Gaining Optimism After Weight Loss Surgery (GOALS) II: Randomized Controlled Trial of a Positive Psychology-based Intervention to Increase Physical Activity After Bariatric Surgery

NCT04868032

Informed Consent Form

1/13/25

Mass General Brigham

Research Consent Form
Certificate of Confidentiality Template
Version Date: February 2021

Subject Identification

Protocol Title: Gaining Optimism After weight Loss Surgery (GOALS): A positive psychology-based intervention to increase physical activity after bariatric surgery

Principal Investigator: Emily Feig, PhD

Site Principal Investigator: N/A

Description of Subject Population: Adults with a history of bariatric surgery and low physical activity [Randomized Cohort]

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Mass General Brigham now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about whether a new 10-week, telephone-based health behavior treatment program (which combines activities to increase positive emotions and

increase motivation to reach physical activity goals) is able to increase mental health and physical activity in patients who have had bariatric surgery.

How long will you take part in this research study?

If you decide to join this research study, it will take you about **26 weeks** to complete the study. During this time, we will ask you to complete 4 study visits. 2 visits will be in person at Massachusetts General Hospital and 2 can be completed in person or remotely.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen:

- **Initial visit (Visit #1):** This initial visit will take place at MGH. This visit will involve reviewing and signing the consent form with a study staff member. We will measure your vital signs, height, weight, waist circumference, body composition, and collect a blood sample, as well as ask you to complete a six-minute walk test. You will fill out questionnaires that ask about your mental and physical health and be asked to wear an accelerometer (i.e. activity tracker) around your waist for 7 days after this initial visit.
  Randomization/Intervention Introduction (Visit #2; in person or remotely): At this second visit, we will check the accelerometer to make sure there is enough information on it. If there is not enough information, we may ask you to wear it again to get more information. Once we confirm that there is enough information on the accelerometer, you will be randomly assigned to either the treatment condition or the control condition. Either way, you will receive a Fitbit Inspire 32 at this time. If you choose to complete this visit remotely, we will ask you to mail the accelerometer back after the 7 days and we will mail you all of the study materials necessary once we verify that there is enough information on it. We will pay you $100 after you complete this visit.
  10 Weekly Phone Calls: If you are in the treatment condition, you will then complete study program activities and speak with your study trainer to review the activities once per week for 10 weeks. These phone calls will be recorded and take 30-45 minutes each week. The sessions will focus on increasing physical activity and learning positive psychological skills to increase psychological well-being. We'll also ask you to wear your Fitbit during this time and you will receive educational information about physical activity. If you are in the control condition, you will receive educational information about physical activity at different points throughout this time, and a phone call at, or around, the midpoint of the intervention to ensure that you are receiving these materials.
  10-Week Follow-up visit (Visit #3): We will ask you to complete a follow-up visit at week 10. We will ask you come to MGH, where we will check your vitals, height, weight, waist circumference, body composition, and collect a blood sample. You will

also be asked to complete the six-minute walk test, the same questionnaires, and wear the accelerometer again. We will pay you $100 after you complete this visit.

24-Week Follow-up Visit (Visit #4; in person or remotely): This final study visit will be identical to Visit #3. At this visit we will help you delete the study account from your Fitibit so that you can use it privately moving forward. If you choose to complete this visit remotely, we will ask you to take your height, weight, and waist measurements yourself. We will also ask you to complete the questionnaires via a secure data collection system (REDCap) and complete the necessary lab work at a local Quest Diagnostics Service Center. Additionally, during this visit, we will ask you some open-ended questions about your experience with the program. We will pay you $100 after you complete this visit.

We also may gather information from your medical record about medical problems, medications, laboratory and testing results, and other characteristics that may help us to better describe the participants in this study.

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include performing more physical activity, which could help you feel better emotionally and physically. Others with a history of bariatric surgery may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include feeling uncomfortable due to the nature of some questions, discomfort during the blood draws, risks to confidentiality, or risks related to increasing physical activity (such as falling).

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called “What are the risks and possible discomforts from being in this research study?”

Other things to consider are the time we will ask you to spend completing the study visits and weekly phone calls.

What other treatments or procedures are available for your condition?

Other treatments or procedures that are available to help you to become more active include regular visits with your physician, physical therapy, or attendance at exercise programs. In addition, mental health treatments are available if this is something you want or need. You can participate in these treatments in addition to being in this study.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Emily Feig, PhD is the person in charge of this research study. You can call her at **617-724-9140 (Monday-Friday from 9am-5pm)**. You can also call Crystal Castillo **at 617-724-9142 (Monday-Friday from 9am-5pm)** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Crystal Castillo **at at 617-724-9142**.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed 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.

Why is this research study being done?

This research study is being done to find out whether a 10-week, telephone program involving positive psychology and motivational interviewing improves mood and physical activity in adults who have recently had bariatric surgery and who currently have low levels of physical activity. Positive psychology involves exercises—short tasks—that are meant to increase good feelings and thoughts. Positive psychology exercises may include remembering positive life events, keeping track of positive feelings, or using perseverance. Motivational interviewing involves helping you to consider increasing your physical activity and to set specific activity goals when you feel ready.

We want to learn whether this new treatment program is well-accepted by patients who have had bariatric surgery and who have low physical activity, and to explore whether it leads to improvement in physical activity and mental and physical health over the 10-week program, compared to people who do not receive this program.

Who will take part in this research?

We are asking you to take part in this study because you are an adult who had bariatric surgery, and because you reported less than 200 minutes/week of moderate-to-vigorous physical activity. You also expressed interest in increasing your physical activity. About 58 people will take part in this research study at MGH. The United States National Institutes of Health is sponsoring this study.

What will happen in this research study?

This is a pilot study, which means that this is a study with a small number of participants as a first step to make sure that the program is well-accepted and appears to be useful before doing a larger project with this new program. This is also a randomized controlled trial, which means that half of participants get the active treatment program that focuses on improving positive emotions and physical activity. The other half still receive a Fitbit and will be provided with educational information about physical activity and its benefits at 4 timepoints throughout the intervention period (in person at Visit #2, mailed or emailed at week 3, week 6, and week 9), but do not receive any treatment program. Participants are randomly assigned to a condition which

means we cannot choose which condition you are in. In this study, you will have two initial study visits at MGH, will complete the program and weekly phone calls over 10 weeks if you are in the treatment condition, and then will have a follow-up study visit at Week 10 back at MGH and the choice to complete a remote or in person follow-up visit at Week 24. If you are in the treatment condition, you will receive a written treatment manual, speak with a study trainer by phone once a week for 10 weeks, and will complete exercises related to positive psychology and physical activity in between the phone calls. Regardless of what condition you are in, you will get a Fitbit Inspire 32 to help you become more active and you will receive information about how to get more active.

Enrollment/Baseline Assessment (Visit #1; Week 0; 90-120 minutes)

This visit will be completed in person at the MGH Translational and Clinical Research Center, and will involve reviewing and signing the study consent form and filling out questionnaires that ask about your mental and physical health. The entire visit will take about 90-120 minutes.

We will review the study consent form with you and ask you to sign it.

You will fill out questionnaires that ask about your mental and physical health.

A nurse will measure your vital signs, height, weight, body composition, and waist circumference.

We will collect a blood sample (1 teaspoon of blood) to test for A1C, lipids, and C-reactive protein (a marker of inflammation).

We will also ask you to perform a six-minute walk test to assess your functional exercise capacity.

We will give you an accelerometer, a small device that you wear around your waist, that you will wear for the next week to measure your level of activity. The accelerometer will give us information about how active you were while wearing it, but it will not record your name or any other identifying information. We will explain how to use this. If you choose to complete Visit 2 remotely, we will also give you all the materials needed to mail the accelerometer back.

We will also ask you to report your weight at home for consistency.

Intervention Introduction (Visit #2; Week 1; 20-90 minutes; in person or remotely)

If you choose to complete this visit in person, it will last approximately 20-30 minutes **and** you will return the accelerometer. If it did not record at least 10 hours of wear for 4 days, we will ask you to wear it for additional time after you leave to make sure we have enough information.

Then you will be randomly assigned to the treatment condition or the physical activity education control condition.

If you are in the treatment condition, we will provide you the treatment manual to be used during the 10-week program.

Everyone will receive a Fitbit Inspire 32 to help encourage and track physical activity and some information about increasing physical activity.
If you choose to complete this visit remotely, you will mail back the accelerometer and we will go through a similar process. If it did not record at least 10 hours of wear for 4 days, we will ask you to wear it for additional time after you leave to make sure we have enough information.
Then you will be randomly assigned to the treatment condition or the physical activity education control condition.
If you are in the treatment condition, we will mail you the treatment manual.
We will also mail you the Fitbit Inspire 32 and the first set of educational materials, and schedule a virtual meeting through either videoconferencing or the phone to show you how to set up your Fitbit using a study-provided login.

Weekly Phone Sessions 1-10 (treatment condition only):

Each phone call will take approximately 30-45 minutes, and will be recorded so that a certain percentage can be reviewed to make sure that your trainer is delivering the program correctly. These recordings will be saved in a secure folder on our network. In the prior week, you will have been assigned a positive psychology activity and will have set a physical activity goal. During the weekly calls, you and your study trainer will review what you wrote about a positive psychology exercise (like remembering values and goals during exercise), how it made you feel, and how you might use this activity in future bouts of physical activity. Then, your trainer will assign you the new positive psychology activity for the next week, which you will complete at your convenience before the next phone appointment. You will also discuss a topic related to improving your physical activity, review your physical activity over the last week, and talk about setting a goal for the week ahead.

10-Week Follow-Up Visit (Week 10; 90-120 minutes).

- At week 10, we will ask you to complete a follow-up visit, which will occur in person at MGH. In this visit, we will complete the same assessments as in the first visit**.**
  During these follow-up visits: A nurse will measure your vital signs, height, weight, body composition, and waist circumference. We will collect a blood sample (1 teaspoon of blood) to test for A1C, lipids, and c-reactive protein. We will also ask you to again perform a six-minute walk test to assess your functional exercise capacity and report your weight at home for consistency.
  Before the follow-up assessment, we will mail you the accelerometer that measures how active you are. Prior to the 10-week visit, you will wear it for 1 week and then bring it to the hospital with you.

24-Week Follow-Up Visit (Week 24; 90-120 minutes; in person or remotely).

If you choose to complete this visit in person, at week 24, we will ask you to complete a final follow-up visit, at MGH. In this visit, we will complete the same assessments as in the first visit**.**

During these follow-up visits: A nurse will measure your vital signs, height, weight, body composition, and waist circumference. We will collect a blood sample (1 teaspoon of blood) to test for A1C, lipids, and c-reactive protein. We will also ask you to again perform a six-minute walk test to assess your functional exercise capacity.

We will also ask you to provide feedback about the program via a brief exit interview.

Before the follow-up assessment, we will mail you the accelerometer that measures how active you are. Prior to the 24-week visit, you will wear it for 1 week and then bring it to the hospital with you.

If you choose to complete this visit remotely, we will ask you to complete the questionnaires via secure online data collection system (REDCap) and complete the weight, height, and waist measurements on your own.

We will mail you a scale and tape measure if you do not have one already, along with instructions on how to complete the waist measurements.

During this time, we will ask you to complete the necessary lab work (blood sample (1 teaspoon of blood) to test for A1C, lipids, and c-reactive protein.) at a local Quest Diagnostics Service Center, mailing or emailing you the laboratory requisition orders beforehand.

We will also include a prepaid envelope with the accelerometer and ask you to mail it back after the 7 day period.

Other information

We will let your surgery center clinician know that you are participating in this study and your participation in the study will be listed in your electronic medical record, but we will not provide any further information to your providers.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples

may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

Blood sample: Blood drawing may cause a small amount of pain. In addition, you may get a temporary bruise or "black and blue mark." Rarely, people faint when their blood is drawn. Very rarely, the vein may become red and swollen, or infected. If this happens, we can treat the problem.

Accelerometer and Fitbit: There are no known physical risks to using the accelerometer or Fitbit. If placed in water, they may stop working, but there is no shock risk. The data we collect from the accelerometer will not include your name or other personal information. We will instead use a numeric code for your data to make sure your identity is protected when we connect the accelerometer to our computers to find out the number of steps you took. There may be other unknown risks of using the accelerometer. The data we extract from the Fitbit website will not include your name or other personal information. In order to use the Fitbit, you must agree to Fitbit's Terms of Service, and the company will own and have access to your Fitbit data as they do for any Fitbit user. The Fitbit Privacy Policy can be found at fitbit.com/global/us/legal/privacy-policy. Pairing the Fitbit with your smartphone could use mobile data, for which you will be responsible. If you would prefer not to use the Fitbit, you can decline and still participate in the study.

Physical activity: In this study, you will be encouraged to participate in physical activity, and there are risks related to increasing physical activity. For example, you could fall down or have new physical symptoms, which could be serious. If you experience any physical discomfort, you will be directed to emergency medical care or to contact your physician. We have physicians on our team to consult in the event that you experience medical symptoms, and we take all steps

possible to ensure that you are treated promptly, include helping to arrange an evaluation in nearest emergency room.

Answering questions: You might feel uncomfortable answering the questionnaires about your mental and physical health. You may skip any questions you don't wish to answer and can stop your participation at any time.

Confidentiality: As with any study, there is a risk to confidentiality (keeping others from knowing about your participation in the information you provide). We have made every effort to protect the confidentiality of all subjects in the study. Your study materials and data will only contain a study number and will not contain your name or other identifying information. There also are risks to confidentiality through use of the Fitbit per the Fitbit Terms of Use.

There may be other risks that are currently unknown. However, we do not foresee any other physical, economic, legal, or social risks.

What are the possible benefits from being in this research study?

It is possible that you may not benefit from being in this research study. However, the positive psychology exercises used in this study have been created to increase positive thoughts and feelings, and you may find that you feel happier, more hopeful, or more confident as a result of completing these activities. Also, earlier studies of positive psychology have found that people who are feeling more hopeful are more likely to be physically active.

Similarly, receiving information about important topics related to physical activity, and engaging in the motivational interviewing program designed to help you complete more physical activity, can be beneficial. Increasing your physical activity may lead to better energy, greater function, and a lower risk of other health problems.

Your participation may also help future people who would like to increase their activity. This study could help in creating a treatment that would try to boost positive thinking and improve health. If it turns out that this new treatment appears to be useful based on the results of this study, it might someday be used as part of regular treatment for adults who have had bariatric surgery and want to increase physical activity.

What other treatments or procedures are available for your condition?

You do not have to take part in this study to receive additional assistance engaging in healthy behaviors (like physical activity). Your doctor can refer you to counseling services or other programs that can help you to become more active or eat healthy foods. He or she can also refer

you to mental health treatment, if this is something you want or need. Mental health treatment may include individual counseling, group therapy, medications, or other treatments. You can discuss these options with your doctor at any time, and you can still be in this study if you also take advantage of those other treatment options.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You may be paid up to $300 to take part in this research study. You will receive a $100 check when you complete the baseline study visits, a $100 check when you complete the 10-week follow-up visit, and a $100 check when you complete the 24-week follow-up visit. You will also receive a free Fitbit Inspire 32 to keep. We will also pay for the cost of parking for study visits. A social security number is required to process the payment checks; this number will be permanently removed from the research record upon study completion.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

You will not have to pay for any part of this research study. Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

Past, present, and future medical records

Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

Mass General Brigham researchers and staff involved in this study

The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research

Other researchers and medical centers that are part of this study

The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research

A group that oversees the data (study information) and safety of this study

Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)

People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers

Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records

Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

Other researchers within or outside Mass General Brigham, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the

hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

I have read this consent form.
This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
I have had the opportunity to ask questions.
I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____
Print Name

_____ _____ _____
Subject Signature Date Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

I have explained the research to the study subject.
I have answered all questions about this research study to the best of my ability.

_____
Print Name

_____ _____ _____
Study Doctor or Staff Member Signature Date Time (optional)

Consent Form Version Date: 1/13/25