BMJ Open

Individual Breastfeeding Support with Contingent Incentives for Low-Income Mothers: The "BOOST" Randomized Controlled Trial Protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034510
Article Type:	Protocol
Date Submitted by the Author:	25-Sep-2019
Complete List of Authors:	Washio, Yukiko; RTI International, Collins, Bradley N; Temple University , College of Public Health Hunt-Johnson, Alison; Temple University, College of Public Health Zhang, Zugui; Christiana Care Health System, Obstetrics and Gynecology Department Herrine, Gail; Temple University Hospital, Obstetrics and Gynecology Department Hoffman, Matthew ; Christiana Care Health System, Obstetrics and Gynecology Department Kilby, Linda Chapman, Donna; Springfield College, Department of Exercise Science and Athletic Training Furman, Lydia; Rainbow Babies and Children's Hospital, Pediatrics
Keywords:	breastfeeding duration, WIC, financial incentives, home-based settings

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Individual Breastfeeding Support with Contingent Incentives for Low-Income Mothers: The "BOOST" Randomized Controlled Trial Protocol

Yukiko Washio, Ph.D.[1]; Bradley N. Collins, Ph.D.[2]; Alison R. Hunt-Johnson, B.S.[2]; Zugui Zhang, Ph.D.[3]; Gail Herrine, M.D.[4]; Matthew K. Hoffman, M.D., M.P.H.[3]; Linda M. Kilby, Ph.D., R.D., L.D.N.[5]; Donna Chapman, Ph.D., R.D.[6]; Lydia Furman, M.D.[7]

Affiliations: RTI International, Research Triangle Park, NC, U.S.A.[1]; Temple University, College of Public Health, Philadelphia, PA, U.S.A.[2]; Christiana Care Health System, Obstetrics and Gynecology Department, Newark, DE, U.S.A.[3]; Department of Obstetrics, Gynecology and Reproductive Sciences, Temple University Lewis Katz School of Medicine, Philadelphia, PA, U.S.A.[4]; N.O.R.T.H., Inc—Philadelphia WIC program, Philadelphia, PA, U.S.A. [5]; Springfield College, Department of Exercise Science and Athletic Training, Springfield, MA, U.S.A.[6]; University Hospitals Rainbow Babies, and Children's Hospital and Case Western Reserve University School of Medicine, Department of Pediatrics, Cleveland, OH, U.S.A.[7]

Author Emails: Yukiko Washio [ywashio@rti.org]; Bradley N. Collins [collinsb@temple.edu]; Alison R. Hunt-Johnson [tuc52754@temple.edu]; Zugui Zhang [ZZhang@christianacare.org]; Gail Herrine [Gail.Herrine@tuhs.temple.edu]; Matthew K. Hoffman [MHoffman@christianacare.org]; Linda M. Kilby [lkilby@northwic.org]; Donna Chapman [dchapman2@springfieldcollege.edu]; Lydia Furman [Lydia.Furman@uhhospitals.org]

Address correspondence to: Yukiko Washio, RTI International, 3040 E. Cornwallis rd. PO Box 12194, Research Triangle Park, NC, 27709, U.S.A., [ywashio@rti.org], (phone) 919-485-2794

Financial disclosure: The author has no financial relationships relevant to this article to disclose.

Conflict of interest: The author has no conflicts of interest to disclose.

Word count: 4,465

Abstract

Introduction. Breastfeeding decreases the risk for infant health issues, including various infectious diseases, diabetes, and mortality, as well as maternal cancers and diabetes. Overall, national breastfeeding rates have improved, however, disparities in breastfeeding rates exist by socioeconomic status and psychosocial factors. Suboptimal breastfeeding overburdens the societal economy by increasing maternal and infant healthcare costs. Use of financial incentives contingent on breastfeeding in preliminary studies show promising effects in sustaining breastfeeding rates among WIC-enrolled mothers. The study examines the effect of monthly financial incentives on breastfeeding and infant outcomes during 12-month postpartum.
Methods and Analysis. This trial uses a parallel randomized controlled trial conducted in two regional sites across separate states in U.S. Eligible WIC-enrolled mothers who initiated breastfeeding (N = 168) are randomized into one of the two study groups: (1) Standard Care Control (SC) group consisting of WIC breastfeeding services and support plus home-based individual support, or (2) Standard Care plus Incentives (SC+BFI) contingent on demonstrating successful breastfeeding. All participants receive standard breastfeeding services and support from the WIC program, home-based individual support, and periodic phone and in-person assessments. Participants in SC receive a lump sum payment at the end of the 6-month period based on the number of completed home visits. Participants in SC+BFI receive an escalating magnitude of financial incentives contingent on observed breastfeeding on a monthly basis, as well as bonus incentives for selecting full breastfeeding packages at WIC. Primary outcomes are breastfeeding rates at 1-, 3-, 6-, 9-, and 12-month, and secondary outcomes are infant physical and medical outcomes over 12 months. **Ethics and Dissemination.** Community stakeholders, policy makers, public health officials, scientific communities, and participants will be informed of the study outcomes. The trial findings will advance knowledge of the effects of community-based behavioral interventions on breastfeeding in underserved populations with low breastfeeding rates.

Trial Registration. NCT03964454

Key words: breastfeeding duration, WIC, financial incentives, home-based settings

Strengths and limitations

- Study tests full efficacy of contingent financial incentives on observed breastfeeding behavior for 12 months.
- Study tests the secondary impact of contingent financial incentives on infant medical outcomes.
- Study implementation is ongoing; thus no outcome data are reported.

Introduction

Breastfeeding Benefits and Prevalence

Exclusive breastfeeding is recommended for the first six 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,[4,5] non-specific gastroenteritis,[4,6] diarrhea,[5,7] atopic dermatitis, asthma (young children),[4] obesity,[8,9] type 1 and 2 diabetes,[9,10] childhood leukemia, sudden infant death syndrome (SIDS), and necrotizing 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 $13 billion could be saved annually in U.S., 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 programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and Medicaid may also benefit from increased rates of breastfeeding given that they spend over $600 million per year to give free formula to mothers.[14]

In 2015, over 57% of U.S. mothers breastfed through six months with approximately 25% of infants exclusively breastfed.[15] Breastfeeding rates in U.S. have increased annually and are getting very close to the Healthy People 2020 Objectives.[15] Unfortunately, disparities in breastfeeding rates exist in U.S., and there are many individual- and family-level factors that contribute to the disparities,[5,16–19] such as previous breastfeeding experiences.[20] Interpersonal factors, such as workplace maternity leave and breastfeeding policy, also contribute to disparities.[21] In the mid-Atlantic region, breastfeeding continuation rates are low among

Medicaid-eligible mothers, non-Hispanic African American women, and Hispanic women with an average duration of a little over 11 weeks.[22] 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] Breastfeeding rates are especially low among under-resourced racial/ethnic minority groups, such as African American and Puerto Rican participants of 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 program is the only federally-funded program in U.S. that attempts to address the nutritional needs of pregnant, breastfeeding and postpartum mothers as well as infants and children under the age of five.[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 dyad.[24] While the cost of postpartum food packages increase with inclusion of formula,[25] there does not seem to be a difference in 3- or 6-month breastfeeding rates across groups of mothers using the different WIC food packages.[26]

Other than WIC breastfeeding support and education around food package choices, breastfeeding education and peer support have been dominant behavioral interventions aimed at prolonging breastfeeding duration among under-resourced mothers.[23,27,28] Breastfeeding education prepares mothers for what to expect during postpartum.[27] Breastfeeding education has been shown to prolong breastfeeding duration among African American and Latina women who

have a supportive partner (median duration: 6.5 weeks vs. 12 weeks; Log-rank p=0.02).[27] However, the same effect is not observed among single, socioeconomically disadvantaged WIC mothers.[29] The effects of peer support have been attributed to its ability to break down barriers within a social network and connect mothers to social support that could facilitate breastfeeding initiation at the optimal time.[30,31] African American mothers find peer support to be a motivating factor for initiating breastfeeding.[28] However, the effects of most individual interventions that include peer support among low-income, Latina and African American mothers appear to be limited to the first 3-month postpartum. [23]

Use of Health Incentives

Financial or non-financial incentives have been effective in promoting health habits and health behavior change when immediately delivered contingent on verified occurrence of the outcome-centered behavior of interest. Such effects have been observed in studies promoting drug and smoking abstinence,[32,33] weight loss or physical activity,[34,35] immunization,[36] and treatment and medication adherence.[37,38] 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.[39] 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.[40,41] A recent, large-scale cluster randomized controlled trial in UK[42] offered shopping vouchers based on self-reported breastfeeding status verified by a clinician's signature across five timepoints during 6-month postpartum for a total potential earning of $250. The approach significantly increased breastfeeding rates during early postpartum up to eight weeks compared to usual care with community-based breastfeeding support.[42]

A recent, small randomized 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 behavior over 6-month postpartum.[43] 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 $270 during their participation. Compared to the control group with WIC breastfeeding support only, the incentive group demonstrated significantly higher breastfeeding rates at 1-, 3-, and 6-month postpartum as well as a trend toward improved infant outcomes on infant weight and reduced emergency department visits.[43] Further investigation is warranted to establish the efficacy and test the generalizability of the 6-month incentive-based approach in a community setting to increase breastfeeding duration in WIC-eligible mothers and test whether effects last up to 12-month postpartum in a larger-scale randomized controlled trial.

Methods and Analysis

Study Objectives

The primary objective of this parallel randomized controlled trial is to examine the efficacy of providing WIC-enrolled mothers monthly financial incentives for 6-month postpartum contingent on observed breastfeeding while monitoring the impact on breastfeeding duration over 12-month postpartum. The secondary study objectives are: (1) to examine the efficacy of the incentive intervention on infant physical and medical outcomes over 12-month postpartum; (2) to explore the effect of changes in theoretically important variables that may either moderate (e.g., demographics, depressive symptoms, smoking status) or mediate (i.e., motivation and breastfeeding self-efficacy) the effect of the intervention on breastfeeding and infant outcomes; (3) to explore community- and policy-level factors that may impact the

sustainability of an incentive-based intervention with community stakeholders (e.g., insurance and healthcare industries); and (4) to track the intervention, formula supplementation, and medical costs for cost-effectiveness analyses. The study design was approved by the related Institutional Review Boards (IRBs). A Data and Safety Monitoring Board (DSMB) was composed with professionals in statistics, pediatrics, breastfeeding, and community-based behavioral interventions who are independent of the study interest. The board meeting occurs annually and as needed to review maintenance of 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.

Study Design and Setting

The study is a multi-site, parallel randomized controlled trial. The study is conducted in two regional sites (in different mid-Atlantic states) that have high concentrations of low-income racial/ethnic minority mothers. Study eligible WIC-enrolled mothers who initiated breastfeeding (N = 168) are allocated into one of the two study groups: (1) A Standard Care Control (SC) group consisting of WIC breastfeeding education and support, plus home-based individual support, or (2) Standard Care plus Incentives contingent on demonstrating successful breastfeeding (SC+BFI).

Participant Eligibility

To be eligible for the study, mothers must (1) initiate breastfeeding; (2) be WIC-enrolled or eligible to enroll in WIC services; (3) reside and plan to stay in the study county for 12-month 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 hospitalized for severe postpartum medical issues, who have ongoing illicit drug use

issues, who had a psychiatric hospitalization within the last three months, or who currently have suicidal thoughts or attempts are excluded from the study enrollment.

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 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 one-to-two weeks to complete the baseline assessment and enrollment process.

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

Randomization

A permuted block random assignment with a block size of six was used,[44] 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 were stratified by study site and race/ethnicity to maximize internal validity. Computer-generated random numbers were generated by a biostatistician (Z.Z.), and concealed allocation to random group assignments was completed in an automated electronic system. The un-blinded project coordinator then calls the participant to tell them what group they have been assigned to.

Study Groups

All participants receive standard breastfeeding services and support from the WIC program. Blinded staff provide monthly home visitations, periodic phone assessments at 1-, 3-, and 6-month postpartum, and in-person assessments at 9- and 12-month postpartum. Phone assessments include self-reported measures around breastfeeding and other health outcomes. Monthly home visitations and in-person assessments include observation and verification of breastfeeding, infant height and weight, self-reported breastfeeding and other nutritional practices, and other psychosocial and medical outcomes. Signs to verify ongoing breastfeeding include audible swallowing of breastmilk, 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 monitor their nutritional habit each month and to complete 24-hour recalls for each month. *WIC support component.* Participants are offered standard services from WIC that include weekly on-site lactation consultation, bilingual peer counseling, and peer support meetings, as well as a free breast pump and food package for breastfeeding mothers. Food packages for breastfeeding mothers are distributed to WIC participants every three months. *Home-based individual support component.* Blinded staff provide individual support in addition to WIC services. 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. Each participant receives a breastfeeding resource book that supplements WIC breastfeeding education and facilitates identification of problem solving strategies around common breastfeeding barriers and concerns. If questions or problems arise, staff are trained to point to relevant pages and encourage participants to contact their WIC office for more specific advice, support and

community referral as needed in order to standardize the degree of support across participants in both groups. For example, when a participant has trouble with breastfeeding, staff refer her to the certified lactation consultant (CLC) 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.

Standard Care Control (SC). Staff check for participants' completion of nutritional monitoring and home visitation assessments. Participants in the SC group can earn up to $240 during the trial ($40 per completed monthly home visit assessment). Payments for the SC group are designed to maximize retention and to be comparable to the experimental SC+BFI group in the amount of attention and compensation to minimize demoralization of treatment assignment to SC as the control group. The difference between the SC+BFI and SC groups is that the payment in the SC group is tied to adherence to the home visit assessments in general and the nutritional monitoring (not to breastfeeding behavior), and, importantly, the provision of the adherence incentive is delayed to the end of 6-month duration and paid in a lump sum.

Standard Care plus Breastfeeding Incentives (SC+BFI). Participants in the SC+BFI group receive an escalating amount of monthly financial incentives contingent on observed breastfeeding delivered immediately after each monthly home assessment and bonus incentives with selection of full breastfeeding WIC food package at every three months during six months. In this group, the incentive amount participants receive is $20.00 for verified breastfeeding at the end of the Month 1 visit. This incentive increases by $10.00 every month of continued breastfeeding until the end of six months. The maximum potential earning is $270.00. The initial incentive value of $20 was determined in the pilot study[43] 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.[45] Participants also receive a bonus incentive of $50 for selecting the full breastfeeding food package from WIC at every three month WIC visit during the 6-month postpartum period.

Payment Procedures. After leaving a home assessment, blinded staff inform the un-blinded project coordinator by phone about a participant's completion of home assessment, effort completing the nutrition assessment, and whether there was verification of breastfeeding. In both groups, if a participant misses an appointment or does not demonstrate breastfeeding, she does not receive a payment. For those in the SC group, the coordinator notes completion of the home assessments during the first six months of the study and provides a total lump sum payment in the form of a gift card based on the number of completed appointments after the Month 6 assessment. Participants in the SC+BFI group receive dollar amount incentives deposited remotely on a pre-paid credit card. The coordinator immediately deposits the appropriate payment for breastfeeding verification at the end of each monthly home assessment and with each WIC food package selection every three months during the 6-month period.

Self-report and Anthropometric Assessments

All participants are asked to complete periodic self-report assessments at 1-, 3-, 6-, 9-, and 12-month postpartum. Because of monthly home visitations occurring in both study groups, periodic assessments at 1-, 3-, and 6-month postpartum are conducted by phone while the 9- and 12-month assessments are conducted at home. Assessments are conducted by blinded staff. If staff get unblinded to participant condition, a new, blinded staff will be assigned for future visits. Phone assessments take approximately 20 minutes, and in-person assessments take approximately 40 minutes. Phone assessments result in $20 compensation, and in-person

assessments result in $40 compensation in the form of a retail gift card. Assessments include interview questions on breastfeeding self-efficacy,[46] motivation, and support, maternal and infant health status, infant sleep,[47] postnatal depression,[48] and other psychosocial and behavioral status. In-person 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 in spreadsheet format as well as PDF files for preventing data loss and protecting the quality of data entry.

Fidelity Monitoring

Blinded staff are trained to the protocol, and are tested by the lead investigators to achieve ≥90% fidelity on essential components and processes related to home-based and telephone assessment protocols. Achievement is determined by observation of 10 items highlighted on a fidelity monitoring form. These ten items cover protocol adherence related to interview data collection, assessment procedures, and interview process and performance (e.g., rapport, protocol drift, etc.). The lead investigators assess maintenance of protocol adherence throughout the trial to ensure that staff maintain ≥90% fidelity. To achieve this goal, all phone assessments are audio-recorded for the fidelity monitoring purpose. At least 20% of recorded telephone assessments and home assessments 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.

Community Stakeholder Interviews

At the end of data collection, investigators will conduct individual interviews and focus group meetings with representatives from insurance companies including Medicaid

representatives, other healthcare industries, WIC and other community health organizations, and corporate representatives. Consent for data collection and audio-recording of interviews will be obtained. Discussion will be centered around what interviewees think of the findings on efficacy and cost of the intervention, strategies to sustain the approach in the community or provide an insurance reimbursement program among Medicaid recipients, and future directions of research that is meaningful to implement and sustain the approach in real world settings.

Cost Tracking

Costs of interventions, formula supplementation, and medical problems will be tracked based on market price. The intervention costs include staff time, transportations for home visitations, and monthly financial incentives. The formula supplementation purchased by participants and medically relevant information including hospitalizations, outpatient procedures and medications, and primary care office visits are filled out monthly. The source for determining medical costs is patient level resource utilization for both groups, converted to payer costs. All cost use 2019 as the base year.

Patient and Public Involvement

The development of the research question and outcome was partially informed by patients' interests in how breastfeeding changes maternal health outcomes. Patients from the preliminary study[43] guided the incentive schedule in the SC+BFI group used in the current protocol. Patients are not involved in the recruitment to and conduct of the study. The preliminary study[43] guided the monthly home visitation as the setting format based on patient feedback on the burden of the intervention.

Power Analysis

A sample of 70 participants per study group is sufficient to test the hypothesis that SC+BFI compared to SC results in 25% more mothers breastfeeding at 6-month postpartum (current average rate in Pennsylvania and Delaware [40.1%] vs. HP2020 goal [60.6%], requiring about at least a 20-percentage point improvement) and significant differences in infant outcomes (i.e., weight gain and emergency room visits) at 3-month postpartum, given a Type I error of 0.05, 80% power with a one-tailed test.[49] Power analysis based on the Monte Carlo approach[50] 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. To compensate for potential loss to follow up, we aim to enroll 84 participants per group for a total of 168 participants randomized in two study groups, and 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 (≥ 80%).[33,51]

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 randomization 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 intent-to-treat analysis treating missing values as non-breastfeeding status. In addition, the mixed

effect models will provide valid estimates of efficacy if the proportion of missing values is less than 10%.[52]

Primary outcome analysis. The primary outcome is the breastfeeding continuation rates at 1, 3, 6, 9, and 12-month postpartum. We hypothesize that the isolated effect of monthly incentives contingent on breastfeeding in the SC+BFI group will increase breastfeeding rates significantly at each time point compared to SC. We also hypothesize there will be significant increases in the rate of selecting the full breastfeeding food package from WIC in the SC+BFI group compared to SC. Logistic regression and generalized equation modeling (GEE) will be used to compare groups on the primary binary outcomes of point-prevalence of breastfeeding status at 1-, 3-, 6-, 9-, and 12-month postpartum; survival analyses will also be used to assess continuation. 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. The Cochran-Armitage Trend Test will be used to examine the trend of breastfeeding from 1-month through 6-month postpartum and from 1-month through 12-month postpartum.

Secondary outcome analyses. The secondary outcomes are infant physical and medical outcomes over 12-month postpartum. We hypothesize that compared to 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 (e.g., number of medical visits) and binary outcomes (e.g., occurrence of medical visits). If no significant differences in these outcomes were detected, 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% confidence intervals, 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 intra-individual and inter-individual differences. Further, we will utilize structural equation modeling (SEM) 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 standardized differences from weight for age z-scores based on the WHO Growth Reference Standards, which are sex-controlled.[53]

Moderator and mediation analyses. The Behavioral Ecological Model[54] will frame our moderator and mediation analyses. The model emphasizes how contingent incentives on breastfeeding, in addition to institutional breastfeeding support such as WIC and home-based individual support, influence continued breastfeeding rates.[55] *Moderator analyses*. We will use non-programmatic variables collected at baseline assessment, that are known to influence breastfeeding rates, including maternal age,[56] pre-pregnancy BMI,[57] postpartum depression,[57] smoking status,[57] previous breastfeeding experience,[58] initiation status,[59] and employment-related structural variables.[60–64] 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 hypothesize that participants in the SC+BFI group will evidence greater increases in the motivation and self-efficacy to breastfeed, which, in turn, will account for between-group differences in outcomes. Specifically, breastfeeding self-efficacy[65] and motivation to continue breastfeeding[66–68] on breastfeeding rates for 12-month postpartum will be examined using causal mediation models that are increasingly used in behavioral science for mediation analyses.[69]

Whether these variables mediate the intervention effect of incentives on continued breastfeeding rates at 6- and 12-month postpartum will be examined.

Stakeholder interviews. The audio-recordings will be transcribed and then verified for accuracy by the research team. Content and thematic analyses will be conducted with research staff for each interview or meeting under supervision by investigators. Transcripts will be coded by research staff. Two members of research staff will independently code and compare documents to ascertain agreement of coding to the text. Coding discrepancies will be discussed and resolved by investigators. Content analyses will examine how often a topic was mentioned and how many members participated in discussion for each topic. ATLAS.ti will be used to identify themes that come up in transcribed texts for topics related to social issues to do with breastfeeding, responses to the intervention and its findings, and implementation and sustainability of the intervention in the community. An initial list of codes and codebooks will be developed based on the categories congruent with the topic areas initially selected for interviews and meetings. A hierarchy of themes will be created to identify key themes and associated classes of themes to guide the content development of the proposed intervention.[70] Coding and analysis will continue iteratively to discover additional themes and issues that may emerge in analysis. All relevant information will be retrieved and examined for further coding designations.[71]

Preliminary health economic analysis. We will assess whether SC+BFI shows preliminary cost-effectiveness compared to SC. Effectiveness consists of two parts: 1) number of months for breastfeeding; 2) number of infant medical visits. Since the distribution of cost data is typically positively skewed, n*on-parametric bootstrapping,* a data-based simulation method for assessing statistical precision will be employed to analyze the mean cost difference and mean

effectiveness difference between two groups. Cost-effectiveness will be expressed as the incremental cost-effectiveness ratio (ICER), the difference in costs of SC+BFI and SC divided by the difference in effectiveness (number of months for breastfeeding or number of infant medical visits):

$$ICER = \frac{Cost_{SC+BFI} - Cost_{SC}}{Effectiveness_{SC+BFI} - Effectiveness_{SC}}$$

We will apply the results in this study to develop a breastfeeding transition, individual microsimulation model to estimate costs, effective unit (number of months for breastfeeding, and number of infant medical visits, separately) of SC+BFI. Further, uncertainty of the main results will be explored using one-way and probabilistic sensitivity analyses. Monte Carlo simulation will be performed to derive the difference in mean effectiveness and cost between the two groups. Stochastic variability will be assessed by bootstrap sampling participants in this study, and bias will be assessed using Bayesian probabilistic sensitivity analysis. We will also calculate incremental net monetary benefit (NMB), defined as the additional cost of implementing SC+BFI subtracted from the additional effect of treatment effectiveness (e.g., difference in number of month for breastfeeding or number of infant medical visits), valued in dollars (NMB = $\lambda * E - C$, *Incremental* NMB = $\lambda * \Delta E - \Delta C$). Where λ is the willingness-to-pay threshold (for example, $500 per infant medical visit), E is the effectiveness in one study arm, ΔE is the difference in effectiveness between study arms, C is the cost in one study arm, and ΔC is the difference in costs.

Trial Status

Trial implementation is ongoing.

Dissemination

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 behavioral intervention during 12-month postpartum. Community stakeholders and policy makers will then be informed of trial findings, cost-effectiveness, 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.

Figure legend

Figure 1. BOOST trial consort diagram

Funding source

The study was supported by an NIH grant, R01HD094877.

Authors' contributions:

- Yukiko Washio has contributed to write the initial draft and finalize the draft of manuscript.
- Bradley Collins and Alison Hunt-Johnson have contributed to finalize the study protocol and review the manuscript.
- Zugui Zhang contributed to statistical methods of the study protocol.
- Gail Herrine, Matthew Hoffman, and Linda Kilby contributed to the clinical and recruitment aspect of the study protocol.
- Donna Chapman and Lydia Furman consulted on the development of overall study protocol as well as review of the manuscript.

Data Sharing Statements

We will make the data and associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify an individual participant; (2) a commitment to securing the data using appropriate

computer technology; and (3) a commitment to destroying or returning the data after analyses are completed.

REFERENCES

1. WHO. WHO | Breastfeeding. 2018. https://www.who.int/nutrition/topics/exclusive_breastfeeding/en/. Accessed March 16, 2019.

2. Wagner C, Greer F, Heinig M, Cohen R, Cook D. Recommendations for Preventive Pediatric Health Care. *Pediatrics*. 2007;120(6):1376-1376. doi:10.1542/peds.2007-2901

3. NEOVITA Study Group. Timing of initiation, patterns of breastfeeding, and infant survival: prospective analysis of pooled data from three randomised trials. *Lancet Glob Heal*. 2016;4(4):e266-e275. doi:10.1016/S2214-109X(16)00040-1

4. Ip S, Chung M, Raman G, et al. Breastfeeding and Maternal and Infant Health Outcomes in Developed Countries: Evidence Report/Technology Assessment, No. 153. 2007.

5. DHHS. *The Surgeon General's Call to Action to Support Breastfeeding*. Washington DC; 2011.

6. Howie PW, Forsyth JS, Ogston SA, Clark A, Florey CD. Protective effect of breast feeding against infection. *BMJ*. 1990;300(6716):11-16.

7. Patel D V, Bansal SC, Nimbalkar AS, Phatak AG, Nimbalkar SM, Desai RG. Breastfeeding Practices, Demographic Variables, and Their Association with Morbidities in Children. *Adv Prev Med*. 2015;2015:892825. doi:10.1155/2015/892825

8. Wang L, Collins C, Ratliff M, Xie B, Wang Y. Breastfeeding Reduces Childhood Obesity Risks. *Child Obes*. 2017;13(3):197-204. doi:10.1089/chi.2016.0210

9. Ip S, Chung M, Raman G, et al. Breastfeeding and maternal and infant health outcomes in developed countries. *Evid Rep Technol Assess (Full Rep)*. 2007;(153):1-186. http://www.ncbi.nlm.nih.gov/pubmed/17764214. Accessed August 6, 2019.

10. Sadauskaite-Kuehne V, Ludvigsson J, Padaiga Z, Jasinskiene E, Samuelsson U. Longer breastfeeding is an independent protective factor against development of type 1 diabetes mellitus in childhood. *Diabetes Metab Res Rev*. 2004;20(2):150-157. doi:10.1002/dmrr.425

11. AHRQ. *Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries*.; 2018. www.ahrq.gov. Accessed April 1, 2019.

12. Bartick M, Reinhold A. The Burden of Suboptimal Breastfeeding in the United States: A Pediatric Cost Analysis. *Pediatrics*. 2010;125(5):e1048-e1056. doi:10.1542/peds.2009-1616

13. Bartick MC, Stuebe AM, Schwarz EB, Luongo C, Reinhold AG, Foster EM. Cost Analysis of Maternal Disease Associated With Suboptimal Breastfeeding. *Obstet Gynecol*. 2013;122(1):111-119. doi:10.1097/AOG.0b013e318297a047

14. Erdmann D. Want to Save Money? Breastfeed! - Breastfeeding Support & Supplies of Omaha.

15. CDC. Breastfeeding Report Card | Breastfeeding | CDC. https://www.cdc.gov/breastfeeding/data/reportcard.htm. Published 2018. Accessed April

9, 2019.

16. Ahluwalia IB, Morrow B, Hsia J. Why do women stop breastfeeding? Findings from the Pregnancy Risk Assessment and Monitoring System. *Pediatrics*. 2005;116(6):1408-1412. doi:10.1542/peds.2005-0013

17. Forste R, Weiss J, Lippincott E. The decision to breastfeed in the United States: does race matter? *Pediatrics*. 2001;108(2):291-296. doi:10.1542/peds.108.2.291

18. Jones KM, Power ML, Queenan JT, Schulkin J. Racial and ethnic disparities in breastfeeding. *Breastfeed Med*. 2015;10(4):186-196. doi:10.1089/bfm.2014.0152

19. Thulier D, Mercer J. Variables Associated With Breastfeeding Duration. *J Obstet Gynecol Neonatal Nurs*. 2009;38(3):259-268. doi:10.1111/j.1552-6909.2009.01021.x

20. Di Manno L, Macdonald JA, Knight T. The Intergenerational Continuity of Breastfeeding Intention, Initiation, and Duration: A Systematic Review. *Birth*. 2015;42(1):5-15. doi:10.1111/birt.12148

21. Lauer E, Armenti K, Henning M, Sirois L. Identifying Barriers and Supports to Breastfeeding in the Workplace Experienced by Mothers in the New Hampshire Special Supplemental Nutrition Program for Women, Infants, and Children Utilizing the Total Worker Health Framework. *Int J Environ Res Public Health*. 2019;16(4):529. doi:10.3390/ijerph16040529

22. Lee HJ, Elo IT, McCollum KF, Culhane JF. Racial/Ethnic Differences in Breastfeeding Initiation and Duration Among Low-income, Inner-city Mothers. *Soc Sci Q*. 2009;90(5):1251-1271. doi:10.1111/j.1540-6237.2009.00656.x

23. Chapman DJ, Perez-Escamilla R. Breastfeeding among minority women: moving from risk factors to interventions. *Adv Nutr*. 2012;3(1):95-104. doi:http://doi.org/10.3945/an.111.001016

24. National Academies of Sciences E and M, Division H and M, Board F and N, Packages C to RWF. *Review of WIC Food Packages*. National Academies Press (US); 2017. doi:10.17226/23655

25. WIC. *Review of WIC Food Packages: Improving Balance and Choice*.; 2017.

26. Langellier BA, Chaparro MP, Wang MC, Koleilat M, Whaley SE. The New Food Package and Breastfeeding Outcomes Among Women, Infants, and Children Participants in Los Angeles County. *Am J Public Health*. 2014;104(S1):S112-S118. doi:10.2105/AJPH.2013.301330

27. Howell EA, Bodnar-Deren S, Balbierz A, Parides M, Bickell N. An intervention to extend breastfeeding among black and Latina mothers after delivery. *Am J Obstet Gynecol*. 2014;210(3):239.e1-5. doi:10.1016/j.ajog.2013.11.028

28. Chapman DJ. Lessons Learned from African American Women who Breastfeed. *J Hum Lact*. 2015;31(1):15-16. doi:10.1177/0890334414560731

29. Chung M, Ip S, Yu W, et al. Interventions in Primary Care to Promote Breastfeeding. *Evid Synth*. 2008;66.

30. CDC. *The CDC Guide to Breastfeeding Interventions*.; 2005.

31. Cronenwett LR, Reinhardt R. Support and breastfeeding: a review. *Birth*. 1987;14(4):199-203.

32. Higgins ST, Delaney DD, Budney AJ, et al. A behavioral approach to achieving initial cocaine abstinence. *Am J Psychiatry*. 1991;148(9):1218-1224.

33. Higgins ST, Washio Y, Heil SH, et al. Financial incentives for smoking cessation among pregnant and newly postpartum women. *Prev Med (Baltim)*. 2012;55 Suppl:S33--40. doi:10.1016/j.ypmed.2011.12.016

34. Volpp KG, John LK, Troxel AB, Norton L, Fassbender J, Loewenstein G. Financial incentive-based approaches for weight loss: a randomized trial. *JAMA*. 2008;300(22):2631-2637. doi:10.1001/jama.2008.804

35. Finkelstein EA, Brown DS, Brown DR, Buchner DM. A randomized study of financial incentives to increase physical activity among sedentary older adults. *Prev Med (Baltim)*. 2008;47(2):182-187. doi:10.1016/j.ypmed.2008.05.002

36. Lagarde M, Haines A, Palmer N. Conditional cash transfers for improving uptake of health interventions in low- and middle-income countries: a systematic review. *JAMA*. 2007;298(16):1900-1910. doi:10.1001/jama.298.16.1900

37. Volpp KG, Troxel AB, Pauly M V., et al. A Randomized, Controlled Trial of Financial Incentives for Smoking Cessation. *N Engl J Med*. 2009;360(7):699-709. doi:10.1056/NEJMsa0806819

38. Kimmel SE, Troxel AB, French B, et al. A randomized trial of lottery-based incentives and reminders to improve warfarin adherence: the Warfarin Incentives (WIN2) Trial. *Pharmacoepidemiol Drug Saf*. 2016;25(11):1219-1227. doi:10.1002/pds.4094

39. Moran VH, Morgan H, Rothnie K, et al. Incentives to promote breastfeeding: a systematic

review. *Pediatrics*. 2015;135(3):e687-702. doi:10.1542/peds.2014-2221

40. Pugh LC, Milligan RA. Nursing intervention to increase the duration of breastfeeding. *Appl Nurs Res*. 1998;11(4):190-194.

41. Thomson G, Dykes F, Hurley MA, Hoddinott P. Incentives as connectors: insights into a breastfeeding incentive intervention in a disadvantaged area of North-West England. *BMC Pregnancy Childbirth*. 2012;12(1):22. doi:10.1186/1471-2393-12-22

42. Relton C, Strong M, Thomas KJ, et al. Effect of Financial Incentives on Breastfeeding. *JAMA Pediatr*. December 2017:e174523. doi:10.1001/jamapediatrics.2017.4523

43. Washio Y, Humphreys M, Colchado E, et al. Incentive-based Intervention to Maintain Breastfeeding Among Low-income Puerto Rican Mothers. *Pediatrics*. 2017;139(3):e20163119. doi:10.1542/peds.2016-3119

44. Matts JP, Lachin JM. Properties of permuted-block randomization in clinical trials. *Control Clin Trials*. 1988;9(4):327-344. http://www.ncbi.nlm.nih.gov/pubmed/3203524. Accessed August 13, 2019.

45. Higgins K. ST& S. *Introduction*. (S. T. Higgins & S. H. Heil KS, ed.). New York, London: Guilford Press; 2008.

46. Dennis C-L, Faux S. Development and psychometric testing of the Breastfeeding Self-Efficacy Scale. *Res Nurs Health*. 1999;22(5):399-409. doi:10.1037/0003-066x.37.2.12210.1037/11144-000.2006-09558-00010.1037/11144-00010.1002/(sici)1098-240x(199910)22:5<399::aid-nur6>3.0.co;2-4

47. Sadeh A. A brief screening questionnaire for infant sleep problems: validation and

findings for an Internet sample. *Pediatrics*. 2004;113(6):e570-7. http://www.ncbi.nlm.nih.gov/pubmed/15173539. Accessed November 28, 2018.

48. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry*. 1987;150:782-786. doi:10.1192/bjp.150.6.782

49. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*.; 1977.

50. Gelman, A., Hill J. *Data Analysis Using Regression and Multilevel/Hierarchical Models*. Cambridge: Cambridge University Press.; 2006.

51. Sharps P, Alhusen JL, Bullock L, et al. Engaging and retaining abused women in perinatal home visitation programs. *Pediatrics*. 2013;132 Suppl:S134-9. doi:10.1542/peds.2013-1021L

52. Bennett DA. How can I deal with missing data in my study? *Aust N Z J Public Health*. 2001;25(5):464-469.

53. WHO. WHO | Weight-for-age. *WHO*. 2016.

54. Hovell, M. F., Wahlgren, D. R., & Gehrman C. The Behavioral Ecological Model: Integrating public health and behavioral science. In: R. J. DiClemente, R. Crosby & MK, ed. *New and Emerging Theories in Health Promotion Practice & Research*. San Francisco CA: Jossey-Bass Inc; 2002:347-385.

55. Sallis, J.F., Owen, N., Fisher EB. Ecological models of health behavior. In: Glanz, K., Rimer, B.K., Viswanath K, ed. *Health Behavior: Theory, Research, and Practice*. San Francisco CA: Jossey-Bass; 2015:465-485.

56. McKechnie AC, Tluczek A, Henriques JB. Maternal Variables Influencing Duration of Breastfeeding Among Low-Income Mothers. *Infant Child Adolesc Nutr*. 2009;1(3):126-132. doi:10.1177/1941406409334379

57. Wallwiener S, Müller M, Doster A, et al. Predictors of impaired breastfeeding initiation and maintenance in a diverse sample: what is important? *Arch Gynecol Obstet*. December 2015. doi:10.1007/s00404-015-3994-5

58. McKinney CO, Hahn-Holbrook J, Chase-Lansdale PL, et al. Racial and Ethnic Differences in Breastfeeding. *Pediatrics*. 2016;138(2):e20152388-e20152388. doi:10.1542/peds.2015-2388

59. Felice JP, Cassano PA, Rasmussen KM. Pumping human milk in the early postpartum period: its impact on long-term practices for feeding at the breast and exclusively feeding human milk in a longitudinal survey cohort. *Am J Clin Nutr*. 2016;103(5):1267-1277. doi:10.3945/ajcn.115.115733

60. Thomas-Jackson SC, Bentley GE, Keyton K, Reifman A, Boylan M, Hart SL. In-hospital Breastfeeding and Intention to Return to Work Influence Mothers' Breastfeeding Intentions. *J Hum Lact*. August 2015. doi:10.1177/0890334415597636

61. Smith-Gagen J, Hollen R, Walker M, Cook DM, Yang W. Breastfeeding Laws and Breastfeeding Practices by Race and Ethnicity. *Women's Heal Issues*. 2014;24(1):e11-e19. doi:10.1016/j.whi.2013.11.001

62. Huang R, Yang M. Paid maternity leave and breastfeeding practice before and after California's implementation of the nation's first paid family leave program. *Econ Hum*

Biol. 2015;16:45-59. doi:10.1016/j.ehb.2013.12.009

63. Monteiro FR, Buccini G dos S, Venâncio SI, da Costa THM. Influence of maternity leave on exclusive breastfeeding. *J Pediatr (Rio J)*. 2017;93(5):475-481. doi:10.1016/j.jped.2016.11.016

64. Mirkovic KR, Perrine CG, Scanlon KS, Grummer-Strawn LM. Maternity Leave Duration and Full-time/Part-time Work Status Are Associated with US Mothers' Ability to Meet Breastfeeding Intentions. *J Hum Lact*. 2014;30(4):416-419. doi:10.1177/0890334414543522

65. Chan MY, Ip WY, Choi KC. The effect of a self-efficacy-based educational programme on maternal breast feeding self-efficacy, breast feeding duration and exclusive breast feeding rates: A longitudinal study. *Midwifery*. 2016;36:92-98. doi:10.1016/j.midw.2016.03.003

66. de la Mora, A., Russell, D. W., Dungy, C. I., Losch, M., & Dusdieker L. The Iowa Infant Feeding Attitude Scale: Analysis of reliability and validity. *J Appl Soc Psychol*. 1999;29(11):2362-2380.

67. Barbosa CE, Masho SW, Carlyle KE, Mosavel M. Factors Distinguishing Positive Deviance Among Low-Income African American Women: A Qualitative Study on Infant Feeding. *J Hum Lact*. November 2016. doi:10.1177/0890334416673048

68. Lange A, Nautsch A, Weitmann K, Ittermann T, Heckmann M. Breastfeeding motivation in Pomerania: Survey of neonates in Pomerania (SNiP-Study). *Int Breastfeed J*. 2016;12(1):3. doi:10.1186/s13006-016-0093-6

69. Imai, K., Keele, L., Tingley D. A general approach to causal mediation analysis. *Psychol Methods*. 2010;15(4):309-334.

70. Villarruel, AM, Jemmolt, LS, Howard, M, Taylor, L, Bush E. Practice what we preach? HIV knowledge, beliefs, and behaviors of adolescents and adolescent peer educators. *J Assoc Nurses AIDS Care JANAC*. 1998;9(5):61-72.

71. Weitzman E, Miles M. *Computer Programs for Qualitative Data Analysis*. Thousand Oaks, CA: Sage; 1995.

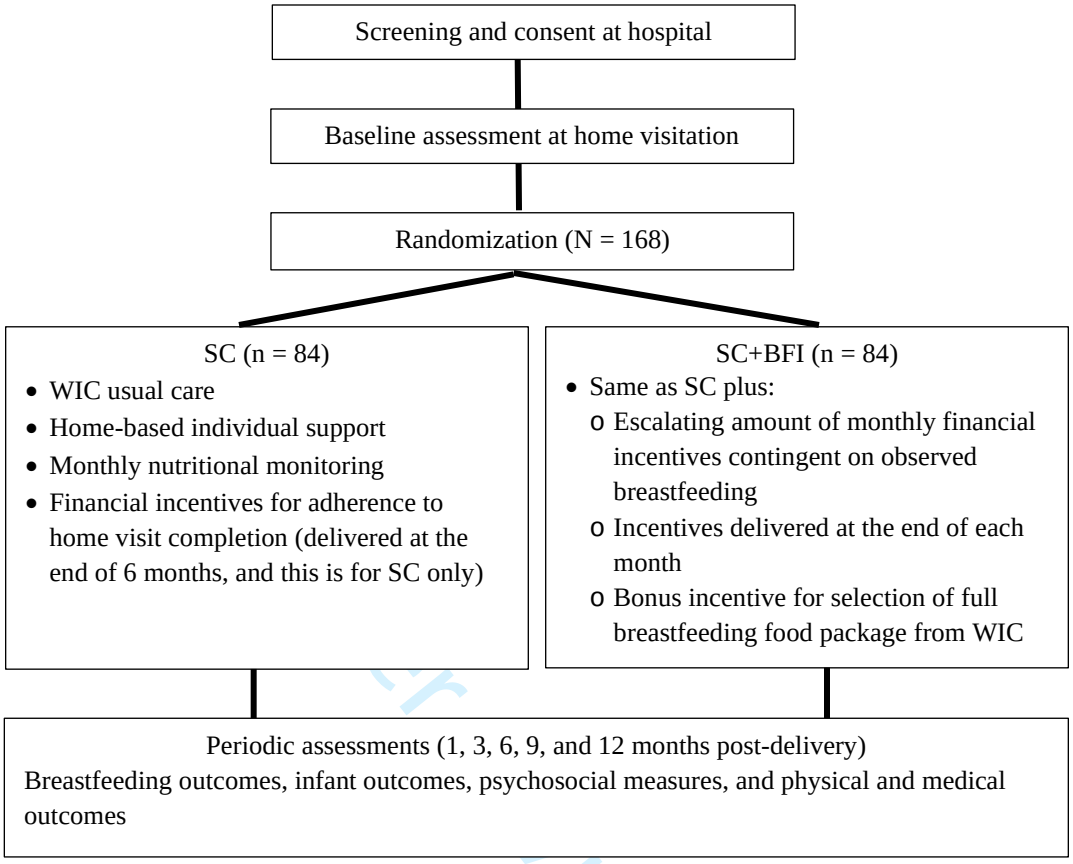

Figure 1. BOOST trial consort diagram

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/A
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and	7

		other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7

Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	7
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	12
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9,10
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1, 11
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque,	8

		sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8,9
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8,11,12

Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10,11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	8, 12
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-17
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14-17
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further	7

		details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	7
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	7
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	7
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	7

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	8
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	18
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18

Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

BMJ Open

Individual Breastfeeding Support with Contingent Incentives for Low-Income Mothers in the United States: The "BOOST" Randomized Controlled Trial Protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034510.R1
Article Type:	Protocol
Date Submitted by the Author:	17-Mar-2020
Complete List of Authors:	Washio, Yukiko; RTI International, Collins, Bradley N; Temple University , College of Public Health Hunt-Johnson, Alison; Temple University, Social and Behavioral Sciences Zhang, Zugui; Christiana Care Health System, Obstetrics and Gynecology Department Herrine, Gail; Temple University Hospital, Obstetrics and Gynecology Department Hoffman, Matthew ; Christiana Care Health System, Obstetrics and Gynecology Department Kilby, Linda Chapman, Donna; Springfield College, Department of Exercise Science and Athletic Training Furman, Lydia; Rainbow Babies and Children's Hospital, Pediatrics
Primary Subject Heading:	Public health
Secondary Subject Heading:	Public health
Keywords:	breastfeeding duration, WIC, financial incentives, home-based settings

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Individual Breastfeeding Support with Contingent Incentives for Low-Income Mothers in the United States: The "BOOST" Randomized Controlled Trial Protocol

Yukiko Washio, Ph.D.[1]; Bradley N. Collins, Ph.D.[2]; Alison R. Hunt-Johnson, B.S.[2]; Zugui Zhang, Ph.D.[3]; Gail Herrine, M.D.[4]; Matthew K. Hoffman, M.D., M.P.H.[3]; Linda M. Kilby, Ph.D., R.D., L.D.N.[5]; Donna Chapman, Ph.D., R.D.[6]; Lydia Furman, M.D.[7]

Affiliations: RTI International, Research Triangle Park, NC, U.S.A.[1]; Temple University, College of Public Health, Philadelphia, PA, U.S.A.[2]; Christiana Care Health System, Obstetrics and Gynecology Department, Newark, DE, U.S.A.[3]; Department of Obstetrics, Gynecology and Reproductive Sciences, Temple University Lewis Katz School of Medicine, Philadelphia, PA, U.S.A.[4]; N.O.R.T.H., Inc—Philadelphia WIC program, Philadelphia, PA, U.S.A. [5]; Springfield College, Department of Exercise Science and Athletic Training, Springfield, MA, U.S.A.[6]; University Hospitals Rainbow Babies and Children's Hospital and Case Western Reserve University School of Medicine, Department of Pediatrics, Cleveland, OH, U.S.A.[7]

Author Emails: Yukiko Washio [ywashio@rti.org]; Bradley N. Collins [collinsb@temple.edu]; Zugui Zhang [ZZhang@christianacare.org]; Gail Herrine [Gail.Herrine@tuhs.temple.edu]; Matthew K. Hoffman [MHoffman@christianacare.org]; Linda M. Kilby [lkilby@northwic.org]; Donna Chapman [dchapman2@springfieldcollege.edu]; Lydia Furman [Lydia.Furman@uhhospitals.org]

Address correspondence to: Yukiko Washio, RTI International, 3040 E. Cornwallis rd. PO Box 12194, Research Triangle Park, NC, 27709, U.S.A., [ywashio@rti.org], (phone) 919-485-2794

Financial disclosure: The author has no financial relationships relevant to this article to disclose.

Conflict of interest: The author has no conflicts of interest to disclose.

Word count: 4,453

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 support 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 Program for Women, Infants, and Children (WIC). **Methods and Analysis.** This trial uses a parallel randomized controlled trial. This trial is conducted at two sites in separate states in the United States. Mothers who were enrolled in WIC and initiated breastfeeding are eligible. Participants (N = 168) are randomized 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 to SC. The primary outcome is the rate of any breastfeeding over 12 months. Randomization 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 (IRB) has approved the study protocol (Pro00033168). Findings will be disseminated to our participants, scientific communities, public health officials, and any other interested community members.

Trial Registration. NCT03964454
Funding. R01HD094877

Key words: breastfeeding, WIC, financial incentives, home visits

Strengths and limitations

- Study recruitment occurs across two separate states in the United States targeting different underserved populations and providing different styles of breastfeeding support, maximizing generalizability of results.
- Study uses a two-group parallel randomized 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 minimize protocol drift among staff.
- Due to the nature of the intervention, participants are not blinded to treatment assignment; therefore there are risks to demoralize 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.

Introduction

Breastfeeding Benefits and Prevalence

Exclusive breastfeeding is recommended for the first six 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,[4,5] non-specific gastroenteritis,[4,6] diarrhea,[5,7] atopic dermatitis, asthma (young children),[4] obesity,[8,9] type 1 and 2 diabetes,[9,10] childhood leukemia, sudden infant death syndrome (SIDS), and necrotizing 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 $13 billion could be saved annually in the U.S., 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 programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and Medicaid may also benefit from increased rates of breastfeeding given that they spend over $600 million per year to give free formula to mothers.[14]

In 2015, over 57% of U.S. mothers breastfed through six months with approximately 25% of infants exclusively breastfed.[15] Breastfeeding rates in the U.S. have increased annually and are getting very close to the Healthy People 2020 Objectives.[15] Unfortunately, disparities in breastfeeding rates exist in the U.S., and there are many individual- 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 program is the only federally-funded program in the U.S. 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 five.[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 dyad;[24] however, the breastfeeding rates have not significantly improved with the different WIC food packages. [25]

Similar to the WIC program for postpartum mothers, other behavioral interventions for breastfeeding emphasize 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 postpartum[26] and may prolong breastfeeding duration among low- 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 behavior 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 low-income, 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 behaviors have been effective in promoting healthier habits and health behavior change when immediately delivered contingent on verified occurrence of the outcome-centered behavior of interest. Such effects have been observed in studies promoting drug and smoking abstinence,[31,32] weight loss or physical activity,[33,34] immunization,[35] 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 randomized controlled trial in the UK[41] offered shopping vouchers based on self-reported breastfeeding status verified by a clinician's signature across five timepoints during 6 months postpartum for a total potential earning of $250. The approach significantly increased breastfeeding rates during early postpartum up to 8 weeks compared to usual care with community-based breastfeeding support.[41]

A recent, small randomized 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 behavior 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 $270 during their participation. Compared to the control group with WIC breastfeeding support only, the incentive group demonstrated significantly higher breastfeeding rates at 1-, 3-, 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 generalizability 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 randomized 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 (e.g., demographics, depressive symptoms, smoking status) or mediate (e.g., motivation and breastfeeding self-efficacy) the effect of the intervention on breastfeeding and infant outcomes.

Study Design and Setting

The study is a multi-site, parallel randomized 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 randomized 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) Standard Care plus Incentives (SC+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 June 19, 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 randomization; (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 hospitalized for severe postpartum medical issues, who have ongoing illicit drug use issues, who had a psychiatric hospitalization within the last three months, or who currently have suicidal thoughts or attempts are excluded from the study enrollment.

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 one-to-two weeks to complete the baseline assessment and enrollment process.

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

Randomization

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 maximize internal validity. Computer-generated random numbers were generated by a biostatistician (Z.Z.), and concealed allocation to random group assignments is completed in an automated electronic system. The un-blinded 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 program. Blinded staff provide home visits for support and brief assessments, periodic phone assessments at 1-, 3-, and 6-month postpartum, and in-home assessments at 9- 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 breastmilk, 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 counseling, 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 three 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 enrollment 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 standardize 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 (CLC) 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.

Standard Care Control (SC). 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 $240 during the trial for completion of assessments during home visits ($40 per completed monthly home visit). The financial compensation in the SC group is necessary to maximize retention and adherence to the monthly assessment schedule, provide comparable remuneration as the SC+BFI group, and minimize demoralization of SC group participants following treatment assignment. All participants are informed of the differential group procedures during the pre-randomization consent process.

Standard Care plus Breastfeeding Incentives (SC+BFI). Participants in the SC+BFI group are asked to complete the same in-home and telephone assessments as the SC group. After randomization, 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 $20.00 incentive payment for verified breastfeeding at the end of the

Month 1 visit. Then, the incentive increases by $10.00 every month of continued breastfeeding until the end of 6 months. The initial incentive value of $20 was determined in the pilot study[42] 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 $50 for selecting the full breastfeeding food package from WIC at baseline, 3- and 6-month respectively. The maximum potential earning of contingent incentives is $270.00 for monthly breastfeeding verification and up to $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 behavior. (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 pre-paid 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-, 3-, 6-, 9-, and 12-month postpartum. Self-report assessments via telephone occur at 1-, 3-, and 6-month postpartum whereas 9- and 12-month self-report and anthropometric assessments are conducted at home. Assessments are conducted by blinded staff. Phone assessments take approximately 20 minutes, and in-home assessments take approximately 40 minutes.

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 behavioral 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: $20 for phone assessments and $40 compensation for assessments collected in home. A bonus compensation is tied to in-home assessments to boost adherence: $60 for participants who attend all monthly home visits and in-home assessments; $40 for those who miss one monthly home visit or in-home assessment; and $20 for those who miss two 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 ≥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 ≥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.

Un-blinded 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 study[42] 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 study[42] 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 to the SC group, the BFI+SC group will have higher rates of any level of breastfeeding at each time point. To compensate for potential loss to follow up, we aim to enroll 84 participants per group for a total of 168 participants randomized 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 (≥ 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 approach[49] 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 randomization 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 intent-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-month postpartum. We hypothesize 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 to SC. We also hypothesize there will be significant increases in the rate of selecting the full breastfeeding food package from WIC in the SC+BFI group compared to SC. Logistic regression and generalized equation modeling (GEE) will be used to compare groups on the primary binary outcomes of point-prevalence of breastfeeding status at 1-, 3-, 6-, 9-, 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 through 12-month postpartum. Duration of breastfeeding will be analyzed 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 hypothesize that compared to 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 (e.g.,

number of medical visits) and binary outcomes (e.g., 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% confidence intervals, 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 intra-individual and inter-individual differences. Further, we will utilize structural equation modeling (SEM) 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 standardized differences from weight for age z-scores based on the WHO Growth Reference Standards, which are sex-controlled.[51]

Moderator and mediation analyses. The Behavioral Ecological Model[52] will frame our moderator and mediation analyses. The model emphasizes 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] pre-pregnancy BMI,[56] postpartum depression,[56] smoking status,[56] previous breastfeeding experience,[57] initiation status,[58] 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 hypothesize that participants in the SC+BFI group will evidence greater increases in the theoretically important social and behavioral constructs (e.g.,

self-efficacy[64] 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 behavioral 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 randomization 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 behavior). One potential consequence of this design is demoralization of participants in the SC group who are not receiving additional incentives related to their breastfeeding behavior (i.e., 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 breastfeeding incentives 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 behavior than any breastfeeding.

Trial Status

Trial implementation is ongoing, and the trial has been registered at ClinicalTrials.Gov (NCT03964454).

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 authorization agreement was obtained by IRBs in each study site. A Data and Safety Monitoring Board (DSMB) was composed with professionals in statistics, pediatrics, breastfeeding, and community-based behavioral 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 behavioral intervention during 12 months postpartum. 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.

Figure legend

Figure 1. BOOST trial consort diagram

Funding source

The study was supported by an NIH grant, R01HD094877.

Authors' contributions:

- Yukiko Washio contributed to the design and conceptualization of the work, design and implementation of the study protocols, and overall project oversight at both sites, drafted the manuscript, and finalized it for submission.
- Bradley Collins contributed to the design and conceptualization 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.
- Alison Hunt-Johnson 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.
- Zugui Zhang contributed to the development of the study's analytic methods and critically reviewed the manuscript adding important statistical content.
- Gail Herrine, Matthew Hoffman, and Linda Kilby contributed to the development of the recruitment protocols and referral resources and critically reviewed the manuscript.
- Donna Chapman and Lydia Furman 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.

Data Sharing Statements

A limited data set in which names and other personal health identifiers are removed, as defined by the Health Insurance Portability and Accountability Act (HIPAA), will be supplied to researchers on request. The data will be made available after the publication of the study results. Analytic files will be collected in Redcap and then prepared in SPSS, R, SAS, or STATA, with online codebooks giving the variable name, label, type, format, positions, consistency codes, and, if applicable, values and value labels. Requesting access to data will involve drafting an abstract, checking the feasibility relative to the available data, and then seeking the permission of the principal investigator and the team for review, if appropriate. The data sets will be ready for use and can be converted to other analytic tools.

REFERENCES

1. WHO. WHO | Breastfeeding. 2018. https://www.who.int/nutrition/topics/exclusive_breastfeeding/en/. Accessed March 16, 2019.

2. Wagner C, Greer F, Heinig M, Cohen R, Cook D. Recommendations for Preventive Pediatric Health Care. *Pediatrics*. 2007;120(6):1376-1376. doi:10.1542/peds.2007-2901

3. NEOVITA Study Group. Timing of initiation, patterns of breastfeeding, and infant survival: prospective analysis of pooled data from three randomised trials. *Lancet Glob Heal*. 2016;4(4):e266-e275. doi:10.1016/S2214-109X(16)00040-1

4. Ip S, Chung M, Raman G, et al. Breastfeeding and Maternal and Infant Health Outcomes in Developed Countries: Evidence Report/Technology Assessment, No. 153. 2007.

5. DHHS. *The Surgeon General's Call to Action to Support Breastfeeding*. Washington DC; 2011.

6. Howie PW, Forsyth JS, Ogston SA, Clark A, Florey CD. Protective effect of breast feeding against infection. *BMJ*. 1990;300(6716):11-16.

7. Patel D V, Bansal SC, Nimbalkar AS, Phatak AG, Nimbalkar SM, Desai RG. Breastfeeding Practices, Demographic Variables, and Their Association with Morbidities in Children. *Adv Prev Med*. 2015;2015:892825. doi:10.1155/2015/892825

8. Wang L, Collins C, Ratliff M, Xie B, Wang Y. Breastfeeding Reduces Childhood Obesity Risks. *Child Obes*. 2017;13(3):197-204. doi:10.1089/chi.2016.0210

9. Ip S, Chung M, Raman G, et al. Breastfeeding and maternal and infant health outcomes in developed countries. *Evid Rep Technol Assess (Full Rep)*. 2007;(153):1-186. http://www.ncbi.nlm.nih.gov/pubmed/17764214. Accessed August 6, 2019.

10. Sadauskaite-Kuehne V, Ludvigsson J, Padaiga Z, Jasinskiene E, Samuelsson U. Longer breastfeeding is an independent protective factor against development of type 1 diabetes

mellitus in childhood. *Diabetes Metab Res Rev*. 2004;20(2):150-157. doi:10.1002/dmrr.425

11. AHRQ. *Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries*.; 2018. www.ahrq.gov. Accessed April 1, 2019.

12. Bartick M, Reinhold A. The Burden of Suboptimal Breastfeeding in the United States: A Pediatric Cost Analysis. *Pediatrics*. 2010;125(5):e1048-e1056. doi:10.1542/peds.2009-1616

13. Bartick MC, Stuebe AM, Schwarz EB, Luongo C, Reinhold AG, Foster EM. Cost Analysis of Maternal Disease Associated With Suboptimal Breastfeeding. *Obstet Gynecol*. 2013;122(1):111-119. doi:10.1097/AOG.0b013e318297a047

14. Erdmann D. Want to Save Money? Breastfeed! - Breastfeeding Support & Supplies of Omaha.

15. CDC. Breastfeeding Report Card | Breastfeeding | CDC. https://www.cdc.gov/breastfeeding/data/reportcard.htm. Published 2018. Accessed April 9, 2019.

16. Ahluwalia IB, Morrow B, Hsia J. Why do women stop breastfeeding? Findings from the Pregnancy Risk Assessment and Monitoring System. *Pediatrics*. 2005;116(6):1408-1412. doi:10.1542/peds.2005-0013

17. Forste R, Weiss J, Lippincott E. The decision to breastfeed in the United States: does race matter? *Pediatrics*. 2001;108(2):291-296. doi:10.1542/peds.108.2.291

18. Jones KM, Power ML, Queenan JT, Schulkin J. Racial and ethnic disparities in

breastfeeding. *Breastfeed Med*. 2015;10(4):186-196. doi:10.1089/bfm.2014.0152

19. Thulier D, Mercer J. Variables Associated With Breastfeeding Duration. *J Obstet Gynecol Neonatal Nurs*. 2009;38(3):259-268. doi:10.1111/j.1552-6909.2009.01021.x

20. Di Manno L, Macdonald JA, Knight T. The Intergenerational Continuity of Breastfeeding Intention, Initiation, and Duration: A Systematic Review. *Birth*. 2015;42(1):5-15. doi:10.1111/birt.12148

21. Lee HJ, Elo IT, McCollum KF, Culhane JF. Racial/Ethnic Differences in Breastfeeding Initiation and Duration Among Low-income, Inner-city Mothers. *Soc Sci Q*. 2009;90(5):1251-1271. doi:10.1111/j.1540-6237.2009.00656.x

22. Lauer E, Armenti K, Henning M, Sirois L. Identifying Barriers and Supports to Breastfeeding in the Workplace Experienced by Mothers in the New Hampshire Special Supplemental Nutrition Program for Women, Infants, and Children Utilizing the Total Worker Health Framework. *Int J Environ Res Public Health*. 2019;16(4):529. doi:10.3390/ijerph16040529

23. Chapman DJ, Perez-Escamilla R. Breastfeeding among minority women: moving from risk factors to interventions. *Adv Nutr*. 2012;3(1):95-104. doi:http://doi.org/10.3945/an.111.001016

24. National Academies of Sciences E and M, Division H and M, Board F and N, Packages C to RWF. *Review of WIC Food Packages*. National Academies Press (US); 2017. doi:10.17226/23655

25. Langellier BA, Chaparro MP, Wang MC, Koleilat M, Whaley SE. The New Food Package

and Breastfeeding Outcomes Among Women, Infants, and Children Participants in Los Angeles County. *Am J Public Health*. 2014;104(S1):S112-S118. doi:10.2105/AJPH.2013.301330

26. Howell EA, Bodnar-Deren S, Balbierz A, Parides M, Bickell N. An intervention to extend breastfeeding among black and Latina mothers after delivery. *Am J Obstet Gynecol*. 2014;210(3):239.e1-5. doi:10.1016/j.ajog.2013.11.028

27. Chapman DJ. Lessons Learned from African American Women who Breastfeed. *J Hum Lact*. 2015;31(1):15-16. doi:10.1177/0890334414560731

28. Chung M, Ip S, Yu W, et al. Interventions in Primary Care to Promote Breastfeeding. *Evid Synth*. 2008;66.

29. CDC. *The CDC Guide to Breastfeeding Interventions*.; 2005.

30. Cronenwett LR, Reinhardt R. Support and breastfeeding: a review. *Birth*. 1987;14(4):199-203.

31. Higgins ST, Delaney DD, Budney AJ, et al. A behavioral approach to achieving initial cocaine abstinence. *Am J Psychiatry*. 1991;148(9):1218-1224.

32. Higgins ST, Washio Y, Heil SH, et al. Financial incentives for smoking cessation among pregnant and newly postpartum women. *Prev Med (Baltim)*. 2012;55 Suppl:S33-40. doi:10.1016/j.ypmed.2011.12.016

33. Volpp KG, John LK, Troxel AB, Norton L, Fassbender J, Loewenstein G. Financial incentive-based approaches for weight loss: a randomized trial. *JAMA*. 2008;300(22):2631-2637. doi:10.1001/jama.2008.804

34. Finkelstein EA, Brown DS, Brown DR, Buchner DM. A randomized study of financial incentives to increase physical activity among sedentary older adults. *Prev Med (Baltim)*. 2008;47(2):182-187. doi:10.1016/j.ypmed.2008.05.002

35. Lagarde M, Haines A, Palmer N. Conditional cash transfers for improving uptake of health interventions in low- and middle-income countries: a systematic review. *JAMA*. 2007;298(16):1900-1910. doi:10.1001/jama.298.16.1900

36. Volpp KG, Troxel AB, Pauly M V., et al. A Randomized, Controlled Trial of Financial Incentives for Smoking Cessation. *N Engl J Med*. 2009;360(7):699-709. doi:10.1056/NEJMsa0806819

37. Kimmel SE, Troxel AB, French B, et al. A randomized trial of lottery-based incentives and reminders to improve warfarin adherence: the Warfarin Incentives (WIN2) Trial. *Pharmacoepidemiol Drug Saf*. 2016;25(11):1219-1227. doi:10.1002/pds.4094

38. Moran VH, Morgan H, Rothnie K, et al. Incentives to promote breastfeeding: a systematic review. *Pediatrics*. 2015;135(3):e687-702. doi:10.1542/peds.2014-2221

39. Pugh LC, Milligan RA. Nursing intervention to increase the duration of breastfeeding. *Appl Nurs Res*. 1998;11(4):190-194.

40. Thomson G, Dykes F, Hurley MA, Hoddinott P. Incentives as connectors: insights into a breastfeeding incentive intervention in a disadvantaged area of North-West England. *BMC Pregnancy Childbirth*. 2012;12(1):22. doi:10.1186/1471-2393-12-22

41. Relton C, Strong M, Thomas KJ, et al. Effect of Financial Incentives on Breastfeeding. *JAMA Pediatr*. December 2017:e174523. doi:10.1001/jamapediatrics.2017.4523

42. Washio Y, Humphreys M, Colchado E, et al. Incentive-based Intervention to Maintain Breastfeeding Among Low-income Puerto Rican Mothers. *Pediatrics*. 2017;139(3):e20163119. doi:10.1542/peds.2016-3119

43. Matts JP, Lachin JM. Properties of permuted-block randomization in clinical trials. *Control Clin Trials*. 1988;9(4):327-344. http://www.ncbi.nlm.nih.gov/pubmed/3203524. Accessed August 13, 2019.

44. Higgins K. ST& S. *Introduction*. (S. T. Higgins & S. H. Heil KS, ed.). New York, London: Guilford Press; 2008.

45. Dennis C-L, Faux S. Development and psychometric testing of the Breastfeeding Self-Efficacy Scale. *Res Nurs Health*. 1999;22(5):399-409. doi:10.1037/0003-066x.37.2.12210.1037/11144-000.2006-09558-00010.1037/11144-00010.1002/(sici)1098-240x(199910)22:5<399::aid-nur6>3.0.co;2-4

46. Sadeh A. A brief screening questionnaire for infant sleep problems: validation and findings for an Internet sample. *Pediatrics*. 2004;113(6):e570-7. http://www.ncbi.nlm.nih.gov/pubmed/15173539. Accessed November 28, 2018.

47. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry*. 1987;150:782-786. doi:10.1192/bjp.150.6.782

48. Sharps P, Alhusen JL, Bullock L, et al. Engaging and retaining abused women in perinatal home visitation programs. *Pediatrics*. 2013;132 Suppl:S134-9. doi:10.1542/peds.2013-1021L

49. Gelman, A., Hill J. *Data Analysis Using Regression and Multilevel/Hierarchical Models*. Cambridge: Cambridge University Press.; 2006.

50. Bennett DA. How can I deal with missing data in my study? *Aust N Z J Public Health*. 2001;25(5):464-469.

51. WHO. WHO | Weight-for-age. *WHO*. 2016.

52. Hovell, M. F., Wahlgren, D. R., & Gehrman C. The Behavioral Ecological Model: Integrating public health and behavioral science. In: R. J. DiClemente, R. Crosby & MK, ed. *New and Emerging Theories in Health Promotion Practice & Research*. San Francisco CA: Jossey-Bass Inc; 2002:347-385.

53. Sallis, J.F., Owen, N., Fisher EB. Ecological models of health behavior. In: Glanz, K., Rimer, B.K., Viswanath K, ed. *Health Behavior: Theory, Research, and Practice*. San Francisco CA: Jossey-Bass; 2015:465-485.

54. McKechnie AC, Tluczek A, Henriques JB. Maternal Variables Influencing Duration of Breastfeeding Among Low-Income Mothers. *Infant Child Adolesc Nutr*. 2009;1(3):126-132. doi:10.1177/1941406409334379

55. Tanda R, Chertok IRA, Haile ZT, Chavan BB. Factors That Modify the Association of Maternal Postpartum Smoking and Exclusive Breastfeeding Rates. *Breastfeed Med*. 2018;13(9):614-621. doi:10.1089/bfm.2018.0079

56. Wallwiener S, Müller M, Doster A, et al. Predictors of impaired breastfeeding initiation and maintenance in a diverse sample: what is important? *Arch Gynecol Obstet*. December 2015. doi:10.1007/s00404-015-3994-5

57. McKinney CO, Hahn-Holbrook J, Chase-Lansdale PL, et al. Racial and Ethnic Differences in Breastfeeding. *Pediatrics*. 2016;138(2):e20152388-e20152388. doi:10.1542/peds.2015-2388

58. Felice JP, Cassano PA, Rasmussen KM. Pumping human milk in the early postpartum period: its impact on long-term practices for feeding at the breast and exclusively feeding human milk in a longitudinal survey cohort. *Am J Clin Nutr*. 2016;103(5):1267-1277. doi:10.3945/ajcn.115.115733

59. Thomas-Jackson SC, Bentley GE, Keyton K, Reifman A, Boylan M, Hart SL. In-hospital Breastfeeding and Intention to Return to Work Influence Mothers' Breastfeeding Intentions. *J Hum Lact*. August 2015. doi:10.1177/0890334415597636

60. Smith-Gagen J, Hollen R, Walker M, Cook DM, Yang W. Breastfeeding Laws and Breastfeeding Practices by Race and Ethnicity. *Women's Heal Issues*. 2014;24(1):e11-e19. doi:10.1016/j.whi.2013.11.001

61. Huang R, Yang M. Paid maternity leave and breastfeeding practice before and after California's implementation of the nation's first paid family leave program. *Econ Hum Biol*. 2015;16:45-59. doi:10.1016/j.ehb.2013.12.009

62. Monteiro FR, Buccini G dos S, Venâncio SI, da Costa THM. Influence of maternity leave on exclusive breastfeeding. *J Pediatr (Rio J)*. 2017;93(5):475-481. doi:10.1016/j.jped.2016.11.016

63. Mirkovic KR, Perrine CG, Scanlon KS, Grummer-Strawn LM. Maternity Leave Duration and Full-time/Part-time Work Status Are Associated with US Mothers' Ability to Meet

Breastfeeding Intentions. *J Hum Lact*. 2014;30(4):416-419. doi:10.1177/0890334414543522

64. Chan MY, Ip WY, Choi KC. The effect of a self-efficacy-based educational programme on maternal breast feeding self-efficacy, breast feeding duration and exclusive breast feeding rates: A longitudinal study. *Midwifery*. 2016;36:92-98. doi:10.1016/j.midw.2016.03.003

65. de la Mora, A., Russell, D. W., Dungy, C. I., Losch, M., & Dusdieker L. The Iowa Infant Feeding Attitude Scale: Analysis of reliability and validity. *J Appl Soc Psychol*. 1999;29(11):2362-2380.

66. Barbosa CE, Masho SW, Carlyle KE, Mosavel M. Factors Distinguishing Positive Deviance Among Low-Income African American Women: A Qualitative Study on Infant Feeding. *J Hum Lact*. November 2016. doi:10.1177/0890334416673048

67. Lange A, Nautsch A, Weitmann K, Ittermann T, Heckmann M. Breastfeeding motivation in Pomerania: Survey of neonates in Pomerania (SNiP-Study). *Int Breastfeed J*. 2016;12(1):3. doi:10.1186/s13006-016-0093-6

68. Imai, K., Keele, L., Tingley D. A general approach to causal mediation analysis. *Psychol Methods*. 2010;15(4):309-334.

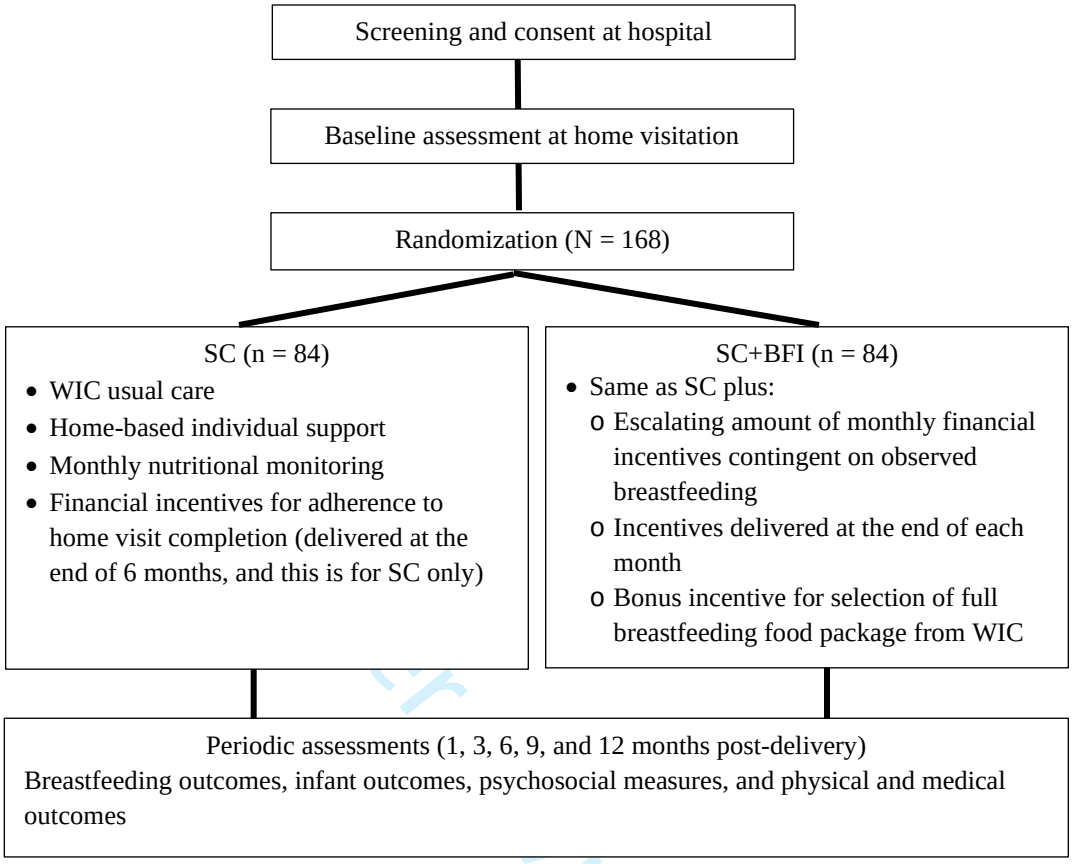

Figure 1. BOOST trial consort diagram

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/A
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	No role of study funder
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and	7

		other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7

Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	7
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	12
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9,10
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1, 11
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque,	8

		sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8,9
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8,11,12

Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10,11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	8, 12
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-17
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14-17
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and	7

		competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	7
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	7
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	7
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	7

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	8
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	18
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18

Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Attached at the end
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Model Documents given to Participants

INFORMED CONSENT FORM

AND

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**National Institute on Child Health and Human Development / "Individual Breastfeeding Support with Contingent Incentives for Low-Income Mothers"**
Principal Investigator:	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Additional Contact(s): **(Study Staff)**	**«AdditionalStaffMemberContacts»**
Address:	**«PiLocations»**

What should I know about this research?

- The study staff will explain this research to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask any questions you want before you decide.

KEY INFORMATION

You and your child are invited to take part in this research study. This research study is studying ways to support breastfeeding (BF) for 6 months among mothers eligible for the Women, Infants, and Children (WIC) program. We are trying to answer if monthly incentives for BF will help mothers to breastfeed for 6 months or longer. If you are interested in BF for more than one month, you might be interested in the study because it may help you BF for the duration you wish. If you are told that for medical reasons BF is not good for you or your baby you will not be able to be part of this study. We expect that you and your baby will be in this research for 1 year. Saliva samples will be collected from you and anal swabs will be taken from your baby. You will also be interviewed in this study. The interview questions ask you information about your attitude towards breastfeeding, history and present status of tobacco, alcohol, or other substance use, body image, and your mental health. You may also be observed while breastfeeding. It is possibly you may feel uncomfortable or embarrassed during some study procedures.

The National Institute on Child Health and Human Development is sponsoring this study. The person in charge of this project study is Principal Investigator listed on the first page of this form along with additional study staff from other study sites.

Please read this form carefully. Take your time to ask the Principal Investigator or study staff as many questions about the study as you would like. The Principal Investigator or study staff can explain words or information that you do not understand. Reading this form and talking to the Principal Investigator or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE

You and your child are being invited to join this research study because you are enrolled in or eligible for WIC, and you have started breastfeeding and intend to breastfeed for at least one month. The study is called "BOOST: Breastfeeding Onset and Onward with Support Tools."

By doing this study, we hope to learn whether monthly incentives help mothers receiving WIC, continue breastfeeding for at least 6 months and decrease health problems for mothers and infants.

We expect that you and your child will be in this research for 1 year.

About 168 mothers and their children will participate in this study.

EXPECTATIONS

As part of the study, study staff will:

- Collect demographic, psychosocial, medical, and BF-related information,
- Observe your BF
- Weigh your baby and yourself
- Measure the length of your baby and of your waist/hips
- Collect saliva samples from you
- Collect anal swab samples from your baby
- Ask for feedback about the study, your satisfaction, and for ways to make the study better

If you participate in this study, you will be expected to:

- Attend monthly home visitations by study staff

- Allow study staff to observe your breastfeeding or pumping
- Answer interview questions by study staff at each home visitation
- Allow study staff to weigh you and your baby
- Allow study staff to take anal swab samples from your baby for looking at microbiological makeups
- Allow study staff to take saliva samples from you for looking at women's hormones, immune responses, and cotinine (a nicotine metabolite).
- Complete phone assessments at 1, 3, and 6-month
- Attend 9 and 12-month in-home assessment

WHAT WILL HAPPEN DURING THE STUDY?

The **total** amount of time you will be asked to spend volunteering for this study will include 9 visits and 3 phone calls spread over the next 12 months for a total of about 10 hours.

Before any study procedures are performed you will be asked to sign and date this consent form. Your participation will include the following:

- Complete about 15 minutes of interview questions after delivery in the hospital or clinic to see if you are eligible for the study.
- If you are eligible and agree to be in the study, we will make a first home visit after you are discharged from the hospital or clinic. At the first home visit the study staff will perform the following:
    - Observe you breastfeeding,
    - Ask you interview questions
        - The interview questions will include information like your attitude towards breastfeeding, history and present status of tobacco, alcohol, or other substance use, body image, and your mental health.
    - Collect height and weight measurements form you and your baby.
    - Collect an anal swab from your infant by gently swabbing at the rectum area, not beyond, and a saliva sample from you.
- The visit takes about 60 minutes to complete.
- After your first home visit, we will randomly assign you into one of the two groups, the study treatment or the control group. Random assignment is like flipping a coin and it makes sure that each person has an equal chance of being in either group (50% chance of either one of the two conditions). No one, including you or study staff, can choose what group you are in.
  No matter what group you are in you will receive standard breastfeeding services from the WIC program along with referrals to extra breastfeeding support, and monthly home visits for 6 months. At each visit, you will be asked to let study staff observe your breastfeeding and take weight and body measurements from you and your infant. You will also be asked about your daily eating habits, your daily infant feeding patterns, and answer interview questions. The questions may include information about any recent medical events for you or your infant, use of any tobacco, alcohol, caffeine or marijuana use, and household environment. We may also request a saliva sample at each visit. The only difference between the two groups is how you are paid.
- Everyone who joins the study completes follow-up assessments at 1-, 3-, 6-, 9-, and 12-months postpartum.
    - Assessments at 1, 3, and 6-month postpartum are over the phone and take about 30 minutes.
    - Assessments at 9 and 12-month postpartum are in person and will take between 30 and 60 minutes. At 6 and 12-month, we will also collect another anal swab from your infant as well as saliva samples from you.

- If you miss an appointment, we will try to reschedule within one week. We will try to reach you by phone to reschedule 3 times. If we still do not reach you by phone, we may visit you at home to see if you and your baby are ok.

This study will use competitive enrollment. This means that when a target number of subjects begins the study, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued before getting your consent if the target number of subjects has already begun the study.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

To the best of our knowledge, participating in the BOOST study, and completing the assessments described above will have no more risk of harm than you and your child would experience in everyday life.

There are potential risks to participating in this study. There are three potential risks listed below:

- *You might feel pressured to participate.* Being in this study is your choice. You will meet with a study staff member in private and can tell her if you do not want to participate. Let the study staff know if you feel pressured.
- *You might feel uncomfortable showing breastfeeding, giving biological samples, and answering questions.* If you feel uncomfortable at any time, please let the study staff know and she will speak with you about it. The study staff are trained to help you in managing difficult feelings. You may ask to stop the study or refuse to show breastfeeding, give biological samples, or answer interview questions at any time, and there will be no consequence for stopping the study or refusing to show breastfeeding, give biological samples, or answer interview questions, other than not receiving research payments. All study staff who will be conducting the assessments at home will be female.
    - Please note, if you are having suicidal thoughts call the Principal Investigator at the telephone number listed on the first page of this form. If you feel in crisis, you can call 911 and/or a Nationwide Suicide Hotline that is answered 24 hours a day with a skilled, trained counselor. One example is the National Suicide Prevention Lifeline at 1-800-273-TALK (8255).
- *There is a small possibility that a person may gain access to the information you gave us without our permission.* We take steps to protect your and your child's information. This is explained more in the section titled "Confidentiality"
- Your baby may feel discomfort during the anal swabs.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your

involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

UNFORESEEN RISKS

Since the study treatment is investigational, there may be other risks that are unknown.

BENEFITS

This study is being conducted for research purposes only. We cannot promise any benefits to you or others from taking part in this research. However, possible benefits include health benefits for you and your baby if you are able to continue BF for 6 months. Such health benefits include avoiding overweight and infectious diseases for your baby, and breast and ovarian cancer for you. This study may also help us create a program to help women and their babies stay healthy through continued BF.

ALTERNATIVES TO PARTICIPATION

This research study is for research purposes only. Instead of being in this research, your choices may include standard breastfeeding support at your WIC office or other free resources available in your state.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

COMPENSATION FOR PARTICIPATION

You can earn up to $480 total if you are in the control group and up to $660 if you are in the study treatment group. Depending on the group you have been assigned to you will receive payments per the information below.

If you participate in this study you will receive the following:

- After the in-person assessments at months 9 and 12 postpartum you will be paid $40.00 in retail gift cards.
- After the phone assessments at months 1, 3 and 6 postpartum you will be paid $20.00 in retail gift cards.
- If you attend in-person assessment at baseline, all monthly home visits for 6 months, and in-person assessments at months 9 and 12 postpartum, you will receive a bonus amount of $60.00 in addition to $40.00 at 12-month postpartum. If you miss one home visit or in-person assessment, the bonus amount will be $40.00. If you miss two home visits or in-person assessments, the bonus amount will be $20.00. If you miss more than two home visits or in-person assessments, there will be no bonus amount.

If you are assigned to the control group you will receive the following:

- $40.00 in retail gift cards for each monthly home visit you complete and for monitoring your diet for 6 months. You can earn up to $240.00, which you will receive after the 6-month intervention period based on the number of completed home visits. If you do not complete your nutrition assessment or miss appointments, you will not receive any payment.

If you are assigned to the study treatment group you will receive the following:

- $20.00 immediately and remotely uploaded to a Master Card, after the you are observed breastfeeding and/or pumping at all 6 monthly home visits. Payments will increase by $10 each month, for a total potential earning of $270 by the end of 6 months. If you select a WIC food package for exclusive breastfeeding moms, we give you another $50 per selection (up to $150). If you do not show breastfeeding or miss appointments, you will not receive any payment.

If you do not finish the study, for any reason, you will be paid for each completed assessment. Please contact study staff if you have any questions regarding compensation for participation.

Federal tax law requires you to report this payment as income to the Internal Revenue Service.

You may be asked to tell us your social security number. If payments are more than $599.00, we will report them to the Internal Revenue Service and send you a Form 1099-MISC. If you do not give us your social security number, you may take part in this research if you agree to not be paid.

COMPENSATION FOR INJURY

If you and/or your child become ill or are injured while participating are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you and your child are participating in this study. If you tell the study staff that you think you and/or your child have been injured then they will help you and/or your child get the care you need. However there no plans to pay for your and/or your child's injury or illness treatment. You will not lose any of your legal rights or release the sponsor, the Investigator, the study staff, or study site from liability for mistakes by signing this consent document.

COSTS

There will be no charge to you for your participation in this study. The study-related procedures and visits will be provided at no charge to you.

CONFIDENTIALITY

Only the Principal Investigator (person in charge of the study) and the study staff have access to your and your child's identifiable information. Study staff will not write your name or your baby's name on any questionnaires or breastfeeding records, other than on a form called Locator Form that asks your contact information. Instead, we use a number to label this information. All forms are kept in locked filing cabinets or a password-protected electronic file on a secure online database at the study sites. All forms with identifiable information will be separate from forms with de-identified information and study ID numbers. Data on hardcopy are transferred in locked baggage. All electronic files are kept in password protected computer files, saved in a secure server of the study site. These files will be electronically transferred by encrypted email communications. Forms and files with your name (like this form) are kept separate from questionnaires, biological samples, and breastfeeding records.

Records of your and your child's participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential

study-related records which identify you and your child by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you and your child will not be identified.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you and your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you and your child are otherwise entitled and without any effect on your and your child's future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The Investigator or the sponsor can stop your and your child's participation at any time without your consent for the following reasons:

- Incarceration during the study treatment period
- Failing to attend scheduled visits for more than 3 months during the study treatment period;
- Moving out of state
- Exhibiting behavior that cause concern for study staff safety
- If you fail to follow directions for participating in the study
- If it is discovered that you do not meet the study requirements
- If the study is canceled
- For administrative reasons

FUTURE RESEARCH STUDIES

Identifiers will be removed from your and your child's identifiable private information or identifiable biospecimens collected during this study and **could then be used for future research studies or distributed to another investigator for future research studies** without additional informed consent. Your data and biospecimens will be stored for 5 years after study completion.

COMMERCIAL PROFIT

Your and your child's biospecimens collected during this study will not be used for commercial profit (even if identifiers are removed) and **you will not share in this profit**.

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading," every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research **will not include** whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

We may want to contact you in the future to see if you would be interested in participating in an optional sub-study. You may decide not to participate in the optional sub-study. If you decide not to participate in the sub-study, your decision will have no impact on your ability to participate in the main study and will have no impact on any other benefits to which you and your child would otherwise be entitled.

Please indicate your preference below:

❒**YES** _____ **(initials)** I agree to be contacted about participating in a sub-study.

❒**NO** _____ **(initials)** I do not agree to be contacted to participate in a sub-study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:

  Study Subject Adviser

  Advarra IRB

  6940 Columbia Gateway Drive, Suite 110

  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00033168.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study with my child until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Printed Name of Child

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the

Consent Discussion

_____ _____

Signature of the Person Conducting the Date

Consent Discussion

AUTHORIZATION TO USE AND DISCLOSE

PROTECTED HEALTH INFORMATION

Information that will be collected from you and your child and disclosed

During the course of this research study, some of your and your child's health information will be collected and disclosed to authorized users described in this document. If you decide to be in this study, the Principal Investigator and study staff will use and share health data about you and your child to conduct the study. Health data may include:

- Your and your child's name.
- Address.
- Phone number.
- Social security number
- Health plan number
- Social Media account.
- Date of birth.
- Medical history
- Information from your and your child's study visits, including all test results with dates relating to tests and procedures.

The following PHI may be disclosed to, collected by, used by and shared with those listed below for purposes of the research study:

- Breastfeeding status
- Infant weight
- Maternal weight
- Medical visit, hospitalization or emergency visit records
- Psychosocial and behavioral health
- Other general maternal and infant health status

This information may come from existing records kept by your primary doctor or other health care workers. This include your and your child's medical records, physical examinations and procedures. The purpose of this collection is to:

- Decide if you are eligible to participate in the research study
- Created because you and your child participate in the research study.

How your and your child's information will be used and to whom it will be disclosed

By signing and dating this authorization form, you give permission to the Principal Investigator, study staff, study sites named on the first page of this form, to use health data about you and your child and to share health data about you and your child with authorized users.

Authorized users may include:

- Representatives of National Institute on Child Health and Human Development.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this research.
- A data safety monitoring board which oversees this research.

Your and your child's health data will be used to conduct and oversee the research, including for instance:

- To see if the financial incentives contingent on breastfeeding helps mothers to breastfeed for at least 6 months.
- To compare the contingent financial incentives to incentives for completing home visitations.
- To see changes in breastfeeding duration also impacts weights of mothers and infants.
- To see changes in breastfeeding duration also impacts medical conditions of mothers and infants.
- To see changes in breastfeeding duration also impacts microbiome composition in infants.
- To see changes in breastfeeding duration also impacts stress and immune responses of mothers.

It is important for you to know that the authorized users will take all reasonable efforts to protect privacy of health data about you and your child and to prevent further use or disclosure by those not authorized to use or disclose health data about you and your child. However, once your and your child's health information is disclosed to the authorized users, then your and your child's health information may no longer be protected by federal privacy

laws and regulations and there is a potential for re-disclosure of this information. However, the laws of your state of residence may provide further privacy protection.

Your permission to use and share health data about you and your child will end in 50 years unless you revoke it (take it back) sooner.

How you can access your and your child's information

You should know that you have the right to see and receive a copy of your and your child's health information that was collected from you and your child during the research study period when this information is maintained by the study site and the Principal Investigator. However, your right to access your and your child's health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your and your child's study health data. There may be associated charges for copying these materials.

How to revoke your authorization

You may revoke (take back) your permission to use and share health data about you and your child at any time by writing to the Principal Investigator at the address listed on the first page of this form. If you do this, you and your child will not be able to stay in this study. No new health data that identifies you and your child will be gathered after your written request is received. However, health data about you and your child that has already been gathered may still be used and given to others as described in this form, for scientific purposes of the research study.

Important notices

You will receive a signed and dated copy of this authorization to acknowledge your approval for the Principal Investigator and study staff to the release your and your child's health information. If you do not sign and date this authorization or if you revoke this authorization, the Principal Investigator, and study site cannot allow you and your child to participate in or to continue to participate in the research study described on the first page of this form.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my and my child's health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

_____

Printed Name of Person Collecting Authorization

_____

Signature of Person Collecting Authorization Date