OPT-IN: Optimization of Remotely Delivered INtensive Lifestyle Treatment for Obesity

Consent Form

National Institutes of Health
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CONSENT FORM AND AUTHORIZATION FOR RESEARCH

Protocol Title: Opt-IN: Optimization of Remotely Delivered INtensive lifestyle Treatment for Obesity

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Supported by: National Institute of Diabetes, Digestive and Kidney Diseases

What is the Purpose of this Study?

You are being asked to take part in a research study. This form has important information about the reason for the study, what you will do, and the way we would like to use information about you if you choose to be in the study.

You are being asked to participate in a research study that is a 6-month, randomized controlled trial. The purpose of this study is to test different strategies to improve weight loss and behavior change in obese adults. All participants in the study will receive free behavioral telephone-based weight loss treatment in the Department of Preventive Medicine at Northwestern University. Participants must be willing to record the foods you eat and physical activity on a smartphone.

What will you do if you choose to be in this study?

As a participant interested in Opt-IN, you will attend a two-hour Orientation session in the Department of Preventive Medicine at Northwestern University (680 N Lake Shore Dr., Suite 1410, Chicago, IL 60611). At the Orientation, you will be given a detailed overview of the study and your rights as a subject before answering any questions or having any measurements taken. If interested, you will be requested to give your consent to participate in the study. If you are eligible and interested in participating, we will schedule you for a Baseline assessment and ask you to track your food intake and physical activity on paper for a 7-day period. Next, you will meet with study staff at your Baseline assessment to determine if you still qualify to participate. This will include answering questions about your health, diet, and behavior and having your blood pressure and other physical measurements taken. You will also be required to get medical clearance to participate in this study, as well as find a Buddy willing to support you during the 6-month study.

After you attend the Baseline assessment and are deemed eligible, you will be scheduled for a Randomization Session. At Randomization, you will learn which group you have been randomly assigned to. Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in any of the 16 groups. Next, we will download the study application on your personal smartphone and review how to use the application.

There will be three assessments throughout the study: Baseline, 3-months, and 6-months. Each assessment will last approximately 60 minutes and will take place at 680 N. Lakeshore Drive, Suite 1410. The assessments will include answering questions about your health, diet, and behavior and having your physical measurements (body weight, height, waist circumference, and blood pressure) taken.

All participants will receive weight loss treatment, and will randomly be assigned to receive a different combination of the following five factors:

1. Number of Telephone Coaching Calls: Participants will receive either 12 *or* 24 telephone coaching sessions with a coach. Each telephone coaching session will last approximately 10-15 minutes.
2. Report to Primary Care Provider (PCP): Participants will either have a personalized weight loss report mailed to their PCP at 3- and 6-months *or* they will have not have anything mailed to their PCP.
3. Text Messages: Participants will either receive regular text messages which provide feedback or encouragement from a coach *or* they will not receive any text messages.
4. Meal Replacement Recommendations: Participants will either receive recommendations to use meal replacements as well as a 1-week supply of meal replacements *or* they will not receive any meal replacement recommendations or samples.
5. Buddy Training: Participants will be asked to name a friend or family member ("Buddy") to provide support. All "Buddies" will receive information on how to best support their friend, and "Buddies" may be trained over the telephone by a coach and asked to attend four online webinars. Each webinar will last approximately 30-45 minutes.

All participants will be given a 7% weight loss goal. Participants will also be given a calorie goal ranging from 1200-2000 kcal/day based on body weight and a fat goal based on 25% of total daily calories from fat. All participants will also receive a physical activity goal that will gradually increase throughout the study from 100 min/wk to 300 min/wk.

All participants will communicate regularly with a coach via phone, email, and/or text message during the 6-month study. Your coach will give you personal feedback and help you make healthy changes to your diet and activity behaviors resulting in weight loss. If your coach is unable to reach you for a regularly scheduled phone call, the study staff will continue to make periodic attempts to reach you and will attempt to contact the individual that consented to serve as your emergency locator person. The study staff may attempt to contact you by making up to 6 phone calls and 4 emails over the course of the 6 months you are enrolled in the study unless they hear from you. After the conclusion of the study, all participants will be invited back for an optional one-hour Results Session. Study staff will overview study findings, and discuss study data and conclusions with participants.

All participants will be assigned a study code number to protect your confidentiality.

At any time in the study, you may decide to withdraw from the study. If you withdraw, no more information will be collected from you. When you indicate you wish to withdraw, the investigator will ask if the information already collected from you can be used.

What are some of the possible risks or discomforts?

Your participation in this study may involve the following risks:

1) You may experience muscle soreness or pain from increasing your physical activity. You are encouraged to stretch. Always exercise in a safe and reasonable manner. If you have any pain from exercising please contact your coach immediately.
2) You may experience an injury as a result of your physical activity. If at any time you are injured, please stop exercising and contact your coach immediately.
3) You may experience feelings of hunger and deprivation from decreasing your calories and fat intake. Your coach will provide you with ways to overcome this and give you support.
4) Some of the questions asked may be upsetting or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it.

You may withdraw from the study at any time.

What are the Possible Benefits for Me or Others?

You are not likely to have any direct benefit from being in this research study. However, you may experience positive changes to your health and mood based on the changes you make. Also, this research may be valuable for learning better ways to aid individuals in losing weight and making healthy lifestyle changes.

What Alternatives are Available?

You may choose to not participate in this research study. If you do not wish to participate in this study, the following alternatives are available: please contact the American Dietetics Association at 1-800-877-1600 Ext. 5000. This agency locates services for people that are interested in diet, nutrition, and/or weight loss. Referrals to other agencies that provide services for weight control or nutrition may be given to you as well.

Financial Information

Participation in this study will involve no cost to you. You will be paid $20 by check or cash for completing each of the two in-person assessments at 3 and 6 months ($40 total). If you drive to any of the five in-person sessions, you will receive a free parking voucher. Any costs due to medical visits or treatments will be your responsibility.

If you are randomized into a group that requires your "Buddy" to attend webinar sessions, your "Buddy" will receive a $5 online gift card after completing each required webinar. If buddies attend at least 3 of the 4 webinars, they will receive an additional $20 online gift card at 6 months.

The Accounting Services at Northwestern University will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

What should I do if I am injured as a result of being in this study?

If you become ill or get an injury or illness as a result of study, you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study coordinator about any illness or injury.

Northwestern University will not pay for medical care required because of a bad outcome resulting from your participating in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

In the event of a high blood pressure reading, you may be required to obtain physician approval in order to continue your participation in the study or a study staff member may contact your physician in order to determine the best course of action. Your physician may ask you to see him/her immediately, schedule an appointment, or be sent to the ER at Northwestern Memorial Hospital. If we are unable to reach your physician or you do not have a physician, study staff will call 911 in order for an ambulance to be dispatched to take you to the ER. Payment for treatment by your physician, the ambulance cost, or treatment at the ER will be your responsibility. If you refuse medical treatment, we will have you complete an elevated blood pressure waiver and your participation in the study will be discontinued. You will be asked if the information already collected from you can be used.

What are my rights as a research subject?

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, your class standing (for students enrolled in a class at NU), or your present or future employment (for employees at NU or its affiliates).

If you want to speak with someone *who is not directly involved* in this research, or if you have questions about your rights as a research subject, contact the Northwestern University Institutional Review Board (IRB) Office. You can call them at 312-503-9338 or send e-mail to irb@northwestern.edu.

What about my confidentiality and privacy rights?

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study devices
- Substance abuse information: Alcohol or Recreational Drug Use
- Mental Health information: Binge Eating Disorder, Bulimia Nervosa, Major Depressive Disorder

The following groups of people may give the researchers information about you:

- All current and previous health care providers, including but not limited to the Rehabilitation Institute of Chicago (RIC), Northwestern Medical Faculty Foundation (NMFF), Northwestern Memorial Physicians Group (NMPG), Northwestern Memorial Hospital (NMH).

Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University and its clinical partners (or affiliates) will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office]

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study),
- Representatives of the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK)
- Representatives of Food and Drug Administration (FDA), and Office for Human Research Protections (OHRP)

Results of this study may also be used for teaching, research, publications, or presentations at scientific meetings. If your individual results are discussed, your identity will be protected by using a code number rather than your name or other identifying information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Audio Recordings

At the end of this consent form, you will be given the option of allowing us to make audio recording of you. If you agree, the individual coaching sessions will be audiotape recorded for research and training purposes. Only study staff will have access to the audiotapes and they will be kept on secure server. At the end of the study, all audiotape recordings will be destroyed.

Whom should I Call if I have Questions or Concerns about this Research Study?

If you have any questions, illness, or injury during your time on this study, call us promptly. Dr. Bonnie Spring is the person in charge of this research study. You can call her at telephone # 312-908-2293 (Monday through Friday, from 9am to 5pm). You can also call Dr. Christine Pellegrini at telephone # 773-234-6711 with questions about this research study.

Consent:

I have read this consent form and the research study has been explained to me. I have been given the opportunity ask questions and my questions have been answered. If I have additional questions, I have been told whom to contact. I agree to participate in the research study described above and will receive a copy of this consent form after I sign it.

Please initial one of the following to indicate your choice:

_____ (initial) I agree to have coaching sessions audiotape recorded.

_____ (initial) I do not agree to have coaching sessions audiotape recorded.

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

_____(initial) I agree to allow the researcher to contact me in the future to see whether I am interested in participating in follow-ups related to this current study

_____(initial) I do not agree to allow the researcher to contact me in the future to see whether I am interested in participating in follow-ups related to this current study

_____(initial) I agree to allow the researcher to contact me in the future to see whether I am interested in participating in other research studies.

_____(initial) I do not agree to allow the researcher to contact me in the future to see whether I am interested in participating in other research studies.

_____ _____

Subject's Name (printed) and Signature Date

_____ _____

Name (printed) and Signature of Person Obtaining Consent Date