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Addressing people and place microenvironments in weight loss disparities (APP-Me): Design of a randomized controlled trial testing timely messages for weight loss behavior in low income Black and White Women

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ABSTRACT

Background: Behavioral interventions for weight loss have been less effective in lower income and black women. These poorer outcomes may in part be related to these women having more frequent exposures to social and physical situations that are obesogenic, i.e., eating and sedentary cues or situations.
Objectives: Working with obese, lower income Black and White Women, Addressing People and Place Microenvironments (APP-Me) was designed to create awareness of self-behavior at times and places of frequent eating and sedentary behavior.
Design: APP-Me is being evaluated in a randomized controlled trial with 240 participants recruited from federally qualified health centers located in a single Midwestern city. All participants complete four weeks of ecological momentary assessments (EMA) of situations and behavior. At the end of the four weeks, participants are randomized to enhanced usual care (UC) or UC plus APP-Me.
Methods: APP-Me is an automated short messaging system (SMS). Messages are text, image, audio, or a combination, and are delivered to participants' mobile devices with the intent of creating awareness at the times and places of frequent eating or sedentary behavior. The EMA data inform the timing of message deliveries.
Summary: This project aims to create and test timely awareness messages in a subpopulation that has not responded well to traditional behavioral interventions for weight loss. Novel aspects of the study include the involvement of a low income population, the use of data on time and place of obesogenic behavior, and message delivery time tailored to an individual's behavioral patterns.

1. Introduction

Obesity rates are high among middle-aged adults, [Ogden] which we here define as 35–64. This is true among poorer and minority adults in particular. Adults living in poverty, for example, have rates that are 50% higher than adults not living in poverty [1]. Racial disparities are also large, and largest in middle-age where 59% of black women have a body-mass index (BMI) of 30 or greater (indicating obesity) while only 36% of white middle-aged women have an obese BMI [2].

Notably, the National Academy of Medicine (formerly the IOM) identified obesity in the urban poor as high priority research [3]. For middle-aged black women, four of five leading causes of death are obesity-related [4]. The concluding article in an October 2014 Obesity Reviews Special Issue on Achieving Healthy Weight in Black American Communities reports that studies of obesity prevention and treatment in black adults are few and insufficient. The authors recommend exploration of electronic health approaches [5].

Weight loss trials have generally had low representation of adults living in poverty [6]. And while black adults have been represented in large weight loss trials such as the Diabetes Prevention Program (DPP) and Look Ahead [7], black women in these trials have consistently lost less weight compared to white women [8–13]. Reasons for this are unclear but qualitative studies point to frequent exposure to obesogenic situations for black women [5,14]. Social support for healthy weight in particular has been hypothesized to be low among black women relative to white [15–17]. Regardless, limited success in weight loss

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among black and poor women translates into significant racial and socioeconomic disparities in health and longevity—a relatively modest weight loss of 2 kg has been shown to meaningfully reduce one's risk of hypertension and diabetes [18,19].

Several recent studies have tested short message service (SMS) "text" messaging as an approach to monitoring and supporting behaviors conducive to weight loss [20–24]. The theoretical frameworks guiding these studies are social cognitive and self-regulation theories, and transtheoretical model. These studies sent messages from the study staff or machine. The frequency of text messaging ranged from two per week to six times a day. Only one study attempted to send text messages that were coordinated with a participant's reported daily schedule [23].

Weight loss success was variable across the studies. However, consistently across all of the studies, participants who interacted most with messaging had greater weight loss. Furthermore, only one study enrolled low-income or black women [23]. Attrition was well over 50% at 6 months in this trial, but among those who did not attrit, weight loss was 3.7 kg for those receiving supportive texts versus those in standard care.

Our project first measures and compares obesogenic behavior and situations to which urban poor black and white middle-aged women are exposed and, second, tests whether timely messaging via a smartphone application can offset some of the influence of these situations. Based upon the theory of automaticity [25,26] and the input of middle-aged, urban poor women who participated in our iterative user-centered design process, both of which are further discussed below, the messages are intended to give timely awareness for physical activity and portion control, as well as general inspiration for health. The Black and White Women in the proposed study live in the same neighborhoods of a single urban county and seek care in the same safety-net health system. This health system operates a lifestyle weight loss program called Healthy Me [10,27], which is part of enhanced usual care. The purpose of this paper is to describe the study design, assessments, and intervention.

2. Methods

Addressing People and Place Microenvironments (APP-Me) is funded by the National Institute of Heart, Lung, and Blood Institute (R01 HL128494). The study is approved by the Indiana University Institutional Review Board and registered in clinicaltrials.gov (NCT03083964).

2.1. Setting and population

This study will recruit a sample of 150 non-Hispanic black women and 150 non-Hispanic white women ages 35–64 who receive care in one of eight federally qualified health centers (FQHC). Participants will reside in Indianapolis, Indiana, a city with slightly less than one million persons as of 2016—66% non-Hispanic white and 28% black—and a median household income of $42,168 [28].

The FQHCs from which participants will be recruited serve a patient population with high rates of poverty—one recently completed study indicated that 50% of obese middle-aged adults in these FQHCs report household incomes of less than $20,000 per year [29]. Further, two thirds of the participants from this study self-identified as black.

Living in the same city, Black and White Women in the study will have been exposed to largely the same macro physical environments (e.g., number of fast food restaurants and signs) but perhaps not the same micro level physical or social environments (e.g., food in the household, social network eating behavior). Given the influence of automaticity on weight-related behaviors [30], addressing the influence of micro level exposures is likely critical to furthering research on disparities in weight loss.

2.2. User-centered design

In the creation of the awareness tool, we adopted a user-centered design process for the development of consumer-facing health information technology [31–35]. This iterative design process was comprised of three phases that (1) sought to understand the users, their tasks and goals, and the different aspects of their surrounding environments (study phase), (2) design abstract representations followed by more traditional artifacts such as wireframes or user interface prototypes, and (3) evaluate the designs against users' needs and goals.

Phase 1: This study phase included conducting 30–60 min semi-structured individual interviews with FQHC health coaches and Black and White Women aged 35–64 years. A basic framework of questions served to probe and understand the characteristics of participants, their perceptions toward nutrition and physical activities, and their corresponding motivations, goals, and barriers. Data collected in this phase were transcribed and used to identify pain points, concerns, needs of users, and implications for design.

We identified three key user requirements that influenced our subsequent design process: (1) lack of information, (2) need for social engagement around weight management, and (3) support while making decisions related to eating or physical activity.

Phase 2: Adapting the work discussed by Iacucci and colleagues [36–39], the design phase included a role-playing game that required players to enact and envision potential products or services that will help support their needs specific to information, social engagement, and support in healthy weight loss behaviors. This game included a board designed to mimic a city and took into account the mobility of users, their various contexts, activities, and group interactions. Each of three games required 4–5 players, with each player enacting a scenario, identifying user needs for the scenario, proposing a solution, and participating in a group-based discussion of the identified needs and solution by all the players. Participants converged on the necessity for increased awareness of obesogenic behavior, which included healthy eating and increased physical activity. From this, our team envisioned a short messaging system (SMS) aimed at creating awareness at the right place and time to offset the influence of obesogenic behaviors.

We then conducted a series of design sessions to identify the product requirements to design a mobile SMS system. These included: (i) push messages in a timely manner (e.g., during times when participates were likely to consume calories or remain sedentary), (ii) push messages depending on location and social context, (iii) push messages users or their close network ties create in addition to those offered by the study, (iv) push messages in multiple modalities (text, audio, and picture), and (v) collect or receive user feedback on each message. Phase 3: A significant need for a timely and context-sensitive messaging system is understanding the user's behavior and schedule. This motivated the need for a mobile ecological momentary assessment (EMA) system, which is capable of performing experience sampling. Hence, working again with potential participants, our team developed a mobile EMA system. EMA assessments occur in the moment and reduce recall bias [40] and is considered the gold standard of experiential sampling [41]. EMA question formats were co-designed and evaluated by users, and include eating, drinking, social interaction, physical activity, and location questions. To achieve maximum timely and context learning, we designed an enrollment process where users set approximate times appropriate to receive EMA messages. From within the EMA application, users set approximate times when they wake up, eat, sleep, and wish to not be disturbed. This information guides the timing of EMA questions for each participant. APP-Me uses this EMA information to learn personalized user behavior and send awareness messages to users at the right time.

Following the design and evaluation of EMA component, our team worked with potential participants to develop the initial awareness messaging library. This process involved participants co-designing some sample awareness messages, evaluating the usability of APPME in