

First Heroes: Engaging Fathers in the First 1000 Days
Detailed Protocol
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I. Background and Significance

Obesity represents a major threat to public health and places a significant burden on morbidity, quality of life, and health care costs. Obesity rates among adults and children have substantially increased worldwide over the past three decades.^{31,32} In the US, 17% of children ages 2 - 19 years have obesity (body mass index [BMI] \geq 95th percentile).¹ In children, obesity is associated with both short- and long-term adverse outcomes including hyperlipidemia, diabetes, and hypertension,³³⁻³⁶ and with higher morbidity and mortality in adulthood.^{37,38} The underlying causes of obesity are modifiable risk factors throughout the life course; these risk factors represent major causes of health inequalities.³⁹ Thus, obesity prevention is considered a global health priority.⁴⁰

Despite evidence of recent progress, overall rates of obesity remain at historically high levels and racial/ethnic and socioeconomic disparities appear to be increasing.^{1,2} Although obesity rates among some US subpopulations may have improved,^{41,42} overall prevalence remains stubbornly high and racial/ethnic and socioeconomic disparities persist.^{41,43} In the US, non-Hispanic black and Hispanic men and women of typical child-bearing age (20-39 years) and their children have higher obesity rates than non-Hispanic whites. The highest prevalence of childhood obesity in the US is among Hispanic (21.9%) and non-Hispanic blacks (19.5%) v. whites (14.7%).⁴⁴ Racial/ethnic minority children also bear a disproportionate share of the burden

of obesity-related co-morbidities.⁴⁵ Obesity disparities are evident as young as 2 years of age. Among 2-5 year olds, Hispanics have three times the rate of obesity than whites (15.6% v. 5.2%) and non-Hispanic blacks have two times the rate of obesity than whites (10.4% v. 5.2%).¹

The importance of a life course approach to addressing obesity and related disparities. The life course approach to chronic disease prevention posits that factors may act in the prenatal period and extend into infancy, childhood, and beyond to determine risk of chronic disease.⁴⁶ Many perinatal risk factors implicated in childhood obesity lie within the family context and are disproportionately prevalent among non-Hispanic black and Hispanic families than non-Hispanic white families. Opportunities exist at every stage of the life course to interrupt this cycle and reduce disparities in obesity. For example, evidence suggests that reducing the prevalence of obesity risk factors during pregnancy, infancy, and early childhood, e.g. the first 1000 days – conception through 24 months – could close the gap in obesity disparities.^{5,47} Substantial evidence also suggests that obesity interventions may produce the largest magnitude of effect if they support changes at the individual, family, and systems-level and are begun in the earliest stages of life.⁵

Although fathers influence their offspring's weight status and obesity risk, few interventions to prevent childhood obesity have engaged fathers. Epidemiologic studies from our group and others suggest that adverse exposures in the intrauterine and infancy periods can “program” trajectories of adiposity and metabolic function throughout life^{49,50} and may increase short- and long-term risks for obesity and its sequelae. Maternal pre-pregnancy weight, gestational weight gain, smoking during pregnancy, and depression have all been associated with obesity in offspring.⁵¹ In children, excess weight gain in infancy and early obesity not only predicts later obesity and cardio-metabolic risk, but also serious morbidity within childhood, including asthma, psychosocial adversity, and increasingly, type 2 diabetes.⁵²⁻⁵⁴ Although less well studied, paternal factors may also influence children's obesity.⁵⁵

Epigenetic and social-behavioral research is increasingly demonstrating the important role of father's diet, physical activity, and obesity on their offspring's weight status and obesity risk.⁶⁻⁹ We found that missing paternal data on the infant birth certificate, a proxy for lack of paternal involvement, was associated with lower birthweight, maternal smoking during pregnancy, non-initiation of breastfeeding, and with infant overweight in the first 2 years of life. Yet, few interventions to reduce childhood obesity risk factors have included fathers or examined the influence of early life interventions on fathers' own obesity-related outcomes. Father's engagement in early life has also been associated with more optimal maternal-infant health outcomes.^{6-9,57,59-61} For example, father engagement in prenatal activities and reports of providing emotional and financial support are associated with a lower likelihood of low birthweight,⁶²⁻⁶⁴ an important precursor of children's metabolic risk. Women whose partners are involved in their pregnancies are also more likely to receive early prenatal care and reduce

cigarette smoking.^{65,66} Indeed, strengthening father's engagement in pregnancy and parenting has been recommended as a potential strategy for reducing health disparities,⁶⁷ but fathers continue to be largely left out of MCH initiatives.⁵⁹ This proposal seeks to shift that paradigm by engaging fathers and acknowledging their positive contributions as early in the life course as possible.

The First 1000 Days Collective Impact Initiative in Boston. Effective interventions for addressing obesity require multi-sector strategies, especially those that invoke change at the individual, family, social environment, and systems-levels.^{5,66,68,69} However, system-wide changes to achieve improved outcomes do not occur because of good will alone. Large scale problems such as obesity and health disparities require a highly structured, collaborative effort to achieve substantial "Collective Impact".⁷⁰ Collective Impact has been loosely defined as "the commitment of a group of important actors from different sectors to a common agenda for solving a specific social problem"⁷⁰⁻⁷² The Collective Impact approach involves a structured process that leads to a common agenda, use of shared metrics of success, continuous communication and mutually reinforcing activities among key stakeholders. These four conditions, as well as having backbone support of the initiative, are the conditions that together produce true alignment of efforts and lead to sustained results. With funding from The Boston Foundation (PI: Taveras), we have used the Collective Impact framework to build cross-sector collaboration and establish a common agenda of obesity and health disparities prevention among key stakeholders from early life systems. The five-year, First 1000 Days study (10/2014–9/2019) implemented obesity prevention interventions across Obstetric and Pediatric primary care, the WIC program, and Home Visiting program to reduce obesity risk factors among racial/ethnic minority mother-infant pairs and close the gap in obesity disparities.⁶⁹

Engaging Fathers in the First 1000 Days to Improve Perinatal and Obesity-Related Outcomes. We now seek to build on the previously completed study and expand the focus of the program beyond maternal-infant outcomes to include a systematic intervention to engage fathers in pregnancy and parenting, reduce fathers' own obesity-related health behaviors, and address fathers' social determinants of health. The fatherhood intervention will include components that have the potential to be scalable, implementable, and sustained in low resource settings. Our intervention has been informed by an advisory group of fathers and stakeholders and individual interviews with fathers. In our intervention we will use multiple modes of engagement, including direct coaching, interactive text messages, and videos to reach fathers from the 2nd trimester ultrasound visit through age 12 months. The intervention is informed by the Collective Impact work that we have already begun among clinicians and public health providers in two community health centers in the greater Boston area and will be theoretically grounded in the Integrated Clinical and Community Systems of Care Model⁷³ that integrates clinical and public health systems to address chronic diseases. While the model's originators have applied it to the care of adult chronic disease, others, including our research team, have successfully adapted it to the management of obesity in children.⁷⁴ Our systematic approach to engaging fathers is also

consistent with the systems-level, framework to prevent obesity of Huang and Glass,⁶⁸ and is rooted in the social contextual theory of behavior change.⁷⁵

II. Specific Aims:

The overall goal of the fatherhood intervention is to influence weight and health trajectories, modify disease risk, and improve health care services for mother-father-infant triads from racial/ethnic minority and health disparity populations.

We will conduct a two-arm, randomized controlled trial recruiting from Massachusetts General Hospital (MGH) obstetrics practices and Brigham and Women's Maternal Fetal Medicine department. We will enroll up to 250 father-mother dyads in the second trimester of pregnancy and intervene through their offspring's 1-year birthday. We will randomly assign each mother-father dyad to one of two arms:

- 1) The current standard of care along with a "Safety Education" initiative. This arm will receive the Obstetric and Pediatric primary care provided by their own obstetric and pediatric primary care practices, with additional infant safety education materials mailed to participants' homes. The current standard of care includes standardized obesity counseling by all providers across Obstetric and Pediatric primary care, as well as screening for social determinants of health and access to resources as needed.
- 2) The First Heroes intervention. This arm will receive the Obstetric and Pediatric primary care provided by their own obstetric and pediatric primary care practices, with additional active and targeted engagement of expectant parents by a health coach. Content will be focused on obesity-related behaviors and access to resources. The health coach will use individual level behavior change coaching, interactive text messages, and videos. (Note: A "Health Coach" may include job titles such as: "Health Educator", "Research Nurse" and/or "Clinical Nutrition Specialist.")

We will examine the comparative effects of the fatherhood intervention vs. the current obstetric and pediatric primary care, on perinatal and obesity-related outcomes. Outcomes will be assessed at birth and 12-months. The primary intent-to-treat analysis will examine the effects of each intervention on perinatal and obesity-related outcomes. We will also assess several family-centered outcomes including parental BMI and obesogenic behaviors, infant feeding, and perinatal health care utilization.

Specific Aims:

1. The primary specific aim is to examine the extent to which the intervention among predominantly racial ethnic minority mother/father dyads or low-income families, compared to the control condition, results in differences in:

- a. Prevalence of rapid infant weight gain (birth to 6 months), weight-for-length z-score and overweight (WFL \geq 97.7th percentile based on World Health Organization standards) at 6- and 12-months of age
2. The secondary specific aims are to examine the extent to which the intervention, compared to the control condition, results in differences in:
 - a. Body mass index (BMI) and obesogenic behaviors in fathers and mothers over the intervention period; prevalence of obesity (BMI \geq 30 kg/m²) and adherence to preventive health service at 12 months;
 - b. Utilization of perinatal health care services (i.e. compliance with prenatal and postpartum visits) and birth outcomes (e.g. prevalence of preterm birth and low birth weight) in mothers over the intervention period;
 - c. Parenting self-efficacy; participation in WIC; perceived stress, parental depression, and family conflict in families.

III. Subject Selection: Study Populations and Recruitment

Setting and Study Population

This trial will be conducted within Brigham and Women's and MGH-affiliated obstetric practices, including hospital based as well as community health centers. Our goal is to recruit 250 mother-father dyads who are pregnant and receiving care at obstetric practices at MGH and BWH. Given disparities in obesity risk, this study aims to target mother-father-infant triads most at risk, including purposively sampling to balance race/ethnicity and income distribution.

Inclusion Criteria

Eligibility criteria will be assessed by research staff and will include:

1. Parental dyads must meet the following criteria:
 - a. Pregnant females and father of the baby, both aged \geq 18 years
 - b. Singleton pregnancy
 - c. Planned involvement during the first year of the child's life
2. Planning to receive obstetric, post-partum care at any practice within the MassGeneral Brigham Healthcare system
3. Ability to speak in English or Spanish
4. Capable of giving consent

Justification for Inclusion Criteria:

1. Pregnant women will be at about 18-24-weeks of their pregnancy. Parental dyads must be legally able to provide consent. Furthermore, given that the intervention involves participation from mother-father-infant triad, both parents must be involved in the upbringing of the child before and after birth.

2. Our study is targeting expectant parents, and dyads who will be raising their child together. In order to maintain the fidelity of the intervention, participants assigned to the intervention arm will receive tips on how to prepare for becoming parents.
3. Recruitment will take place at the BWH and MGH obstetrics practices and ultrasound locations, so women should intend on receiving their care at those in clinics at the time of consent. Parents of children who receive pediatric care outside an MGB institution must agree to provide relevant pediatric medical records to the study team in order to facilitate medical record abstraction for height and weight data. If participants unexpectedly transfer care to an outside institution after consent, a medical records release will be requested from participants. Given potential barriers to timely receipt of medical record requests, participants will also be asked to self-report growth measurements (i.e. length and weight by accessing Patient Portal, Well Visit After Visit Summary, etc., if available) at time of call to obtain medical records release. To decrease participant burden, they will also have the option to provide growth measurements by sending a screenshot of their medical records (i.e. length and weight by accessing Patient Portal, Well Visit After Visit Summary, etc., if available) to the MGH, secure, study email.
4. Comfort speaking and reading English or Spanish is required because the survey and health coaching intervention will be administered in English and Spanish.
5. Use of a legal guardian or authorized representative for consent purposes is not permitted.

Exclusion Criteria

We will exclude:

1. Dyads whose unborn child is found to have a severe defect or comorbidity upon 18-20 week ultrasound.
2. Mothers who intend on raising a child alone without any participation from the father of the child.

Justification for Exclusion Criteria

1. Children identified pre- or post-natal to have severe co-morbidities from whom it would be inappropriate to be involved in the study will not be enrolled. This will be assessed using information available in the medical record by study staff and investigators.
2. Both parents must plan to be engaged in the life of the child for at least 12 months after birth in order to participate.

Recruitment

Mother-father dyads receiving care at BWH and MGH obstetric practices will be recruited during the second trimester of pregnancy. Eligible mothers will be identified by their appointment status for the anatomy scan ultrasound appointment performed at approximately 18-24-weeks gestation. Recruitment will occur either virtually over the phone or in person at the MGH Vincent Obstetrics ultrasound location, MGH's affiliated Northshore Danvers Obstetrics

ultrasound location, and BWH obstetrics ultrasound location. We will recruit all eligible parents who are scheduled for an ultrasound visits from the time the study begins until 250 participant dyads are enrolled.

Eligible participants will be identified using medical record information from mothers in an Epic data pull performed by research study staff. A waiver of consent and authorization is requested to obtain names, basic demographics, contact information, and parent related data for recruitment purposes.

Research staff will perform weekly data pulls from MassGeneral Brigham Electronic Data Warehouse (EDW) and Epic to identify potentially eligible participants for the study. Data pulls will be performed by pulling information from medical records for pregnant women who have established prenatal care at an MGH practice or BWH during an obstetrics intake visit or who will have an ultrasound appointment at MGH Vincent Obstetrics, Northshore Danvers Obstetrics, and BWH Maternal Fetal Medicine, or other BWH ultrasound location.

Specifically, this data pull will include:

- Pregnant mother's name, address, and phone number
- Father's name (if available in record)
- Prenatal/obstetric location where care is received
- Ultrasound appointment site (if scheduled)
- Date/time of the scheduled visit (intake visit and ultrasound visit)
- Name of prenatal clinician/primary care provider
- Insurance provider
- Race/ethnicity
- Language
- Educational attainment
- Medical Record Number
- Date of Birth
- Gender

Data pulls will continue for the duration of the recruitment period. This data will be kept on file for the duration for recruitment and will be stored securely. The file itself will also be password protected. No data will be transferred via email or saved on the hard drive of a computer. Pregnant women included in the data pull will be individually screened by study staff to ensure eligibility and confirm the date and time of ultrasound appointments.

Potentially eligible patients identified will be sent a letter recruitment letter through Patient Gateway and/or mailed a study letter from the study PI, BWH Site PI, and MGH Obstetrics Service, and the study's fact sheet at least three weeks before their 18-24 week ultrasound

appointment (see Recruitment Letter). The letter will explain that the recipient may be eligible and will provide contact information regarding how to opt out of being further contacted about participation before their 18-24 week ultrasound. In recognition with MassGeneral Brigham policy during the COVID-19 public health crisis and decreased face-to-face contact with patients when possible, this study plans to recruit participants either virtually or in person. Potential subjects will be given the opportunity to “opt out” of being contacted via telephone, email, or Patient Gateway.

If approached virtually, research staff will call eligible partners who received a letter at week 17-24 gestational age (+/- 7 days). Mothers will be called first, as this contact information will be available in our recruitment data pulls and will be reached out to up to eight times. During this call, the purpose and requirements of study participation will be explained, all questions about participating in research will be addressed. If these mothers are interested in participating, eligibility will be confirmed by research staff and verbal consent will be document if given. If fathers are available at the time of the call, they study will be explained, questions will be addressed, and their eligibility and verbal consent will also be established and collected (See Mother and Father Approach Scripts). Eligible partners will have up to one week after being contacted to determine if they would like to participate. This will be the primary method of recruitment while COVID-19 mitigation efforts remain in place. Eligible part

If recruitment is done in person, research staff will approach patients at the time of a prenatal visit (between 8 and 24 weeks gestational age) or their ultrasound visit. If approached at a prenatal visit (between 8-24 weeks gestational age) before a patient has had their 18-20 week ultrasound appointment, only study information will delivered to patients, including a study letter, fact sheet, and flyer. Research staff will explain if dyads are eligible and interested in participating, they may be contacted (or contact the study team) by phone or at a future visit for verbal consent and enrollment into the study. If approached during an ultrasound visit, research staff will call participants approximately two weeks before their appointment to confirm they are interested in learning more about participating in the study. At the ultrasound appointment, research staff will provide parents with another copy of the study fact sheet (see Fact Sheet). Eligibility will be confirmed by research staff at that visit and all questions about participating in research will be addressed. Eligible partners will have one week to determine if they would like to participate. If partners choose to take home the fact sheet and later choose to participate within this timeline, both will be consented to participation over the phone.

Posters and flyers will be used at obstetric care locations to increase the awareness of the study. Posters summarizing the study aims and eligibility criteria will be featured in patient care areas such as waiting rooms, exam rooms, and restrooms in an effort to increase awareness of the study and improve the response to phone calls and outreach attempts to eligible mothers. Flyers summarizing the study aims and eligibility criteria will also be circulated through obstetric

practices to increase awareness of the study. Flyers and posters will include the contact information of the study team, but all dyads will still receive a study letter with fact sheet before they are contacted for screening and consent.

Enrollment is not complete until both parents have verbally consented to the study and eligibility is confirmed. If only one parent consents, the dyad will not be enrolled. Baseline surveys will be collected from both parents before randomization occurs. Results of the 18-20-week ultrasound will be reviewed by study staff to confirm that no fetal defects were identified at the visit to ensure eligibility. Upon completion of this review, dyads will be officially enrolled to the study.

IV. Subject Enrollment

Consent

Eligible parents will be verbally consented to the study. Study staff will review the fact sheet with subjects, answer all questions, and ask subjects to provide verbal consent. Consent may be obtained from mother-father dyads either virtually during a phone call or in person at an ultrasound visit or prenatal visit. Research staff will call all dyads who were identified in the recruitment data pull mailed a letter to screen, discuss questions, and consent to the study. If done in person at the 18-20-week ultrasound visits, research staff will approach patients and their partners who were identified in the recruitment data pull, screened for eligibility by research staff, and who received a study letter. Eligibility will be confirmed by research staff at that visit. If subjects are undecided on study participation at time of visit or phone call, they have the opportunity to consider the study and consent within **1 week** by phone.

Consent will be recorded and the date, time, and initials of the research staff member who conducted the consenting process noted. Additional documentation will be made regarding if participants consent to receiving text messaging and/or unencrypted emails.

Enrollment is not complete until both parents have verbally consented to the study. If only one parent consents, the dyad will not be enrolled.

Randomization

Once the dyad provides consent and completes the baseline survey, participants will be randomized into one of two groups. Randomization will be performed in REDCap by study staff after consent has been obtained and eligibility has been confirmed. The randomization list in REDCap will be generated by the study statistician. Patients will be randomized according to the order in which their consent was obtained and stratified by site of primary obstetric care.

Participants will be randomized to one of two different programmatic interventions focusing on expectant parents, involving different content areas. Please see Section V for more information

on the intervention arms. Participants will be blinded to the type of intervention they receive but will be sent a study letter explaining schedule of visits and/or distribution of study materials as well as information about study assessments like survey timing and frequency. As this is a randomized controlled trial with blinding, participants will not be explicitly given information about which arm they have been assigned to (i.e. obesity prevention intervention vs control safety intervention).

Participating dyads in both the intervention and safety control groups will receive a study kit by mail after randomization occurs. As this study will recruit and consent eligible dyads remotely due to COVID-19 considerations, study kits will include a scale for the collection of parent weight information. Kits will also include small token gifts for expectant parents, such as a child's bib and outlet socket covers. Letters will be included with study kits boxes welcoming dyads to the study, explaining the box's contents, how to use the scale for body measurements. It will also include information on health coaching virtual visits for the intervention arm dyads. A form will be included with the study kit to be completed by participants in both the intervention and safety control group upon receipt of their study kits. This form collects height and weight information from participants using the scale included in the study kit. This form will be accompanied by a self-address pre-paid envelop to be returned to the study team. Participants can also complete the form online via REDCap, and dyads will be reminded by phone and email to complete this after receipt of their kit. A follow up weight collection form will be used after the birth of a dyad's child (in either arm) to collect follow up weight data at 6-weeks, 6-months, and 12-months. These forms may also be returned to the study team by participants taking a picture of the form and sending it via email or by text to the study cell phone.

Remuneration

Each parent will receive up to \$45 for their participation. Remuneration will be in the form of a \$15 gift card (purchased with a MassGeneral Brigham Corporate Card). Gift cards will be given for completion of each survey.

Participating dyads (both mothers and fathers) who complete all three surveys at baseline, 6-months, and 12-months (a total of six surveys) will be entered into a random drawing to receive a gift bag with baby supplies. The gift bag will be valued at approximately \$30. The study staff will periodically review the list of dyads who should have completed all three surveys on a quarterly basis, then enter the participant dyads into a excel spreadsheet. Using a random number generator, the study staff will select a participant ID to win and be award the gift bag. This spreadsheet will never be saved. Participants will be sent a flyer to inform them about this incentive (see attachments).

Participants who have completed the intervention arm of the study and agree to complete an individual, semi-structured interview with study staff at the end of their participation will receive a \$25 gift card for their participation.

V. Study Procedures: Visits and Data Collection

Please see the attached Schedule of Assessments for an overview of the research activities for this study.

Participants in both arms of this study will be asked to complete three surveys during the course of their participation. Once consented, dyads will be asked to complete the baseline survey in person, by email, or by phone. (see Mother Baseline Survey, Father Baseline Survey). We will send a similar parental follow-up survey again when the child is 6 months old, and again at the child's 12-month birthday, as a means to assess quality of the intervention and safety control arm.

Surveys completed in person will be done so on paper or on a study-provided iPad. Surveys may also be emailed to participants and will be accessible through a link to REDCap, where survey data will be entered and stored.

After parents complete each survey, we will send him/her an email with a link to an electronic gift card or physical gift card worth \$15 (see Gift Card and Thank You Letter). For parents who opt to complete the survey by mail, we will also include a postage-paid business reply envelope for the return of the surveys if they are mailed to the participants. If the surveys are not returned 10 business days after consent, study staff will make eight attempts by phone to collect baseline surveys. Parents may choose to complete the survey over the phone with research study staff.

Intervention Group

Father-mother dyads randomized to this experimental arm will be exposed to the enhanced perinatal care described above as well as the following components of the intervention. The intervention for this study will consist of three elements:

- (1) Access to educational materials, including text messages;
- (2) Visits with a health coach; and
- (3) Connection to community resources.

1. Educational materials focusing on key areas of parents and raising a child

Father-mother dyads will receive the following modules throughout the course of the intervention:

1. After randomization, mothers will receive the New Mom's Prenatal Guide while fathers will receive New Dad's Prenatal Guide. These modules will be accompanied by a letter from the study team. These modules will focus on mother/father health; preparing to be parents; responsive parenting techniques related to feeding, sleep and activity; and access to resources related to social determinants of health. After completion of baseline survey and receipt of module, the study team will conduct a follow-up call to answer any questions or refer to any additional resources. Material within this module will be reviewed at the third trimester virtual visit.
2. Prior to the third trimester virtual visit, mother-father dyads will receive a letter from their Health Coach providing additional information on community resources.
3. Following the infant's birth, dyads will receive a New Parent Post-Natal Guide and a 5.5 month guide on feeding, sleeping, and play. These modules will be accompanied by a letter from the study team congratulating the family on their child's. This module will focus again on mother/father health; transitioning to the role of parents; responsive parenting techniques related to feeding, sleep and activity; and access to resources related to social determinants of health. Material within this module will be reviewed at the 3-4 week and 3-4 month health coaching visits. These materials will also be reinforced with the text messaging program and Constant Contact materials which summarize these educational materials.

Parents will indicate their preference to receive these materials in printed form OR electronic form via email.

2. Individual-level motivational behavior change counseling provided to fathers by health coaches:

Coaches will be trained on:

- 1) Direct coaching of prospective fathers on fathering skills using an established curriculum and
- 2) Linking fathers to clinical and community resources for primary care, behavior change and social support resources.

This will be accomplished through **three** study visits:

- 1) Third Trimester (30-34 weeks of pregnancy) virtual visit
- 2) Virtual visit 3-4 weeks after child's birth
- 3) Virtual visit 3-4 months after child's birth

These visits will be scheduled using the following procedures:

Approximately 4 weeks following study enrollment, parents will be contacted by study staff to schedule the first study visit, the **Third Trimester Virtual Visit**. Study staff will call parents until they are reached to schedule the video visit and will not leave voicemails more than once

every other day. If a parent cannot be reached after approximately 1 week, a letter or email will be sent to the parent asking them get in touch with us via phone or email.

At the end of the virtual visit, the next visit (**3-4 Week Virtual visit**) will be scheduled for approximately 3-4 weeks after the mother's due date, up to 8 weeks after the child's birth. Virtual visits will be conducted via video call. We will send parents an email to confirm the visit after it is scheduled and call with a reminder about 1-2 days before the appointment date. Health coaches may check in with parents intermittently by email.

An additional visit (**3-4 Month Virtual Visit**) will also be scheduled at the end of the 3-4 week visit for when the baby is approximately 3-4 months old. The same methods to schedule, remind, and conduct the visit are the same as those listed above for the 3-4 Week Virtual visit. Health coaches may check in with parents intermittently by email.

Visit Content

During each visit, the health coach will coach the parent/child triads on improving obesity-related behaviors. Particular emphasis will be made on coaching fathers on how to interact with their babies, support the needs of mothers, and manage their own health effectively. These contacts will be structured to:

1. review a tailored map that highlights resources available in their community that support healthy behavior change;
2. direct them to appropriate resources and community partners as desired, using a study-specific community resource guide for reference;
3. review social contextual and motivational factors affecting behavior change;
4. set behavioral goals; and
5. share educational materials.

If the parent misses or cancels a visit, the health coach will attempt to reschedule the visit by calling, emailing and/or texting the parent. If the visit is not rescheduled, it will be documented as a missed visit. If the first visit (prenatal visit 1) is missed, the dyad will be disenrolled from the study.

If at the end of the visit window we are unable to complete the first study visit, we will send an email including the "Our health coaches are here to support you" message, and include previously approved health coaching participant documents as attachments. Summary videos, detailing the key content of each video will be sent to the dyads along with an after visit summary, checking in on goal set during the first visit.

We will implement a quality assurance review to assure consistency across health coaches and fidelity to the health coaching protocol. To do this, health coaching visits may be audio recorded,

with permission from each of the participants. Parent participation in the audio recording is entirely voluntary and visits will only be recorded if participant consent is granted at the beginning of the health coach visit. If the participant says no, the visit will proceed but not be recorded. Audio recordings will be identified by participant ID. A designated research staff member will review the recordings using the QA checklist to assess consistency across the health coaches and fidelity to the protocol, and to note any areas for improvement. These checklists and notes will subsequently be reviewed with the health coaches.

3. Text messages to prospective parents:

In most weeks, parents will receive 1-4 study text messages per week related to one of the behavioral targets. Text messages will be unidirectional and will contain links to video content addressing key educational messages related to paternal health, infant health, and social determinants of health.

Although owning a cell phone is not included in the eligibility criteria for this study, participants will be informed of the possibility that if selected for this intervention group, they will be sent text messages. Participants will be informed that cell phones will not be provided and normal text messaging rates will apply. If participants do not have a cell phone that supports text messaging or choose not to receive text messages, they will be offered the opportunity to receive the messages by email. The content and frequency of the email messages will be the same as the text messages.

Instructional videos: We will create a series of 12 short, single-topic videos that engage parents topics including perinatal health and health care and family obesity prevention. The videos will be delivered via text messages or QR codes that link to video platform within printed materials. They will be available in English and Spanish. The videos topics will include:

- 1) Pregnancy and infancy health services;
- 2) Public health services e.g. WIC;
- 3) Breastfeeding;
- 4) Promotion of responsive feeding practices;
- 5) Avoiding early introduction of solid foods;
- 6) Discouraging the introduction and intake of sugar-sweetened beverages;
- 7) Discouraging introduction of fast foods;
- 8) Improving infant and parent sleep quality, duration, and practices;
- 9) Decreasing exposure to screen media;
- 10) Promoting age-appropriate active play;
- 11) Promoting fruit and vegetable intake; and
- 12) Developing household routines to facilitate the uptake of protective behaviors.

Intervention post-natal newsletters: videos and post-natal content will be delivered intervention group participants after the birth of their child, through the first year of life. This content will be sent via Constant Contact to intervention group dyads who consent to receiving unencrypted emails, or via “Send Secure” emails from the MGH study email address for those who did not consent to receive unencrypted emails.

Safety Group (Control) We will provide current “best practice” for infant safety to the control arm. We will provide this group with written materials which they will receive by mail approximately one month before the due date of their child and periodically during the first year of their child’s life, at birth, 1 month, 3-4 months, and 5.5 months. In addition to survey reminders, control group participants will be contacted via email every 1-2 months to keep them engaged in the study for the duration of one year. We will not encourage this group to do self-monitoring, send them any individualized feedback, or offer any other tailored or direct support.

Disenrollment If at any time during the study a participant requests to change participation, we will take the following steps to document the participant’s change in study involvement:

- If the participant requests to disenroll while on the phone, when possible, the participant will be transferred to speak with the study project manager. The project manager, or study staff if the project manager is not available, will discuss participation alternatives with the parent (e.g. completing surveys but not receiving additional health education intervention).
- The project manager or study staff who completed the call will document in the database the parent’s request to change their involvement in the study.
- Responses will be documented and saved with study files. Any changes to study involvement from the previous phone call will be updated in the study database.

Additionally, mother-father dyads will be considered ineligible for continued study participation if any of the following conditions are met:

- Preterm birth (before 35 weeks gestational age), miscarriage, significant co-morbidities.
- If there is any concern for DCF involvement, this will be discussed with IRB for appropriate guidance.
- If participants are unresponsive to attempts to schedule the first health coaching visit and miss Visit 1. If dyads have no intention of ever completing a health coaching visit, these dyads will also be disenrolled.

Qualitative Interviews with Intervention Group Participants:

Intervention group participants will be invited to complete an individual, semi-structured interview with study staff at the end of their participation to gather information on the acceptability and use of the First Heroes program. This interview is optional.

Interest for participating in this optional interview will be initially assessed using the final 12-month follow up survey. The survey includes a box for participants to give permission to be contacted by study staff to provide additional feedback on the First Heroes program to learn more about their experience. Individual participants (not dyads) who indicated they are interested in providing additional feedback will be mailed or emailed (based on how they have already consented to receive communications from our study team) a letter sign by the study's PI formally inviting them to participate in a 30-minute interview with study staff by Zoom (same modality as delivery of intervention health coaching) to give their opinion on what was useful about the program, modifications to program components, and the study's impact. If a participant did not complete the 12-month survey and did not have an opportunity to express interest, they will also receive a letter. Phone outreach to participants will begin one week after the mailing is sent. Three phone call attempts to reach participants who received a letter will be made by study staff. The target sample size will be determined by the study team when saturation is reached with regard to emerging themes. No more than 30 interviews will be conducted.

Verbal consent to participate in the interview will be collected at the beginning of the interview, at which time audio recording will begin. Study staff will follow the semi-structured interview guide to complete the interview. The interview will be audio recorded and transcribed for analysis. Interviews will only be conducted in English. Participants who complete this interview will receive a \$25 gift card.

Interviews will undergo content analysis incorporating the principles of the immersion-crystallization method. This qualitative approach consists of repeated cycles of immersion into the collected data with subsequent emergence, after reflection, of an intuitive crystallization of the dominant themes. Our analysis will also include iterative discussions among the study team to enrich and modify the intervention and implementation strategies.

The only possible potential risk in interview administration involves the social-psychological risk for the individual resulting from inadvertent disclosure of information or discomfort in answering questions. All research staff conducting interviews will be trained on standardized techniques for interviewing and fathers do not have to answer any question they are not comfortable answering.

Evaluation Measures:

Primary and secondary outcomes for this study will be collected for infant-father-mother triads at baseline, birth, 6-months and 12-months on study. All outcomes will be assessed by subpopulation of interest including sociodemographic, obesogenic risk, and the extent of program participation.

Primary outcome data will be collected from the electronic health records and health coaching visits for infants included in study for weight-for-length z-score at 12 months. Secondary outcome including paternal changes in BMI and obesogenic behaviors, utilization of perinatal healthcare services, and improving family-centered perinatal outcomes will be collected from electronic health record data, health coaching visits, and from participant surveys. Tables below show a summary of outcome variables for infants, mothers, and fathers.

INFANT OUTCOME VARIABLES				
Variable	Measure (Source)	Timing		
		Birth	6 Months*	12 Months
Primary Outcome(s) – Infant Overweight				
-Weight for length z-score	EMR		X	X
-Weight for length >97.7 th percentile	EMR		X	X
-Rapid infant weight gain	EMR		X	X
Secondary Outcomes - Infants				
Variable	Measure (Source)			
Preterm Birth	EMR	X		
Low Birthweight	EMR	X		
Breastfeeding	Infant Feeding Practices Survey (IFPS) (Survey)		X	X
Introduction of Solids			X	X
Infant Feeding Practices			X	X
SSB Intake			X	X
Sleep	Brief Infant Sleep Questionnaire (Survey)		X	X
Covariates				
Infant development/ behavior	Survey of Well-being of Young Children (Survey)		X	X

MOTHER OUTCOME VARIABLES					
Variable	Measure (Source)	Timing			
		Baseline	Birth	6 Months*	12 Months
Obesity-related variables					

Maternal gestational weight gain	EMR	X	X		
SSB Intake	NHANES (<i>survey</i>)	X		X	X
Sleep	NHANES (<i>survey</i>)	X		X	X
<i>Perinatal-health related variables</i>					
Mother prenatal care	Adequacy of Prenatal Care Utilization Index (<i>EMR</i>)	X		X	X
Parenting self-efficacy	Infant parenting self-efficacy scale (<i>survey</i>)			X	X
Stress	Perceived Stress Index (<i>survey</i>)	X		X	X
Parental depression	PHQ-2	X		X	X
Family functioning	SWYC- IPV Screen	X		X	X
WIC & SNAP Enrollment	EMR	X		X	X
<i>Covariates</i>					
Sociodemographic factors	NHANES; <i>survey</i>	X			
Food insecurity	Hager et al. scale (<i>Survey</i>)	X		X	X

FATHER OUTCOME VARIABLES					
Variable	Measure (Source)	Timing			
		Baseline	Birth	6 Months*	12 Months
Obesity-related variables					
Father BMI	Self-report or EMR	X	X	X	X
SSB Intake	NHANES (survey)	X		X	X
Sleep	NHANES (survey)	X		X	X
Perinatal-health related variables					
Father primary care visit	Self-report or EHR	X	X	X	X
Parenting self-efficacy	Infant parenting self-efficacy scale (survey)			X	X
Stress	Perceived Stress Index (survey)	X		X	X
Parental depression	Edinburgh Post-natal depression	X		X	X
Family functioning	McMaster Scale (survey)	X		X	X
WIC & SNAP Enrollment	Self-report (survey)	X		X	X
Father engagement	ECLS-B (survey)			X	X

<i>Covariates</i>					
Sociodemographic factors	NHANES; <i>survey</i>	X			
Food insecurity	Hager et al. scale (<i>Survey</i>)	X		X	X

Study Technology

REDCap: REDCap (Research Electronic Data Capture) will be used to collect and store patient data, including eligibility data, outcomes data from health records, and participant surveys. REDCap is a free, secure, HIPAA compliant web-based application hosted by MassGeneral Brigham HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS). Only study team members will have password protected access to the REDCap project in which data is collected and stored.

Text Messaging from Study Cell Phone: The text messages will be sent through an iPhone purchased through MassGeneral Brigham and enrolled in MobileIron. Once parents agree to be sent text messages, we will log the participants' phone numbers and unique IDs in REDCap. Text messages will be sent out by a member of the study team on a schedule based on the completion of the phone calls/meetings with the study health coaches. The text messages will be sent for approximately 18 months, the duration of the intervention.

Constant Contact: For intervention group dyads who consent to receive unencrypted emails, post-natal intervention content will be additionally delivered to them via Constant Contact. No email addresses will be stored in Constant Contact.

Video Conferencing

Patients will be given the option to “meet” with their health coach at their virtual visits via video conferencing. Telehealth, Zoom, Doxy.me, Doximity, or InTouch, which are videoconferencing platforms where clinicians and patients can use personal computers, tablets, and smart phones to communicate easily and securely using real time video and audio. Visits will be conducted remotely over the MassGeneral Brigham-approved video platform, which is HIPAA-compliant and provides a 256AES encryption from end to end. All usernames and passwords are stored securely behind a protected firewall within an externally hosted and Partners-approved location. We will send parents a letter with instructions regarding setting up the program on their personal devices. We will also send emails to the parent with the videoconference link and login information. This technology is preferred over Skype as it is more secure. There is a multitude of information readily available on the internet on how to “hack” in to Skype and steal user information such as names, addresses, credit card, and even phone numbers. This is not an issue with Telehealth.

The technology uses a virtual waiting room that is specific to each patient encounter. This mitigates the risk of two patients accidentally calling into the same session simultaneously. This method also avoids an issue where the patient could inadvertently call another clinician without clinician involvement.

We will send parents a letter with instructions regarding setting up the program on their personal devices. We will also send emails to the parent with the video conference link and login information.

Website: All intervention materials for participants randomized to Group 1 will be available on a study website hosted by MassGeneral Brigham.

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