-income perinatal women, and I have participated in many studies focused on the prevalence of depression in community samples, postpartum depression screening, and programmatic response to maternal depression. In addition, as PI or co-Investigator on several extramurally funded projects, I have participated in the development and implementation of maternal stress and depression preventive interventions among perinatal populations. In particular, I was PI of an RCT of the Mothers and Babies intervention that is the focus of this application, conducted in home visiting (HV) programs in Baltimore which demonstrated the efficacy of the intervention in preventing the worsening of depressive symptoms and onset of major depression. I also served as co-investigator of a recently completed RCT of Mothers and Babies in HV programs in Hawaii that found similar effects on depressive symptoms. We are currently conducting an efficacy study of the 1-on-1 version of Mothers and Babies with a network of HV programs in Illinois, with preliminary findings indicating support for the intervention's efficacy in reducing depressive symptoms. Eight of these HV programs are the sites for this application—an indication of these programs' interest in the intervention and strength of the relationships between HV programs and my Northwestern research team. As such, this application is a natural progression of my research examining the efficacy and effectiveness of Mothers and Babies. I am currently the lead faculty for a Maternal and Child Health Bureau Collaborative Improvement and Innovation project aimed at helping HV programs across the United States better address maternal depression among their clients and have been invited to participate in numerous local and national panels, webinars, and conference presentations on intervention strategies to address perinatal depression among HV families. I also have considerable expertise in the science and practice of community engaged research, characterized by the meaningful collaboration between researchers and community stakeholders. My own mental health research has used a community engaged framework which explicitly includes patients and community stakeholders as research collaborators. I was previously Director of the community engagement core of the Clinical and Translational Science Award (CTSA) at Johns Hopkins University, where I was the architect of several activities and programs to promote the practice of community-university partnerships. I am currently the Associate Director of the Center for Community Health at Northwestern University, which helps facilitate the engagement of patients and stakeholders into the research process. I am also a member of the Patient Centered Outcomes Research Institute's (PCORI) inaugural Patient Engagement Advisory Panel, and was selected co-chair of this Panel by my fellow members.

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We will recruit a total of 22 male partners who have received FAB (post-intervention) for focus group and key informant interviews. to inform which aspects of FAB content and delivery are working well and which require modification. We will develop focus group guides and semi-structured interviews

that prompt discussion about the following topics: (1) satisfaction with the existing FAB Course, identifying the most and least enjoyable, understandable, and useful content; (2) effectiveness of content delivery (e.g., web-based links to content, text-messages); (3) additional topics that should be included to meet the needs of new fathers and families; and, (4) methods to best engage fathers in the FAB intervention. Focus groups and key informant interviews will be audio-recorded, transcribed, and then analyzed to identify common themes to guide FAB Course revisions. In keeping with a collaborative approach that our research team has undertaken throughout our MB and FAB work, during our focus group and key informant interviews we will identify 2-3 fathers from different cultural backgrounds to serve as consultants, who will remain engaged in an iterative process of review and feedback about FAB revisions.