Official title: **Text4Father Pilot Feasibility, Acceptability Study**

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JHM IRB - eForm A – Protocol

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1. Abstract

While father engagement programming is widely advocated, few clinical and public health approaches engage expectant fathers early during pregnancy or in the first months after an infant's birth. A large body of literature shows that fathers play a key role in promoting child health and development beginning even before their children are born. Interventions to actively engage fathers, particularly early in pregnancy, have been shown to improve infant outcomes (e.g., physical, social, and emotional health and development), the well-being of the parents, and transform couples' relationships, especially among lower income individuals. However, readily scalable approaches that effectively translate evidence-based guidance to engage lower income fathers during the prenatal period to improve infant and mother outcomes are lacking. Not engaging fathers not only fails men, but also compromises the quality of care delivered to mothers and children. Our formative work demonstrates that lower income fathers identify a variety of infant care knowledge, skill, and support gaps and are interested to receive such information via a text-messaging platform. Further, substantial research supports the use of texting interventions for vulnerable and difficult-to-reach populations. Thus, a readily-scalable, easily adaptable intervention that could reach lower income fathers has the potential to substantially impact child, parent, and family health at the population level.

Text4Father, a multi-modal texting program, is designed to increase first-time lower income fathers' knowledge, self-efficacy, and behavioral engagement on parenting and infant care. In a prior approved protocol (IRB00117690), we conducted formative research with lower income parents of young children in Baltimore and found fathers had substantial gaps in their knowledge and skills during their child's prenatal and early postnatal periods but wanted to have learned more about infant physical and cognitive development and skills related to feeding, personal care, and safety; having few resource supports. They also shared that getting such information via text messages would have been helpful for them – indicating initial proof of concept. As part of this formative work, fathers shared that their access and strategies to engage with their pregnant partner and infant depended on their residence status. We also conducted a 6-week Text4Father feasibility pilot with 25 adult fathers at the Hopkins Fetal Assessment Center and found that it was feasible to recruit fathers and fathers reported being satisfied with the texting platform and messages. In this Text4Father study, we propose to examine feasibility, acceptability, and preliminary efficacy of Text4Father through the latter half of pregnancy up to approximately 2 months of postnatal life. The partners (pregnant women) will also be recruited to compare outcome data and the fathers' interactions with parents and other caregivers. Study results will help determine if using a texting approach can be successful in building a bridge to underserved lower income and non-resident fathers, and to inform a larger randomized controlled trial.

2. Objectives

Primary objective**:** To evaluate feasibility, acceptability, and preliminary efficacy of Text4Father through 2 months of postnatal age, and to generate effect sizes to inform a larger trial.

Secondary Objectives

1. To demonstrate the feasibility of implementing Text4Father with lower income resident and non-resident fathers in Baltimore, MD as evidenced by recruitment and retention in the intervention.
2. To demonstrate acceptability of Text4Father as indicated by technology usability and acceptability, and intervention satisfaction among participating fathers.
3. To demonstrate preliminary efficacy of Text4Father on fathers' knowledge, beliefs, and self-efficacy in parenting and infant care (primary outcomes) and partner relationship quality and infant care behaviors (secondary outcomes) compared to usual care through 2 months of age.

3. Background

Even before their children are born, fathers play an important role in promoting child health and development. Paternal engagement in the prenatal and infant periods is associated with improved infant outcomes (e.g., physical, social and emotional health and development), and parental well-being.[1-14] While father engagement programming is widely advocated,[15-17] few public health and clinical approaches aim to engage expectant fathers during the prenatal period and first months after birth. This critical window of opportunity has been insufficiently leveraged to promote father engagement.[18-22] Not engaging fathers fails men, but also compromises the quality of care delivered to mothers and children.[19] Improving father engagement in prenatal care could reduce healthcare costs; even a moderate 25% increase in father engagement would yield from $105 to $169 million in cost savings in annual U.S. healthcare expenditures.[23]

Past research, including our own, indicates that fathers, particularly lower income and non-resident fathers, feel left out of maternity care and have gaps in infant care knowledge, skills, and support, especially in the first months after an infant's birth.[20-22, 24-26] Father inclusive perinatal education improves father involvement through increased knowledge and skills.[1] Cooperative coparenting education also increases partner relationship quality and father involvement.[1, 2] Promoting positive relationships among fathers, mothers, and other caregivers is key to engaging fathers over time,[27, 28] especially non-resident fathers who are often still in relationships with their partners[29] and a growing population over the past 50 years.[30] Fathers who are attached and bonded with their infant are also more likely to continue to be involved postnatally[31] and through toddlerhood.[32-35]

Potential strategies to reach fathers include the use of mobile health (mHealth). mHealth can improve upon traditional in-person approaches that have, historically, limited reach and capacity, not engaged fathers early, and not successfully recruited and engaged fathers in greatest need (e.g., lower income, non-resident).[9, 36] Texting is used by almost all U.S. adults (93%).[37] It has been shown to more effectively change health behaviors compared to other mHealth approaches (e.g., apps)[38] while reaching more difficult-to-reach populations.[39-42] Text4baby, a well-known mHealth program that promotes infant care, is designed with mothers in mind,[43-45] but has limited content to support expectant fathers.[45] Not surprisingly, less than 3% of its users are fathers.[46]

We developed Text4Father, an evidence-based texting intervention, to increase expectant fathers' knowledge, self-efficacy, and behavioral engagement in parenting and infant care. Informed by the Integrated Behavioral Model,[47] Text4Father consists of approximately twice-weekly texts written at a 5th grade reading level starting mid-pregnancy and continuing through 2 months of age. Texts included resource links and instructions to support behavior change (e.g., videos, infographics), starting mid-pregnancy and through 2 months of postnatal age. Text4Father is programmed to push/receive reminders to tailor content based on: gestational age/infant age after birth, and father's resident status (i.e., whether father lives with mother and child). Text design and content were informed by: 1) systematically-collected consensus-based expert feedback,[48] 2) evidence-based guidance,[2, 49, 50] 3) formative feedback with lower income resident and non-resident fathers and mothers in Baltimore,[24] and 4) a 6-week

feasibility pilot with 25 fathers in Baltimore.[51]

The research team is led by **Dr. Arik V. Marcell, MD, MPH** (PI), an Associate Professor of Pediatrics and Public Health and expert on men's health. His research aims to examine ways in which to improve young men's healthcare use, and providers' delivery of quality of care to young men. He has led national efforts to inform clinical care guidelines for care delivery to reproductive-aged men and adolescents. He conducts community- and clinic-based research, including working with lower income fathers of young children, using mixed-methods and interventional approaches. **Dr. Alain Labrique, PhD, MHS** (co-I), an Associate Professor of International Health and Epidemiology who directs the Hopkins Global mHealth Initiative, contributes expertise on developing, implementing, and evaluating this mHealth intervention, including providing guidance on mHealth evidence reporting and assessment, metrics of program scalability, and mHealth monitoring and evaluation, based on guidance he developed in collaboration with the WHO and UN Foundation. **Dr. Tim Nelson, PhD** (co-I), a Senior Lecturer and Sociologist at Princeton University, contributes expertise on his research with fatherhood experience among inner-city men and recruiting and retaining lower income couples in longitudinal research. **Dr. Sara Johnson, PhD, MPH** (co-I), an Associate Professor of Pediatrics, contributes expertise on program evaluation with vulnerable populations and social influences in child development. **Dr. Dustin Gibson, PhD** (co-I), an Assistant Scientist of International Health, contributes expertise on applying and evaluating mHealth technologies to strengthen health systems and generate demand for health services, and serve as lead quality control-treatment fidelity technician for Text4Father. **Dr. Kathryn Van Eck, PhD** (co-I), an Assistant Professor of Psychiatry, contributes expertise on advanced biostatistics, research on parenting and child development, database design, data collection and management, staff training on data quality, and quantitative analyses.

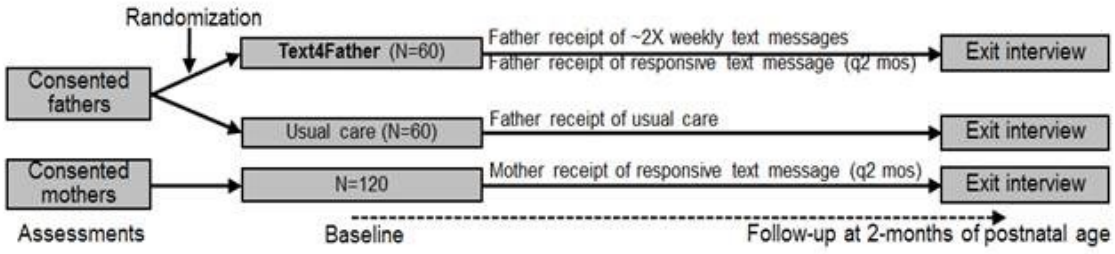
4. Study Procedures

STATEMENT OF COMPLIANCE

This acceptability, feasibility, and preliminary efficacy study will be conducted in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP), applicable United States (US) Code of Federal Regulations (CFR), and the NICHD Terms and Conditions of Award.

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

Figure 1. Overview of Study Procedures



Baseline survey:	Time 1				
Monitoring responsive texts:		2 months	4 months	6 months	
Follow-up survey:					Time 2 (7-months)

Table 1. Schedule of Activities

	Pre-screening Pre-consent)	/isit 1/ Time 1	ext 1 2 months)	ext 2 4 months)	ext 3 6 months)	/isit 2/ Time 2 7 months+/1 weeks)
Review eligibility (phone/in-person)	X					
Informed consent (phone/in-person)		X				
Demographics/background characteristics		X				
Outcome evaluation						
rent knowledge, self-efficacy, behavior survey		X				X
ntervention acceptability survey						X
Monitoring responsive texts			X	X	X	
Randomization		X				
Control & Experimental Interventions – Text4Father		X	X	X	X	
Adverse Events Reporting		X	X	X	X	X

Setting. We will conduct this study and recruit participants in Baltimore. Baltimore is a community with marked health disparities related to maternal and infant outcomes. In 2015 in Baltimore, the infant mortality rate was almost 2 times higher for black (9.7/1,000 live births) than white infants (5.4/1,000); this rate was 1.3 times greater than Maryland's rate;[52] and 12% of babies born were low birthweight versus a national average of 8%.[53, 54] Settings will include the Hopkins Maternal-Fetal Medicine (MFM) Clinic and Fetal Assessment Center where we successfully collaborated for the 6-week feasibility pilot that informs this proposal. Dr. Jeanne Sheffield, Professor and Director of the Johns Hopkins' Division of MFM, facilitated MFM staff education for the pilot and is committed to ensuring this project's feasibility. The Center sees over 21,000 fetal ultrasound exams and delivers over 2,400 babies each year. The majority of patients are publicly insured (62%) and half are African American. Based on our preliminary work, we estimate that 865 infants each year will have first-time lower income fathers.

Participants and Recruitment. Research staff will recruit 120 adult expectant fathers and their female partners (120 pregnant females) (60 dyads per study arm) from the Hopkins' MFM Clinic and Fetal Assessment Center to be enrolled through 25 weeks gestation. The index participant and their partner will contact study staff to be scheduled for a research visit. An eligibility screener will be individually completed with both members of the dyad to determine study eligibility. Our target is to have complete data on 48 dyads so we set sample size at 60 in order to account for attrition.

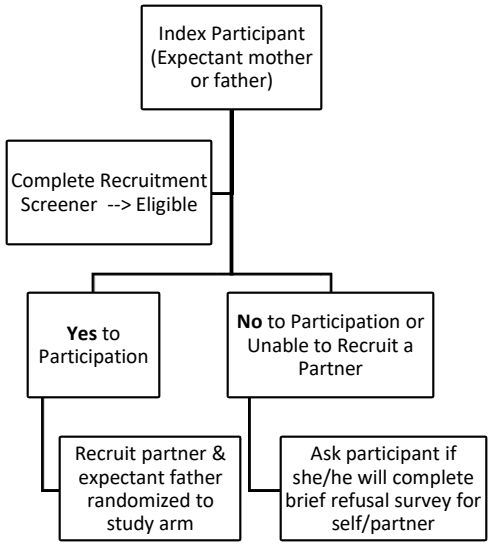
We will use the following recruitment strategy: 1) upon entry into prenatal care, pregnant women will receive informational study flyers to contact study staff for participation and referral of their male partners; 2) we will actively recruit at prenatal and ultrasound visits since many fathers accompany their partners to these visits and clinic staff will call prior to appointments to share study information, assess interest, and if interested share to have father join them at their appointment when they can complete study procedures; and 3) we will recruit unaccompanied pregnant women and get permission to recruit their male partners. We will build on established relationships with other metro Baltimore MFM settings if we need other settings for this trial. We will also plan to disseminate study flyers and posters to post and distribute at other locations, such as adult outpatient settings, WIC, home visiting programs for pregnant and parenting families, and other OB settings, share existing recruitment materials (e.g., study flyer) via website posting, and social media (e.g., Facebook). We will also inform interested participants that they can refer other individuals to the study.

Enrollment, and Consent. Recruiters will be available via phone during office and some evening hours for participant recruitment. Providers will refer eligible participants or expectant parents can contact study staff directly. Individuals who agree to be contacted will be approached by a recruiter in person or via phone and an eligibility screener will be individually completed with both members of the dyad to

determine study eligibility. If eligible, they will complete oral informed consent and intervention procedures. The index patient and partner will be consented individually. At enrollment, the research staff will perform a detailed review of the Text4Father study with informed consent, and collect baseline measures. Completion of informed consent will be documented in RedCap by study staff at the time of enrollment and online questionnaire will be automatically uploaded to a secure server for warehousing in a central database. This study will not involve linkage to medical records.

Randomization Schedule will be set before the study and remain masked until after a father completes the consent process and baseline survey. Each father will then be randomly assigned to receive Text4Father or a usual care control arm to ensure group balance using a computer generated randomization assignment.

Figure 2. Text4Father Study Recruitment Algorithm



Intervention.

Conceptual Framework. This study is informed by the Integrated Behavioral Model (**IBM**) that asserts behavior (i.e., father engagement) is influenced by core constructs of behavioral attitudes, perceived norms, and personal agency (Figure 1).[47] Each construct is determined by underlying beliefs: attitudes are specific beliefs about performing a behavior, perceived norms are influenced by what others think about behavioral performance, and personal agency is one's confidence to perform the behavior (self-efficacy). Other constructs (e.g., background factors) influence behavior via these beliefs. Text4Father content focuses on improving fathers' knowledge of infant development, father role beliefs, attachment beliefs, parenting self-efficacy, infant care self-efficacy, and cooperative coparenting (primary outcomes) that may result in increased partner relationship quality and behavioral engagement in infant care (i.e., specific activities and time spent with infant, use of infant safe sleep and

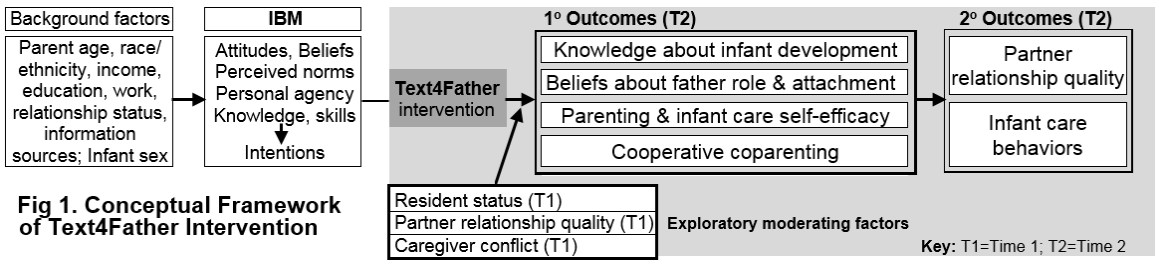


Fig 1. Conceptual Framework of Text4Father Intervention

injury prevention behaviors) at follow-up. We are also interested to explore whether fathers' baseline resident status, partner relationship quality, and caregiver conflict moderate the association between intervention receipt and study outcomes.

Text4Father is a multi-modal texting program consisting of approximately twice-weekly texts written at a 5th grade reading level to initiate between 20-25 weeks gestation. Texts include resource links and instructions to support behavior change (e.g., videos, infographics) and start mid-pregnancy and continuing through 2 months of age. Text content provides a father with educational/informational guidance to support his infant, partner, and own well-being. Content was developed with feedback from the target population, consensus-building with experts, and an evidence-based review (see Prelim Studies). Text4Father is programmed to push/receive texts that tailor content receipt based on: gestational age/infant age after birth and father's resident status, and will remind fathers to share updates. When developing texts, we relied on evidence about writing text messages for behavior change: 1) using motivational language rather than just information; 2) actively involving learners with specific tasks to complete related to the desired behavior change; 3) sharing credible information; and 4) personalizing and tailoring messages. Personal health information will not be shared or requested as part of the text messaging platform.

Table 1. Text4Father objectives, covered content, & example messages by fathers' resident status

Objective	# text	Covered content	Ex. message for resident father & timing	Ex. message for non-resident father & timing
For infant				
To develop a nurturing bond	8	Initiate daily routines, hold infant skin- to-skin	Hold your baby skin-to-skin on your chest. This helps your baby cry less & builds a strong relationship with your baby [Infant Wk 1]	Holding your baby skin-to-skin on your chest helps your baby cry less & builds a strong relationship with your baby. Discuss with mom about when is best [Infant Wk 1]
To support infant's physical, mental & emotional health	27	Attend well-visits, understand shots & infant development, engage in age-specific play/verbal stimulation	Your voice can calm & soothe your baby. Learn about the 5 S's: Swaddle, Side, Shush, Swing, & Suck: Learn more here [Infant Wk 1]	Your voice can calm & soothe your baby. Learn about the 5 S's: Swaddle, Side, Shush, Swing, & Suck: Learn more here [Infant Wk 1]
To create a safe environment	13	Baby proof house, address lead; Install car seats, smoke/carbon monoxide detectors; Support safe sleep; Engage in healthy behaviors	Safe Sleep is key to your baby's health. DO: use a crib & put them on their back. DO: use a firm mattress & a fitted sheet DON'T: put pillows, blankets, bumper pads, toys, or stuffed animals in the crib Learn more here [Infant Wk 2]	Share with mom that Safe Sleep is key to your baby's health. DO: use a crib & put them on their back. DO: use a firm mattress & a fitted sheet DON'T: put pillows, blankets, bumper pads, toys, or stuffed animals in the crib Learn more here [Infant Wk 2]
For partner/relationship				
To discuss logistics, divide roles	9	Prepare for birth/delivery; Communicate about dividing role	Get ready! Make a delivery day plan. Tour the hospital, plan how to get there, & pack your bags. Don't forget your cell phone & charger [Pregnancy Wk 34]	Planning for the day of delivery? Talk with mom about how to help get ready (tour the hospital, how to get there, what to bring) [Pregnancy Wk 34]
To maintain positive & open communication	4	Communicate with each other about pregnancy & be(com)ing parents	Being a parent can be hard (lack of sleep, more responsibility). Talk with mom about how you can support each other [Infant Wk 9]	Being a parent can be hard (more responsibility). Agree on what you can do to support each other [Infant Wk 9]
To support her physical, mental, & emotional health	18	Issues prior to after birth, healthy diet, mental health, timing/spacing pregnancy, breastfeeding	Mom will need rest after birth. Ways you can support her: do housework, cook, spend time with your baby [Pregnancy Wk 36]	Mom will need rest after birth. Discuss ways she wants support after birth [Pregnancy Wk 36]
For father				
To develop & create a plan for father involvement	14	Consider role as father; initiate daily routines; Understand parental leave policies	Plan to do something every day (make a routine) with your baby, like read or sing to them before bedtime. Routines help build your baby's brain & will help you & your baby build a strong relationship [Pregnancy Wk 30]	Doing something on a regular basis (make a routine) with your baby helps build your baby's brain & will help you & your baby build a strong relationship. Discuss with mom about how you can make a routine with your baby [Pregnancy Wk 30]
To support his physical, mental, & emotional health	8	Address health/other needs (e.g., insurance, job, school); see health provider; Engage support network	Do you need help with: health insurance, education, job, or legal? Learn more here [Pregnancy Wk 23 & Infant Wk 4]	Do you need help with: health insurance, education, job, or legal? Learn more here [Pregnancy Wk 23 & Infant Wk 4]

We will use SMS services through a licensed commercial provider such as EngageSpark, TextNow, or RapidSMS for communicating with father and mother participants in all arms of the study. Each of these companies allow for texting and calling and can be enabled for use on a phone, tablet, or computer that makes this platform optimal for this study. Further, each of these companies has strict policies to protect the user to prevent unauthorized disclosure of information and physical, electronic, and procedural safeguards are in place according to industry standard procedures and security procedures. Research staff will be responsible for monitoring fidelity of the texts sent and using the online account to register and send any interim text-message to participants in the study. Since a telephone number is created with each account, the telephone number will be recognizable to participants as Text4Father communication.

Finally, all participants will be encouraged to use standard safety mechanisms such as a pin or password to lock access to their cell phones by others, if not already in place.

Control Groups. The usual care arm will receive 3 interim texts (1 text each at 2 months, 4 months, and 6 months) that will assess distress and perceptions of caregiver conflict between the father and other caregivers. The usual care arm will not receive any additional interaction since maternity care typically does not provide any organized educational approach.

For ethical reasons all arms will receive at baseline a new parent handout about local birth resources/hotlines.

End-of-Study Definition
A participant is considered to have completed the study if he has completed the baseline assessment, participation in Text4Father if assigned to this study arm, and the 7-month follow-up assessment. The end of the study is defined as completion of the 7-month follow-up assessment as shown in the Table 1 Schedule of Activities.

Quality Control
1. Quality Control-Treatment Fidelity. Drs. Marcell, Labrique, and Gibson will train and supervise research staff to ensure appropriate protocol execution. Research staff will activate Text4Father for consented participants randomly assigned to the intervention. Dr. Gibson will continually monitor and document fidelity via: 1) Technical functionality (Does technology operate as intended?) assessed by confirming that the system sends the welcome text and is received by participants at enrollment; 2) Technical stability (Does technology consistently operate as intended?) assessed by ensuring texts are consistently delivered as intended with minimum system failures/bounce backs. At the follow-up visit, study staff will ask participants assigned to the intervention arm to verify text receipt as well as to record unread texts. Study staff will ask them to open their phone to view the number of unread texts and then record the number of unread texts from Text4Father. If no texts are present, they will be asked why the texts were deleted. Study staff will also record texts that were received to ensure technical stability. The study team will also ensure 3) Technical quality assessed by keeping content up-to-date.

2. Recruitment Screener. Includes collection of basic demographic data and the outcome of recruitment effort so that we can keep an accurate account of referral patients who are ineligible and/or refuse to participate in the intervention.

3. Surveys. We developed a survey to collect information about fathers' knowledge, self-efficacy, and behavioral engagement in parenting and infant care, as well as technology acceptability.

From fathers, we will collect self-report responses about their background sociodemographic factors, including use of other pregnancy/parenting/infant care resources, perceptions of caregiver conflict, and about their infant, as well as their knowledge, self-efficacy, beliefs, and behaviors related to involvement in pregnancy and with their infant, cooperative coparenting, and relationship quality with partner and personal health behaviors, using a survey instrument at baseline and at 2 months of postnatal age (7-month follow-up) in-person, via phone, or electronically via Qualtrics. At follow-up (7-months), we will also assess intervention fathers on technology usability, acceptability, and satisfaction. This survey takes about 40-45 minutes to complete.

From mothers, we will collect self-report responses about their background sociodemographic factors, including use of other pregnancy/parenting/infant care resources, and their perceptions about fathers' caregiver conflict, and about their infant, as well as their perceptions of father's parenting and infant care self-efficacy, cooperative coparenting, relationship quality, and partner behavioral engagement in

infant care, using a shorter survey instrument at baseline and 2 months of postnatal age (7-month follow-up) in-person, via phone, or or electronically via Qualtrics. This shorter survey takes about 15-20 minutes to complete.

Measures Table

Variable	Item #	Content & references	R
Primary outcomes			
Infant develop. knowledge	30	Higher score indicates higher knowledge of infant development[55]	FR
Father role beliefs	15	Higher score indicates more positive beliefs in father's role in child care[56]	FR
Attachment beliefs	35	Higher scores indicate more positive beliefs about fetal/infant attachment[57]	FR
Parenting self-efficacy	17	Higher score indicates greater confidence in overall parenting skills[58, 59]	FR/MR
Infant care self-efficacy	15	Higher score indicates greater confidence in infant care[60]	FR/MR
Cooperative coparenting	10	Higher scores indicate greater coparenting agreement & support[61]	FR/MR
Secondary outcomes			
Partner relationship quality	12	Higher score indicates greater perceived partner relationship quality (T2)[62]	FR/MR
Infant care behaviors			
Infant engagement	17	Higher score indicates higher father engagement in infant care activities[63]	FR/MR
Time spent with infant	2	Days per week spent with infant; Hours per day spent with infant[64]	FR/MR
Safe sleep care	14	Higher score indicates greater adherence to 6 safe sleep AAP guidance[65]	FR
Injury prevention care	12	Higher score indicates greater adherence to 5 child injury AAP risk areas[66]	FR
Moderator factors			
Resident status	3	Living together with mother (current; history of gap; length of gap)	FR/MR
Caregiver conflict	12	Higher score indicates greater perceived caregiver conflict[67, 68]	FR/MR
Partner relationship quality	12	Higher score indicates greater perceived partner relationship quality (T1)[62]	FR/MR
Background factors			
About parents	8	Age, race/ethnicity, income, education, occupation, # people in household, relationship status, prior parenting experience, exposure to pregnancy/ parenting/infant care info[69], father present at prenatal, birth, WCC	FR/MR
About father	22	Personal health behaviors (substance use, irritability)	FR/MR
About infant	6	Sex, gestation weeks, birth weight; WCC receipt	FR/MR
Process measures			
Technology usability	12	Higher score indicates greater technology usability[70]	FR
Technology acceptance	8	Higher score indicates greater technology acceptance[71, 72]	FR
Intervention satisfaction	1	Higher score indicates greater intervention satisfaction[71]	FR

R=Reporter; FR=Father report; MR=Mother report; WCC=Well-child care; T1=Time 1; T2=Time 2; AAP=Am Academy of Pediatrics

b. Study duration and number of study visits required of research participants.

The study will last 7 months. Participants will be recruited through 25 weeks of gestation and followed 2 months after the infant's birth. For fathers who meet the study criteria and consent to participate in the study, they will complete two study visits: a survey at baseline and another at 7-month follow up; fathers assigned to the Text4Father in the interim will receive approximately two texts a week for 7 months. For mothers who meet the study criteria and consent to participate in the study, they will complete two study visits: a shorter survey at baseline and another at 7-month follow up. All study participants (fathers and mothers) will receive text at the beginning a flyer jpeg about the study to share with their partner and 3 interim texts (1 text each at 2 months, 4 months, and 6 months) that will assess distress and perceptions of caregiver conflict between the father and other caregivers.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.

This will not be a blinded study. The intervention consists of receiving text messages which, by definition, is a non-blinded activity.

d. Justification of why participants will not receive routine care or will have current therapy

stopped.
Not applicable.

e. Justification for inclusion of a placebo or non-treatment group.
Not applicable.

f. Definition of treatment failure or participant removal criteria.
For the purposes of this behavioral study, treatment failure is not applicable. Criteria for participant removal: if system error from text messaging platform indicates that a participant's cell phone number is no longer active and we are unable to contact participants' shared contacts after no more than 3 attempts with each contact in the first 10 days that is repeated no more than twice thereafter.

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
Participation in this study will not impact participants' usual care regardless of how the study ends or if a participant's participation in the study ends prematurely.

5. Inclusion/Exclusion Criteria

Inclusion criteria: In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form
2. Stated willingness to comply with all study procedures and availability for the duration of the study
3. Self-reported expectant father and pregnant partner (expectant mother)
4. Aged ≥18 years
5. In a romantic relationship and expect to continue to be in this relationship during the study period
6. Willingness to adhere to the Text4Father regimen (for fathers)
7. English speakers only: The Text4Father content was not developed for use with non-English speakers or hearing-impaired individuals. Therefore, non-English speakers and hearing-impaired individuals will not be included.
8. Lower socioeconomic status (SES) (e.g., less than a 4-year college degree, or vocational/trade school or less, or qualify for Medicaid/public insurance)
9. Access to necessary resources for participating in a technology-based intervention (i.e., cell phone) and willing/able to receive/send texts

Exclusion criteria: An individual who meets any of the following criteria will be excluded from participation in this study:

1. Individuals who are not able to provide informed consent.

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used.
Not applicable

b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.
Not applicable

c. Justification and safety information if non-FDA approved drugs without an IND will be administered.

Not applicable

7. Study Statistics

Name	Parenting Sense of Competence (PSOC)
Type	Primary
Time Frame	Baseline; post-treatment at follow-up
Brief Description	Measures parents' perceived confidence (self-efficacy) with overall parenting and parenting skills

Name	Technology usability
Type	Other
Time Frame	Post-treatment at follow-up
Brief Description	Assesses technology usability among participants assigned to the intervention
Name	Technology acceptance
Type	Other
Time Frame	Post-treatment at follow-up
Brief Description	Assesses technology acceptance among participants assigned to the intervention

a. Statistical plan including sample size justification and interim data analysis.

Number of subjects expected to enroll: Total of N=240 (120 fathers; 120 mothers) or 60 couples per group (treatment, and standard of care control).

Expected effect size: Moderate effect size (i.e., $d \geq 0.472$).

Power. We evaluated power for the fixed effects in a hierarchical linear model including four discrete covariates to consider the average rate of change in paternal parenting constructs due to the intervention over duration of the study time period. With a sample size of N=60 participants per study arm, we will have 80% power to detect moderate effect size (i.e., $d \geq 0.472$) in outcomes. This power calculation also accounts for study attrition (anticipated at 20% loss to follow-up over the 7-month study period). We used one of the few studies that evaluated changes in parenting constructs comparing treatment for father engagement to a control group only at the end of treatment to inform these calculations and expected effect size.[73] This study found treatment fathers had 12.7% higher paternal infant engagement at the end of the treatment compared to the control group; and parenting self-efficacy was 6.2% higher in treatment than in control group participants.[73]

Statistical methods

Aims 1 and 2. Feasibility and Acceptability. Using completed clinic appointment, screener, and consent data, we will assess feasibility of overall recruitment by calculating the proportion of eligible fathers who consent to study participation and recruitment by resident status. Based on our pilot work, we anticipate recruiting ≥70% of fathers who are approached. We will calculate feasibility of retention as the proportion of enrolled participants who complete 7-month follow-up survey (2-months of postnatal age). We will calculate study retention overall and separately by treatment assignment and use Chi-square tests to determine if we achieved follow-up of ≥80% by treatment assignment.

In the Text4Father arm, we will calculate the proportion of individuals completing the

intervention and assess at exit these participants' technology usability (12 items), acceptance (8 items), and satisfaction (1 item) (on 5-point scales from "strongly disagree" to "strongly agree").[70-72] We will examine whether we achieved ≥75% agree/strongly agree usability/acceptability rates and generate means (SD) for each.

Aim 3. Efficacy. We will examine the effect of the randomization scheme and explore missing data due to survey non-response and attrition. We will then apply separate random intercept coefficient regression models for each study outcome accounting for two levels of nesting (repeated measures and individuals). Each model will estimate differences among intervention and usual care control arms identifying change in each study outcome between baseline and follow-up. This type of analysis will allow for examining 1) within-individual change over time in an outcome, accounting for dependency among observations within individuals by modeling within-person error,[74] 2) between-individual variation over time,[75] and 3) between-subjects effects based on group assignment to identify significant differences in content (Text4Father) as compared to usual care. Our sample size should be large enough to adequately power analyses for examining change in fathers' engagement (see below). The fixed effects from these analyses will help determine the expected effect size for other outcomes to inform power calculations for a larger R01-funded trial.

Exploring moderating factors. We will explore the moderating effect of fathers' resident status, partner relationship quality, and caregiver conflict from perspectives of both parents on the study's outcomes given that each of these may influence fathers' access and experience with infant engagement, as well as other background factors. These findings will inform sampling decisions and future research questions for a larger trial. We will also explore how infant sex as a biological variable might impact father engagement; however, this is not supported by past work in this area.

We will also explore differences among intervention and usual care control arms for each maternal and infant outcome between baseline and follow-up.

b. Early stopping rules.

This study may be stopped prior to its completion if:

(1) participants experience (adverse events) AEs or severe AEs (SAEs) that are felt to be related to study participation, at which point consideration will be given to temporarily or permanently suspending study activities and/or enrollment. This decision would be made in consultation with the study's IRB and sponsor (NICHD);
(2) difficulty in study recruitment or retention will significantly impact the ability to evaluate the study endpoints. The investigators will consult with the study monitors to assess the impact of significant data loss due to problems in recruitment, retention, or data collection;
(3) any new information becomes available during the trial that necessitates stopping the trial; or
(4) other situations occur that might warrant stopping the trial.

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

There are no significant medical risks involved in this study. This study falls in the category of "research not involving greater than minimal risk," described by federal regulations as "the risks of harm anticipated in the proposed research are not greater considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Research in this category includes: "…confidential survey research that collects identifying information, with or without sensitive information."

This study will involve the use of surveys and receipt of text messages. All participants will be informed

that participation in the study is completely voluntary and will be reminded that they can decide not to answer any question on the brief survey and that they can stop participating at any time. Potential risks for participants who participate in this study include distress related to the research study (e.g., personal nature of questions asked). While the study will attempt to preserve patient confidentiality, there is potential for breaches of confidentiality, but miniscule given the limited number of personnel with access to participant information. It is also possible that by promoting father engagement, the intervention could increase friction between parents and/or other key caregivers that could also result in distress and/or conflict. However, past perinatal research focused on father involvement suggest that programs to enhance maternal-paternal relationships actually improve maternal mental health outcomes and has not found harms associated with father-mother relationships as a result of greater father involvement. We have developed a monitoring plan to assess for these issues and resources to refer participants as needed.

b. Steps taken to minimize the risks.

Human subject approval has been granted for prior formative work and pilot feasibility testing of this research protocol by the Johns Hopkins institutional review (IRB00117690) that has informed the current protocol. Significant attempts will be made to minimize risks to participants.

The research team on this project has training and experience in the protection of human research participants and the treatment of protected health information as evidence by completion of their institutional compliance courses that are reviewed every 3 years per Johns Hopkins Medicine faculty and staff requirements. New staff without prior training must complete human subjects training through the Johns Hopkins Committee on Clinical Investigation courses as a part of orientation training and as a condition of their employment. All research staff who will conduct assessments and introduce program materials will also be trained about how to interact with participants in sensitive ways and watch for signs of distress during survey administration. Research staff will be supervised to ensure that they are following specified procedures.

Regarding participant assessments, we do not anticipate medical risks to the participant related to completing study assessments. If a participant shows any sign of significant psychological distress, they will be referred to the primary investigator or to the emergency department for further evaluation and management. Participants in our pilot research did not display or report discomfort or distress as a result of assessment procedures.

We have developed a monitoring plan to specifically assess fathers' and mothers' distress as a parent and perceptions of caregiver conflict between the father and other caregivers over the course of the study. We will assess all participants in the baseline and follow-up surveys and assess all mothers and intervention fathers at 2-month intervals using text message queries of abbreviated measures. Any participant with an affirmative response will be provided resources/hotlines about supporting partner relationships, reducing stress, and mental health, including the Hopkins' Division of MFM's Social Work team. The monitoring approach is as follows:

For father participants

- At baseline, all fathers will receive a new parent resource handout, including birthing support groups and resources/hotlines to support relationships, stress, and mental health, and study contact information to reach out at any point to study team members for assistance.
- Fathers will receive additional interval texts that will query him on the following:
  Q1. How's your relationship with your partner (better, same, worse)?
  Q2. How's your relationship with other caregivers in your infant's life (better, same, worse)?

Q3. Becoming a father can be stressful. Would it help you to talk to somebody for support (yes, no, unsure)?
Any father who answers "worse" to Q1 and/or Q2, or "yes" or "unsure" to Q3 will be provided contact information for the Hopkins Division of MFM's Social Work team and the study team, and a weblink that will host resources/hotlines that address stress/mental health and relationship supports.

For mother participants

- At baseline, all mothers will receive a new parent resource handout, including birthing support groups and resources/hotlines to support relationships, stress, and mental health, and study contact information to reach out at any point to study team members for assistance.
- All mothers will also receive interval texts that will query her on the following:
  Q1. How's your relationship with your partner (better, same, worse)?
  Q2. How's your partner's relationship with other caregivers in your infant's life (better, same, worse)?
  Q3. Becoming a mother can be stressful. Would it help you to talk to somebody for support (yes, no, unsure)?
  Any mother who answers "worse" to Q1 and/or Q2, or "yes" or "unsure" to Q3 will be provided contact information for the Hopkins Division of MFM's Social Work team and the study team, and a weblink that will host resources/hotlines that address stress/mental health and relationship supports.

If participants reveal that they or their children are currently being abused or harmed in any way, or this is suspected, steps will be taken to ensure their safety, which may include contacting local authorities (e.g., law enforcement, child protective services). If participants exhibit behaviors that indicate they may hurt themselves or others, steps will be taken to ensure their safety, and the participant will be referred for appropriate psychiatric evaluation, as is standard medical practice.

As previously noted, all participants will provide informed consent and will be informed that their participation in the study will have no effect on subsequent medical care, that their study participation is voluntary, reminded they can choose not to answer any item, and can stop participating at any time. All patient data will be kept confidential and secure.

Due to the longitudinal nature of this study, we will collect tracking information from participants. We will assign a unique identification number to each participant as they enter the study that will allow us to link data over time and to their partner. We will maintain a separate database from participant response data that links a participant's unique identification number to personal tracking contact information and to their partner to ensure integrity of participants' identification number across time. This master list will be kept on a password protected computer in the PI's locked office. All other data will be non-identifiable. All identifying information will be destroyed using paper shredders upon completion of the study.

The research team will manage data and maintain records for all collected data including data checking, cleaning, coding and entering. Standard security procedures will be followed, including use of password protection and secure daily backup and storage locations. We will develop a database management system for all collected data that will be confidential, accurate, and secure to house all data. Data will be collected and stored within JHU's secure, institutionally managed REDCap survey and research database platform. Data transferred for additional analysis will take place within JHU's virtual cloud storage and analysis platform (SAFE Desktop) that maintains HIPAA security standardsUse of a computer-based survey platform will minimize data entry errors and missing data. The data manager will perform weekly systematic protocols for data cleaning, and check for consistency and completeness (e.g., skip pattern error, duplicate or inconsistent responses).

Data Safety Monitoring Plan. The study will employ a data safety-monitoring plan consistent with NIH guidelines. Dr. Marcell will be responsible for monitoring and handling adverse events and will assume responsibility for the ethical integrity of the proposed work. All investigators and research staff will meet weekly and a portion of these meetings will be dedicated to communicating about ethical issues related to the study, including patient safety, changes in risk/benefit ratio, and regulatory issues.

The PI will review the safety and progress of the study on an ongoing basis. Enrolled participants will be monitored throughout the study for untoward incidents (e.g., "Adverse Events") occurring during the study. Study Reports will be generated focusing on subject recruitment, retention, and adverse events (AEs) that will give an in-depth synopsis of (1) study accrual; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. The PI and co-Investigators will conduct regular monitoring for enrollment rates, study data acquisition, and safety events, as a part of continuous oversight to comply with human subject safety requirements.

Frequency of Monitoring
The PI will review Study Reports (e.g., acquired data and available safety information) on a weekly basis and will share safety and progress reports with all co-Investigators on a weekly basis.

Formal interim monitoring will be performed by the PI annually. For both continuous and interim monitoring, safety occurrences will be evaluated for severity, attribution, and possible trends.

- All adverse events that are anticipated or described in the informed consent form will be logged appropriately and reported to the IRB on at least an annual basis (e.g., at continuing review).
- Any Unanticipated Problems or unexpected "Serious Adverse Events" (SAEs) related to the study intervention and affecting the risk/benefit profile of the study, will be reported to the IRB promptly, and, in all cases, within 10 business days of discovery.
- Unplanned and non-emergent deviations from the IRB approved protocol will be logged, include a corrective action plan, if necessary, and be reported to the IRB annually at continuing review; all planned deviations will be submitted as a Change in Research to the IRB for approval and prior to implementation. All other event reporting requirements will be followed and all necessary parties will be notified of events/problems encountered in the study and/or changes in research, in accordance with all applicable regulations and guidelines.

Interim monitoring findings and corrective actions will be summarized in a report to be retained in the regulatory file.

Study report outline (Interim or Annual Reports): The study team will generate Study Reports and will provide information on accrual rates, retention, adverse, and severe adverse events to track the study's progress. Study Report tables will be generated using aggregate data (not by group assignment).

REVIEW TABLE

Data type	Frequency of review	Reviewer
Subject accrual (including compliance with protocol enrollment criteria)	Quarterly	Investigators
Status of all enrolled subjects, as of date of reporting	Semi-annually	Investigators
Adherence data regarding study visits and intervention	Quarterly	Investigators
AEs and rates (including out-of-range lab values)	Semi-annually	Investigators
SAEs	Per occurrence	Investigators, Sponsor (NICHD)

c. Plan for reporting unanticipated problems or study deviations.

Any unanticipated problems or adverse events will be reported to the IRB immediately. Deviations from the original study protocol will be requested through a change in research request.

Collection and Reporting. For this study, the following standard AE definitions will be used:

Adverse Event (AE): Any unfavorable and unintended diagnosis, sign (including an abnormal laboratory finding), symptom, syndrome, or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen. All adverse events will be recorded.

Unanticipated Problems (UP): Unanticipated problems involve risks to subjects or others include, in general, any incident, experience, or outcome that meets all of the following criteria:

– Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
– Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
– Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Unanticipated problems will be recorded in the data collection system throughout the study.

Serious Adverse Event (SAE): Any AE that results in any of the following outcomes:

– Death
– Life-threatening event
– Event requiring inpatient hospitalization or prolongation of existing hospitalization
– Persistent or significant disability/incapacity
– An important medical event based upon appropriate medical judgment

All serious adverse events will be recorded.

Characteristics of an AE:

Relationship to Study Intervention: To assess relationship of an event to study intervention, the following guidelines will be used:

1. Related (Possible, Probable, Definite)
   a. The event is known to occur with the study intervention.
   b. There is a temporal relationship between the intervention and event onset.
   c. The event abates when the intervention is discontinued.
   d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
   a. There is no temporal relationship between the intervention and event onset.
   b. An alternate etiology has been established.

Expectedness of SAEs: The PI will be responsible for determining whether an SAE is expected or unexpected. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention.

Severity of Event: We will use the following scale to grade adverse events:

1. Mild: no intervention required; no impact on activities of daily living (ADL)
2. Moderate: minimal, local, or non-invasive intervention indicated; moderate impact on ADL
3. Severe: significant symptoms requiring invasive intervention; subject seeks medical attention, needs major assistance with ADL

Reporting Procedures: The anticipated potential adversity inherent in participation is limited to those

situations described above and will be addressed by the timely intervention of research staff members skilled in risk assessment and mandatory reporting requirements.

Reporting Procedure for Serious Unanticipated Adverse Events: In the event of an unanticipated serious adverse event occurring during study enrollment, the project PI will ensure that these events are reported to the IRB and sponsor (NICHD) within 7 days by phone, fax, and/or email. Incidents or events that meet the criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. The following information will be included when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

– Appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
– A detailed description of the adverse event, incident, experience, or outcome;
– An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;
– A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

– Unanticipated problems that are serious adverse events will be reported to the IRB and sponsor (NICHD) within 7 days of the investigator becoming aware of the event.

AE Reporting of Non-Investigational New Drug (IND) Studies: SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the IRB and sponsor (NICHD) in accordance with requirements.

- Unexpected fatal or life-threatening SAEs will be reported to the IRB and the sponsor (NICHD) within 3 days of the PI becoming aware of the event. Other serious and unexpected AEs related to the intervention will be reported within 7 days.
- Anticipated or other SAEs will be handled in a less urgent manner but will be reported to the IRB and sponsor (NICHD), and other oversight organizations in accordance with their requirements.

All other AEs documented during the course of the trial will be reported to the sponsor (NICHD) on an annual basis by way of inclusion in the annual report and in the annual AE summary which will also be provided to the IRB.

Data Sharing Plan (as required per NIH guidance)

Data Access and Security. Quantitative survey data will be de-identified (all sensitive identifiable or potentially identifiable information will be protected). Data will be stored on an enterprise network encrypted secure server for direct access at JH's institutional OneDrive, which has HIPAA security levels, as a secondary location for data that has removed non-essential direct identifiers. No data will be used and/or released without prior approval by the principal investigator. Any activity through this site is log accessible to the editor. Any material with personal health information (i.e., consent forms with identifiers) will be kept separately from data in a key-locked filing cabinet in a secure/private office space during the project period and destroyed immediately after the project period. Appropriate consents for deposition of survey data into public databases for future use will be obtained through the formal consent process.

Data Documentation. The research team will develop data documentation materials that describe the method of data collection, data codebook/data dictionary, and other documentation of the study variables that will be useful during later access by the study team and with the final archival files.

Data Archiving and Long-term Preservation. The final version of the collected dataset will be made available within thirty (30) months after the end of the data collection. For data underlying scientific publication, the data will be made available to coincide with publication of the paper, unless the dataset is already available via a release or sharing mechanism. At a minimum, release of the dataset will consist of a machine-readable version of the data tables shown in the paper.

Datasets 1 and 2 (see table below) will be preserved and made accessible along with the data codebook and other relevant documentation via the chosen repository. We will make the data available through open access (Open Inter-university Consortium for Political and Social Research (ICPSR)) if possible. JHU School of Medicine will review the disclosure protection of the de-identified datasets. If they conclude that the risk of disclosure is too great for public access, then ICPSR's Traditional Restricted Data or Physical Data Enclave will be used for some or all of the data, with restricted access solely to approved researchers. The project may consider the SOM's fee-based service for de-identifying the dataset. Open ICPSR is a research data-sharing service of the Inter-university Consortium for Political and Social Research. ICPSR is a leading resource in the field for social science, government, and public health data and has a nearly 50-year track record for preserving and making data available. Through ICPSR, whether using the open archive or the restricted options, these particular research datasets and associated documentation will be preserved and made accessible to researchers in the social sciences, public health, medical communities, and beyond. JHU may provide a restricted access data repository at that time which we may consider as an alternative, as well as any repositories recommended by NIH for this grant.

Datasets (Input and/or Output)		Format(s)	Est size/amount	Shared?
1	Quantitative acceptability of technology usability, acceptance, and satisfaction data among father participants assigned to Text4Father	CSV	60 respondents	Yes, de-identified or with restricted access only
2	Quantitative baseline and follow-up data of father and mother participants in all arms	CSV	Baseline: 120 respondents Follow-up: 96 respondents	Yes, de-identified or with restricted access only

Descriptions of the data to be produced in the proposed project

- Quantitative acceptability of technology usability, acceptance, and satisfaction data will be collected among father participants assigned to Text4Father.
- Quantitative baseline and follow-up data will be collected among father and mother participants in all arms assessing fathers' resident status, exposure to pregnancy/parenting/ infant care information, and caregiver conflict; and knowledge about infant development, beliefs about father role and attachment, self-efficacy about parenting and infant care, cooperative coparenting, relationship quality, and behavioral engagement in infant care, including safety/injury prevention.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

There are no anticipated legal risks associated with study participation except if participants reveal that they or their children are currently being abused or harmed in any way, or this is suspected. In these circumstances steps will be taken to ensure their safety, which may include contacting local authorities (e.g., law enforcement, child protective services).

e. Financial risks to the participants.

There are no anticipated financial risks to participations that are unaccounted for in the support and remuneration plan.

9. Benefits

a. Description of the probable benefits for the participant and for society.

All father and mother participants will receive information about local resources for new parents, and some subjects will receive additional knowledge, skills, and resources as part of Text4Father text messaging program.

Despite well-documented benefits of early father engagement on child development and maternal and paternal outcomes, and fathers' interest to learn how to be involved during maternity and infant care, no standard approach exists to engage expectant fathers, particularly lower income fathers, that can be easily disseminated. This feasibility, acceptability and preliminary efficacy study will provide important evaluation data for Text4Father and its ability to better meet the needs of lower income fathers, and improve fathers' knowledge, confidence, and ability to be engaged during pregnancy and early infancy. The potential benefits of the knowledge to be gained from the proposed study outweigh the potential risks to the subjects.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

Father participants who consent, enroll, and complete the baseline survey will receive $35 in remuneration; mother participants who complete the shorter baseline survey will receive $15 in remuneration. After 7 months, father participants who complete the follow-up exit survey will receive $75 in remuneration and mother participants who complete the shorter follow-up exit survey will receive $40. Remuneration accounts for incentives and costs related to participating in the study (e.g., transportation, receiving/sending mobile phone text messages, data associated with viewing internet-related resources on phone, etc.). For retention, participants will be instructed to share with us any changes in their contact information or mobile phone number and $5 gift cards will be provided to participants who contact us with any changes during the course of the study period. Participants who refer others who complete an eligibility screener will also be provided a $5 gift card.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

There are no anticipated costs to participants that are unaccounted for in the support and remuneration plan for the study and/or usual care.

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