IRB Approval:	4/1/2019
IRB Accepted:	4/1/2019
IRB Expiration:	8/8/2019

Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

- ☐ Rhode Island Hospital
- ☐ Bradley Hospital
- ☒ The Miriam Hospital
- ☐ Newport Hospital
- ☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

2118-18
Committee #

Name of Study Volunteer

Phone coaching and Internet-delivered weight loss

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study: You are being asked to take part in a research project because you are between the ages of 18 and 70 and you meet all of the other eligibility criteria for this study. The purpose of this study is to examine whether adding phone coaching to an Internet-based weight loss program can improve weight loss outcomes at 4 months and 1 year. We expect to enroll approximately 450 individuals. The study is sponsored by a National Institutes of Health grant awarded to Dr. Jessica Unick.

2. Explanation of Procedures: If you participate in this study, you will receive a 4-month, Internet-based behavioral weight loss program followed by an 8-month, Internet-based weight loss maintenance program. As part of this program, you will be asked to view video lessons and log your calorie intake, weight, and physical activity on the study website weekly. In addition to the Internet program, some individuals will also receive phone coaching. You may be randomly assigned to either 3 weeks of phone coaching, 12 weeks of phone coaching, or no phone coaching. You cannot choose whether or not you receive the phone coaching, rather it is determined by a method similar to flipping a coin. It is estimated that approximately 50% of individuals will receive phone coaching. We will conduct assessments of weight, diet, physical activity, and various questionnaire measures at baseline, 4, and 12 months. More details regarding the internet program, phone coaching, and assessment visits can be found below.

Internet-based weight loss and weight loss maintenance program – All individuals enrolled in this study will receive a 4-month Internet-based weight loss program followed by an 8-month Internet-based weight loss maintenance program. During the first 4 months, each week you will be asked to view a 10-15-minute multi-media lesson (one per week). These lessons focus on behavioral principles for changing your diet and physical activity behaviors. You will also be given weight loss, calorie intake, and physical activity goals. You will be taught how to self-monitor this information and be instructed to submit it weekly on the study website. After you submit this information, you will receive a weekly individualized feedback message. Following the 4-month weight loss program you will receive an 8-month weight loss maintenance program. During this time, you will be asked to view monthly video lessons which focus on strategies for successful WL maintenance and you will be instructed to continue to self-monitor your weight, calorie intake, and physical activity minutes on the study website for one week per month. Feedback will be provided based upon this data.

Phone coaching – In addition to the Internet program described above, some individuals enrolled in this study will be selected to receive phone coaching. All calls will be audio recorded so that content from the session can be coded and analyzed for research and quality control purposes. Individuals will not be identified in any way and all information will be kept confidential. Those selected for 'brief' phone coaching will be asked to complete 3 phone calls with a coach between weeks 5-8 of the study and those selected to receive 'extended' phone coaching will be asked to complete 12 phone calls with a coach between weeks 5-16. The first coaching call will be approximately 45 minutes in duration and all subsequent calls will be 10-15 minutes in duration. The coach will individually work with you to help you to overcome any barriers that you may be experiencing and to help you develop an individualized meal plan. After you have completed 3 or 12 coaching calls (depending upon which group you were assigned to), you will have no additional interaction with the coach, but you will remain enrolled in the Internet program.

Assessments

All study participants will complete assessments at baseline, 4 months, and 12 months. These assessments include measures of height and weight, diet, physical activity, and various questionnaire measures (see details below). You will be compensated $50 in cash for completing the 4-month assessment visit and $75 in cash for completing the 12-month assessment visit. All assessments will take place at The Miriam Hospital's Weight Control and Diabetes Research Center at 196 Richmond Street in Providence, RI.

- Physical activity assessment: You will be asked to wear an Actigraph GT9X Link activity monitor for 1-week at each assessment time point, during all waking hours. This device is worn on your waistband and provides a measure of your physical activity.

- Dietary assessment: At each assessment time point, we will also ask you questions about your diet. We will have you complete the web-based Dietary Screener Questionnaire to provide us with a measure of diet quality. Also during the 1-week assessment period, you will be asked to record everything that you ate and drank, and portion sizes using a self-monitoring record. This will provide us with a measure of total energy intake.

- Questionnaire measures: At each assessment you will be asked to complete a variety of questionnaires related to factors which may be associated with weight loss.

Costs for participating in this study

Some of the services you will receive are being performed only because you are participating in this research study. An example of these 'research only' services include an Internet-based weight loss program and phone coaching. Those services will be paid for by the study and will not be billed to you or your health insurance company. Other services you will receive during this research study are considered "routine clinical services" that you would have received even if you were not in the research study. Examples are services you receive through your primary care provider or other healthcare professional outside of the Weight Control and Diabetes Research Center during the course of this study**.** These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

Contact Information:

Please call Dr. Jessica Unick at 401-793-8966 if you have any questions about these procedures for the study.

3. Discomforts and Risks

The risks of participating in this study are minimal. The programs may not be effective in helping you lose weight. It is possible that you could feel some hunger if you reduce your food intake to try to lose weight, or could be injured from exercise during this program. You may also experience mild skin irritation from wearing the armband, although this is not typical.

4. Benefits

All participants in this study will receive information about weight loss, healthy eating, and physical activity. Participation in this program may help you lose weight; however, there is no guarantee that this program will help you lose weight.

5. Alternative Therapies

A variety of weight control programs are available from physicians, health clinics, and commercial programs.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible. In addition, the sponsor may choose to end the study at any time, for reasons unrelated to health care. Finally, if you were to become pregnant while enrolled in this study, you will no longer be able to participate.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the

study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor: NIH
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights; European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;

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- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

Permission to contact

_____ (initials) **YES**, I give permission to be contacted in the future for research studies.

_____ (initials) **NO**, I do not give permission to be contacted in the future for research studies.

Note: Your name and contact information will be stored separately from your personal health information (e.g. weight, questionnaire data, etc.).

Clinical Trials:
Additionally, 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.

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SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document expires on 8/8/2019.
DO NOT sign this document after this expiration date.

The Researcher is required to provide a copy of this consent to you.

Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

Signature of witness (required if consent is presented orally or at the request of the IRB) Date

Signature of Translator Date

Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.