Improving Care Giver Adherence to Recommended Infant Care Practices (AKA SMARTER)

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Protocol Revisions and IRB Approvals

Revision #1

Protocol V 3.2	IRB Approval Date: 20Dec2021
Section	Revision Description
9.2.3	1- If participant texts 'stop', they must reply to a stop confirmation text in order to stop TodaysBaby. If they confirm stop will be withdrawn from study. 2- Participants who respond to a study text indicating they are no longer pregnant, will receive a follow-up text asking them to confirm that they are no longer pregnant. If they confirm they are no longer pregnant, participant will be withdrawn immediately.
9.9	Addition of a stop confirmation text to participants
9.10	Removed Amazon as gift card option. Added CVS Pharmacy as gift card option. Added Target as preferred gift card retailer.
10.2	Modified REDCap message for participants who respond anything other than "Never" to Q10 on EPDS. Have added statement that survey responses are not monitored in real time.

Revision #2

Protocol V 3.3	IRB Approval Date: 14Apr2022
Section	Revision Description
7.2	Exclusion Criteria updated to reflect that contraindication to breastfeeding and/or supine sleep position will not be assessed on initial eligibility screening. It will be assessed at 30+1 gestational weeks (via text query) and on the birth survey.
9.10	Reimbursements updated to reflect that participants will receive gift card for survey completion within 7 days of completing a survey.
16.0	Updated Pre-Observation Period weekly text messages. Participant now receives on gestational week +0 instead of +1 (ex. 32+0) Added additional survey reminder text messages.

Revision #3

Protocol V 3.4	IRB Approval Date: 01Aug2022
Section	Revision Description
7.2	Exclusion Criteria updated to reflect that participants who do not complete the Agile Health Onboarding process by 32+1 weeks gestation are not eligible for the study.
9.8	Early Terminations/Withdrawals section updated to indicate that participants will be ineligible for the study if they do not complete the following enrollment procedures by 32 weeks plus 1 days gestation.
9.9	Updated follow-up section for participants Who text 'Stop' • If participant has not undergone randomization #1 – they will be withdrawn from the study. • If participant has undergone randomization #1 – they will continue with the study and receiving any remaining study surveys via text or email.
10.4	Stopping Rules revised. Added scenarios that participant will be withdrawn from study prior to undergoing randomization #1 • Participant texts 'STOP" and confirms they want to stop receiving the TodaysBaby program. • Participant informs study that they are no longer pregnant.

Revision #4

Protocol V 3.5	IRB Approval Date: 14Oct2022
Section	Revision Description
5.0	Updated Study Design: Data Collection Methods Have added a short TodaysBaby Program Discontinued Survey, for participant who elect to stop receiving the TodaysBaby Program via text, and are still enrolled in the study.
9.9	Updated follow-up section for participants who do not respond to text queries or open intervention videos. • If staff are unable to reach participant to follow-up by phone, they may attempt to contact participant via email (if email was provided at the time of enrollment). Email will only be used if there is concern that participant is not receiving text messages. Updated follow-up section for participants Who text 'Stop' • Participants who have undergone randomization #1, stop receiving the TodaysBaby program prior to their infant reaching 6 months of age, will be asked to complete a short TodaysBaby Program Discontinued Survey.

Revision #5

Protocol V 3.6	IRB Approval Date: 11Jan2023
Section	Revision Description
10.2	Updated the response survey response participants receive if they respond anything other than 'None' on the EPDS Question 10 (thoughts of harming themselves). • Updated the Suicide and Crisis Lifeline information. • Added statement that a clinician from the study will call them to discuss their survey response.

Revision #6

Protocol V 4.0	IRB Approval Date: 13Jun2023
Section	Revision Description
5.B.c.	Updated Randomization Section to include that randomization stratification will be assigned by State WIC region.
5.C.	Updated Study Team Institutional Roles and Responsibilities to include that study staff at UVA, WUSTL and UMASS Medical Center, may assist in participant recruitment at participating WIC centers and Federally Qualified Health Centers (FQHC).
9.1.1	Added that participants may be identified at participating FQHC.
9.1.3	Modified Participant ID # to indicate three-digit WIC *Region* number.
10.2.C.	Updated Safety Review section to indicate that clinicians following-up with a Spanish speaking participant because of a positive Q10 EPDS score, may use hospital interpreter services when following-up with participant.

Revision #7

Protocol V 5.0	IRB Approval Date: 06Dec2023
Section	Revision Description
7.1	Participant Inclusion Criteria has been updated Added: If potential participant is not enrolled in participating WIC Center they must have either Medicaid or no insurance
10.2	DSMP has been modified. Participants will have option to opt-out of receiving contact by the study physician if they respond positively on the EPDS to thoughts of harming themselves. We will add a statement at the beginning of the EPDS Section of the Baseline, Birth and Postnatal Surveys to inform participants that they may receive a call from study clinician to discuss some of their responses in this section. We have added an additional participant resource in the event of miscarriage, infant death or stillbirth. https://www.postpartum.net/get-help/loss-grief-in-pregnancy-postpartum/

Revision #8

Protocol V 5.1	IRB Approval Date:
Section	Revision Description
3.0	Study Design: Study Team Institutional Roles and Responsibilities Starting 2025 – A UVA study coordinator will oversee the management of participant outreach and follow-up work that BU RAs are responsible for. As part of this oversight the UVA Coordinator will have access to SMARTER participants reports and data through a secure VPN connection to the BU databases and the Agile Health platform.
8.2	DSMP has been modified. a. For participants who answer question 10 of the EPDS (thoughts of harming themselves) with any response other than 'never', and who do NOT opt-out of a follow-up call with a clinician, but who we are not able to reach after 3 attempts, we will now send them a text letting them know we were not able to reach them along with a link to resources if they ever should need them. b. For participants who answer question 10 of the EPDS (thoughts of harming themselves) with anything other than never, and who OPT OUT of a follow-up call with a clinician - we will now send them a text acknowledging their response and include a link to resources if they ever should need them.
9.4	Management of Information Starting 2025, a UVA coordinator will have access to participant data via a secure VPN connection to study databases housed on a secure BU server.

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List of Abbreviations

Abbreviation	Abbreviation definition
AAP	American Academy of Pediatrics
BAA	Behavioral Affective Associations Model
EDD	Estimated Due Date
FQHC	Federally Qualified Health Center
ICP	Infant Care Practices
mHealth	Mobile Health
PMT	Protection Motivation Theory
SMART	Social Media and Risk Reduction Training study
SIDS	Sudden Infant Death
SUID	Sudden Unexplained Infant Death
TPB	Theory of Planned Behavior
WIC	Supplemental Nutrition Program for Women, Infants, and Children
SUPERSONIC	Support via Online Social Networks to Promote Safe Infant Care Practices toward Reducing Racial Disparities in Infant Mortality

Protocol Summary

Title:	Social Media and Risk Reduction Teaching Enhanced Reach (SMARTER)
Population:	Pregnant women from participating health or WIC centers who are less than 31 weeks plus 6 days gestation, sample size=2,500, age = reproductive age
Intervention:	Prenatal Interventions: 1) Infant care practices messaging with an emphasis on supporting best practices for infant feeding. 2) Infant care practices messaging with an emphasis on supporting best practices for infant sleep. Postnatal Interventions: 1) Infant care practices messaging with an emphasis on supporting best practices for infant feeding. 2) Infant care practices messaging with an emphasis on supporting best practices for infant sleep.
Objectives:	Overall study goals are to improve adherence to safe sleep recommendations and improve rates of initiation and duration of any and exclusive breastfeeding.
Design/Methodology:	Prenatal randomization at 33 plus 6 days gestation to one of two study arms (in 1:1 ratio): Prenatal Breastfeeding or Prenatal Safe Sleep; Postnatal randomization at birth ascertainment to one of two study arms (in 1:1 ratio): Postnatal Breastfeeding; Postnatal Safe Sleep.
Total Study Duration:	Participants can enroll at any time prior to 31 weeks plus 6 days gestation. Study continues until participant's infant is 6 months of age. Therefore, maximum total study duration may range from about 36 to 60 weeks depending on the gestational age at which the participant enrolls.
Subject Participation Duration:	Varies by participant between 8-12 months.

1 Background/Rationale & Purpose

1.1 Background Information

The SMARTER Study is the successor to the Social Media and Risk Reduction Training (SMART) study that was conducted by this study team from 2012 - 2018. The SMART study was a randomized trial using mobile health (mHealth) strategies (those that use mobile communication devices [e.g., cell phones] to provide health services and information) to improve caregiver adherence to American Academy of Pediatrics (AAP) recommended infant care practices related to safe sleep.
The SMART study sought to improve the design, implementation, and effectiveness of interventions to prevent Sudden Infant Death Syndrome (SIDS) and unintentional injury-related infant deaths associated with the sleep environment.

These deaths, which we will refer to as sleep-related deaths, remain the leading cause of US postneonatal mortality,[1] with ~3500 deaths each year. Many of these deaths are preventable by improving adherence to AAP safe infant sleep guidelines:[2] infants should always sleep in the supine position, roomshare without bedsharing, avoid soft bedding, and use a pacifier when placed for sleep. In addition, the AAP recommends exclusive breastfeeding for the first 6 months and continued breastfeeding thereafter to 1 year, since breastfeeding is associated with many health benefits,[8,9] including a decreased risk of SIDS.[10] However, adherence to these recommendations continues to be suboptimal, particularly in low-income groups.[3-6]

While the national Back to Sleep public health campaign was very successful in decreasing infant mortality from 1990 to 2000,[1] adherence to supine sleep recommendations has plateaued since 2001.[11] Further, US public health efforts have been less successful in changing behaviors with regard to soft bedding and bedsharing.[3,12] Rates of prone positioning, parent-infant bedsharing, and use of soft bedding are higher among those of lower educational and socioeconomic status.[13-16] Sleep-related infant deaths most commonly occur in the presence of multiple unsafe sleep practices (such as prone/side positioning, use of soft bedding, bedsharing, and pacifier non-use).[17,18]

The benefits of breastfeeding increase with exclusivity and longer duration of breastfeeding. One study estimated that if 90% of infants were exclusively breastfed for 6 months, 911 US deaths, most of them in infants, would be prevented annually.[19] Unfortunately, only 44% and 22% of US mothers are breastfeeding exclusively by 3 and 6 months, respectively, and only 31% are still doing any breastfeeding at 1 year.[20] Certain groups, including mothers who are younger, have lower income and educational levels, or participate in the national WIC program have lower breastfeeding rates.[21-25] Black women have lower breastfeeding initiation rates (59% in 2008, vs 75% White and 80% Hispanic). At 6 and 12 months, rates decline to 30% and 13%, respectively.[26]

The SMART study showed that a postnatal mHealth intervention improved safe sleep adherence by ~10 percentage points compared to control, while in-hospital education alone did not. Further, our data suggest that low-income mothers represent a group that may benefit most from such an intervention. Prior to widespread dissemination, we believe that it is critical to replicate and expand

the successful postnatal intervention and to assess a prenatal mHealth intervention as a potentially more effective replacement for the in-hospital education.

Assessing the intervention on a statewide basis in WIC centers will allow us to focus on low-income mothers, who are at high risk for both nonadherence[13- 16] and infant mortality,[27] and ultimately set the stage for large-scale implementation.

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

1.2 Rationale and Purpose

SMARTER is a randomized controlled trial (RCT) that will assess newly developed mHealth prenatal interventions to promote parental choices of best practices recommendations regarding infant sleep and feeding practices, while also providing an additional assessment of the simultaneously replicating and expanding on the SMART postnatal mHealth infant care practice interventions. SMARTER also assess Spanish language materials.

Our history as a team of defining current practices with NISP (National Infant Sleep Position)[3,11,12,] SAFE (Study of Attitudes and Factors Effecting Infant Care Practices)[28,29] and other studies,[4,30-40] followed by subsequent testing of a postnatal mHealth intervention (SMART) places us in a unique position to use what we have learned to enhance and refine the messaging, add the prenatal component, and study the interventions in a population at high risk for sleep-related death and low rates of breastfeeding, i.e., low-income women.

In the sections below, we: 1) explain our rationale for focusing on WIC-eligible mothers as our target population, 2) describe the rationale for adding a prenatal intervention, 3) explain the rationale for selecting mHealth as our strategy, and 4) describe social marketing principles that inform our mHealth interventions.

<u>Rationale for Using WIC Centers for Recruitment</u>: Low socioeconomic status is a risk factor for sleep-related deaths,[7,42] and Black infants, who are more likely to have low socioeconomic status,[43] are twice as likely to die from these deaths.[44,45] The increased risk among these groups may in part be due to lack of adherence to recommended guidelines. Our data among low-income and Black mothers show that both groups are significantly less likely to place their infant supine,[4,11,31,33] more likely to bedshare,[3,45,46] more likely to use soft bedding,[12] and less likely to exclusively breastfeed.[28] This may be due to specific beliefs and attitudes (e.g., infants are more likely to choke when supine[11] or Breast Milk is no better than formula[48]), or a lack of appropriate role modeling by healthcare providers.[31]

In our survey of low-income US mothers, only 42% reported receiving advice from nurses to place infants supine.[31] However, these disparities may be amenable to change. We have shown that an intervention at WIC centers that addressed maternal concerns and misconceptions was effective at improving knowledge, changing attitudes, and modifying intention.[49] In addition, our SMART

mHealth intervention improved safe sleep practices in these high-risk populations to levels comparable to the others. In the subgroup of SMART participants who were WIC recipients (51.6%), effect sizes were in general stronger; e.g., those who received both safe sleep interventions had a 20 percentage point higher rate of supine placement than controls (93% vs 73%; a OR 5.2, 95% CI 3.7-7.4). Effect sizes were also greater among WIC participants for roomsharing without bedsharing, and no soft bedding use. Thus, we have experience and demonstrated success with culturally competent messages that resonate with low-income mothers.

WIC is a national program whose mission is to "safeguard the health of low-income women, infants, and children up to age 5 who are at nutrition risk by providing nutritious foods to supplement diets, information on healthy eating, and referrals to health care."[50] After May 2017, to be WIC eligible, one's gross income must be ≤185% of US Poverty Income Guidelines.[50] WIC eligibility is thus an easily verifiable proxy for income that does not depend on self-report. Almost 900,000 pregnant women (20.3% of whom are Black[51]) are enrolled in WIC annually, with >90% enrolling before 24 weeks gestation.[51] Thus, WIC centers are an efficient way to reach high-risk pregnant women in a systematic manner. A well-designed, targeted intervention utilizing what we have learned, which would be feasible to implement in WIC offices nationwide, could have broad implications for infant health and could potentially decrease the persistent income and racial disparities in postneonatal deaths and infant health. We have extensive experience working with WIC populations. We have recruited WIC patients for various studies, including an otitis media study,[52] face-to-face interviews[31] and interventions.[39,40,48] We have current working relationships with statewide WIC in Virginia and Massachusetts, respectively. Both states have expressed support for this study. 34% and 24% of Virginia WIC recipients are Black and Hispanic, respectively; in Massachusetts, 22% and 43% are Black and Hispanic, respectively.

<u>Rationale for interventions during the prenatal period</u>

The prenatal period provides a unique venue for intervention for several reasons.[30,52] First, mothers experience excitement and anticipation, but are not yet exhausted and preoccupied with infant care, allowing an opportunity to absorb information. With regards to breastfeeding, most women, particularly WIC-eligible mothers, decide how they are going to feed their baby prior to birth;[39] yet, women do not receive adequate prenatal education on breastfeeding.[53]

Second, the safe sleep and breastfeeding practices that we are targeting should ideally start immediately after birth, and there is not always time to adequately reach everyone during the hospital stay prior to the first feedings and sleep periods. Thus, the hospital stay is not an optimal time to provide new information that could impact on decision-making; this may in part explain the lack of impact of our SMART in-hospital intervention. Third, knowledge, realistic expectations, and self-efficacy prior to the baby's birth are associated with better breastfeeding outcomes,[54-56] and we suspect that this may also be true for safe sleep outcomes. Finally, little is known about whether prenatal safe sleep education impacts sleep practices. Only 2 studies have reported prenatal safe sleep education; while both studies showed increased knowledge about safe sleep guidelines, there was no follow-up to look at actual practices after the infant's birth.[57, 58]

Enhanced prenatal education increases breastfeeding rates,[59] and for low-income women, both prenatal and postnatal interventions are needed.[61] As there is little information regarding safe sleep education in the prenatal period, it will be important to test this strategy. SMARTER has the potential to enhance prenatal safe sleep and breastfeeding education with messages that target the specific barriers that low income women face, contain risk reduction information about conditions that uniquely affect them, and feature women of color as role models.

Rationale for mHealth (mobile health) interventions in high-risk groups

There is wide acceptance for accessing and receiving health information on mobile devices (e.g., smart phones).[61-67] Systematic reviews of interventions using mHealth technologies found positive impacts on appointment attendance, immunization rates, medication adherence, and diabetes self-management.[68-70] In addition, the use of video health education has been effective in improving understanding, knowledge, and self-efficacy,[71,72] and changing behavior,[73,74] and are more appealing to patients than written pamphlets.[71,72] Videos may also be a more effective means of providing health information to low-literate families. In addition to these studies, SMART demonstrated the effectiveness of a mHealth approach in changing infant care practices in the postnatal period. 99% of mothers approached had daily email or SMS access, and we demonstrated high engagement among mothers (>50% video view and query response rates),[41] and increased adherence with safe sleep practices among those who received the safe sleep videos. Therefore, we believe that this mHealth approach, due to its accessibility, efficiency in delivering messages, capacity to reach low-literate populations, and demonstrated effectiveness in SMART will also be effective when used prenatally in SMARTER.

Rationale for social marketing and culturally competent approaches in health promotion

Social marketing is the use of commercial marketing concepts to design and implement programs to effect social change and is guided by the following principles: 1) the ultimate objective is to influence action; 2) action occurs when the target population perceives the benefits to outweigh the costs of the action; 3) programs are more effective when based on an understanding of the target population's perceptions; 4) target populations are rarely uniform in perceptions and/or responses to social marketing efforts; 5) there are always behaviors that compete with recommended behaviors, and these must be understood and addressed; and 6) because of constant changes in the "marketplace," there must be frequent monitoring in order to rapidly alter strategies as needed.[76] Many health campaigns, however, have a one-size-fits-all approach (e.g., Back to Sleep), and thus are not necessarily effective in reaching all targeted audiences.

Culturally and linguistically competent health promotion approaches respect cultural values, beliefs and practices of the target population; therefore, health promotion messages should ideally reflect these health beliefs and practices. This is often a challenge, as some beliefs and practices may be inconsistent with emerging knowledge of behaviors that support healthy outcomes. Culturally competent health promotion supports and honors those practices and beliefs that are protective or benign, and respectfully helps to identify and change those that have a negative health impact.[77]

Our interventions will incorporate techniques to favorably influence infant care practices, while respecting parental beliefs. Our goal is to build on the success of the SMART safe sleep and breastfeeding postnatal mHealth intervention, as well as the lessons learned in the SAFE, SMART and All Breasts Matters surveys, in order to incorporate a prenatal component, incorporate even more racial/ethnic and culturally competent messaging, and target the specific challenges of low-income women.

2 Objectives

2.1 Study Objectives

Aim 1: To assess the effectiveness of mHealth prenatal and postnatal interventions aimed at promoting safe sleep practices and breastfeeding.

Aim 2: To assess social cognitive mediators of the intervention effects on infant care practices that may inform further refinements to optimize intervention effectiveness.

2.2 Study Outcome Measures

2.2.1 Primary Outcome Measures

The following primary outcome measures will be obtained by maternal survey completed between two and six months after infant date-of-birth:

1. Usual infant sleep position in the previous two weeks
2. Usual infant sleep location in the previous two weeks
3. Soft bedding use in the previous two weeks
4. Pacifier use in the previous two weeks
5. Breast Milk feeding in the previous two weeks

2.2.2 Secondary Outcome Measures

The following secondary outcome measures will be obtained by responses to weekly text messages beginning on infant day of life two until six months of age.

1. Age in weeks when Infant stopped supine sleep position
2. Age in weeks when infant stopped room sharing without bed sharing
3. Age in weeks when infant starts using soft bedding
4. Age in weeks when infant Breast Milk feedings change

3 Study Design

A. Study Population

SMARTER will enroll up to 2,500 pregnant women who are clients at participating FQHCs and WIC centers located throughout the United States, to achieve a target of randomization of 2,000 women.

B. Study Design

The study will utilize a two-stage randomization approach in which pregnant women are randomly assigned to one of the two prenatal interventions (infant sleep practices messaging vs. infant feeding messaging) and then, at the time of birth ascertainment, randomization to one of two postnatal interventions (infant sleep practice messaging vs. infant feeding messaging). This will result in a classic 2 x 2 design where approximately 25% of participants will have been assigned to each of the four possible combinations of interventions (1 - prenatal sleep practices/ postnatal sleep practices; 2 - prenatal sleep practices/postnatal feeding practices; 3 – prenatal feeding practices/postnatal sleep practices; 4 – prenatal feeding practices/postnatal feeding practices). This design will permit assessment of the impact of each intervention alone, as well as possible incremental effects of combinations of interventions.

a. Development of Intervention

There are three theoretical models that have informed the study design and intervention materials:

- Theory of Planned Behavior (TPB)
- Protection Motivation Theory (PMT)
- Behavioral Affective Associations Model (BAAM)

The Theory of Planned Behavior is our framework for understanding the factors that are important in influencing the health-related behaviors of interest. According to the TPB, intention to perform a certain behavior is influenced by 3 main factors: a) attitudes and beliefs (e.g., baby might choke if he's on his back); b) perceived social norms (e.g., my friends don't put their babies on the back to sleep, so I won't, either); and c) perceived control (e.g., I would put my baby on the back, but my mother takes care of her and likes the stomach).

The Behavioral Affective Associations model, introduces the importance of affective (emotional) associations and cognitive beliefs as influences on behavior, and the PMT, which emphasizes perceived risk as a motivator.

b. Delivery of Intervention to Participants via Short Message Service (SMS)

The TodaysBaby Interventions will be delivered via SMS text message by Agile Health. SMS allows for text messages (up to 140 characters in length) to be sent to participant's mobile phone. SMARTER participants will receive text queries and text links to TodaysBaby videos and study surveys.

All study text messages will be sent to participants between the hours of 9:00 AM and 9:00 PM (participant local time). Text messages will be sent at random times throughout the day with the majority of text messages being sent between 9-11 AM and 5-7 PM.

c. Randomization

Mothers will be randomized on an individual level in two stages (prenatal randomization at 34 weeks plus 0 days gestation, and postnatal immediately upon birth ascertainment) such that participants are assigned to one of the 4 study groups (i.e. each of the four combinations of prenatal/postnatal interventions). Randomizations will be stratified (by WIC center or State WIC region and pre-randomization participation level), and blocked (so that the number of mothers from each stratum within WIC center/region assigned to each of the study groups will balance after 4 or 8 mothers). Randomization will be based on computer-generated random numbers and stratified by WIC center/region and 2 categories of pre-randomization study participation (higher vs. lower engagement in mHealth activities during a 2-week window (32 weeks plus 0 days through 33 plus 6 days gestation)). This randomization stratification will help achieve balance in gestational age at enrollment, and balance across study groups in likely mHealth video viewing and exposure to breastfeeding counseling (which may differ by WIC center/region). We will also collect WIC site data with regards to breastfeeding support and safe sleep education, and query participants about what prior education they received from WIC. If there is a site effect, we will conduct exploratory analyses to assess any differences between sites.

SMARTER will randomize participants at two study time points:

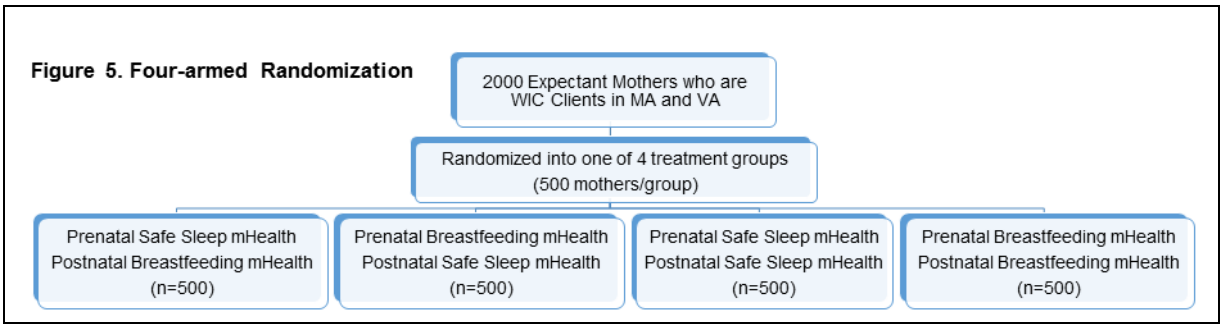
- Randomization #1 (33 plus 6 days gestation) – Assignment to Prenatal TodaysBaby Intervention

- Randomization #2 (immediately following infant birth) – Assignment to Postnatal TodaysBaby Intervention

  Participants must undergo randomization #1 in order to be eligible for randomization #2.

Randomization will be based on computer-generated random numbers, block sizes of 4, and be stratified by WIC center/region, language, level of participant engagement during the Observation Period (viewing videos/responding to text messages).

This randomization stratification will help achieve balance in gestational age at enrollment, and balance across study groups in likely post-randomization mHealth video viewing rates.



Blinding: Investigators and study staff will be blinded to participant's assigned prenatal and postnatal intervention. Participant intervention arm will be maintained by the Boston University Database Programmer in a separate database.

d. Data Collection Methods

The TodaysBaby prenatal and postnatal mHealth interventions will be evaluated through initial and follow-up surveys and text messages.

The surveys will assess both behavior change mechanisms/process constructs (risk perception, benefits/barriers, affective associations, efficacy, and intention), mood and anxiety. Surveys and text messages will evaluate initiation and maintenance behavioral outcomes.

Participant Surveys

Participant surveys will be administered at various times throughout the study.

Participants will be asked to complete five surveys during the course of the study. A subset of participants will be asked to complete an additional short Breastfeeding Cessation Survey.

In addition, participants who elect to stop receiving the TodaysBaby program, after completing randomization #1, will be asked to complete a short survey indicating why the stopped the TodaysBaby Program.

i. *Enrollment Survey*
Completed by participant after informed consent has been obtained and prior to the participant completing the mHealth on-boarding process via Agile Health. Data collected includes: demographic information, household characteristics, and plan for infant feeding.

ii. *Baseline Survey*
This survey will be completed when the participant is between 32 weeks plus 1 day through 33 plus 6 days gestation. Data collected includes: past obstetrical history/delivery history, past breastfeeding history, ICP intention (breastfeeding, sleep position, sleep

location), TPB domains, affect, breastfeeding self-efficacy, past smoking history, PHQ-4 ultra-brief screening scale for anxiety and depression. Mothers who screen positive on the PHQ-4 (score ≥3 for either depression or anxiety) will complete the Edinburgh Postnatal Depression Screen (EPDS).

iii. Prenatal Intervention Survey

This survey will be completed during the Prenatal Intervention Period. This survey will be sent to participants after they have received the majority of the prenatal intervention.

Data collected includes: ICP intention (breastfeeding, sleep position, sleep location), TPB domains, affect, breastfeeding self-efficacy, and participant assessment of TodaysBaby postnatal intervention.

iv. Birth Survey

This survey will be completed at the start of the Postnatal Intervention Period. Data collected includes: information about the infant birth (ex. number of births, infant's DOB), length of infant hospital stay, if infant has received any Breast Milk since birth, if participant plans to breastfeed infant, and the PHQ-4 ultra-brief screening scale for anxiety and depression. Mothers who screen positive on the PHQ-4 (score ≥3 for either depression or anxiety) will complete the EPDS.

Participants who indicate that the baby they delivered first (index child) was not liveborn, will have an abbreviated survey. The abbreviated survey will not include in the PHQ-4 and EPDS screening.

v. Postnatal Intervention Survey

This survey will be completed during the Postnatal Intervention Period, after participant has received all postnatal intervention videos.

Data collected includes: brief obstetrical, delivery, and post-discharge, smoking history, ICP actual practice- (breastfeeding, sleep position, sleep location, sleep objects, sleep outfits, falling asleep with baby, smoking), ICP intention- breastfeeding, sleep position, sleep location, TPB domains, maternal work information, social determinants of health/discrimination/details on housing, breastfeeding initiation/cessation, participant assessment of TodaysBaby postnatal intervention, and the PHQ-4 ultra-brief screening scale for anxiety and depression. Mothers who screen positive on the PHQ-4 (score ≥3 for either depression or anxiety) will complete the EPDS.

vi. Breastfeeding Cessation Survey

Those participants who report, on the Postnatal Intervention Survey, that their infant received any Breast Milk (in the previous two weeks), will be asked to complete a short Breastfeeding Cessation Survey if they subsequently responds to two consecutive feeding plan practice/intent text queries indicating that their infant has only received formula for

the past seven days and the participant plans to only feed formula for the next seven days.

vii. TodaysBaby Program Discontinued Survey

Participants will be asked to complete this survey if the elect to stop the TodaysBaby program after they have completed randomization #1 and prior to their infant reaching six months of age.

Participants can stop the TodaysBaby program by texting 'STOP' and confirming that they wish to stop receiving the program, or by calling/emailing the study office to request that program be stopped.

Should a participant text 'STOP', they will receive a text asking that they confirm they would like to stop receiving the TodaysBaby Program. If the participant confirms that they want to stop the TodaysBaby program, the will receive the following final text that contains a link to the TodaysBaby Program Discontinued Survey.

You have stopped the TodaysBaby video/text program. You will continue to receive remaining study surveys and gift cards for completing surveys *You can stop your participation in the study anytime by calling 617-206-6269 or emailing tdybaby@bu.edu* *Please complete this short survey to let us know why you stopped the program <Link>*

Should a participant contact the study office by phone to indicate they would like to stop the TodaysBaby Program, study staff will complete the TodaysBaby Program Discontinued Survey over the phone.

Should a participant contact the study office by email to indicate they would like to stop the TodaysBaby Program, study staff will confirm with the participant that they will stop receiving the TodaysBaby program and will send a link to the TodaysBaby Program Discontinued Survey via email.

Study staff may reach out to participants by phone to request that the participant complete the survey.

Survey data will be captured in the Boston University's REDCap System. REDCap has been selected for its' mobile phone interface.

Participants will have the option of completing surveys via the REDCap link or over phone with study staff.

Participant Text Messages Queries during Prenatal and Postnatal Interventions
Participant will receive interactive text queries during the prenatal and postnatal interventions. All participants will receive the same text queries at the same delivery cadence regardless of assigned prenatal or postnatal intervention.

C. Study Team Institutional Roles and Responsibilities

Boston University
Is responsible for recruitment of WIC centers, FQHC and all study participants, management and analysis of all study data. Boston University will oversee management and tracking of the mHealth delivery platform through Agile Health.

Washington University in St. Louis, University of Virginia (UVA), and Other Investigators
Investigators and colleagues are responsible for development of study materials (text messages and TodaysBaby videos) and will provide assistance with recruitment of WIC centers, FQHC, and data analysis.

Study staff may assist with participant recruitment. Staff may visit high-traffic WIC offices and FQHC and set-up a table in offices to be able to talk with patients/clients about the study and answer any questions, as assist interested participants with electronic screening, consent and sign-up if they are interested.

Starting 2025 – A UVA study coordinator will oversee the management of participant outreach and follow-up work that BU RAs are responsible for. As part of this oversight the UVA Coordinator will have access to SMARTER participants reports and data through a secure VPN connection to the BU databases and the Agile Health platform.

Agile Health
Agile Health is the mHealth delivery platform that will be used for this study. Agile Health is an authorized Business Associate of Boston University.

Agile Health is a mobile healthcare solutions provider dedicated to changing lives and improving healthcare outcomes. They leverage the mobile phone to: 1) engage members/patients in an intensive and highly personal process of behavior change, and 2) help clients and business partners fundamentally change the way they engage members/patients to deliver health improvement and care management services.

4 Potential Risks and Benefits

4.1 Risks

Risk of loss of confidentiality
To reduce the risks, appropriate measures will be taken to ensure confidentiality, including securing all data on secure websites, password-protected computers, and locked cabinets. Participants will

be reminded to take appropriate measures with their mobile phone when responding to study texts and completing study surveys.

Risk of discomfort answering survey questions or text queries
Participants will be informed that they do not have to answer any survey questions or text queries.
Risk of psychological harm
There is a minimal risk of psychological harm related to the nature of the questions and the content of the interventions, should mothers suffer either an adverse outcome, (e.g., mothers who experience infant loss may feel guilt, depression, or suicidal thoughts). To reduce this potential risk, videos have been tested with study population, and messages in our interventions are accepted, well vetted public health messages that are endorsed by the American Academy of Pediatrics, Centers for Disease Control and Prevention, and other national health care organizations.

Risks associated with participants being distracted if they to text while driving or walking
To reduce this risk, participants will be reminded, during the consent process, to not text when driving or walking.

4.2 Potential Benefits

Participants may benefit from participation by receiving up-to-date expert messaging about creating a safe infant sleep environment and infant feeding practices.

4.3 Analysis of Risks in Relation to Benefits

The risks to subjects are low, and reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

5 Study Participant Selection

5.1 Participant Inclusion Criteria

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

- Must be enrolled at a participating WIC center
- If not enrolled in participating WIC Center must have either Medicaid or no insurance
- Must be English or Spanish speaking
- Must be pregnant and less than 31 weeks plus 6 days gestation
- Must live in the United States
- Must have SMS access (mobile phone)

5.2 Participant Exclusion Criteria

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

- Not planning to live in same home as infant after birth.
- Prenatal diagnosis expected to impact on infant care practices in a manner not compatible with study goals, including contraindications to breastfeeding.^^
- Prenatal diagnosis expected to impact on infant care practices in a manner not compatible with study goals, including contraindications to supine infant sleep positioning.^^
- Known or reported mental health or other issues that would preclude custody of the infant or being able to participate in the informed consent process.
- Meets the definition of a minor according to applicable state law.**
- Participants who consent to participation in the study, must complete the Agile Onboarding process before they reach 32+1 weeks gestation.[##]

^^Contraindications to breastfeeding and supine sleep position will not be assessed on initial eligibility screening. Contraindications will be assessed on enrolled participants at gestational age 30+0 (via text query) and on the Birth Survey. Staff will follow-up with all participants who indicate a contraindication at these study time points to determine if participant should be withdrawn from study for not meeting eligibility criteria.

**The study coordinating center (Boston University) will work with State WIC leadership to understand the laws surrounding the definition of a minor for research purposes. If individuals < 18 who are making their own healthcare decisions are considered adults under state law the coordinating center will work with WIC State leadership to ensure any required State approvals (or review) are obtained.

[##]In order to onboard to the Agile text message platform, participants must successfully enroll in the program. Enrollment in the program consists of a) ensuring that their Smartphone can receive short code text messages; and b) texting 'yes' when prompted if they agree to enroll in program being delivered by text message. Participants who do not complete the Agile onboarding process by the time they reach 32+1 weeks gestation are no longer eligible for study.

6 Study Intervention

This study consists of 4 interventions:

<u>Prenatal Interventions</u>
1. Infant care practices messaging with an emphasis on supporting best practices for infant feeding.
2. Infant care practices messaging with an emphasis on supporting best practices for infant sleep.

<u>Postnatal Interventions</u>
1. Infant care practices messaging with an emphasis on supporting best practices for infant feeding.
2. Infant care practices messaging with an emphasis on supporting best practices for infant sleep.

The TodaysBaby program consists of prenatal and postnatal videos, text message queries and information developed by the study team aimed at promoting adherence to AAP infant feeding and safe sleep recommendations.

TodaysBaby videos will be delivered to participants via SMS text message link. Videos range from 30 seconds to 3 minutes and are designed to provide important information on specific safe sleep and breastfeeding infant care practices.

The TodaysBaby program was initially developed by the study team for use in the SMART study and consisted of a postnatal intervention video/text curriculum only.

The revised TodaysBaby program has been updated specifically for this study. The revised TodaysBaby program includes a *prenatal* and *postnatal* curriculum. TodaysBaby videos have been re-designed and/or developed based on qualitative work completed in 2020 and 2021, which included focus groups and in-depth interviews with WIC clients and staff.

The revised TodaysBaby program has been expanded to include translation of materials into Spanish, and the SMARTER study will include both English and Spanish speaking participants.

A. TodaysBaby Curriculum Components

a. TodaysBaby Safe Sleep Videos
The TodaysBaby Safe Sleep Video Curriculum consists of 41 videos. (See Appendix 1 for list of video topics).

b. TodaysBaby Breastfeeding Videos
The TodaysBaby Breastfeeding Video Curriculum consists of 41 videos. (See Appendix 1 for list of video topics).

c. TodaysBaby Prenatal and Postnatal Intervention Text Queries

i. *Prenatal Intervention:* Text queries will ask participants about their *plan* for sleep and feeding behaviors of interest (ex. Bedsharing, room sharing, breastfeeding) once their infant is born.

ii. *Postnatal Intervention*: Text queries will ask about sleep and feeding behaviors of interest (ex. Bedsharing, room sharing, breastfeeding). Queries will be formatted in a manner that asks participant about their *practice* for the past week and their *intention* for the coming week.

All participants will receive the same text message queries regardless of assigned prenatal and postnatal interventions.

Feedback to Participants Based on Assigned Intervention

i. *Sleep Text Queries*

Participant Assigned to Prenatal/Postnatal Interventions with Sleep Emphasis: Participants will receive positive feedback (via text response) for responding to queries indicating that their plan/practice/intention aligns with AAP safe sleep recommendations. If the plan/practice/intention does not align with AAP recommendations, participants will receive feedback that promotes AAP recommendations.

Participant Assigned to Prenatal/Postnatal Interventions with Feeding Emphasis: Participants will not receive any positive or corrective feedback. Participants will be thanked for providing their response.

ii. *Feeding Text Queries*

Participant Assigned to Prenatal/Postnatal Interventions with Feeding Emphasis: Participants will receive positive feedback (via text response) for responding to queries indicating that their plan/practice/intention aligns with AAP breastfeeding recommendations. If the plan/practice/intention does not align with AAP recommendations, participants will receive feedback that promotes AAP recommendations.

Participant Assigned to Prenatal/Postnatal Interventions with Sleep Emphasis: Participants will not receive any positive or corrective feedback. Participants will be thanked for providing their response.

B. TodaysBaby Prenatal Curriculum

The TodaysBaby Prenatal Intervention will begin when the enrolled the participant reaches 34 weeks plus 0 days gestation and continues until the birth of the participant's infant.

During this period, participants will receive:

- Up to 25 Intervention specific videos and 2 Non-intervention videos
- Infant care practice text queries and feedback
- Birth ascertainment and informational text queries
- Text link to the Prenatal Intervention Survey and several text survey reminders if survey is not completed.

Participants will receive the same mHealth message and video cadence regardless of their assignment to the prenatal feeding or sleep interventions.

Participants will receive a text link to the Prenatal Intervention Survey on gestational week 36 weeks plus 1 day gestation. Text reminders will be sent to participants on gestational weeks

36+3; 36+5; 37+2; 37+5, if the Prenatal Intervention Survey has not been completed. Staff will also follow-up with participants by phone for incomplete survey as described in section 9.9.

The Prenatal Intervention Survey must be completed prior to the start of the postnatal intervention. If the survey is not completed by that time, it will be considered incomplete.

C. TodaysBaby Postnatal Curriculum

The TodaysBaby Postnatal Intervention will begin the day after the birth of participant's infant and will continue until the infant reaches 6 months of age.

During this period, participants will receive:

- 28 Intervention specific videos
- Infant care practice text queries and feedback
- Text message reminding videos can be viewed on study participant website
- Text link to two study surveys: Birth Survey and Postnatal Survey, along with several text survey reminders if surveys are not completed.

Participants will receive the same mHealth message and video cadence regardless of their assignment to the postnatal feeding or sleep interventions.
Participants will receive a text link to the Birth Survey on day 1 of the postnatal intervention. Text reminders will be sent to participants on days 3, 6, 9, 13, if the Birth Survey has not been completed.

Participants will have the option of providing the name of their baby on the birth survey if they would like future text messages to be personalized with their infant's name.

Participants will receive a text link to the Postnatal Intervention Survey on intervention day 60 of the postnatal intervention. Text reminders will be sent to participants on intervention days 61, 64, 71, 78, 85, 92, 113 if the Postnatal Intervention Survey has not been completed.
Staff will also follow-up with participants by phone for incomplete surveys as described in section 9.9.

If the Birth Survey is not completed at the time the Postnatal Survey is sent to participant, it will be appended to the Postnatal Survey.

Women whose pregnancy result in multiple births, will be asked to use the first born infant as the index infant for all study surveys and text queries.

D. Participant Web Portal

Participants will have access to a web portal where intervention specific videos will be maintained if they want to re-watch a video or share videos with others.

7 Study Procedures

7.1 Enrollment Procedures

Participant enrollment procedures consist of the following:

- Eligibility Screening
- Informed Consent
- Assignment of Participant ID Number
- Completion of Enrollment Survey
- On-boarding to the mHealth messaging platform

Participants must complete all enrollment procedures by 31 weeks plus 6 days gestation. Participants who do not complete all enrollment procedures by that time will be withdrawn from the study.

7.1.1 Eligibility Screening

Potential study participants will be identifed at participating WIC centers and FQHC. WIC staff will introduce the study to pregnant WIC clients. Health Center and Hospital staff will introduce the study to all patients. Flyers will be provided to WIC, Health Center and Hospital staff. These flyers provide contact information for Boston University study staff. Interested participants will be instructed to contact Boston University if they have any questions or are interested in the study.

Potential participants will reach out to Boston University by scanning a study QR code (or entering a study URL into a web browser). Potential participants will be directed to a study webpage where they can request to be contacted by study staff to discuss the study, or can complete eligiblity screening electronically to see if the are eligible to participate in the study.

Participant Information obtained during screening process: Participants will review a brief screening information form and must agree to screening. When participant has agreed to screening the following information will be obtained:

- First/Last Name
- Mobile Phone #
- Alternate Phone #'s
- Email Address
- Home Address
- Participant confirmation of eligibility criteria
- Participant's Expected Due Date (EDD)

The EDD, defines the date on which the gestational age of the infant is considered to be 40 weeks plus 0 days. The current gestational age for any prenatal date can then be calculated relative to

EDD, and this calculation will be used for assessing study eligibility and for the timing of all prenatal study procedures.

Potential participants who screen as not eligible: will be informed that they do not meet eligibility criteria, and will be informed that they can call the study office if they would like to discuss eligibly with study staff.

Participants who elect to complete screening electronically, without talking to study staff: If a potential participant elects to complete screening without talking to a study staff, and does not complete the screening, study staff will attempt to contact the participant by phone to complete the screening.

7.1.2 Informed Consent

Potential participants will provide informed consent prior to being enrolled in the study. There are two options to provide informed consent for this study.

A. Talk with study staff over the phone and provide verbal consent.
B. Provide consent electronically without the requirement of talking to study staff.

7.1.3 Participant ID Number

Each enrolled participant will be assigned a Participant ID number. Participant ID numbers will include:

- A three-digit WIC Region number – Ex. 001
- A two-character State Abbreviation – Ex. MA
- 4-digit sequential participant ID number starting at 1001

Participant ID number will appear as *WIC Region-State Abbreviation-Sequential ID* (ex. 001-MA-1001)

7.1.4 Enrollment Survey

Once informed consent has been obtained and participant ID number has been assigned, participants will complete a short Enrollment Survey. This suvey can be completed electronically or over the phone. The Enrollment Survey must be completed before the participant can onboard to the Agile Health mHealth platform.

7.1.5 mHealth Text Platform Access

Participants must complete an on-boarding process to the study mHealth platform to begin receiving study text messages.

The following participant information will be provided from Boston University to Agile Health for participant on-boarding:

- First and Last Name
- Gender
- Mobile Phone Number
- Zip Code
- Language Preference (English or Spanish)
- Participant Self-Reported EDD
- Participant ID Number
- Gift Card Preference

The mHealth platform will send the participant a text message confirming they would like to enroll in the in the TodaysBaby program. Participants will need to respond to the text to confirm they wish to enroll in program.

As part of the onboarding procedures participants will receive a text messaging indicating they can text 'stop' at any time to discontinue receiving text messages (see section 9.8)

7.2 Post Enrollment Procedures

The post enrollment study procedures can be divided into the following time periods:

1) Pre-Randomization/limited engagement (enrollment through 31 weeks plus 6 days gestational age),
2) Pre-Randomization/Engagement Observation (32 weeks plus 0 days through 33 weeks plus 6 days),
3) Prenatal Intervention (34 weeks plus 0 days through birth ascertainment),
4) Postnatal Intervention (birth ascertainment until 6 months postnatal age).

As noted above, during eligibility screening each participant will provide a self-report of their EDD. This EDD, will be the date used to calculate gestational age for all prenatal study procedures.

7.2.1 Pre-Randomization/Limited Engagement Period

The Pre-Randomization/Limited Engagement Period begins once participant has satisfied all enrollment procedures, and will continue until the participant is 31 weeks plus 6 days gestation.

During this period, participant will receive one weekly text message/query. The weekly text messages have been designed to a) keep participant engaged with study team by providing generic pregnancy information and text queries, and; b) re-visit several eligibility criteria, prior to the start of the Pre-Randomization/Engagement Observation Period, in case anything has changed with the participant's pregnancy that may make them no longer eligible for study participation.

If participant responds to text queries during this period, indicating they no longer meet eligibility criteria, study staff will call participant to confirm eligibility status and participant will be withdrawn.

See Appendix 2 for Pre-Randomization/Limited Engagement Period Diagram.

7.2.2 Pre-Randomization/Engagement Observation Period

The Pre-Randomization/Engagement Observation Period begins when participant reaches 32 weeks plus 0 days gestation and continues until participant reaches 33 weeks plus 6 days gestation.

During this 14 day period, participants will receive 7 interactive non-intervention text queries, and text links to 4 non-intervention study videos. These text queries and videos have been designed to a) provide participant with information about the TodaysBaby program, b) continue to ask non-intervention general pregnancy questions and; c) confirm that participant is still pregnant, and eligible for the study.

The level of participant engagement with text queries and videos during this period during will be used as one of the strata in randomization sequence #1 and randomization sequence #2. Participants will receive a text link to the Baseline Survey when they reach 32 weeks plus 1 day gestation. Text reminders will be sent to participants on gestational weeks 32+3; 32+5; 33+0; 33+3; 33+5, if the Baseline Survey has not been completed.

The Baseline Survey must be completed prior to the start of the Prenatal Intervention. If the survey is not completed by that time, it will be considered incomplete. Staff will follow-up with participants by phone for incomplete survey as described in section 9.9.

7.2.3 Ascertainment of Infant Birth or Fetal Demise Prior to Randomization #1

Participants who inform the study team of a fetal demise or infant birth during the Pre-Randomization/Limited Engagement and Pre-Randomization/Engagement Observation Periods (prior to randomization #1) will be withdrawn from the study. Infant birth/fetal demise prior to randomization #1 will be ascertained as follows:

a. *Participant Texts 'Birth' to Study Team*
Participants will be informed during the consent process that they should text 'Birth' to let the study team know when they have given birth. Participants will also be reminded (via text), during the Pre-Randomization/Limited Engagement and Pre-Randomization/Engagement Observation Periods, that they can text 'Birth' at any time.

If a participant texts 'Birth' prior to randomization #1, they will immediately receive a text message asking to confirm that they have given birth. If participant responds to this text and confirms they have given birth, they will be immediately withdrawn from the TodaysBaby

program and the study. Study staff will attempt to call participant to explain why they have been withdrawn.

If participant does not respond to the confirmation text, they will continue with the TodaysBaby program and study. Study staff will attempt to call participant to confirm the birth and withdraw if necessary.

b. *Participants Call Study Office to Report Change in Pregnancy Status*
Participants will be informed during the consent process and on text queries sent on gestational weeks 14+1, 19+1, 25+1 that they should call the study office if there is a change in their pregnancy status during the Pre-Randomization/Limited Engagement and Pre-Randomization/Engagement Observation Periods.
Study staff will discuss change in pregnancy status with participant and determine if participant should continue or be withdrawn from the study.

c. *Text Queries During Pre-Randomization/Limited Engagement and Pre-Randomization/ Engagement Observation Periods*
During these period participants will receive three text queries (at 31+1, 33+0, 33+5, weeks gestation) to confirm if they are still pregnant.

- If participant responds to any of the text queries indicating they are still pregnant they will continue with the study protocol.

- If participant responds to text query and indicates they are no longer pregnant, they will immediately receive a text message asking to confirm they are no longer pregnant. If participant responds to this text and confirms they are no longer pregnant, they will be immediately withdrawn from the TodaysBaby program and the study. Study staff will attempt to call participant to explain why they have been withdrawn.

  If participant does not respond to the confirmation text, they will continue with the TodaysBaby program and study. Study staff will attempt to call participant to confirm if they are still pregnant and withdraw if necessary.

- If participant does not respond to 'Are you still pregnant' text queries, they will continue with study protocol.

7.3 Randomization Sequence #1

Randomization sequence #1 will randomize participant to the TodaysBaby Prenatal Sleep emphasis or Prenatal Feeding emphasis interventions.

Randomization sequence #1 will occur when participant has completed the Pre-Randomization/Engagement Observation.

7.4 Prenatal Intervention Period

This period will begin when the participant is at 34 weeks plus 0 days gestation and will continue until ascertainment of participant's infant birth. (See section 8 for TodaysBaby Prenatal Sleep and Feeding Intervention descriptions)

7.5 Ascertainment of Infant Birth After Assignment to Prenatal Intervention

Participants who give birth *after* completion of randomization #1 will immediately undergo randomization #2 (assignment to postnatal intervention). Randomization #2 will occur regardless of how much of the prenatal intervention participant has completed.

Infant birth *after* randomization #1 will be ascertained by:

a. *Participant Texts 'Birth' to Study Team*
Participants will be informed during the consent process that they should text 'Birth' to let the study team know when they have given birth.

b. *Prenatal Intervention Period*
During this period participants will receive birth ascertainment text queries on gestational weeks: 35+0; 37+2,+4,+6; 38+1,+2,+3,+4,+5,+6; 39+0,+1,+2,+3,+4,+5,+6; 40+1,+2,+3,+4,+5,+6.

- If participant responds to a birth ascertainment query indicating they have given birth, participant will immediately undergo randomization #2.

- If participant responds to a birth ascertainment query indicating that they are still pregnant they will continue with the TodaysBaby Prenatal Intervention.

- If, during gestational week 40 weeks plus 0 days through 40 weeks plus 6 days, participant responds to birth ascertainment query indicating they are still pregnant, they will continue to get daily birth ascertainment queries until they respond that they have given birth or there has been three consecutive days of no participant response to the birth ascertainment text queries. After three days of no response, participant will automatically undergo randomization #2 and be assigned to the TodaysBaby Postnatal Intervention.

- If participant does not respond to any birth ascertainment queries, the study team will attempt to contact participant by phone to confirm that participant is still pregnant. If study team is unable to reach participant by phone, participant will automatically undergo randomization sequence #2 at 40 weeks plus 6 days gestation.

7.6 Randomization Sequence #2

Once infant birth has been ascertained, participant will undergo randomization sequence #2 and will be randomized to either the TodaysBaby Postnatal Sleep emphasis or TodaysBaby Postnatal Feeding emphasis interventions.

7.7 Postnatal Intervention

The Postnatal Intervention Period will begin the day after randomization #2 and will continue until the infant is six months of age. (See section 8 for TodaysBaby Postnatal Sleep and Feeding Intervention descriptions)

7.8 Early Terminations/Withdrawals

A. Prior to Pre-Randomization/ Engagement Observation Period
Participants will be ***ineligible*** for this study if they do not complete the following enrollment procedures by 32 weeks plus 1 days gestation:
- Enrollment Survey
- On-boarding to the study mHealth Platform

B. Prior to Randomization Sequence #1
Participants will be ***ineligible*** for this study for the following:
- Study team is notified that participant no longer meets any eligibility criteria.
- Study team is notified that participant is no longer pregnant (for any reason).
- Study team is notified that participant no longer wishes to participate in study.

C. After Randomization Sequence #1
Participants will be ***withdrawn*** from the prenatal and postnatal interventions for the following:
- Study team is notified that participant's infant was born with contraindications to safe sleep or breastfeeding.
- Study team is notified that participant no longer wishes to participate in study.

D. Withdrawn Participants - Study Surveys
As in drug intervention trials where a participant stops taking the study drug, participants, who withdraw from the TodaysBaby intervention after randomization #1, will continue to be followed for study outcomes. Participants will stop receiving all prenatal and postnatal intervention content (videos and text messages). Participants will continue to receive remaining study surveys. In the event of an infant death or fetal demise all study procedures will be discontinued upon study staff learning of the event.

Participants who do not complete the Baseline, Prenatal, and/or Birth** surveys will not be withdrawn from the study, as the Postnatal survey will include data on key final study outcomes.

** If a participant does not complete the Birth Survey, prior to administration of Postnatal Survey, the Birth Survey will be appended to the Postnatal Survey.

7.9 Participant Follow-Up

A. Participants Who Do Not Respond to Text Queries or Open Intervention Video Links
The study team will closely monitor participant's interaction with text queries, videos and surveys. If participant is non-responsive the participant will receive check-in text messages and/or phone call from the study team to make sure they are not having any technical difficulties with the mHealth Platform and to address any concerns or problems. If study staff are unable to reach participants by text or phone, and there is concern that the participant is not receiving text messages, staff may contact participants by email (if an email address was provided during the enrollment process)

B. Participants Who Text 'Stop'
Participants who text 'Stop' will receive a second text asking them to confirm that they want to stop the program. If the participant does not confirm that they want to stop the program, they will continue to receive the TodaysBaby program.

If a participant confirms that they want to stop they will stop receiving the TodaysBaby program (videos and text messages).

- If participant has not undergone randomization #1 – they will be withdrawn from the study.
- If participant has undergone randomization #1 – they will continue with the study and receiving any remaining study surveys via text or email.

  Participants will receive one final text message from within the Agile platform that confirms they have stopped the TodaysBaby program, that they will continue to receive study surveys, and request that they complete the TodaysBaby Program Discontinued Survey.

C. Study Team Follow-Up With Participants by Phone
There are multiple study scenarios where study staff may need to follow-up with a participant by phone (ex. incomplete surveys, check on birth status, etc.). To ensure thorough follow-up for each situation, study staff will attempt to contact participants up to 6 times for each situation.

7.10 Reimbursements and Lotteries

A. Reimbursements
Participants will receive up to $50 in electronic gift card as a reimbursement for their time for completing the following study surveys:

Survey	Gift Card Amount
Baseline Survey	$10
Prenatal Survey	$10
Birth Survey	$10
Postnatal Survey	$20

Participants will have the option of selecting an electronic gift card (eGift card) from the following National retail stores: Target, Walmart, CVS Pharmacy. Target will be the default gift card for all participants; However, participants will be able to choose a Walmart or CVS Pharmacy gift card.

Participants can switch their desired gift card at any time by notifying study staff. Participants may also request to receive a physical card via mail.

eGift Cards will be sent to participants via text. Participants will receive their gift card within 7 days of completion of each survey.

B. Monthly Lottery

To encourage participants to respond to text queries and complete study surveys, participants will be eligible for a monthly lottery during the course of their participation in the study. Each monthly lottery will consist of a $100 eGift Card to Walmart, Target, CVS Pharmacy.

When a participant responds to a text query that begins with a '$', they will receive one entry into the monthly lottery.

When a participant completes any of the study surveys, they will receive three entries into the monthly lottery.

Participants will be eligible to win up to four monthly lotteries during the course of their participation in the study. Odds of winning the monthly lottery will depend on the number of entries received each month.

Agile Health will be responsible for managing and conducting the lotteries. Agile Health will provide Boston University with documentation of the date and URL of each eGift card texted to study participants.

See the Appendix 2 for the schedule of events.

8 Assessment of Safety and Data Safety Monitoring Plan (DSMP)

In this study, participants will receive health information about sleep or feeding beginning at 34 weeks plus 0 days gestation and extending until their infant is 2 months of age. The risks in this study are minimal, and based on the investigators extensive experience, it is highly unlikely that there will be any adverse events (AE) or serious adverse events (SAE) related to participation in the study.

8.1 Definitions

The following definitions will be used in the assessment of safety:

Adverse Event (AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious Adverse Event (SAE) is any adverse event that
(1) results in death;
(2) is life-threatening;
(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

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

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:
- is unexpected; AND
- is related or possibly related to participation in the research; AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

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

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

8.2 Safety Review

Both the risks listed in Section 6.1 and unknown risks will be monitored by the study Principal Investigators on an ongoing basis.

The following Data Safety Monitoring Plan will be followed to monitor the safety of study participants:

A. The principal investigators and co-investigators will be responsible for monitoring individual events and determining whether the study protocol needs modification to minimize risk.

B. Dr. Corwin, the administrative PI, will review, collate and evaluate AEs on an on-going basis. Serious AEs will be reviewed within 24 hours of notification by research staff. Serious/life-threatening events will be reported as required.

C. A Data and Safety Monitoring Committee (DSMC), comprised of 3 individuals unaffiliated with the study, will monitor participant safety, data quality, and study progress. The DSMC will include experts in or representatives of the fields of pediatrics, clinical trial methodology, and/or biostatistics. The DSMC's objective and external role will be to review recruitment, protocol deviations, protocol amendments, and all adverse events or complications related to the study; and to make recommendations for protocol changes if indicated. The DSMC will meet at least twice annually by teleconference and as needed should participant safety questions or other unanticipated problems arise.

D. The Baseline, Birth and Postnatal surveys will screen for depression and anxiety. Participants who screen positive on the PHQ-4 (score ≥3 for either depression or anxiety) will complete the Edinburgh Postnatal Depression Screen (EPDS). This 2-step approach will decrease survey burden for >80% of mothers, while still identifying those at risk.

Participant EPDS scores will trigger messages as follows:

a. Score 10-15 or higher will trigger a message within the survey with links to Postpartum Support International (which includes national and local resources), and a recommendation to talk to her health care professional;

b. Score 16 or higher will trigger a more extensive message within the survey with the same links and a recommendation to call her health care professional today;

c. Q.10 on the EPDS inquires about a participant's thoughts about harming themself. Should a participant response to this question be anything other than "Never" the following plan is in place:

The following message will display within the survey:

> *"Pregnancy (-or- Giving birth) can be an emotional time, and you may feel stressed, anxious, or just not yourself. If you find that your mood changes during or after your pregnancy, we recommend reaching out to your healthcare provider for support. You may also find support on-line at Postpartum Support International https://www.postpartum.net/get-help/help-for-moms/"*
>
> *If you have thoughts or feelings of harming yourself there is hope and help! You should reach out for help immediately by calling your healthcare provider or 911.*
> *You can also contact the 988 Suicide & Crisis Lifeline by dialing 988 or 1-800-273-8255, which offers a free and confidential network of crisis centers nationwide 24 hours a day; 7 days a week. The 988 Suicide & Crisis Lifeline website is: www.988lifeline.org*
>
> *Your responses to the survey questions are not monitored in real-time. That means it may take us several days or more to review your responses once you complete a survey."*
>
> *A study doctor will try to give you a call in the next few days to discuss some of our responses to survey questions.*

Additionally, a research staff member (licensed physician), will attempt to follow-up with the participant by phone to recommend appropriate follow-up. We will first reach out to the participant by text message to alert them to the clinician trying to speak with them, and allow the opportunity to opt out of this follow-up if they do not wish to speak to the study clinician.

Should a participant opt-out of contact or the clinician is unable to speak with them after 3 attempts the study team will send a text message to the participant acknowledging we were unable to reach them and include a link to resources if they ever should need them. The resource link sent to participant is: https://www.postpartum.net/get-help/help-for-moms/

For Spanish speaking participants, the clinician may use hospital interpreter services for follow-up calls.

Participants will be informed during the consent process, and again at the beginning of each EPDS survey section, that we plan to assess for mood and anxiety, and that a member of the research team may follow-up with them by phone.

E. Should any member of the study research team identify that a participant's physical or mental health could be compromised, including suicidal risk, the following procedures will be followed:

   a. If a participant expresses risk for harm while on phone with study staff, the team member will use the 3-way call feature to immediately connect the participant with the appropriate crisis hotline.

b. For non-urgent medical or psychiatric related issues, the participant will be referred to the participant's primary care provider, if considered appropriate by study investigator(s).

F. Should a participant experience prenatal or postnatal loss, the study research team will immediately express condolences and then ensure that all study procedures and interventions are discontinued as soon as we are notified. The study research team will provide information about grief and bereavement resources, if desired by the participant.

- If infant death – First Candle (https://firstcandle.org/)
- If Stillbirth – Star Legacy Foundation (https://starlegacyfoundation.org/)
- If miscarriage, infant death, or stillbirth - https://www.postpartum.net/get-help/loss-grief-in-pregnancy-postpartum/

G. In the event that concern for child neglect or abuse is raised, the study research team members will immediately contact the investigators. Mandated reporting guidelines, including reporting to Child Protective Services, will be followed.

H. Withdrawal of enrolled participants will be assessed on a case by case basis, depending on the situation and whether there are any potential risks to following the study protocol. The decision to withdraw a participant from the study and/or to halt data and/or sample collection for medical risk reasons will ultimately be made by the principal investigators. Should a participant who was assigned to either intervention develop an exclusionary condition, she will be given the opportunity to continue receiving the intervention text messages and videos if she feels that they are useful.

8.3 Reporting Plans

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

- Unanticipated Problems occurring at BMC/BU Medical Campus involving a fatal or life-threatening event will be reported to the IRB within 2 days of the investigator learning of the event.
- Unanticipated Problems occurring at BMC/BU Medical Campus not involving a fatal or life-threatening event will be reported to the IRB within 7 days of the investigator learning of the event.
- Reports from safety monitors with recommended changes will be reported to the IRB within 7 days of the investigator receiving the report.
- Adverse Events (including Serious Adverse Events) will be reported in summary at the time of continuing review, along with a statement that the pattern of adverse events, in total, does not suggest that the research places subjects or others at a greater risk of harm than was previously known.
- Reports from safety monitors with no recommended changes will be reported to the IRB at the time of continuing review.

8.4 Stopping Rules

A subject will be withdrawn from the study and all intervention and study procedures will be discontinued if:

Prior to Randomization #1:

- Participant texts 'STOP" and confirms they want to stop receiving the TodaysBaby program.
- Participant informs study that they are no longer pregnant.

After Randomization #1

- If the participant has informed the study team that their infant (Baby A if multiple birth) has died.

9 Data Handling and Record Keeping

9.1 Confidentiality

To ensure confidentiality the following procedures are in place:
Each participant will be assigned a unique study ID number. All study data will be managed at either Boston University or Agile Health only. All study staff will receive training on confidentiality procedures.

9.2 Data Managed at Boston University

Data managed at Boston University will be managed as outlined in the IRB application and approved by the BUMC/BU IRB. Data will be managed and stored as required by Boston University institutional requirements. Starting 2025, a UVA coordinator will have access to participant data via a secure VPN connection to study databases housed on a secure BU server.

9.3 Data Managed at Agile Health

Their Agile Health platform is a rules-based engine that schedules and delivers text messages. It is an intelligent and responsive system that provides a highly personalized user experience. Their secure coaching dashboard can be viewed from any computer that will allow the study team to monitor incoming and outgoing messages in real-time, input participant personalization settings without the help of a programmer, and respond to participant inactivity. The Agile Health platform is HIPAA compliant, with all PHI/PII data encrypted in transit and at rest, and messages are delivered through a secure gateway in an encrypted format.

Study participants who have been onboarded and consented through the Boston University REDCap system will be automatically enrolled in the Agile Health program through a secure API interface between the platforms. Only the minimum information necessary for Agile Health to deliver the personalized messaging protocols will be provided to Agile's platform. Additional data exchanges will take place between the platforms via secure API protocol to communicate when specific

activities have been performed by the study participant, such as watching a video, responding to a text message, indicating the birth of the child (by texting in BIRTH or responding via text to an explicit question about birth status), or completing the messaging curriculum. These exchanges are bi-directional in nature and are initiated by the platform in which the activity has taken place.

9.4 ClinicalTrials.gov

This study is registered on ClinicalTrial.gov. The study team will review and update the ClinicalTrials.gov listing on an annual basis and whenever any changes to the study protocol have been approved by the IRB.

9.5 Source Documents

All data collected for the study will be via online surveys, text queries or documented by study staff during participant phone follow-up. No data will be derived from medical records. The surveys will be completed online with data going directly to into REDCap database. Text message query responses will flow into the mHealth platform and will be forwarded to Boston University based on when the responses are needed (during data collection or after all data collections procedures have stopped).

9.6 Study Records Retention

The BMC/BU Medical Campus IRB requires that documentation of informed consent of subjects be retained for at least seven years after the study is closed, unless the IRB waived the requirement for informed consent or documentation of informed consent. Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized individuals

10 Statistical Plan

Study records including documentation of informed consent of subjects will be retained for at least seven years after the study is closed, unless the IRB waived the requirement for informed consent or documentation of informed consent.

10.1 Study Hypotheses

Hypothesis (Aim1): For each recommended safe sleep practice (supine sleep position, roomsharing without bed sharing, avoiding use of soft bedding, and pacifier use), compared to mothers receiving only breastfeeding interventions, higher adherence will be reported among mothers receiving prenatal or postnatal safe sleep interventions and greatest adherence will be reported among mothers receiving both safe sleep interventions.

Hypothesis (Aim1): For breastfeeding initiation and breastfeeding duration (for any and exclusive breastfeeding), compared to mothers receiving only safe sleep interventions, higher adherence

will be reported among mothers receiving prenatal or postnatal breastfeeding interventions and greatest adherence will be reported among mothers receiving both breastfeeding interventions.

Hypothesis (Aim 2): The effect of the interventions on infant care practices will be mediated by: a) perceived risk for the health issue (e.g., infant death, lower IQ) associated with the infant care practice; b) cognitive constructs from the Theory of Planned Behavior (attitudes, subjective norms, perceived control); and c) affective associations with the infant care practice.

10.2 Sample Size Determination

We will enroll 2,500 participants and estimate that 2,000 participants will undergo randomization sequence #1, yielding randomization samples of 500 mothers in each study group. Based on our SMART experience, we anticipate 80% retention through the transition to the postnatal interventions, giving an analysis sample of 400/study group, or 1600 overall at the time of this transition, and retention of 80% from transition through the 2-6 month follow-up survey, for an analysis sample of 320/group or 1280 overall. Sample size considerations focus on Aim 1, the effect of intervention on safe sleep or breastfeeding outcomes.

From our SMART study, the prevalence of safe sleep outcomes for mothers who did not receive any safe sleep intervention was ~70% for no soft bedding use and roomsharing without bedsharing, and 80% for supine position; for mothers who did not receive any breastfeeding intervention, prevalence of any and exclusive breastfeeding at follow-up was ~75% and 35%, respectively. The odds ratio for the mHealth postnatal intervention was ~2.0 for both supine sleep and roomsharing without bedsharing, and 1.8 for no soft bedding use. The mHealth intervention did not have a significant effect on breastfeeding. In the absence of interaction, the current study is powered to detect an intervention odds ratio of 1.7, which corresponds to an increase in prevalence from 70% to 80%, or from 80% to 87%. For baseline prevalence of 70% and 80%, power of detecting an intervention odds ratio of 1.7 is 0.93 and 0.81 (adjusting for multiple comparisons and testing at the family-wise 2 tailed $p<0.05$ level). With a baseline prevalence of 70%, on odds ratio of 1.7 corresponds to a 10 percentage point increase in prevalence. To detect interaction, stronger effects are needed. For example, the expected sample size gives 0.80 power to detect interaction for a scenario with prevalence in the no-intervention group of 70%, no effect of the prenatal intervention alone, a weak effect of the postnatal intervention alone (OR=1.5, corresponding to prevalence of 78%), and a strong interaction effect (OR=2.5, corresponding to a prevalence for those receiving both interventions of 89%) (power for interaction determined through simulation).

10.3 Statistical Methods

Our study follows a 2x2 factorial design testing the effectiveness of the safe sleep and breastfeeding prenatal and postnatal mHealth interventions. Preliminary analyses will examine loss to follow-up from prenatal enrollment and intervention to transition to the postnatal intervention and 2-6 month follow-up, both examining demographic characteristics related to drop out and comparing rates of follow-up across the 4 study groups.

Based on our experience with the SMART and All Breasts Matter studies, we do not anticipate problems related to follow-up; however, if there are problems, multiple imputation procedures will be used to account for potential drop out-related bias. We use the fully conditional specification[101] to multiple imputation, modeling dichotomous, multinomial, and continuous variables through logistic, multinomial logistic, and linear regression, respectively, with the number of imputation data sets based on the percent of missing data.[102] As noted in the study overview, recruitment and sample size plans were developed based on estimates of loss to follow-up rates from previous studies.
While group differences are not anticipated due to randomization, preliminary analyses will also compare demographic characteristics of mothers and infants across the four study groups, to identify demographic characteristics to be examined as potential confounders in our primary analyses. Finally, preliminary analyses will examine pre-intervention differences in the key decision-making constructs. If pre-intervention differences are found, those differences will be controlled for in analyses.

Data analysis for Specific Aim 1. The primary hypotheses for this aim are that, relative to control messaging, mothers receiving the risk reduction messaging will have higher uptake rates for each safe sleep outcome (hypothesis 1a), and each breastfeeding outcome (hypothesis 1b), and that receipt of both prenatal and postnatal interventions will be more effective than one intervention; breastfeeding messaging serves as the control for safe sleep outcomes, and safe sleep messaging serves as the control for breastfeeding outcomes. We will assess 4 different behavioral outcomes related to each intervention: 1a) safe sleep: supine position, sleep location of roomsharing but not bedsharing, no soft bedding use, and usual use of a pacifier (yes/no for all four), and 1b) breastfeeding: any breastfeeding (yes/no); exclusive breastfeeding for at least 8 weeks (yes/no); duration of any and duration of exclusive breastfeeding (time-to-event data modeled as days postpartum; we will be ascertaining breastfeeding behavior each week through 6 months using mHealth queries, as well as at the time of the 2-6 month survey).

Dichotomous outcomes will be modelled through logistic regression, and time-to-event outcomes will be modeled through Cox proportional hazards regression. Mothers will be enrolled through an anticipated 10-20 WIC centers per state; since randomization is at the individual level, we don't expect clustering by center to affect power, but we will control for clustering by WIC center by using the generalized estimating equation approach (GEE) with sandwich estimators for logistic regression and a marginal approach with a robust sandwich estimate for proportional hazards regression.[103] For each outcome, we will first fit a multiplicative interaction model, with indicator variables representing the prenatal mHealth intervention, the postnatal mHealth intervention and their interaction. We will also include a variable for infant age at the 2-6 month survey (for dichotomous outcomes) to account for differences in age at follow-up. If the interaction term is significant, this model will be used to describe the effects of each intervention alone and in combination vs. those receiving both the pre- and post-natal control interventions. If the interaction term is not significant, we will fit a main effect model to test and describe the separate effects of the prenatal mHealth intervention and the postnatal mHealth intervention. The logistic and proportional hazards modeling approach allows us to control for potential confounding due to demographic factors found in preliminary analyses to differ between the 4 study groups and child

age at interview. To acknowledge the multiple comparisons issue in evaluating the effectiveness of intervention on 4 safe sleep (or 4 breastfeeding) outcomes, we will use the Hochberg adjustment to maintain a family-wise 2-tailed alpha level of 0.05 when testing for intervention effects.

Data analysis for Specific Aim 2. The primary hypothesis for this aim is that the impact of the intervention on behavioral outcomes will be mediated by effects on both cognitive and affective components of perceived risk. As for Aim 1, separate sets of analyses will examine effects of the safe sleep interventions on safe sleep outcomes, and the breastfeeding interventions on the breastfeeding outcomes. To test these hypotheses, we will first use the GEE logistic regression (for dichotomous outcomes) and marginal proportional hazards (for time-to-event outcomes) modeling approach described above to assess the effect of experimental condition on perceived risk. We will separately examine measures of risk conditioned on behavior (e.g., for safe sleep, risk of SIDS if baby placed prone) and not conditioned on behavior. To the extent that the intervention successfully communicates the risk message, the highest conditioned risk, for safe sleep outcomes, will be in the safe sleep pre/post condition and the lowest conditioned risk will be in the breastfeeding pre-post condition (e.g., mother will correctly understand and report that supine position lowers risk for SIDS).

Primary analyses for Aim 2 will examine the mechanistic roles of risk perception, cognitive constructs, and affective constructs as motivators of behavior by testing whether the intervention effects tested in Aim 1 are mediated by changes in perceived risk. Our primary approach to mediation analysis will use causal mediation methods based on a counterfactual framework.[102,103] This approach is less susceptible to bias than traditional methods, allows for decomposition of effects into natural direct (effects of intervention on outcome that cannot be explained through the mediator) and indirect (effects of the intervention due to the effect of intervention on the mediator and the mediator on outcome) effects, and that it can be used with both dichotomous and time-to-event outcomes.[106] The extent of mediation is measured through an odds ratio (for dichotomous outcomes and logistic regression) or hazard ratio (for time-to-event outcomes and proportional hazards regression) and 95% confidence interval for the indirect effect. A limitation to the causal mediation approach is that current SAS macros do not account for clustering. As a secondary approach, if there is a strong cluster effect in our data, we will consider structural equation mediational models[107] using bias corrected bootstrapped confidence intervals to test indirect effects, using the MPlus software package.[108]

11 Ethics/Protection of Human Subjects

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

This protocol and any amendments will be submitted to the Boston Medical Center and Boston University Medical Campus IRB, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. The consent form will be submitted with the protocol for review and approval by the IRB. The consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. Consent will be documented as required by the IRB.

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13 Appendix 1 – TodaysBaby Intervention Videos

TodaysBaby Safe Sleep Emphasis Videos

Video Topic	Prenatal Intervention	Postnatal Intervention
Prenatal Intervention-Congratulations	X	
Back Sleeping Safest	X	
Sleep Location Important	X	
Health Babies Wake Easily/Often	X	
Firm Mattress	X	
Never too Late to Quit Smoking	X	
Pacifier A (Should you give Baby)	X	
Safe Sleep for Premature Babies	X	
Good Sleeper	X	
Babies Don't Just Sleep at Night	X	
Breathe Better on Back	X	
Pacifiers B (Pacifiers are Safe)	X	
Prenatal Intervention Summary	X	
Drugs & Alcohol During/After Pregnancy	X	X
No Side Sleeping	X	X
Good Airway – Open and Straight	X	X
Calming a Fussy Baby	X	X
Sleep Products	X	X
Planning for Back to School/Work	X	X
Swaddling/Sleep Sacks	X	X
Flat Head/Tummy Time	X	X
Overbundling	X	X
Safe Baby Wearing Carriers!	X	X
What its Really Like to be Postpartum**	X	X
Take Care of Yourself**	X	X
Postnatal- Intervention-Introduction		X
Postnatal-What You Will Learn		X
Roomshare not Bedshare		X
Won't Choke on Back		X
Why No Bedsharing		X
Bedding and Bumpers		X
Feed/Bed, Sleep/Crib		X
Good Sleepers		X
Comfortable on back		X
Pacifier C (Safe Sleep)		X
Smoking around baby not recommended		X
Bedsharing – dangerous circumstances		X
Advice from Others		X
Pacifier D (Not Too Late)		X
Perinatal Mood and Anxiety**		X
Postnatal-summary-Thank you		X

TodaysBaby Feeding Emphasis Videos

Video Topic	Prenatal Intervention	Postnatal Intervention
Prenatal Intervention-Congratulations	X	
Your Body Knows What to Do	X	
Good Start in Hospital/Breast Crawl	X	
How to Know When Baby is Hungry	X	
Good Latch	X	
Output Patterns	X	
Breastfeed for year	X	
Breastfeeding Premature Babies	X	
How Often To Feed Your Baby	X	
Nutrition for Mothers	X	
What to do When Baby is Fussy Baby	X	
Avoid Nipple Pain Discomfort	X	
Prenatal Summary-Your Journey	X	
Busting Myths	X	X
What if Baby Needs Supplementation	X	X
How Long for Breast Milk to Come In	X	X
Breastfeeding in Public	X	X
Pumping Work/School	X	X
Support From Friends	X	X
Smoking and breastfeeding and Medications	X	X
Advice From Others	X	X
Breastfeeding is Convenient	X	X
Feedings When Tired	X	X
What its Really Like to be Postpartum**	X	X
Take Care of Yourself**	X	X
Breast Milk Best Milk		X
Nipple Pain Troubleshooting		X
Why Babies Cry		X
Baby Want to Eat all the Time		X
Worries About Supply and Weight Gain		X
Why Stick with Breastfeeding		X
Babies Should Wake Easily and Often		X
Worries About Milk Supply		X
Why Breast Milk is Best		X
Breastfeeding is Team Effort		X
Problems Breastfeeding		X
Keeping Toddlers Occupied		X
Back to School/Work		X
Late BF Stooling Pattern		X
Breastfeeding Save Time and Money		X
Perinatal Mood and Anxiety**		X

**videos shown to both intervention arms.

14 Appenix 2 – Schedule of Events

Pre-Randomization/Limited Engagement Period

Gest Wks	Time Sent	Text Message Topic
9+0	PM	Message: Morning Sickness
10 +0	PM	Message: Feeling Tired
11+0	PM	Message: Videos Begin 34 Wks
12+0	PM	Message: Baby Size Plum
13+0	PM	Message: Letting Family Know Pregnant
14+0	PM	Message: Welcome 2nd trimester
15+0	PM	Message: Healthy Snacks
16+0	PM	Message: WIC Offerings
17+0	PM	Message: Normal Weight Gain
18+0	PM	Message: Trouble Sleeping
19+0	PM	Message: Child Birth Classes
20+0	PM	Message: Halfway There
21+0	PM	**-$$-** Message: Sex of Baby
22+0	PM	Message: Drink Water
23+0	PM	Message: Feel Baby Kicks
24 +0	PM	Message: You Are Doing Great
25 +0	PM	Message: Exercise Can by Great for you and baby
26+0	PM	**-$$-** Message: Live in Same Home After Birth?
27+0	PM	**-$$-** Message: Change in Due Date?
28+0	PM	Message: Baby Size Eggplant
29+0	PM	Message: Third Trimester
30+0	PM	**-$$-** Message: Told Not to Breastfeed or Place on Back
30 +0	AM	Message: Daily Text/Video Starts Soon
31+0	PM	Message: Are you still pregnant?

-$$- = Participant response to this text – they obtain entry into monthly lottery

Pre-Randomization/Limited Engagement Observation Period

Gest Wk	Time Sent	Video Title, Text Message, Survey
32 +0	PM	Video: What to Expect
32 +1	PM	Baseline Survey Sent
32 +2	PM	Message: Reminder $ Texts
32 +3	AM	Baseline survey REMINDER
	PM	Video: Videos Start Soon
32 +4	PM	Message: Pregnancy Challenges
32 +5	AM	Message: Visit TodaysBaby Website Yet?
	PM	Baseline survey REMINDER
32 +6	PM	*(No interactive text sent)*
33 +0	AM	Confirm Pregnant/Delivered Baby
	PM	Baseline survey REMINDER
33 +1	PM	Message: Favorite way to relax
33 +2	PM	Video: Videos Tailored to Baby's Birth
33+3	AM	Baseline survey REMINDER
	PM	Message: Prenatal Vitamins
33 +4	AM	Video: Study Videos/ Website
33 +5	PM	Message: Confirm Pregnant/Delivered Baby
	PM	Baseline survey REMINDER
33 +6	AM	Message: Do You Know Type 'Birth' Anytime?
	PM	Message: TodaysBaby Videos Start Tomorrow

TodaysBaby/SMARTER Prenatal Intervention Curriculum

Feeding Emphasis Cohort Video
Sleep Emphasis Cohort Video
Text Message to Both Cohorts
Survey Link and/or Reminder to Both Cohorts

Gest Wks Int Day	Time Sent	Video Title, Text Message, or Survey	Video URL#
34 +0 (1)	PM	BF Video Title: BF-Pre-Intro-Congratulations	Video URL#: 1010
	PM	SS Video Title: SS-Pre-Intro-Congratulations	Video URL#: 1051
34 +1 (2)	AM	Message: Received First Video	
	PM	BF Video Title: BF-Body Knows	Video URL#: 1011
	PM	SS Video Title: SS-Back Sleeping Safest	Video URL#: 1052
34 +2 (3)	PM	BF Video Title: BF-Busting Myths	Video URL#: 1012
	PM	SS Video Title: SS-SMART-Good Sleeper	Video URL#: 1064
34 +3 (4)	AM	Message: Feeding Plan	
	PM	BF Video Title: BF-Good Start	Video URL#: 1013
	PM	SS Video Title: BF/SS-Postpartum	Video URL#: 1048
34 +4 (5)	PM	BF Video Title: BF-Baby Hungry	Video URL#: 1014
	PM	SS Video Title: SS-Calming Baby	Video URL#: 1053
34 +5 (6)	AM	Message: Sleep Location (Bedsharing)	
	PM	BF Video Title: BF-Supplementation	Video URL#: 1015
	PM	SS Video Title: SS-No Side Sleeping	Video URL#: 1062
34 +6 (7)	PM	BF Video Title: BF-Good Latch	Video URL#: 1016
	PM	SS Video Title: SS-Sleep Location	Video URL#: 1054
35 +0 (8)	AM	Message: Birth Ascertainment	
	PM	BF Video Title: Output Patterns	Video URL#: 1017
	PM	SS Video Title: SS-Wake Easily/Often	Video URL#: 1055
35 +1 (9)	PM	BF Video Title: BF-Breastfeed for year	Video URL#: 1018
	PM	SS Video Title: SS-Sleep Products	Video URL#: 1056

Gest Wks Int Day	Time Sent	Video Title, Text Message, or Survey	Video URL#
35 +2 (10)	AM	Message: Sleep Position	
	PM	BF Video Title: BF-How Long Milk	Video URL#: 1019
	PM	SS Video Title: SS-Firm Mattress	Video URL#: 1057
35 +3 (11)	PM	BF Video Title: BF-Breastfeeding Preemies	Video URL#: 1020
	PM	SS Video Title: SS-Quit Smoking	Video URL#: 1058
35 +4 (12)	AM	Message: Sleep Location (Room Sharing)	
	PM	BF Video Title: BF-How Often To Feed	Video URL#: 1021
	PM	SS Video Title: SS-Pacifier A (Should you give Baby)	Video URL#: 1059
35 +5 (13)	PM	BF Video Title: BF-Breastfeeding in Public	Video URL#: 1022
	PM	SS Video Title: SS-Drugs & Alcohol	Video URL#: 1060
35 +6 (14)	AM	Message: Type Birth	
	PM	BF Video Title: BF-Pumping Work/School	Video URL#: 1023
	PM	SS Video Title: SS-Safe Sleep Preemies	Video URL#: 1061
36 +0 (15)	PM	BF Video Title: BF-Support	Video URL#: 1024
	PM	SS Video Title: SS-Good Airway	Video URL#: 1063
36 +1 (16)	AM	Message: Falling Asleep	
	PM	**Prenatal survey – Sent**	
36 +2 (17)	PM	BF Video Title: BF/SS-Take Care	Video URL#: 1050
	PM	SS Video Title: SS- Back To School/Work	Video URL#: 1065
36 +3 (18)	AM	Message: Study Website	
	PM	Prenatal survey REMINDER	
36 +4 (19)	PM	BF Video Title: BF-Nutrition for Mothers	Video URL#: 1025
	PM	SS Video Title: SS- Babies don't just sleep at night	Video URL#: 1066
36 +5 (20)	AM	Prenatal survey REMINDER	
	PM	Message: Soft Bedding	

Gest Wks Int Day	Time Sent	Video Title, Text Message, or Survey	Video URL#
36 +6 (21)	PM	BF Video Title: BF-Fussy Baby	Video URL#: 1026
	PM	SS Video Title: SS-Breathe Better on Back	Video URL#: 1067
37 +0 (22)	AM	Message – Birth Ascertainment	
37 +1 (23)	PM	BF Video Title: BF-Smoking	Video URL#: 1027
	PM	SS Video Title: SS-Swaddling/Sleep Sacks	Video URL#: 1068
37 +2 (24)	AM	Message – Birth Ascertainment	
	AM	Prenatal survey REMINDER	
37 +3 (25)	PM	BF Video Title: BF-Advice From Others	Video URL#: 1028
	PM	SS Video Title: BF/SS-Take Care	Video URL#: 1050
37 +4 (26)	AM	Message – Birth Ascertainment	
37 +5 (27)	PM	Prenatal survey REMINDER	
	PM	BF Video Title: BF- Convenient	Video URL#: 1029
	PM	SS Video Title: SS-Flat Head/Tummy Time	Video URL#: 1069
37 +6 (28)	AM	Message – Birth Ascertainment	
	PM	BF Video Title: Ascertain Birth**	Video URL#: 1005
	PM	SS Video Title: Ascertain Birth**	Video URL#: 1005
38 +0 (29)	AM	Message – Type Birth	
	PM	BF Video Title: BF/SS-Postpartum	Video URL#: 1048
	PM	SS Video Title: SS-Pacifiers B (Safe)	Video URL#: 1070
38 +1 (30)	AM	Message – Birth Ascertainment	
38 +2 (31)	AM	Message – Birth Ascertainment	
	PM	BF Video Title: BF-Feedings When Tired	Video URL#: 1030
	PM	SS Video Title: SS-Overbundling	Video URL#: 1071
38 +3 (32)	AM	Message – Birth Ascertainment	

Gest Wks Int Day	Time Sent	Video Title, Text Message, or Survey	Video URL#
38 +4 (33)	AM	Message – Birth Ascertainment	
	PM	BF Video Title: BF-Nipple Pain Discomfort	Video URL#: 1031
	PM	SS Video Title: SS-Safe Baby Wearing Carriers!	Video URL#: 1072
38 +5 (34)	AM	Message – Birth Ascertainment	
38 +6 (35)	AM	Message – Birth Ascertainment	
	PM	BF Video Title: BF-Pre-Summary-Your Journey	Video URL#: 1032
	PM	SS Video Title: SS-Prenatal-Summary	Video URL#: 1073
39 +0 (36)	AM	Text Message – Birth Ascertainment	
	PM	BF Video Title: Break from Videos**	Video URL#: 1006
	PM	SS Video Title: Break from Videos**	Video URL#: 1006
39 +1 (37)	AM	Message – Birth Ascertainment	
39 +2 (38)	AM	Message – Birth Ascertainment	
39 +3 (39)	AM	Message – Birth Ascertainment	
39 +4 (40)	AM	Message – Birth Ascertainment	
39 +5 (41)	AM	Message – Birth Ascertainment	
39+6 (42)	AM	Message – Birth Ascertainment	
40+0 (43)	AM	Message – Birth Ascertainment	
40+1 (44)	AM	Message – Birth Ascertainment	
40+2 (45)	AM	Message – Birth Ascertainment	
40+3 (46)	AM	Message – Birth Ascertainment	
40+4 (47)	AM	Message – Birth Ascertainment	
40+5 (48)	AM	Message – Birth Ascertainment	
40+6 (49)	AM	Message – Auto tx to Postnatal intervention	

**non-intervention video

TodaysBabys/SMARTER - Postnatal Intervention

Feeding Emphasis Cohort Video
Sleep Emphasis Cohort Video
Text Message to Both Cohorts (-$$- Lottery Text)
Survey Link and/or Reminder to Both Cohorts

Gest Wks Int Day	Time Sent	Video title, Text Message, Survey	Video URL#
Wk 1/D1 (1)	AM	BF Video Title: BF-Breast Milk Best Milk	Video URL#: 1033
	AM	SS Video Title: SS-postnatal-intro-Choose	Video URL#: 1075
	PM	**-$$-** Text Message – # Months Plan Breastfeeding	
	PM	BF Video Title: BF-Busting Myths	Video URL#: 1012
	PM	SS Video Title: SS-Postnatal-Intro-Keep Program	Video URL#: 1074
	PM	Birth Survey	
Wk 1/D2 (2)	AM	BF Video Title: BF-Nipple Pain Troubleshooting	Video URL#: 1034
	AM	SS Video Title: SS-Good Airway	Video URL#: 1063
	PM	**-$$-**Message: Feeding Plan (Practice-Since Birth/Intent)	
	PM	BF Video Title: BF-Why Babies Cry	Video URL#: 1035
	PM	SS Video Title: SS-Roomshare not Bedshare	Video URL#: 1076
Wk 1/D3 (3)	AM	BF Video Title: BF-How Long Milk	Video URL#: 1019
	AM	SS Video Title: SS-Overbundling	Video URL#: 1071
	PM	Message: Sleep Position (Practice-Since Birth/Intent)	
	PM	BF Video Title: BF-Baby Eats All Time	Video URL#: 1036
	PM	SS Video Title: SS- Won't Choke on Back	Video URL#: 1077
	PM	Birth Survey - Reminder	
Wk 1/D4 (4)	AM	BF Video Title: BF-Problems Breastfeeding	Video URL#: 1043
	AM	SS Video Title: SS-Why No Bedsharing	Video URL#: 1078
	PM	**-$$-**Message: Sleep Location-Bed Sharing (Practice-Since Birth/Intent)	
	PM	BF Video Title: BF-Worries and Weight Gain	Video URL#: 1037
	PM	SS Video Title: SS-Bedding and Bumpers	Video URL#: 1079

Gest Wks Int Day	Time Sent	Video title, Text Message, Survey	Video URL#
Wk 1/D5 (5)	AM	BF Video Title: BF-Stick with Breastfeeding	Video URL#: 1038
	AM	SS Video Title: SS-Calming Baby	Video URL#: 1053
	PM	Message: Decide When to Feed Baby	
	PM	BF Video Title: BF-Supplementation	Video URL#: 1015
	PM	SS Video Title: SS-Feed/Bed, Sleep/Crib	Video URL#: 1080
Wk 1/D6 (6)	AM	BF Video Title: BF-Feedings When Tired	Video URL#: 1030
	AM	SS Video Title: SS-SMARTER-Good Sleepers	Video URL#: 1081
	AM	Birth Survey Reminder	
	PM	Message: Sleep Location (Room sharing) (Practice/Intention)	
Wk 1/D7 (7)	PM	**-$$-**Message: Soft Bedding (Practice /Intent)	
Wk 2/D1 (8)	AM	BF Video Title: BF-Babies Wake Often	Video URL#: 1039
	AM	SS Video Title: SS-Comfortable on back	Video URL#: 1082
	PM	**-$$-**Message: Falling Asleep (Practice Only)	
Wk 2/D2 (9)	PM	Message: Feeding Plan (Practice /Intent)	
	PM	Birth Survey Reminder	
Wk 2/D3 (10)	AM	BF Video Title: BF-Worries Milk Supply	Video URL#: 1040
	AM	SS Video Title: SS-No Side Sleeping	Video URL#: 1062
	PM	**-$$-**Message: Sleep Position (Practice/Intention)	
Wk 2/D4 (11)	PM	Message: Sleep Location-Bed Sharing (Practice/Intention)	
Wk 2/D5 (12)	AM	BF Video Title: BF/SS-Postpartum	Video URL#: 1048
	AM	SS Video Title: SS-Swaddling and sleep sacks	Video URL#: 1068
	PM	**-$$-**Message: Decide When to Feed Baby	
Wk 2/D6 (13)	PM	Birth Survey Reminder	
	PM	**-$$-**Message: Sleep Location (Room sharing) (Practice/Intention)	

Gest Wks Int Day	Time Sent	Video title, Text Message, Survey	Video URL#
Wk 2/D7 (14)	AM	BF Video Title: BF-Why Breast Milk is Best	Video URL#: 1041
	AM	SS Video Title: SS-Pacifier C (Safe Sleep)	Video URL#: 1083
	PM	Message: Soft Bedding (Practice /Intent)	
Wk 3/D1 (15)	PM	Message: Pacifier (practice)	
Wk 3/D2 (16)	AM	BF Video Title: BF-Smoking	Video URL#: 1027
	AM	SS Video Title: SS- Smoking around baby not recommended	Video URL#: 1084
	PM	**-$$-**Message: Feeding Plan (Practice /Intent)	
Wk 3/D3 (17)	PM	Message: Sleep Position (Practice/Intention)	
Wk 3/D4 (18)	AM	BF Video Title: BF/SS-Take Care	Video URL#: 1050
	AM	SS Video Title: SS- bedsharing – dangerous circumstances	Video URL#: 1085
	PM	**-$$-**Message: Sleep Location-Bed Sharing (Practice/Intention)	
Wk 3/D5 (19)	11-1 PM	Message: Decide When to Feed Baby	
Wk 3/D6 (20)	AM	BF Video Title: BF-Team Effort	Video URL#: 1042
	AM	SS Video Title: BF/SS-Take Care	Video URL#: 1050
	PM	Message: Sleep Location (Room sharing) (Practice/Intention)	
Wk 3/D7 (21)	11-1 PM	**-$$-**Message: Soft Bedding (Practice /Intent)	
Wk 4/D1 (22)	AM	BF Video Title: BF- Convenient	Video URL#: 1029
	AM	SS Video Title: SS-Advice from Others	Video URL#: 1086
	PM	Message: Study Website	
Wk 4/D2 (23)	11-1 PM	Message: Feeding Plan (Practice /Intent)	

Gest Wks Int Day	Time Sent	Video title, Text Message, Survey	Video URL#
Wk 4/D3 (24)	AM	BF Video Title: BF-Back to School/Work	Video URL#: 1045
	AM	SS Video Title: BF/SS-Postpartum	Video URL#: 1048
	PM	**-$$-**Message: Sleep Position (Practice/Intention)	
Wk 4/D4 (25)	PM	Message: Sleep Location-Bed Sharing (Practice/Intention)	
Wk 4/D5 (26)	AM	BF Video Title: BF-Breastfeeding in Public	Video URL#: 1022
	AM	SS Video Title: SS-Sleep Products	Video URL#: 1056
	PM	**-$$-**Message: Decide When to Feed Baby	
Wk4 /D6 (27)	PM	**-$$-**Message: Sleep Location (Room sharing) (Practice/Intention)	
Wk4 /D7 (28)	AM	BF Video Title: BF-Late BF Stooling Pattern	Video URL#: 1046
	AM	SS Video Title: SS- Back To School/Work	Video URL#: 1065
	PM	Message: Soft Bedding (Practice /Intent)	
Wk5 /D1 (29)	PM	**-$$-**Message: Falling Asleep (Practice Only)	
Wk5 /D2 (30)	AM	BF Video: BF/SS-Perinatal Anxiety	Video URL#: 1049
	AM	SS Video Title: SS-Safe Baby Wearing Carriers!	Video URL#: 1072
	PM	**-$$-**Message: Feeding Plan (Practice /Intent)	
Wk5/D3 (31)	PM	Message: Sleep Position (Practice/Intention)	
Wk5 /D4 (32)	AM	BF Video Title: BF-Keeping Toddlers Occupied	Video URL#: 1044
	AM	SS Video: BF/SS-Perinatal Anxiety	Video URL#: 1049
	PM	**-$$-**Message: Sleep Location-Bed Sharing (Practice/Intention)	
Wk5 /D5 (33)	PM	Message: Decide When to Feed Baby	
Wk5 /D6 (34)	PM	Message: Sleep Location (Room sharing) (Practice/Intention)	
Wk5/D7 (35)	PM	**-$$-**Message: Soft Bedding (Practice /Intent)	
Wk6 /D1 (36)	PM	Message: Pacifier	
Wk6/D2 (37)	PM	Message: Feeding Plan (Practice /Intent)	

Gest Wks Int Day	Time Sent	Video title, Text Message, Survey	Video URL#
Wk6/D3 (38)	PM	**-$$-**Message: Sleep Position (Practice/Intention)	
Wk6 /D4 (39)	AM	BF Video Title: BF-Save Time & Money	Video URL#: 1047
	AM	SS Video Title: SS-Drugs & Alcohol	Video URL#: 1060
	PM	Message: Sleep Location-Bed Sharing (Practice/Intention)	
Wk6/D5 (40)	PM	**-$$-**Message: Decide When to Feed Baby	
Wk6 /D6 (41)	PM	**-$$-**Message: Sleep Location (Room sharing) (Practice/Intention)	
Wk6 /D7 (42)	PM	Message: Soft Bedding (Practice /Intent)	
Wk7 /D1 (43)	PM	Message: Website	
Wk7 /D2 (44)	PM	**-$$-**Message: Feeding Plan (Practice /Intent)	
Wk7/D3 (45)	PM	Message: Sleep Position (Practice/Intention)	
Wk7 /D4 (46)	AM	BF Video Title: BF-Advice From Others	Video URL#: 1028
	AM	SS Video Title: SS-Pacifier D (Not Too Late)	Video URL#: 1087
	PM	**-$$-**Message: Sleep Location-Bed Sharing (Practice/Intention)	
Wk7 /D5 (47)	PM	Message: Decide When to Feed Baby	
Wk7 /D6 (48)	PM	Message: Sleep Location (Room sharing) (Practice/Intention)	
Wk7 /D7 (49)	PM	**-$$-**Message: Soft Bedding (Practice /Intent)	
Wk8 /D1 (50)	PM	Message: Falling Asleep (Practice Only)	
Wk8 /D2 (51)	PM	Message: Feeding Plan (Practice /Intent)	
Wk8/ D3 (52)	PM	**-$$-**Message: Sleep Position (Practice/Intention)	

Gest Wks Int Day	Time Sent	Video title, Text Message, Survey	Video URL#
Wk8 /D4 (53)	AM	BF Video Title: BF-Support	Video URL#: 1024
	AM	SS Video Title: SS-Flat Head/Tummy Time	Video URL#: 1069
	PM	Message: Sleep Location-Bed Sharing (Practice/Intention)	
Wk8 /D5 (54)	PM	Message: Pacifiers	
Wk8 /D6 (55)	PM	**-$$-**Message: Sleep Location (Room sharing) (Practice/Intention)	
Wk8 /D7 (56)	PM	Message: Soft Bedding (Practice /Intent)	
Wk9 /D1 (57)	PM	**-$$-**Message: Decide When to Feed Baby	
Wk9 /D2 (58)	PM	**-$$-**Message: Feeding Plan (Practice /Intent)	
Wk9/ D3 (59)	PM	Message: Sleep Position (Practice/Intention)	
Wk9 /D4 (60)	AM	BF Video Title: BF-Pumping Work/School	Video URL#: 1023
	AM	SS Video Title: SS-Postnatal-summary-Thank you	Video URL#: 1088
	PM	Postnatal Survey	
Wk9 /D5 (61)	PM	Postnatal Survey Reminder	
Wk 10/D1 (64)	AM	Postnatal Survey Reminder	
Wk 11/D1 (71)	PM	Message: Feeding Plan (Practice /Intent)	
	AM	Postnatal Survey Reminder	
Wk 11/D4 (74)	PM	**-$$-**Message: Sleep Location-Bed Sharing (Practice/Intention)	
Wk 12/D1 (78)	PM	**-$$-** Message: Feeding Plan (Practice /Intent)	
	AM	Postnatal Survey Reminder	
Wk 12/D4 (81)	PM	Message: Sleep Location-Bed Sharing (Practice/Intention)	

Gest Wks Agile Timing	Time Sent	Video title, Text Message, Survey
Wk 13/D1 (85)	PM	Message: Sleep Location (Room sharing) (Practice/Intention)
	PM	Postnatal Survey Reminder
Wk 13/D4 (88)	PM	**-$$-**Message: Soft Bedding (Practice /Intent)
Wk 14/D1 (92)	PM	**-$$-**Message: Sleep Location (Room sharing) (Practice/Intention)
	PM	Postnatal Survey Reminder
Wk 14/D4 (95)	PM	Message: Soft Bedding (Practice /Intent)
Wk 15/D1 (99)	PM	**-$$-**Message: Sleep Position (Practice/Intention)
Wk 15/D4 (102)	PM	Message: Feeding Plan (Practice /Intent)
Wk 16/D1 (106)	PM	Message: Sleep Position (Practice/Intention)
Wk 16/D4 (109)	PM	**-$$-**Message: Feeding Plan (Practice /Intent)
Wk 17/D1 (113)	PM	**-$$-**Message: Sleep Location-Bed Sharing (Practice/Intention)
	PM	Postnatal Survey Reminder
Wk 17/D4 (116)	PM	Message: Sleep Location (Room sharing) (Practice/Intention)
Wk 18/D1 (120)	PM	Message: Sleep Location-Bed Sharing (Practice/Intention)
Wk 18/D4 (123)	PM	**-$$-**Message: Sleep Location (Room sharing) (Practice/Intention)
Wk 19/D1 (127)	PM	**-$$-**Message: Soft Bedding (Practice /Intent)
Wk 19/D4 (130)	PM	**-$$-**Message: Sleep Position (Practice/Intention)
Wk 20/D1 (134)	PM	Message: Soft Bedding (Practice /Intent)
Wk 20/D4 (137)	PM	Message: Sleep Position (Practice/Intention)
Wk 21/D1 (141)	PM	Message: Feeding Plan (Practice /Intent)
Wk 21/D4 (144)	PM	**-$$-**Message: Sleep Location-Bed Sharing (Practice/Intention)

Wk 22/D1 (148)	PM	**-$$-**Message: Feeding Plan (Practice /Intent)
Wk 22/D4 (151)	PM	Message: Sleep Location-Bed Sharing (Practice/Intention)
Wk 23/D1 (155)	PM	Message: Sleep Location (Room sharing) (Practice/Intention)
Wk 23/D4 (158)	PM	**-$$-**Message: Soft Bedding (Practice /Intent)
Wk 24/D1 (162)	PM	**-$$-**Message: Sleep Location (Room sharing) (Practice/Intention)
Wk 24/D4 (165)	PM	Message: Soft Bedding (Practice /Intent)
Wk 25/D1 (169)	PM	**-$$-**Message: Sleep Position (Practice/Intention)
Wk 25/D4 (172)	1PM	Message: Feeding Plan (Practice /Intent)
Wk 26/D1 (176)	PM	Message: Sleep Position (Practice/Intention)
Wk 26/D4 (179)	PM	**-$$-**Message: Feeding Plan (Practice /Intent)
Wk 26/D7 6 Months (182 days)	PM	Message - THANK YOU Study Complete

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