Study Title: Efficacy of a Dissonance Based Eating Disorder Program
NCT Number: 03796091
ID: 1516-105-GRE
Date of IRB Approval: December 5, 2018 (revised versions of informed consent statements)
Document Type: Informed Consent Documents (revised versions of informed consent statements)
PI: Dr. Melinda Ann Green
Institution: Cornell College

INFORMED CONSENT DOCUMENT: SCREENING

Title of Study: **A Screening for a Clinical Trial Evaluating the Efficacy of Disordered Eating Interventions**

Investigators: Dr. Melinda Green, Principal Investigator
Gabby Carlson, Kamryn Hogan, Elisabeth Sage, Yumeng Tao, John Bogucki, Julian Smith, Skylar Ulku, Undergraduate Research Assistants
Anne Roche, Cara Weinkes, Mallory Bolenbaugh, Marcie King, Graduate Research Assistants
Dr. Jen Rogers, Recruitment Coordinator

Medical Monitor: Dr. Monica Meeker

Data Safety and Monitoring Board Members: Dr. Monica Meeker, Dr. Scott Eilers

Contact Information for Principal Investigator: Dr. Melinda Green, 106E Law Hall, 895-4313, mgreen@cornellcollege.edu

This is a research study. Please take your time in deciding if you would like to participate. Please feel free to ask questions at any time. Please feel free to terminate your participation at any time. Feel free to decline to answer any questions which you find uncomfortable.

INTRODUCTION

This is a screening to determine whether you are eligible to participate in our eating disorder treatment study. The purpose of this screening is to determine if you meet criteria to be enrolled in our full scale study. To be eligible for enrollment, participants must be women, between the ages of 15-34, premenopausal, not pregnant, and must currently have some symptoms of disordered eating. These symptoms may include body dissatisfaction, dieting, binge behaviors, purge behaviors (including the use of laxatives, diuretics, fasting, excessive exercise, or other unhealthy behaviors designed to control weight) We intend to recruit 180 women between the ages of 15-34 with symptoms of disordered eating. Recruitment will end once these numbers are achieved.

If your screening results indicate you are eligible for the full-scale study, you are not obligated to participant. We will contact you at that point to assess whether you are still interested. If so, we will provide complete details about the study via a separate informed consent statement. In brief, participants in the full-scale study will be randomly assigned to a treatment condition which may consist of an educational brochure or a 4-session group therapy intervention which meets for 1-hour weekly. Eating disorder symptoms and associated psychological and cardiac risk factors will be evaluated immediately before each intervention, after each intervention, , and 2 months following the completion of each intervention.

DESCRIPTION OF PROCEDURES

In the next 10-20 minutes you will answer a series of questions via an online survey. You will complete a demographic questionnaire which includes questions about your medical history and a questionnaire regarding your eating patterns, weight, and body satisfaction. Some of the questions are of a personal psychological nature and may make you feel uncomfortable.

Based on your responses to the screening questions, researchers will decide if you meet criteria for further participation in the full scale study.

As part of the screening, you will be asked to provide your contact information. If you meet eligibility criteria for the full scale study, a member of the research team will contact you to provide further directions and to schedule your first assessment.

RISKS

Examining eating and weight-related thoughts, emotions, and behaviors may cause discomfort and may precipitate a negative psychological reaction in some individuals. Should you experience a negative psychological reaction to the study, please contact the Principal Investigator (Dr. Melinda Green), whose contact information is provided above. You may also want to contact the Cornell College Institutional Review Board Chair, Dr. Misha Quill,, at 895-4482 or mquill@cornellcollege.edu.

You will be solely responsible for payment associated with psychological services sought for any negative psychological reactions appearing before or after this study. The researchers assume no liability for the quality of the mental health services provided. Participants are responsible for conducting their own research on the quality of a mental health provider prior to seeking services from any provider or agency.

Medical expenses associated with any atypical medical conditions appearing during or after this study are not the responsibilities of the experimenters, Cornell College, or the agencies providing funding for this study. Participants will assume financial responsibility for the coverage of medical expenses associated with atypical medical conditions appearing during or after the study.

BENEFITS

If you decide to participate in the screening for this study, there may be a benefit to you if you are selected to participant in the full-scale study. The intervention programs implemented in this study have been shown to reduce eating disorder symptoms and associated risk factors; they are being provided at no cost to the participants included in this study. However, there may be variability with regard to outcomes and you may not experience this symptom reduction. Data from the full-scale study will help to increase scientific knowledge regarding the effectiveness of eating disorder intervention programs.

COSTS AND COMPENSATION

You will not have any costs from participating in this screening. For completing this screening, you will be entered into a drawing to win one of two Amazon gift certifications worth $25 each as compensation for your time. The chances of winning depend on the number of participants who complete the screening.

If you decide not to continue your participation in the screening, you will remain eligible for the Amazon gift certificate incentive.

If you are selected to participate in the full-scale study, you will receive a $40 Amazon gift card for attending each of the three assessment sessions ($40 Amazon gift card x 3 sessions = $120 total). This amount will be available to participants in all conditions. Participants in the educational brochure condition will not receive additional compensation for reading the brochure since this takes only approximately 10 minutes.

If you are assigned to one of the group therapy intervention conditions, you will receive an additional $160 in Amazon gift cards for attending the four 1-hour intervention sessions and $70 in Amazon gift cards for completing all homework assignments. Combined with the $120 in Amazon gift cards awarded for participating in the assessment sessions, total compensation for the group therapy conditions equals $350.

PARTICIPANT RIGHTS

Your participation in this screening is completely voluntary and you may decide to leave the study at any time. ***If you decide to leave early due to discomfort, it will not result in any penalty or loss of benefits to which you are otherwise entitled.***

CONFIDENTIALITY

All records will be kept confidential to the extent permitted by applicable laws and regulations. Your records will not be made publicly available. Data from your screening will be coded with an experimental number and will be stored on a password protected network drive. Only the research team members will have access to your data. Federal government regulatory agencies and the Cornell College Institutional Review Board (a committee which reviews and approves studies using human participants) may inspect and/or copy your records for quality assurance and data analysis. If you win a gift card, the Cornell College Grants Compliance Officer will have access to your name and address to determine whether an IRS threshold of $600 in annual compensation for Cornell College is met; if so the money earned in the present study will have to be claimed as income and you will be contacted by the Compliance Officer to submit a W-9. The Compliance Officer will not know you participated in this experiment; the officer will only receive your name, address, and amount of money earned (the purpose of this payment will not be disclosed beyond the phrase, “Research Participant”).

Data will be analyzed by student researchers and the Principal Investigator Dr. Melinda Green. The resulting dataset will be analyzed and summarized in a publication intended to appear in a scientific journal.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during the study.

- For further information about the study contact: Dr. Melinda Green, 106E Law Hall, 895-4313, mgreen@cornellcollege.edu
- If you have any questions about the rights of research participants or research-related injury, please contact the Cornell College Institutional Review Board Chair, Dr. Misha Quill, 895-4482 or mquill@cornellcollege.edu.
- If you experience an unexpected negative psychological reaction to the study that does not remit, please contact a trained mental health service provider. Mental health service agencies in the area include, but are not limited to: Cornell College Counseling Service (available to Cornell students only, 895- 4292), the University of Iowa Counseling Service (available to University of Iowa students only, 335-7294), Tanager Place (available for adolescents, 365-9164), or Family Psychology Associates PC (378-1199). A list of psychologists in the Iowa City and Cedar Rapids areas who are on the National Health Registry in Psychology is available at http://www.nationalregister.org/psychologists.html. You may also want to ask your health service provider for a referral to a psychologist in the area. Please note that Tanager Place, Family Psychology Associates, and the practitioners listed on the National Health Registry in Psychology charge a fee for service. ***You will be solely responsible for payment associated with the psychological services administered by these agencies. Also, the researchers assume no liability for the quality of the mental health services provided by these practitioners.***

PARTICIPANT SIGNATURE

Your signature indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read this document, and that your questions have been satisfactorily answered. ***Please note if you are below age 18 that you must also have your parents sign this form indicating that they have read this document and they agree that you may voluntarily participate in this study. Their signature line appears below.***

Signature (printed): _____

Signature (signed): _____ Date: _____

INVESTIGATOR STATEMENT

I certify that the participant has been given adequate time to read and to learn about the study and that all of their questions have been answered. It is my opinion that the participant understands the purpose, risk, benefits, and procedures that will be followed in this study and has voluntarily agreed to participate.

Experimenter's Signature: _____ Date: _____

If you are below age 18, please complete the section below. If you are not below age 18, this section is not required.

PARENT SIGNATURE

Your signature indicates that you voluntarily agree that your minor child (listed above) may voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read this document, and that you have contacted the investigators via phone or e-mail if you had any questions and that your questions (if applicable) were satisfactorily answered.

Parent's Signature (printed):_____

Signature (signed): _____ Date: _____

INFORMED CONSENT DOCUMENT: FULL SCALE STUDY

Title of Study: **A Clinical Trial Evaluating the Efficacy of Disordered Eating Interventions**

Investigators: Dr. Melinda Green, Principal Investigator
Gabby Carlson, Kamryn Hogan, Elisabeth Sage, Yumeng Tao, John Bogucki, Julian Smith, Skylar Ulku, Emma Hartman, Lexi Ferenzi, Undergraduate Research Assistants
Anne Roche, Cara Weinkes, Mallory Bolenbaugh, Marcie King, Graduate Research Assistants
Dr. Jennifer Rogers, Recruitment Coordinator

Medical Monitor: Dr. Monica Meeker

Data Safety and Monitoring Board Members: Dr. Monica Meeker, Dr. Scott Eilers

Contact Information for Principal Investigator: Dr. Melinda Green, 106E Law Hall, mgreen@cornellcollege.edu; 319-895-4313 (office)

This is a research study. Please take your time in deciding if you would like to participate. Please feel free to ask questions at anytime. Please feel free to terminate your participation at anytime. Feel free to decline to answer any questions which you find uncomfortable.

INTRODUCTION

The purpose of this clinical trial is to investigate whether symptoms of disordered eating change among participants who complete an intervention. Participants will be randomly assigned to one of three intervention conditions and will undergo assessments of symptoms before, after, and 2 months after each intervention. We are evaluating which interventions are most effective in reducing eating disorder symptoms and disorder-related psychological and cardiac risk factors. A more comprehensive overview of the procedures appears below.

DESCRIPTION OF PROCEDURES

Three Assessment Sessions: As stated above, participants in all conditions will participate in a series of 3 assessment sessions. Prior to each session, participants will complete online questions assessing eating disorder symptoms and associated psychological risk factors. This process will take approximately 40 minutes. Next participants will report to the laboratory at their scheduled appointment time to have their cardiac function assessed via blood pressure measurements and electrocardiography (EKG or ECG). Participants' height and weight will also be recorded.

Prior to each assessment session, participants should:

- Complete the online survey (if not completed prior to each laboratory appointment this will need to be completed at the lab appointment)

- Fast (not consume any food or beverages other than water) for at least 3 hours.
- Refrain from using nicotine for at least 3 hours.
- Refrain from vigorous physical exercise for at least 24 hours.
- Not show any symptoms of acute physical illness for 48 hours.

It is important for participants to follow these directions so we can gather the most accurate data. If participants forget to follow these guidelines, or if an illness occurs, participants should contact their experimenter to reschedule.

On the day of an assessment session, participants will drive to the assessment location. Participants will receive directions via e-mail prior to each session. During the assessment session, participants will lie down on a laboratory cot for 10 minutes while preparation for electrocardiography (EKG or ECG) occurs. Electrodes will be applied to the chest and torso and lead wires will be attached to the electrodes. Participants' blood pressure will be assessed several times throughout this interval. Next, the experimenter will collect a 5 minute and 30 second recording of participants' cardiovascular data via electrocardiography (ECG or EKG). This data will later be analyzed to examine cardiac function.

Next experimenters will assess participants' height and weight.

Participants will be compensated via Amazon gift card in the amount of $40 in exchange for participation at each assessed session (3 sessions x $40 each = $120 total). Participants will sign a form indicating that compensation was received.

After each assessment session, participants' eating disorder symptoms, psychological risk factors, and cardiac indices will be evaluated by the research team. If the team determines that symptoms or cardiac indices are atypical and indicate a further need for evaluation, the participant will be contacted via both e-mail and phone to be informed results are atypical and the participant will be referred for further evaluation by a medical provider. If the participant is a minor, this information will be provided both to the participant and to the participant's parent and/or the participant's legal guardian. If participants' symptoms or risk factors worsen significantly over the duration of the trial, participants will also be contacted and provided with referral recommendations.

All participants will receive a comprehensive symptom report at the end of the trial. Referral resources will be provided again at that time if significant eating disorder symptoms remain.

Please note atypical results do not necessarily indicate a medical problem. Atypical results can be caused by many factors; participants will be informed of the atypical results and will be encouraged to follow-up with a medical or behavioral health care provider for further evaluation. Our research protocols were not developed to diagnose health conditions but we inform participants of assessment results and atypical results so participants can follow-up as necessary. Please note we are not responsible for any payment associated with follow-up visits to interpret or evaluate atypical test results.

As a courtesy to us and our experimenters, we ask that you do your best to attend your scheduled assessment sessions. In the unlikely event that you do need to reschedule, we ask

that you provide 24-hours-notice whenever feasible. It is difficult for us to accommodate last minute cancellations; advance notification makes this more feasible for us.

Treatment Conditions*:* Participants will be randomly assigned to 1 of 3 treatment conditions.

Brochure Treatment Condition: Participants randomly assigned to the educational brochure will receive two educational brochures which discuss eating disorder symptoms. The brochures will also include treatment referral information and recommended resources for persons struggling with disordered eating. The brochure will take approximately 10 minutes to read; follow-up with treatment or self-help referral resources is completely voluntary. Compensation will not be provided for reading the brochure or completing follow-up referrals. Participants in the educational brochure condition will receive $40 in Amazon gift cards for completing each of the 3 assessment sessions described above ($120 total in Amazon gift cards). Total time commitment for participants in this condition will be approximately 3 hours, 10 minutes plus commute time (i.e., three 60-minute assessment sessions, 10 minutes reading brochure).

Group Therapy Treatment Conditions: Participants randomly assigned to one of the two group treatment intervention conditions will complete a 4-week group treatment program with 5-8 other women and 2 trained treatment co-facilitators. For approximately 1 hour each week, participants will meet in this group to complete a series of readings, written activities, and verbal activities designed to reduce disordered eating. During the 4 intervention sessions, participants will be asked to analyze the weight and appearance-related messages received from the media, peers, family, romantic partners, and other sources. Participants will also be asked to record, analyze, and evaluate weight and appearance-related thoughts, emotions, and behaviors. Participants will engage in a variety of exercises designed to evaluate the meaning of thinness in our culture and its personal impact. These exercises are designed to combat the detrimental impact of messages which promote thinness.

Other risk factors will also be addressed, depending upon program. Participants may talk about the pressures women receive to focus on appearance. The relationship between these appearance-related pressures and eating disorder symptoms will be explored. Participants will explore the way they compare themselves to others and participate in a series of discussions and activities designed to decrease appearance-based comparisons with others.

After the 4-week program is complete, participants in both intervention conditions will continue to work on homework assignments related to the program for a period of 2-months until the final assessment session.

Participants in the intervention conditions will receive $230 in Amazon gift cards. Participants will receive $40 in Amazon gift cards for attending each intervention session (4 x $40 = $160 in Amazon gift cards), $10 in Amazon gift cards for completing each weekly homework assignment for sessions 1-3 of the intervention ($30 total in Amazon gift cards) and $40 in Amazon gift cards for completing the final homework assignment.

Participants in the intervention conditions will also receive $120 in Amazon gift cards for attending the three assessment sessions ($40 in Amazon gift cards per assessment session x 3 sessions = $120 in Amazon gift cards for attending all assessment sessions). Therefore, the total compensation available in the 4-session intervention conditions will be $350 in Amazon gift cards ($230 for attending all 4 group therapy sessions and completing all homework; $120 for attending all 3 assessment sessions).

To help ensure the integrity of the study, participants will be expected to attend all assessment and intervention appointments and to complete all assigned homework. In the unlikely event that participants cannot attend a session, a make-up session will be scheduled. If participants do not attend a make-up session, participants cannot continue to participate in the study and compensation will be provided only commensurate with the portion of the sessions completed. If participants partially complete a session (arrive late or leave early) or partially complete a homework assignment, partial compensation will be provided commensurate with the portion of the session or homework assignment completed.

A summary table of time commitment, compensation, and expected tasks for each group is provided at the end of this section.

All intervention sessions will be videotaped to provide feedback to program facilitators. If you do not wish to be videotaped, the co-facilitators will ask you to sit outside the field of view of the video. If you sit outside the field of view, your voice will still be heard on the videotape but your image will not be visible. The videotapes will be used only to provide supervision to the group co-facilitators to be sure they are correctly implementing the interventions. Recordings will be viewed by the research team for supervision purposes only and will be deleted after viewing.

**Please initial on this line to indicate you understand the sessions will be videotaped for supervision purposes, that you may sit outside of the camera view, that videotapes will be deleted after supervision occurs, and that you are still comfortable participating. _____

Table 1. Compensation and Time Schedule

Group	Compensation	Time	Activities
Education Brochure	$120 Gift Cards	~ 190minutes	3 Evaluation Sessions + 10 minutes reading brochure
Intervention 1	$350*Gift Cards	~600-630 minutes	3 Evaluation Sessions + 4 Intervention Sessions + Homework
Intervention 2	$350*Gift Cards	~600-630 minutes	3 Evaluation Sessions + 4 Intervention Sessions + Homework

**I understand the obligations of each condition, the compensation involved, and the activities that I will complete. Please initial on the line below if you understand each component. If not, please ask your investigator to explain each condition further. Your investigator will not know what condition you are in (please do not reveal this to them), but they will be able to explain both conditions in more detail (if needed). _____ (initials)

CONFIDENTIALITY CLAUSE FOR GROUP TREATMENT

This trial incorporates a group therapy intervention for those assigned to the group treatment conditions. There is a chance that participants may know others in the group. Members will reveal sensitive information during group treatment sessions. It is an expectation of this group that all members keep the identity of other members and personal information shared during the group confidential.

**I understand that this trial may assign me to a group therapy treatment, that others in the group will know my identity, and that the group may include people who I know. _____ (initials)

**I will keep the identity of other group members, as well as their personal information shared during the group, confidential. _____ (initials)

ATYPICAL RESULTS

After each assessment session, the research will evaluate your assessment results. If your results are atypical, you will receive both an e-mail report and a phone call notifying you of your atypical results and encouraging you to follow-up with a medical provider to evaluate whether there is a need for additional evaluation. Please note that ECG/EKG, blood pressure, height/weight, and psychological testing results are not to be interpreted as diagnostic of any disorder, disease, illness, or health condition. If the findings reveal atypical results, the Laboratory Coordinator or the Principal Investigator will contact you, provide a copy of your results, and encourage you to seek a physical or behavioral health professional's counsel for further evaluation and assessment.

If your symptoms worsen significantly over the course of the trial, or indicate a high level of symptomatology, the Principal Investigator or Laboratory Coordinator will refer the impacted participant to a primary care physician and a behavioral health provider specializing in the treatment of eating disorders. A high level of symptoms may preclude participation in the trial until a physician provides notification the participant is medically able to participate.

RISKS

The foreseeable risks inherent in this study slightly exceed those encountered in everyday life. Examining weight-related thoughts, emotions, and behaviors may cause discomfort and may precipitate a negative psychological reaction in some individuals. Should you experience a negative psychological reaction to the study, please contact the Principal Investigator (Dr. Melinda Green), whose contact information is provided above. You may also want to contact the Cornell College Institutional Review Board Chair, Dr. Misha Quill, at

mquill@cornellcollege.edu or 319-895-4482. As noted above, if atypical results appear in your ECG/EKG, blood pressure, or psychological assessment results, the Laboratory Coordinator or Principal Investigator will contact you both via e-mail and via phone, provide a copy of the atypical results, and encourage you to seek a health professional's counsel for further evaluation and assessment.

If you experience an unexpected negative psychological reaction to the study that does not resolve, please contact a trained mental health service provider. Mental health service agencies in the area include, but are not limited to: Cornell College Counseling Service (available to Cornell students only, 895- 4292), the University of Iowa Counseling Service (available to University of Iowa students only, 335-7294), Tanager Place (available for adolescents, 365-9164), or Family Psychology Associates PC (378-1199). A list of psychologists in the Iowa City and Cedar Rapids areas who are on the National Health Registry in Psychology is available at http://www.nationalregister.org/psychologists.html or at the Psychology Today website at https://www.psychologytoday.com/us/therapists. You may also want to ask your health service provider for a referral to a mental health provider in the area. Please note these mental health providers charge a fee for service.

You will be solely responsible for payment associated with psychological services sought for any negative psychological reactions appearing before or after this study. Also, the researchers assume no liability for the quality of the mental health services provided by the practitioners listed in the paragraph above. Participants are responsible for conducting their own research on the quality of a mental health provider prior to seeking services from these providers or agencies.

Medical expenses associated with any atypical medical conditions appearing during or after this study are not the responsibilities of the experimenters, Cornell College, or the agencies providing funding for this study. Participants will assume financial responsibility for the coverage of medical expenses associated with atypical medical conditions appearing during or after the study.

Do not participate in this study if you anticipate an adverse negative reaction to a 3-hour fast, to having your blood pressure monitored via a blood pressure cuff, or to having your cardiac function measured via ECG/EKG. Do not participate if you anticipate an adverse reaction to having your height or weight measured. Also, do not participate if you anticipate a negative psychological reaction to examining your weight-related attitudes and behaviors during a series of prevention exercises.

**I understand the risks inherent in this study. Please initial the line below if you understand each component. If not, please ask your investigator to explain each risk further. Your investigator will not know what condition you are in (please do not reveal this to them), but they will be able to explain each condition in more detail (if needed). _____

BENEFITS

If you decide to participate in this study, there may be a direct benefit to you. Participation in this trial provides free eating disorder assessment services (all conditions) and free group therapy

treatment services if assigned to 1 of the 2 intervention conditions (a $300-$800 value depending upon condition). Previous findings indicate participants in similar intervention programs have experienced lower symptoms of disordered eating and associated risk factors. However, there may be variability with regard to outcomes and you may not experience this symptom reduction. Data from participants in all conditions will help to increase scientific knowledge regarding the effectiveness of eating disorder intervention programs.

COSTS AND COMPENSATION

As compensation for your time and transportation expenses, you will receive $120 in Amazon gift cards exchange for your participation in the 3 evaluation sessions (3 sessions x $40 per session = $120 in Amazon gift cards) and an additional $230 dollars if you are assigned to either of the two group treatment conditions where you attend 4 intervention sessions and complete all homework exercises. The compensation table is outlined above.

For tracking purposes, participant names, addresses, and signatures will be transmitted to a Grant Compliance Officer at Cornell College. Compensation will be tracked but will not be claimed as income on tax returns unless the participant earns more than $600 yearly from Cornell College for research or other miscellaneous purposes. In the event that more than $600 is earned annually, participants will be contacted by the Grants Compliance Officer to complete a W-9 form for miscellaneous expenses reimbursed by the College. Reimbursement above the $600 threshold should be reported as income on participants' tax statements. Please note this $600 threshold will not be triggered via this study alone (as the $600 threshold far exceeds the total available compensation from this particular study) but this may be a possibility if participants are receiving income from the College via other research-related reimbursements or other forms.

PARTICIPANT RIGHTS

Your participation in this study is completely voluntary and you may decide to leave the study at any time. ***If you decide to leave early due to discomfort, it will not result in any penalty or loss of benefits to which you are otherwise entitled.***

**I understand the researchers involved in this study will need to break confidentiality and report my behavior to authorities in order to ensure my safety and the safety of other if I express at any point in the research process that I am an imminent harm to myself or an imminent harm to others. My initial on this line indicates that I understand this limitation to my rights _____

CONFIDENTIALITY

All records will be kept confidential to the extent permitted by applicable laws and regulations. Your records will not be made publicly available. ***The exception to this is any participants in the intervention program who choose to upload data or video of your interventions to your social media sites in order to discourage eating disorder symptoms among other women and girls. This is encouraged as part of the program but is not required. This portion of the program is completely voluntary. If you choose to upload images of yourself, these images and messages are publicly available.***

Participants in all conditions will be assigned an experimental number which will appear on all study materials. Only the researchers involved in the study will have access to a file which links your name to your experimental number; this file will be used for administrative purposes only. All of your data will be kept in a locked laboratory location. On-line data will be downloaded to a password-protected electronic file.

Federal government regulatory agencies and the Cornell College Institutional Review Board (a committee which reviews and approves studies using human participants), the trial's Data Safety and Monitoring Board (a committee which monitors symptom changes to ensure the safety of human participants), and the trial's Medical Monitor (a physician which monitors symptoms changes to ensure the safety of human participants) may inspect and/or copy your records for quality assurance, to ensure participant safety, or for compliance or data analysis purposes. The Cornell College Grants Compliance Officer will have access to your name and address to determine whether an IRS threshold of $600 in annual compensation for Cornell College is met; if so the money earned in the present study will have to be claimed as income and you will be contacted by the Compliance Officer to submit a W-9. The Compliance Officer will not know you participated in this experiment; the officer will only receive your name, address, and amount of money earned (the purpose of this payment will not be disclosed).

Data from the present study will be analyzed by student researchers and by the Principal Investigator. The resulting dataset will be analyzed and summarized in a publication intended to appear in a scientific journal. Again, your data will never be linked to you personally. This dataset will be archived in a password protected file for future analysis and publications by the Principal Investigator. The dataset may also be made available for analysis by outside researchers in the future if they make a formal request for the dataset and sign a confidentiality agreement not to distribute the dataset beyond their laboratory. The dataset will contain your experimental number and your data only; outside researchers will have no access to your personal information (i.e., your name, contact information, etc.). A copy of the dataset will also be posted on ClinicalTrials.gov so that other researchers and members of the public have access to this dataset. Again, your data will be included but not your name; your data will never be linked to you personally.

**I understand the manner in which my data will be protected in this study. Please initial the line below if you understand each component. If not, please ask your investigator to explain each risk further. Your investigator will not know what condition you are in (please do not reveal this to them), but they will be able to explain each condition in more detail (if needed).

_____

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during the study.

- For further information about the study contact: Dr. Melinda Green, 106E Law Hall, 895-4313, mgreen@cornellcollege.edu
- If you have any questions about the rights of research participants or research-related injury, please contact the Cornell College Institutional Review Board Chair, Dr. Misha Quill, mquill@cornellcollege.edu, 319-895-4482.

PARTICIPANT SIGNATURE

Your signature indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that the informed consent document has been read aloud to you, and that your questions have been satisfactorily answered. ***Please note if you are below age 18 that you must also have your parents sign this form indicating that they have read this document and they agree that you may voluntarily participate in this study. Their signature line appears below. Also, if you are below age 18, any atypical results flagged in the psychological, ECG/EKG, height/weight, or blood pressure assessment findings will be communicated to both you and your parents via e-mail and via phone. Results of all assessments will be communicated to you via e-mail after the final assessment.***

Signature (printed): _____

Signature (signed): _____ Date: _____

INVESTIGATOR STATEMENT

I certify that I have read this informed consent statement aloud to the participant, that the participant has been given adequate time to learn about the study, and that all of their questions have been answered. It is my opinion that the participant understands the purpose, risk, benefits, and procedures that will be followed in this study and has voluntarily agreed to participate.

Experimenter's Signature (printed): _____

Experimenter's Signature (signed): _____ Date: _____

SIGNATURE FOR CONSENT TO POST SOCIAL MEDIA MESSAGE (APPLICABLE FOR GROUP INTERVENTION CONDITIONS ONLY-THIS IS COMPLETELY VOLUNTARY AND IS NOT A REQUIRED PORTION OF THE PROGRAM)

I understand that one component of the intervention programs may entail posting a series of messages about the risks of pursuing the thin-ideal, the cultural objectification of women, and appearance-based social comparison among women on my social media account. I understand that I can choose to post these messages if I am comfortable but I am not required to post these messages. ***I understand that if I choose to post my messages on social media that these messages will be accessible to others on my social networking sites. I understand that if my accounts are not private and (depending upon the privacy policies of the site) that these materials can be accessed by any member of the public via the Internet. I understand this material can be viewed by others and my identity may be discoverable. I understand this information may also be saved by others in the public (this is always a risk of information posted on social media). In that regard, this information may remain accessible to others even after it is deleted from the site. I understand the risks of posting messages on social media and will consider these risks when I decide whether to voluntarily post social media messages as part of this clinical trial.***

Signature (printed): _____

Signature (signed): _____ Date: _____

If you are below age 18, you parents must complete the portion below. If you are not below age 18, this section is not required.

PARENT SIGNATURE

Your signature indicates that you voluntarily agree that your minor child (listed above) may voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read this document, and that you have contacted the investigators via phone or e-mail if you had any questions and that your questions (if applicable) were satisfactorily answered. Also, please note that ***any atypical results flagged in the psychological, blood pressure, or ECG assessment findings will be communicated directly to you via phone and e-mail. Results from all assessment sessions (if not atypical) will be communicated to your minor child via e-mail after the final assessment session.***

Parent's Signature (printed): _____

Parent's Signature (signed): _____ Date: _____

PARENT SIGNATURE FOR CONSENT TO POST SOCIAL MEDIA MESSAGES

If you are under 18, a parent's consent is also required to provide permission for you to voluntarily post messages on social media (if you choose to do so). Please have your parent read and sign the section below.

I understand that one component of the group intervention sessions will entail my minor child being presented with the voluntary option to post messages on social media regarding the risks of pursuing the thin-ideal and appearance-related pressures experienced by women. I understand that my minor child can choose to post these messages if she is comfortable but she is not required to post these messages. ***I understand that if my child chooses to post messages on social media that these messages will be accessible to others on these social networking sites. I understand that if my child's accounts are not private and depending upon the privacy policies of the site, that these materials can be accessed by any member of the public via the Internet. I understand this material can be viewed by others and my child's identity may be discoverable. I understand this information may also be saved by others in the public (this is always a risk of information posted on social media websites). In that regard, this information may remain accessible to others even after it is deleted from the site. I understand the risks of posting messages on social media and will consider these risks when I decide whether to allow my child to voluntarily post social media messages as part of this clinical trial.***

Parent's Signature (printed): _____

Parent's Signature (signed): _____ Date: _____

Primary Investigator Signature: _____ Date:_____