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

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1. PURPOSE OF THE STUDY

a. Brief Summary

This proposed pilot study will directly compare two delivery methods for a body acceptance/ eating disorder program to assess whether this program is more effective when delivered virtually. We will evaluate whether virtual groups produce greater reductions in eating disorder risk factor symptoms (pursuit of the body ideal, body dissatisfaction, dieting, dietary restraint and negative affect), eating disorder symptoms, and future onset of eating disorders when all other factors are held constant.

b. Objectives

Aim 1: Evaluate whether virtual delivery of an eating disorder prevention program produce greater reductions in eating disorder risk factor symptoms, eating disorder symptoms, and eating disorders when compared to in-person groups. Results will provide critical information regarding the possibility of broad implementation via virtual delivery.
Aim 2: Determine any distinguishing factors that make virtual delivery more effective than in-person delivery in producing a larger reduction in outcomes. Results will highlight any differences between the two forms of delivery that can be transferred to in-person groups, improving both conditions.

c. Rationale for Research in Humans

This study must use humans due to the nature of body image disturbances and eating disorders occurring only in humans, but not in other animals to our knowledge. Because the programs require speech as a method of communication, human subjects are necessary due to the fact animals do not engage in this form of communication.

2. STUDY PROCEDURES

a. Procedures

1) Young adult females will learn about the study through the study team's recruitment efforts, including online advertisements through Facebook, Instagram, Craigslist, and

Reddit, flyers posted near college campuses flyers posted in high traffic areas on Stanford's campus (dorms, dining halls) and distributed/promoted by Vaden Student Health Services, listservs for different communities/clubs, social media platforms (Instagram, Facebook, Twitter), Reddit

2) Potential participants who express interest will be given
a link to a secure online Qualtrics screening questionnaire for the research study (this link will also be available directly from advertising material). Upon completion of the questionnaire, potential participants will then be contacted via phone or email. After eligibility is determined, they will be scheduled for a consent and baseline assessment.

3) After it has been determined that potential participants are a good fit for the study and they have offered consent to participate, they will be instructed to complete a short survey-based assessment.

Assessments
a) EDDI: A standardized measure that measures the presence of an eating
disorder and the severity of the characteristic psychopathology of eating disorders.
b) Survey: Demographics, Thin Ideal Internalization Scale , Body Dissatisfaction Scale, Positive and Negative Affect Scale and Dutch Restrained Eating Scale

4) All participants will receive the same 4 session eating disorder prevention program, albeit virtual groups or in-person groups. Participants will be randomized to a virtual delivery condition condition or an in-person delivery condition. Participants have a 50/50 chance of being randomized to either condition. Participants will be assigned to a 5–6-person group run by trained peer educators, and engage in 4 sessions of the Body Project over the course of 4 weeks. These sessions will take place either online using Zoom, a videoconferencing tool, or in-person on Stanford's campus (following university COVID-19 safety protocols and precautions).

5) Once the 4 sessions have been completed, participants will be contacted to complete a short set of post-test surveys.

Assessments
a) EDDI: A standardized measure that measures the presence of an eating
disorder and the severity of the characteristic psychopathology of eating disorders.
b) Survey: Demographics, Thin Ideal Internalization Scale , Body Dissatisfaction Scale, Positive and Negative Affect Scale and Dutch Restrained Eating Scale

6) At 3-months, participants will be contacted to complete a short set of post-test surveys at follow-up and diagnostic interviews will be given.

Assessments
a) EDDI: A standardized measure that measures the presence of an eating
disorder and the severity of the characteristic psychopathology of eating disorders.
b) Survey: Demographics, Thin Ideal Internalization Scale, Body Dissatisfaction Scale, Positive and Negative Affect Scale and Dutch Restrained Eating Scale

b. Procedure Risks

The research procedures described above poses non-significant risks for participants and the research staff involved in this project are fully trained in their assigned responsibilities. Adherence to the program protocol will be monitored by the PIs for this pilot study and participants will be instructed that they may drop out of the study at any point.

c. Use of Deception in the Study

No deception will be used.

d. Use of Audio and Video Recordings

Video recordings of the virtual sessions will occur using the built-in recording tool on Zoom and an audio recorder for the in-person sessions. The recordings are necessary to ensure adherence to protocol and quality of both the virtual and in-person delivery of the Body Project. No PHI (participant health information) or participant identifying information will be recorded. In the event that this does occur, this information will be edited out before it is saved to the hard drive and shared with any other study personnel. All video files will be downloaded and stored in the HIPPA compliant Stanford Medicine Box hard drive.

e. Alternative Procedures or Courses of Treatment

This pilot study is comparing the effects of a virtual delivery versus in-person delivery of an eating disorder prevention program. Everyone in the trial will receive the Body Project, an effective eating disorder prevention program, meaning that everyone who participates will benefit. There will be no alternative courses of treatment to offer. This program is designed for prevention, to prevent the likelihood of onset of an eating disorder. Thus, it is not intended to treat any conditions. The only other alternative would be to not participant in this study. There are no known risks associated with participation in this eating disorder prevention program, although some sensitive topics may cause participant's discomfort. This program has the potential to aid participants in resolving some or all struggles and difficulties with body image. Additionally, this study will not hinder participants with a DSM-5 eating disorder from continuing or pursuing any outside treatment whilst they are enrolled in the study. Previous research has shown that there are stronger reductions in eating disorder symptoms for participants with a DSM-5 eating disorder than participants without an eating disorder.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

If there are participants who meet criteria for a DSM-5 eating disorder at the termination of the study, the appropriate referrals will be provided. This study will not interfere with their current levels of care or their future levels of care.

g. Study Endpoint(s)

If there is such a discrepancy between the two different conditions, they will be evaluated by the principal investigators in terms of terminating the study prematurely. Otherwise, we shall examine the program's effectiveness at the end of the study and study participation will be completed within 24-weeks, including a 3-month follow up after the conclusion of Body Project groups.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

The severity of eating disorders are extreme, with all eating disorders having an increased risk of mortality and increased likelihood of functional impairment and suicide attempts than other psychiatric disorders (Smink, van Hoeken and Hoek, 2012; Arcelus et al., 2011). The economic burden of eating disorders is massive and only increasing. An estimated 28.8 million Americans will have an eating disorder in their lifetime and the economic burden of treating an eating disorder is $64.7 million each year (Sonneville & Lipson, 2018). For the current cost of treating one eating disorder, between 32 and 186 cases could be prevented (Akers, Rohde, Shaw and Stice, 2021). This does not even take into consideration the fact that 80% of individuals with eating disorders never seek treatment and current treatments fail to produce lasting results, with less than 40% of eating disorder patients making a full recovery (Swanson et al.,2011). Thus, there is a critical need for a paradigm shift in our approach to eating disorders: transitioning from reactive medicine to preventive medicine as a public mental health issue.

The Body Project eclipses numerous other reputable eating disorder prevention programs that have been evaluated. Indeed, solely the Body Project has proved effective in a) reducing eating disorder risk factors, symptoms, and onset through 2-4 year follow-up b) reduce these outcomes when compared to several other valid alternative interventions c) proven to affect the intervention target (appraisal of the thin ideal) d) affect objective biological outcomes (reduction in brain reward circuitry response to thin models) and e) produce effects that are consistently replicated independent of one another (Stice et al.,2017). Furthermore, the robust economic value of the Body Project makes it an ideal candidate for furthering the field of eating disorder prevention, with delivery costs of the Body Project being significantly less than the current costs for treating an eating disorder ($20,300 for CBT for BN to approximately $119,200 for treatment of AN) (Akers, Rohde, Shaw and Stice, 2021).

In a piloted virtual trial of the Body Project conducted last year, virtual groups showed significantly greater pretest-to-posttest reductions in pursuit of the thin ideal, body dissatisfaction, dieting, negative affect, and eating disorder symptoms when compared to in- person groups. In fact, the Body Project groups conducted last year produced the largest reductions in outcomes that have ever been observed when it was delivered virtually via zoom. Thus, virtual delivery could make broad implementation possible and result in better outcomes, which could be effectively carried over to in-person groups as well.

b. Findings from Past Animal Experiments

N/A

4. RADIOISOTOPES OR RADIATION MACHINES

a. Standard of Care (SOC) Procedures

Identify Week/Month of Study	Name of Exam	Identify if SOC or Research
N/A	N/A	N/A

b. Radioisotopes

None

c. Radiation Machines – Diagnostic Procedures

None

d. Radiation Machines – Therapeutic Procedures

i. Area treated, dose per fraction/number of fractions, performed as part of normal clinical management or due to research participation (well-established procedures)

N/A

ii. FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions (if procedure is not well-established)

N/A

5. DEVICES USED IN THE STUDY

a. Investigational Devices (Including Commercial Devices Used Off-Label)

None

b. IDE-Exempt Devices

None

6. DRUGS, BIOLOGICS, REAGENTS, OR CHEMICALS USED IN THE STUDY

a. Investigational Drugs, Biologics, Reagents, or Chemicals

None

b. Commercial Drugs, Biologics, Reagents, or Chemicals

None

7. DISINFECTION PROCEDURES FOR MEDICAL EQUIPMENT USED ON BOTH HUMANS AND ANIMALS

N/A

8. PARTICIPANT POPULATION

a. Planned Enrollment

(i) We expect to enroll 60 participants at Stanford.
(ii) We expect to enroll 60 participants total at all sites. Stanford is the only site of this study.
(iii) Healthy, adult females 18-40 are the target population for this eating disorder prevention program. Using participants that fit this description enables the research team to evaluate the effectiveness of virtual delivery versus in-person delivery of this prevention program and discern the specific factors that may contribute to virtual delivery being more effective in reducing eating disorder risk factors and symptoms and risk for future eating disorders.

b. Age, Gender, and Ethnic Background

Target participants will be females age 18-40, we will not exclude on the basis of ethnic background.

c. Vulnerable Populations

Young adult females are included in this study because they are at elevated risk for future eating disorder onset. Information on the risks and benefits of the program and their rights and welfare will be addressed in the Informed Consent forms.

If participants are too young (below 18), they will be excluded from this study. We plan to ask for dates of birth from all interested participants during the screener in order to determine if they are at an appropriate age to participate in the study. Dates of birth from all interested participants will be required during the screener in order to determine if they are at an appropriate age to participate in the study.

d. Rationale for Exclusion of Certain Populations

The purpose of this study is to evaluate two delivery methods for a body acceptance/eating disorder prevention class to test whether the program is more effective when implemented virtually. Children are not the target population of this study, as we are examining the effectiveness of the program in adult women, which are typically above 18 years of age.

e. Stanford Populations

Stanford students, employees, or laboratory personnel may be eligible to participate in the research study. We cannot estimate how many that might be. If any such participants are enrolled, they will follow standard procedure as any participant would and complete a consent form.

f. Healthy Volunteers

The target population of this study are healthy participants due to its preventative nature as a body acceptance class. The risks for healthy volunteers is extremely low. There is potential for participants to feel distressed when disclosing personal information during

the assessment visits or during the group sessions. However, based on previous experience, the associated risk of this occurring is a very low and the effects would be short-lived. These assessments have been used by thousands of young women with almost no distressing outcomes.

There is a small risk that healthy volunteers may experience some psychological stress as a result of finding out new information about their psychological health that was revealed in the course of the study. However participants are fully informed of these risks at the time of consent. All collected information is kept confidential in order to protect participant's identity and participants are informed that they are free to exercise their right to withdraw from the study at any time without adverse consequence.

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g. Recruitment Details

Recruitment will take place using both online and in person strategies.

In person - flyers will be posted in high traffic community areas on Stanford's campus (dorms, dining halls, learning hubs, student health services, etc.)

Online - Ads will be posted on the internet using social media sites: Facebook and Instagram, community forums: Craigslist and Reddit, and e-mails sent to community listservs. We will manage an instagram and facebook page with postings about the study using the approved images and captions. All posts on the page will be moderated and set to block commenting or posting by the public. Posting of online ads will be managed based on inclusion criteria, i.e. Stanford students, age, etc.

Social media recruitment posts will be set up such that the security settings do not allow participants or others from the public to post on the wall/public forum. If this is not possible due to the social media platform's settings, the social media posts will be monitored and any disclosures of PHI removed.

Once the potentially eligible participants complete the screener we will reach out to them via email or telephone to clarify points of eligibility, and if eligible, schedule an assessment.

Additionally, all families who call the Stanford clinic for services are asked about their willingness to be contacted for research. Individuals who may potentially meet study inclusion criteria will be called and asked if they are willing to hear about a Stanford research study.

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h. Eligibility Criteria

i. Inclusion Criteria

i. Female
ii. Ages 18 - 40

iii. Fluently speak and read English and have access to a computer or tablet with internet iv. Must live within the United States

ii. Exclusion Criteria

N/A

i. Screening Procedures

Interested participants will be asked to fill out a brief online screening questionnaire. Only information pertaining to the inclusionary & exclusionary criteria will be included in the questionnaire. Participants have the option to terminate the online screening questionnaire at any time. The participant will be contacted to schedule an assessment upon review of their questionnaire. For participants that complete the online screener, the participants rights will be clearly stated before proceeding with the screening. Additionally, they can call the research personnel prior to continuing if they have any questions.

j. Participation in Multiple Protocols

As a part of the informed consent process, subjects will be asked if they are participating in any other research projects. Their participation in other protocols will not exclude them from participation in this study.

k. Payments to Participants

N/A

l. Costs to Participants

N/A

m. Planned Duration of the Study

The estimated duration of the entire study is eight months, in line with the timeline for completion of a Master's thesis and summer quarter conferral.
i. The screening will consist of the online questionnaire (about 10 minutes), and the baseline assessment (about 1-2 hours).
ii. Active participation will be 4 months (4 weeks of Body Project sessions, and 3 month follow-up assessment)
iii. Analysis of participant data will take about 2-3 months.

9. RISKS

a. Potential Risks

i. Investigational devices

N/A

ii. Investigational drugs

N/A

iii. Commercially available drugs, biologics, reagents or chemicals

N/A

iv. Procedures

N/A

v. Radioisotopes/radiation-producing machines

N/A

vi. Physical well-being

There are no risks to physical well-being

vii. Psychological well-being

Participants may feel distressed when disclosing personal information during the assessment visits or during the group sessions. Based on previous experience, the associated risk of this occurring is a very low and the effects would be short-lived. These assessments have been used by thousands of young women with almost no distressing outcomes. Participants have the option to not answer any question if they feel uncomfortable.

viii. Economic well-being

N/A

ix. Social well-being

There is a small chance that participants may be assigned to a group led by a peer educator that they know outside of the context of this program. When groups are assigned to the peer educators, we will ask them to check the list to ensure they do not have a personal relationship with any of the participants assigned to their group. In the case that they do, the participant will be placed into a different group led by a peer educator with whom they do not know.

Additionally, peer educators may know that a group member is participating in the program. However, they will be extensively trained on the importance of confidentiality and protecting participant information. The peer educator group leaders might know a group member from outside of the group and might discuss confidential information about that group member to others who are not part of the group. However, peer educators will be put through an application process and extensive training to ensure they understand the importance of protecting information and dealing with sensitive matters.

x. Overall evaluation of risk

Low risk

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b. International Research Risk Procedures

N/A

c. Procedures to Minimize Risk

i) If interested participants do not consent their information will not be retained.
(ii) All electronic information will be maintained on password-protected files on encrypted devices at Stanford.
(iii) Participants' data that will not contain PHI will be identified by assigned identification codes (ID numbers) that will not be determined by any personal identifiers so that participants' identification and privacy will be protected.
(iv) Access to files and identifiers will be restricted to Stanford researchers involved in the study.
(v) The study will protect against risks of confidentiality by securing all data containing PHI in locked files, assigning ID numbers for data collection, and reinforcing the policies of confidentiality among the study researchers according to Stanford's guidelines.

d. Study Conclusion

Data collection for each participant will terminate once they've completed the study (4 weeks of Body Project Sessions, posttest and 3 month follow up assessments). The entire study will terminate when all sessions assessments have been completed for all participants.

If the participant wants to terminate the experiment at any time, they can do so. If the investigator determines that participation would be harmful to the subject or investigator in any way, they can terminate the experiment.

e. Data Safety Monitoring Plan (DSMC)

i. Data and/or events subject to review

N/A

ii. Person(s) responsible for Data and Safety Monitoring

N/A

iii. Frequency of DSMB meetings

N/A

iv. Specific triggers or stopping rules

N/A

v. DSMB Reporting

N/A

vi. Will the Protocol Director be the only monitoring entity? (Y/N)

Yes

vii. Will a board, committee, or safety monitor be responsible for study monitoring? (Y/N)

No

f. Risks to Special Populations

N/A

10. BENEFITS

Because this is a prevention program, the most salient potential benefit is the reduction of eating disorder risk factors/symptoms and the potential prevention of future eating disorders in participants. Additionally, there is the potential benefit of altruism from participation in personally relevant research, a better understanding of eating disorders, and receiving referral information for local low/no cost resources for eating disorders and other mental health concerns.

11. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.