Official Title of the Study: Impact of a Smartphone Application on Postpartum Weight Loss and Breastfeeding Rates among Low-income Urban Women

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BACKGROUND AND OVERVIEW

The high rate of obesity in the United States is a significant health concern for people of all ages. For example, nearly 1 in 3 children ages 2–19 and roughly half of reproductive-age women are overweight or obese. Notably, these rates are highest among low-income populations. Obesity and overweight put women and children at increased risk of numerous poor health outcomes, including cardiovascular disease and diabetes. Thus, we must identify interventions that can promote weight loss and improve health, especially among low-income populations.

Breastfeeding is a simple intervention that is protective against childhood obesity and beneficial for long-term neurodevelopment, immunity, nutrition, and overall health. Breastfeeding is also beneficial to mothers: women who breastfeed have long-term cardiovascular health benefits and lose more weight by six months postpartum than those who don't breastfeed. For these and many other reasons, numerous public health organizations are focused on increasing initiation and continuation of breastfeeding, particularly exclusive breastfeeding. However, although 75% of women initiate breastfeeding nationally, only 59% of African-American women and 53% of teenagers do so, and these rates may be even lower among low-income urban women. For example, our unpublished data demonstrate that only 34% of Medicaid recipients receiving prenatal care at Barnes-Jewish Hospital (BJH) exclusively breastfeed by two days postpartum. This low rate of exclusive breastfeeding is particularly notable given that BJH is a Baby Friendly Hospital, which means the BJH Obstetrics unit has met a rigorous international standard shown to optimize breastfeeding initiation and continuation.

The low breastfeeding rate among low-income women is attributed, in part, to misconceptions about breastfeeding benefits and poor social support. To overcome these barriers, we propose the first-ever randomized controlled trial assessing the impact of a smart phone application (app) on breastfeeding rates among low-income women. We chose an app because nearly 66% of American adults and 90% of those under the age of 29 have smart phones, and over 66% of Americans with smart phones use them to obtain health information via new media (blogs, websites, and apps). Additionally, physician-designed new media interventions for low-income women have improved intrauterine device uptake rates, increased weight loss, and decreased rates of postpartum smoking. To develop our app – *Breastfeeding Friend (BFF)* – we first used a well-validated survey to identify barriers low-income urban women perceive as preventing them from breastfeeding. Next, we used these data, and input from neonatologists, certified lactation consultants, and focus groups of low-income pregnant women, to create BFF. BFF functions as a virtual lactation consultant, increasing breastfeeding knowledge while providing interactive assistance and access to in-person resources. Here, we will test the ability of BFF to increase rates of breastfeeding and promote postpartum weight loss.

RESEARCH DESIGN

Objective(s): To assess the effects that a novel smartphone application has on breastfeeding rates and postpartum weight loss among low-income women

Background: Prior metaanalyses have demonstrated that the highest increases in breastfeeding rates occur from individual-level breastfeeding education and support interventions available both during pregnancy and after delivery. Thus, we will recruit women during their third trimester of pregnancy and expose half of them to BFF, which provides individual-level educational and support, for one month during pregnancy and three months postpartum. Our *overall hypothesis* is that BFF users will have higher rates of breastfeeding and more postpartum weight loss than those in the control group. To provide the first data on the ability of a new media intervention to increase breastfeeding and postpartum weight loss among low-income women, we will pursue three *specific aims*:

Specific Aim 1: Determine the effects of BFF on exclusive breastfeeding rates at two days postpartum.
Hypothesis: Exposure to BFF will increase rates of exclusive breastfeeding at two days postpartum.

Specific Aim 2: Assess the ability of BFF to increase postpartum weight loss.
Hypothesis: Exposure to BFF will increase maternal weight loss by six months postpartum.

Specific Aim 3: Determine the impact of BFF on breastfeeding from two days to six months postpartum.

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Hypothesis: Exposure to BFF will increase rates of non-exclusive breastfeeding at two days postpartum and exclusive breastfeeding at three weeks, three months, and six months postpartum.

Study Design: Randomized controlled trial.

Primary Outcome: Exclusive breastfeeding on postpartum day 2

Secondary Outcomes: Breastfeeding initiation; exclusive and non-exclusive breastfeeding at 6 weeks, 3 months, and 6 months after delivery; non-exclusive breastfeeding at 2 days postpartum; timing of formula initiation; postpartum weight loss; patient-reported best breastfeeding or pumping support tool during and after hospitalization

Subject selection: Women will be included if they are nulliparous, plan to deliver at the clinical site and have singleton pregnancies without known severe fetal malformations or genetic conditions at 36 weeks' gestation. Women will be excluded if they have a contraindication to breastfeeding.

Randomization and Treatment: Patients meeting inclusion criteria will be enrolled, provided a complimentary smartphone, and randomized in a 1:1 ratio using computer generated randomizaed sequence to one of the two treatment protocols:

1) *BreastFeeding Friend* (*BFF*): a novel smartphone application with on-demand videos on breastfeeding and educational support for infant development.
2) A skeleton app: designed to look similar to *BFF*, the skeleton app will contain only digital breastfeeding handouts provided in routine prenatal care

Methods: Nulliparous women with singleton pregnancies will be recruited at 36 weeks' gestation at their routine Obstetric appointments at the prenatal clinic at the Center for Outpatient Health. Consenting women will complete an intake questionnaire to obtain sociodemographic information as well as self-reported prepregnancy weight, height, and breastfeeding intentions. They will then be randomized into two groups: BFF and a dummy app. The dummy app looks identical to BFF but contains only the limited breastfeeding content available during routine prenatal care. Each participant will receive a complimentary Android phone with three months of prepaid internet service. Sprint has heavily discounted smart phones and internet plans for use in this study. At two days, three weeks, three months, and six months postpartum, participants will complete telephone questionnaires derived from the Infant Feeding Practices Study II, a well-validated survey created by the Centers for Disease Control. This survey has been slightly modified to better target the study's breastfeeding and weight-loss aims. Women will also be weighed on postpartum day two to obtain data on their gestational weight gain. The six-month follow-up questionnaire prompts participants to weigh themselves during the survey. Postpartum weight loss will be obtained by subtracting the reported weight at six months postpartum from the weight measured in the hospital on postpartum day two.

Sample size: 170 women over an estimated 12 months

Sample size justification: Our study will include 170 patients: 85 randomized to BFF and 85 randomized to a dummy app. Our statistical power estimates assumed a baseline rate of exclusive breastfeeding of 34%. A sample size of 79 women in each group (anticipating 6 will be lost to follow-up) will afford 80% power to detect a 65% increase in exclusive breastfeeding at two days postpartum. Assuming a baseline postpartum weight loss of 10 kilograms by six months postpartum, our study population will also afford us 80% power to detect a difference in weight loss of two kilograms between women randomized to BFF and those randomized to the dummy app.

Statistical Analysis Plan: Primary analysis will follow intention-to-treat analysis. Dichotomous endpoints including breastfeeding at two days postpartum and exclusive breastfeeding will be analyzed by using chi-square tests. Continuous measures including duration of exclusive breastfeeding, duration of any breastfeeding, and maternal weight

loss will be analyzed by using Student's t-test. We will calculate crude and unadjusted risk estimates and differences. We will use multivariable logistic regression to adjust for potential confounders.

COMMUNITY BASIS

Our study takes place in the predominantly low-income population of women who receive prenatal care at the Center for Outpatient Health. These women have significantly lower rates of breastfeeding than do higher-income women and have higher rates of obesity, putting them and their infants at increased risk of adverse health outcomes. If the trial proposed here demonstrates that Breastfeeding Friend improves breastfeeding rates among low-income women, then the Missouri Foundation for Health has encouraged us to apply to them for funding to provide the app free-of-charge to low-income women throughout Missouri. Because breastfeeding has significant health benefits extending beyond infancy, including lower rates of childhood obesity and higher rates of postpartum weight loss, widespread implementation of BFF could improve long-term health for low-income women and their children in our state.

RELATIONSHIP TO OBESITY PREVENTION OR TREATMENT

Obesity is a substantial public health problem in the United States that disproportionately affects low-income women. Compared to infants born to normal-weight women, those born to obese mothers have a higher risk of becoming obese, developing early-onset insulin resistance and diabetes, and having early cardiovascular disease, resulting in a cycle of maternal and offspring obesity and metabolic disease. Breastfeeding has significant benefits for infant health outcomes, including appropriate growth and weight gain, and has been proposed as a mechanism to decrease child obesity. Breastfeeding also increases rates of maternal weight loss postpartum. However, low-income women are less likely than moderate- and high-income women to breastfeed. This proposal—the first of its kind—will test an intervention to increase breastfeeding rates in this high-needs population, potentially resulting in improved neonatal and maternal health outcomes. If this study demonstrates that BFF improves breastfeeding rates, future work will be directed toward statewide dissemination, thereby improving the health of Missouri's low-income women and their children.