



Using social media to deliver weight loss programming to young adults: Design and rationale for the Healthy Body Healthy U (HBHU) trial

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ABSTRACT

Background: The transitional period from late adolescence to early adulthood is a vulnerable period for weight gain, with a twofold increase in overweight/obesity during this life transition. In the United States, approximately one-third of young adults have obesity and are at a high risk for weight gain.

Purpose: To describe the design and rationale of a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) sponsored randomized, controlled clinical trial, the Healthy Body Healthy U (HBHU) study, which compares the differential efficacy of three interventions on weight loss among young adults aged 18–35 years.

Methods: The intervention is delivered via Facebook and SMS Text Messaging (text messaging) and includes: 1) targeted content (Targeted); 2) tailored or personalized feedback (Tailored); or 3) contact control (Control). Recruitment is on-going at two campus sites, with the intervention delivery conducted by the parent site. A total of 450 students will be randomly-assigned to receive one of three programs for 18 months. We hypothesize that: a) the Tailored group will lose significantly more weight at the 6, 12, 18 month follow-ups compared with the Targeted group; and that b) both the Tailored and Targeted groups will have greater weight loss at the 6, 12, 18 month follow-ups than the Control group. We also hypothesize that participants who achieve a 5% weight loss at 6 and 18 months will have greater improvements in their cardiometabolic risk factors than those who do not achieve this target. We will examine intervention costs to inform implementation and sustainability other universities. Expected study completion date is 2019.

Conclusions: This project has significant public health impact, as the successful translation could reach as many as 20 million university students each year, and change the current standard of practice for promoting weight management within university campus communities.

ClinicalTrials.gov: NCT02342912

1. Introduction

Young adulthood is a public health risk period for weight gain. The greatest incidence of major weight gain (defined by $> = 5$ kg or more) occurs among those aged 25–34 years [1]. When examining national

data, there is an increasing trend in obesity prevalence by age with 17% of children and adolescents (ages 2–19) having obesity, compared with 32.3% of young adults (ages 20–39) and 40.2% of adults (ages 40–59) [2]. When including overweight, the trend indicates an almost doubling of obesity risk: the prevalence of overweight/obesity among 12–19 year

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olds averages about 33.6% [3], while prevalence among 20–39 year olds averages 63.5% for men and 59.5% for women [4]. The health effects of obesity are well documented and range from increased risk of cardiovascular disease and diabetes [5] to depression and stigmatization [6]. Metabolic risks are largely unstudied among young adults; however, undiagnosed cardiometabolic dysfunction is of primary concern [7]. Among college students, 26–40% had at least one abnormal component of the Metabolic Syndrome [7,8]. Young adulthood appears to be a potent time-frame for early intervention to address overweight and other risk factors for chronic disease [1,7].

Digital strategies, such as social media, are broadly used and accepted as forms of communication among college students [9–12]. There are over 1.7 billion active Facebook users worldwide, which is more than Gmail, Yahoo, and Hotmail combined [13,14]. According to 2015 data, approximately 80% of young adults were Facebook users [15]. Text messaging among young adults was also high: 100% of those ages 18–29 years and 98% those ages 30–49 years reported using their phone to text [16]. Among those aged 18–49 years, text messaging was used more frequently than email, voice calling and video calling [16]. This high use indicates that social media might be a good channel for reaching young adults. Indeed, digital strategies have been shown to deliver effective weight loss programs and have included channels such as the Internet [17–19], Twitter [20,21], self-weighing with electronic feedback [22], and personal digital assistants (PDA's) [23–25]. However, none of these studies were designed specifically for young adults. Pilot work by the investigative team demonstrated short term efficacy of a personalized weight loss program delivered to college students via Facebook and text messaging, with weight losses of 2.4 kg at 8 weeks [26]. This pilot study was designed to use popular digital channels for delivering weight loss information to extend the reach of programming to young adults.

University campus communities offer a range of health and mental health services. Approximately 20 million students are enrolled in an undergraduate or post-baccalaureate program [27,28]. Yet, obesity treatment and prevention efforts have lagged behind other health-related programming on campuses [29]. For example, of the 10 universities with the largest student enrollment, only 3 offered weight loss programming specific for undergraduates, on campus at no additional cost, and delivered by university-funded treatment providers. In comparison, all of these schools offered no-cost and continual enrollment programming for the other high-risk health needs, including alcohol and other drug services and eating disorders [29]. University settings could provide sustainable locations for the identification of health risks, such as overweight and obesity, and provide additional offerings for health related programming, such as evidence-based weight loss programs.

2. Overview/primary research goals

The aim of this randomized controlled trial is to examine the efficacy of two 18-month weight loss treatments compared with an 18-month contact control group, with intervention content delivered via Facebook and text messaging. In this trial, 450 students (ages 18–35) with overweight/obesity will be recruited from two sites: The George Washington University (GWU) and University of Massachusetts-Boston (UMB). Ages 18–35 were selected as a target range for young adults, which consistent with other US-based (e.g., [30,31] and International Trials [32]. Social media as an intervention tool was chosen in that it is technology that the students are already accustomed to and it does not require face-to-face intervention sessions. Assessments are conducted at baseline, 6, 12, and 18 months post baseline, with the primary outcome being weight loss at 18 months. The secondary aim is to evaluate changes in metabolic risk factors among those participants who have maintained at least 5% weight loss at 18 months. Finally, additional formative work is being conducted to evaluate the implementation feasibility of this intervention on university campuses, including an

assessment of costs as well as the sustainability infrastructure using the PRISM (Practical, Robust Implementation and Sustainability Model) [33] model as a guide.

3. Study design/methods

3.1. Settings

The recruitment sites for this study are The George Washington University and the University of Massachusetts-Boston, with Institutional Review Board approval being obtained from both sites. While those two universities were the primary target, students within the greater Washington DC and Boston areas were eligible to take part in the study.

3.2. Participants and enrollment

Participants are enrolled in cohorts, beginning in May 2015, and continuing through December 2017. A total of 450 students (225 at each site) are randomized into one of three treatment arms. Enrollment occurs across multiple cohorts throughout the year. Several methods are used to recruit and enroll participants in the study, including mass emails, listserv emails, classroom talks, flyers, tabling events, health and wellness fair presentations, shuttle bus posters, Facebook advertisements, and local and college newspapers. Mass emails and listserv emails are proving to be the most effective methods of recruitment. The study was titled, Healthy Body Healthy U, or HBHU for short, and the recruitment materials place an emphasis on it being a research study to interested individuals. The recruitment materials also place an emphasis on helping to promote a healthier lifestyle via social media so that it is convenient for participants.

Individuals are eligible if they are aged 18–35 years, have a BMI of 25–45 kg/m², attend a college/university in the Greater DC/Boston area, are active Facebook users (logged in within the last month), fluent in English, and had regular text message access. Participants are excluded if they reported currently trying to gain weight, using steroids, a history of weight loss surgery, or are participating in another weight loss or physical activity study. Additional exclusion criteria are based upon participant safety for a weight loss program, or causing unintentional weight change making study effects difficult to determine. Health-care provider clearance is required prior to participation for those individuals who endorsed “yes” for any Physical Activity Readiness Questionnaire (PAR-Q) [34] questions, and any reported diagnosis of untreated hypertension, hyperlipidemia, type 2 diabetes, or heart disease. Specific inclusion/exclusion criteria are summarized in Table 1.

Potential participants complete an online screening questionnaire, which is then reviewed by trained study team members. Study team members contact individuals by phone for further screening, and those who meet criteria are scheduled for an in-person screening visit (Pre-Enrollment Visit). At the Pre-Enrollment session, the following steps are taken: 1) verify eligibility criteria, including height, weight, and blood pressure measurements, 2) explain the study in more detail prior to obtaining written consent, 3) provide participants with an ActiGraph accelerometer, access to the online ASA-24 food recall system and to the online survey to complete psychosocial measures, and 4) schedule the participant for his/her second baseline visit (First Checkpoint Visit). Pre-Enrollment sessions last approximately 40–50 min.

Participants return for their First Checkpoint Visit no < 7 days after their Pre-Enrollment visit, allowing sufficient time for participants to complete the ActiGraph wear-time, online dietary recalls, and psychosocial surveys. At this visit, body weight and abdominal circumference are measured by trained research assistants, and a fasting blood sample is obtained for the determination of glucose, insulin, lipid profile including triglyceride concentrations. See Table 2 for an overview of all measures and their administration time points, which are discussed in

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