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Cornell College IRB-Approved Protocol

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Medical Monitor: Dr. Monica Meeker
Data Safety and Monitoring Board Members: Dr. Monica Meeker, Dr. Scott Eilers, Yunkyong Garrison

Study Protocol:

Participants: All participants will be treated in accordance with federal guidelines (Title 45, Code of Regulations Part 46) for the treatment of human participants. The sample will include female participants ages 15-34 (postmenarcheal and premenopausal) who are not pregnant. Participant selection was limited to this group to control for the effects of estrogen on cardiac function and in accordance with meta-analytic findings which suggest that a) dissonance-based programs are most effective when offered solely to females and that b) program effect sizes are greatest for females over the age of 15 (Stice & Shaw, 2004).

Our preliminary data indicate age did not significantly predict program efficacy at postintervention or 2-month follow-up in regression models; preliminary results suggest the program is effective when delivered to a group of women ages 14-34. Results provide support for conducting the proposed full scale trial with women of this age group (though the lower limit of this age range was adjusted up from 14 to 15 years, per the recommendation offered by Stice & Shaw, 2004). Consistent with the methodology of the preliminary trial, participants will not be excluded from the sample if they are seeking other eating disorder treatment or prevention services; this will be treated as a covariate in a secondary analysis to control for the effect of external treatment or external prevention services on trial outcomes.

Also consistent with the methodology of the preliminary trial, diagnostic level (clinical, subclinical) will be initially screened online via the Questionnaire for Eating Disorder Diagnoses (Q-EDD; Mintz, O'Halloran, Mulholland, & Schneider, 1997) with scoring criteria adapted for the Diagnostic and Statistical Manual of Mental Disorders 5th

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edition (DSM-5; American Psychiatric Association, 2013). Diagnostic status will be confirmed during the baseline assessment session via the Eating Disorder Examination Edition 16.0D (Fairburn, Cooper, O'Connor, 2008). Clinical status will be assigned for participants meeting DSM-5 diagnostic criteria for bulimia nervosa, anorexia nervosa, bulimia nervosa, binge eating disorder, or other specified feeding or eating disorder. Subclinical status will be assigned via recommendations offered by Mintz and colleagues (1997) for designating symptomatic (i.e., subclinical) eating disorder status (see Green et al., 2017; Green et al., in press for a description in the preliminary trial). Symptom status will be monitored by the Principal Investigator and the Laboratory Coordinator over the duration of the trial via symptoms reported on the EDE-Q at each assessment interval; participants with deteriorating symptoms will be given information regarding treatment resources. For minor participants, this information will be provided both to the minor participants and their parents or legal guardians.

Participants will be recruited via letters sent to inpatient and outpatient behavioral and medical treatment facilities in Eastern Iowa, via letters mailed to sororities at nearby universities, via flyers posted at local businesses and fitness centers in Eastern Iowa, via an advertisement posted on the social networking sites Instagram and Facebook, via advertisements posted in local newspapers, via advertisements posted on websites for the Academy for Eating Disorders and the National Eating Disorders Association, via fliers posted in area high schools, colleges, and universities, via announcements made on a local radio station, and via advertisements on radio and public transit, and via the e-mail listserv of a nearby large university. Intentional efforts will be made to increase the representation of ethnic minority women in the sample.

Procedure: Postings and mailings will advertise a study examining eating disorder treatment and prevention practices. All participants will be screened to ensure they meet inclusion criteria for the trial. Participants interested in completing a screening will contact the Principal Investigator or Laboratory Coordinator via e-mail to indicate interest. The Principal Investigator or Laboratory Coordinator will e-mail interested participants the informed consent statements for the screening and the full-scale trial and will provide a URL for the online screening survey (administered via Qualtrics). The online survey will again display the informed consent statement for the screening. Participants will be asked to electronically indicate their consent to participation before completing the screening. In the case of minors, parents will indicate their online consent and minors their online assent.

Once consent is secured, participants will complete an online demographic questionnaire which includes an assessment of participants' medical history, pregnancy status, and current medication status. Participants will also complete an online version of the Questionnaire for Eating Disorder Diagnoses (Q-EDD; Mintz, O'Halloran, Mulholland, & Schneider, 1997). This screening will take approximately 20 minutes to complete. At the end of the screening, an electronic debriefing will appear. Participants will be asked to provide their contact information so researchers can contact them if they meet the inclusion criteria for the full-scale trial. Screening participants will be

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entered into a drawing to win one of two $25 gift certificates to Amazon.com. Diagnostic status (clinical, subclinical, asymptomatic) will be determined according to the Q-EDD scoring criteria outlined by Mintz and colleagues (1997) with clinical criteria adapted for DSM-5 (American Psychiatric Association, 2013); clinical diagnostic status will be conformed via the EDE 16.0D (Cooper et al., 2008) administered at baseline.

All participants meeting the inclusion criteria for the full scale trial will be contacted via e-mail by the Principal Investigator or the Laboratory Coordinator. In this e-mail, each participant will be given an electronic version of the informed consent statement for the full scale study and will be asked to indicate e-mail consent. For minors, assent and parental consent will be required. If participants consent, the Principal Investigator or Laboratory Coordinator will schedule a research appointment and will verify the participant's home address. A copy of the full scale study informed consent statement, a map to the laboratory location, and pre-appointment instructions will be mailed to the participant's home approximately one week before the scheduled research appointment. Finally, an e-mail reminder will be sent by the Laboratory Coordinator one day before the scheduled research appointment.

Participants will be randomly assigned to the expanded dissonance-based condition, the traditional *Body Project* condition, or to an educational brochure control condition. The experimenter will be blind to their condition. Participants in all conditions will complete on-line assessments of body dissatisfaction, self-esteem, self-objectification, thin-ideal internalization, maladaptive social comparison, trait anxiety, and eating disorder symptoms at baseline, postintervention, and 2-month follow-up (see the list of specific measures below). Participants will come to the laboratory at each assessment period to have their height, weight, and cardiovascular function assessed.

Participants will be instructed to avoid food, coffee, and nicotine for 3 hours prior to each laboratory appointment (see Low, 2003). Participants will be instructed to abstain from vigorous physical exercise for 24 hours prior to their appointment and will show no signs of acute physical illness for 48 hours prior to their appointment. If signs of acute physical illness develop, participants will be instructed to contact the Laboratory Coordinator to reschedule the appointment.

Upon entry into the laboratory, an experimenter will greet the participants and will read the informed consent statement aloud. The participant will be given an opportunity to ask questions. If the participant provides consent, the laboratory protocol will begin. Minors will provide assent and parental or legal guardian consent.

Participants will be placed in a supine posture for a 10-minute equilibration period; a blood pressure cuff with a heart rate monitor will be secured to the left arm. Blood pressure and heart rate indices will be checked at two 5-minute intervals to assess cardiac equilibration. Participants will be prepared for electrocardiography (ECG) during this equilibration period. 3 self-adhesive electrodes will be secured using a lead II chest configuration; ECG lead wires will be attached and a sample (~5-second) ECG recording will be obtained to check signal quality. Immediately after the 10-minute equilibration period, participants will be instructed to remain silent in a resting supine

posture while a 5-minute and 30-second ECG recording is conducted. Next participants' height and weight will be assessed in the laboratory. At the conclusion of each assessment session, participants will be compensated via a $40 online Amazon gift card in exchange for their participation. They will be debriefed after the final assessment session and will receive an assessment report containing the assessment data from each of their 3 assessment sessions.

After the baseline session, participants in the expanded dissonance-based condition will complete an altered version of the *Body Project*, adapted for the present trial to address maladaptive social comparison and objectification. Participants in the traditional *Body Project* condition will complete the standard program as specified by Stice and colleagues (2001). Participants in the enhanced and traditional conditions will meet in four 60-minute group sessions, once per week, for one month. Homework will be assigned between group sessions and during the 2-month follow-up assessment period. Group sessions will be facilitated by the Principal Investigator, the Laboratory Coordinator, or one advanced graduate student in a Clinical Psychology program at a large Midwestern university and a Cornell College undergraduate student.

Session content in the expanded condition will be identical to the traditional *Body Project* prevention program with the following exceptions: 1) the concept, origins, and consequences of cultural objectification will be introduced and discussed alongside the thin-ideal during the first session; 2) a thought record exercise designed to monitor and reframe appearance-based maladaptive upward social comparison will be added to session one homework; 3) behavioral exercises designed to decrease the frequency of trait self-objectification and maladaptive social comparison will be added to session three; 4) a behavioral exercise designed to increase understanding of the consequences of the cultural objectification of women and trait self-objectification will be added to session four; and 5) homework designed to decrease the frequency of maladaptive social comparison will be added to the final homework exercise. Across both dissonance conditions, participants will be compensated $40 in Amazon gift cards for each program session, $10 in Amazon gift cards for each set of homework activities between sessions, and $40 for the final homework conducted over the 2-month follow-up period.

Participants in the educational brochure control condition will receive a 2-page handout from the National Eating Disorder Association which describes negative and positive body image, delineates the relationship between negative body image and disordered eating, and offers strategies for improving body image. This educational brochure control condition was used by Stice and colleagues (2014) in the evaluation of the efficacy of a dissonance-based prevention program.

Measures:

Questionnaire for Eating Disorder Diagnoses (Q-EDD). The Questionnaire for Eating Disorder Diagnoses (Q-EDD: Mintz et al., 1997) was used to determine diagnostic status. The Q-EDD is a self-report questionnaire used to assess level of eating disorder symptomatology. The Q-EDD operationalizes diagnostic criteria for eating disorder diagnoses according to the *Diagnostic and Statistical Manual of Mental Disorders, 4th*

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edition, Text Revision (DSM-IV-TR; American Psychiatric Association, 2000). Q-EDD scoring criteria will be adapted in the proposed trial to fit criteria specified by the *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition* (DSM-5; American Psychiatric Association, 2013). The Q-EDD has good convergent validity when compared to the Revised Bulimia Test (BULIT-R; Thelen, Farmer, Wonderlich, & Smith, 1991) and the Eating Attitudes Test (EAT; Garner & Garfinkel, 1979) in undergraduate and community samples.

Rosenberg Self-Esteem Scale (RSE). The Rosenberg Self-Esteem Scale (RSE: Rosenberg, 1965) is a widely used measure designed to assess global feelings of self-worth and self-esteem. Originally designed as a Guttman scale, the RSE is now conceptualized and scored as a Likert scale. The RSE includes 10 items (e.g. "I feel that I'm a person of worth) rated on a four-point scale (1 = *strongly disagree*, 4 = *strongly agree*). Higher scores indicate higher levels of self-esteem. The RSE has high test-retest reliability, typically ranging from .82 to .88 depending upon the sample (Blascovich & Tomaka, 1993). Coefficient alphas range from .73 to .85 (Corning, Krumm & Smitham, 2006; Hawkins, Richards, Granley & Stein, 2004).

Eating Disorder Examination (EDE-Q 16.0D) & Eating Disorder Examination Questionnaire (EDE-Q). The Eating Disorder Examination-Questionnaire 16.0D is the gold standard semi-structured diagnostic interview for evaluating eating disorder symptoms, adapted from the original Eating Disorder Examination (EDE: Cooper, Cooper, & Fairburn, 1989). The EDE will be used to confirm diagnostic level for participants with clinical symptoms. The EDE-Q shows high convergent validity with EDE subscales (Mond, Hay, Rogers, Owen, & Beumont, 2004); it will be used to evaluate level of eating disorder symptoms at each assessment.

Body Shape Questionnaire (BSQ). The Body Shape Questionnaire (BSQ: Cooper, Taylor, Cooper, & Fairburn, 1986) is a 34-item measure designed to assess body dissatisfaction. Items are measured on a 6-point Likert scale designed to measure the frequency of negative body-related thoughts (1= *never*, 6 = *always*). Higher scores indicate higher frequency of negative body-related thoughts and higher levels of body dissatisfaction. The BSQ shows strong test-retest reliability and good convergent validity when compared with other measures of body dissatisfaction in clinical and nonclinical college and community samples (Rosen, Jones, Ramirez, & Waxman, 1996).

Social Comparison Rating Scale (SCRS). The Social Comparison Rating Scale (SCRS: Allan & Gilbert, 1995) is an 11-item scale designed to assess perception of social rank. The scale consists of a series of bipolar adjectives (e.g., inferior/superior) separated by the numbers 1 through 10. For each adjective pair, participants are asked to rank themselves in comparison to others. A score around 60 indicates a person, on average, sees themselves approximately equal to others. Higher scores indicate higher levels of favorable social comparison and higher perceived social rank. Test-retest reliability of the 11-item scale is high (Cronbach's α = .88).

Self-Objectification Questionnaire (SOQ). The Self-Objectification Questionnaire (SOQ: Fredrickson et al., 1998) was used to assess trait self-objectification. The SOQ is a

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10-item self-report inventory designed to assess the relative importance of body competence versus body appearance in physical self-concept (Fredrickson et al., 1998). Participants are asked to rank 5 appearance-based attributes (e.g., physical attractiveness) and 5 competence-based attributes (e.g., physical coordination) in order of their impact on physical self-concept. Attributes are ranked from 0 to 9 with higher scores representing higher importance. An overall trait self-objectification score is computed by summing competence and appearance ratings and subtracting the sum of competence ratings from the sum of appearance ratings. Resulting scores range from -25 to 25. Higher scores denote higher levels of trait self-objectification. According to Noll & Fredrickson (1998), the Self-Objectification Questionnaire displays acceptable convergent validity when compared to the Body Image Assessment (Williamson, Davis, Bennett, Goreczny, & Gleaves, 1985) and the Appearance Anxiety Questionnaire (Dion, Dion, & Keelan, 1990) in a college student sample. The measure also demonstrates acceptable internal consistency (α = .80) in a college student sample (Hebl, King, & Lin, 2004).

Ideal Body Stereotype Scale – Revised. The Ideal Body Stereotype Scale - Revised (IBSS-R: Stice, 2001) was used to assess the extent to which participants internalized the cultural feminine thin-ideal. The IBSS-R is a self-report inventory which asks participants to report their level of agreement with 6 statements which indicate what attractive women look like on a 5-point scale ranging from *strongly disagree* (1) to *strongly agree* (5). Responses are averaged to compute a total score. Higher scores indicate higher levels of thin-ideal internalization. The scale demonstrates acceptable internal consistency (α = .83-.89) and discriminant, convergent, and predictive validity in college student samples (see Stice, 2001).

State Trait Anxiety Inventory – Form Y. The State Trait Anxiety Inventory- Form Y (STAI: Spielberger, Gorsuch, & Lushene, 1970) is a 20-item self-report measure designed to assess level of trait anxiety. Each item consists of a statement which assesses feelings of anxiety or relaxation on a 4-point scale ranging from 1 (*not at all*) to 4 (*very much so*). Scores range from 20 to 80. Higher scores indicate higher levels of anxiety. The STAI demonstrates high internal consistency in college student samples, as well as strong reliability and validity indices (see Spielberger, 1983).

Body Mass Index: Body mass index (BMI) will be calculated based on height and weight data [weight (kg)/height (m^2)] (see Garrow & Webster, 1985).

Cardiac Indices: The ECG signal will be acquired via PowerLab 16/35 psychophysiological data acquisition system with a sampling rate of 1000 Hz. Hardware setup will include an ECG100C amplifier with a 35Hz LPN filter and a .5Hz HP filter. HRV data and ECG data will be analyzed via PowerLab LabChart 8 software.

Data and Human Protections:

Human Participant Training: All members of the research team will review the Cornell College IRB handbook available at https://www.cornellcollege.edu/irb/files/Handbook%202018.pdf. Please note the NIH

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human subjects training was no longer available as of September 26th, 2018 but all members of the current team completed this training prior to its removal. All members of the team signed Cornell College confidentiality assurance forms available at https://www.cornellcollege.edu/irb/files/WebConfAssur2018.pdf.

All records will be kept confidential and participants' records will not be made publicly available. Participants in all conditions will be assigned an experimental number which will appear on all study materials. There will be a separate master file which links experimental numbers to participant names. Only research team members will have access to this data file. All data will be kept in a locked laboratory location. On-line data will be downloaded to a password-protected electronic file. Data from the present study will be analyzed by the research team. The resulting dataset will be analyzed and summarized in a publication intended to appear in a scientific journal. This dataset will be archived in a password protected file for future analysis and publications by the Principal Investigator. The dataset without participants' names or identifiers will be available on ClinicalTrials.gov and will be submitted to journals alongside published articles for interested readers to access on journal websites. It may also be requested for re-analysis by interested persons reading the relevant research articles. Again, the data will contain no identifying information.

Protection of sensitive data collected online. An online data acquisition platform (Qualtrics) will be used for the collection of all screening and assessment data. Qualtrics uses TLS encryption for all transmitted data and participants will be sent password protected survey links (a function available in Qualtrics). The Qualtrics security statement is available at https://www.qualtrics.com/security-statement/. Only laboratory members have access to the Qualtrics login information for the laboratory.

Qualtrics data is downloaded to the Cornell College server to a password protected shared drive that only laboratory members have access to. The Cornell College also has a high-end firewall systems and the IT staff regularly assesses and ameliorates vulnerabilities to the secure server. Cornell College retains a certified secure 3rd party storage and disaster recovery site roughly 25 miles from our campus, to store our retained data and nightly/weekly backups. All student data and financial records/data are encrypted and transferred through secure, encrypted connections. All administrative system user and administrator logins and passwords are stored in a centralized, encrypted password vault.

At the start of a relationship with the College and annually thereafter, every College employee, student, and contracted worker is required to read a statement of responsibility for the security and confidentiality of data and data networks and agree to the following conditions: Keep personal passwords private. Assume responsibility and be held accountable for all data modifications made using his/her ID and password. Not allow unauthorized use of any information in files or databases. Not provide or permit access to College data infrastructure or networks by any unauthorized individuals. Not seek personal benefit or permit others to benefit personally through the use of any confidential information which has come to him/her through his/her work assignment.

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Not exhibit or divulge the contents of any record or report to any person except in the conduct of his/her regular work assignment. Not aid, abet, or act in conspiracy with any person to violate any part of the statement of responsibility.

Assessment of Medical Risks and Appropriateness for Outpatient Treatment:
Medical risk will be assessed at baseline, post, and follow-up. The medical monitor will be responsible for monitoring eating disorder risk status, cardiac risk, and BMI at each assessment session and will work with the Laboratory Coordinator and the PI to communicate this information to participants who have indicators of medical risk or worsening symptoms. In the case of minor participants, this information will also be communicated to parents directly. This will be done both via a written letter and a phone call from the study staff.

All ECG strips which deviate from typical human physiological function be reviewed by the medical monitor and the medical monitor will sign off on any referral letters. Participants with atypical ECG findings will receive a copy of their ECG strip and will be referred to their primary care physician to determine if additional testing or intervention is needed.

Participants in the high medical risk category will also be given a list of local mental health providers specializing in eating disorder treatment and will be referred to a mental health care specialist for additional eating disorder assessment and treatment planning. If the trial does not interfere with other treatment services recommended by the primary care physician and mental health care specialist, then the participant will remain eligible for the trial.

Assessment of Medical Risks at Baseline: With regard to the assessment of medical risk at baseline, research indicates eating disorder patients with body mass indices (BMI) < 18 are at a significantly greater risk for negative physical outcomes, most notably disorder-related cardiac risks (see Fairburn, 2008; Swenne & Larsson, 1999). Patients with low BMIs (regardless of electrolyte status) are significantly more likely to show QTc interval prolongation and dispersion, indicators of increased risk for sudden cardiac arrhythmia and death (Swenne & Larsson, 1999). Participants meeting this low weight criterion (BMI < 18) or with QTc interval duration of >500msec (Swenne & Larsson, 1999) will be considered to have an initial high risk symptom presentation and will be referred to their primary care physician for a medical assessment prior to beginning the trial.

According to American Psychiatric Association level of care guidelines for patients with eating disorders (Yager et al., 2006), patients are considered at to be at a medically high risk (and in potential need of inpatient care) if they demonstrate a HR < 40 bpm or BP < 90/60. Participants meeting one or both of these criteria will be similarly referred to a primary care physician for a medical assessment prior to beginning the trial.

According to American Psychiatric Association guidelines (Yager et al., 2006), patients are also at high medical risk (and in potential need of inpatient care) if they are unable to control multiple daily episodes of purging that are severe, persistent, and

disabling. In line with these recommendations, patients demonstrating multiple daily episodes of self-induced vomiting, daily laxative abuse, daily diuretic, or > 3 episodes of 24-hour fasts per week in the past 28 days as assessed by the Q-EDD (Mintz et al., 1997) will be considered to be at medically high risk and will be referred to their primary care physician for a medical assessment prior to beginning the trial.

Assessment of Medical Risks Throughout the Trial: Eating disorder symptom severity, BMI, and cardiac risk indices will be assessed at baseline, postintervention (4-6 weeks after the baseline assessment), and 2-month follow-up. Tracking eating disorder symptom status, BMI, and cardiac function at the 3 assessment periods will allow for the careful monitoring of symptom deterioration over the duration of the trial.

Eating disorder symptom severity will be assessed by the global scale of the Eating Disorder Examination – Questionnaire (Fairburn et al., 2014) and via the Questionnaire for Eating Disorder Diagnoses (Mintz et al., 1997), both reliable and valid indicators of eating disorder pathology. The same medical risk criteria outlined in the "Assessment of Medical Risks at Baseline" section above will be applied throughout the trial. Increased frequency of binge and purge behaviors as indicated on the Q-EDD (Mintz et al., 1997) and the EDE-Q (Fairburn et al., 2014) will be evaluated in conjunction with BMI and cardiac risk indices (QTc interval length > 500 msec, mean R wave amplitude < .5 mV) by the medical monitor to determine medical risk and need for referral. Participants demonstrating deterioration on these indices across assessment periods will be referred by the medical monitor to their primary care physicians for medical assessment and to local mental health providers specializing in eating disorder treatment.

Group Intervention: Confidentiality Risks. Participants will be notified in the informed consent document that the trial incorporates a group intervention, that there is a chance they may know others enrolled in the group, and that group interventions pose inherent risks for confidentiality since others in the group will know their identities. Participants will be asked to check a series of boxes on the informed consent documents which indicate they acknowledge these unique risks. In an attempt to reduce the risk that confidential information discussed during the group intervention will be shared outside of the group, each participant will be asked to sign a confidentiality agreement in which they promise to keep the identity of other groups members private and not to discuss group content outside of the group context. We believe this approach will inform participants of the unique confidentiality concerns associated with group interventions and will discourage sharing of confidential group data outside of the group context.

Qualifications and Supervision of Group Facilitators: Graduate facilitators will be second to fourth year doctoral students from nearby PhD programs in Clinical and Counseling Psychology who have previous practicum experience with the administration of group interventions and preferably experience with the administration of eating disorder interventions. Graduate facilitators will have taken at least one course in counseling theories and techniques and had at least 1 practicum experience in an applied mental

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health setting. Undergraduate facilitators will be required to have completed one counseling and psychotherapy course and to be an ongoing member of the student-faculty research team with previous team-based training in dissonance-based eating disorder interventions.

All facilitators will undergo facilitator training during which they learn to administer the intervention programs. During the training, facilitators will practice all components of the intervention protocol and will review safety guidelines and procedures for adverse group events (including if a participant experiences an adverse health event during a group intervention session or if a group member expresses ideas of self-harm during a group intervention session).

During group intervention sessions, the Laboratory Coordinator will be present in the building and the Principal Investigator will be on call. If a group member expresses ideas of self-harm, facilitators will inform the participant they would like to explore the issue more fully following the conclusion of the group session. The facilitators will notify the Laboratory Coordinator who will promptly call the PI. The PI and Laboratory Coordinator will then meet with the participant immediately after the group session to conduct a thorough suicide assessment and to determine the appropriate level of care. The PI will then facilitate needed referrals. If it is clear the participant is at imminent risk for self-harm, the PI will offer to transport the participant voluntarily to the emergency department of a local hospital for a psychiatric assessment. If the participant is at imminent risk for self-harm but refuses voluntary transport, campus safety and local law enforcement will be contacted and the imminent risk for self-harm explained. If the PI is unable to be on-call for a given session, the PI will recruit another licensed psychologist who is familiar with the intervention paradigms to be on-call in her absence.

All intervention sessions will be rated for fidelity and compliance in order to provide supervision on the protocol. Formal rating forms will be completed by trained raters in order to provide feedback on the fidelity and compliance.

Data Safety and Monitoring: Despite overall low risk to participants in the trial, we will be instituting a fully independent DSMB to maximally ensure patient safety. The DSMB will operate in compliance with NIH Policy for Data and Safety Monitoring (1998) as specified at https://grants.nih.gov/grants/guide/notice-files/not98-084.html. We will be recruiting DSMB members who meet the NIH guidelines, and will include least one eating disorders expert and one biostatistician. One DSMB member will be a physician who will also serve as the study's medical monitor (see "Assessment of Medical Risks" section below for additional details about this role).

Serious Adverse Events (SAE) will be identified, monitored, and reported throughout the study in accordance with the NIH Reportable Events Policy (April 16, 2015) as specified at https://www.nimh.nih.gov/funding/clinical-research/nimh-reportable-events-policy.shtml.

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Active or Passive Deception: This protocol involves no active or passive deception.

Inherent 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 a participant experience a negative psychological reaction to the study, they will be asked to contact the Principal Investigator for further direction on services available to them in the area. Participants will also be given contact information for the IRB Chair. If a participant experiences an unexpected negative psychological reaction to the study that does not remit, a list of mental health service agencies in the area are listed out in the Informed Consent document. If atypical results appear in a participants' ECG results, the Primary Investigator (Dr. Melinda Green) will send the relevant data to the medical monitor who will then make a recommendation on whether or not participants should receive an atypical results letter and phone call.

Benefits and Compensation: The present study may be a direct therapeutic benefit to the participant if they are in the traditional or the expanded Body Project intervention conditions. Previous findings indicate participants in a similar intervention programs experienced lower symptoms of disordered eating and associated risk factors. However, there may be variability with regard to outcomes and all participants may not experience this reduction. Data from this trial will help to increase scientific knowledge regarding the effectiveness of eating disorder treatment and prevention programs.

As compensation for the participants' time and transportation expenses participants will receive Amazon gift cards. Each participant will receive $120 in exchange for their participation in the 3 evaluation sessions (3 sessions x $40 per session = $120). If the participant is assigned to either the traditional Body Project or the expanded Body Project interventions, they will receive an extra $40 for each intervention attended (4 sessions x $40 = $160). Participants in these conditions will also receive an extra $30 ($10 each sessions) for completing homework for sessions 2-4) and and $40 for the final homework assigned over the 2-month follow-up period ($350 total for participants in the traditional and expanded Body Project intervention conditions: $120 assessments, $160 intervention program, $70 homework). Participants in the educational brochure condition will not receive compensation for reading the educational brochure but will receive $120 in compensation for attending the 3 assessment sessions.

Inclusion of Special Populations: Adolescent women between the ages of 15 and 17 will be admitted into the study since eating disorders commonly onset during the adolescent period. Based on our recruitment strategy (a portion of which occurs in area high schools and clinics which serve adolescents), and statistics from our previous samples which used the same recruitment strategy, we anticipate approximately 10-20% of our sample will be comprised of women in the 15-17 age range. We chose to include women in this age range based on the fact that eating disorder symptoms commonly onset

during this age and earlier treatment and prevention interventions are critical to positive outcomes. By excluding this population, we would be limiting prevention and treatment research essential for this group.

That said, we are very mindful that the inclusion of adolescents in this research requires extra protections for this population. As delineated in our human participants section, minor assent and parental/legal guardian consent is required for inclusion in this trial. In addition, any assessments outcomes which indicate symptom deterioration or atypical results in ECG findings will be communicated to both minor participants and parents/legal guardians. Any necessary treatment referrals will also be communicated to both parties by the PI or the Laboratory Coordinator. In addition, any adverse reactions to the trial (assessed at all assessment intervals) reported by an adolescent in the study will result in the PI or the Laboratory Coordinating contacting both the minor participant and the parents/legal guardian to discuss the adverse reaction and to provide appropriate treatment referrals and follow-up resources.

In recognition of the important of protecting children in research, our IRB follows the relevant federal guidelines (see below). With regard to the proposed trial, written parental consent is required for all participants under age 18 and written assent is required by the child. The IRB has determined that parents are to be made aware that they have the right to have complete access to their child's assessment results if they are requested. The minor child is made aware of this parental right as well as part of the informed consent statement.

§46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the

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permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

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INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

May 8, 2018

IRB—Determination for Proposal # 1516-105-GRE

Dear Prof. Green, this letter is in response to your request for changes to the IRB approved project (#1516-105-GRE) *Efficacy Trial of a Dissonance Based Eating Disorder Program* at Cornell College. The IRB has reviewed the modifications to your previously approved study and approved the renewal with the stated modifications. You may begin your data collection using the methods approved in this proposal for one year from this date (May 8, 2018). In addition, please have any students working on the project fill out the Confidentiality Assurance before they begin collecting data and send an electronic version to the IRB chair for his file on the project.

If you wish to collect additional data after this date, and there is no change to the project as described in the original proposal you may receive expedited review. If there are changes please, consult with the chair of the IRB before submitting a new proposal for an initial determination of the review category that is most appropriate. If the change is deemed substantial, a separate proposal must be submitted for review.

Please remember that you are obligated to *promptly* report any unanticipated problems or adverse effects of the research to the Institutional Review Board. The IRB must be notified if adverse events occur and what actions the investigator has taken to respond.

Changes in the procedures of collecting data from human subjects must be re-reviewed and approved by the IRB.

The IRB requires you to keep all documentation, particularly Informed Consent Forms, for three years following the termination of the project.

Please contact wdragon@cornellcollege.edu if you have questions.

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