Study Protocol

Title: An Intervention to Promote Smoking Cessation among Adults with Food Insecurity

ClinicalTrials.gov Identifier NCT05259852

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1.0 Objectives

Tobacco use continues to be a leading cause of preventable disease and early death. The majority of people who smoke are interested in quitting and attempt to quit each year, but successfully quitting can be challenging for many reasons. In particular, smoking cessation can be especially hard when smokers are dealing with unmet social and health needs and areas of financial stress, which are disproportionately experienced by low-income smokers. In this study, we extend previous research showing that food insecurity is independently associated with higher odds of smoking and can act as a barrier to quitting smoking. Therefore, we design and test a 12-week intervention to assist food-insecure smokers who are ready and willing to make a quit attempt. Beyond providing the quit assistance that smokers normally receive, the research seeks to address food insecurity in the short-term by providing economic food assistance during the quit attempt that will help to meet food needs. We will adapt a patient navigation model in which a designated study navigator can help bridge resources and referrals related to tobacco cessation and food access, and provide economic food assistance based on individualized needs. We will recruit 60 participants for a 12-week study, and all participants will be smokers who are ready to quit and have recently experienced food insecurity. All participants will receive quit assistance and information on local food assistance resources, and a monthly check-in from the navigator. In addition, half of the participants (n=30) will be randomly assigned to the intervention arm, and will receive economic food assistance to partially meet their food needs and reduce food insecurity during the cessation attempt. We will assess feasibility and acceptability of the intervention, and preliminary outcomes related to smoking cessation, such as the number of quit attempts lasting 24 hours or more and the longest length of abstinence from tobacco. By conducting this study, we seek to understand whether this type of intervention is feasible to conduct, and acceptable to those who participate. The study findings will serve as the basis of future research on understanding and addressing tobacco-related and food insecurity-related health disparities. Our main research question is whether addressing food insecurity specifically during a smoking cessation attempt is helpful for increasing quitting success rates.

2.0 Background

2.1 Relevant Prior Experience and Gaps in Current Knowledge

In the U.S., the existence of socioeconomic disparities in tobacco use is a widely known public health problem.[1] Of the numerous factors that account for socioeconomic disparities in smoking, one major reason is due to disparities in successful quitting. That is, regardless of socioeconomic background, the majority of smokers are interested in quitting (68%), and over half (55%) report making at least one 24-hour quit attempt in the past 12 months.[2] However, there are disparities in rates of successful quitting by socioeconomic status.[3] There is a need to consider novel strategies to address cessation disparities to mitigate the disproportionate burden of tobacco-related health problems in socioeconomically disadvantaged population groups.

2.2 Relevant Preliminary Data

There are many sources of socioeconomic stress that disproportionately affect populations with disadvantage. Food insecurity occurs when there is lack of access at all times to enough food for an active, healthy life.[4] In 2019, 35% of households living below the federal poverty level (FPL) experienced food insecurity, compared to 5% of households above 185% of FPL.[4] Food insecurity is also significantly higher among racial/ethnic minority households, female-headed households, and households with children.[4] Food insecurity is an important social determinant of health that is independently predictive of a range of chronic disease outcomes[5], influencing health behaviors related to chronic diseases (such as medication adherence, diet quality, eating behaviors, and substance use). As such, food insecurity's effects on health behaviors are most widely considered within specific chronic diseases that are diet-sensitive (such as diabetes, hypertension, and hyperlipidemia), or are transmitted through risky behaviors especially among vulnerable populations (such as people living with HIV). Beyond behaviors within specific chronic diseases, food insecurity has also been linked with tobacco smoking behavior.[6] Food insecurity is known to increase the odds of current smoking, independent of poverty and other socioeconomic indicators[7], as well as mental health characteristics that increase likelihood of smoking.[6]

A growing body of research has suggested a bidirectional and mutually reinforcing relationship between food insecurity and tobacco use.[6] Food insecurity is conceptualized to pose a unique barrier to quitting[8,9] due to factors such as psychological stress from food insecurity and appetite regulation from nicotine. In turn, however, tobacco-related expenditures can compete with household spending (a phenomenon known as smoking-induced deprivation[10]) to exacerbate food insecurity. While the body of research suggests that addressing food insecurity could enhance cessation outcomes, this has not been formally tested to our knowledge. That is, such findings on food insecurity and smoking cessation are drawn mainly through epidemiological studies following a nationally representative sample of smokers over time[8], or cross-sectional studies estimating the quit ratio[9] (i.e., the proportion of former smokers among ever smokers). In order to examine food insecurity's potential effects on the cessation process and outcomes, and whether addressing food insecurity results in more favorable cessation outcomes, there is a need to conduct more rigorous clinical and intervention-based studies.

2.3 Scientific Rationale and Significance

This proposal is significant for smoking cessation research because there are relatively few evidence-based cessation interventions that seek to address the role of socioeconomic stress (such as food insecurity) to improve cessation outcomes. This proposal is also significant for food security research. With food insecurity's wide-ranging adverse impacts on chronic disease and health outcomes, food insecurity has been estimated to contribute $77.5 billion annually in excess healthcare costs[11]. The latest food security evidence review by Feeding America (the largest hunger relief organization in the U.S.) included smoking as a known factor that increases the risk of food insecurity[12]. By addressing food insecurity as a potential strategy to promote successful quit attempts, this research

has implications for addressing the double burden of food insecurity and tobacco use. As one of the first interventions to examine whether addressing food insecurity affects cessation outcomes, this research provides innovative directions in tackling socioeconomic disparities in smoking.

3.0 Study Endpoints

As a pilot study, primary endpoints are feasibility and acceptability of the intervention. Secondary endpoints are the number of quit attempts lasting 24 hours or more over the past 3 months, and the longest length of smoking abstinence in days over the past 3 months.

4.0 Study Intervention

Experimental procedures involve the provision of economic food assistance throughout the 12-week duration of the study. Participants in the intervention group will be provided with extra funds intended to provide short-term relief from food insecurity during the tobacco cessation attempt. Funds are distributed by either VISA gift cards, a check, direct deposit, or a Zelle transaction, based on the participant's choosing. This is done on a monthly basis for 3 months, at a maximum of $250, divided across 3 months.

5.0 Procedures Involved

5.1 Study Design (Overview)

For most participants, the full length of participation is about 2.5-3 hours spread across 13 weeks (intervention is 12 weeks, and an additional week is included as pre-intervention baseline). For a small proportion of participants (n=8-10) who agree to participate in an end-of-study qualitative interview to share their experiences of the study, the full length of participation is about 2.5-3.5 hours.

1. Telephone conversation to discuss study, assess interest and eligibility, answer participant questions, and provide instructions on consent process (30 minutes)

2. Receive consent form via mail. Prior to randomization, complete a baseline assessment via telephone/online survey (30-45 minutes)

3. At week 1 post-randomization, connect with study navigator by telephone to receive information and referrals about tobacco cessation and food assistance (30 minutes)

3a. Participants in the intervention arm will receive instructions about funds (5-10 minutes)

4. Week 4 post-randomization, check-in call with study navigator (10-15 minutes) 4a. Participants in the intervention arm receive additional funds (0-1 minute required for participant)

5. Week 8 post-randomization, check in call with study navigator (10-15 minutes)

5a. Participants in the intervention arm receive additional funds (0-1 minute required for participant)

6. Week 12 post-randomization, follow-up assessment (30-45 minutes)

7. Post-intervention qualitative interviews (30-45 minutes)

5.2 Detailed Description of Procedures

POTENTIAL PARTICIPANT IDENTIFICATION: We will use the electronic health record (EHR) to prescreen potential participants for this study. Potential participants will comprise of current patients MetroHealth patients from a total of 7 MetroHealth sites within Cuyahoga county. We will use the EHR to prescreen for age (21 years or older), smoking status as documented in the EHR (documented as currently smoking), and food insecurity status (documented as food insecure based on social determinants of health screening conducted during the most recent visit). Using this list, we will send out a recruitment packet in the mail, consisting of a 1-page study flyer with key information and a copy of the informed consent document, in the form of a non-return cover memo. The flyer will instruct potential participants to contact the study team by telephone for further information about the study, and to see if they qualify.

As needed and based on recruitment rate, the research team will also make telephone calls to follow-up with potential participants, after having sent recruitment letters (i.e., there is no “cold” calling without sending letters beforehand). Using the prescreened list of individuals, we will randomly follow up with individuals on the list until we reach the enrollment target for the wave (n=15-20 enrolled in each wave; 3-4 enrollment waves; 60 participants in total will be recruited for this study).

RECRUITMENT, CONSENT, and BASELINE SURVEY: Recruitment will be conducted by telephone, and there will be no face-to-face visits as part of this study. The study coordinator will use a script to inform participants about the research study being conducted, to assess interest in participating, and to conduct an eligibility screening for interested participants. Individuals will be informed prior to the eligibility screening that not all people who are interested will qualify for the study based pre-determined eligibility criteria. For those who are interested, meet eligibility criteria, and wish to participate, the coordinator will go over the consent form, give the opportunity to ask any questions, and after all questions have been addressed, will collect verbal consent. Verbal consent will be documented on REDCap, including an attestation section from the research coordinator collecting consent. All potential participants will have been mailed a hard copy of the consent form (non-return cover memo) at the recruitment phase. Participants can be sent another copy as needed. After the research team receives verbal consent, the baseline assessment will be conducted by the research coordinator via an online or telephone survey (based on participants' preference) that is expected to last up to 45 minutes.

RANDOMIZATION, ALLOCATION: After the baseline telephone (or online) survey is completed, participants will be randomized in the Intervention arm or the Control arm with a 50/50 chance to be randomized in either arm. The study analyst who has no contact with participants will use a computer-generated random number table to assign participants. In either arm, in Week 1 of the study, all participants will be connected to receive usual care for tobacco cessation, based on their preferences. In either arm, the study navigator (a community health worker) will review participant responses from the baseline telephone survey and reach out to all participants by telephone. This conversation may involve referrals to the tobacco quitline, referrals to counseling/classes offered at MetroHealth or in the community (such as Freedom from Smoking classes), nicotine replacement therapy and/or pharmacotherapy as prescribed by their primary care provider. The study navigator will provide linkages and information to the services available to the participant, which will be documented in a semi-structured call log, and used as the basis of following up on use of tobacco cessation services in subsequent telephone check-ins in Week 4 and Week 8.

In either arm, participants also receive information from the study navigator about local food assistance resources available to them, such as a list of food pantries and community meal sites and eligibility information about federal food assistance programs. Provision of this information will also be documented by a semi-structured call log, and will be used as the basis of following up on food assistance resources in subsequent check-ins in Week 4 and Week 8. Information about tobacco cessation and food assistance resources are provided by telephone and/or in writing, which is within the scope of work for a community health worker.

In the Intervention arm only, participants will receive economic food assistance to meet their individual food and grocery needs during the cessation attempt/study period. This is provided on a monthly basis (3 times during the 12 weeks of the study) during Week 1, Week 5, and Week 9.

Participants in the Intervention arm will be provided $83 per month (for a total of $250 for the 12 weeks) to partially support the cost of food (i.e., provide short-term food insecurity relief) during the cessation attempt. These funds will be in the form of VISA gift cards, a check, a direct deposit transaction, or a Zelle transaction, depending on the participant's choosing. The check, direct deposit, and Zelle options are processed through PNC Bank's E-payment system. We are NOT collecting any bank information from the participants. The participant will confirm their bank account information with PNC to deposit the funds or mail the check, but the researchers will not see that information.

Follow-ups: About 4 weeks after randomization, the study navigator will conduct a general check-in call with all participants by telephone to follow-up on referrals provided and additional referrals needed. The length of the call is anticipated to be 15 minutes. The content/topics and length of discussions will be documented through call logs.

About 8 weeks after randomization, the study navigator will conduct a general check-in call with all participants by telephone to follow-up on referrals provided and additional referrals needed. The length of the call is anticipated to be 15 minutes. The content/topics and length of discussions will be documented through call logs.

Twelve weeks after randomization (end-of-study), the study coordinator will contact participants to complete the follow-up telephone or online REDCap survey, which is expected to last 30-45 minutes.

END-OF-STUDY QUALITATIVE INTERVIEWS: Participants who were randomized to the intervention group and have completed the protocol will be invited to participate in an end-of-study qualitative interview to provide more context about food access, and to share their experiences with the intervention. Recruitment: Similar to the recruitment procedures for the overall study, we will first mail an invitation letter to prior participants, who can contact the research team if they are interested and willing to discuss their food access and study intervention experiences through a telephone interview. As needed, we will follow up with a telephone call to the target subsample of participants who were sent invitation letters. Consent: Verbal consent will be documented on REDCap, including an attestation section from the research staff member collecting consent. All potential participants will have been mailed a hard copy of the consent form (non-return cover memo) with their invitation letter. Qualitative interviews: Semi-structured, one-on-one interviews will be conducted by telephone or Zoom, and is expected to last 30-45 minutes. The semi-structured interview will ask questions related to participants' food shopping habits and practices, and participants' perceptions about the impact of the economic intervention.

5.3 Risk Minimization Procedures and Data Collection Materials

To minimize risks related to annoyance or discomfort over study-related assessments (i.e., surveys and check-in calls with the study navigator), we will inform all potential participants that assessments may ask personal questions, and the estimated duration of the assessments. Participants have the option to skip any question that they do not wish to answer in the surveys. To minimize risks related to potential breach of confidentiality of research participants, we will use secure research systems, namely REDCap, for store any research-related information. To minimize any unforeseeable economic risks (e.g., potential theft of the VISA gift cards), we will ask all participants to keep their participation in this study private (such as not posting on social media about participation). All data collection materials include an Eligibility Script, a Baseline/Follow-up Survey, a Call Log, and a Qualitative Interview Document. All of these sources are attached in the IRB submission.

5.4 Type of Data Collected and How Data is Obtained

We are collecting both existing and prospective data. Existing data are collected using electronic health records to ascertain potential participants' age, smoking status, and food insecurity screening status. Prospective data are obtained through a baseline and 12-week follow-up survey, collected through REDCap (survey-administered telephone survey, or self-completed survey), and through semi-structured telephone call logs kept by the study navigator.

For end-of-study qualitative interviews, the interviews will be audio-recorded and transcribed verbatim.

6.0 Inclusion and Exclusion Criteria

6.1 Screening Process

Participant eligibility will be determined using a screening questionnaire, by the research coordinator. Prior to administering the eligibility questions, all potential participants will be notified that there are specific inclusion criteria for the study, and not everyone will qualify for the study. Potential participants will be notified after the end of the screening questionnaire whether they are eligible or ineligible based on their responses. In some cases, it is possible that eligibility may not be readily apparent. In those cases, potential participants will be informed that their responses will be reviewed by the study PI, and they will be followed up in the next few days.

6.2 Inclusion and Exclusion Criteria

Inclusion:

- Aged 21 or older
- Current tobacco smoker, defined as having smoked daily over the past 7 days
- Willing to make a serious quit attempt in the next 30 days (“Yes” to “In the next 30 days, are you willing to try quitting smoking for at least 24 hours?”)
- Considered food insecure, based on past 30-day screening using the 2-item Hunger Vital Sign, or by virtue of having visited a food pantry in the past 30 days
- A reliable telephone number and a local mailing address where participant can be reached during the duration of the study

Exclusion:

- Aged 20 or younger
- Non-smoker, or a current tobacco smoker who did not smoke daily over the past 7 days
- Not interested in quitting at this time, assessed by unwillingness to make a serious quit attempt in the next 30 days (“No” to “In the next 30 days, are you willing to try quitting smoking for at least 24 hours?”)
- Did not recently experience food insecurity, based on past 30-day screening using the 2-item Hunger Vital Sign, or has not visited a food pantry in the past 30 days
- Does not have a reliable telephone number and a local mailing address where participant can be reached during the duration of the study

7.0 Recruitment Methods

7.1 When, Where, and How Potential Participants are Recruited

Recruitment will be conducted by telephone, and there will be no face-to-face visits as part of this study. The study coordinator will use a script to inform participants about the research study being conducted, to assess interest in participating, and to conduct an eligibility screening for interested participants. Individuals will be informed prior to the eligibility screening that not all people who are interested will qualify for the study based pre-determined eligibility criteria. For those who are interested, meet eligibility criteria, and wish to participate, the coordinator will go over the consent form, give the opportunity to ask any questions, and after all questions have been addressed, will collect verbal consent.

7.3 Methods Used to Identify Potential Participants

We will use the electronic health record (EHR) to prescreen potential participants for this study. Potential participants will comprise of current MetroHealth patients from a total of 7 MetroHealth sites within Cuyahoga county. We will use the EHR to prescreen for age (21 years or older), smoking status as documented in the EHR (documented as currently smoking), and food insecurity status (documented as food insecure based on social determinants of health screening conducted during the most recent visit). Using this list, we will send out a recruitment packet in the mail, consisting of a 1-page study flyer with key information and a copy of the informed consent document, in the form of a non-return cover memo. The flyer will instruct potential participants to contact the study team by telephone for further information about the study, and to see if they qualify.

As needed and based on recruitment rate, the research team will also make telephone calls to follow-up with potential participants, after having sent recruitment letters (i.e., there is no “cold” calling without sending letters beforehand). Using the prescreened list of individuals, we will randomly follow up with individuals on the list until we reach the enrollment target for the wave (n=15-20 enrolled in each wave; 3-4 enrollment waves; 60 participants in total will be recruited for this study).

To identify potential participants for the end-of-study qualitative interviews, we will attempt to contact everyone who would be eligible based on their intervention assignment and completion of the protocol.

7.4 Materials Used to Recruit Participants

We will send out a recruitment packet in the mail, consisting of a 1-page study flyer with key information and a copy of the informed consent document, in the form of a non-return cover memo. The flyer will instruct potential participants to contact the study team by telephone for further information about the study, and to see if they qualify. The study coordinator will use an eligibility script to inform participants about the research study being conducted, to assess interest in participating, and to conduct an eligibility screening for interested participants.

To recruit potential participants for the end-of-study qualitative interviews, we will send an invitation letter and a separate informed consent form as a non-return cover memo.

7.5 Amount and Timing of Participant Payments

Participants can receive up to $105 for participation in the research study, specifically for their time in completing the baseline telephone survey ($20) and the 12-week telephone survey ($35, as increased incentive to complete the follow-up survey), and the post-intervention qualitative interview ($50, as increased incentive to participate in the interview). These will be paid as a separate VISA gift card each time the participant completes the survey, and will be sent by mail.

8.0 Withdrawal of Participants

Participants will be removed from the study for any significant medical events, such as hospitalization, or any significant legal events, such as incarceration. Participant non-compliance with research can also be a reason for removing a participant from the study.

9.0 Risks to Participants

Breach of confidentiality is a potential risk associated with this study; however, this risk will be minimized via secure storage of the records. Feeling uncomfortable answering questions is a potential risk for this study; however, this risk will be minimized by allowing participants to skip any questions they do not wish to answer.

10.0 Potential Benefits to Participants

For participants in either group, a potential benefit to participants is that they have several opportunities to connect with a study navigator who can provide them with useful/relevant information and referrals for tobacco cessation and food assistance.

For participants in the intervention group, a potential benefit of participating in the research is that they may experience short-term relief from food insecurity while they are undergoing a smoking cessation attempt.

11.0 Data Analysis Plan

As a pilot study, the primary outcomes pertain to the assessment of feasibility and acceptability, and to derive preliminary estimates of tobacco cessation measures and food security status. We will conduct t-tests and chi-square tests to explore group differences. Feasibility will be assessed by examining the number of participants screened, percent eligible to participate, refusal rate, and attrition rate between baseline and 12-week follow-up. We will examine participants' utilization of resources related to tobacco cessation and food assistance, to examine feasibility of the navigation model. We will gain feedback from the navigator regarding the process of providing referrals and individualized food assistance. We will evaluate acceptability through open-ended questions to elicit participant feedback regarding their perceptions of helpfulness of food assistance in meeting food needs, helpfulness of food assistance specifically during cessation attempt, and additional barriers and facilitators to making a quit attempt or staying quit.

Qualitative interviews will be transcribed and analyzed using inductive and deductive coding process.

11.1 Data Handling and Security

The records for this study are all electronic. No information will be stored in paper files. We are using MetroHealth's REDCap to store all of our data. Audio-recordings of qualitative interviews will be kept in the REDCap file repository until they are transcribed verbatim, removing any identifying information in the transcription process. After that, we will destroy the audio files, and store interview transcript data as a text file. Only authorized personnel assigned to the study will have access to the study on REDCap. All personnel are affiliated with MetroHealth.

We will keep records for 6 years after study completion. Records are stored on REDCap only. Identifiable data on REDCap will be deleted permanently. Dataset that has removed ALL identifiers will be kept

indefinitely. The study coordinator, the P.I., the study navigator, data analyst, and co-investigators will have access to REDCap. All team members are assigned to this study.

12.0 Consent Process

Potential participants will receive a complete explanation of the study and be asked to consent verbally. Participants will receive a non-return cover memo in the mail as a summary of the research. Participants will not be asked to sign a consent form.

Once a potential participant is identified, the study coordinator will go over the study information by telephone, and will follow the non-return cover memo that was mailed to potential participants. The potential participant will have the opportunity to ask any questions they may have prior to providing their verbal consent by telephone. The eligibility screening and study information process will explicitly mention that potential participants should discuss the study with their family or friends before consenting, should they wish to take their time in deciding. The study coordinator will answer participant questions, and will defer any questions that the coordinator cannot answer to the investigators.

We will use the same consent process for the qualitative interviews.

12.1 Process to Document Consent in Writing

Potential participants will be told about the study and its risks and benefits, and if interested, will be consented. Participants will be given a copy of a non-return cover memo, which can be found in the local sites documents portion of this IRB application. The date and time of consent will be recorded, as well as the name of the research personnel who was present at the time of consent. The personnel will provide an electronic signature to confirm the consent was received.

13.0 References

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