STUDY TITLE:

Evaluating a Digital Intervention for Binge Eating and Weight Management among Adults with Food Insecurity

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)	☒ This is funded by the American Diabetes Association to a NIH-funded P30 Center at Northwestern University & the University of Chicago, who administers the pilot award to the study PI

1.0 Purpose of the study:

The purpose of this study is to (1) adapt the mobile intervention, FoodSteps, to address food insecurity (i.e., tailor the intervention, offer financial support for accessing food to facilitate implementing healthy behavior changes), and (2) test its feasibility, acceptability, and preliminary efficacy to inform a future R01 clinical trial of FoodSteps among this subpopulation. The Specific Aims are to:

Aim 1: Determine the feasibility of delivering the FoodSteps intervention among adults with food insecurity, recurrent binge eating, and diabetes. Feasibility will be based on study recruitment and retention rates, retention to treatment, and adherence documenting prescribed intervention strategies.

Aim 2: Assess the acceptability of FoodSteps by applying user-centered design methodology via qualitative interviews and self-report surveys, which will inform future intervention enhancements.

Aim 3. Derive estimates of the preliminary efficacy of FoodSteps on changes in weight and binge eating from baseline to post-intervention. Efficacy estimates will be used to power a future R01 trial.

Background / Literature Review / Rationale for the study:

Two in five U.S. adults have obesity,[1] which is associated with morbidity, mortality, and high healthcare costs.[2-4] Up to 30% of adults with obesity engage in binge eating,[5] an eating disorder behavior characterized by eating a large amount of food and experiencing a loss of control while eating.[6] Binge eating causes excess weight gain, undermines weight control treatment outcomes, and confers risk for comorbidities including metabolic syndrome.[7,8] Despite their substantial overlap and tendency to persist in the absence of treatment, no intervention sufficiently addresses both obesity and binge eating,[9-11] which results in a pressing clinical gap.

To fill these gaps, we created FoodSteps, the first intervention for both obesity and binge eating, delivered by mobile device to increase scalability. In the first trial of FoodSteps (K01 DK116925; PI Graham), we rigorously designed the intervention with user input and tested its feasibility. Preliminary findings show that FoodSteps is engaging with high rates of completion and adherence, unlike most apps.[12] But, FoodSteps has not been adapted for nor tested among a subpopulation of people with binge eating, obesity, and food insecurity.

Food insecurity, defined as inadequate/inconsistent access to food required for a healthy life,[13] is increasingly being linked to binge eating.[14] Only 9 people (15%) who enrolled in the K01 clinical trial reported having food insecurity, as recruitment was not designed to target this subpopulation. To inform a future R01 clinical trial of FoodSteps among people with food insecurity, we need to pilot test this intervention among a larger sample. Additionally, FoodSteps has not been tested in people with weight-related health problems such as type 2

diabetes mellitus, a clinically important extension given the prevalence (up to 20%) and negative impact of binge eating among people with diabetes.[15,16]

Therefore, the overarching goal of this study is to conduct a pilot test of the FoodSteps intervention among adults with recurrent binge eating, Type 2 diabetes, and food insecurity to determine its feasibility, acceptability, and preliminary efficacy among this population.

2.0 Enrollment Criteria:

Participants will be non-pregnant, English-speaking adults age ≥18 years with recurrent binge eating (≥12 episodes in the past 3 months), type 2 diabetes (self-reported as a current diagnosis), and food insecurity (≥2 on the 6-item Short Form Food Security Survey Screener). 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. Participants will also need to have sufficient capacity for calls and text messaging through their cellular carrier plan, have a valid e-mail address so that they can receive study information, and complete relevant study procedures (e.g., consent form, REDCap link with questionnaires), and have a valid five-digit zip code.

Participants will be excluded if they self-report a diagnosis for which the study/intervention is not clinically indicated (e.g., psychosis, mania, dissociation, cognitive impairment). Participants may be excluded if they are currently working with a clinical professional to receive services for management of weight/binge eating or started/recently changed dosage of a medication for binge eating, weight loss, or diabetes.

3.0 Sample Size:

Up to 40 participants will be enrolled in the study.

4.0 Recruitment and Screening Methods:

Recruitment Methods: 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 (e.g. WIC clinics, IDHS offices offering SNAP applications or mental health services, Greater Chicago Food Depository food pantries), 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. Additionally, we will recruit potentially eligible participants who have filled out an eligibility screener for a concurrent study and who have consented to having their screener data shared with other approved research projects by the PI. Across all recruitment pathways, information/study advertising content will remain consistent with

IRB-approved recruitment language.

Screening Methods: Interested individuals will complete an online screener survey administered via REDCap to assess for potential eligibility. The online screener will include questions about the individual's contact information, demographics, food security status, smartphone ownership, access to a scale, current treatment utilization, mental and physical health concerns (e.g., type 2 diabetes), and interest/capacity to participate in study activities. Interested individuals also will be asked to self-report their height, weight, and number of episodes of binge eating over the past 3 months. "Helper text" may be added in REDCap to questions that appear challenging to understand to improve reading comprehension.

Individuals recruited from the concurrent study will complete a shortened screener via REDCap which will only include questions about the individual's food security status (i.e., items not assessed on the other study's screener); these individuals' responses to the other items from the concurrent study's eligibility screener will be copied to this study's REDCap.

Potentially eligible individuals will then be invited to complete an assessment to confirm eligibility. This assessment will occur via videoconference or telephone call (e.g., via Zoom, CiscoJabber). First, participants will complete informed consent. Consenting individuals then will complete the assessment, which will include a semi-structured interview with a trained assessor to assess for the number of binge episodes over the past three months and other eating disorder pathology. Individuals will also be asked to complete surveys, which will be sent as a REDCap link via email. Questionnaires will assess participants' demographics not captured at screening (e.g., marital status, education level, employment status, income, insurance), height, weight, eating-related symptoms, food security, and mood. Participants can skip any questions as a part of the interviews or questionnaires and can stop their participation at any time. "Helper text" may be added in REDCap to questions that appear challenging to understand to improve reading comprehension.

Of those eligible, participants will be selected with a range of backgrounds to ensure a diverse and representative sample of target users. Ineligible individuals will be offered referral information for treatment.

5.0 Research Locations:

Research procedures will occur at the Center for Behavioral Intervention Technologies (CBITs) lab space at Northwestern University and/or remotely (e.g., via Zoom, telephone, CiscoJabber). CBITs has private offices and a usability lab.

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 decision-making 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____

Eligible individuals will be invited to enroll in the pilot trial. Participants who elect to enroll will be sent an electronic scale and will schedule an onboarding call. This call will occur by telephone or an internet-based phone service (e.g., Google Hangouts/Voice, CiscoJabber, Zoom). During the onboarding call, enrolled participants will provide their weight using the electronic scale and onboard to the FoodSteps intervention. Participants will keep the electronic scale from onboarding for use throughout the remainder of the study; they will be allowed to keep the scale after the study ends. Within one month of participants discontinuing or completing the 16-week trial, we will alert the electronic scale contractor (BodyTrace) to request termination of data transmissions from the participant's scale to the research team. Each enrolled participant will also receive a stipend of $10 per week (up to $160 total) to support implementing healthy behavior changes during the intervention. The stipend will be prorated and given to participants at the beginning of every week of the intervention. If a participant chooses to withdraw from the intervention before the end of the study, they will not continue to receive the stipend. Additionally, to sustain participant engagement over the 16-week study, enrolled participants may be sent variable promotional, study-branded materials—and not extra compensation—such as a tote bag, sticker, and/or water bottle (valued at ~$2-20) during the study period.

Intervention: Enrolled participants will be offered access to the mobile intervention, FoodSteps, with coaching for 16 weeks. All participants will receive the intervention; there is no inactive control. 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 a website app on a smartphone or on a computer or tablet. Participants can choose to 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 intervention will not include anything that can identify them except for their email address, phone number, and zip code.

Coaching: Each participant will be assigned a coach, who is trained and supervised weekly by a 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, set expectations for the coach-participant relationship, and make the participant aware that they can request treatment referral information any time as well as explain how to navigate to the intervention's Resources page which includes treatment referral information. 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, with potential for additional calls as needed. After participants schedule their coaching call, they may receive emails and/or text messages (up to 4) reminding them of their upcoming appointment. Participants who have already consented into the study will not receive text message reminders.

Study assessments will occur again at mid-intervention (8-weeks) and post-intervention (16-weeks). Baseline (i.e., the eligibility assessment), mid-intervention, and post-intervention assessments will include interviews and/or questionnaires. After participants schedule their research assessments, they may receive emails and/or text messages (up to 4) reminding them of their upcoming appointment. Participants who have already consented into the study will not receive text message reminders. Interviews and questionnaires will assess the following topics: personal and demographic information, treatment and stipend utilization, height, weight, number of binge episodes over the past three months, eating-related symptoms, stress, shame, food security, and experiences with technology. The following questionnaires will be administered via a

REDCap survey link:

Measure	**Timepoint**		
	Baseline	*Mid-intervention*	*Post-intervention*
Demographic Information	X		
Eating Questionnaire	X	X	X
Stipend Questionnaire			X
CIA 3.0	X	X	X
CESDR-10	X	X	X
6-item FI Screener		X	X
System Usability Scale		X	X
Treatment Utilization		X	X
Perceived Stress Scale	X	X	X
Personal Feelings Questionnaire	X	X	X
Implementation Questionnaire (Baseline)	X		
Implementation Questionnaire (Post-Intervention)			X

Intervention use data (from start of intervention through 16-week post-intervention) and weights from the electronic scale also will be automatically collected.

Interviews will be conducted via Zoom video call or telephone by a trained assessor and questionnaires will be e-mailed as a REDCap survey link to participants. Height and weight will be self-reported as a part of the questionnaires; at mid-intervention and post-intervention, participants also will be asked to provide a weight using their electronic scale. Participants can choose not to answer any questions as a part of the interviews or questionnaires and can stop the assessments at any time. “Helper text” may be added in REDCap to questions that appear challenging to understand to improve reading comprehension.

Intervention use data will be downloaded monthly from the intervention and in entirety at the end of the study by an approved research team member. 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 within the Research Electronic Data Capture (REDCap)

program on a HIPAA-compliant server with secure access for approved study staff.

9.0 Research with Vulnerable Populations

NA

10.0 Incomplete Disclosure or Deception:

NA

11.0 Consent Process:

Screening: Interested individuals will complete an online consent form prior to beginning the online screening survey or the shortened screening survey. The online consent form will describe the online screening survey in REDCap.

Eligible individuals who are invited to participate in the eligibility assessment will be asked to complete an online consent form via REDCap prior to beginning the assessment. A PDF copy of the consent form will be emailed to participants prior to the assessment so they can review the form in advance. Then during the assessment, 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. The assessor will then provide the participant with the REDCap link so the participant can e-sign the form. Individuals who do not consent to study procedures will be unable to participate.

12.0 Waiver of Participant Signature on Consent Form:

N/A

13.0 Waivers and Alterations of Consent Information:

NA

14.0 Financial Compensation:

Compensation will be prorated in the study. Participants will receive increasing amounts for each assessment they complete: $20 for baseline (eligibility), $25 for mid-intervention (8-weeks), and $30 for post-intervention (16-weeks). To encourage participants to complete all assessments, they can earn an additional $15 for completing all assessments. This means participants have potential to be compensated $90 total for completing all study activities. Hyperwallet electronic gift cards (e-gift cards) will be provided to participants. Hyperwallet e-gift cards may be used anywhere Visa is accepted. Participants also will be allowed to keep their electronic scale. Participants will not be compensated for completing the intervention or communicating with their coach.

1.0 Audio/Video Recording/Photography

Interview assessments will be audio and/or video recorded to assess reliability of assessors in administration or for subsequent qualitative analyses.

After each session, audio and/or video files will be transcribed (e.g., automatically by Zoom, manually by an approved research member) and the recordings and transcriptions will be uploaded to the FSM research files and removed from the recording device. Additional edits may be made to the transcription files by an approved research team member. All transcripts of the recordings will be de-identified. Recordings and transcripts will be stored on password protected computers and secure servers only accessible to approved study staff.

15.0 Potential Benefits to Participants:

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 trial.

16.0 Risks to Participants:

There are minimal risks associated with participating in the 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. 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 questions the participant has about this. There is also the remote possibility that research records will be subpoenaed by a court of law. All 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 treatment referral information. 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.

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

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, will be obtained. Identifying information will be obtained with the screen to allow for the study team to contact the potential participants to schedule the eligibility assessment. Participants' identifying information will be kept private. All participants will receive a study ID to protect their identity during assessments and for data analysis.

All self-report questionnaire 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. Research interviews will occur by video or telephone call, and questionnaires will be e-mailed as a link for participants to complete on their own. 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 using the intervention will create a unique password to use with the intervention. Passwords will only be known to participants.

Participant data that are exported from the mobile intervention will be 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 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 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. 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.

18.0 Data Monitoring Plan to Ensure the Safety of Participants:

Any participants who do not show symptom improvement by the end of the intervention will be offered referral information for treatment. The principal investigator will be responsible for assembling the 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 accrual and retention will be presented to the study team on a monthly basis.

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.

19.0 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.

20.0 Qualifications of Research Team to Conduct the Research:

The study team has expertise spanning all areas required to successfully conduct this study. **Dr. Graham**'s research program focuses on designing, optimizing, and implementing digital interventions, primarily for eating disorders and obesity. She has been working on trials of digital interventions for more than 12 years. **Dr. Wildes** is a renowned leader in the treatment of eating disorders and obesity, specializing in evaluating mechanisms of aberrant eating pathology.

References

1. Steirman B, National Center for Health S. *National Health and Nutrition Examination Survey 2017 - March 2020 prepandemic data files : development of files and prevalence estimates for selected health outcomes*. National health statistics reports no 158. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics; 2021.
2. Di Angelantonio E, Bhupathiraju SN, Wormser D, et al. Body-mass index and all-cause mortality: individual-participant-data meta-analysis of 239 prospective studies in four continents. *The Lancet*. 2016;388(10046):776-786. doi:10.1016/S0140-6736(16)30175-1
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*. Jan 2013;309(1):71-82. doi:10.1001/jama.2012.113905
4. Kim DD, Basu A. Estimating the Medical Care Costs of Obesity in the United States: Systematic Review, Meta-Analysis, and Empirical Analysis. *Value Health*. Jul-Aug 2016;19(5):602-13. doi:10.1016/j.jval.2016.02.008
5. Wilfley DE, Citrome L, Herman BK. Characteristics of binge eating disorder in relation to diagnostic criteria. *Neuropsychiatr Dis Treat*. 2016;12:2213-23. doi:10.2147/ndt.s107777
6. American Psychiatric Association. *Diagnostic and statistical manual for mental disorders*. 5th ed. American Psychiatric Association; 2013.
7. Mitchell JE. Medical comorbidity and medical complications associated with binge-eating disorder. *Int J Eat Disord*. Mar 2016;49(3):319-23. doi:10.1002/eat.22452
8. Meany G, Conceição E, Mitchell JE. Binge eating, binge eating disorder and loss of control eating: effects on weight outcomes after bariatric surgery. *Eur Eat Disord Rev*. Mar 2014;22(2):87-91. doi:10.1002/erv.2273
9. Iacovino JM, Gredysa DM, Altman M, Wilfley DE. Psychological treatments for binge eating disorder. *Curr Psychiatry Rep*. Aug 2012;14(4):432-46. doi:10.1007/s11920-012-0277-8
10. Grilo CM. Psychological and Behavioral Treatments for Binge-Eating Disorder. *J Clin Psychiatry*. 2017;78(Suppl 1):20-24. doi: 10.4088/JCP.sh16003su1c.04.
11. Davis HA, Graham AK, Wildes JE. Overview of Binge Eating Disorder. *Current Cardiovascular Risk Reports*. 2020/11/04 2020;14(12):26. doi:10.1007/s12170-020-00664-2

12. Yardley L, Spring BJ, Riper H, et al. Understanding and Promoting Effective Engagement With Digital Behavior Change Interventions. *Am J Prev Med*. Nov 2016;51(5):833-842. doi:10.1016/j.amepre.2016.06.015
13. Household Food Security in the United States in 2018, ERR-270. (Economic Research Service.) (2019).
14. Hazzard VM, Loth KA, Hooper L, Becker CB. Food Insecurity and Eating Disorders: a Review of Emerging Evidence. *Curr Psychiatry Rep*. Oct 30 2020;22(12):74. doi:10.1007/s11920-020-01200-0
15. Harris SR, Carrillo M, Fujioka K. Binge-Eating Disorder and Type 2 Diabetes: A Review. *Endocr Pract*. Feb 2021;27(2):158-164. doi:10.1016/j.eprac.2020.10.005
16. Chevinsky JD, Wadden TA, Chao AM. Binge Eating Disorder in Patients with Type 2 Diabetes: Diagnostic and Management Challenges. *Diabetes Metab Syndr Obes*. 2020;13:1117-1131. doi:10.2147/dmso.S213379