Protocol Title: Psychological Mechanisms Linking Food Insecurity and Obesity: A Quantitative Pilot Study (Food Mind Pilot I)

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Summary:

This pilot study will investigate an emergent risk factor for obesity: food insecurity, which is defined as the limited or uncertain availability of nutritionally adequate and safe foods. While paradoxically linked, numerous studies have shown a significant association between food insecurity and obesity. Moreover, recent narrative works have developed new, untested hypotheses linking food insecurity and obesity positing the causal role of psychological mechanisms. Given this, this quantitative pilot study will collect new psychological data in a sample of food secure and food insecure adults with and without obesity to examine the connections between food insecurity, body weight, and psychological constructs. The overarching objective of the study is to gather pilot data to identify potentially new intervention targets that will be used in future studies to more rigorously investigate the relationship between food insecurity and obesity.

Background:

Food insecurity is defined as a lack of "nutritionally adequate and safe foods" or the limited or uncertain ability "to acquire acceptable foods in socially acceptable ways"[1] and is most often determined by household income, or restricted monetary resources.[2] In 2015, 12.7 percent of U.S. households were food insecure at some point during the year,[3] with the prevalence being even greater in Louisiana at 25.7%.[4] Food insecurity is now recognized as a pressing health issue in the United States given its linkage to greater body weight.[5-8] The relationship between food insecurity and obesity has been labeled a paradox given that food insecurity potentially causes reduced food availability and obesity is often related to increased food intake.[5,9,10] However, nationally representative data indicate that on average women who report being food insecure weigh 5.2 kilograms more than those who are food secure.[11]

Food insecurity has also been shown to impede intervention response and effectiveness.[12,13] Evidence from intervention-based studies demonstrates that food insecure participants often do not experience equivalent response in intervention targets. For example, studies have found that food insecure individuals did not see equivalent decreases in blood pressure compared to food secure participants.[12] Similarly, food insecurity has been shown to be a barrier to diabetes self-management[13,14] and antiretroviral therapy adherence.[15]

Most research evidence has largely implicated diet and eating behaviors in the linkage between food insecurity and obesity, which includes maladaptive dietary behaviors and poor diet quality,[16,17] and physiological adaptations to episodes of food insecurity, or 'feast-famine' cycles associated with an abundance of food followed by food shortage.[9,16,18,19] While this evidence demonstrates that food insecurity is a risk factor for obesity and related comorbidities (e.g., metabolic syndrome, poor cardiovascular health),[20,21] more research is needed to better elucidate the key mechanisms that work in this pathway.

Recently, a body of narrative literature has been published that develops new conceptual frameworks and hypotheses that posit causal explanations in the relationship between food insecurity and increased body weight.[7,22,23] The common theme shared among these reviews is the explicit designation of the role of decision-making psychological

mechanisms in the relationship between food insecurity and obesity. While there is empirical evidence linking psychological constructs, such as *delay discounting*, less *grit* (perseverance), and lack of *future time orientation*, to greater body weight,[24-26] there is a dearth of studies taking similar approaches in samples that explicitly include food insecure individuals. Only a single study has demonstrated the association of delay discounting and poor future time orientation with food insecurity, yet this study did not triangulate these associations with body weight.[27] Further, theoretical and empirical evidence also points to the importance of *perceived social status* in the association between food insecurity and weight status.[22,28]

Specific Aim:

Food insecurity may play a significant role in the etiology of obesity, as well as the treatment and prevention of weight gain and concomitant adverse health outcomes. The current pilot study will examine emergent hypotheses by investigating the role of *psychological mechanisms* in the relationship between *food insecurity* and *obesity*. We will be the first to assess four key psychological constructs (delay discounting, grit, future time perspective, and subjective social status) in a sample of food secure and food insecure adults with and without obesity. This objective will be achieved via a cross-sectional, observational pilot study collecting quantitative data. The following specific aim will be addressed:

<u>Aim 1.</u> Examine associations among psychological mechanisms, food security status, and body mass index (BMI).

We will measure and evaluate four key psychological constructs via direct assessment in normal weight and overweight/obese adults. Participants will be categorized as food secure or food insecure. From these data, we will examine associations between food security status, weight status, and each of the following potential psychological mechanisms drawn from the extant literature:

1) delay discounting
2) grit
3) future time perspective
4) subjective social status

Study Overview/Design:

This is a cross-sectional, observational pilot study to collect quantitative data. Key independent variables are food security status and BMI. Primary endpoints are four psychological constructs: 1) delay discounting, grit, future time perspective, and 4) subjective social status. We will also assess a number of key measures, including health literacy, sociodemographics, food assistance use, and dietary quality. This study is community-based, with all screening and study assessments conducted in designated community locations, including partnering food pantries, local YMCAs, and other community centers.

Study Participants:

The target study sample will be no more than 60 food secure and food insecure women and men aged 18 to 49 years with a BMI of 20.0 kg/m^2 or greater. Food security status will be determined by the 6-item Food Security Scale. Participants will be matched on race for each of the four participant categories with approximately 14 subjects in each category (see Table 1).

Table 1. Sample size		Food security status	
		Food secure	Food insecure
BMI	< 25 (Normal)	~14	~14
	≥ 25 (Overweight/Obese)	~14	~14

Recruitment:

Participants will be recruited in designated community locations by trained study staff who will assess each potential participant's interest in participating in the study and screen for eligibility. Our community outreach efforts may include, but are not limited to, flyers, presentations, health fairs, and attendance at site-specific community events. Additional recruitment efforts may include email blasts, social media posts, newsletters, etc.

Eligibility Criteria:

We will perform a screening assessment to determine initial eligibility. Eligibility will be assessed with the following criteria (see below). If deemed eligible, participants will be enrolled into the study.

Eligibility criteria include:

- Age 18-49 years
- BMI ≥ 20.0 kg/m^2
- Able to read and write using the English language
- Willing to provide written informed consent

Exclusion criteria include:

- Pregnancy

Study Timeline:

Screening and study assessments will comprise a single study visit (see Table 2). However, if a participant is unable to complete all study assessments in a single visit, they will be allowed to schedule an additional study visit. Participants will be screened on-site at designated community locations to assess eligibility. Informed consent will be obtained during the screening assessment. Participants will be formally oriented to the study by receiving information on the purposes and goals of the study, as well as study measures and procedures. Eligible participants who provide informed consent will complete all study assessments.

Table 2. Schedule of study procedures

Screening Assessments
Informed consent
Anthropometrics (height and weight; BMI)
Health literacy assessment
Food security questionnaire
Sociodemographic questionnaire
Study Assessments
Food assistance question
Dietary quality
Psychological questionnaires

Measures and Procedures:

Anthropometrics. Height and weight will be measured using a portable stadiometer and digital scale, respectively. Measurements will be taken without shoes and recorded to the nearest 0.1 cm and 0.1 kg, respectively. Body Mass Index (BMI; weight in kilograms/height in meters^2) will be calculated and used to categorize an adult participant as normal weight, overweight/obese.

Health literacy. The REALM short form (SF) will be used to measure health literacy in participants. This assessment is a standardized series of seven words. The score (0-7) provides an assessment of how well the participant will be able to understand the additional questionnaires. Participants scoring 0-3 on the REALM SF will be provided assistance by study staff in completing the other questionnaires. Patients scoring 4-7 on the REALM SF will be allowed to complete the other questionnaires on their own, but will be offered assistance as needed.

Food security. Self-reported food security status over the previous 12 months will be measured using the 6-item Food Security Scale.[29,30] This scale is a well-validated measure of food security developed by researchers at the National Center for Health Statistics. Two or more affirmative answers (>2) indicate food insecurity. Participants can also be categorized by levels of food security: 1) high or marginal (0-1), 2) low (2-4), and 3) very low (5-6).[12,27]

Sociodemographics. Participants will be asked to complete a questionnaire that will assess age (date of birth), race/ethnicity, sex, marital status, highest level of education completed, annual household income, number of people in the household, occupation, employment status, and home street address.

Food assistance. Participants will be asked about their use of Federal food assistance, e.g., SNAP (food stamps), WIC, and other forms of non-Federal food assistance (e.g., food pantries, soup kitchens).

Dietary quality. A questionnaire that assesses dietary fat, fruit, vegetable, and alcohol intake will be completed by participants. The questionnaire contains scales from several sources. The National Cancer Institute (NCI) fat screener estimates the percentage of energy from fat by asking participants to report the frequency of consuming specific foods over the past 12 months.[31,32] A standard 7-item fruit and vegetable screener developed by the NCI and National 5 a Day Program asks how often fruit and vegetables were consumed in the past month.[33,34] Three questions related to the frequency of alcohol intake (beer, wine, hard liquor) were adapted from the Brief Questionnaire to Assess Habitual Beverage Intake (BEVQ-15).[35]

Psychological questionnaires. A series of psychological questionnaires will be administered to measure the primary endpoints of interest, which include: 1) delay discounting; 2) grit, 3) future time perspective, and 4) subjective social status.

Delay Discounting is a bias toward smaller, immediate rewards versus larger, delayed rewards[36] and will be assessed via the 27-item monetary choice questionnaire.[37] This questionnaire presents participants with a set of choices between smaller, immediate monetary rewards and larger, delayed monetary rewards. Participants who discount the value of the delayed rewards more steeply are considered to be more impulsive.[37]

Grit is a measure of trait-level perseverance and passion for long-terms goals and will be assessed using the 8-item Short Grit Scale (Grit-S).[38] Scores range from 1 (not at all gritty) to 5 (extremely gritty).

Future Time Perspective is a comprehensive assessment of one's orientation toward the future.[25,27] We will assess future time perspective using 4 instruments.

The future scale of the Zimbardo Time Perspective Inventory (ZTPI) measures psychological orientation toward the future.[39] This scale is comprised of 13 statements with Likert-type responses. Higher scores indicate greater future time perspective.

The Consideration of Future Consequences Scale (CFCS) assesses how individuals consider future outcomes in choosing current behavior.[40,41] This scale contains 14 statements for which individuals indicate whether or not the statement is characteristic of them on a scale of 1-7. Higher scores indicate greater consideration of future consequences, respectively.

Participants will be asked a single question to assess the time period considered for financial planning: "In planning your, or your family's, saving and spending, which of the following time periods is more important to you and your partner, if you have one?" with the following response options: no planning, day to day, the next few weeks, next few months, next year, next few years, next 5-10 years, longer than 10 years.[42,43] Higher values indicate greater future time perspective.

Last, participants' subjective appraisal of longevity will also be assessed via a single question: "What do you think are the chances you will live to age 75 or more (where 0 means there is not a chance you will live to 75 or more, and 100 means you will definitely live to 75 or more)?".[42,43] Higher values indicate greater future time perspective.

Subjective Social Status is one's self-perceived social position in U.S. society and will be measured using the MacArthur Scale of Subjective Social Status.[44] This scale presents a 'ladder' and asks participants to select a rung on which they feel they stand relative to other people in the U.S. Scores range from 1-10, with higher scores representing higher subjective social status.

Power Analysis and Sample Size:

Given that this is a pilot and feasibility study, power analysis and sample size calculations were not performed. It is anticipated that this study will provide variance estimates to inform power and sample size calculations for future grant applications and studies.

Statistical Analysis:

Descriptive statistics will be computed for all variables. Bivariate associations (chi-square tests and Pearson/Spearman correlations) will be assessed between food security status, BMI, and psychological assessment scores. Linear and logistic regression will be used to estimate associations between food security status, BMI, and psychological outcomes. Regression models will include key demographic covariates.

Data Management:

All data will be collected and managed electronically via the Research Electronic Data Capture (REDCap) system. When necessary, data may be collected via paper forms and then entered by study staff into the REDCap system.[45] REDCap is a secure, HIPAA-compliant, web-based application that can be utilized for electronic collection and management of research and clinical trial data. Study data and electronic data capture tools are housed in a secure data center at Pennington Biomedical, and all web-based information transmission is encrypted. The server is backed up nightly and is protected by an enterprise network security firewall. REDCap

will be accessed through the Pennington Biomedical secure website, https://redcap.pbrc.edu, where research personnel are required to enter user ids and passwords previously approved and set up by the Pennington Biomedical REDCap Administrator.

Risks to Subjects and Potential Benefits:

This study does not pose more than minimal risk to participants. This study will be required to have approval from the PBRC Institutional Review Board. PBRC has full accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). All participants will be given time to read the consent form and ask questions with study staff. To continue, the participant must read and sign an informed consent to participate in further assessments. All volunteers are assured of their confidentiality both verbally and in the informed consent form. Efforts to minimize the potential risks of the assessment methods include frequent monitoring by the investigators to assure no participant suffers any adverse effects from participating in the research study. Potential risks associated with study procedures include:

- Height and weight. There is a minimal risk to participants from these measurements.
- Self-report questionnaires. There are no anticipated risks from completing self-report questionnaires. Due to the potentially sensitive nature of the questionnaires, participants may choose to not answer questions.

There are no direct benefits for participation in this study.

Confidentiality:

All attempts will be made to maintain a subject's privacy. Safeguards such as password protected computer and networks have been put in place in order to limit access to subject data. Subjects will be given ample time to read over the consent, ask questions, and agree to participate in the research study. Subjects may decline answering questions they are not comfortable with. Each procedure will be explained to the subject before it is performed. We will always ensure the privacy of the subjects. However, someone from the Pennington Biomedical Research Center may inspect and/or copy the medical records related to the study. Results of the study may be published; however, we will keep participants' names and other identifying information private. Other than as set forth above, participants' identities will remain confidential unless disclosure is required by law.

Sharing of Results with Study Participant:

Participants will be provided a summary results card at the completion of their study visit that will include body composition results.

Data Safety Monitoring Plan:

Food Mind Pilot I is a study with a minimal level of risk to study participants and does not warrant the establishment of an independent Data and Safety Monitoring Board. This plan describes the safety monitoring procedures for the proposed study. The plan will help ensure the safety of all participants. The PI will communicate via electronic submission to the IRB all unanticipated problems as defined by the IRB.

The study investigators will monitor conduct of Food Mind Pilot I. The PI will schedule monthly meetings with study staff to review data on eligibility and recruitment problems. Any significant health problems coming to our attention during the study will be referred to the participant's usual source of medical care, with his/her permission. We will cooperate fully with his/her physician by providing relevant medical records.

Setting:

This study, including screening and assessments, will take place in designated community locations across Baton Rouge.

Compensation:

Participants in this study will receive $25 compensation for participation.

Compensation for Research-Related Injury:

No compensation will be provided for research-related injury.

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