Development and Validation of a Brief Food Noise Questionnaire

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Background Information

As weight loss drugs have become increasingly commonplace and positive results are observed in real-life clinical settings[1], news articles have documented anecdotes from patients who reported having "food noise" in their heads quieted after taking these drugs (particularly semaglutide) for weight management[2–4]. Based on these anecdotal reports, one previous review defined food noise as "heightened and/or persistent manifestations of food cue reactivity, often resulting in intrusive food thoughts and maladaptive eating behaviors[5]." This definition, however, views food noise largely as a cue reactivity phenomenon, which is not inclusive of reports of food noise from patients since they report experiencing food noise even in the absence of food cues[6]. Many patients also report that food noise diminishes or disappears when they take GLP-1 receptor agonists[2–4,6], and patients report that food noise can be fairly constant and is frequently intrusive. They also indicate that food noise can disrupt daily life or quality of life and it can make engaging in health behaviors difficult. Thus, we propose the following definition: "Constant, intrusive thoughts about food that are disruptive to daily life and make healthful behaviors extremely difficult."

Currently, there are no validated questionnaires to assess food noise. As such, the purpose of this study is to develop and validate a brief food noise questionnaire. A total of 400 participants will be asked to complete the new food noise questionnaire. A subsample will also be asked to complete the questionnaire a second time to evaluate test-retest reliability. Similarly, a separate subsample will also complete additional questionnaires to test convergent and discriminant validity. These details are outlined below.

Study Objectives

The purpose of the research reported herein is to develop and test the reliability and validity of a brief questionnaire to measure food noise.

Study Timeline

We expect the study to be completed within 6 months.

Setting
This study consists of online electronic surveys (required for participation).

Study Endpoints
Study endpoints include participants' responses to the food noise items and the questionnaires outlined herein. Demographic information will be collected and analyzed, including education level, household income, employment status, age, sex, race, height, weight, weight history (e.g., history of weight gain or loss, diet attempts, weight fluctuations, disordered eating, etc.), medical conditions, and medication usage.

Prior Approvals
This study will receive Institutional Review Board approval from Pennington Biomedical Research Center prior to survey distribution and data collection.

Procedures and Recruitment Methods
Reliability Tests:

a. Internal consistency reliability (Cronbach's Alpha)[7] will be assessed with the entire dataset (N=400). Sample sizes were developed based on the assumption that the instrument would have no more than ten items and only one factor[8].
b. Test re-test reliability will be assessed by administering the food noise questionnaire two times, approximately 7 days apart, in a subsample of 150 participants (see Table 1).

Validity Tests:

a. The construct will be first defined via a literature review and ongoing discussions with the study team. Then, approximately 10-15 items will be generated, which will likely be reduced to ~6-8 items prior to subsequent item analysis. Items that the team does not believe represent the construct of interest will be eliminated.
b. Content validity will be examined by asking 4-6 experts and ~10 laypersons to review the items and report if they adequately assess the construct of interest. This will be completed either via interview, focus groups, and/or ratings on a questionnaire that includes open-ended questions.
c. Subsequently, an exploratory factor analysis (EFA) will be conducted with 150 participants from the main sample, followed by a confirmatory factor analysis (CFA) with the remaining 250 people from the main sample.
d. *Construct validity (n=250).* In addition to completing the demographics form and the new food noise questionnaire, 250 participants from the sample will also complete the following five instruments to assess convergent and discriminant validity.
    a. *Convergent validity will be assessed with the following instruments.*
        i. The Food Preoccupation Questionnaire[9]. This questionnaire is a 26 item self-reported measure of thoughts about food. Of these, 3 assess frequency, and 23 assess emotional valence of thoughts, which could be either positive (9 items), negative (9 items) or neutral (5 items). The response options are rated on a 5-point scale ('completely disagree', 'disagree a bit', 'neither agree nor disagree', 'agree a bit', 'completely agree'). Four items were reverse scored. For the present validation study, only the 3 frequency subscale items will be administered.

ii. Food Craving Questionnaire – Trait (FCQ-T)[10]. The FCQ-T measures the stable (trait) dimensions of food cravings. The FCQ-T consists of 39 items and items are scored on a 6-point scale ranging from never to always. Its original form comprises nine subscales measuring food cravings as (1) intentions to consume food, (2) anticipation of positive reinforcement, (3) relief from negative states, (4) lack of control over eating, (5) preoccupation with food, (6) hunger, (7) emotions, (8) cues that trigger cravings, and (9) guilt. For the present validation study, only the six items on the preoccupation with food subscale will be administered.

b. *Discriminant validity will be assessed with the following instruments.*
   i. The Patient Health Questionnaire (PHQ-8)[11]: The PHQ-8 contains the first eight items of the PHQ-9 and it does not assess suicidal ideation or intent.
   ii. The Perceived Stress Scale (PSS)[12]. The PSS is a 10-item instrument designed to measure the degree to which situations in one's life are considered stressful.
   iii. General Anxiety Disorder-7 (GAD-7)[13]. The GAD-7 is a 7-item self-report questionnaire, assessing anxiety symptoms in the past two weeks (e.g. "Feeling nervous, anxious, or on the edge").

As mentioned above, all 400 participants will first complete the demographic information survey and the new food noise questionnaire. Of these 400 participants, 250 participants will then complete the questions outlined above to assess construct validity. The remaining 150 participants will be asked to complete the food noise questionnaire again in approximately 1 week to assess test-retest reliability.

Participants will be offered an opportunity to complete the survey via a third-party panel provider that is in partnership with the WW team. The survey will be conducted using the Qualtrics system, which is a HIPAA compliant system[14]. Participants will be offered an opportunity to complete the survey on Qualtrics secure web application. Participants will learn of the study via email from the panel provider, which is the company who will administer the survey and who retains an email list of possible survey respondents. We aim to recruit a heterogeneous sample of participants. In line with the latest Centers for Disease Control and Prevention (CDC)[14] and U.S. Census Bureau report[15], our goal is to recruit a balanced sample of participants in terms of BMI, race, and ethnicity. Thus, recruitment will be stratified based on BMI, race, and ethnicity. We plan to recruit approximately 31% of participants with overweight (BMI between 25 to 29.9 kg/m^2), 42% with obesity (BMI over 30 kg/m^2), and 9% with severe obesity (BMI over 40 kg/m^2). In addition, we plan to recruit a sample that is approximately 60% white, 18% Hispanic or Latino, 12% Black, 5% Asian and 5% other races. The panel provider will monitor the stratified recruitment for the initial survey with the entire sample (n=400) and for the 150 participants who complete test-retest reliably and the 250 participants who will answer additional questions to assess construct validity.

The food noise questionnaire will take ~5 minutes to complete. The additional questionnaires will take ~20 minutes to complete, and this is restricted to the subsample of 250 participants who will complete the additional questionnaire to evaluate construct validity. Data collection consists of responding to multiple choice response questions.

Table 1. Summary of study procedures

The Initial Surveys **400 participants** will fill out: - Demographics survey - Food Noise Questionnaire **Time required:** ~ 25 minutes	
The Test-retest Reliability Sample A random subset of **150 participants** will repeat the Food Noise Questionnaire (8 items) about 7 days after the first assessment (**Test re-test reliability**)	**The Construct Validity Sample** A random subset of **250 participants** will also complete questions from the following questionnaires (**Construct validity**) For convergent validity: - The Food Preoccupation Questionnaire- 3 items - Food Craving Questionnaire – Trait – 6 items For discriminant validity: - The Patient Health Questionnaire – 8 items - The Perceived Stress Scale – 10 items -General Anxiety Disorder-7- 7 items
Time required: ~5 minutes	**Time required:** ~20 minutes
Compensation: $25	**Compensation:** $25

Number of Participants

The goal is to recruit no more than 400 individuals.

Inclusion and Exclusion Criteria

Inclusion Criteria: This study is open to adults (aged 18 years and above) who reside in the United States.
Exclusion Criteria:

- Individuals who do not provide informed consent will not progress to the survey questions
- Individuals who are currently participating in a weight loss program
    - Participating in a structured program (WW, Optifast, Noom Weight, etc.)
    - Using a prescription or over-the-counter medications
    - Participating in a structured lifestyle change program (e.g., DPP).
- Individuals who have a BMI lower than 18.5 kg/m^2

Consent Process

Prior to beginning the survey, participants will receive instructions that explain the purpose of the study, that their participation is voluntary, and if they agree to start the survey, they are providing electronic consent to participate. The instructions will also alert them to the minimal required set of responses for all questions and their respective time commitment for each form. Specifically, 95% of items from the surveys must be answered to be considered complete.

Compensation

Participation in this study is voluntary. Participants who successfully complete the surveys can receive $25 compensation via either a cash payout or $25 worth of points on a gift card. Successful completion of the surveys is defined in the survey documents. A proprietary algorithm with approximately 32 digital fingerprints will be used to ensure participants do not complete the survey twice and to eliminate bots

from completing surveys. Any identifiable information of the participants held by the panel provider will not be shared with the investigators.

Risks and Benefits to Participants

This study involves minimal risk to participants. There is no known or anticipated risk to completing this self-report survey. This study confers no direct benefits for participation.

Withdrawal of Participants

Participation involves completing online surveys in either one sitting or two sittings. The investigators do not have the ability to withdraw participants during survey completion.

Data and Participant Confidentiality

All attempts will be made to maintain a participant's privacy. Personal identifying information will be collected by the panel provider and kept separate from the research data. The panel provider will adhere to all laws and regulations around data storage and will not share personal identifying information without respondents' consent and fully complies with guidelines for online data collection and privacy. In addition, each participant will be assigned a participant ID. The investigators at PBRC and WW will have access to the participant ID and the deidentified research data.

Sharing of Results with Participants

Individual results will not be shared with participants. Compiled results will be shared in scientific presentations, manuscript publications and future possible grant submissions.

Provisions to Monitor the Data to Ensure the Safety of Participants

This study involves no greater than minimal risk to the participants; however, we will follow all standard procedures of clinical research at Pennington Biomedical to ensure subject privacy.

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