

FEATURE-BASED DESIGNS TO INCREASE THE REACH OF EFFECTIVE WEIGHT-
LOSS PROGRAMS

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Keywords: Obesity, overweight, weight loss, computer, Internet, eHealth, reach

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ABSTRACT

Because of the prevalence and associated health-care costs of obesity, it is widely recognized today as a serious public health issue. The Affordable Care Act (ACA) passed in 2010 includes provisions for all adults to be screened and behavioral intervention offered to those with a body mass index (BMI) of ≥ 30 kg/m².¹ While the measure is intended to improve access to weight-loss resources for millions of Americans affected, it may not achieve its intended effect in part because of the inability of disadvantaged populations for whom the burden of obesity is the greatest to access ACA-supported services.^{2,3} The objectives of this study were to identify the characteristics that, paired with an evidence-based weight-loss intervention, will have the highest potential reach while achieving a clinically meaningful weight loss, and whether likely participation differs by gender, race, ethnicity or socioeconomic status. Using characteristics from the most effective adult weight-loss studies that use technology to expand reach, three alternative interventions were examined.^{4,5} Findings show that, while the majority of participants favor the traditional ACA face-to-face model, a program delivered completely online may appeal to racial and ethnic minority groups, which were more likely to choose alternative program structures. Alternative program structures should continue to be explored as an important next step toward developing viable referral options for primary care physicians and could have far-reaching impact toward reducing the disparity of obesity and obesity-related disease among disadvantaged populations.

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GENERAL AUDIENCE ABSTRACT

The majority of adults in the U.S. are overweight or obese, placing them at risk for serious health problems. Because of its prevalence and associated health-care costs, obesity is widely recognized today as a serious public health issue. The Affordable Care Act (ACA) passed in 2010 includes provisions for all adults to be screened and behavioral intervention offered to those with a body mass index (BMI) of ≥ 30 kg/m².¹ While the measure is intended to improve access to weight-loss resources for millions of Americans with obesity, it may not achieve its intended effect for a variety of reasons, including the inability of disadvantaged populations for whom the burden of obesity is the greatest to engage in ACA-supported services. The objectives of this study were to identify the characteristics that, paired with an evidence-based weight-loss intervention, will have the highest potential reach while achieving a clinically meaningful weight loss, and whether likely participation in response to different characteristics differs by gender, race, ethnicity or socioeconomic status. Adult participants (n=185) from Omaha, Nebraska, were recruited to participate in a survey in which they were presented with a “basic” program based on ACA-covered features (e.g., 20 in-person weight loss sessions over a 6-month period) and three alternative programs that included feature enhancements: weight-loss medication (Program A), online delivery (Program B), and a combination of the two (Program C). Participants were asked to choose in which program they would be most likely to participate. Statistical analysis included cross tabulation by gender, race, ethnicity, education, income and BMI and chi square analyses to determine whether the differences between the sub groups were statistically significant. The sample (n=185) was predominantly female (73%), 42 percent of participants were black and 43 percent were Hispanic. The majority of the sample (84%) were overweight or obese (55% ≥ 30 ; 29% $26 \leq 29$; 13% ≤ 25). Ages ranged from 21 to 86 (mean age 47 +/-14/7). The majority of participants (88%) selected the ACA-based program over Program A (22%) regardless of participant attributes. Similarly, the majority selected ACA (70%; 81%) over Programs B (30%) and C (19%), respectively. Program selection by gender and weight status was not significantly different. The majority of participants selected the ACA-based program (81%;78%) over Program A (19%) and Program B (22%) regardless of race. However, when contrasting Program B with the ACA program, black participants (43%) were more likely white (21%) participants to select Program B (p<0.05). A similar pattern was found for Hispanic participants with non-Hispanics (42%; 28%) being significantly more likely to select Program B than Hispanic participants (16%; p<0.05). and Program C (8%; p<0.05). Upper income participants (40%) were more likely to select Program C over the ACA program when compared to both middle (18%, p<0.05) and lower household income (9%, p<0.05) participants. Finally, Participants with a college education or professional degree were more likely to select Program B (46%, p<0.05) and Program C (31% p<0.05), when compared to participants without a college degree (22%; 14%, respectively). The development of alternative program structures should continue to be explored among disadvantaged groups and evaluated to determine their appeal. Identifying the characteristics that paired with a structured, behaviorally based program achieve the highest reach while producing a clinically meaningful weight loss is an important next step toward developing viable referral options for primary care physicians and could have far-reaching impact as more Americans seek such services.

Keywords: Obesity, overweight, weight loss, computer, Internet, eHealth, reach

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CHAPTER 1: Introduction

The majority of adults in the U.S. are overweight or obese, placing them at risk for serious health problems, such as heart disease, Type 2 Diabetes (T2D), asthma, sleep disorders and low self-esteem.^{1,2} As a result, obesity is a major contributor to the escalating and unsustainable health care costs in America.^{1,3}

Because of its prevalence and associated health-care costs, obesity is widely recognized today as a serious public health issue. The Affordable Care Act (ACA) passed in 2010 includes provisions for all adults to be screened and behavioral intervention offered to those with a body mass index (BMI) of ≥ 30 kg/m².⁴ The behavioral intervention may include 12 to 26 group or individual sessions with a health care professional without a co-pay or other additional cost to the patient.

The ACA's obesity treatment coverage is based on earlier evidence that shows high-intensity weight-loss programs delivered in person, face-to-face by a medical professional to be most effective treatment for weight loss.⁵ While the ACA is intended to improve access to weight-loss resources for the millions of Americans with obesity, it may not achieve its intended effect due to the barriers to access for disadvantaged populations for whom the burden of obesity is the greatest, particularly women.⁶

Overall, 42.5 percent of Hispanics and 48.1 percent of non-Hispanic blacks are obese, significantly higher than obesity prevalence of 34.5 percent of non-Hispanic whites.⁷ The burden of obesity is the greatest for black and Hispanic women.⁷ Among black women, 56.9 percent are obese compared with 37.5 percent of black men.⁷ For Hispanic women, the prevalence is similar: Overall 45.7 percent of women are obese compared with 39 percent of men.⁷

Low income women especially are at high risk for obesity. While obesity prevalence among men is similar across all income levels, the data show an inverse relationship between female obesity and income. Overall, 29 percent of women who live in households with income at or above 350 percent of the poverty level are obese compared with 42 percent of women with income below 130 percent of the poverty level. The relationship between obesity and education is similar: Just over 42 percent of women with less than a high school degree are obese compared with 23.4 percent of college-educated.⁷

Few weight-loss studies have involved low-income minority participants and those that do have produced outcomes well below that expected. Low-income and minority groups face a variety of barriers in accessing to weight-loss programs. They include lack of transportation, limited literacy, insufficient time, child care responsibilities and other resources required to participate in intensive, face-to-face programs.^{8,9} Therefore, program features and delivery methods that use digital technology to overcome personal “cost” barriers are being studied with the goal of improving the reach of weight-loss programs already known to be effective.

In the United States, 72 percent of adults use the Internet and 52 percent use SmartPhones to find health-related information.¹⁰ Twenty-four percent look online for information about controlling or losing weight. The rate of Internet usage is similar across minority groups and socioeconomic levels, with 76 percent of those with incomes less than \$30,000 a year and 70 percent of those with high school diplomas using the Internet.⁸ Such widespread use of technology makes the Internet a promising vehicle for reaching large groups at a low cost.

Previous research has shown that the Internet is a viable method for delivering structured, behaviorally based weight loss programs and those that include some form of regular

individualized feedback are more effective than self-directed programs.³ Additional features such as weight-loss medication and meal replacements have been shown enhance effectiveness.^{11,12}

The objectives of this study were to identify the characteristics that, paired with an evidence-based weight-loss intervention, will have the highest potential reach while achieving a clinically meaningful weight loss, and whether likely participation in response to different characteristics differs by gender, race, ethnicity or socioeconomic status. A review of the literature was used to identify the most effective weight-loss interventions that incorporate technology-based delivery methods to support scalability. The ultimate intent of the study is to identify the characteristics that will contribute to the development of a viable referral option for primary care physicians which could have far-reaching impact as more Americans seek such services.

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CHAPTER 2: Literature Review

The review paper, *eHealth Interventions for the Prevention and Treatment of Overweight and Obesity in Adults: a Systematic Review with Meta-analysis* examined randomized controlled trials published in English between 1995 and September 17, 2014, to evaluate the effectiveness of “eHealth” interventions for the prevention and treatment of overweight and obesity in adults.¹ While the Internet is the technology predominantly used in the delivery of the interventions evaluated in the article, studies using other technologies such as email, text messages, monitoring devices, mobile apps, computer programs, podcasts, personal digital assistants (PDAs) and digital games also were included. Hutchesson and colleagues produced the first systematic review to broadly evaluate all information technology and the combined use of different technologies in preventing and treating overweight and obesity, including weight-gain prevention.¹ The review covers 127 papers describing 84 randomized controlled trials.

Clinically Meaningful Weight Loss

To identify potential intervention structures to present to study participant we categorized all studies included in the systematic review as achieving a clinically meaningful weight loss (i.e., $\geq 5\%$ of initial body weight), on average, or not. All those that achieved a clinically meaningful weight loss also achieved the ACA required 3 kilograms (6.6 pounds) lost over 6 months. Studies that produced clinically meaningful results ranged from the most intense² with 30 hour-long, face-to-face group sessions during the first six months and 30 mid-week check-ins via phone, fax or email to the least intense³ with only one face-to-face meeting and online chat rooms. Steinberg and colleagues⁴ exhibited the greatest use of technology paired with the least in-person contact with only a single face-to-face session and 49 non-face-to-face contacts. Some studies did not employ any face-to-face or other contact and still produced clinically meaningful

results⁵; On the other hand, one study used daily text messages and an interactive website and was not effective at achieving either clinically meaningful or reimbursable weight loss.⁶

Not surprisingly, the majority of interventions classified as neither clinically effective or ACA reimbursable were control, usual care or self-help groups and many included face-to-face sessions. This finding underscores that current practice is insufficient in addressing the chronic health problem of obesity. Compared with control and minimal interventions, eHealth interventions resulted in significantly greater weight loss, according to Hutchesson's meta-analyses. Also, the magnitude of weight loss in eHealth interventions with components such as email feedback and social support, was significantly greater compared with standard eHealth programs although no clear pattern emerged as to the optimal combination of components.

The most effective intervention was part of a six-month randomized open-label study conducted by Digenio and colleagues to evaluate the effects of adding lifestyle counseling to weight-loss medication frequently prescribed by physicians with minimal or no counseling.⁵ The study took place at 12 independent research clinics in the U.S. In addition to face-to-face methods, alternatives such as telephone and email and varying the frequency of contact were explored. A total of 376 obese patients (87% female) were assigned to five intervention groups. All groups received the same medication and Diabetes Prevention Program-based lifestyle modification program that included print materials and access to a weight-loss website. The High-Frequency Face-to-Face and High-Frequency Telephone groups lost the most weight (-8.5 kg, 8.9% and -7.2 kg, 7.7%). Additionally, these two groups had the greatest proportion weight losses greater than 5% (65%, 49%). While significantly lower, the results of the High-Frequency Email, Low-Frequency Face-to-Face and Self-Help groups were still clinically meaningful (5.5 kg, 5.9%; 6 kg, 6.4%; and 5 kg, 5.2%), reinforcing benefit of weight-loss medication as a

program component. This trial furthermore demonstrated that, combined with an evidence-based lifestyle modification program, high frequency telephone contact with a dietitian could be as effective as in-person contact. Noted as a limitation was the study population of predominantly white women.

Other trials examined the use of weight-loss websites. Gold and colleagues conducted a 12-month randomized controlled trial among 124 overweight or obese adults to compare the effectiveness of a structured behavioral weight-loss website (VTrim) to a self-help commercial weight-loss website (eDiets.com).⁷ The majority of participants were white, highly educated women. At six months, findings showed that the Vtrim group lost significantly more weight than the eDiets.com group (-8.3kg, 9% vs. -4.1kg, 4.5%) and maintained a greater loss at 12 months (7.8 kg, 8.4% vs. -3.4 kg, 3.7%), underscoring the importance of a therapist-led, structured behavioral approach in the delivery of online programs. Sixty-five percent of those using the VTrim website lost 5% or more of body weight compared with 37% of the eDiets.com group.⁷

Using the same weight-loss website (VTrim) in a second 12-month study, Micco and colleagues experimented with combining the online program with monthly in-person meetings to learn whether the results of pairing the two interventions would be similar to those of traditional in-person programs.⁸ One hundred twenty five participants (83% female, 90% white, 74% college educated) were randomized to Internet-only or Internet plus in-person treatment. Both groups completed the same online behavioral program. Instead of the online chat, the in-person group attended monthly meetings. Findings showed no significant difference between the two groups at either six months (-9.2 kg, 10% vs. -6.9 kg, 8%) or 12 months (-8.1 kg, 8.1% vs. -5.6 kg, 6.5 %), demonstrating that a structured, behavioral program delivered entirely online could

be an effective way reach large numbers of people for whom in-person treatment is not easily accessible.⁸

Shape Up Road Island (SURI), a 3-month statewide community weight-loss program, provided Leahey and colleagues an opportunity to learn whether a behaviorally based online program could enhance the results of a program reaching thousands of people.⁹ While the reach of such community weight-loss programs is typically great, weight loss is only modest. The SURI enhanced program components included an evidence-based behavioral website with weekly automated feedback and optional group sessions. Two hundred thirty overweight or obese adults were randomized to three groups. The addition of the evidence-based website led to weight loss of more than three times that of SURI alone. The addition of optional group sessions further enhanced weight loss. The proportion of those who lost 5% or more was the greatest among those who had the optional group sessions (54%) compared with those who used the behavioral website alone (42%).⁹ The proportion of participants who lost 5% or more using SURI alone is not available. Additionally, the cost per kilogram lost was similar between the two enhanced groups (\$39 and \$35). This study demonstrated that incorporating behavioral components into a community weight-loss program is important and cost-effective.⁹ Of those who met the inclusion criteria for the study, 82% were female, 91% were white and nearly 70% were college-educated.

Further exploring cost-effectiveness, Tate and colleagues conducted a six-month randomized controlled trial to evaluate the effectiveness of computer-automated feedback as an alternative to human email counseling in an Internet weight-loss program.¹⁰ One hundred ninety-two overweight or obese adults were assigned to three treatment groups: no counseling, computer automated feedback and human email counseling. All participants received one group

session, coupons for meal replacements and access to the program website. At three months, computer automated counseling was found to be as effective as human email counseling (-5.3 kg, -6.1 kg). By six months, however, the human emailing counseling resulted in significantly greater weight loss than either group (-7.3 kg, 8.2% vs. -4.9 kg, 5.5% and -2.6 kg, 2.9%).¹⁰ While both methods of email feedback produced clinically meaningful results, these findings suggest that computer automated feedback could be an effective weight-loss component longer term if combined with other strategies to promote adherence. The study population was predominantly female (84%), with more than half having a college education. The “fairly homogenous and educated sample” was noted as a study limitation.¹⁰

Based on the findings of these studies, the use of technology in the delivery of weight loss programs presents a promising alternative to the gold standard of face-to-face counseling by a physician, serving to both lower the cost and increase reach of important obesity interventions. Technology also may provide an effective strategy for reducing the length and frequency of in-person visits or replacing them altogether, further lowering program delivery costs. The use of community health coaches rather than physicians appears to be another promising way to lower the cost of program delivery.

Based on the current literature, alternatives to the traditional face-to-face structure for weight-loss programs could and should be available for health care organizations to use in a reimbursable way. Many studies were conducted using populations of predominantly white, well-educated women, limiting the generalizability of their findings. Further research is needed to determine which interventions are most effective at reaching minority populations, as well as the optimal mix of in-person and digital program components.

Primary Aims and Hypotheses

The aims of this study are to determine:

1. Whether varying the characteristics of ACA-supported obesity treatment to overcome person “cost” barriers (time, convenience, money) increases the likelihood of participation by obese healthcare consumers. Characteristics examined will include a variety of methods for delivering evidence-based interventions as a complement to in-person individual or group sessions.
2. Whether likely participation in response to different characteristics differs by gender, race, ethnicity or socioeconomic status. A better understanding of the decisionmaking framework as it relates to weight-loss programs will help identify the characteristics that, paired with an evidence-based weight-loss intervention, will provide the necessary scalability to achieve the greatest public impact.

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CHAPTER 3: Feature-based Designs to Increase the Reach of Effective Weight-loss Programs

ABSTRACT

The majority of adults in the U.S. are overweight or obese, placing them at risk for serious health problems. Because of its prevalence and associated health-care costs, obesity is widely recognized today as a serious public health issue. The Affordable Care Act (ACA) passed in 2010 includes provisions for all adults to be screened and behavioral intervention offered to those with a body mass index (BMI) of $\geq 30 \text{ kg/m}^2$.¹ While the measure is intended to improve access to weight-loss resources for millions of Americans with obesity, it may not achieve its intended effect for a variety of reasons, including the inability of disadvantaged populations for whom the burden of obesity is the greatest to engage in ACA-supported services. The objectives of this study were to identify the characteristics that, paired with an evidence-based weight-loss intervention, will have the highest potential reach while achieving a clinically meaningful weight loss, and whether likely participation in response to different characteristics differs by gender, race, ethnicity or socioeconomic status. Adult participants (n=185) from Omaha, Nebraska, were recruited to participate in a survey in which they were presented with a “basic” program based on ACA-covered features (e.g., 20 in-person weight loss sessions over a 6-month period) and three alternative programs that included feature enhancements: weight-loss medication (Program A), online delivery (Program B), and a combination of the two (Program C). Participants were asked to choose in which program they would be most likely to participate. Statistical analysis included cross tabulation by gender, race, ethnicity, education, income and BMI and chi square analyses to determine whether the differences between the sub groups were statistically significant. The

sample (n=185) was predominantly female (73%), 42 percent of participants were black and 43 percent were Hispanic. The majority of the sample (84%) were overweight or obese (55% ≥ 30 ; 29% $26 \leq 29$; 13% ≤ 25). Ages ranged from 21 to 86 (mean age 47 $\pm 14/7$). The majority of participants (88%) selected the ACA-based program over Program A (22%) regardless of participant attributes. Similarly, the majority selected ACA (70%; 81%) over Programs B (30%) and C (19%), respectively. Program selection by gender and weight status was not significantly different. The majority of participants selected the ACA-based program (81%; 78%) over Program A (19%) and Program B (22%) regardless of race. However, when contrasting Program B with the ACA program, black participants (43%) were more likely white (21%) participants to select Program B ($p < 0.05$). A similar pattern was found for Hispanic participants with non-Hispanics (42%; 28%) being significantly more likely to select Program B than Hispanic participants (16%; $p < 0.05$). and Program C (8%; $p < 0.05$). Upper income participants (40%) were more likely to select Program C over the ACA program when compared to both middle (18%, $p < 0.05$) and lower household income (9%, $p < 0.05$) participants. Finally, Participants with a college education or professional degree were more likely to select Program B (46%, $p < 0.05$) and Program C (31% $p < 0.05$), when compared to participants without a college degree (22%; 14%, respectively). The development of alternative program structures should continue to be explored among disadvantaged groups and evaluated to determine their appeal. Identifying the characteristics that paired with a structured, behaviorally based program achieve the highest reach while producing a clinically meaningful weight loss is an important next step toward developing viable referral options for primary care physicians and could have far-reaching impact as more Americans seek such services.

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INTRODUCTION

The majority of adults in the U.S. are overweight or obese, placing them at risk for serious health problems, such as heart disease, Type 2 Diabetes (T2D), asthma, sleep disorders and low self-esteem.^{2,3} As a result, obesity is a major contributor to the escalating and unsustainable health care costs in America.^{2,4}

Because of its prevalence and associated health-care costs, obesity is widely recognized today as a serious public health issue. The Affordable Care Act (ACA) passed in 2010 includes provisions for all adults to be screened and behavioral intervention offered to those with a body mass index (BMI) of ≥ 30 kg/m².¹ The behavioral intervention may include 12 to 26 group or individual sessions with a health care professional without a co-pay or other additional cost to the patient.

The ACA's obesity treatment coverage is based on earlier evidence that shows high-intensity weight-loss programs delivered in person, face-to-face by a medical professional to be most effective treatment for weight loss.⁵ While the ACA is intended to improve access to weight-loss resources for the millions of Americans with obesity, it may not achieve its intended effect due to the barriers to access for disadvantaged populations for whom the burden of obesity is the greatest, particularly women.⁶

Overall, 42.5 percent of Hispanics and 48.1 percent of non-Hispanic blacks are obese, significantly higher than obesity prevalence of 34.5 percent of non-Hispanic whites.⁷ The burden of obesity is the greatest for black and Hispanic women.⁷ Among black women, 56.9 percent are obese compared with 37.5 percent of black men.⁷ For Hispanic women, the prevalence is similar: Overall 45.7 percent of women are obese compared with 39 percent of men.⁷

Low income women especially are at high risk for obesity. While obesity prevalence among men is similar across all income levels, the data show an inverse relationship between

female obesity and income. Overall, 29 percent of women who live in households with income at or above 350 percent of the poverty level are obese compared with 42 percent of women with income below 130 percent of the poverty level. The relationship between obesity and education is similar: Just over 42 percent of women with less than a high school degree are obese compared with 23.4 percent of college-educated.⁷

Few weight-loss studies have involved low-income minority participants and those that do have produced outcomes well below that expected. Low-income and minority groups face a variety of barriers in accessing to weight-loss programs. They include lack of transportation, limited literacy, insufficient time, child care responsibilities and other resources required to participate in intensive, face-to-face programs.^{8,9} Therefore, program features and delivery methods that use digital technology to overcome personal “cost” barriers are being studied with the goal of improving the reach of weight-loss programs already known to be effective.

In the United States, 72 percent of adults use the Internet and 52 percent use SmartPhones to find health-related information.¹⁰ Twenty-four percent look online for information about controlling or losing weight. The rate of Internet usage is similar across minority groups and socioeconomic levels, with 76 percent of those with incomes less than \$30,000 a year and 70 percent of those with high school diplomas using the Internet.⁸ Such widespread use of technology makes the Internet a promising vehicle for reaching large groups at a low cost.

Previous research has shown that the Internet is a viable method for delivering structured, behaviorally based weight loss programs and those that include some form of regular individualized feedback are more effective than self-directed programs.⁴ Additional features such as weight-loss medication and meal replacements have been shown enhance effectiveness.^{11,12}

The objectives of this study were to identify the characteristics that, paired with an evidence-based weight-loss intervention, will have the highest potential reach while achieving a clinically meaningful weight loss, and whether likely participation in response to different characteristics differs by gender, race, ethnicity or socioeconomic status. A review of the literature was used to identify the most effective weight-loss interventions that incorporate technology-based delivery methods to support scalability. The ultimate intent of the study is to identify the characteristics that will contribute to the development of a viable referral option for primary care physicians which could have far-reaching impact as more Americans seek such services.

MATERIALS AND METHODS

A search of literature published between 2004 and 2015 regarding weight-loss studies for adults that use technology to expand reach and enhance outcomes was performed using PubMed and Google Scholar. The search produced two systematic reviews. One was more exhaustive and included studies from eight databases. It forms the content basis of this study and was used to identify articles to examine characteristics of weight-loss interventions that have been effective (i.e., achieved ≥ 5 percent initial body weight loss, on average).¹⁰

The 127 papers describing 84 randomized controlled trials referenced were retrieved and each of the study arms was coded by length of study and weight loss outcomes at six months and the longest duration beyond six months, as shown in Figure 8 in Appendix A. The proportion of each intervention group that achieved a clinically meaningful weight loss also was noted by study, where available. The majority of studies (n=61) examined weight loss programs, although several programs addressed longer term weight-loss maintenance (n=10) and even weight-gain prevention (n=8), as well as weight-loss and maintenance (n=5).

The studies whose primary outcome was weight loss were categorized by magnitude of effect as: Clinically Meaningful (at least 5 percent of baseline weight) (Figure 9, Appendix A), Reimbursable per ACA standards (3 kgs within first six months) (Figure 10, Appendix A), or Neither (Figure 11, Appendix A). A truth table was created to clearly identify which program elements were both necessary and sufficient to produce weight loss. Of particular interest was the presence and number of face-to-face and non-face-to-face contacts, as it was hypothesized the success or failure of programs would relate to their level of intensity and some optimal combination of in-person and non-in-person contact.

About two-thirds (20) of the 32 clinically effective interventions included a face-to-face component. The remaining third (12) were delivered completely online with no in-person interaction. What almost all these interventions had in common were a website or smartphone application and regular contact either via telephone, text, and email. Many of the interventions that met only the threshold for ACA reimbursement included some in-person contact, but contact – whether human or non-human – was generally not as frequent as in the most effective interventions.¹³⁻³⁵ For study arms that included one or more face-to-face sessions, additional detail was captured regarding the frequency, duration and personnel used to deliver the program.

Selecting Evidence-Based Alternatives to the ACA-covered Weight Loss Program

The top ten most successful trial arms based on percent weight loss and involving samples of 50 or more participants were further examined to identify the theoretical basis of the intervention content.^{11,12,36-38} All ten interventions included self-monitoring, one of five self-regulation techniques derived from control theory which have been shown to be most effective in targeting health behaviors relating to healthy eating and physical activity.³⁹ Self-monitoring requires individuals to keep a record of a specific behavior, such as a diary of physical activity.

Other self-regulation techniques are intention formation, goal setting, feedback, and review of goals. Interventions that combine self-monitoring with at least one other technique derived from control theory are more effective, and those that combine all five are significantly more effective.³⁹

Of the top interventions reviewed, the two most effective that combined the greatest number of self-regulation techniques were identified as the comparators for potential program structures relative to the ACA model currently covered by insurance. In addition to face-to-face sessions, intervention components included weight-loss medication; online diaries, message boards and an “e-buddy” for social support; human email counseling; and free or discounted meal replacements.

These components were used to develop three program designs as alternatives to the ACA covered program. The first, “Program A,” mirrors the features of the ACA-covered program, including in-person office visits with a doctor, dietitian or qualified health care provider, goal setting for healthy eating and physical activity, use of a personal workbook to record meals, snacks and physical activity, and regular weigh-ins. In addition, Program A included a daily dose of weight-loss medication, a component of one of the two top performing interventions from the review of literature.¹²

A second program design, “Program B,” is delivered entirely online after an initial group session to set personal diet and exercise plans and replicates the second of the top two performing interventions.¹¹ It includes individualized emails from a weight-loss counselor, online diaries to record diet and physical activity and report weight, and an online message board and weight-loss “e-buddy” for support. Program B also provides free or discounted liquid meal replacements.¹¹

A third alternative was recreated to reflect a combination of the top two performing interventions identified through the review of literature. Thus, “Program C,” was described as an option that included electronically facilitated content similar to Tate and colleagues’¹¹ approach while adding weight loss medication, similar to Digenio and colleagues’ approach.¹²

Survey Development

Using these alternative program designs, a survey was developed to learn which of these program features would appeal to various market segments. To ensure readability by those with lower educational attainment, the survey was written at a 5th grade level. Participants were first presented with the basic program design that included the ACA-covered features. They were then presented with the three alternative programs that included the feature enhancements described above. In three successive scenarios, recipients were asked to choose in which program they would be most likely to participate. Finally, the survey included a series of basic demographic questions. Specifically, race, ethnicity, and household income were assessed. In addition, self-reported height and weight were assessed. While it has been established that stated “willingness to participate” in health interventions exceeds that of actual participation, there is a significant relationship between willingness and actual participation, in addition, the pattern of participation rates are considered to be reliable.⁴⁰

Before fielding the survey, it was pilot-tested with the staff of the University of Nebraska Medical Center's Center for Reducing Health Disparities (CRHD). CRHD, part of the university’s College of Public Health, provides education and outreach to underserved communities, particularly low-income and rural populations, and racial and ethnic minorities, and supports research aimed at reducing the prevalence and incidence of disease among these

underserved groups. In addition, the CRHD staff represents a diverse group of employees across racial and ethnic categories similar to those intended to complete the study survey.

CRHD staff suggested replacing the clip art with more culturally relevant images and adding a question at the beginning to gauge the respondent's satisfaction with their current weight since norms may vary among ethnic groups. As many Hispanics have difficulty understanding the concept of race, it was suggested that a category "Don't Know/Not Sure" be added to the question regarding race. Also, CHRD staff strongly encouraged the use of an incentive, such as a \$10 gift card, to increase participation. The survey was revised based on this feedback and translated into Spanish by CRHD staff.

Both English and Spanish versions of the survey were programmed into Qualtrics and loaded onto iPads. Paper copies also were made to accommodate respondents' preferences. Populations that experience the greatest disparity in obesity, such as Hispanics, African Americans, were targeted specifically for recruitment to ensure sufficient data for comparisons among these sub groups.

Subjects and Design

One hundred eighty-five subjects in Omaha, Nebraska, completed surveys between March 23 - 31, 2017. Institutional Review Boards from both Virginia Tech and the University of Nebraska Medical Center approved the study protocol. Interested participants were enrolled in the study if they met the eligibility requirement as age 19 or older (age of majority in Nebraska). Participants completed the survey in either English or Spanish using either an iPad or hard copy.

Procedures

Because the prevalence of overweight and obesity is 68% among the general adult population and the challenges of screening based on weight, the survey was administered broadly

at public places, with particular emphasis on those areas with a higher proportion of Hispanics and African Americans. In all cases, the survey was completely voluntary, however, to encourage participation, a \$10 gift card was offered. No personally identifiable information was collected. Consent was implied by return of a completed survey.

To ensure oversampling of Hispanic and African American participants, the survey was administered at locations where members of these communities aggregated. Specifically, community members were approached at sites including a hair salon, gym, restaurant, grocery store and other public places in Hispanic areas of South Omaha. While the survey could be taken on an iPad, with few exceptions those who identified as Hispanic chose to complete a paper copy of the survey. African American participants were recruited at an annual community health fair sponsored by the Black Family Health & Wellness Association in North Omaha.

Somewhat surprisingly, visits to other locations typically frequented by members of the Hispanic community, such as the Mexican Consulate and a church food pantry, were not fruitful due to heightened concern of deportation by undocumented immigrants. President Donald Trump's more aggressive stance regarding enforcement had spurred rumors of U.S. Immigration and Customs Enforcement raids at the area's meatpacking plants.

Data Management and Analysis

Data were coded for statistical analysis using standard software (MicroSoft Word Excel 2010). Each of the three program choices were cross tabulated by gender, race, ethnicity, education, income and BMI to determine whether program preferences differed by group. Chi square analyses were performed to determine whether the difference between the observed and expected data was statistically significant. This process was repeated if a finding was significant for a variable that had more than two levels (e.g., race). A p-value > .05 allowed us to reject the

null hypothesis and state that a relationship exists between the demographic variable and the program choice. All statistical models are included in Appendix B.

RESULTS

Participant characteristics are presented in Table 1. The sample (n=185) was predominantly female (73%) and reflected efforts to oversample minority populations for whom the burden of obesity is greatest. With regard to race, the sample was 42 percent black (33% were white, 3% Asian, 1% Native American and 21% other or did not respond) and 43 percent Hispanic. The majority of the sample (84%) were overweight or obese (54% \geq 30; 30% 25-29; 11% \leq 24) relative to 68 percent in the general population and the majority felt they should be pursuing weight loss. Healthy weight individuals were included in the analysis, as they are likely candidates for weight-loss in the future, given the current trend. Ages ranged from 21 to 86 (mean age 47 +/-14/7).

Comparisons of the selection across programs based on gender were not statistically significant. That is, men and women selected programs at a similar rate—across all four options. The majority of participants (78%) selected the ACA-based program over Program A (22%) regardless of participant attributes. Similarly, the majority selected ACA (70%; 81%) over Programs B (30%) and C (19%), respectively. Figure 1 below shows the number of participants that selected each program by gender.

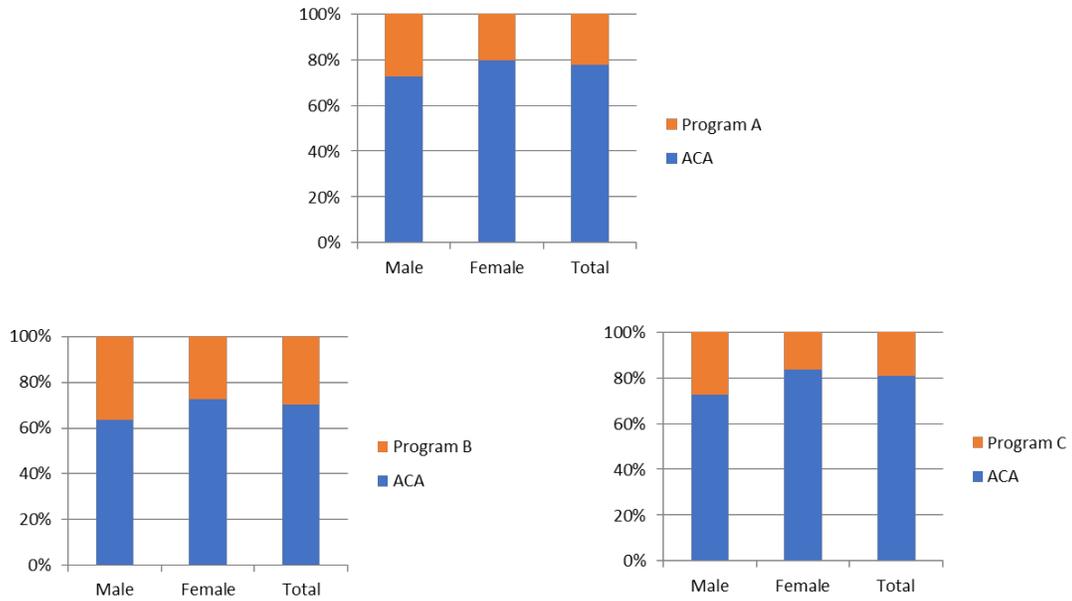


Figure 1. Program selection by gender.

Comparisons of program selection based on BMI status were also not statistically different from the rates that would be expected. That is, healthy, overweight, and obese participants selected across the four programs at a similar rate. The majority of participants (77%) selected the ACA-based program over Program A (22%) regardless of BMI status. Similarly, the majority selected ACA (70%; 80%) over Programs B (30%) and C (20%), respectively. Figure 2 below shows the number of participants that selected each program by BMI status.

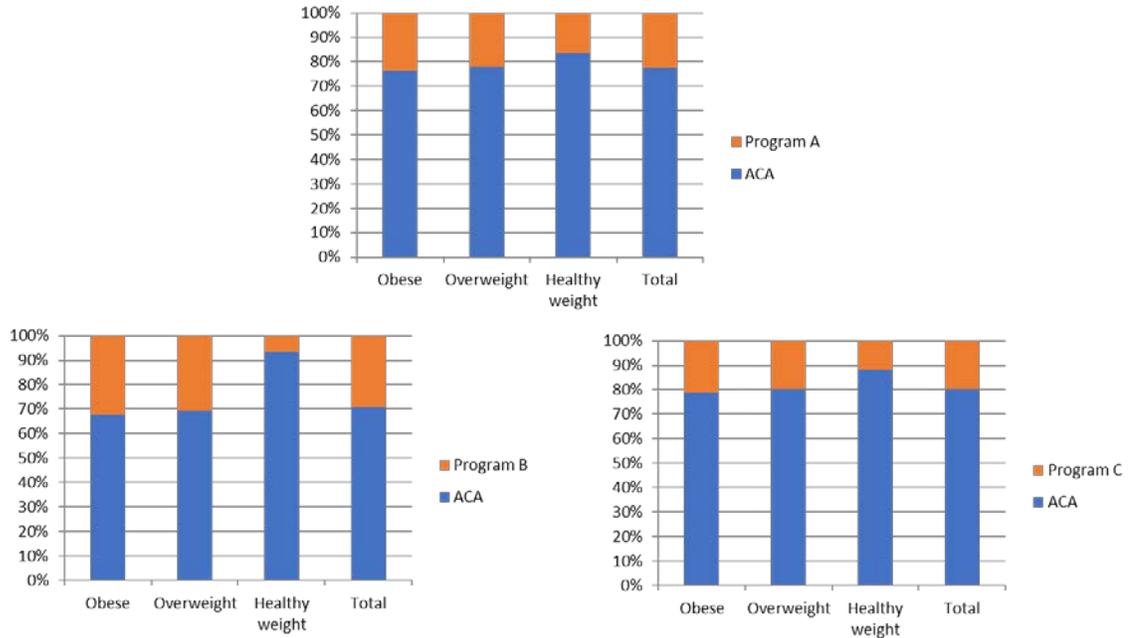


Figure 2. Program selection by BMI status.

Comparisons by race were limited to comparing black and white participants due to small sample sizes for other racial groups. The majority of participants (81%) selected the ACA-based program over Program A (19%) regardless of race. This was similar to the finding when comparing the ACA (78%) program with Program C (22%)—no statistical difference by race. However, when contrasting Program B with the ACA program, black participants (43%) were more likely white (21%) participants to select Program B ($p < 0.05$). Figure 3 below shows the number of participants that selected each program by race.

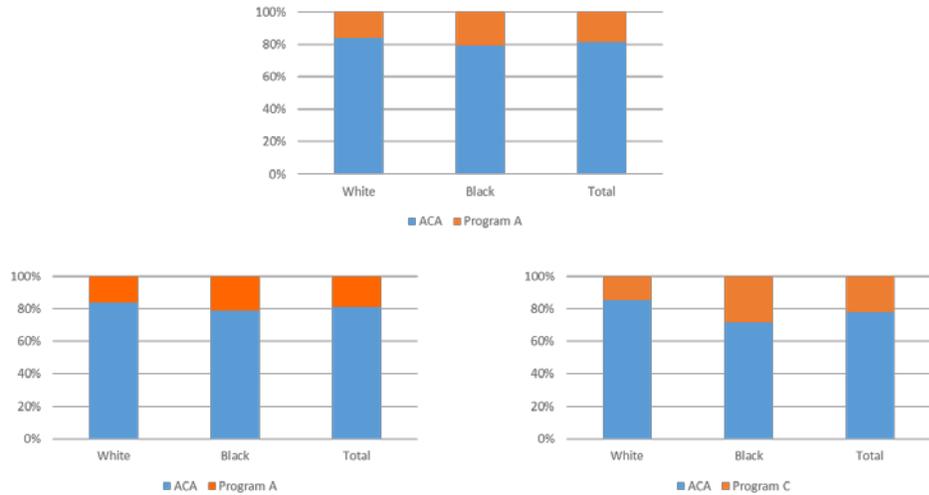


Figure 3. Program selection by race.

Examining participant choices by ethnicity, again, we found that Hispanic and non-Hispanic participants did not differ on the proportion that selected the ACA program (78%) when contrasted with Program A (22%). Non-Hispanics (42%) were significantly more likely to select Program B than Hispanic participants (16%; $p < 0.05$). Similarly, Non-Hispanic participants (28%) were more likely than Hispanic participants (8%) to select Program C ($p < 0.05$).

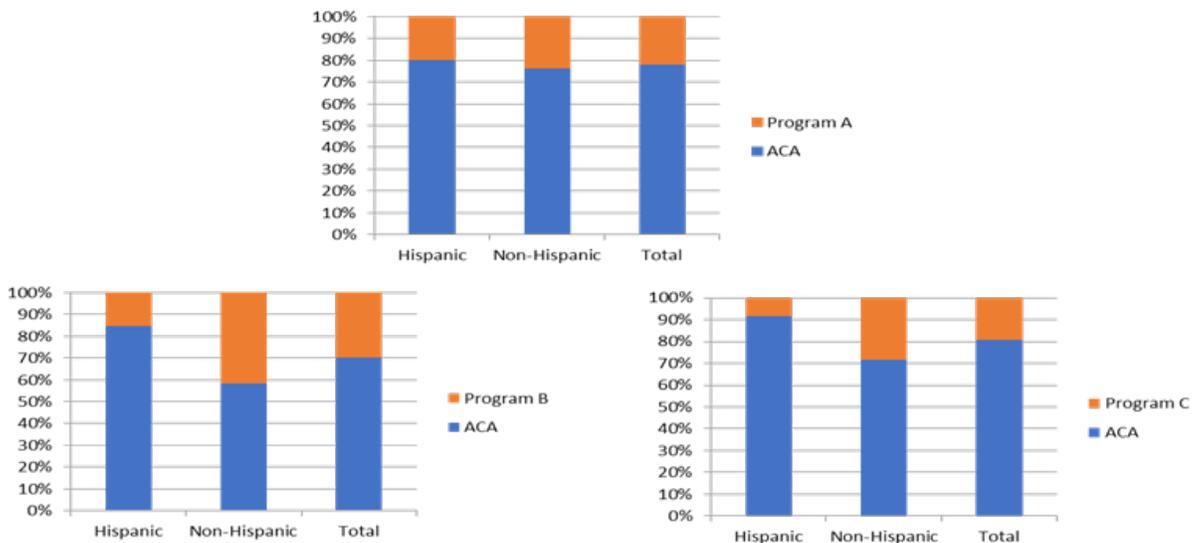


Figure 4. Program selection by ethnicity.

When considering income level we collapsed participants into three categories—lower income (\leq \$30,000/year, n=89), middle income ($>$ \$30,001 < \$60,000/year, n=41), and higher income ($>$ \$60,001, n=46) households—to have an adequate number of participants in each cell. The initial chi squared comparison by income level when participants considered the ACA program compared to Program A was not significant. As with other comparisons, approximately 21% of the sample selected Program A with the remainder selecting the ACA program. Again, the proportion of participants that selected Program B (28%) over the ACA program (72%) was not statistically significant by income level.

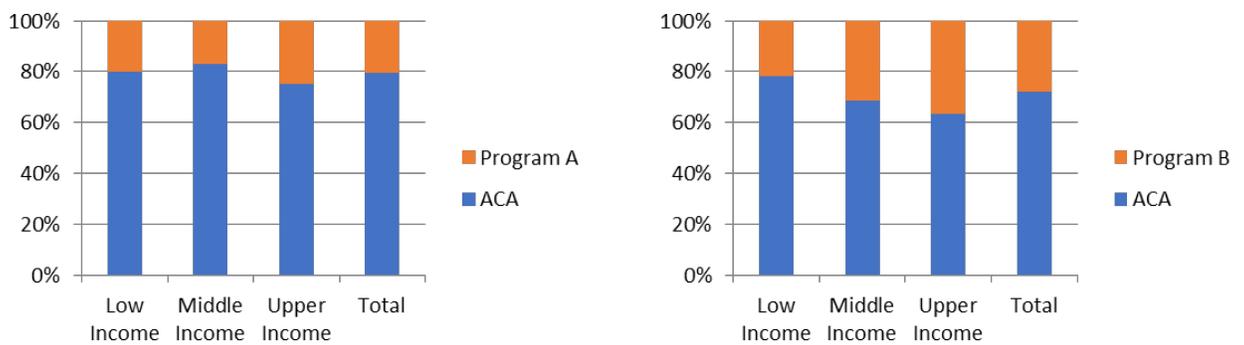


Figure 5. Program selection by household income for Programs A and B.

When comparing participant selections between the ACA program and Program C, the initial chi square was significant ($p < 0.05$). Follow-up analyses demonstrated that participants from the upper income category (40%) were more likely to select Program C over the ACA program when compared to both middle (18%, $p < 0.05$) and lower household income (9%, $p < 0.05$) participants. Middle and lower income household participants did not differ significantly in their choice between these two programs.

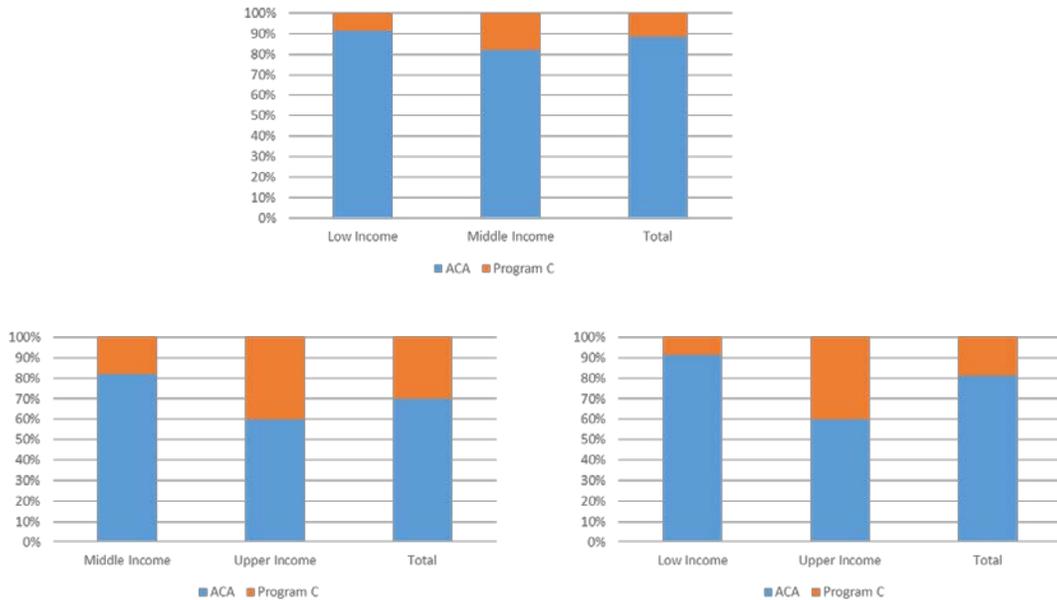


Figure 6. Program selection by household income for Program C.

Finally, when considering education level we collapsed participants into two categories—less than college education (n=126) and college or professional degree (n=57—to have an adequate number of participants in each cell. The initial chi squared comparison by education level when participants considered the ACA program compared to Program A was not significant. Approximately 22% of the sample selected Program A with the remainder selecting the ACA program. However, participants with a college education or professional degree were more likely to select Program B (46%, $p < 0.05$) and Program C (31% $p < 0.05$), when compared to participants without a college degree (22%; 14%, respectively).

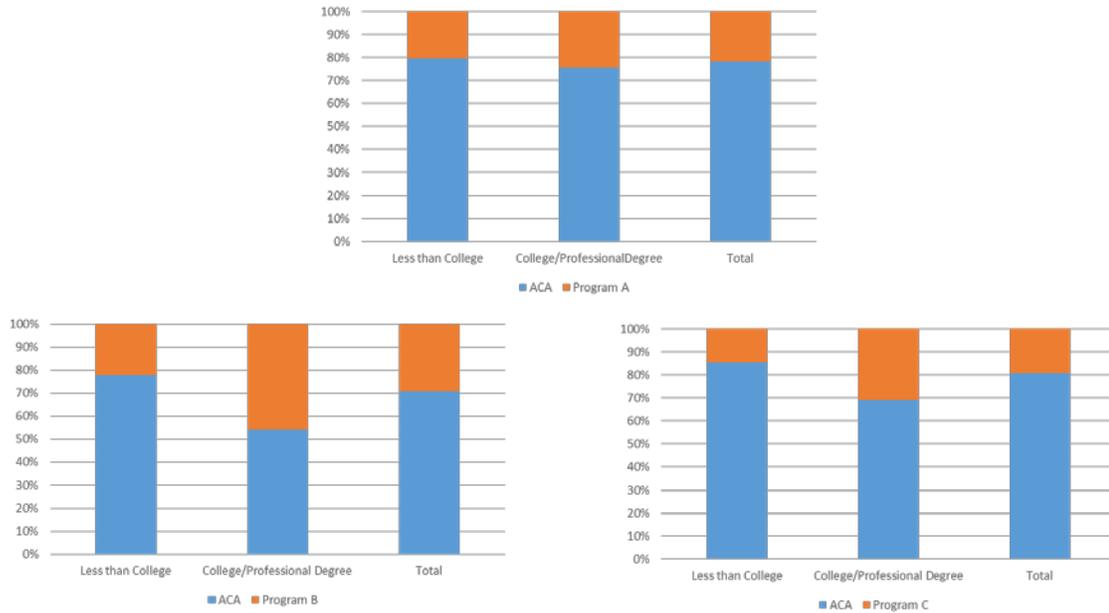


Figure 7. Program selection by education level.

DISCUSSION

The objectives of this study were to identify the characteristics that, paired with an evidence-based weight-loss intervention, will have the highest potential reach while achieving a clinically meaningful weight loss, and whether likely participation in response to different characteristics differs by gender, race, ethnicity or socioeconomic status. Our initial review of literature led to existing systematic reviews that provided information on the effectiveness of existing weight loss interventions. These included interventions similar to the lifestyle intervention used as the basis for ACA weight loss coverage, but surprisingly, some of the most effective interventions were delivered via interactive technology, used pharmacological support, and included meal replacements. We used these studies as the basis for the three alternative interventions presented to participants in our survey study—with some interesting findings.

It was initially thought that the ACA-covered weight-loss program based on the traditional face-to-face delivery model would have limited appeal among disadvantaged

populations due to the variety of access barriers related to socioeconomic status.⁶ Specifically, travel and time barriers are regularly identified in the literature. Further, high levels of Internet usage among minority and low-income groups, it was believed, offered new opportunities for broad dissemination of programs known to be effective.⁸ However, analysis on income-level, education, and ethnicity did not follow the same pattern. Indeed, even with the differences that did exist, the majority of participants preferred ACA program. This finding supports earlier studies that demonstrated higher reach using digital delivery and other enhanced features among more educated, affluent groups.^{11,36}

Our study builds on the work of Gold and colleagues, Micco and colleagues, and Leahey who demonstrated the effectiveness of an Internet-based weight loss intervention among minority participants.^{6,8,9,41} The findings are promising in that they show that a program delivered completely online may be appealing to racial and ethnic minority groups, which were more likely to choose alternative program structures. Our overall findings do suggest that black participants were more likely than white participants to select the Internet-based program over the traditional ACA face-to-face intervention.

Interestingly, there was an avoidance of medication-based interventions across all groups, with the exception of more educated and affluent participants. We were surprised by this finding given the tendency for healthcare professionals to perceive that patients are simply looking for a quick fix for obesity. None of our assessments or comparisons demonstrated a preference for adding medications to the current ACA format which may lead to the conclusion that pharmacological approaches are not preferred. While this may be true for black, Hispanic, and lower socio-economic status participants, more affluent survey respondents were more likely to identify Program C—the combined technology and medication approach—over less affluent

respondents. Future research could examine the degree to which medication is preferred within scalable weight loss interventions.

Finally, our findings provide some practical information for practice. First, the current ACA model for weight loss is attractive to under-represented minority participants. This is a practical finding for health care providers and insurers and may suggest that adding specific recruitment and engagement strategies to existing programs could lead to greater uptake and, ultimately, a stronger impact. Second, adding medication to an ACA-like program will not improve reach. This could argue against some current recommendations to integrate lifestyle and pharmacological approaches. Third, there is a large proportion of respondents who are interested in alternative, scalable interventions—even though the majority favor more traditional models. This finding suggests that health care systems and personnel may want to provide options for participation to patients—those that range from an intensive lifestyle intervention to those that include primarily Internet-based support and meal replacement options.

There are a number of limitations of this study. One, we used a design that assessed only potential participation and not actual participation. As we noted earlier, while these data are likely not precise estimates of the actual proportion of respondents that would participate in this type of program, it does provide a reliable estimation of the types of programs that are preferred. Two, our interactive technology option was designed to align with the most effective intervention from the literature in this area—which happened to also include meal replacements, thus making it unclear if participants joined or avoided the program based on the scalability or the meal replacements. Jeffery and colleagues have studied the role of meal replacements on reach and found that it does not tend to increase reach, minimizing our concern on this limitation.⁴² Three, our findings may have been affected by health insurance status, current

events relating to health care reform and the uncertainty of access to insurance coverage through state exchanges as well as the availability of subsidies. Finally, the literacy of our sample may have affected their ability to understand and evaluate the programs, perhaps leading to greater reliance on the programs' pictorial representation. This concern is not likely, as the survey was administered in person by health outreach professionals experienced with disadvantaged and minority populations.

CONCLUSIONS

Given the overall preference for the ACA program, future efforts may focus on lowering its delivery costs to disadvantaged populations through the use of health professionals other than physicians, other alternative delivery methods, including via telephone, as well as increased outreach to promote the availability of covered programs. The development of alternative program structures should continue to be explored among disadvantaged groups and evaluated to determine their appeal. Additionally, qualitative research should be conducted to better understand the reasons behind the different program preferences. Identifying the characteristics that paired with a structured, behaviorally based program achieve the highest reach while producing a clinically meaningful weight loss is an important next step toward developing viable referral options for primary care physicians and could have far-reaching toward reducing the disparity of obesity and obesity-related disease among disadvantaged populations.

TABLE 1
Participant Characteristics

	Total Sample	Male	Female
Total number of participants, <i>n</i>	185	49	135
Age (y), mean +/- SD	47+/- 14.7	49 +/- 14	47 +/- 15
Bodyweight, mean +/-	189+/-47.7	202 +/- 52	184 +/- 45.3
BMI (kg/m ²) mean +/- SD	31.5+/-6.8	30.4 +/- 5.6	31.9 +/- 7.2
Obese, n (%)	98 (54)	28 (57)	70 (52)
Overweight, n (%)	56 (30)	13 (28)	43 (31)
Healthy weight, n (%)	21 (11)	6 (11)	15 (12)
Did not respond	9 (4)	2 (5)	7 (4)
Race, n (%)			
White	61 (33)	13 (21)	48 (79)
Black	77 (42)	28 (36)	49 (64)
Other	27 (15)	8 (30)	19 (70)
Did not respond	20 (11)	4 (16)	17 (84)
Ethnicity			
Hispanic	79 (43)	16 (20)	63 (80)
Non-Hispanic	105 (57)	36 (34)	69 (66)
Education			
Less than College	126 (68)	38 (30)	88 (70)
College graduate/Professional degree	57 (31)	14 (25)	43 (75)
Did not respond	2 (1)		
Household Income			
<\$30,000 per year	89 (48)	20 (22)	69 (78)
\$30-60,000 per year	41 (22)	15 (36)	26 (63)
>60,000 per year	46 (25)	15 (33)	31 (67)
Did not respond	9 (5)	2 (25)	6 (75)

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CHAPTER 4: Conclusions

Given the overall preference for the ACA program, future efforts may focus on lowering its delivery costs to disadvantaged populations through the use of health professionals other than physicians, other alternative delivery methods, including via telephone, as well as increased outreach to promote the availability of covered programs. The development of alternative program structures should continue to be explored among disadvantaged groups and evaluated to determine their appeal. Additionally, qualitative research should be conducted to better understand the reasons behind the different program preferences. Identifying the characteristics that paired with a structured, behaviorally based program achieve the highest reach while producing a clinically meaningful weight loss is an important next step toward developing viable referral options for primary care physicians and could have far-reaching toward reducing the disparity of obesity and obesity-related disease among disadvantaged populations.

APPENDIX A

Figure 8
E-health interventions coded by length and weight-loss outcomes at six months and longest duration.

Study ID	Intervention Description	Length (mos)	Weight Loss Outcome (mean) (6 mos)	Longest Duration (mos)	Weight Loss Outcome (mean) (Longest Duration)	Clinically meaningful (5%)	Proportion on that met 5%	ACA (3 kg)	Notes
1. Adelman 2014 (1)	1. VOD only (16 sessions DPP lifestyle intervention via video on demand cable TV)		n/a	5 mos.	3.2 kg (3.3%)	no	33%	yes	diabetes prevention programming using cable TV
2. Adelman 2014 (2)	2. VOD+Plus (includes + interactive web portal)		n/a	5 mos.	3.2 kg (3.3%)	no	33%	yes	6.9% for participants who viewed 59 episodes
3. Allen 2013 (2)	1. intensive counseling (14 indiv. face to face)		-2.4 kg (2.5%)	6 mos.	-2.4 kg (2.5%)	no	n/a	yes	
4. Allen 2013 (3)	2. intensive counseling + smartphone app		-5.4 kg (5.4%)	6 mos.	-5.4 kg (5.4%)	yes	n/a	yes	
5. Allen 2013 (4)	3. has intensive (7 indiv. face to face) + smartphone app		-3.3 kg (3.2%)	6 mos.	-3.3 kg (3.2%)	no	n/a	yes	
6. Allen 2013 (5)	4. smartphone app only		-1.8 kg (1.7%)	6 mos.	-1.8 kg (1.7%)	no	n/a	no	
7. Appel 2011 (1) POWER Trial	1. remote website + phone counseling + email reminders	24 mos.	-1.1 kg (0.9%)	24 mos.	4.6 kg (4.7%)	no	38.3%	yes	
8. Appel 2011 (2)	2. in-person website + face to face (1 ind) + remote support	24 mos.	-5.6 kg (5%)	24 mos.	5.3 kg (4.8%)	no	41.4%	yes	
9. Appel 2011 (3)	3. self-directed control brochures/list of recommended websites	24 mos.	-1.4 kg (1.5%)	24 mos.	-1.8 kg (1.8%)	no	18.8%	no	
10. Rubin 2013 (4) HROL of POWER Trial see Appel above									Wt loss is a key factor in improving HROL
11. Bennett 2012 (1) counseling	1. website or IVR + telephone (18) + opt gp sessions (12) + written materials	24 mos.	-1.25 kg	24 mos.	-1.53 kg (1.5%)	no	20%	no	
12. Bennett 2012 (2)	2. User care self-help booklet	24 mos.	-1.9 kg	24 mos.	-1.5g (0.49%)	no	19.50%	no	
13. Bennett 2012 (3)	3. control: usual care		n/a	12 wks.	-2.71 kg (2.6%)	no	25.6%	no	
14. Booth 2008 (1)	1. website: exercise only (EX)		n/a	12 wks.	-0.34 kg (34%)	no	0	no	
15. Booth 2008 (2)	2. website: exercise & diet (ED)		n/a	12 wks.	-1.9 (2.1%)	no		no	
16. Brandt 2012 (1)	1. website: information based		n/a	12 wks.	4.15%	no	23.7%	n/a	web-based, lifestyle intervention, no in-person contact. Used Total Weight Being Diet; attrition high in all groups
17. Brandt 2012 (2)	2. website: supportive		n/a	12 wks.	4.22%	no		n/a	23.7% lost 5% or more, no difference between groups
18. Brandt 2012 (3)	3. website: personalized supportive		n/a	12 wks.	3.97%	no		n/a	
19. Brundel 2013 (1)	1. static website w/ no features, only info		n/a	12 wks.	4.3%	no	38%	insuff data	
20. Brundel 2013 (2)	2. interactive website w/ tool for monitoring wt, diet, social norms		n/a	12 wks.	4.3%	no		insuff data	
21. Brundel 2013 (3)	3. interactive website + recipe recommender		n/a	12 wks.	4.3%	no		insuff data	
22. Cadmus-Bertman 2013 (1)	1. telephone counseling (11) + website		n/a	12 wks.	3.3 kg (3.7%)	no		yes	
23. Cadmus-Bertman 2013 (2)	2. control (written information)		n/a	12 wks.	gained 9 kg	no		no	
24. Carnie 2013 (1)	1. website (internet-based wellness info (WI) + weekly educ gp sessions (GS)) for 3 mos, then monthly w/ maintenance focus		-2.7 kg (2.9%)	6 mos.	-2.7 kg (2.9%)	no	27%	n/a	WI + GS lost more weight at 3 mos. Than WI.
25. Carnie 2013 (2)	2. Wellness information (WI) alone		-2 kg (2.2%)	6 mos.	-2 kg (2.2%)	no	18%	n/a	
26. Chumbales 2011 (1)	1. website + email + face to face (1 gp + 3 indiv) basic		n/a	12 wks.	2.7 kg	insuff data		no	
27. Chumbales 2011 (2)	2. website + email feedback & newsletters + face to face (1 gp with 8T + 3 indiv) + telephone counseling (3) - enhanced		n/a	12 wks.	2.5 kg	insuff data		no	
28. Chumbales 2011 (3)	3. control		n/a	12 wks.	3 kg	insuff data		no	
29. Christian 2011 (1)	1. computer kiosk w/ tailored feedback report + face to face (1 indiv) + comprehensive written materials		insuff data	12 mos.	-1.5kg (3.3 lb)	1.60%	26.3%	no	
30. Christian 2011 (2)	2. control: written materials (1 indiv: baseline usual care visit)		insuff data	12 mos.	-1.5 kg (0.33 lb)	n/a	8.5%	no	
31. Colapies 2012 (1)	1. computer kiosk w/ tailored feedback report + face to face (1 indiv) + comprehensive written materials		insuff data	12 mos.	-1.5kg (3.3 lb)	1.60%	26.3%	no	
32. Colapies 2012 (2)	2. control: written materials (1 indiv: baseline usual care visit)		insuff data	12 mos.	-1.5 kg (0.33 lb)	n/a	8.5%	no	
33. Colapies 2012 (3)	3. control		insuff data	12 mos.	-1.5 kg (0.33 lb)	n/a	8.5%	no	
34. Digenio 2009 (1)	1. HF-F2F abutramine + website + written manual + face-to-face (high frequency 20 indiv) weekly for first 3 mos, every other week following 3 months		-8.5 kg (8.9%)	6 mos.	-5.5 kg (8.9%)	yes	62%	n/a	
35. Digenio 2009 (2)	2. LF-F2F abutramine + website + written manual + face-to-face (low frequency 6 indiv) monthly		-4 kg (6.4%)	6 mos.	-4 kg (6.4%)	yes	42%	n/a	
36. Digenio 2009 (3)	3. control		insuff data	6 mos.	insuff data	no		no	High-frequency phone contact w/ dietitian was similar to HF-F2F for supporting lifestyle mod

The 127 papers describing 84 randomized controlled trials referenced were retrieved. Study arms were coded by length of study and weight loss outcomes at six months and the longest duration beyond six months. The proportion of each intervention group that achieved a clinically meaningful weight loss also was noted by study, where available.

Figure 9
Interventions that met threshold for clinical meaningfulness.

Intervention ID	Intervention Description	Weight Loss (kg)	Weight Loss (percent)	Clinically meaningful	Notes
1. Behavior 2002 (1)	1. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
2. Behavior 2002 (2)	2. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
3. Behavior 2002 (3)	3. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
4. Behavior 2002 (4)	4. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
5. Behavior 2002 (5)	5. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
6. Behavior 2002 (6)	6. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
7. Behavior 2002 (7)	7. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
8. Behavior 2002 (8)	8. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
9. Behavior 2002 (9)	9. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
10. Behavior 2002 (10)	10. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese

Figure 10
Interventions that met only the ACA weight-loss threshold within six months

Intervention ID	Intervention Description	Weight Loss (kg)	Weight Loss (percent)	Clinically meaningful	Notes
1. Behavior 2002 (1)	1. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
2. Behavior 2002 (2)	2. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
3. Behavior 2002 (3)	3. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
4. Behavior 2002 (4)	4. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
5. Behavior 2002 (5)	5. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
6. Behavior 2002 (6)	6. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
7. Behavior 2002 (7)	7. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
8. Behavior 2002 (8)	8. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
9. Behavior 2002 (9)	9. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese
10. Behavior 2002 (10)	10. 100% only 100% sessions 200% sessions 300% sessions 400% sessions 500% sessions 600% sessions 700% sessions 800% sessions 900% sessions 1000% sessions	1.0 kg (3.9%)	1.0%	No	1.0% for patients who are not at all obese

Studies whose primary outcome was weight loss were categorized by magnitude of effect. Figure 9 above shows those interventions that produced clinically meaningful results, e.g., weight loss of at least 5 percent of baseline. Figure 10 shows interventions that met the weight-loss requirement per ACA standards (3 kgs within first six months).

Figure 11
Interventions that produced weight-loss below both ACA and clinically meaningful thresholds.

Study ID	Intervention	Weight Loss Outcome	Longest Duration	Weight Loss Duration	Change in Weight	Proposed ACA Rate
1. Adams 2001 (10)	1. control intervention	10%	12 wks	12 wks	-1.1 kg (2.7%)	10%
2. Adams 2001 (10)	2. DSD (+)w/14 sessions	10%	8 wks	8 wks	-0.2 kg (0.5%)	10%
3. Adams 2001 (10)	3. DSD (+)w/21 sessions (+over software)	10%	8 wks	8 wks	-0.8 kg (1.8%)	10%
4. Adams 2001 (10)	4. control (face-to-face)	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
5. Adams 2001 (10)	5. self-help (computer-based)	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
6. Adams 2001 (10)	6. self-help (computer-based) + 10 min face-to-face	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
7. Adams 2001 (10)	7. self-help (computer-based) + 10 min face-to-face + 10 min phone	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
8. Adams 2001 (10)	8. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
9. Adams 2001 (10)	9. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group + 10 min phone	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
10. Adams 2001 (10)	10. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group + 10 min phone + 10 min group	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
11. Adams 2001 (10)	11. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group + 10 min phone + 10 min group + 10 min phone	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
12. Adams 2001 (10)	12. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group + 10 min phone + 10 min group + 10 min phone + 10 min group	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
13. Adams 2001 (10)	13. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group + 10 min phone + 10 min group + 10 min phone + 10 min group + 10 min phone	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
14. Adams 2001 (10)	14. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
15. Adams 2001 (10)	15. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group + 10 min phone	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
16. Adams 2001 (10)	16. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
17. Adams 2001 (10)	17. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group + 10 min phone	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
18. Adams 2001 (10)	18. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
19. Adams 2001 (10)	19. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group + 10 min phone	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%
20. Adams 2001 (10)	20. self-help (computer-based) + 10 min face-to-face + 10 min phone + 10 min group	10%	8 wks	8 wks	-0.4 kg (1.0%)	10%

Studies whose primary outcome was weight loss were categorized by magnitude of effect. Figure 11 shows those interventions that did not meet either the criteria for clinically meaningful weight loss or reimbursement per ACA guidelines. Not surprisingly, the majority of these interventions were usual care, control or self-help groups, and many included face-to-face sessions.

APPENDIX B

Table 2
Program preference by gender

OBSERVED	ACA	Program A	Total
Male	29	11	40
Female	101	26	127
Total	130	37	167

P 0.350664217

OBSERVED	ACA	Program B	Total
Male	26	15	41
Female	92	35	127
Total	118	50	168

P 0.271729421

OBSERVED	ACA	Program C	Total
Male	29	11	40
Female	101	20	121
Total	130	31	161

P 0.127116887

Table 3
Program preference by race

OBSERVED	ACA	Program A	Total
White	47	9	56
Black	53	14	67
Total	100	23	123

P= 0.494393063

OBSERVED	ACA	Program B	Total
White	46	12	58
Black	37	28	65
Total	83	40	123

P= 0.008150052

OBSERVED	ACA	Program C	Total
White	47	8	55
Black	46	18	64
Total	93	26	119

P= 0.073886061

Table 4
Program preference by ethnicity

OBSERVED	ACA	Program A	Total
Hispanic	60	15	75
Non-Hispanic	70	22	92
Total	130	37	167

P= 0.544744234

OBSERVED	ACA	Program B	Total
Hispanic	65	12	77
Non-Hispanic	53	38	91
Total	118	50	168

P= 0.000218071

OBSERVED	ACA	Program C	Total
Hispanic	67	6	73
Non-Hispanic	63	25	88
Total	130	31	161

P= 0.001218862

Table 5
Program preference by weight status

OBSERVED	ACA	Program A	Total
Obese	71	22	93
Overweight	39	11	50
Healthy weight	15	3	18
Total	125	36	161

P= 0.806630328

OBSERVED	ACA	Program B	Total
Obese	65	31	96
Overweight	36	16	52
Healthy weight	14	1	15
Total	115	48	163

P= 0.124658267

OBSERVED	ACA	Program C	Total
Obese	71	19	90
Overweight	41	10	51
Healthy weight	15	2	17
Total	127	31	158

P= 0.672991675

Table 6
Program preference by education

OBSERVED	ACA	Program A	Total
Less than College	93	24	117
College/Professional Degree	37	12	49
Total	130	36	166

P= 0.570632629

OBSERVED	ACA	Program B	Total
Less than College	91	26	117
College/Professional Degree	27	23	50
Total	118	49	167

P 0.001996301

OBSERVED	ACA	Program C	Total
Less than College	96	16	112
College/Professional Degree	34	15	49
Total	130	31	161

P 0.015628755

Table 7
Program preference by income

OBSERVED	ACA	Program A	Total
Low Income	68	17	85
Middle Income	29	6	35
Upper Income	30	10	40
Total	127	33	160

P= 0.688259271

OBSERVED	ACA	Program B	Total
Low Income	68	19	87
Middle Income	24	11	35
Upper Income	31	18	49
Total	123	48	171

P= 0.15799

OBSERVED	ACA	Program C	Total
Low Income	74	7	81
Middle Income	27	6	33
Upper Income	24	16	40
Total	125	29	114

P= 0.000181

OBSERVED	ACA	Program C	Total
Middle Income	27	6	33
Upper Income	24	16	40
Total	51	22	73

P= 0.043181464

OBSERVED	ACA	Program C	Total
Low Income	74	7	81
Upper Income	24	16	40
Total	98	23	121

P= 3.54052E-05

OBSERVED	ACA	Program C	Total
Low Income	74	7	81
Middle Income	27	6	33
Total	101	13	114

p 0.146135379



Weight Loss Survey

From Virginia Tech and the
University of Nebraska Medical Center



Paul Estabrooks

Department of Health Promotion, Social & Behavioral Health
University of Nebraska Medical Center

Feature-based Designs to Increase Reach of Effective Weight-Loss Programs

UNMC IRB # 161-17-EX

Dear Participant,

You are being asked to be in a research study that may help design weight-loss programs for people who need them most.

Your decision to participate is voluntary. If you want to take part, you just have to do this survey.

The questions ask about different parts of weight-loss programs that have been shown to work.

It may take about 15 minutes to complete. As a token of our appreciation, you'll get a \$10 gift card.

Your answers will be kept confidential. No information that identifies you will be given to anyone, and the researchers will not be able to connect your answers to your name.

Please do not write your name on this survey.

If you have questions about your rights as a research subject, you may contact the University of Nebraska Institutional Review Board at (402) 559-6463.

For questions about the research or any other concerns you may have, please contact Paul Estabrooks at (402) 559-4325. Your feedback is valuable to us.

Thank you for your help!

Section I.

1. Thinking about your current weight, to be healthier you should:

Please check one box:

Lose a lot	Lose a little	Stay about the same	Gain a little	Gain a lot

1.a. If you wrote that you wanted to lose some weight (a little or a lot), how ready are you to make the changes needed?

Please check one box:

- I'm not ready to lose weight and don't expect to be ready anytime soon.
- I'd like to lose weight within the next 6 months.
- I'm ready to lose weight now.
- I'm already trying to lose weight.

2. Program Description

Some people can get help losing weight from their doctor for free. The program includes about 22 visits with your doctor or healthcare provider. Each visit is about 15 minutes.

During the visits, people get help setting weight-loss goals. They also learn about healthy foods and physical activity.

The program has:

- 1 visit per week for the first month
- 1 visit every two weeks for 5 months
- If you lose 6½ pounds in the first 6 months, you can continue with one visit per month for another 6 months.

Each picture below represents one part of this program.

Basic Program	
	<p>Coaching and support</p> <p>Have in-person office visits with a doctor, dietitian or other health care provider.</p>
	<p>Diet and exercise tracking</p> <p>Use a workbook to record meals, snacks and physical activity.</p>
	<p>Diet and exercise plan</p> <p>Set goals for healthy eating and physical activity to support weight loss.</p>
	<p>Regular weigh-ins</p> <p>Keep on track with regular weigh-ins During office visits.</p>

3. You can get help from different people. Who would you prefer to have support from?

Please check one box:

Doctor

Nurse

Dietitian

Other health care provider, please specify _____

4. When deciding whether to join the weight-loss program described above, how important would each part of the program be to you?

Please rate how important each part of the program would be to you by checking one box on the following 7-point scale. (1 = Not at all important to 7 = Extremely important)

		Not at all important				Extremely Important		
Coaching and support		1	2	3	4	5	6	7
Diet and exercise plan		1	2	3	4	5	6	7
Diet and exercise tracking		1	2	3	4	5	6	7
Regular weigh-ins		1	2	3	4	5	6	7

5. Would you participate in this weight-loss program?

Please check one box:

Yes

Maybe

5a. If you answered Yes or Maybe, are there other features you'd want included in this weight-loss program? If so, please describe them.

No

5b. If you answered No, what are the reasons you would not participate?

Section II.

The next questions ask you to choose between some of the best weight-loss programs and the one described in Section I.

The different parts of the program are shown side-by-side so you can easily compare them.

For each question, please answer as if you were really going to join the program and keep in mind the changes you'd need to make every day. Sometimes people choose a program because they think it is a good idea, but they would not actually participate in it.

Please choose a program only if you are sure you would really do it.

Consider these two weight-loss programs.

The only difference between these two programs is that Program A includes a daily dose of weight-loss medication. The medication helps you make the lifestyle changes needed to lose weight and keep it off. All other parts of the programs are the same.

	Basic Program	Program A
Coaching and support	 Have in-person office visits with doctor, dietitian or qualified health care provider.	 Have in-person office visits with doctor, dietitian or qualified health care provider.
Diet and exercise plan	 Set goals for healthy eating and physical activity to support weight loss.	 Set goals for healthy eating and physical activity to support weight loss.
Diet and exercise tracking	 Use a personal workbook to record meals, snacks and physical activity every day for 6 months..	 Use a personal workbook to record meals, snacks and physical activity every day for 6 months..
Regular weigh-ins	 Keep on track with regular weigh-ins during office visits.	 Keep on track with regular weigh-ins during office visits.
Medication	None.	 Take a daily dose of weight-loss medication for 6 months to help lose weight and keep it off. Possible side effects: nausea, vomiting bloating, diarrhea..

2.1 If these two programs were offered to you at no additional cost, which weight-loss program would you pick?

Please choose a single program and answer the question/s below your choice, if present.

Basic Program

2.1a. If you chose this program, would you need an incentive to participate in Program A instead of the Basic Program?

Yes.

If you answered Yes, how much incentive would it take?

Amount \$ _____ / month

No.

Program A (with medication)

2.1b. If you chose Program A, how much money would you be willing to personally pay if the program required an additional charge?

Amount \$ _____ / month

I would not choose either program.

Now, please consider these two programs.

Both programs have similar features, but are delivered differently. The Basic Program is in-person, while Program B is completely online with feedback from a weight-loss counselor based on your information. Program B also includes social support and meal replacements.

	Basic Program	Program B
Coaching and support	 Have in-person office visits with doctor, dietitian or qualified health care provider.	 Receive individualized emails from a weight-loss counselor based on your progress.
Diet and exercise plan	 Set goals for healthy eating and physical activity to support weight loss.	 Have a one-time group session to set personal diet and exercise plans and learn about the program website.
Diet and exercise tracking	 Use a personal workbook to record meals, snacks and physical activity every day for 6 months.	 Use an online diary to record your diet and physical activity every day for 6 months.
Regular weigh-ins	 Keep on track with regular weigh-ins during office visits.	 Report your weight in the online diary when prompted via regular email reminders.
Social engagement	None	 Post messages to your group's online message board. Find a weight-loss "e-buddy" for support.
Meal replacements	None	 Use free or discounted liquid meal replacements to help meet your caloric goals.
Medication	None	None

2.2 Which weight-loss program would you pick, assuming both were offered at no additional cost to you?

Please choose a single program and answer the questions below your choice, if present.

Basic Program

2.2a. If you chose this program, would you need an incentive to participate in Program B instead of the Basic Program?

Yes.

If you answered Yes, how much incentive would it take?

Amount \$ _____ / month

No.

Program B (online with meal replacements)

2.2b. If you chose Program B, how much money would you be willing to personally pay if the program required an additional charge?

Amount \$ _____ / month

I would not choose either program.

Please consider these two programs.

Now consider the same two programs with the addition of weight-loss medication to Program C.

	Basic Program	Program C
Coaching and support	 Have in-person office visits with doctor, dietitian or qualified health care provider.	 Receive individualized emails from a weight-loss counselor based on your progress.
Diet and exercise plan	 Set goals for healthy eating and physical activity to support weight loss.	 Have a one-time group session to set personal diet and exercise plans and learn about the program website.
Diet and exercise tracking	 Use a personal workbook to record meals, snacks and physical activity every day for 6 months.	 Use an online diary to record your diet and physical activity every day for 6 months..
Regular weigh-ins	 Keep on track with regular weigh-ins during office visits.	 Report your weight in the online diary when prompted via regular email reminders.
Social engagement	None	 Post messages to your group's online message board. Find a weight-loss "e-buddy" for support.
Meal replacements	None	 Use free or discounted liquid meal replacements to help meet your caloric goals.
Medication	None	 Take a daily dose of weight-loss medication to help make and sustain the long-term lifestyle changes required to lose weight and keep it off. Possible side effects: nausea, vomiting bloating, diarrhea..

2.3 Which weight-loss program would you pick if both were offered at no additional cost to you? Please choose a single program and answer the questions below your choice, if present.

Basic Program

2.3a. If you chose this program, would you need an incentive to participate in Program C instead of the Basic Program?

Yes.

If you answered Yes, how much incentive would it take?

Amount \$ _____ / month

No.

Program C (online with meal replacements and medication)

2.3b. If you chose Program C, how much money would you be willing to personally pay if the program required an additional charge?

Amount \$ _____ / month

I would not choose either program.

Section III.

These last few questions will help us understand more about you and your health. It will help us learn how different groups respond to our survey. Your answers are strictly confidential.

3.1 Are you:

- Male
- Female
- Other

3.2 What year were you born? __ _ __ _

3.3 How many children under the age of 18 live in your household?

3.4 In total, how many people live in your household including you?

3.5 What is your marital status? Are you:

Please check one box:

- Single
- Married/Long term partner
- Divorced
- Widowed

3.6 About how much do you weigh?

If you do not know for sure, please estimate.

_____ pounds

3.7 How tall are you?

___ feet, ___ inches

3.8 Are you Hispanic, Latino/a, or Spanish origin?

Yes

3.8a. If you answered Yes, are you:

Please check all that apply.

Mexican, Mexican American, Chicano/a

Puerto Rican

Cuban

Other, please specify: _____

No

Don't know

3.9 Which of one of these groups would you say best represents your race?

Please check one box.

White

Black or African American

American Indian or Alaska Native

Asian

Pacific Islander

Other

Don't know/Not sure

3.10 In what country were you born?

United States

Somewhere else/Don't Know

3.11 What is the highest level of education you have completed?

Please check one box:

- 8th grade or less
- Some high school
- High school graduate or GED certificate
- Some technical school or vocational training
- Technical school graduate
- Some college or associate degree
- College graduate (bachelor's degree)
- Postgraduate or professional degree

3.12 Has your doctor diagnosed you with any of the following?

Please check all that apply:

- Arthritis
- Asthma
- Depression
- Diabetes
- Heart disease
- High blood pressure
- High cholesterol
- Obesity
- None of the above

3.13 What is your current employment status?

Please check one box:

- Employed part time (including students who work on or off campus)
- Student (full time)
- Employed (full time)
- Unemployed/Not working
- Homemaker (unpaid)
- Retired
- On disability

3.14 Which of the following categories best describes your household income in 2016 before taxes?

Please check one box:

- \$10,000 or less
- \$10,001 - \$20,000
- \$20,000 - \$30,000
- \$30,001 - \$40,000
- \$40,001 - \$50,000
- \$50,001 - \$60,000
- \$60,001 - \$75,000
- \$75,001 - \$100,000
- \$100,001 - \$125,000
- More than \$125,000

3.15 Do you currently have health insurance?

Yes

3.15 a. If you answered Yes, what category best describes your insurance coverage?

- Private health plan sponsored by my employer
- Individual plan ----purchased through my state's health Exchange
- Medicare
- Medicaid
- Other, please specify: _____

No

Thank you for your help!

We appreciate the time you took to be part of this important study.

Feel free to leave any comments you have about the survey.

APPENDIX D



NEBRASKA'S HEALTH SCIENCE CENTER

Office of Regulatory Affairs (ORA)
Institutional Review Board (IRB)

March 16, 2017

Paul Estabrooks, PhD
COPH Hlth Pr, Soc & Behv Health
UNMC - 4365

IRB # 161-17-EX

TITLE OF PROPOSAL: Feature-based Designs to Increase Reach of Effective Weight-Loss Programs

The Office of Regulatory Affairs (ORA) has reviewed your application for *Exempt Educational, Behavioral, and Social Science Research* on the above-titled research project. According to the information provided, this project is exempt under 45 CFR 46:101b, category 2. You are therefore authorized to begin the research.

It is understood this project will be conducted in full accordance with all applicable HRRP Policies. It is also understood that the ORA will be immediately notified of any proposed changes for your research project.

Please be advised that this research has a maximum **approval period of 5 years** from the original date of approval and release.

If the research is completed prior to 5 years, please notify the Office of Regulatory Affairs at irbora@unmc.edu. If this study continues beyond the five year approval period, the project must be resubmitted in order to maintain an active approval status.

Sincerely,

Signed on: 2017-03-16 15:26:00.000

Gail Kotulak, BS, CIP
IRB Administrator III
Office of Regulatory Affairs

MEMORANDUM

DATE: March 7, 2017 

TO: Wen You, Linda L Staley, Paul Estabrooks

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires January 29, 2021)

PROTOCOL TITLE: Feature-based Designs to Increase Reach of Effective Weight-Loss Programs

IRB NUMBER: 16-858

Effective March 7, 2017, the Virginia Tech Institution Review Board (IRB) Chair, David M Moore, approved the Amendment request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at: <http://www.irb.vt.edu/pages/responsibilities.htm>

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As: **Exempt, under 45 CFR 46.110 category(ies) 2**
Protocol Approval Date: **November 3, 2016**
Protocol Expiration Date: **N/A**
Continuing Review Due Date*: **N/A**

*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

Date*	OSP Number	Sponsor	Grant Comparison Conducted?

* Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

If this IRB protocol is to cover any other grant proposals, please contact the IRB office (irbadmin@vt.edu) immediately.

MEMORANDUM

DATE: November 4, 2016
TO: Wen You, Linda L Staley, Paul Estabrooks
FROM: Virginia Tech Institutional Review Board (FWA00000572, expires January 29, 2021)
PROTOCOL TITLE: Feature-based Designs to Increase Reach of Effective Weight-Loss Programs
IRB NUMBER: 16-858

Effective November 3, 2016, the Virginia Tech Institutional Review Board (IRB) Chair, David M Moore, approved the New Application request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at: <http://www.irb.vt.edu/pages/responsibilities.htm>

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As: **Exempt, under 45 CFR 46.110 category(ies) 2**
Protocol Approval Date: **November 3, 2016**
Protocol Expiration Date: **N/A**
Continuing Review Due Date*: **N/A**

*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

