The Body Project: Comparing the Effectiveness of an In-person and Virtually Delivered Intervention

NCT: 05794763

04/01/2022

Are you participating in any other research studies? _____ Yes _____No

Your consent is being sought for participation in a study evaluating two delivery methods for a body acceptance class, the Body Project. This is an evidence-based, peer led group program to improve body satisfaction and prevent related problems.

Participation in the research study will include attending one-hour weekly group sessions over the course of four weeks. You will also be asked to complete three assessments (for surveys and measurement) over the course of the study: one at the beginning of the study; one following the 4-week program; and one 3 months after the end of the program. As part of this research study, you will complete a brief, structured interview with a member of trained research staff, complete surveys, and engage in a variety of verbal, written, and behavioral exercises as part of the program.

Your participation in this study is completely voluntary. Some possible risks and inconveniences of the study include psychological discomfort during interviews and group sessions. Some possible benefits of participating in this research are an improvement in body satisfaction as well as a contribution to research.

PURPOSE OF RESEARCH

You are invited to participate in a research study evaluating two delivery methods for a body acceptance class to test whether this program is more effective when implemented virtually or in-person. We hope to learn 1) which method of delivery produces greater reductions in eating disorder risk factor symptoms and 2) determine any distinguishing factors that make virtual delivery more effective than in-person delivery in producing a larger reduction in outcomes. You were selected as a possible participant in this study because you match our demographics of women between the ages of 18-40

If you decide to terminate your participation in this study, you should notify Dr. Eric Stice at 650-497-7408.

This research study plans to recruit 60 women between the ages of 18 – 40 from the United States. Stanford University expects to enroll 60 research study participants.

If you are coming in-person to research visits, you are required to be fully vaccinated—2 doses (1 for Johnson and Johnson), 2 weeks out and to provide proof of your

vaccination (e.g., CDC COVID-19 Vaccination Card, e-Health record, etc.) to the researcher prior to study participation. Alternately, you can provide a negative COVID test within 72 hours of your visit.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take eight months. Your participation will only occur over the course of approximately 4 months. Each participant will complete:

1. One baseline assessment, for about 30 min.

2. Four one-hour weekly group interventions that will take place for four consecutive weeks.

3. One post-test assessment, for about 30 min.

4. One three-month follow-up assessment, for about 30 min

PROCEDURES

If you choose to participate, Dr. Stice and his research study staff will coordinate a time with you to complete the various steps of the study.

After completion of the online and/or phone screener, a baseline assessment will take place over Zoom, a video conferencing tool, to confirm eligibility for participation in the study. The interview asks about eating and exercise habits, body image, and mood.

Following enrollment in the study, you will be randomly assigned to one of two conditions: an immediate, virtual Body Project group or a 4-week delay in-person Body Project group. You will have a fifty percent chance of being assigned to either study condition (like flipping a coin). In one condition you will be immediately assigned to a virtual Body Project group, in the second condition you will need to wait four weeks and

will then be assigned to an in-person Body Project group. These are one-hour weekly groups that will take place for four consecutive weeks. These groups will be conducted virtually using Zoom, a video conferencing tool or in-person at a secure location on campus. Following the end of the program, participants are asked to complete a post-test assessment. A follow-up assessment visit will take place three months after completion of the program. These activities are further outlined below.

Assessments:

Over the course of the study you will complete three assessments with a member of the personnel over Zoom, a video conferencing tool: one visit at beginning of the study; one visit following the 4-week group program; and one three months from the date of completion of the program. Each of these visits will include:

1. A diagnostic interview assessing eating behaviors and attitudes.
2. A written survey that will address eating and exercise habits, body image, and mood.

Group Sessions:

Participants will engage in the same intervention but will be assigned to groups of 5-6 people. These groups will meet online weekly using the video conferencing platform, Zoom. Groups last one hour, and you will be asked to complete verbal, written, and behavioral activities. There are four weekly meetings.

The group sessions will be video recorded to provide supervision to the group leaders. The use of video-recordings will be limited to research and training of project staff under the supervision of the project directors. The tapes will be stored and kept locked in a HIPAA-compliant encrypted online server and will be labeled by group and session number. Your permission to be video recorded is required to participate in the study.

Future Use of Private Information and/or Specimens:

Identifiers might be removed from identifiable private information, and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Eric Stice at 650-497-7408.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. Your participation in this study may involve risks that are currently unforeseeable due to the investigational nature of the study. However, you will be informed if any new risks become apparent. The following explains the possible risks involved and the precautions we are taking.

You may feel uncomfortable by some of the questions in the interviews and surveys. You have the right to refuse to answer any question. In addition, the interviewers are closely trained and supervised to be sensitive to your feelings.

Participants involved in the group sessions may feel uncomfortable with some of the activities; the exercises are designed to help participants practice new behaviors to improve functioning and reduce eating disorders. Your participation in all activities is completely voluntary. In addition, group facilitators are closely trained and supervised to be sensitive to your feelings.

With participation in a group intervention there is potential for a loss of privacy due to the sharing of personal information with other participants. We take several precautions to prevent any loss of information. Research assistants will ensure that all participants are aware of the importance of maintaining confidentiality and must agree to keep all information they hear in group private before participating further. All participants may also refuse to answer any questions or withdraw consent to participate at any time.

Participants may have or develop an eating disorder and/or other serious mental health problem during their participation. If any Body Project participant develops an eating disorder during the intervention that comes to the peer educator's attention, peer educators will be encouraged to meet with the person afterwards so that they can be given a referral and strongly encouraged to seek treatment. Peer educators will consult with the protocol director in the rare instances where this might occur to ensure that the feedback is provided in a clinically sensitive manner

POTENTIAL BENEFITS

There are also some benefits to you for taking part in this research project. The primary benefits from being in the study are an improvement in body satisfaction. In addition, participants often derive a sense of altruism and accomplishment in knowing that they are contributing to understanding how we can better help other women overcome body

image and eating problems. Participation will inform the widespread distribution of an effective evidence-based eating disorder prevention program.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative to participating in this study is to not participate.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. You have the right to refuse to answer particular questions. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

We will strive to keep your information as confidential as possible. However, if information is disclosed to us during this study regarding suspected child abuse or neglect, suspected elder abuse or neglect, or the intent to hurt oneself or others - we must report it for legal and ethical reasons.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to learn which methods are most successful in reaching women dealing with body image difficulty and to learn about the effectiveness of this body acceptance program in reducing eating disorder risk factors. Your health information will be used to confirm eligibility to participate in this research study. If your information is used for publication, any identifying information will be removed.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using

your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Eric Stice at: 401 Quarry Rd., Stanford, CA 94305-5719

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, name, basic demographic information (age, gender, ethnicity), date of birth, medication history, eating behaviors and disorder history, and other health information relating to weight and weight management.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Eric Stice
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on 02/28/2050 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment/Reimbursement
You will not be paid to participate in this research study.

Costs
There is no cost to you for participating in this study, other than basic expenses and the personal time it will take to come to all of the study visits.

Sponsor
Stanford University is providing financial support and/or material for this study.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Eric Stice. You may contact him now or later at 650-497-7408.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Eric Stice at 650-497-7408.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact the research coordinator Victoria Franco, at 910-229-1298.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant