STUDY TITLE:

Testing Intervention Strategies for Addressing Obesity and Binge Eating

PRINCIPAL INVESTIGATOR:

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Indicate Vulnerable Population(s) to be Enrolled	☒ Children ☐ Cognitively Impaired Adults ☐ Pregnant Women (IF the research activities will affect the pregnancy or the fetus) ☐ Prisoners (or other detained/paroled individuals)
International Research (check this box if you will collect data from individuals located outside the United States)	☐
Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates)	☐
Research has U.S. Federal government funding (e.g., NIH, NSF, other federal agencies/departments)	☒

1.0 Purpose of the study:

The purpose of this study is to design a mobile intervention that targets obesity and binge eating. Two studies will be conducted with adults with obesity (BMI ≥30) and recurrent binge eating (≥12 binge episodes in the past 3 months). The first study will employ a user-centered design approach to design a 16-session guided self-help, mobile intervention and conduct usability testing to inform intervention refinements prior to a pilot trial. The second study will involve a randomized pilot trial that will determine the feasibility of delivering the intervention protocol and generate preliminary data on the effect of the intervention on changes in weight and binge eating at 16 weeks (post-intervention) and 3 months post-intervention (follow-up). Additional design sessions (as part of Study 1) will be conducted with adolescents (ages 13-17 years) with elevated weight status (BMI≥75th percentile for age and sex) and who endorse loss of control eating or overeating (≥3 loss of control and/or overeating episodes in the past 3 months). The specific aims and hypotheses of this research are to:

Aim 1: Employ a user-centered design approach to design a mobile intervention that targets obesity and binge eating and conduct usability testing to inform intervention refinements prior to the pilot trial.
Hypothesis 1: Quantitative and qualitative data from usability testing will inform intervention refinements prior to the pilot.

Aim 2: Conduct a randomized pilot trial of the mobile intervention that targets obesity and binge eating, using a 2^3 full factorial design, to (2a) determine the feasibility of delivering the intervention, and (2b) derive estimates of the effect of 3 intervention components on changes in weight and binge eating at post-intervention and follow-up to inform a future R01 trial.
Hypothesis 2: Feasibility will be based on study recruitment and retention rates, acceptability, retention to treatment, and compliance documenting prescribed strategies. Effect sizes estimates will be used to power a R01 trial.

Exploratory Aim 3: Explore if intervention components interact to change weight and binge eating at post-intervention and follow-up.
Hypothesis 3: The factorial design will enable me to test if the effect of a component is moderated by another component, to ensure the optimized intervention retains components that directly or indirectly impact outcomes.

Background / Literature Review / Rationale for the study:

Obesity affects one third of US adults.[1] Obesity is associated with medical and psychosocial morbidities, impaired quality of life, increased mortality, and high health care costs.[2-8] Up to 30% of treatment-seeking adults with obesity engage in binge eating,[9-11] an eating disorder behavior characterized by eating a large

amount of food and experiencing loss of control.[12] More than 75% of people with recurrent binge eating also have overweight or obesity.[13] First-line interventions are face-to-face treatments for obesity or binge eating,[14-16] but face-to-face treatment cannot reach all people in need.[17-19]
A novel solution to tackle comorbid obesity and binge eating entails designing a new intervention and delivery approach. First, an intervention needs to target both weight and binge eating. No existing behavioral weight loss (BWL) or psychological treatment resolves both conditions,[20-23] likely because these treatments fail to address factors that drive both weight change and binge eating. Second, an intervention needs to be efficient yet potent. Retention rates show patients drop out of psychological treatment when weight loss is a focus only after binge eating resolves.[23] Identifying the "active ingredients" of psychological treatments that reduce binge eating in the context of BWL will help to optimize an intervention for efficiency while preserving its potency. Third, an intervention needs to be scalable to large populations of users. In contrast to face-to-face treatment, mobile interventions hold promise for increasing access to care,[17-19] and have efficacy for reducing weight[24,25] or binge eating.[26-29]

The mobile intervention will target dietary intake and physical activity, which impact weight. These are key targets of BWL interventions.[30,31] Three additional targets—which are the intervention component "ingredients" under investigation in this study—are key treatment targets to address binge eating in psychological interventions, but are not components of BWL. *Overvaluation of weight and shape* refers to concerns about weight or appearance, which can result in excess attention to weight/shape relative to other areas of one's life. For cognitive-behavioral therapy (CBT), this is the core psychopathology of eating disorders,[32] and it is associated with increased impairment among those with binge eating.[33,34] Weight/shape concerns can be exacerbated by weight gain, lead to unhealthy weight control practices and binge eating, and increase negative affect. *Unhealthy weight control practices* are behaviors that occur in response to weight/shape concerns, such as restrictive dieting, eliminating particular foods, or skipping meals. These behaviors can increase binge eating through dysregulated appetite and elevated hunger, drive negative affect, and lead to inappropriate and unsuccessful attempts to lose weight. This construct is a core target in CBT.[32] *Negative affect* is characterized by low mood/depression or emotional distress, and mediates the relation between interpersonal problems and binge eating.[35-37] Negative affect also can affect dietary intake and physical activity. No study has (a) tested an intervention that targets all three components within BWL, or (b) determined which components are the active ingredients for improving weight and binge eating.

2.0 Enrollment Criteria:

Participants will be non-pregnant, English-speaking adults age ≥18 years with obesity (BMI ≥30) and recurrent binge eating (≥12 episodes in the past 3

months). Adolescent participants (ages 13-17 years) will have elevated weight status (defined as BMI≥75th percentile for age and sex) and endorse ≥3 loss of control eating and/or overeating episodes in the past 3 months. Individuals will be eligible if they indicate they want to lose weight, are willing to use a mobile application ("app"), and have a Smartphone with Internet access and capacity for calls and text messaging. Participants enrolled after July 2020 will be required to have a valid e-mail address so they can receive study information and complete any relevant study procedures (e.g., consent form, REDCap link with questionnaires). Teens will only need to endorse willingness to use an app so as to reflect future app intervention users. Participants enrolled in the Study 2 randomized pilot trial will be required to have access to a scale for weight verification purposes (i.e., to take a photo and upload it into REDCap survey). Participants in Study 2 will be excluded if they self-report a diagnosis for which the study/intervention is not clinically indicated (e.g., schizophrenia/psychotic use disorders, bipolar disorder/manic depression/mania, dissociative disorder, dementia or cognitive impairment), are currently working with a clinical professional to receive services for management of weight or binge eating, or started or recently changed dosage for a medication for weight loss or binge eating.

To mimic Study 1 design activities that occur in person, any remote design and usability testing sessions, including field trial assessments, among adults will require participants reside in the Chicagoland area, confirmed based on the first three digits of their zip code.

For the Study 2 randomized pilot trial, participants will not be required to live in the Chicagoland area, but will be required to have a valid five-digit zip code.

3.0 Sample Size:

In total, up to 122 participants will be included.

Study 1 All Activities: 25 participants will complete a needs assessment, up to 10 participants will complete design and usability testing sessions, and up to 5 participants will complete the field trial. Up to 10 adolescents will invited to complete design sessions.

Study 2 Randomized Pilot Trial: Up to 96 participants will be enrolled into the trial. The pilot trial was not powered for hypothesis testing, as the goal of the pilot is to inform a R01 trial of an optimized intervention. This goal will be achieved by evaluating feasibility and generating effect sizes of each component on changes in outcomes.[39-41] The effect sizes will inform which components to retain in the optimized intervention and be used to power a subsequent trial. However, a power calculation was run to determine the effect size this pilot trial will be powered to detect. Using intent-to-treat analyses with n=36/group for tests of each component (Aim 2b), assuming 80% power, 5%

alpha, and a two-sided test, there is power to detect main effects of d=0.67. This effect is in the range of past trials of digital BWL and CBT.[26-29,42-47] It is acknowledged that this is a large effect; however, because the primary purpose of this research is for training and to collect pilot data, increasing the sample size could decrease feasibility and threaten these two goals. As such, a smaller N to maintain appropriate scope was prioritized.

4.0 Recruitment and Screening Methods:

Recruitment Methods, Study 1 Needs Assessment: Participants will be recruited from potentially eligible individuals who have consented on dscout to complete screens and be considered for qualitative research projects (i.e., "missions").

Recruitment Methods, Study 1 Design & Usability Testing (including the Field Trial) and Study 2 Randomized Pilot Trial: Participants will be recruited from clinics at Northwestern University (e.g., Center for Lifestyle Medicine) and the University of Chicago (e.g., Eating Disorders Program, Center for Surgical Treatment of Obesity) and the community via flyers, media (including online social media such as Facebook, Instagram, Reddit, and Craigslist), newsletters, referrals, and word of mouth. We also will recruit participants using ResearchMatch and The New Normal, which are free participant recruitment online platforms that are accessible to researchers at participating institutions including Northwestern University, and Northwestern's StudyTracker. Across all recruitment method platforms, information/study advertising content will remain consistent with IRB-approved recruitment language.

Screening Methods, Study 1 Needs Assessment: For the Study 1 needs assessment, screening will involve recruiting and consenting individuals, and inviting interested individuals who consented to complete a screener via an application. The application includes open-ended questions, multiple choice questions, and uploading a 30-second video describing the impact that binge eating and weight has on their lives. The multiple choice questions assess for eligibility criteria, information about the impact of weight and binge eating, and demographic information.

Screening Methods, Study 1 Design & Usability Testing (including the Field Trial): A research assistant will conduct a telephone screen with interested participants to determine their eligibility for participation. The telephone screen will be conducted using a work telephone or CiscoJabber, a 3rd party vendor contracted through Northwestern that is accessible to Northwestern staff and faculty (with NU credentials) and allows them to make phone calls that appear as their work phone number. Interested individuals will be asked to complete a verbal consent form prior to completing the telephone screen. A copy of the verbal consent form will be emailed to participants (who have a working email address) prior to (when possible), during, or following

the telephone screener. For adolescent participants, verbal assent and parental consent will be obtained prior to completing the telephone screen. This will occur at the start of the call prior to conducting the telephone screen, or will be done on a separate call beforehand as needed for scheduling purposes between parent and teen.

The screener will include questions about contact information (i.e., email, phone), personal information (i.e., age, gender, race, ethnicity, height, weight), episodes of binge eating or overeating (as relevant), and other relevant questions pertaining to the particular study activities (e.g., availability for participation). During any remote procedures, adult participants will also be asked to provide their zip code (i.e., to confirm whether they reside in the Chicagoland area).

Participants' responses to the telephone screen will be directly entered into the Research Electronic Data Capture program (REDCap) by an approved research team member. Individuals who are not eligible will be offered referral information for treatment. Of those eligible, participants will be selected with a range of backgrounds to ensure a diverse and representative sample of target users.

Screening Methods, Study 2 Randomized Pilot Trial: Interested individuals will complete an online screener survey administered via REDCap survey to assess for potential eligibility.

The online screener will include questions about the individual's contact information, demographics, smartphone and email ownership, access to a scale for weight verification purposes, current treatment utilization, and availability to participate in study activities. Interested individuals will be asked to self-report their height, weight, and episodes of binge eating over the past 3 months. Participants' responses to the online screener will be captured in REDCap.

Potentially eligible individuals will then be invited to complete a baseline assessment to confirm study eligibility. The assessment will include an interview and surveys. This assessment will occur in person or via videoconference call (Zoom). For the interview, a trained assessor will administer a semi-structured interview to assess for the number of binge episodes over the past 28 days and other eating disorder pathology. More detailed information about the screening consent process can be found in Section 11.

Ineligible individuals who provide a working email address will be offered referral information for treatment.

5.0 Research Locations:

The Study 1 needs assessment will be conducted using the secure dscout platform.

For all other study 1 and study 2 activities, research procedures will occur at the Center for Behavioral Intervention Technologies (CBITs) lab space at Northwestern University. CBITs has private offices (for research assessments) and a usability lab (for usability testing). However, during any remote work requirements, study activities will be conducted by video call via Zoom (a videoconferencing software that is accessible to Northwestern University faculty and staff using their NU credentials) and/or by telephone or an internet-based phone service (e.g., Zoom, Google Hangouts/Voice, CiscoJabber). Participants and research team members will have the option to conduct any study activities remotely or in-person.

6.0 Multi-site Research (research that involves external collaborating institutions and individuals):

NA

7.0 International Research (where data collection will occur outside the United States and U.S. territories)

NA

8.0 Procedures Involved:

Please check the boxes for all applicable data collection procedures you plan to use:

☒One-on-one interviews

☒Focus Groups

☒Questionnaires/surveys

☐Analysis of secondary data (medical record data, educational records, government or private sector datasets, etc.)

☐Ethnographic observation

☐Physiological measurements (e.g., EEG, EKG, MRI)

☐Biospecimen collection (saliva samples, blood draws, hair samples, etc.)

☐Mobile applications/data collection devices (e.g., Fitbits, actigraphs, etc.)

☐Behavioral decisionmaking tasks (e.g., puzzles, interactive games, etc.)

☐Physical activities such as walking and other forms of exercise

☒Other procedures (briefly list types of procedures here if not covered by the check-boxes above): ____Measure height and weight ____

Study 1 Needs Assessment: We will conduct a needs assessment with 25 individuals via the secure dscout platform. Dscout is a service that facilitates

conducting qualitative research, through which you can recruit participants from >100,000 consented "scouts," conduct a qualitative research study (called a "mission"), and tag and export data for qualitative analysis. The needs assessment will take approximately one month to complete. Eligible scouts (n = 25) will enroll in a 9-part mission. The mission asks participants to help us understand ways to help individuals lose weight and reduce episodes of binge eating, in order to design tools that can help people achieve these goals. First, participants will share how things have been going when it comes to their binge eating and weight (Part 1). Then, they will share moments when binge eating and weight impact them as they go about their daily life (Part 2). Third, participants will share things that help them or could help them manage their binge eating and weight (Parts 3-4). In the final parts, participants will rate their experiences and interests using a variety of techniques that have helped people work on these problems (Parts 5-7), practice implementing one of the techniques over the course of one week (Part 8), and then reflect on the experience (Part 9). Each part involves multiple choice questions, open-ended questions, uploading a 60-second video, and/or uploading a photograph. For Parts 2, 3, & 8, participants are asked to submit up to 4 entries. Given the potentially sensitive nature of this topic, participants will be encouraged to complete the parts in a private, comfortable setting. They can skip any questions they do not feel comfortable answering.

De-identified written transcripts from the Study 1 needs assessment interviews will be analyzed using Dedoose, a qualitative data analysis software. Dedoose has been widely used for qualitative analyses, and it conforms to the data security and protection standards ISO 27001 and SOC 2 Type 2. Dedoose also participates in and is certified in compliance with the EU-US Privacy Shield Framework with respect to data transfers to the U.S. More details about Dedoose are described here: https://www.dedoose.com/about/security.

All data will be stored in FSM research files on password protected computers on secure servers.

Study 1 Design & Usability Testing (Not Including the Field Trial): Up to 10 adult participants and up to 10 adolescent participants will participate in one or more individual or small group design and usability testing sessions. For adult participants, each session will last up to two hours. For adolescent participants, sessions will last up to one hour. Adult participants will be invited to complete up to 3 design sessions and may be invited to participate in additional sessions. We expect each session will take place a few days or weeks apart, based on participant availability. Adolescent participants will be invited to complete 1 design session. For adult participants, study procedures will occur in a private room, or be conducted remotely during any remote work requirements. Upon return to work, design and usability testing sessions will have the option to be conducted remotely or in person. For adolescent participants, all procedures will be remote.

Sessions will be conducted in-person or by video call on Zoom. During these sessions, participants will work with members of the research team to explore what components of a mobile app intervention would most effectively support management of weight and binge eating. Each of these sessions will involve activities such as one-on-one or group discussions, drawing, visualizing, and/or interacting with paper or digital (i.e., on a computer, tablet, or smartphone) prototypes of a mobile app intervention. For adolescent participants, only individual sessions will be conducted.

Afterwards, adult participants will complete questionnaires and height and weight measurements. Adolescent participants will not be asked to complete questionnaires. Height and weight will be measured by an approved research member or self-reported as a part of the questionnaires. Procedures for in-person height/weight measurements include up to three measurements if needed to resolve any measurement discrepancies, and the average will be used. Questionnaires will be completed on paper or via REDCap on a computer. For remote sessions, a REDCap link will be e-mailed after the videoconference call has ended. Questionnaires will assess participants' demographic information (e.g., age, marital status, education level, employment status, income, insurance), eating-related cognitions, behaviors, and impairment, as well as their impressions of and experiences with the technology. To improve reading comprehension in the questionnaires, "helper text" may be added in REDCap to questions that appear challenging to understand. For example, if a question asks "How many times per month on average over the past 3 months have you experienced X", helper text may be added such as, "If you experienced this 1 time EACH MONTH for the past the 3 months, you would choose answer "1". Participants can skip any questions as a part of the interviews or questionnaires, and can stop the sessions at any time.

All data will be stored in FSM research files on password protected computers on secure servers, or in REDCap on a HIPAA-compliant server with secure access for approved study staff.

Study 1 Field Trial: Up to 5 participants will be invited to complete a single-arm usability field trial of the intervention over 4 weeks to ensure it works. Before, during, and after the field trial, qualitative and quantitative data will be collected.

Before beginning the intervention (at baseline), participants will be invited to complete an interview in-person or by video call with an assessor, followed by questionnaires administered via REDCap. Questionnaires will assess participants' demographic information (e.g., marital status, education level, employment status, income, insurance), height, weight, eating-related cognitions and impairment, food security, eating and physical activity behaviors, social support for diet and exercise, and mood. Throughout the 4-

week intervention, participants will be provided a log to track any usability problems they uncover and prompted to complete weekly self-report usability questionnaires. At post-intervention, participants will be invited to complete the same questionnaires as they did at baseline, except for the one on demographics, and to provide feedback on their impressions of and experiences of the technology through a semi-structured interview and two questionnaires. To improve reading comprehension in the questionnaires, "helper text" may be added in REDCap to questions that appear challenging to understand. Participants can skip any questions as a part of the interviews or questionnaires and can stop the sessions at any time.

All data will be stored in FSM research files on password protected computers on secure servers, or in REDCap on a HIPAA-compliant server with secure access for approved study staff.

Study 2 Randomized Pilot Trial: Study 2 will use a 2^3 full factorial trial design[48,49] to test the effect of 3 binary components that are delivered in a mobile intervention. All participants (up to 96) will receive the intervention for 16 weeks; there is no inactive placebo. Individuals also will be randomized to 1 of 8 experimental conditions (see Table 4, below). As shown in the Table, everyone will receive "weight loss" and up to 3 additional components (content areas) based on their randomization assignment. Participants' experimental condition will be masked to them.

Table 4. Full Factorial Design

Experimental Condition	Weight Loss	Decrease Overvaluation of Weight & Shape	Decrease Unhealthy Weight Control Practices	Decrease Negative Affect
1	Yes	No	No	No
2	Yes	No	No	Yes
3	Yes	No	Yes	No
4	Yes	No	Yes	Yes
5	Yes	Yes	No	No
6	Yes	Yes	No	Yes
7	Yes	Yes	Yes	No
8	Yes	Yes	Yes	Yes

Potentially-eligible individuals will be invited to complete a baseline assessment. First, participants will complete informed consent. Consenting individuals then will complete the baseline assessment, which will include a semi-structured interview with a trained assessor, followed by questionnaires administered via REDCap to confirm eligibility. Following the session, participants will be emailed their eligibility status. Ineligible individuals will be notified via e-mail that they are ineligible and offered referral information for treatment. Eligible individuals will be notified via e-mail that they are eligible and will be invited to enroll in the pilot trial. Enrolled participants will be randomly assigned to 1 of 8 experimental conditions; randomization will be performed using a computerized random-number generator to assign participants to an experimental condition with an 8:1 ratio. Enrolled participants

will then be contacted by a member of the research team to schedule a call with their Coach to begin the intervention. The call will occur by telephone or an internet-based phone service (e.g., Google Hangouts/Voice, CiscoJabber, Zoom).

Intervention: Participants will be offered access to the mobile intervention, FoodSteps, with coaching for 16 weeks. Participants can continue using the intervention after the 16 weeks of coaching ends. The intervention is focused on addressing binge eating and weight management, with recommended weekly modules for participants to complete. Participants will access the intervention by creating a personal password known only to the participant. FoodSteps can be accessed as an app on a smartphone or as a website on a smartphone or computer. Participants can use or not use the intervention and still be enrolled in the study. The intervention and data are hosted on a secure, encrypted server. The information that participants enter into the app will not include anything that can identify them except for their email address, phone number, and zip code, and will not include the information they provide in the study assessments.

Coaching: Each participant will be assigned a coach, trained and supervised weekly by a licensed clinical psychologist. Coaching follows a low-intensity model aimed at encouraging participants to use the intervention and practice skills in their daily lives, as well as provide some technical support as needed. Coaches will use messaging such as text or e-mail to communicate with participants through a password-protected website on a secure server. Coaching will begin with an initial ~30-minute phone call to establish goals and build rapport, ensure the participant can access the intervention, and set expectations for the coach-participant relationship. Thereafter, participants will receive ~1-2 messages per week from their coach to offer encouragement, reinforce app use, and check-in on progress or challenges. Coaches also will aim to respond to participant-initiated messages within 1 working business day. An optional ~10-minute call at week 8 (mid-way through the intervention) will be offered to participants to check in on their progress.

Study assessments will occur at the following intervals: baseline, mid-intervention (5-weeks and 10-weeks), post-intervention (16 weeks) and follow-up (3-months post-intervention). Baseline, post-intervention, and follow-up assessments will include interviews and questionnaires; mid-treatment assessments will only include questionnaires. Interviews and questionnaires will assess the following topics: personal and demographic information, treatment utilization, height, weight, number of binge episodes over the past 28 days, eating-related, cognitions, behaviors, and impairment, food security, eating and physical activity behaviors, social support for diet and exercise, mood, and experiences with technology. Intervention use data (from start of

intervention through 3-month follow-up) also will be automatically collected. Study procedures will be conducted remotely during remote work requirements. Upon return to work, participants and researchers will have the option conduct these activities remotely or in-person.

For in-person procedures, interviews and questionnaires will be conducted in a private room at CBITs. Height and weight will be measured by an approved research member. Procedures for in-person height/weight measurements include up to three measurements if needed to resolve any measurement discrepancies, and the average will be used. For remote procedures, interviews will be conducted using Zoom video call and questionnaires will be e-mailed as a REDCap link to participants after the call ends. For remote procedures, height and weight will be self-reported as a part of the questionnaires; participants also will be asked to upload a photo of their weight on a scale to verify their weight. If needed (e.g., due to social distancing guidelines), participants will be presented the option to participate in assessments remotely if they started the baseline in-person, and vice versa.

As noted, questionnaires will be delivered via REDCap survey and interviews will be administered by a trained assessor. Participants can choose not to answer any questions as a part of the interviews or questionnaires and can stop the assessments at any time. To improve reading comprehension in the questionnaires, "helper text" may be added in REDCap to questions that appear challenging to understand. As Study 2 is a clinical trial, the study will be registered in Clinicaltrials.gov within 21 days of the first enrolled participant beginning the study.

Intervention use data will be downloaded monthly from the intervention and in entirety at the end of the study by an approved member of the research team. Following the study, all intervention use data will be removed from the intervention host server. All data will be stored in FSM research files on password protected computers on secure servers, or the Research Electronic Data Capture program on a HIPAA-compliant server with secure access for approved study staff.

9.0 Research with Vulnerable Populations

Study 1 design sessions with adolescents (ages 13-17 years) involves research with vulnerable populations (i.e., individuals ≤17 years old). Additional safeguards for conducting research with this population include using an assent form with developmentally tailored language. We will be conducting a shortened design session (i.e., maximum one hour) and eliminated the use of questionnaires to reduce burden on the adolescent participant. Consent/assent will be conducted in the presence of a parent, but the screening questions and design sessions will be conducted only with the adolescents so they feel comfortable discussing the

potentially sensitive topic of eating and weight. These topics also are appropriate to discuss without parents as they are not about safety-related issues. The purpose of the design sessions is to understand participants' interests in and preferences for a technology-based intervention; therefore, questions are appropriate to adolescents since they are consumers of technology. Because session prompts include the potentially sensitive topic of eating and weight, adolescents will be reminded all questions are optional and can stop any time.

10.0 Incomplete Disclosure or Deception:

NA

11.0 Consent Process:

Individuals who meet eligibility criteria will be invited to participate in one of the two studies.

Study 1 Needs Assessment: Online consent with a waiver of documentation of informed consent will be obtained. More specifically, scouts on dscout will complete an online consent form after reviewing recruitment materials, prior to completing the screen. Individuals who do not consent to the research or who do not answer this question will be unable to complete the screen. Individuals will be informed they can save a copy of the consent form from the application.

Study 1 Design & Usability Testing (including the Field Trial): Prior to administering a telephone screener to determine eligibility for the study, verbal consent from adults and consent/assent from parents/adolescents will be obtained by telephone. To address privacy considerations for the screener, participants will be encouraged to find a private, quiet location for the call, and not to complete the call while driving. If the telephone screen is conducted during any remote work requirements, an approved research team member will conduct the screen using CiscoJabber, and participants also will be informed that CiscoJabber is not HIPAA compliant.

Eligible adult individuals who are invited to participate in the main study procedures will be asked to provide written informed consent or verbal informed consent (i.e., in which an approved member of the research team will sign to confirm that the participant has consented) prior to beginning study procedures. Verbal consent will be obtained if a session is conducted remotely over video call. A copy of the consent form will be emailed to participants prior to the session and/or provided at the session. Eligible adolescents and their parents will be asked to provide verbal informed assent/consent respectively prior to beginning study procedures. This will occur at the start of the design session prior to conducting the design session activities, or on a separate telephone or Zoom call beforehand as needed for scheduling purposes between parent and teen.

Written informed consent will occur in a private room at CBITs. To address privacy considerations for remote procedures, participants will be notified prior to, as well as on the day of the call, that they are encouraged to find a private, quiet location for the session, and not to complete the study while driving. Participants also will be informed about the use of Zoom and that it is not HIPAA compliant. For Study 1 design sessions among adults, informed consent (i.e., written or verbal) may be conducted in a group or individual format depending on the number of participants.

An approved member of the research team will explain the study and procedures, and participants will be allowed as long as needed to review the consent form and ask any questions they may have. Individuals who do not consent to study procedures will be unable to participate.

Study 2 Randomized Pilot Trial:
Interested individuals will complete an online consent form prior to beginning the online screening survey. The online consent form will describe the online screening survey in REDCap and a brief description about how a subsequent baseline assessment will be used to confirm their eligibility for the pilot trial. For all interested individuals who complete the online screener, a PDF copy of the consent form will be available for download.

Based on the online screener, potentially eligible individuals who are invited to participate in the baseline assessment will be asked to provide informed consent prior to beginning the baseline assessment.

For remotely-conducted baseline assessments, verbal informed consent will be obtained over video call on Zoom. A copy of the consent form will be emailed to individuals prior to or after the session. A research team member will sign to confirm that the individual has consented to participate in the pilot trial and study procedures. To address privacy considerations for remote procedures, individuals will be notified prior to, as well as on the day of the call, that they are encouraged to find a private, quiet location for the call, and not to complete the call while driving. Individuals also will be informed about the use of Zoom and that it is not HIPAA compliant and involves minimal risk of breach of confidentiality.

For in-person baseline assessments, written informed consent will be obtained at the start of the session. A copy of the consent form will be provided in-person or e-mailed to individuals prior to or after the session. The individual will sign to confirm they have consented to participate in the pilot trial and study procedures. To address privacy considerations for in-person procedures, all assessments will take place in a private room at CBITs.

For all baseline assessments, an approved member of the research team will explain the study and procedures, and participants will be allowed as long as

needed to review the consent form and ask any questions they may have. Individuals who do not consent to trial enrollment at baseline will be unable to participate.

12.0 Waiver of Participant Signature on Consent Form:

For any Study 1 and 2 remotely conducted research procedures, participants will be asked to provide verbal consent instead of in-person written consent, because asking participants to provide in-person written consent during remotely conducted study procedures is not feasible.

13.0 Waivers and Alterations of Consent Information:

NA

14.0 Financial Compensation:

Study 1 All Activities: Participants completing the needs assessment will receive $100 each. Adult and adolescents participants who complete design sessions in the laboratory or remotely will receive $20 for each design session completed. Participants who complete the 4-week single arm usability field trial will receive $50.

There will be no prorating for compensation in Study 1. For remote procedures, electronic gift cards (e-gift cards) will be provided to participants. For in-person procedures, parking reimbursement will be provided in the form of a parking ticket for participants that drive to the lab and park in the nearby garage (Erie and Huron garages). This information and directions to the lab will be provided to all participants as an option beforehand.

Study 2 Randomized Pilot Trial: Compensation will be prorated in Study 2. Participants will receive increasing amounts for each assessment they complete: $10 for baseline; $15 for mid-intervention at 5 weeks; $15 for mid-intervention at 10 weeks; $20 for post-intervention (16-weeks); $30 for 3-month follow-up. To encourage participants to complete all assessments, they can earn an additional $10 for completing all assessments. This means participants have potential to be compensated $100 total for completing all study activities. Payment will be provided in the form of a gift card in-person or as an e-gift card for remote assessments. Participants will not be compensated for completing the intervention or communicating with their coach.

For in-person procedures, parking reimbursement will be provided in the form of a parking ticket for participants who drive to the lab and park in the nearby garage (Erie and Huron garages). This information and directions to the lab will be provided to all participants as an option beforehand.

15.0 Audio/Video Recording/Photography

Study 1 All Activities: Study 1 will involve audio- and/or video-recording (e.g., using a "think aloud" strategy during design sessions to describe reactions while using the intervention). Photographs or screenshots of artifacts (e.g., drawings from design sessions) may be taken as well.

During remote procedures for design and usability testing sessions, the audio and/or video recording feature in Zoom will be used to record participants.

After each in-person session, audio and/or video files will be manually transcribed by an approved research member and transcriptions will be uploaded to the FSM research files. After each remote session, audio and/or video files will be automatically transcribed in Zoom, and additional edits may be made to the transcription file by an approved research member. Then, the video recording and transcription will be uploaded to the secure FSM research files and removed from Zoom if transcribed there. All transcripts of the recordings will be de-identified. Recordings and transcripts will only be accessible to approved study staff.

Study 2 Randomized Pilot Trial: Interview assessments will be audio-recorded to assess reliability of assessors in administration or for subsequent qualitative analyses. Recordings will be stored on password protected computers and secure servers accessible only to approved study staff. During remote procedures, we will use Zoom to audio record and transcribe interviews. After each remote session, recordings and transcription files will be moved to the secure FSM research files and removed from Zoom. Additional edits may be made to the transcription files by an approved research team member. During in-person procedures, an approved research team member will manually transcribe recordings, and transcriptions will subsequently be uploaded to the FSM research files and removed from the recording device. All transcripts of the recordings will be de-identified. Recordings and transcripts will only be accessible to approved study staff.

16.0 Potential Benefits to Participants:

Study 1 All Activities: There may be no direct benefits in terms of changes in participants' weight and frequency of binge eating. However, participants may benefit from knowing that their feedback is helping to design an intervention that may improve the precision and efficacy of care for individuals with obesity/elevated weight status and binge eating/overeating. Individuals participating in field trial may benefit from the knowledge gained from using the intervention in real-world settings. All participants will be provided with referral information for treatment following the design and usability testing sessions, including the field trial.

Study 2 Randomized Pilot Trial: Participants may experience reductions in

weight and binge eating, as well as improvements in core psychopathology (i.e., overvaluation of weight and shape, unhealthy weight control practices, and negative affect). These changes have potential to reduce the onset or maintenance of medical problems and total health care service use and costs associated with obesity and binge eating. Participants may also benefit from knowing that their use of the intervention and feedback will help inform improvements to the intervention that may improve the precision and efficacy of care for individuals with obesity and binge eating. All participants will be provided with referral information for treatment following the pilot trial.

17.0 Risks to Participants:

Study 1 All Activities: There are no high-risk or hazardous aspects of design or usability testing or of the proposed intervention. There is potential for participants to feel bored or possibly distressed during the design and usability testing sessions given the potentially sensitive nature of discussing of eating and weight-related topics. Participants can choose not to answer any questions within the questionnaires or during the interview.

Individuals completing the 4-week field trial will be informed in advance that the goal of the field trial is to confirm the intervention works when deployed and not to change clinical outcomes (although these data will be assessed as practice for the Study 2 randomized pilot trial). As such, it is possible that participants will experience no change or worsening of symptoms. Participants completing design and usability testing sessions, including the field trial, will be offered referral information for treatment. If any participant appears to be in crisis during the usability testing, appropriate action will be taken based on an established crisis assessment protocol.

For remotely conducted design and usability testing procedures, there is the potential for breach of confidentiality or loss of data due to the use of CiscoJabber and Zoom, which are both 3rd party vendors contracted with Northwestern that require NU credentials to use but are not HIPAA-compliant.

Study 2 Randomized Pilot Trial: There are minimal risks associated with participating in this study. Potential risks that might exist fall into the following four categories: (a) risks associated with the intervention; (b) risks associated with study assessments; (c) risks associated with potential loss of confidentiality; and (d) risks of worsening symptoms.

(a) Risks associated with the intervention: Digital mental and behavioral health interventions have not been shown to cause any harm. All intervention activities are optional, and participants can discontinue using the intervention at any time, while still participating in the study.

(b) Risks associated with study assessments: Study assessments include

questions about eating disorder behaviors and other mental and emotional problems that may make study participants experience discomfort or anxiety. All participant responses to assessment questions are voluntary; they are told that they can decline to answer any questions that they choose or stop the assessment. The instruments and methodologies used throughout the study are well tested and are not known to cause problems or distress on the behalf of the participants.

(c) Risks associated with potential loss of confidentiality. Every possible measure will be taken to minimize the potential risk of loss of confidentiality. For use of the intervention, transmissions are protected using a Transport Security Layer and communication occurs within a secure messaging platform; however, there is the possibility that others may see the participant's open webpage or smartphone. There is also the possibility that databases may be hacked. For remote procedures, there is the potential risk of breach of confidentiality or loss of identifying information due to the use of Zoom (a 3rd party vendor contracted with Northwestern that requires NU credentials to use but is not HIPAA-compliant) and internet-based phone services (e.g., Zoom, Google Hangouts/Voice, CiscoJabber). A research team member will explain all risks involved with the study during the consent process and answer any question about this. There is also the remote possibility that research records will be subpoenaed by a court of law. All of these potential losses of confidentiality will be disclosed in the consent documents.

(d) Risks of worsening symptoms: There is potential for participants to show no change or worsening in binge eating or weight. It is not believed that the risk of these or other adverse outcomes are increased as a function of being enrolled in this study. If a participant does not show symptom improvement following the intervention or at the follow-up assessment, this individual will be offered referral information for in-person treatment. Individuals also may request this information at any point during the active intervention period. If any participant appears to be in crisis during the intervention or assessments, appropriate action will be taken based on an established crisis assessment protocol.

18.0 Provisions to Protect the Privacy and Confidentiality of Participants and the Research Data:

For both studies, the overall risks for study participation are minimal, and any possible risk will be minimized as much as possible. Personal identifiers, namely via video/audio recordings and photographs, will be obtained during the needs assessment using the secure dscout server and during the design sessions. Identifying information will be obtained with the screen to allow for the study team to contact the potential participants to schedule the design and usability testing sessions, including field trial assessments, (Study 1) or pilot trial baseline assessment (Study 2), as well as to confirm residence in the Chicagoland area for relevant sub-studies. Participants' identifying information will be kept private. All participants will receive a study ID to protect their identity during assessments and for data analysis.

For Study 1 design and usability testing and Study 2 randomized pilot trial, data collection will occur using a REDCap survey. REDCap is a secure, web-based data collection and management software program that will be accessible to only approved study members. Remotely-conducted telephone screens will be conducted using CiscoJabber and participants' responses will be inputted directly into REDCap by an approved research team member. In-person research assessments will occur in private rooms to protect the anonymity of the participant and any written data (e.g., from questionnaires completed on paper and/or from height/weight measurements) will be inputted into REDCap. Remotely-conducted research interviews will occur by video call on Zoom and questionnaires will be e-mailed as a link for participants to complete on their own after the call has ended. For these sessions, participants will be encouraged prior to and on the day of to find a private space to complete the call and questionnaires, and not while driving. Participants and researchers will be encouraged to avoid indicating any identifying information during the session.

For participants using the intervention during the field trial (Study 1) or pilot trial (Study 2), participants will create a unique password to use with the intervention. Passwords will only be known to participants. Initial onboarding calls will occur via telephone or internet-based phone services (e.g., Google Hangouts/Voice, CiscoJabber, Zoom). Participants will be provided with the contact information of the study staff. If any participant appears to be in crisis during the intervention or assessments, appropriate action will be taken based on an established crisis assessment protocol. If a participant does not show symptom improvement following the intervention or (for Study 2 only) at the 3-month follow-up assessment, this individual will be offered referral information for in-person treatment. Any adverse event will be reported promptly to the mentorship team, the NIH, and the IRB.

Participant data that are exported from the mobile intervention will uploaded to the secure, password-protected FSM research servers. Following the study, all intervention use data will be removed from the intervention host platform. All other study-related records (e.g., consent forms, payment materials, study assessment data) will be stored for at least 3 years following the end of the

study in locked file cabinets, on secure, password-protected servers, and/or password-protected file or software program(s) (e.g., REDCap, StudyTracker). Only approved study staff will have access to a password-protected file or software program(s) (e.g., REDCap) that link participants with their study IDs and usernames. Among individuals who complete the verbal consent, data collected from the telephone or online screeners will be retained for research purposes in the event that information needs to be reported (e.g., for research publications) comparing differences between eligible and non-eligible participants. Screener and questionnaire data collection will occur through REDCap surveys. Audio and/or video recordings will be kept on secure, password-protected files (i.e., FSM research files) and removed from the audio recording device after they are uploaded.

For analyses of qualitative data (e.g., from the Study 1 needs assessment), de-identified data from participants' transcripts will be uploaded and analyzed using Dedoose, described in Section 8.0: Procedures.

19.0 Data Monitoring Plan to Ensure the Safety of Participants:

As this research is being conducted via a NIH career development award, the mentorship team (i.e., 3 faculty members at Northwestern University and 2 faculty members at the University of Chicago) will serve as a data and safety monitoring committee.

The data safety and monitoring plan for the randomized pilot trial includes close monitoring by the principal investigator and mentorship team. Any adverse event will be reported promptly to the NIH and to the IRB. For Study 1, all participants completing usability testing, including the field trial, will be offered referral information for in-person treatment. For Study 2, participants who do not show symptom improvement by the end of the intervention or follow-up period will be offered referral information for in-person services. The principal investigator will be responsible for assembling data safety and monitoring data and producing data safety and monitoring reports. Information will be documented on each participant who drops out of the study. Results of participant retention will be presented to the mentorship team on an annual basis.

For both studies, significant adverse events are not anticipated because usability testing and the intervention follow standard practice guidelines. For Study 2, there is the potential for lack of improvement or worsening of symptoms. To ensure participant safety, the principal investigator will keep a log of any issues perceived to be related to testing or the intervention or that might require further assessment or attention. Any potentially adverse events will be evaluated by the principal investigator within 72 hours. Serious adverse events will be promptly reported to the IRB at Northwestern University and to the NIH; all other adverse events will be included in the annual report to the NIH.

No standards have been established to suggest an expected adverse event rate; thus, adverse event discontinuation rules have not been established. Rather, data will be collected on events and these data will be presented to the mentorship team, the IRB, and the NIH. Because no guidelines exist to determine when usability testing or the trial should be discontinued, the principal investigator will rely on the mentorship team's professional judgment to justify discontinuation.

20.0 Long-term Data and Specimen Storage and Sharing:

Data generated from this project may be shared with other investigators who provide a proposal with a strong research question and appropriate rationale and analytic plan. In such a case, data would be de-identified as per HIPAA regulations to protect the confidentiality of participants, and the investigators would work closely together to ensure high quality output and meet all compliance regulations of participating institutions.

21.0 Qualifications of Research Team to Conduct the Research:

I, the principal investigator, am a licensed clinical psychologist and health services researcher. This research project is a natural extension of my prior research. I have shown that people with overweight or obesity experience problematic eating behaviors[50-53] and that eating disorder pathology is highest among young adults with overweight/obesity compared to under- or normal weight.[54] I have co-authored papers that link overvaluation of weight/shape, unhealthy weight control practices, and negative affect.[55-60] I have collaborated on studies that demonstrate the efficacy of digital interventions using BWL[61,62] and CBT approaches,[63,64] including showing improvements in overvaluation of weight/shape, unhealthy weight control behaviors, and negative affect in women with eating pathology.[64] My work indicates that a CBT-based online intervention for eating disorder pathology benefits from coaching,[63] and I have served as a coach for digital interventions in previous NIH-funded trials (e.g., R01 MH081125, R01 MH100455). I anticipate success recruiting my sample as I have worked on teams to enroll >1,000 people into studies of digital tools.[61,62,64-66]

References

1. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *JAMA.* 2014;311(8):806-814.
2. Chang SH, Pollack LM, Colditz GA. Life Years Lost Associated with Obesity-Related Diseases for U.S. Non-Smoking Adults. *PLoS One.* 2013;8(6):e66550.
3. Flegal KM, Kit BK, Orpana H, Graubard BI. Association of all-cause mortality with overweight and obesity using standard body mass index categories: a systematic review and meta-analysis. *JAMA.* 2013;309(1):71-82.
4. Juonala M, Magnussen CG, Berenson GS, et al. Childhood adiposity, adult adiposity, and cardiovascular risk factors. *N Engl J Med.* 2011;365(20):1876-1885.
5. Finkelstein EA, Trogdon JG, Cohen JW, Dietz W. Annual medical spending attributable to obesity: payer-and service-specific estimates. *Health Aff (Millwood).* 2009;28(5):w822-831.
6. Thorpe KE, Florence CS, Howard DH, Joski P. The impact of obesity on rising medical spending. *Health Aff (Millwood).* 2004;Suppl Web Exclusives:W4-480-486.
7. Wang YC, Pamplin J, Long MW, Ward ZJ, Gortmaker SL, Andreyeva T. Severe Obesity In Adults Cost State Medicaid Programs Nearly $8 Billion In 2013. *Health Aff (Millwood).* 2015;34(11):1923-1931.
8. Wang YC, McPherson K, Marsh T, Gortmaker SL, Brown M. Health and economic burden of the projected obesity trends in the USA and the UK. *Lancet.* 2011;378(9793):815-825.
9. Mitchell JE, King WC, Courcoulas A, et al. Eating behavior and eating disorders in adults before bariatric surgery. *Int J Eat Disord.* 2015;48(2):215-222.
10. Wilfley DE, Citrome L, Herman BK. Characteristics of binge eating disorder in relation to diagnostic criteria. *Neuropsychiatr Dis Treat.* 2016;12:2213-2223.
11. Dingemans AE, Bruna MJ, van Furth EF. Binge eating disorder: a review. *Int J Obes Relat Metab Disord.* 2002;26(3):299-307.
12. American Psychiatric Association. *Diagnostic and statistical manual for mental disorders.* 5th ed. Washington, DC: American Psychiatric Association; 2013.
13. Brownley KA, Berkman ND, Peat CM, et al. Binge-Eating Disorder in Adults: A Systematic Review and Meta-analysis. *Ann Intern Med.* 2016;165(6):409-420.
14. Kass AE, Kolko RP, Wilfley DE. Psychological treatments for eating disorders. *Curr Opin Psychiatry.* 2013;26(6):549-555.
15. Moyer VA, Force USPST. Screening for and management of obesity in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2012;157(5):373-378.
16. Kushner RF, Ryan DH. Assessment and lifestyle management of patients with obesity: clinical recommendations from systematic reviews. *JAMA.* 2014;312(9):943-952. doi: 910.1001/jama.2014.10432.
17. Fairburn CG, Patel V. The impact of digital technology on psychological treatments and their dissemination. *Behav Res Ther.* 2017;88:19-25.
18. Kazdin AE, Fitzsimmons-Craft EE, Wilfley DE. Addressing critical gaps in the treatment of eating disorders. *Int J Eat Disord.* 2017;50(3):170-189.
19. Kazdin AE, Blase SL. Rebooting Psychotherapy Research and Practice to Reduce the Burden of Mental Illness. *Perspect Psychol Sci.* 2011;6(1):21-37.

20. Wilson GT, Wilfley DE, Agras WS, Bryson SW. Psychological treatments of binge eating disorder. *Arch Gen Psychiatry.* 2010;67(1):94-101.
21. Grilo CM, White MA, Gueorguieva R, Barnes RD, Masheb RM. Self-help for binge eating disorder in primary care: a randomized controlled trial with ethnically and racially diverse obese patients. *Behav Res Ther.* 2013;51(12):855-861. doi: 810.1016/j.brat.2013.1010.1002. Epub 2013 Oct 1019.
22. Grilo CM, Masheb RM. A randomized controlled comparison of guided self-help cognitive behavioral therapy and behavioral weight loss for binge eating disorder. *Behav Res Ther.* 2005;43(11):1509-1525.
23. Grilo CM, Masheb RM, Wilson GT, Gueorguieva R, White MA. Cognitive-behavioral therapy, behavioral weight loss, and sequential treatment for obese patients with binge-eating disorder: a randomized controlled trial. *J Consult Clin Psychol.* 2011;79(5):675-685. doi: 610.1037/a0025049.
24. Hutchesson MJ, Rollo ME, Krukowski R, et al. eHealth interventions for the prevention and treatment of overweight and obesity in adults: a systematic review with meta-analysis. *Obes Rev.* 2015;16(5):376-392.
25. Flores Mateo G, Granado-Font E, Ferre-Grau C, Montana-Carreras X. Mobile Phone Apps to Promote Weight Loss and Increase Physical Activity: A Systematic Review and Meta-Analysis. *J Med Internet Res.* 2015;17(11):e253.
26. Wagner B, Nagl M, Dolemeyer R, et al. Randomized Controlled Trial of an Internet-Based Cognitive-Behavioral Treatment Program for Binge-Eating Disorder. *Behav Ther.* 2016;47(4):500-514.
27. Ljotsson B, Lundin C, Mitsell K, Carlbring P, Ramklint M, Ghaderi A. Remote treatment of bulimia nervosa and binge eating disorder: a randomized trial of Internet-assisted cognitive behavioural therapy. *Behav Res Ther.* 2007;45(4):649-661.
28. Hildebrandt T, Michaelides A, Mackinnon D, Greif R, DeBar L, Sysko R. Randomized controlled trial comparing smartphone assisted versus traditional guided self-help for adults with binge eating. *Int J Eat Disord.* 2017;50(11):1313-1322.
29. Carrard I, Crepin C, Rouget P, Lam T, Golay A, Van der Linden M. Randomised controlled trial of a guided self-help treatment on the Internet for binge eating disorder. *Behav Res Ther.* 2011;49(8):482-491.
30. Butryn ML, Webb V, Wadden TA. Behavioral treatment of obesity. *Psychiatr Clin North Am.* 2011;34(4):841-859.
31. Wadden TA, Butryn ML, Wilson C. Lifestyle modification for the management of obesity. *Gastroenterology.* 2007;132(6):2226-2238.
32. Fairburn CG. *Cognitive Behavior Therapy and Eating Disorders.* New York, NY: The Guilford Press; 2008.
33. Grilo CM, White MA, Gueorguieva R, Wilson GT, Masheb RM. Predictive significance of the overvaluation of shape/weight in obese patients with binge eating disorder: findings from a randomized controlled trial with 12-month follow-up. *Psychol Med.* 2013;43(6):1335-1344. doi: 1310.1017/S0033291712002097. Epub 0033291712002012 Sep 0033291712002012.
34. Goldschmidt AB, Hilbert A, Manwaring JL, et al. The significance of overvaluation of shape and weight in binge eating disorder. *Behav Res Ther.* 2010;48(3):187-193.

35. Rieger E, Van Buren DJ, Bishop M, Tanofsky-Kraff M, Welch R, Wilfley DE. An eating disorder-specific model of interpersonal psychotherapy (IPT-ED): causal pathways and treatment implications. *Clin Psychol Rev.* 2010;30(4):400-410.
36. Stein RI, Kenardy J, Wiseman CV, Dounchis JZ, Arnow BA, Wilfley DE. What's driving the binge in binge eating disorder?: A prospective examination of precursors and consequences. *Int J Eat Disord.* 2007;40(3):195-203.
37. Ansell EB, Grilo CM, White MA. Examining the interpersonal model of binge eating and loss of control over eating in women. *Int J Eat Disord.* 2012;45(1):43-50.
38. Faulkner L. Beyond the five-user assumption: benefits of increased sample sizes in usability testing. *Behav Res Methods Instrum Comput.* 2003;35(3):379-383.
39. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol.* 2010;10:67.
40. Bowen DJ, Kreuter M, Spring B, et al. How We Design Feasibility Studies. *American Journal of Preventive Medicine.* 2009;36(5):452-457.
41. Orsmond GI, Cohn ES. The Distinctive Features of a Feasibility Study: Objectives and Guiding Questions. *OTJR (Thorofare N J).* 2015;35(3):169-177.
42. Crane MM, Lutes LD, Ward DS, Bowling JM, Tate DF. A randomized trial testing the efficacy of a novel approach to weight loss among men with overweight and obesity. *Obesity (Silver Spring).* 2015;23(12):2398-2405. doi: 2310.1002/oby.21265.
43. O'Brien KM, Hutchesson MJ, Jensen M, Morgan P, Callister R, Collins CE. Participants in an online weight loss program can improve diet quality during weight loss: a randomized controlled trial. *Nutrition journal.* 2014;13:82.
44. Hales S, Turner-McGrievy GM, Wilcox S, et al. Social networks for improving healthy weight loss behaviors for overweight and obese adults: A randomized clinical trial of the social pounds off digitally (Social POD) mobile app. *International journal of medical informatics.* 2016;94:81-90.
45. Thomas JG, Leahey TM, Wing RR. An automated internet behavioral weight-loss program by physician referral: a randomized controlled trial. *Diabetes Care.* 2015;38(1):9-15.
46. Morgan PJ, Callister R, Collins CE, et al. The SHED-IT community trial: a randomized controlled trial of internet- and paper-based weight loss programs tailored for overweight and obese men. *Ann Behav Med.* 2013;45(2):139-152.
47. Bennett GG, Herring SJ, Puleo E, Stein EK, Emmons KM, Gillman MW. Web-based weight loss in primary care: a randomized controlled trial. *Obesity (Silver Spring).* 2010;18(2):308-313.
48. Collins LM, Dziak JJ, Kugler KC, Trail JB. Factorial experiments: efficient tools for evaluation of intervention components. *Am J Prev Med.* 2014;47(4):498-504.
49. Collins LM, Dziak JJ, Li R. Design of experiments with multiple independent variables: a resource management perspective on complete and reduced factorial designs. *Psychol Methods.* 2009;14(3):202-224.
50. Kass AE, Wang AZ, Kolko RP, et al. Identification as overweight by medical professionals: Relation to eating disorder diagnosis and risk. *Eat Behav.* 2014;17C:62-68.

51. Kass AE, Wilfley DE, Eddy KT, et al. Secretive eating among youth with overweight or obesity. *Appetite.* 2017;114:275-281.(doi):10.1016/j.appet.2017.1003.1042.
52. Kass AE, Theim Hurst K, Kolko RP, et al. Psychometric evaluation of the youth eating disorder examination questionnaire in children with overweight or obesity. *Int J Eat Disord.* 2017;15(10):22693.
53. Kass AE, Wildes JE, Coccaro EF. Identification and regulation of emotions in adults of varying weight statuses. *Journal of Health Psychology.* In press.
54. Kass AE, Jones M, Kolko RP, et al. Universal prevention efforts should address eating disorder pathology across the weight spectrum: Implications for screening and intervention on college campuses. *Eat Behav.* 2016.
55. Fitzsimmons-Craft EE, Eichen DM, Kass AE, et al. Reciprocal longitudinal relations between weight/shape concern and comorbid pathology among women at very high risk for eating disorder onset. *Eating and weight disorders : EWD.* 2017.
56. Vannucci A, Theim KR, Kass AE, et al. What constitutes clinically significant binge eating? Association between binge features and clinical validators in college-age women. *Int J Eat Disord.* 2013;46(3):226-232.
57. Boyd HK, Kass AE, Accurso EC, Goldschmidt AB, Wildes JE, Le Grange D. Relationship between desired weight and eating disorder pathology in youth. *Int J Eat Disord.* 2017;21(10):22720.
58. Aspen V, Weisman H, Vannucci A, et al. Psychiatric co-morbidity in women presenting across the continuum of disordered eating. *Eat Behav.* 2014;15(4):686-693.
59. Mischoulon D, Eddy KT, Keshaviah A, et al. Depression and eating disorders: treatment and course. *J Affect Disord.* 2011;130(3):470-477.
60. Gibbs EL, Kass AE, Eichen DM, Fitzsimmons-Craft EE, Trockel M, Wilfley DE. Attention-deficit/hyperactivity disorder-specific stimulant misuse, mood, anxiety, and stress in college-age women at high risk for or with eating disorders. *J Am Coll Health.* 2016;64(4):300-308.
61. Jones M, Taylor Lynch K, Kass AE, et al. Healthy weight regulation and eating disorder prevention in high school students: a universal and targeted Web-based intervention. *J Med Internet Res.* 2014;16(2):e57.
62. Taylor CB, Taylor K, Jones M, et al. Obesity prevention in defined (high school) populations. *Int J Obes Suppl.* 2012;2:S30-S32.
63. Kass AE, Trockel M, Safer DL, et al. Internet-based preventive intervention for reducing eating disorder risk: A randomized controlled trial comparing guided with unguided self-help. *Behav Res Ther.* 2014;63:90-98.
64. Taylor CB, Kass AE, Trockel M, et al. Reducing eating disorder onset in a very high risk sample with significant comorbid depression: A randomized controlled trial. *J Consult Clin Psychol.* 2016;84(5):402-414.
65. Jones M, Kass AE, Trockel M, Glass AI, Wilfley DE, Taylor CB. A population-wide screening and tailored intervention platform for eating disorders on college campuses: the healthy body image program. *J Am Coll Health.* 2014;62(5):351-356.
66. Graham AK, Minc A, Staab EM, Beiser DG, Gibbons RD, Laiteerapong N. Validation of the Computerized Adaptive Test for Mental Health in an adult primary care population. *Annals of Family Medicine.* Under review.