


BMJ Open Individual breastfeeding support with contingent incentives for low-income mothers in the USA: the 'BOOST (Breastfeeding Onset & Onward with Support Tools)' randomised controlled trial protocol

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ABSTRACT

Introduction National breastfeeding rates have improved in recent years, however, disparities exist by socioeconomic and psychosocial factors. Suboptimal breastfeeding overburdens the society by increasing healthcare costs. Existing breastfeeding supports including education and peer support have not been sufficient in sustaining breastfeeding rates especially among low-income women. The preliminary outcomes of contingent incentives for breastfeeding in addition to existing support show promising effects in sustaining breastfeeding among mothers in the Special Supplemental Nutrition Programme for women, infants and children (WIC).

Methods and analysis This trial uses a parallel randomised controlled trial. This trial is conducted at two sites in separate states in the USA. Mothers who were enrolled in WIC and initiated breastfeeding are eligible. Participants (n=168) are randomised into one of the two study groups: (1) standard care control (SC) group consisting of WIC breastfeeding services plus home-based individual support or (2) SC plus breastfeeding incentives (SC +BFI) contingent on demonstrating successful breastfeeding. All participants receive standard breastfeeding services from WIC, home-based individual support and assessments. Participants in SC receive financial compensation based on the number of completed monthly home visits, paid in a lump sum at the end of the 6-month intervention period. Participants in SC +BFI receive an escalating magnitude of financial incentives contingent on observed breastfeeding, paid monthly during the intervention period, as well as bonus incentives for selecting full breastfeeding food packages at WIC. The primary hypothesis is that monthly incentives contingent on breastfeeding in SC +BFI will significantly increase rates of any breastfeeding compared with SC. The primary outcome is the rate of any breastfeeding over 12 months. Randomisation is completed in an automated electronic system. Staff conducting home visits for support and assessments are blinded to study groups.

Ethics and dissemination The Advarra Institutional Review Board has approved the study protocol

Strengths and limitations of this study

- Study recruitment occurs across two separate states in the USA targeting different underserved populations and providing different styles of breastfeeding support, maximising generalisability of results.
- Study uses a two-group parallel randomised controlled trial with staff blind to participant assignment.
- Study includes outcome measures obtained by direct observation as well as self-report.
- Study uses rigorous staff training and quality assurance monitoring and feedback protocols to maintain measurement integrity and minimise protocol drift among staff.
- Due to the nature of the intervention, participants are not blinded to treatment assignment; therefore, there are risks to demoralise the control group participants and potentially contribute to differential attrition as a common limitation in efficacy trials testing the effect of health incentives.
- The contingent incentive is on any level of breastfeeding, not on exclusive breastfeeding because increasing the rate of any level of breastfeeding is an appropriate goal among the populations known to have low rates of breastfeeding.

(Pro00033168). Findings will be disseminated to our participants, scientific communities, public health officials and any other interested community members.

Trial registration number NCT03964454

INTRODUCTION

Breastfeeding benefits and prevalence

Exclusive breastfeeding is recommended for the first 6 months of an infant's life and any breastfeeding with complimentary feeding up to a year or beyond.^{1 2} Breastfeeding decreases infants' risks for various health conditions such as infant mortality in the



first 6 months,³ acute otitis media, severe lower respiratory tract infections,⁴⁵ non-specific gastroenteritis,⁴⁶ diarrhoea,^{5 7} a topic dermatitis, asthma (young children),⁴ obesity,^{8 9} type 1 and 2 diabetes,^{9 10} childhood leukaemia, sudden infant death syndrome and necrotising enterocolitis.^{4 5} Breastfeeding also protects mothers against breast cancer, epithelial ovarian cancer, hypertension and type 2 diabetes.¹¹ If 90% of mothers exclusively breastfed their children as recommended, approximately US\$13 billion could be saved annually in the USA, while simultaneously preventing additional 911 infant deaths.^{5 12} Cost savings also include cost reduction in treatment by delaying the incidence of breast cancer.¹³ Government programmes such as the Special Supplemental Nutrition Programme for women, infants and children (WIC) and Medicaid may also benefit from increased rates of breastfeeding given that they spend over US\$600 million per year to give free formula to mothers.¹⁴

In 2015, over 57% of US mothers breastfed through 6 months with approximately 25% of infants exclusively breastfed.¹⁵ Breastfeeding rates in the USA have increased annually and are getting very close to the Healthy People 2020 Objectives.¹⁵ Unfortunately, disparities in breastfeeding rates exist in the USA, and there are many individual-level and family-level factors that contribute to the disparities.^{5 16–20} In the mid-Atlantic region, breastfeeding continuation rates are low among mothers who are younger than 25 years old, receive public aid, receive WIC service and are Puerto Rican descents, with an average duration of a little over 11 weeks.²¹ For example, younger women and those with limited socioeconomic resources stop breastfeeding within the first month due to sore nipples, perceived inadequate milk supply, their infant having difficulties in latching and the perception that the infant was not satiated.¹⁶ Interpersonal factors, such as workplace maternity leave and breastfeeding policy, also contribute to disparities.²² Breastfeeding rates are especially low among under-resourced racial/ethnic minority groups, such as African American and Puerto Rican participants enrolled in WIC.^{18 23} Overweight and obesity, as well as having unintended pregnancies, also increase risk for not initiating and continuing breastfeeding among African American and Hispanic women.¹⁸

Efforts to prolong breastfeeding duration

The WIC programme is the only federally-funded programme in the USA that attempts to address the nutritional needs of low-income pregnant, breastfeeding and postpartum mothers as well as infants and children under the age of 5.²⁴ WIC provides breastfeeding education and support as well as food vouchers, nutritional assessments, maternal and child nutrition education, and referrals to healthcare and social services.²⁴ Postpartum mothers have a choice of WIC food packages for mother–infant dyads including one for the fully breastfeeding dyad, partially breastfeeding dyad or formula-feeding dyad²⁴; however, the breastfeeding rates have not significantly improved with the different WIC food packages.²⁵

Similar to the WIC programme for postpartum mothers, other behavioural interventions for breastfeeding emphasise the importance of education and peer support aimed at prolonging breastfeeding duration among under-resourced mothers.^{23 26 27} Breastfeeding education prepares mothers for what to expect during postpartum²⁶ and may prolong breastfeeding duration among low-income and middle-income mothers, such as African American and Latina women who have a supportive partner (median duration: 6.5 weeks vs 12 weeks; log-rank $p=0.02$).²⁶ However, the same effect is not observed among single, socioeconomically disadvantaged WIC mothers.²⁸ Peer support can break down health behaviour barriers within a social network and can introduce connections with services that facilitate breastfeeding initiation.^{29 30} African-American mothers find peer support to be a motivating factor for initiating breastfeeding.²⁷ However, the effects of most individual interventions that include peer support among socioeconomically disadvantaged, Latina and African American mothers appear to be limited to the first 3 months postpartum.²³

Use of health incentives

Financial or non-financial incentives for effortful health behaviours have been effective in promoting healthier habits and health behavioural change when immediately delivered contingent on verified occurrence of the outcome-centred behaviour of interest. Such effects have been observed in studies promoting drug and smoking abstinence,^{31 32} weight loss or physical activity,^{33 34} immunisation³⁵ and treatment and medication adherence.^{36 37} Contingent incentives also have been used to increase breastfeeding rates. However, effects of this strategy have shown mixed results, probably because of inconsistency in the application of incentive methods.³⁸ Studies using tangible incentives such as gift packages and vouchers or intangible incentives such as support for household chores and childcare by nurses showed positive breastfeeding outcomes.^{39 40} A recent, large-scale cluster randomised controlled trial in the UK⁴¹ offered shopping vouchers based on self-reported breastfeeding status verified by a clinician's signature across five time points during 6 months postpartum for a total potential earning of US\$250. The approach significantly increased breastfeeding rates during early postpartum up to 8 weeks compared with usual care with community-based breastfeeding support.⁴¹

A recent, small randomised controlled trial (which serves as the basis of the present study protocol) provided an escalating magnitude of financial incentives contingent on monthly, directly observed breastfeeding behaviour over 6 months postpartum.⁴² The study focused on WIC-enrolled Puerto Rican mothers in an urban setting. Participants received financial incentives immediately after breastfeeding verification up to a total potential earning of US\$270 during their participation. Compared with the control group with WIC breastfeeding support only, the incentive group demonstrated significantly

higher breastfeeding rates at 1-month, 3-month and 6-month postpartum as well as a trend toward improved infant outcomes on infant weight and reduced emergency department visits.⁴² The present study is warranted to establish the efficacy and test the generalisability of the 6-month incentive-based approach in a community setting to increase breastfeeding rates in WIC-eligible mothers and test whether effects last up to 12-month postpartum in a larger-scale randomised controlled trial.

METHODS AND ANALYSIS

Study objectives

The primary objective of this trial is to examine the efficacy of monthly financial incentives contingent on observed breastfeeding for 6 months postpartum among WIC-enrolled mothers on breastfeeding rates over 12 months. The secondary study objectives are: (1) to examine the efficacy of the incentive intervention on infant physical and medical outcomes over 12 months postpartum and (2) to explore the effect of changes in theoretically important variables that may either moderate (eg, demographics, depressive symptoms, smoking status) or mediate (eg, motivation and breastfeeding self-efficacy) the effect of the intervention on breastfeeding and infant outcomes.

Study design and setting

The study is a multisite, parallel randomised controlled trial. The study is conducted in two sites located in different mid-Atlantic states that have high concentrations of low-income racial/ethnic minority mothers. Eligible WIC-enrolled mothers who initiated breastfeeding (n=168) are randomised into one of the two study groups: (1) A Standard Care Control (SC) group consisting of WIC breastfeeding service plus home-based individual support or (2) SC plus Incentives (SC+breastfeeding incentives (BFI)) contingent on demonstrating successful breastfeeding. Participants in the SC group receive financial compensation for completing monthly home visits for support and assessments during the 6-month intervention period, which is paid in a lump sum based on the total number of completed home visits. Alternatively, participants in the SC +BFI group receive an escalating magnitude of financial incentives contingent on observed breastfeeding, paid after each monthly home visit during the 6-month intervention period. These participants also receive a bonus incentive each time they select the full breastfeeding food packages at WIC at months 0, 3 and 6. The start date of the study was on 19 June 2019, and planned end date of study completion is in December 2022.

Participant eligibility

To be eligible for the study, mothers must (1) initiate breastfeeding on the postpartum hospital unit post-delivery; (2) be WIC-enrolled prior to randomisation; (3) reside and plan to stay in the study county for 12 months

postpartum; (4) voluntarily consent; (5) understand fifth grade level of English and (6) be at least 18 years old. Mothers whose babies are medically contraindicated against breastfeeding, who are hospitalised for severe postpartum medical issues, who have ongoing illicit drug use issues, who had a psychiatric hospitalisation within the last 3 months, or who currently have suicidal thoughts or attempts are excluded from the study enrolment.

Participant screening and recruitment

Hospital staff on the postpartum floor refer mothers who initiated breastfeeding to research staff for study screening. Eligibility screening is conducted on the postpartum floor during hospital stay. Research staff then review and provide eligible mothers with informed consent and the Health Insurance Portability and Accountability Act (HIPAA) forms to ensure participants understand procedures, risks and benefits, alternatives, and human subject protections. Signed consent and HIPAA forms are stored in a locked filing cabinet at each study site. Consented participants are scheduled for the first home visitation in 1–2 weeks to complete the baseline assessment and enrolment process.

The in-home baseline assessment takes about 1 hour and includes questions on sociodemographic, breastfeeding-related and medical and psychosocial status. Participants are compensated with a US\$40 gift card for their time completing the baseline assessment.

Randomisation

A permuted block random assignment with a block size of six is used,⁴³ assigning participants into two study groups: SC or SC +BFI (figure 1). This allows us to keep group sizes approximately equivalent between the two groups. Participants are stratified by study site and race/ethnicity to maximise internal validity. Computer-generated random numbers were generated by a biostatistician

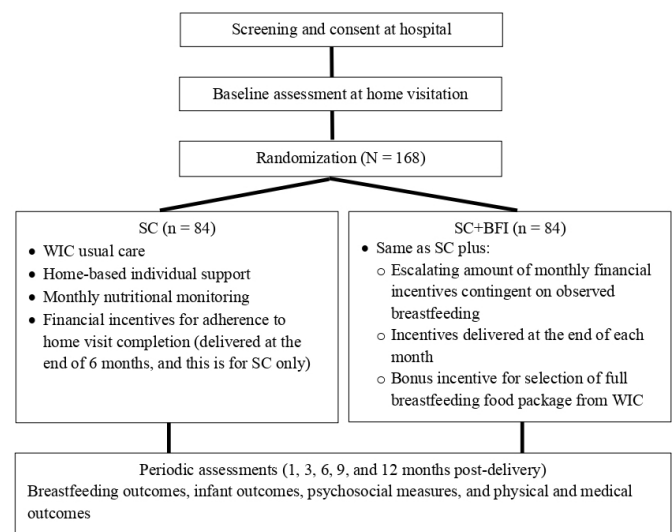


Figure 1 BOOST trial consort diagram. BFI, breastfeeding incentives; SC, standard care; WIC, women, infants and children.

(ZZ), and concealed allocation to random group assignments is completed in an automated electronic system. The unblinded project coordinator then calls the participant to inform them of their group assignment after completion of the baseline home visit. All home and telephone assessment staff remain blinded to participants' group assignment throughout the study. If staff accidentally become unblinded to participant condition, a new, blinded staff gets assigned for future visits.

Study groups

All participants receive standard breastfeeding services and support from the WIC programme. Blinded staff provide home visits for support and brief assessments, periodic phone assessments at 1-month, 3-month and 6-month postpartum, and in-home assessments at 9-month and 12-month postpartum. Phone assessments include self-reported measures around breastfeeding and other health outcomes. Monthly home visits and in-home assessments include observation and verification of breastfeeding, infant height and weight, maternal weight and waist measurement, self-reported breastfeeding and other nutritional practices, and other psychosocial and medical outcomes. Observational signs to verify ongoing breastfeeding in this study include audible swallowing of breast milk, regular suck/swallow/breathing patterns, visible milk in an infant's mouth, and (in case of pumping moms) pumped milk and successful feeding of an infant. Participants are also asked to complete a 24-hour dietary recall during the past week for each month.

WIC support component: All participants are offered standard services from WIC that include weekly on-site lactation consultation, bilingual peer counselling, and peer support meetings, as well as a free breast pump and food package for breastfeeding mothers. Vouchers for food packages are distributed to WIC participants every 3 months either electronically or at a WIC office.

Home-based individual support component: All participants receive home-based individual support from blinded staff in addition to WIC services. There are six home visits at the end of each postpartum month, following the enrolment home visit after the hospital discharge. At each home visit, blinded staff ask participants to demonstrate breastfeeding, praise participants' efforts to continue breastfeeding, identify barriers to breastfeeding, and help participants identify other medical and psychosocial needs. To standardise the type and degree of support across participants in both groups, each participant receives a breastfeeding resource booklet to guide the support process. This booklet supplements WIC breastfeeding education and facilitates identification of problem-solving strategies around common breastfeeding barriers and concerns. If breastfeeding questions or problems arise during a home visit, staff are trained to point to relevant referral contact information in the resource book and encourage participants to contact their WIC office for more specific personal advice, support, and additional community referral as needed. For example,

when a participant has trouble with breastfeeding, staff refer her to a certified lactation consultant in their WIC clinic or community. Should a participant report any adverse maternal and infant outcome during the study period, staff document the event and offer to connect the participant to WIC staff, who can make a referral.

SC control: At each monthly home visit during the 6-month intervention period, staff verify breastfeeding, review participants' completion of nutritional monitoring, track recent medical visits and medication use for participants and their infants, take infant height and weight, and take maternal weight and waist measurement. Participants in the SC group can receive up to US\$240 during the trial for completion of assessments during home visits (US\$40 per completed monthly home visit). The financial compensation in the SC group is necessary to maximise retention and adherence to the monthly assessment schedule, provide comparable remuneration as the SC +BFI group, and minimise demoralisation of SC group participants following treatment assignment. All participants are informed of the differential group procedures during the prerandomisation consent process.

SC plus BFI (SC +BFI): Participants in the SC +BFI group are asked to complete the same in-home and telephone assessments as the SC group. After randomisation, SC +BFI participants are informed that they will receive an escalating amount of monthly financial incentives contingent on observed breastfeeding delivered after each monthly home visit: They receive a US\$20 incentive payment for verified breastfeeding at the end of the month 1 visit. Then, the incentive increases by US\$10 every month of continued breastfeeding until the end of 6 months. The initial incentive value of US\$20 was determined in the pilot study⁴² based on inputs from participants as the minimum amount of monthly incentives that would motivate them to breastfeed. An escalating schedule of monthly incentives was employed based on successes of previous incentive-based interventions to encourage continuous abstinence from substance use.⁴⁴ Participants also receive a bonus incentive of US\$50 for selecting the full breastfeeding food package from WIC at baseline, 3 and 6 months, respectively. The maximum potential earning of contingent incentives is US\$270 for monthly breastfeeding verification and up to US\$150 for selection of the full breastfeeding food package from WIC.

The primary differences in procedures between the SC +BFI and SC groups are (1) the SC group does not receive monthly payments, but receive a lump sum payment after completing the 6-month home visit that is tied to the number of completed monthly home visits. Remuneration is tied explicitly to assessment adherence, not to the target health behaviour. (2) Monthly incentive payments in the SC +BFI group are tied to breastfeeding achievement and paid after each monthly home visit.

Payment procedures: Immediately after leaving each home visit, blinded staff text the un-blinded project coordinator to inform about a participant's completion of

monthly home visit, WIC food package chosen, degree of nutrition assessment completion, and whether breastfeeding was verified during the visit. This text prompts the project coordinator to immediately follow these steps: (1) identify the participant's group assignment and (2) for SC +BFI participants who achieved verified breastfeeding, send a congratulatory text message informing them that they receive an electronic deposit on their prepaid debit card within the next 12 hours for their ongoing breastfeeding. Similarly, a deposit is made to a SC +BFI participants' card when the project coordinator is notified of the WIC food package selection. For those in the SC group, the coordinator tracks completion of monthly home visits during the 6-month intervention period. At the end of 6 months, the coordinator sends a gift card with the appropriate lump sum payment based on the number of completed monthly home visits.

Self-report and anthropometric assessments

All participants are asked to complete self-report assessments at 1-month, 3-month, 6-month, 9-month and 12-month postpartum. Self-report assessments via telephone occur at 1-month, 3-month and 6-month postpartum whereas 9-month and 12-month self-report and anthropometric assessments are conducted at home. Assessments are conducted by blinded staff. Phone assessments take approximately 20 min, and in-home assessments take approximately 40 min.

Assessments include interview questions on breastfeeding self-efficacy,⁴⁵ motivation and support, maternal and infant medical visits and medications, infant sleep,⁴⁶ postnatal depression,⁴⁷ and other psychosocial and behavioural status. In-home assessments also include breastfeeding observation as described above, infant height and weight measurement using portable scales, and maternal weight and waist measurement. All data are entered directly into a secure, password-protected data management system. Entered data are saved regularly for preventing data loss and protecting the quality of data entry. Participants are compensated via separate gift cards for completing each self-report assessment: US\$20 for phone assessments and US\$40 for assessments collected in home. A bonus compensation is tied to in-home assessments to boost adherence: US\$60 for participants who attend all monthly home visits and in-home assessments; US\$40 for those who miss 1 monthly home visit or in-home assessment; and \$20 for those who miss 2 monthly home visits or in-home assessments.

Quality assurance monitoring

Blinded staff are trained according to the research protocol, and are tested by the lead investigators to achieve $\geq 90\%$ fidelity on essential components and processes related to monthly home visits, phone and in-home assessments, adherence to masking, assessment questions, data collection and breastfeeding support. Achievement is determined by observation of 10 items highlighted on a fidelity monitoring form. The lead

investigators assess maintenance of protocol adherence throughout the trial to ensure that staff maintain $\geq 90\%$ fidelity. To achieve this goal, all phone assessments are audio-recorded for the fidelity monitoring purpose. At least 20% of recorded phone-based and in-home performance are to be observed by the lead investigators. During these observations, the lead investigators complete a fidelity monitoring form. Fidelity monitoring forms are reviewed for feedback during weekly staff meetings.

Unblinded project coordinator tracks time stamps of when staff send text messages to the project coordinator after each home visit and time stamps of when the project coordinator sends a text message to the participant as well as when electronic payments to the participants in the SC+BFI group are made to ensure immediate provision of contingent incentives on observed breastfeeding.

Patient and public involvement

The development of the research question and outcome was partially informed by prior patients' interests in how breastfeeding changes maternal health outcomes. Patients from the preliminary study⁴² guided the incentive schedule in the SC+BFI group used in the current protocol. Patients are not involved in recruitment or the conduct of the study. The preliminary study⁴² guided the monthly home visitation as the setting format based on patient feedback on the burden of the intervention.

Power analysis

A final sample of 70 participants per study group at 12-month follow-up is sufficient to test our primary hypothesis that, compared with the SC group, the BFI+SC group will have higher rates of any level of breastfeeding at each time point. To compensate for potential lost to follow-up, we aim to enrol 84 participants per group for a total of 168 participants randomised in two study groups. We expect to recruit half of them from each site. We allowed for up to 20% attrition given the general follow-up rate among low-income mothers and prior studies with prenatal smoking cessation ($\geq 80\%$).³²⁻⁴⁸ Power analysis suggests that with this sample size, an effect of at least 25% difference between groups would be required to detect statistically significant differences in breastfeeding at 6-month (primary outcome) and infant health outcomes at 3-month (secondary outcome), given a one-sided test at the 0.05 significance level and 80% power. Power analysis based on the Monte-Carlo approach⁴⁹ on mediational models reveals that on the basis of the proposed sample size and the difference between two groups, the power will be 90%, 86% and 81% for the single mediator model, mediation with multiple mediators, and mediation models with multiple mediators in latent growth curve models, respectively.

Data analyses

Data quality management: All data will be reviewed for valid values/data entry errors, outliers, the extent and pattern of missing data. Consistency and logic checks that

constitute standard review/cleaning procedures will be applied. Internal validity (how well the randomisation worked to create similar study groups) will be checked by comparing the groups on relevant background and baseline measures using analyses of variance for continuous variables and log-linear models for discrete or ordinal responses.

Missing values: We will use an intention-to-treat analysis treating missing values as non-breastfeeding status. The mixed-effect models will provide valid estimates of efficacy if the proportion of missing values is less than 10%.⁵⁰ The impact of the proportion of missing values on the outcomes will be assessed in scenario sensitivity analysis.

Primary outcome analysis: The primary outcome is the rate of any level of breastfeeding at 1, 3, 6, 9, and 12 months postpartum. We hypothesise that the isolated effect of monthly incentives contingent on breastfeeding in the SC +BFI group will increase rates of any level of breastfeeding significantly at each time point compared with SC. We also hypothesise there will be significant increases in the rate of selecting the full breastfeeding food package from WIC in the SC +BFI group compared with SC. Logistic regression and generalised equation modelling will be used to compare groups on the primary binary outcomes of point prevalence of breastfeeding status at 1-month, 3-month, 6-month, 9-month and 12-month postpartum. The models will include terms for study group, time and the group by time interaction. Theoretically important covariates and differences will be considered for inclusion in adjusted analyses to improve their precision.

In addition, the Cochran-Armitage trend test will be used to examine the trend of breastfeeding rates from 1-month through 6-month postpartum and from 1-month to 12-month postpartum. Duration of breastfeeding will be analysed in the Kaplan-Meier curve analysis with the stop-breastfeeding as event. In addition, stop-breastfeeding as event and duration of breastfeeding as time will be used in survival regression analysis.

Secondary outcome analyses: The secondary outcomes are infant physical and medical outcomes over 12 months postpartum. We hypothesise that compared with SC, participants in the SC+BFI group will have significantly lower infant weight gain as well as incidents of infant emergency room visits especially at 3-month postpartum. Secondary outcomes will be evaluated using regression models for linear and non-linear mixed effect models for continuous (eg, number of medical visits) and binary outcomes (eg, occurrence of medical visits). If no significant differences in these outcomes were detected, the resampling Bootstrap method will be used to estimate effect sizes (Cohen's *d* for continuous variables and Cohen's *h* for categorical variables) and its 95% CIs, considering potential non-normal distribution of data. Given that the development of infants is systematically related to the passage of time, growth curve analysis (or latent growth curve analysis) will be applied in the study to identify individual differences in growth. Growth curve

analysis examines both intraindividual and interindividual differences. Further, we will use structural equation modelling to conduct latent growth curve analysis for its greater flexibility and capacity of handling a larger number of variables. These analyses will be applied both to the absolute values and standardised differences from weight for age z-scores based on the WHO Growth Reference Standards, which are sex controlled.⁵¹

Moderator and mediation analyses: The Behavioural Ecological Model⁵² will frame our moderator and mediation analyses. The model emphasises how contingent incentives on breastfeeding, in addition to institutional breastfeeding support such as WIC and home-based individual support, influence breastfeeding rates.⁵³

Moderator analyses: We will use non-programmatic variables collected at baseline assessment, that are known to influence breastfeeding rates, including maternal age,⁵⁴ maternal education,⁵⁵ prepregnancy body mass index,⁵⁶ postpartum depression,⁵⁶ smoking status,⁵⁶ previous breastfeeding experience,⁵⁷ initiation status⁵⁸ and employment-related structural variables.^{59–63} The mixed-effects models will include the effect of a moderator, its interaction with the breastfeeding status, and the group by time interactions.

Mediation analyses: We hypothesise that participants in the SC+BFI group will evidence greater increases in the theoretically important social and behavioural constructs (eg, self-efficacy⁶⁴ and motivation^{65–67} to breastfeed), which, in turn, will account for between-group differences in breastfeeding rates. Specifically, the mediational effects of these constructs on breastfeeding rates for 12 months postpartum will be examined using causal mediation models that are increasingly used in behavioural science for mediation analyses.⁶⁸ Whether and how these constructs mediate the intervention effect of incentives on continued breastfeeding rates for 12 months will be examined.

Methodological limitations

One limitation of this study is that it is not double blinded. All project staff providing home visitations are blinded to the study groups. However, participants are informed of group differences during consent procedures and of their assigned study group after randomisation procedures. This decision is integral to the study design which requires (1) explicit instructions and expectations among participants in the SC+BFI group that they receive immediate monetary payments contingent on the achievement of monthly verified breastfeeding (part of the experimental manipulation) and (2) contrasting instructions that all payments in the SC group are tied to attendance to monthly home visits (not contingent on breastfeeding behaviour). One potential consequence of this design is demoralisation of participants in the SC group who are not receiving additional incentives related to their breastfeeding behaviour (ie, selection of WIC breastfeeding food package). Nevertheless, this design is required to test whether the addition of contingent incentives for

breastfeeding, added to breastfeeding support services, will increase breastfeeding rates as opposed to services alone. Another limitation is that BFI are contingent on the target goal of any level of breastfeeding, not on exclusive breastfeeding. However, this target goal is appropriate in a population known to have low uptake and duration of any breastfeeding. Future studies could examine the effects of incentives on exclusive breastfeeding as a more challenging health behaviour than any breastfeeding.

ETHICS AND DISSEMINATION

The study design was reviewed and approved by the Advarra Institutional Review Board (IRB) as the IRB of record (Pro00033168). Following the study approval by the Advarra IRB, an authorisation agreement was obtained by IRBs in each study site. A data and safety monitoring board (DSMB) was composed with professionals in statistics, paediatrics, breastfeeding and community-based behavioural interventions who are independent of the study interest and funding source. The board meeting occurs annually and as needed to review maintenance of the study protocol, potential adverse events, and study progress and findings. Adverse events are reported to IRBs and DSMB, and interim results will be shared with DSMB.

The trial findings would contribute to the body of knowledge regarding how breastfeeding rates as well as maternal and infant health are impacted by a community-based behavioural intervention during 12 months post-partum. Community stakeholders and policy-makers will then be informed of trial findings and feasibility and acceptability of implementing and sustaining the intervention component in public and private sectors. Specifically, trial findings will address the influence and usefulness of contingent financial incentives on promoting breastfeeding in at-risk populations. Findings will be disseminated to our participants, scientific communities, public health officials, and any other interested community members.

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Contributors YW contributed to the design and conceptualisation of the work, design and implementation of the study protocols, and overall project oversight at both sites, drafted the manuscript, and finalised it for submission. BNC contributed to the design and conceptualisation of the work, design and implementation of

the study protocols, and project oversight at the Temple site and critically edited the manuscript adding important intellectual content. AH-J contributed to the development and implementation of the study protocols and project coordination at the Temple site and critically reviewed the manuscript adding important details of the study procedure. ZZ contributed to the development of the study's analytic methods and critically reviewed the manuscript adding important statistical content. GH, MH, and LK contributed to the development of the recruitment protocols and referral resources and critically reviewed the manuscript. DC and LMF consulted on the development of overall study design and protocol and critically reviewed the manuscript. All authors gave final approval of the manuscript and agree to be accountable for all aspects of the work and its integrity.

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