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Sustaining the Reach of a Scalable Weight Loss Intervention through Financial Incentives- A pragmatic, online randomized trial protocol

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Abstract

Background: High attrition following initial enrollment in evidence-based weight loss programs is a common, challenging, and under-studied issue. A behavioral economics approach consisting of modest monetary incentives may help to engage participants beyond enrollment to close the initial attrition gap.

Purpose: To describe the methods and design of a pragmatic, online randomized controlled trial (RCT) of an incentivized, technology-facilitated weight loss program through an innovative research-practice partnership involving primary care, health promotion researchers, and a small business.

Methods: This study is a four-arm (1:1:1:1) RCT that compares the efficacy of outcome-based (weight loss), process-based (weighing in), a combination of outcome- and process-based, or choice-based incentives on sustaining program reach after initial enrollment for an evidence-based

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Conflict of interest: Todd McGuire is employed by, holds the patent to, and is a part owner of IncentaHEALTH LLC.

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weight loss program. The study will enroll 400 individuals aged 19 and older who have a body mass index ≥ 25 kg/m², and have reliable access to the Internet or a smart phone. Participants will be followed for 3, 6, 9, and 12 months to assess program reach and representativeness, and continued participation after enrollment. The secondary outcomes include weight loss and program implementation costs. We will conduct participant focus groups to understand the barriers and facilitators of participation and key informant interviews focusing on clinic managers and care providers to explore the potential for future adoption and implementation of the evidence-based program.

Discussion: This study possesses the potential to close the attrition gap after initial enrollment in a web-based digital weight loss intervention in the primary care and community settings.

[Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04225234) registration: [NCT04225234](https://clinicaltrials.gov/ct2/show/study/NCT04225234).

Keywords

behavioral economics; implementation strategy; attrition; uptake; primary care; disparity

1. Introduction

In response to the obesity epidemic, several weight loss interventions have been implemented in community or clinical settings and demonstrated effectiveness [1–3]. A consistent implementation issue has arisen across weight loss programs delivered in the typical settings—high initial program attrition. For example, when considering one of the largest scaled clinical weight loss programs to date, the Veterans Health Administration Move program, one study documented nearly half of the participants completed only a single encounter with the program regionally [4] compared to a national evaluation of 38% [5]. Glasgow et al. [6] similarly found that 50% of participants did not engage with an electronic weight loss intervention beyond an initial session.

Providing incentives for weight loss has a long scientific history with early behavior-modification approaches finding some success with increasing the frequency of program attendance and weigh-in behavior (i.e. self-monitoring) [7–13]; while more recent approaches have a theoretical grounding in behavioral economics [14]. A behavioral economics approach is based on the use of external incentives as a way to compensate participants to forgo preferred lifestyle behaviors related to eating high calorie, flavorful foods and sedentary behaviors and to engage in less preferred but more healthful eating and activity behaviors [15]. Across studies, the success of incentive-based programs has been varied and the effectiveness in producing weight loss is dependent on magnitude (larger incentives are better) and type of incentive (cash better than reductions in premiums), timing of incentive payment (regular intervals better than at program completion) or the way incentives were combined with other strategies (when combined with evidence-based approaches have limited added benefit) [10, 11, 16–19]. The findings for maintenance of weight loss have been more consistent—once incentives are removed weight regain follows [17–21].

An alternative behavioral economics approach is to consider a financial incentive as an implementation strategy to *nudge individuals to participant in the initial phases of an evidence-based, technology facilitated weight loss program* with the hypothesis that healthful behaviors will become more preferred due to the benefits perceived by participants reducing the dependence on financial rewards for compensation [22, 23, 15]. Research in this area has demonstrated that providing a very modest monetary incentive (\$1/percent weight loss/month) can significantly increase participation in weight loss programs when compared to a no-incentive comparison condition [23] and that this same incentive strategy increases the initial enrollment rates of African American participants [22]. Further, modest financial incentive structures that could be more attractive to participants with different demographic background. Specifically, under hypothetical incentive options, African Americans indicated a higher likelihood of participation if incentives were tied to weight loss or if they could choose between three or more options that included incentives for weigh-ins or a combination of weigh-ins and weight loss. However, there is little evidence related to the effect of different economic incentives on real-world participation in weight loss programs and the comparative effectiveness of these incentives in closing the initial attrition gap. This proposed study will assess the effect of different incentive options on *actual* participation and the ability of these incentives on closing the initial attrition gap.

2. Methods

The primary objective is to assess the comparative effectiveness of different incentive options (outcome- or process-based, combination of outcome and process, and choice-based) in sustaining the program reach of an evidence-based weight loss program following initial enrollment when implemented in a primary care setting. As one of the indicators of RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework [24], reach is defined as the percent and representativeness of at-risk individuals willing to participate. The secondary aims are to: (1) assess the costs associated with each incentive option to determine the incremental cost per additional percentage of retention rate for sustaining the reach at 3, 6, 9 and 12 months, respectively; (2) explore racial differences in responsiveness to different incentive strategies and percentage of participants achieving a 5% or more weight loss after 3, 6, 9 and 12 months of participation; (3) collect qualitative data that can facilitate future adoption of the evidence-based weight loss program with tailored incentive packages for its seamless integration into primary care and/or community settings.

2.1 Study design

This study employs a pragmatic, randomized clinical trial (RCT) design. Individuals who meet the eligibility criteria will be randomized (1:1:1:1) to receive one of the following 12-month interventions:

1. Weight loss program + financial incentives based on the degree of weight loss (outcome-based incentive),
2. Weight loss program + financial incentives based on the frequency of weigh-ins (process-based incentive),

3. Weight loss program + financial incentives based on the combination of outcome and process (blended condition), or
4. Weight loss program + financial incentives where participants choose one of the first three options (choice-based incentive).

Weight loss program content is identical across all groups, such that the only difference between groups is the mechanism of incentives.

The outcome-based incentive group will be used as a control group for measuring the impact of financial incentives between four intervention arms. We selected this group rather than no incentive as we found that when this incentive was used previously there was still a significant initial program attrition (i.e., ~40% initial attrition) [22]. We considered using a no-incentive control, but our community advisory board indicated that this would be perceived poorly by those participants randomly assigned to that condition—especially in light of their consideration of some of our earlier work that demonstrated financial incentives significantly increase initial weight loss program reach [25]. This study protocol was approved by the Institutional Review Board of the University of Nebraska Medical Center and was registered in [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04225234) (NCT04225234).

2.2 Participant, recruitment, and enrollment process

Participants will be recruited through a combination of primary care provider referral, advertisement in the communities and at the kiosk, and word-of-mouth. The study kiosk is placed at primary care clinics, where 58% of the ~5,000 patients are African American with ~45% being considered obese. Primary care providers from the clinics will identify eligible patients through their electronic medical records and refer them to the kiosk located at the same clinics. Although the study kiosk being placed at a clinical setting, recruitment is not limited to patients who receive healthcare services at the clinics.

Eligible participants are individuals aged 19 and older who have a body mass index (BMI) $\geq 25 \text{ kg/m}^2$, and have reliable access to the Internet. To participate in the study, eligible individuals will be required to complete a 2-step enrollment process consisting of (1) an online registration intake form with online consent embedded in the study web-based platform (UNMC2.incentaHEALTH.com); and (2) a weigh-in using the HEALTHspot® kiosk, including a calibrated scale synchronized to a built-in digital camera (Figure 1), located at participating primary care clinics. Figure 2 illustrates the study enrollment flow. While verifying participants' BMI eligibility and documenting their initial body weight, the patented kiosk records a full-length photo (i.e., a health selfie) to track visually-authenticated improvements and sustained BMI reduction [22, 23]. The kiosk securely transmits the weigh-in data to each participant's management dashboard on the study platform to display live performance results for the entire enrolled population.

Once potential participants initiate the enrollment process (either the online intake or the kiosk weigh-in), they will have one month to complete both steps. For those who do not complete both steps in the same day, email reminders will be sent on days 1, and 3, 7, 14, and 21 to prompt them to finalize the enrollment process. Participants will be assigned

following a randomization table created by the study statistician after completing the 2-step enrollment process.

Upon randomization, participants will receive an automated email message indicating their assigned intervention group. For participants who are randomized to the choice-based group, they will receive an email prompting them to choose one of the three incentive options. Additionally, participants will be encouraged to log into the study platform to view their randomization assignment and weigh loss progress.

2.3 Interventions

2.3.1 The evidence-based weight loss program—The 12-month web-based digital intervention (accessed via smart phone or computer) was developed to support weight loss via the promotion of a healthful diet (e.g. low fat, high fiber, emphasis on fruits and vegetables, choose water instead of sugary drinks) and regular physical activity (e.g. 150 minutes of physical activity/week) [26]. The weight loss program was informed by research findings [27–29] and designed to be convenient (e.g., no group meetings). The program includes a website, social cognitive theory-based daily health coaching [30], tailored messaging delivered via email and text messaging, access to online health coaches, and objective weight assessment through private yet accessible kiosks located in the community. The program website serves as an electronic support system by providing video explanations of exercises, links to recipes, discussion forums, and links to an electronic fitness advisor. Key features of the website also include the management dashboard including photos from the weigh-ins, information on weight loss, and self-monitoring logs for physical activity and dietary intake. In addition, this program incorporates a number of activities to initiate and sustain behavior change that are influenced by social cognitive constructs, such as self-efficacy, outcome expectations, social support, goal setting, and an individual's interaction with their environment. These activities include motivational interviewing, knowledge and skill building, positive imaging and feedback, environmental control, social contracting and helping relationships, reinforcement, and modeling [30]. Over the 12-month intervention, the initial 6 months is designed to focus on weight loss strategies, whereas the final 6 months focuses on relapse prevention and maintenance strategies.

Daily emails are the active delivery channel of behavioral strategies. These emails are tailored to each participant based on gender (male/female), fitness program choice (foundation/intermediate/advanced) and location (home/gym), and barriers selected during the enrollment process. Table 1 presents seven different email formats used across the program spectrum. Specifically, the weight loss program targets self-efficacy by including activities to increase the likelihood that participants will track and visualize performance success through a number of strategies including: photo transformation (i.e., seeing physical changes due to weight loss through a “healthy selfie” captured at weigh-in kiosks), online dashboard indicator highlights successful completion of intervention task, and tracking weight trends. Participants are exposed to weekly success stories, fostering vicarious learning. Individual affective state is enhanced by health coach support and motivational quotes, and graduated exercise plans are offered to tailor to participants' fitness levels.

2.3.2 Financial Incentive options

The four incentive options are, respectively, tied to percent of initial body weight loss (outcome incentive), frequency of weigh-ins (process incentive), a blended condition where incentives are tied to both weight loss outcome and weigh-ins, and an incentive choice condition where participants are prompted to choose one of the aforementioned three incentive programs. Table 2 describes the reward structure and timeline for each option. For example, in the outcome-based incentive arm, participants who achieve 1% weight loss earn \$1 earned per month, if sustained, and thus \$3 per quarter for losing 1% body weight. The reward amounts in the process-based and blended conditions are both designed to match the monetary amounts that can be earned for the outcome-based incentive. Over the 12-month study period, participants will have an opportunity to receive approximately \$60-\$120, on average, regardless of randomization assignment. Our previous work focusing on outcome-based only incentive indicated the average percent weight loss ranged between 1–10% for participants who had returned after initial weigh-in (i.e., overcome the initial attrition gap) and was estimated at 50–75% of the overall participants [22].

To qualify for the reward, participants who are randomized to the outcome-based or blended condition incentive arms will need to have at least one returning weigh-in using the study kiosk each quarter to document and verify their weight loss progress. For those who randomized to the process-based incentive arm, up to 12 weigh-ins per quarter qualify to earn an incentive, in order to equal to the average incentive amount can be earned for the outcome-based incentive. The rationale underlying the incentive timing and amount is threefold. First, the amount of incentive (\$1/percent body weight lost/month) was selected to avoid the use of unhealthy eating or activity patterns that may be used to lose weight quickly [31]. Second, by including only a modest incentive the likelihood of inhibiting intrinsic motivation would be low [32]. Third, the incentive scheme of \$1 per percent weight lost per month is easily communicated to, and understood by, participants.

2.4 Study outcomes

To examine the impact of financial incentive options on the temporal reach [33] of the study, the primary outcome of the trial is the percent of participants returning for a subsequent weigh-in in 3 (Quarter 1), 6 (Quarter 2), 9 (Quarter 3), and 12 months (Quarter 4) after initial weigh-in for enrollment. The secondary outcomes include absolute weight loss achieved at 3, 6, 9, and 12 months, respectively, and the percent of participants achieving clinically significant weight loss (3%, 5%, or 7% of the initial bodyweight). Additionally, we will collect intervention cost data using all program invoices related to program implementation and further grouped into technical systems support, program delivery personnel, kiosk leasing, marketing personnel and activities, and program incentives as categorized in our previous cost-effectiveness assessment of the program [34].

2.5 Program evaluation/implementation assessment

For quality improvement and future adoption of the evidence-based weight loss program, we will conduct two focus groups with participants and semi-structured, one-on-one interviews with clinic administrators and care providers to collect qualitative data. The first focus group will target participants (n=8–10) who had completed the enrollment process and initial

weigh-in, but did not return for any subsequent weigh-in to understand the reason why they did not have subsequent weigh-ins and identify associated barriers. The second focus group will focus on participants (n=8–10) who had at least one subsequent weigh-in using the study kiosk to gather information on factors that had motivated them to continue their participation, and also gain their perspective on the acceptability of the intervention and ideas for potential adaptation. The semi-structured interviews with care providers (n=6–8) and clinic managers (n=3) will assess administrators' and staff's views on the feedback and advice of the intervention program, and on challenges that would need to be overcome if the clinic were to decide to implement the program. The focus groups and interviews will be audio recorded and transcribed.

2.6 Sample size and data analysis

An intention to treat approach will be used. Participants will be analyzed according to the randomization assignment status regardless of levels of participation in their assigned programs. We did not find any relevant study in the literature that would allow us to conduct the power analysis. We selected our sample size (n=100 for each arm; n=400 in total) and will have the power ($\beta=0.8$ as default) to detect a 50% reduction of the attrition rate relative to the outcome-based incentive intervention arm. Fifty percent was selected because our previous work indicated that a 40% attrition rate was found in the outcome-based incentive group [22]. We hypothesize that the choice-based incentive arm will likely achieve this reduction and that smaller reductions will be associated with randomization assignment to the process-based and blended condition incentive arms.

The study is a four-arm RCT design, and thus we will use the Holm-Bonferroni method to examine the program reach across four incentive options, controlling the type I error. Pairwise comparisons will be used to identify the source of a significant difference. We will test the hypothesis that participants assigned to the choice-based incentive group are more likely to sustain engagement compared to those who are assigned to other three intervention arms beyond enrollment (initial weigh-in) and at 3-, 6-, 9- and 12-months post enrollment. Generalized linear mixed models will be conducted for: (1) weight change over time; and (2) weight change over time by race (Caucasian vs. African American), after enrollment, and also using an intention-to-treat analysis with multiple imputation to include all participants with baseline weight measurements. A subject-specific intercept representing baseline weight will be included as a random effect of the model.

We will estimate incremental costs associated with an outcome-based, a process-based, a blended condition, and a choice-based incentive arms. Specifically, across study arms, we will estimate marginal costs per additional participation rate or representativeness on reducing the attrition gap, costs per participant, costs per participants who achieved 5% weight loss, costs per pound weight lost, and costs per pound weight lost per weigh-in. All costs will be estimated and evaluated in constant dollars using the appropriate index for price adjustment.

To examine the barriers and facilitators for future scaling up within typical clinical settings, a hybrid deductive and inductive qualitative analysis approach will be used for analyses. We will use semi-structured interviews with clinic manager, staff, healthcare providers, and

focus groups with participants based on the Integrated Promoting Action on Research Implementation in Health Services (iPARIHS) framework [35]. Specifically, to analyze the data, we will use a deductive approach that will broadly align information across the categories of: (1) financial incentive evidence to close the attrition gap, (2) contextual readiness for an incentive-facilitated weight loss program, (3) factors that would facilitate implementation, (4) factors influencing program acceptability and engagement, and (5) indicators of successful implementation. An inductive approach will be used to generate themes and sub-themes from these data. This summative information derived from the focus groups and interviews will provide direction for a future larger pragmatic trial involving several primary care clinics across multiple healthcare systems.

3. Discussion

High attrition following enrollment in evidence-based weight loss programs is a common, challenging, and yet, an under-studied issue. It is possible that a behavioral economics approach that uses modest monetary incentives could help engage participants beyond enrollment to close this initial attrition gap [22, 36, 37, 3]. Key to addressing the initial attrition gap with financial incentive is the use of modest monetary amount (e.g., \$1/per percentage weight loss) to encourage individuals at risk to take action in the initial phase. In this trial, we propose to examine the efficacy of an outcome-based, process-based, blended condition, and choice-based incentives on reducing the attrition gap for an evidence-based weight loss program after enrollment. In particular, this study will provide information about what type of economic incentive, if any, is more efficacious in certain race/ethnicity groups than other groups. This knowledge would greatly benefit researchers and practitioners looking to improve program engagement among groups that could most benefit. Additionally, understanding what methods are successful for retaining a maximum number of participants in a weight loss program may aid the success and speed of scale up efforts in typical clinical and community settings.

Findings from a quasi-experiment study [22] suggested that community-based, incentivized weight-loss programs might be more effective in motivating African Americans to achieve 5% weight loss and remain enrolled in the program compared to non-African American participants. These important findings, however, have not been verified in an RCT with multiple incentive options. By conducting the trial in local clinics primarily serving African Americans, we anticipate that findings from the trial will not only illustrate the overall efficacy of different incentive designs in retaining participants in the weight-loss intervention, but at the same time also reveal the particular incentive designs that prove uniquely appealing to African American participants. This will facilitate tailoring prevailing weight-loss interventions in a way that can increase their reach to African American participants and reduce health disparities.

This study has several strengths. First, to the best of our knowledge, we are among the first to examine the hypothesis that the incentive based on participants' preference would produce greater reduction in the initial program attrition than other incentive/reward systems and further explore whether this effect differs among race/ethnicity groups. In a previous study, Cawley and Price [25] documented extremely high attrition in workplace wellness programs

offering both reward- (55%) and deposit-based financial incentives (25%), adding the caveat that while the deposit contract resulted in lower attrition rates than the positive reward system, the enrollment rates were much lower [27]. Other studies have focused on providing incentives based on process (e.g., weighing in) versus outcomes (e.g., weight loss), but have focused on weight loss achievement rather than closing the initial attrition gap [14].

Another strength is that this study pragmatically focuses on integrated research-practice partnerships involving primary care, research expertise, and a small business. This collaboration presents a mechanism to ensure that the community where the research is being conducted has the opportunity to meet an existing need while concurrently advancing science related to behavioral economics as applied to a significant, consistent, and understudied phenomenon of initial program attrition. Moreover, another unique feature of this study is collaborating with a small business (incentaHEALTH, LLC.), the provider of the incentivized, highly scalable, technology-supported weight loss program, to utilize their existing infrastructure and experiences to study pragmatic interventions that deliver both internal and external validity for the study findings [38]. The study platform is a web-based portal that integrates recruitment, self-administered enrollment intake form, the randomization process, receipt of data from kiosk (weight and healthy selfie), health messaging (text, email, or voice), and distribution of financial incentives into a digital system that requires little staff effort to implement and manage, and offers a unique combination of low cost, high engagement, and measurable and visible outcomes authenticated by the HEALTHspot[®] kiosk. With the deployment of kiosks and the platform, the study is conducted with minimal effort where eligible participants are automatically enrolled with informed consent, body weight measurement, healthy selfie, data collection, and follow-up.

This study has some limitations that need to be noted. This study requires participants have access to the internet to use the online platform and receive the email intervention materials, which may reduce generalizability, however this is small limitation as 90% of U.S. adults currently have internet access [39]. Another limitation is that this study employs a two-step enrollment process (kiosk weigh-in and online registration) which may to some extent exclude eligible participants who may be the individuals in greater need for the intervention and/or may most benefit from participating.

In sum, this study possess the potential to close the well-known attrition gap after the initial enrollment of a web-based digital weight loss intervention in the primary care and community settings.

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Figure 1.
The study kiosk.

Figure 2.
Study Enrollment flow.

Table 1.

Summary of daily e-mail content by day of week and program cycle [23].

Day of Week	A Better Way (1 st Quarter)	Climb the Hill (2 nd Quarter)	Become the Expert (3 rd Quarter)	Automatic Habits (4 th Quarter)
Monday: Success Stories	Highlights people who have just began to lose weight	Highlights people who have sustained and continued weight loss for 6 months or more	Highlights people who have advocated successfully for organizational change to support healthy lifestyles	Highlights long time advocates and people who have lost substantial weight and kept it off for over a year.
Tuesday: Exercise	Safe and slow progression	Additional benefits of moderate exercise and weight training	Explores worksite policies or resources that would allow for exercise breaks	Advocating for healthier worksite policy and support for regular exercise.
Wednesday: Healthful Eating	The information basics on what foods are most healthful	Quick, easy, and healthful meal preparation	Explore worksite opportunities for healthful snacks. Identify unhealthy eating practices or policies.	Advocating for healthier worksite policy and support for healthful eating.
Thursday: Barriers & Solutions	Personal obstacles and strategies to overcome them.	Obstacles that could lead to relapse and strategies to overcome them.	Obstacles to environmental change and strategies to overcome them.	Successfully implementing environmental changes.
Friday: Ask the Expert	Based on frequently asked questions from preliminary studies.	Based on frequently asked questions from preliminary studies related to relapse prevention.	Based on research literature related to community and environmental change implementation.	Based on research literature related to community and environmental change implementation.
Saturday: Portion Sizes	The information basics on portion sizes across food groups.	Maintaining healthful portion sizes when eating out	Methods to change your home eating environment to encourage appropriate portion sizes	Methods to change your work eating environment to encourage appropriate portion sizes
Sunday: Motivation	Goal setting, weekly journaling, and feedback on progress.	Goal setting, weekly journaling, and feedback on progress.	Goal setting, weekly journaling, and feedback on progress.	Goal setting, weekly journaling, and feedback on progress.

Table 2.

Financial rewards by incentive structure and schedule.

Timeline	Incentive option		
	Weight Loss	Weight-in*	Weight loss & weight-in (blended condition)
Quarter 1 (Months 1–3)	5%–\$15	\$1.25/weight-in (up to \$15)	\$0.65/weight-in (up to \$7.80)
Quarter 2 (Months 4–6)	10%–\$30		
	15%–\$45	\$2.50/weight-in (up to \$30)	\$1.25/weight-in (up to \$15)
Quarter 3 (Months 7–9)	20%–\$75		
	25%–\$105	\$3.50/weight-in (up to \$42)	\$1.75/weight-in (up to \$21)
Quarter 4 (Months 10–12)	30%–\$150		
		\$5.00/weight-in (up to \$60)	\$2.50/weight-in (up to \$30)
			5%–\$7.50
			10%–\$15
			15%–\$22.50
			20%–\$37.50
			25%–\$52.50
			30%–\$75

* Weight-in up to 12 times per quarter for rewards. (Limited to one weight-in per week)