

Research paper

Design of a novel digital intervention to promote healthy weight management among postpartum African American women

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ABSTRACT

Background: Excess weight retention among postpartum women is a risk factor for long term obesity, and African American women are at heightened risk. New solutions, including digital technologies and community-based approaches are needed. Digital platforms, like social media, provide opportunity for participant co-creation (i. e., content co-generated by users and investigators) of health messages and may allow for adaptation of evidence-based weight management interventions to reduce participant burden. The BeFAB intervention, a branded, digital weight management program, tests this hypothesis.

Methods: BeFAB content comprises culturally-specific nutrition, physical activity, stress management, health information seeking and related weight management messages and content designed for African American women. The intervention is 12 weeks in duration, delivered through a mobile phone app, and is designed to target specific behavioral predictor beliefs and attitudinal measures (e.g., self-efficacy to achieve weight management goals) based on the culturally-specific content. Use of personal, culturally-specific video-based narratives in the app, and through a secret Facebook group, are included to help model HEAL behaviors and brand BeFAB. Intervention development consisted of iterative formative research steps to engage African American women. The program will be evaluated in a small randomized trial among patients recruited at a clinical facility. **Conclusions:** BeFAB applies evidence-based content using a promising digital approach. It is novel in its use of branding, culturally-tailored content, and digital technology for behavior change. Evaluation of BeFAB will contribute to the growing literature on digital health behavior change interventions for weight management.

1. Introduction

Postpartum weight retention averages between 0.5 and 3 kg; estimates among some women approximate 18 kg [1]. Excess weight retention among postpartum women is a risk factor for long term obesity [2,3], and represents a teachable moment for delivering weight and physical activity (PA) messaging [4]. New solutions are needed to address this problem, including community-based approaches, culturally relevant interventions, and digital technologies [5].

African American (AA) women are more likely to start pregnancy overweight or obese than Hispanic or white women [6]. These findings are in context of the obesity and diabetes health disparities among AA women [7,8]. Thus, there is a need to develop and evaluate (via

state-of-the art measures) weight loss interventions specifically designed to reach and engage AA women. While there has been initial success in preventing excess gestational weight gain (GWG) and promoting weight loss in AA women [9], culturally tailored strategies and community-based principles to increase buy-in and sustainability, as well as use of tailored digital technologies that may increase intervention engagement, have been lacking.

Trials have examined prevention of excess GWG [10–12]. Of those randomized controlled trials (RCTs), treatments have shown efficacy among normal weight women [10,12,13], but null results among overweight and obese women [10,13]. In recent years, some RCTs have been completed, or are in progress, with a focus on weight loss among postpartum women [14–16]. One found no effect on diet or PA [14];

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investigators suggest non-face-to-face delivery may be needed to minimize barriers. One study used digital technology to prevent excess GWG and postpartum weight retention among a diverse sample, including AA women [17]. Findings suggest the need for novel interventions targeting at risk populations to promote healthy eating and active living (HEAL), which in turn are associated with healthy weight management.

Digital technologies have been successfully used to deliver weight management interventions. Behavioral techniques in programs include tailored feedback and self-monitoring [18]. Web-based programs for diet and PA have proved efficacious for weight loss among adults [19–22]. Among postpartum women, studies have used Facebook to promote PA [23], and a digital mediated approach to prevent excess GWG and postpartum weight retention among AA women [24]. There is potential to further adapt these strategies using mobile health (mHealth), such as with apps used on a smartphone, and social media to extend and build on previous Web-based interventions.

Digital platforms, like social media, provide opportunity for participant co-creation (i.e., content co-generated by users and investigators) of health messages [24]. A systematic review explored eHealth interventions for weight management in racial and ethnic minorities and found promising short-term efficacy among the studies reviewed that had at least 50% racial/ethnic minorities [25]. *Notably, even with relative success, none included culturally-specific approaches.* Evidence continues to support greater smartphone ownership and use of data features among racial and ethnic minorities, which translates into increased usage, utility, and potentially as a health intervention channel [26–28]. There is an opportunity to leverage the high usage rates of mobile devices among AAs [29], while also addressing the digital divide with regard to internet usage on mobile devices. AAs of all ages and socioeconomic levels report using the internet to seek health information [30], albeit at lower rates than other groups [31]. A systematic review highlighted that lack of time and child care are barriers to postpartum weight loss, especially among at risk women [32]. Studies have adapted the intensive Diabetes Prevention Program (DPP), including a small trial [33] for low income minority postpartum women. However, studies have also found that DPP and adaptations of this highly successful program place significant requirements and burden on participants [33]. While effective, the demands of DPP-based program may exceed the time, effort, and willingness to participate of many, reducing dissemination potential to some populations and circumstances.

Research shows that a lifestyle intervention can have clinically-meaningful effects on weight loss, as well as diabetes outcomes [31]. Use of technology for self-monitoring and counselor feedback enhances weight loss [34,35], as does engagement and monitoring via online posts [26,27,34]. User-generated content can increase engagement and social support [38,39]. Support is critical for coping and stress reduction [40]. Connections in social networks influences weight loss intentions and weight status, and may increase engagement through branding [32,41]. A 2015 systematic review on weight loss in postpartum women also recommended home and technology-based programs [42]. Intensive interventions suffer from barriers to delivery (e.g., time, child care), which may be especially true among new mothers [32]. Novel solutions are needed to reduce burden and increase engagement [43,44].

To address these translational and adoption challenges, we developed *BeFAB (Be Fabulous After Baby, with a dual meaning of Be Fit After Baby)*, a novel digital postpartum weight management intervention. One insight from the literature is that, while the technology and content components noted above have been developed and tested, they have not previously been integrated into a product for seamless delivery. Thus *BeFAB* is delivered via mobile app, one integrated solution to achieve this objective. The audience is low-income, overweight and obese AA or Black postpartum women. *BeFAB* is culturally specific, tailored, easy to use, and engaging. It is aimed to address the need to balance evidence-based information content with engagement features and relative ease of use to lower barriers to entry and participation. This approach has been demonstrated in previous trials – a focus on identifying a threshold of

participant demand while at the same time maximizing intervention engagement.

The specific objectives of this article are to describe the design and initial development of *BeFAB*. We report on the content, technology, and delivery methodology for the intervention. This study is part of a larger project that involves both formative research with the intended audience, AA postpartum women, and a randomized controlled pilot evaluation.

2. Methods

2.1. Conceptual model and approach

By using an app with integrated digital media, *BeFAB* is designed to increase engagement in program content, reduce barriers to participation, and broaden reach, impact, and sustainability of postpartum weight loss interventions. Focusing on engagement, structure, social support (through peer support and virtual coaching) and how to maximize it is a novel approach. Maximizing participant engagement (i.e., identification with the program, benefits it offers, opportunities to co-create and share user-generated content, personal motivation) will be a critical focus. These elements combined with social, environmental and community participation provide the conceptual model for *BeFAB*, summarized in Fig. 1. We hypothesize that identification with *BeFAB* and its benefits will mediate treatment effects on outcomes. We further hypothesize that stress (e.g., due to lack of sleep, demands of new role as a mother) related to having a new baby [45] and social support will be moderators of effects on weight, and will measure them [46] (see Fig. 2).

BeFAB content focuses primarily on shifting self-efficacy, norms, and expectations. Kim et al. (2015) noted that women who had positive expectations for their weight and their child's health were more likely to self-monitor and set goals [47]. AA women were less likely to do so, hence the need for tailoring [47].

BeFAB is a branded program, following principles of health branding, which aims to create a sense of positive identification and association with health behavior change programs [48]. *BeFAB* has been designed to be of, by, and for AA women, reflecting their norms and community, as a means to increase engagement. This is accomplished by employing a community-based perspective, and seeking community participation and engagement, that includes seeking guidance from a community of women, caregivers, and providers for the duration of the project. This was accomplished both through formative research and through input from a community advisory board (CAB).

The sharing of messages and experiences will lead to an intervention that is co-created by the participants [34,49]. This approach is fundamental to not only ensuring that the intervention addresses the needs, resources, barriers of this population but increases the sustainability potential of the behavior change. Branding advances theories of behavior change by specifying a mechanism underlying social role modeling [50,51]. The brand equity construct has been measured through positive associations with what the brand represents [52,53]. We hypothesize that *BeFAB* social support and peer modeling of HEAL and weight loss will improve behavioral (improved nutrition and increased physical activity) and weight management outcomes.

2.2. Intervention content and app design

The first step in *BeFAB* design was a content development phase. In this phase, we identified evidence-based content from previous online and in-person weight management interventions [54] with particular emphasis on those designed for AA/Black women. Evidence-based weight loss content from the DPP [26] (i.e., weight, PA and calorie goals, self-monitoring, social support) was included in this review and adapted to the objectives of delivering a streamlined, engaging, easy to use digital intervention.

The overall design process was iterative. We began with a review of

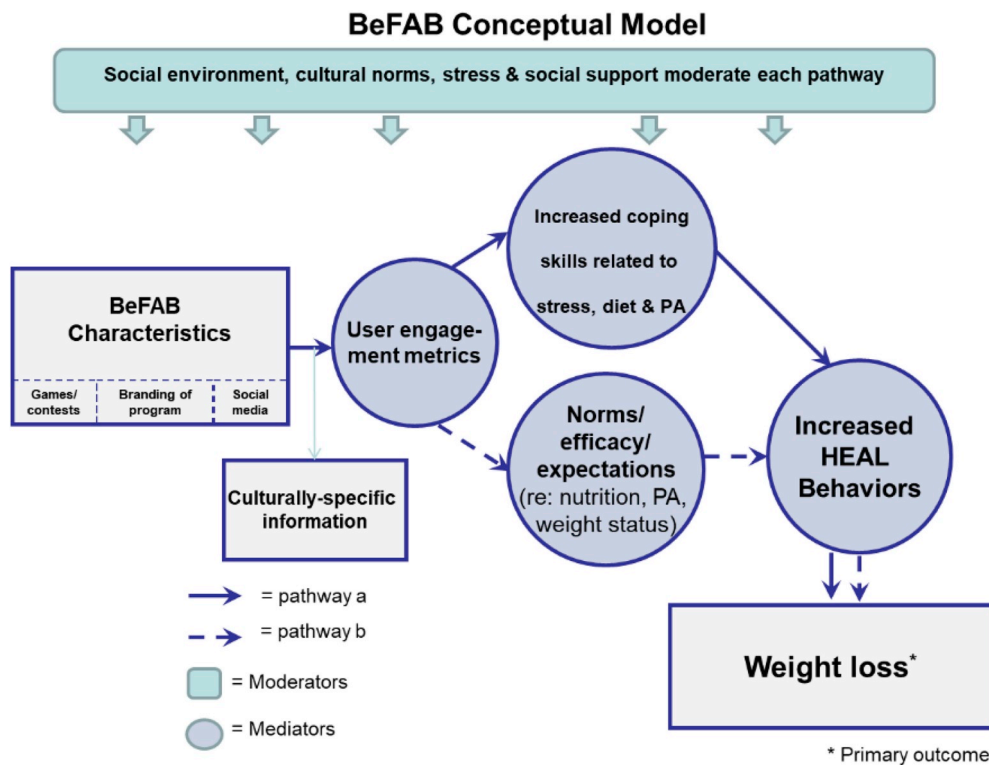


Fig. 1. BeFAB conceptual model.

existing mHealth weight management interventions, summarized above. Based on lessons from previous interventions, we designed and conducted formative research (phase 1 of the project). Results of this work were then used to develop the prototype app content, which was then prototype tested in a final design phase before implementation in an RCT.

Content and delivery (e.g., social networking, text messaging) was also modeled after the digital weight loss intervention developed by Napolitano et al. [40,55]. This included tailoring each lesson topic to the environmental context of having a new baby, as well as the social, cultural and environmental context and needs identified in our Phase 1 formative work. This content was designed to be audience co-created (through formative research) with videos and vignettes illustrating topics. Breastfeeding status will be assessed, and calorie goals will be adjusted accordingly. Finally, we tailored on stress coping.

BeFAB content comprises culturally-specific nutrition, physical activity, stress management, health information seeking and related weight management messages and content based on formative research results. The intervention was designed to target specific behavioral predictor beliefs and attitudinal measures (e.g., self-efficacy to achieve weight management goals) based on the culturally-specific content. Culturally-specific content addressed ease of use and other barriers to adopting HEAL behaviors among AA women, including examples of how other women have coped with stress, improved their nutrition and PA postpartum. Use of personal, culturally-specific narratives in social media were included to help model HEAL behaviors and brand BeFAB, following the conceptual model [56–59]. Examples of culturally-specific content include the use of authentic, relatable AA female and male individuals in the video content, including both didactic presentation of advice to promote healthy weight management, and a narrative-based educational entertainment video series to dramatize the challenges and opportunities to achieve healthy weight postpartum.

2.2.1. Translation of content

Based on other work with postpartum women [32], we selected 12

core weekly topics (based on evidence-based content including the Diabetes Prevention Program [33] and relevant studies among African American women) [51], to be adapted for *BeFab*. The weekly topics were delivered via three didactic videos, (“Dr. C’s Coaching Corner”) ranging from 2 to 5 min in length. Dr. C is a African American woman who is relatable to the audience and provides trustworthy, helpful advice to enable participants navigate *BeFAB* and achieve their weight management goals. To provide variety of formats and avoid boredom, three weeks had an altered content structure but a similar total amount of content time delivered. For example, one week contained a short didactic video and a cooking demonstration and another followed a similar format but with a “interview with an expert” on stress management. Content is culturally-specific to AA women’s preferences, customized with narratives and examples [54,60], shown in examples below. Participants are given a calorie and PA goal (i.e., women weighing 175–215 pounds will receive a goal of 1500 kcal/day (42 g fat) [31], adjusted for breastfeeding; work up to 150 min/week of moderate PA). BeFAB aimed to deliver easy to understand HEAL and weight loss messages via preferred media to increase compliance and to help overcome barriers. See an example in the following app screenshot.

The second step, based on the initial content development, was to develop the intervention prototype which included an integrated suite of app functionality. Before and during the content development process, we consulted with the community advisory board and got their feedback. We also conducted formative research with representative women from the community who would potentially be users of BeFAB, and incorporated their detailed feedback into the design. The intervention content included 1) video content, both educational entertainment and didactic coaching and expert support, 2) reminder and “nudge” in-app messages designed to encourage participation, use of content, and specific actions like seeking more information about nutrition and physical activity, 3) setting and achieving behavioral goals for nutrition and physical activity, 4) self-monitoring of weight, 5) achievement of weight goals through self-reported weight recording, 5) “badges” (i.e., virtual rewards signifying achievement of behavioral goals) that can be earned

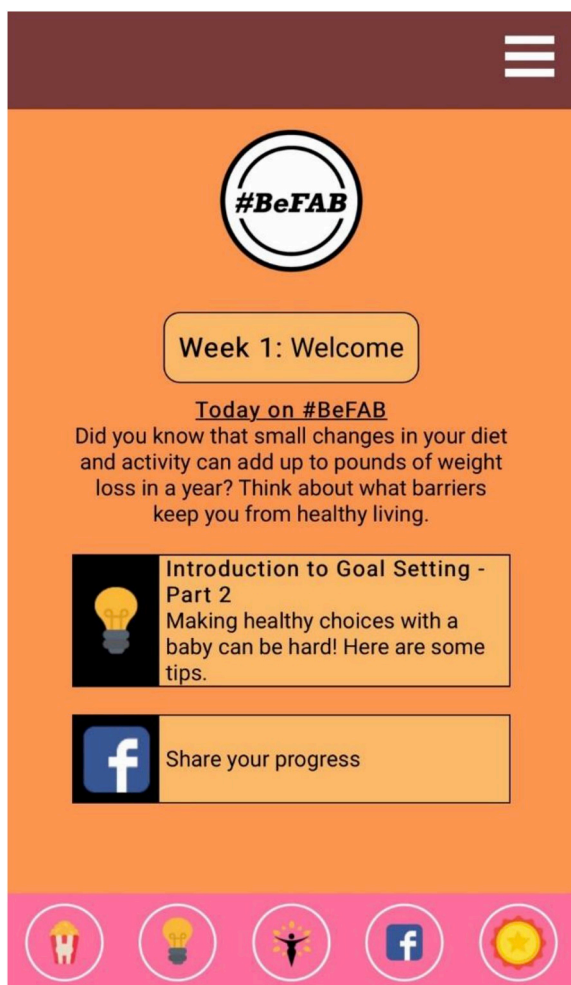


Fig. 2. Screenshot of BeFAB in-app HEAL message.

throughout the program, and 6) social networking (for peer support and information sharing) through a secret Facebook group accessible only to the participants and project staff.

See Napolitano et al. (2013) [40] for an example of a digital weight loss program, and Evans and colleagues (2015) and Andrade and colleagues (2015) for use of social media in developing a branded participant message co-creation program on which the *BeFAB* prototype was modeled [41,42,54]. The following describes specific app features to deliver the *BeFAB* content.

2.2.2. Behavioral goals

Because one primary objective of *BeFAB* is to reduce participant burden, intensive time requirements, and other participation barriers, we designed relatively simple behavioral goals based on those used in previous studies, rather than setting highly specific self-monitoring benchmarks. Goals were designed to be achieved (or achievable) on a daily basis, with more days of success per week translating into greater progress as signified by unlocking badges (see Table 2 below). To enhance user control and mastery, the participants will choose the key target behaviors on which they will work. The nutrition goals were as follows:

1. Limit sugary drinks like juice and soda to no more than 1 per day
2. Limit junk and high fat foods to no more than 1 per day
3. Cover one-half of the plate with vegetables at lunch and dinner
4. Have a regular meal pattern, eat a meal or a healthy snack every 4 h
5. Consume 1200 to 1500 calories per day

Table 1
Weekly schedule of topics.

Week 1	Welcome
Week 2	Getting Started With Losing Weight: Goal Setting and Monitoring
Week 3	Physical Activity: A way of life
Week 4	Meal makeovers
Week 5	Take charge of what's around you
Week 6	Tip the calorie balance
Week 7	Social support and social cues
Week 8	Time and sleep strategies
Week 9	Being active with family
Week 10	Stress, family, and your weight
Week 11	Staying motivated
Week 12	Transition and wrap-up

Table 2
Behavioral goals, activities, and badges for achievement.

Diet	Activity	Other	Badge Alternatives/ Points
1. Limit sugary drinks like juice and soda to no more than 1 per day 25 PTS. PER DAY THAT GOAL WAS MET	1. Do 10 min of physical activity like walking or working around the house 25 PTS. PER DAY THAT GOAL WAS MET	1. Weigh yourself weekly 50 PTS. PER WEEKLY ENTRY	Badge 1.200 points to "Path to Wellness" Badge
2. Limit junk and high fat foods to no more than 1 per day 25 PTS. PER DAY THAT GOAL WAS MET	2. Do 30 min of physical activity like walking or working around the house 25 PTS. PER DAY THAT GOAL WAS MET	2. Weigh yourself weekly 50 PTS. PER WEEKLY ENTRY	Badge 2.225 points to "Healthy Me" Badge
3. Cover one-half of the plate with vegetables at lunch and dinner 25 PTS. PER DAY THAT GOAL WAS MET	3. Take the stairs instead of the elevator at least once per day 25 PTS. PER DAY THAT GOAL WAS MET	3. Weigh yourself weekly 50 PTS. PER WEEKLY ENTRY	Badge 3.250 points to "Happy Healthy Life" Badge
4. Have a regular meal pattern, eat a meal or a healthy snack every 4 h 25 PTS. PER DAY THAT GOAL WAS MET	4. Push the stroller for 30 min today—in the hallway or outside! 25 PTS. PER DAY THAT GOAL WAS MET	4. Weigh yourself weekly 50 PTS. PER WEEKLY ENTRY	Badge 4.275 points to "Focus on Fitness" Badge
5. Consume 1200 to 1500 calories per day 25 PTS. PER DAY THAT GOAL WAS MET	5. Watch 2 h or less of TV per day 25 PTS. PER DAY THAT GOAL WAS MET	5. Weigh yourself weekly 50 PTS. PER WEEKLY ENTRY	Badge 5.300 points to "Getting in Shape" Badge
6. No late-night meals or snacks after 8 p.m. 25 PTS. PER DAY THAT GOAL WAS MET	6. Get a workout for at least 30 min, like go to the gym, take Zumba, or join a streaming fitness class (at-home) 35 PTS. PER DAY THAT GOAL WAS MET	6. Weigh yourself weekly 50 PTS. PER WEEKLY ENTRY	Badge 6.350 points to "Being FAB" Badge

6. No late-night meals or snacks after 8 p.m.

The physical activity goals were as follows:

1. Do 10 min of physical activity like walking or working around the house

2. Do 30 min of physical activity like walking or working around the house
3. Take the stairs instead of the elevator at least once per day
4. Push the stroller for 30 min today—in the hallway or outside!
5. Watch 2 h or less of TV per day
6. Get a workout for at least 30 min, like go to the gym, take Zumba, or join a streaming fitness class (at-home)

2.2.3. Badges

For each daily behavioral goal achieved (based on participant self-report and recording in the app), the individual earned points. When the individual reached a threshold, various badges were unlocked. There were a total of 6 “basic” badges, with a 2nd or “super” level achievable for each badge, resulting in 12 total badges corresponding to the 12 weeks of *BeFAB*. Badges were designed to be achieved by compiling points from both the nutrition and physical activity goal set for that week (a combination of points compiled from achieving each daily goal). The badges were as follows (x2 for the “super” level for each badge):

- Badge 1 “Path to Wellness” Badge
- Badge 2 “Healthy Me” Badge
- Badge 3 “Happy Healthy Life” Badge
- Badge 4 “Focus on Fitness” Badge
- Badge 5 “Getting in Shape” Badge
- Badge 6 “Being FAB” Badge

2.2.4. Social network

A secret (only available by invitation) Facebook social media group was created with: 1) gaming to increase competition; 2) prizes and incentives; 3) polls, events to create sense of community; 4) personal stories and sharing of experiences; 5) posts by the research team to generate discussion and share information about nutrition and physical activity opportunities in the local community. The group was moderated to ensure only appropriate content was posted.

2.2.5. In-app messaging

We used in-app messages (text messages sent to users within the app) each week which were thematic to the topics described in [Table 1](#) above. These messages were to provide tips and strategies, to remind participants about participation, and to encourage participation in activities. Messages were generally sent 6 times per week, beginning with a welcome/introduction to the weekly topic on Sunday, and messages arriving most other days except Fridays. The Thursday message included an option with a weblink to click and learn more about the weekly topic (e.g., at an online evidence-based resource), and the Saturday message included a reminder to interact on the secret *BeFAB* Facebook group (as well as nudges to use the social media group at other times). See [Table 3](#) below for a sample week of messages.

2.2.6. BeFAB series videos

The educational entertainment videos represented a continuing story that depicted three women in the primary audience names Erin, Denise, and Heather. They were each young women with babies and in some cases other young children who had the same lifestyle challenges and circumstances as the audience. There was one video for each week of the program, and the content of each episode depicted scenes in which some of the ladies were in life situations related to the content. The purpose of this component was to build a sense of program identification, to brand *BeFAB*, and to make the program fun, entertaining, create anticipation for each new week of content, and a sense of connection and feeling that *BeFAB* was a trusted friend that was for the participant. This approach has been widely used in the entertainment education and the research team’s previous research [28,34].

Table 3
Sample *BeFAB* App Messages.

NOTIFICATION DAY	Topic	MESSAGE
SUNDAY	BeFAB Series Episode: Hear the #BeFAB ladies work through setting diet and activity goals.	Self-Monitoring & Goal Setting the topics for this week. Setting goals to monitor your diet, activity, and weight will help you reach your target.
MONDAY	Coaching Corner #1: Diet goals means knowing what you are eating.	Did you know there are easy ways to learn to set good goals? A couple of key skills like reading labels and cutting calories can help. {Link to the video}
TUESDAY	Coaching Corner #2: Get an overview of reading a nutrition label and making healthy food.	Setting diet and nutrition goals is up to you and can be simple—focus on one target for your food [Link to solution video which will cover those key target diet]
WEDNESDAY	Coaching Corner #3: Setting activity goals? Work about easy ways to work activity in your day.	Setting activity goals is up to you and can be simple—focus on gradual changes {Link to the video}
THURSDAY/WANT TO LEARN MORE	Want to learn more? – Link	Want to learn more about: <ul style="list-style-type: none"> • Reading a label < https://www.youtube.com/watch?v=Orj7p3KQcyQ> • What is a calorie? https://www.youtube.com/watch?v=VEQaH4LruUo • Review SMART goals from Week 1 <https://www.youtube.com/watch?v=vRvrfGZzCU>
SATURDAY/FACEBOOK POST	Social Environment* - FB Post	FB post: Share how a friend or family member can help you meet your goals this week.

2.2.7. Coaching corner videos

We also created a series of didactic educational videos presented by Dr. C that provided detailed advice on nutrition, physical activity, wellness, stress reduction, and how to achieve behavioral goals that represent the focus of *BeFAB*. These videos provide science-based information and support to help participants achieve behavioral goals and get the most out of the *BeFAB* content and the app.

Based on the video content and in-app messaging, participants have opportunities throughout the 12-week program to explore topics in more detail and to “learn more.” One way this is done is through the secret Facebook group. [Fig. 3](#) shows a screenshot of this feature in the app.

Based on feedback from our formative research and lessons from previous studies [40,54], *BeFAB* was designed to be delivered exclusively via a mobile app developed and customized specifically for the project, including all of the content on HEAL behaviors and weight management objectives described earlier.

2.3. Evaluation of efficacy in a randomized controlled trial (RCT)

BeFAB has been designed to be evaluated in an RCT. Participants will be randomly assigned to the *BeFab* intervention or usual care. Hypotheses are as follows: 1) there will be a significant difference between the *BeFab* and usual care groups on weight loss and self-reported behavioral endpoints; 2) engagement in the *BeFAB* program as measured by type, amount, and duration of engagement will mediate treatment effects on weight loss. Specifically, we hypothesize that brand equity will mediate treatment effects on self-efficacy and related beliefs, which in turn will

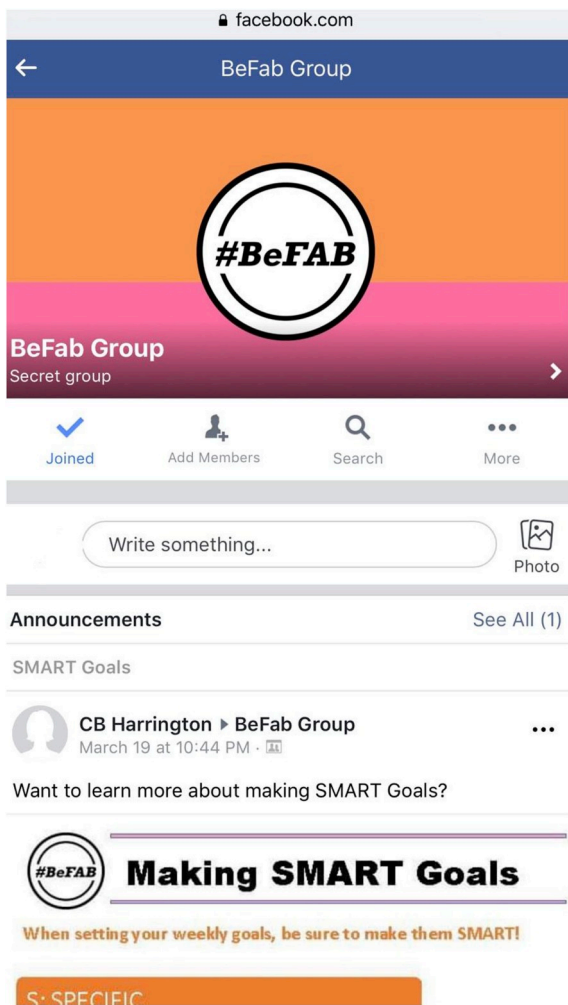


Fig. 3. BeFAB screenshot showing “want to learn more” content and link to Facebook group.

mediate behavioral and weight management outcomes.

Participants in the randomized pilot evaluation who enroll and are randomly assigned to the treatment group receive the *BeFAB* app and begin immediately using it for 12 weeks. During this time, they are encouraged to use all of the content and app features, and to share their experiences, photos, self-created videos, and other digital material they create in the secret Facebook group [40]. Audience generated content on Facebook helps to build identification with the program brand and increase engagement, and extends the intervention with new content. This will also enhance tailoring, as women will share personal experiences.

2.3.1. Outcomes

We have developed a set of outcome measures and scales linked to the *BeFAB* conceptual model and hypotheses. Outcomes are measured through pre-test (immediately after consent and enrollment and before intervention delivery) and using the same behavioral and weight status outcome measures at the conclusion of the 12-week intervention period (repeated measures).

- **Height and weight.** Height will be taken using a stadiometer to the nearest ¼ in. Body weight will be measured on a calibrated scale to the nearest ¼ kg; BMI will be calculated as follows: $BMI = \text{weight [kg]} / \text{height}^2 [\text{m}^2]$. Measures will be taken on the same scale at each time point. Other measures will be extracted from patient records and entered into a de-identified database including breastfeeding, depression, and other co-morbidities (e.g., gestational diabetes).

- **Physical Activity:** The International Physical Activity Questionnaire (IPAQ) [61] will be administered; this measure assesses time spent in walking, moderate and vigorous intensity activity, as well as sedentary behavior. While we recognize the limitations of self-reported measures, we opted to reduce burden by administering the IPAQ which has been shown to be effective for detecting change in total physical activity and moderate to vigorous PA [61], and is currently being used in a GWG prevention trial [62].
- **Nutrition behaviors.** Nutrition will be assessed by questions derived from the Centers for Disease Control and Prevention Behavioral Risk Factor Surveillance Survey and as adapted in the lead author’s previous research and other recent studies [63–66].
- **Self-efficacy:** *Exercise self-efficacy (ESE)* [67,68]. The ESE is a 5-item questionnaire assessing one’s confidence she can be active when faced with 5 common barriers (e.g., bad weather, lack of time; $\alpha = 0.76$) [68,69]. *Weight self-efficacy (WEL)* [69]. The WEL measures perceived control over food-related behaviors, and incorporates 20 different food-related situations (e.g., social events); α ’s range from 0.70 to 0.90 [69].
- **Social Support.** We will assess three components of social support [70]: *Perceived social support* (6 items from the Interpersonal Support Evaluation List (ISEL), rated on a 5-point Likert scale; $\alpha = 0.85$); *Social self-efficacy* (10-items rated on a 5-point Likert scale; $\alpha = 0.94$); *Social outcome expectations* (8-items on a 5-point Likert scale assessing outcome expectations (pleasure, affection, relaxation, and control); $\alpha = 0.84$).
- **Sleep.** The Pittsburgh Sleep Quality Index [71] (PSQI) will be used to assess sleep quality, patterns, duration (with questions about the individual’s partner excluded).
- **Stress and Coping.** The Rhode Island Stress and Coping Inventory (RISC) will be used to measure mothers’ stress and coping strategies adopted in relation to having a newborn baby [37].
- **Depressive symptoms** will be measured using the Edinburgh Postnatal Depression Scale (EPDS) [72,73].
- **Brand Equity Scale.** Dr. Evans has validated an 18-item scale to measure identification and engagement with a behavior change program brand (scale alpha .94) and is hypothesized to mediate HEAL behaviors [39,41].

Additionally, in the evaluation, app data is available on all aspects of content utilization, including what content is viewed, for how long, when, with what frequency. Thus, detailed program dosage is available that can be used to measure engagement. This kind of exogenous measure of program dosage provides an important dimension to be able to assess engagement and the relationship between intervention participation and outcomes [74,75].

2.3.2. Process measures

We also collect a number of engagement and other process measures to assess acceptability and potentially explain observed variation in program participation.

- **Social Media Engagement.** A 5-item measure [76,77] will assess engagement in and perceptions of Facebook [76]. A metric for messages delivered within the *BeFAB* app will be based on Dr. Evans’ *text4baby* study [78].
- **Engagement.** As in Napolitano et al. [55], and Andrade et al. [79], we will quantify social media posts as a measure of engagement. We also will track participants’: 1) type and frequency of content accessed; 2) use of the app-based weight and activity tracker.
- **Consumer Satisfaction Measure.** This measure, also used by Napolitano et al. [40,55], assesses program satisfaction and perceived level of program involvement.

2.3.3. Sample size

We calculated power based on the weight loss treatment

recommendations in previous research [18] of 1–2 pounds per week (5.45 kg total), compared with a loss of 1 kg among the Standard care group, a conservative estimate based on a comparable trial [17] and Cochrane review [80] indicating that weight gain retention at 1 year postpartum averages 0.5–4.0 kg. Assuming women start the program at 180 lbs., and lose 1 pound per week, this would equate to an approximate 6.6% weight loss. Several reports have concluded that weight loss in the 5–9% range (of pre-intervention weight) contributes to important health benefits and is clinically meaningful in evaluating weight loss programs and medications [81,82]. Using Proc GLMPower in SAS Enterprise, with a post-test sample size of 54 per group, a pooled SD of 13 kg, a pre-post correlation of 0.9, $\alpha = .05$, and a 2-sided test, we estimated 80% power to detect a mean weight loss difference between the two groups of 4.45 kg. Assuming an attrition rate of 20%, this results in sample of 68 per arm (136 total).

2.3.4. Randomization

We created a simple random assignment table in the REDCap [83] online study management and data collection platform. Assignments are made based on the randomized list in REDCap during the enrollment process.

2.3.5. Analysis

Overall, the analysis has two main objectives, which are to evaluate hypotheses 1 and 2. First, to examine 2, we will determine if *BeFAB* is effective in reducing weight by 4.45 kg or more among the treatment group. Second, to examine 3, we will test our conceptual model (Fig. 1) through a structural equation model (SEM).

Demographic data will be compared at baseline using unpaired t-tests and Chi-square tests. For weight loss, group differences over time will be analyzed using intention-to-treat methods. Mixed model repeated measures analyses of variance (ANOVAs), with time, group and the interaction of both as independent variables, will be used to compare changes in all anthropometric data, physical activity, social support and other psychosocial variables between the two groups. Data from all participants will be included, even those who did not complete the 12-week follow-up period (following intent to treat principles). We will examine baseline differences between completers and non-completers. Sensitivity analysis will be performed using last observed weight for all subsequent time points. Following intent-to-treat principles, participants who decline, withdraw, or are otherwise lost to follow-up will be included. We will use the multiple imputation technique of iteratively chained equations, apply the above analytic model, and compile the results in the MI commands in Stata 13 [84,85]. A p -value < 0.05 will be considered significant for all initial analyses, using SAS statistical software for Windows [86].

Hypothesis 1. To test intervention effects on weight loss and self-reported behavioral endpoints, we will conduct intent-to-treat analyses suited to the study design, including randomization and the availability of baseline and follow-up repeated (pre- and post-test) measures of weight loss and behaviors. For each outcome the statistical model will be an ANCOVA style regression. Linear mixed effect models of this type (maximum likelihood) are widely used to analyze data from randomized trials, and with continuous dependent variables give estimates that are virtually identical to those for the population averaged model (generalized estimating equations) [87,88].

Hypothesis 2. (mediation): The mediation hypothesis will be modeled using Structural Equation Modeling (SEM) in which engagement with the intervention and dosage will be represented as mediators of intervention effects on outcomes [89]. We will develop a *BeFAB* dosage index based on the app usage data and self-report data and use confirmatory factor analysis (CFA) to model dosage as a latent variable [78,90]. We will use experimental condition as the independent variable, engagement and dosage mediators, and weight loss as the dependent variable to estimate model pathways (see Fig. 1).

3. Discussion

The *BeFAB* approach is both novel and significant in that it focuses on increasing participant engagement by making weight loss and weight management more fun and easier to do. Using evidence-based practices, *BeFAB* attempts to address one of the central challenges of weight loss programs, that they demand too much attention and effort on the part of participants. This new program tests the hypothesis that digital technology, entertainment, and brand marketing strategies can be wedded to evidence-based strategies to achieve greater behavioral and weight loss outcomes [91].

Weight management interventions face challenges in terms of both adoption and maintenance of behavior change. While the DPP represents a gold standard, it is time consuming and difficult for many people to consistently participate and achieve lasting results. *BeFAB* attempts to solve these challenges by offering a relatively easy to use, low intensity approach. It's use of cultural tailoring and social support further reduces barriers to adoption and continued participation. This approach tests the hypothesis that reducing participant burden and increasing engagement may produce improved health behavior change outcomes, for which some previous mHealth provide preliminary evidence [78,92].

BeFAB is innovative in its attempt to engage participants through branding, creating a program identity that is appealing and creates a sense of belonging to "something bigger" that offers support and encouragement. Digital media is a platform through which the brand identity can be delivered, and allows the participant to engage with *BeFAB* content anytime, anywhere, through interaction both with intervention content and with peers [93]. The hypothesis, to be tested in a randomized trial, is that this approach will produce meaningful changes in HEAL behaviors and weight outcomes.

While other interventions have used the internet, mobile phones, and digital media more generally, none have applied the integrated content and app-based approach of *BeFAB*. This approach is innovative in that it harnesses the power of a mobile app to create a "one stop" solution that is always with the participant. The ability to communicate directly with participants both through "push" (eg, app-based messages, social media posts) and "pull" (eg, new weekly content, narrative stories, didactic information) is a major strength of the program. The question for *BeFAB* to answer is what is the added value of this integrated approach.

Because *BeFAB* is delivered in an app, dose and usage information is available for analysis. Future research on *BeFAB* and new interventions in the field should examine the dose-response effects of digital platforms and their effects of HEAL behavior and weight outcomes [94]. As seen in other interventions, such as *text4baby*, dosage may be a powerful predictor of behavior change outcomes among pregnant and postpartum women [78]. Understanding dosage may also enable interventions to optimize delivery and health outcomes over the long-term [95]. Future trials should experimentally examine the effects of dosage and results should be used to optimize new and improved weight management interventions.

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