

Study Title: Internet Assisted Obesity Treatment Enhanced With Financial Incentives (iREACH3)

NCT#02688621

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Informed Consent

Title of Research Project: Internet Obesity Treatment Enhanced with Financial Incentives
Principal Investigator: Jean Harvey, PhD, RD

Sponsor: National Institutes of Health; National Institute of Diabetes, Digestive and Kidney Disorders

You are being invited to participate in a research study designed to investigate the effectiveness of a weight loss program delivered over the Internet. This study is being conducted by the Department of Nutrition and Food Sciences at the University of Vermont in collaboration with Dr. West at the University of South Carolina. Currently, millions of Americans are overweight. Unfortunately, high-quality, behavioral weight loss treatment programs are not always available for people who need to access them. One of the ways it might be possible to improve access is to offer these behavioral weight loss programs over the Internet. However, recent data suggests that Internet-based weight loss programs, while effective, do not produce the same level of weight loss as in-person, face-to-face treatments. The addition of financial incentives to supplement Internet weight loss programs may increase the weight losses that people can achieve in Internet-delivered programs. We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make the decision about whether you wish to participate in the study.

Why is This Research Study Being Conducted?

The purpose of this study is to test the effectiveness of offering a weight loss program delivered using the Internet vs. the same Internet-delivered weight loss program plus financial incentives.

How Many People Will Take Part in The Study?

Approximately 416 individuals (men and women) will be asked to participate in the study, with 208 enrolled locally at the University of Vermont site and 208 at the University of South Carolina site.

What is Involved in The Study?

Participation involves a minimum time commitment on your part of 18 months. At 5 different intervals during the 18 months, we will be conducting assessments. These assessments will occur before you begin treatment, 2 months after you begin treatment, and then at 6, 12 and 18 months for a total of five assessments. Each assessment will require you to come into Marsh Life Sciences on the University of Vermont campus to allow us to measure your weight and height. You will also be asked to complete some online questionnaires at each of these assessments. The questionnaires will ask about your diet, exercise, weight control behaviors and motivations for weight loss, quality of life, treatment satisfaction, and demographic data. You will not have access to review the questionnaires after completion or to make changes after submitting the forms. You will be provided with a helpline contact should you encounter difficulty in completing the forms. If you prefer, you can complete the forms using a paper copy rather than on-line using the computer. Each assessment visit will take approximately 60 minutes in total.

After initial assessments are completed, you will be assigned at random to participate in one of two groups. All of these groups will participate in an Internet behavioral weight loss program. This weight control program will be conducted entirely over the Internet. During this treatment you will be

required to attend a weekly Internet chat session with your group members and one of the behavioral weight control therapists. You will also complete a behavioral lesson during the week by accessing the study website. The weight loss lesson and chat sessions are where you will learn the principles of managing your eating and exercise behaviors. Each chat session will last about an hour. You will be asked to keep a record of the foods you've eaten each day and you will submit this electronically each day. Part of your treatment program is exercise. You will be asked to exercise (what we recommend is walking) on your own and use a tracking device that monitors your steps. You will be asked to send your step information to the research team. You will also be asked to monitor your body weight daily and submit your weight electronically to study personnel for monitoring. All participants will be contacted via e-mail individually by their group leader, who will monitor their progress and offer advice and encouragement. Your treatment program will focus on assisting you in losing weight during the first 6 months and you will receive weekly emails from your group leader during this period; in months 6 through 18 of the treatment program, the focus will be on helping you maintain the behavior changes you have made and sustain your weight management progress. During the maintenance period you will be required to attend a monthly Internet chat session with your group members and your behavioral weight control therapist, and you will receive a monthly email from your group leader offering encouragement and suggestions for weight control success. You will be assigned by chance to one of the two treatments, internet class with financial incentives possible if you perform certain behaviors and lose weight, or internet class without possibility of financial incentives. There will be a 50% chance that you would be placed in either treatment.

All participants will have their picture displayed on the chat page and on the biography page for their group when they use the study web site. The purpose is to help you put names with faces while participating in your group. You may opt out of this feature if you are not comfortable with displaying your picture on the website. Only study staff and other group members in your individual group (and not other study participants in other groups) will have access to your photo and all photos will be destroyed at the end of the study. Your e-mail address will also be displayed on the site to facilitate communication between group members. You can also opt out of this feature if you would prefer that your e-mail address not be shared.

What are The Risks and Discomforts of The Study?

There are minimal risks for participating in behavioral weight control programs. You may feel uneasy about answering the personal questions included in the interview. However, you do not have to answer any questions that make you feel uncomfortable. The information you provide will be kept confidential and not shared with non-research staff. No identifiable information about you will ever be published or shared without your consent.

It is also possible that some individuals will experience initial muscle soreness from the exercise program. You will be taught warm-up and stretching techniques to use before all exercise sessions to minimize the chance of muscle soreness. It is also possible that some participants may not lose weight. Finally, it is possible that a breach of confidentiality could occur. In this case, your identity could become known to other individuals in the group to which you are assigned.

What are The Benefits of Participating in The Study?

We hope that individuals who participate will learn the skills and behaviors necessary to enable them to lose weight and maintain that loss. However, you may or may not benefit from participating in this study as responses to weight loss programs vary from person to person. Everyone, however, will get

expert feedback on their eating and exercise behaviors.

What Other Options Are There?

Any number of commercial weight loss programs are available as alternatives to participation in this study. It is also possible to seek the guidance of a physician or registered dietitian who may help facilitate your weight loss efforts. Finally, weight loss medications or surgery are available for those who are considered by their physicians to be appropriate for these approaches.

Are There Any Costs?

There is no cost for participation other than your time. In the first 6 months of the program, it will take you approximately 5 hours a week to complete the exercise prescribed, attend your treatment meeting and complete your food and exercise diary. After the first 6 months, you will not be attending weekly meetings, so your time commitment will be diminished. On 5 occasions over 18 months, you will need to complete online questionnaires and then travel to the University for an in-person assessment appointment. It will take approximately 30 minutes to complete the online assessment questionnaires and the in-person assessment appointment will last less than 30 minutes (a total of 60 minutes on each occasion). You will need to park at a meter in the visitor section of the parking lot closest to the Marsh Life Sciences Building. The cost for parking at a meter will be approximately 0.50 cents for 30 minutes.

What is The Compensation?

One internet-based group will have the opportunity to earn economic incentives if they have performed key behaviors which are associated with successful weight loss and long-term weight maintenance. There are three self-management behaviors that are targeted for incentives: (1) weighing yourself daily; (2) recording the foods and drink you consume daily; and (3) achieving a "step goal" designed to get you more physically active. We will be examining your behaviors weekly, and if you are assigned by chance to the Internet+Incentives treatment, you will have the opportunity to earn incentives based on the degree to which you adhered to program goals. **If you did not engage in the targeted behaviors for that week, you will receive no incentive.** You will be notified by email or text (your preference) of the incentive received for each behavior and the total amount received each week. The message will highlight the incentive you received AND the incentive you could have received if you had consistently engaged in the prescribed self-management behaviors. Incentives will be redeemable on Amazon.com. We will email you a code which will allow you to post the money to your personal Amazon account and spend as you wish.

Over the course of the initial two months, you will have the opportunity to earn up to \$15/week (up to a possible total of \$120) if you monitor your dietary intake daily and report your weight daily (in other words, 2 behaviors a day over 7 days or 14 total reported behaviors). If you report these behaviors at least 10 times over the week, you can earn \$10/week for a total of \$80 in the first 2 months. From months 2-6, there will be no financial incentives.

From months 6 to 9, you will have the opportunity to earn up to \$20/week (up to a possible total of \$240) if you report your weight daily and meet the weekly step goal. If you report your weight on all seven days in the week, you will earn \$10 that week; if you report your weight on at least 5 days of that week, you will earn \$5. If you walk 70,000 steps in a week you can earn \$10; if you walk at least 50,000 steps you can earn \$5.

From months 9 to 12, you will still be able to earn incentives for reporting your weight and your step count daily as described above for months 6-9, however, the weeks of your payout will be inconsistent and you will not know in advance if it is a "payout week." The payout weeks will be selected by study staff, with a total of 6 incentive weeks selected during this period. In months 9-12 you have the opportunity to earn up to \$120. From months 12 to 18 there will be no incentives.

In addition to the weekly incentives described above, if you are randomly assigned to the Internet+Incentive condition, you will also have the opportunity to earn incentives based on your weight loss as measured during the 2, 6 and 12 month assessment visits. At 2 months, if you have lost at least 3% of your baseline weight, you will earn \$25; if you have lost at least 5% you will earn \$35. At month 6, if you have lost at least 5% of your baseline weight you will earn \$50; if you have lost at least 10% you will earn \$75. At the 12-month assessment, if you haven't gained any weight since your 6-month assessment and your weight is lower than your baseline weight, you will earn \$75.

If you are in the Internet+Incentive condition and you meet all weekly behavior goals and achieve the highest weight loss target at each assessment period, you have the potential to earn \$665 by your 12-month appointment. Alternatively, if you fail to meet any behavioral goals or achieve the weight loss goals, you will not be eligible for any incentive payouts.

You will not be compensated for participating in the Internet only condition.

We will gather social security numbers of all participants on a form that includes only your unique participant identification number. The form will be stored in a locked file cabinet in a locked office, with access available only to research personnel. No other identifying information (your name, address, birthdate, etc) will be on the form. *If you are randomized to the Internet only condition, this form will be shredded right after randomization.* If you are randomized to the Internet+Incentive condition, this form will be kept in the locked file in the locked room for the 12 months during which financial incentives are available to you and your social security number may be provided to UVM if required by internal revenue service regulations. Once the incentive phase of the program ends, the form with your social security number on it will be shredded.

Possible Incentive Which Can be Earned in Each Period			
Study Month	Intervention Contact	Incentive Schedule	Payouts
Months 1 to 2	Weekly chat sessions (Total = 8)	Dietary intake and weight reported daily; payout at end of week Total= 8 payouts	Maximum Payout = \$120 (8 * \$15)
Upon weight verification at 2-month Data Collection Lost <3% No Incentive Lost ≥3% Earn \$25 Lost >5% Earn \$35			
Months 2 to 6	Weekly Chat Sessions (total = 16 sessions)	No Incentives	
Upon weight verification at 6-month Data Collection Lost <5% No Incentive Lost ≥5% Earn \$50 Lost >10% Earn \$75			
Months 6 to 9	Monthly Chat Sessions (total = 6 sessions)	Weight and step count reported daily; payout at end of week Total= 12 payouts	Maximum Payout = \$240 (12 * \$20)
Months 9 to 12	Monthly Chat Sessions (total = 6 sessions)	Weight and Step count reported daily; payout on selected weeks Total= 6 payouts	Maximum Payout = \$120 (6* \$20)
Upon weight verification at 12-month Data Collection No weight gain above 6-month assessment weight (and weight below baseline value) = \$75			
Months 13 to 18	Monthly Chat Sessions (total = 6 sessions)	No Incentive	

Can You Withdraw or Be Withdrawn From This Study?

You may choose to end your participation in the study at any time. Should you, at any time during the study, join another weight control program (such as Weight Watchers, Jenny Craig, NutriSystems, etc.) or begin to take weight loss medications, you will be asked to withdraw from the study. Participants who become pregnant over the course of the 18-month study will be withdrawn from the study. Participants who experience other medical problems during the course of the study will be referred to their personal physician for care and withdrawn from the study if continued participation presents health risks. Finally, the investigators reserve the right to end your participation in the research at any time.

What About Confidentiality?

All the information you give us will be kept strictly confidential. You will be assigned identification numbers for the purposes of data collection and names will not be connected to ID numbers. A record of your progress will be kept in confidential form in the Marsh Life Sciences Building at the University of Vermont. Our study computers will require a password to use and they will be encrypted, which is a special protection against people who do not have the password from gaining access to the information on the computer.

Additionally, the results of this study may eventually be published and information may be exchanged between investigators, including those at the University of South Carolina and University of Tennessee Health Sciences Center; however, your confidentiality will be maintained during this process. The study sponsor (The National Institute of Diabetes, Digestive and Kidney Disorders) or their appointed designees, as well as the University of Vermont Institutional Review Board and regulatory authorities, will be granted direct access to your original research records for verification of research procedures and/or data.

It is also important to remember that the Internet groups will have their picture displayed on the chat page and on the biography page when they use the study web site. You may opt out of this feature if you are not comfortable with displaying your picture on the website. Only other group members and study staff will have access to your photo and all photos will be destroyed at the end of the study. Your e-mail address will also be displayed on the site to facilitate communication between group members. You can also opt out of this feature if you would prefer that your e-mail address not be shared.

Finally, if information is disclosed by you that indicates you have a plan or intend to harm yourself or others, we must tell a crisis intervention service (for example, University of Vermont Medical Center Psychiatric Service, Howard Mental Health, your personal doctor or mental health provider).

STATEMENT OF CONSENT

Internet Obesity Treatment Enhanced with Financial Incentives

You have been given and have read or have had read to you a summary of this research study. It has been explained to your full satisfaction. Should you have any further questions about the research, you realize you are free to contact the person conducting the study at the address and telephone number given below.

You understand the exact procedures you will undergo, including any potential benefits, risks, or discomforts.

You acknowledge that your participation is voluntary and are aware that you may refuse to participate or withdraw at any time without penalty or prejudice.

You understand that a record of your progress will be kept in confidential form in Marsh Life Sciences at the University of Vermont. You understand that the results of this study may eventually be published and that information may be exchanged between investigators, but that your confidentiality will be maintained.

You understand that you may contact the Director of the Research Protections Office at the University of Vermont (245 South Park/Suite 900, 656-5040) should you have any questions about your rights as a participant in a research study or for more information on how to proceed should you believe that you have been injured as a result of these research procedures.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

Signature of Subject Date

Name of Subject Printed Date

This form is valid only if the Committee on Human Research's current stamp of approval is shown below.

Signature of Principal Investigator or Designee Date

Name of Principal Investigator or Designee Printed Date

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