Helping the Poor Quit Smoking: Specialized Quitlines and Meeting Basic Needs

NCT03194958

3/13/20

1. Protocol

1.1 Is there a separate, written protocol that will be submitted in addition to this form? (Note: a grant application is not considered to be a protocol)

No

1.2 Select up to three key words below that best describe this research study:

- Psychology
- Clinical
- Public Health
- Social Work

1.3 Provide a short summary/abstract of the purpose and procedures of the study proposed in this IRB application.
DO NOT include information on studies not proposed in this application.
Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.
DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.

The current application is for regular review of our future intervention that will be developed in year 1 with our partners United Way 211 and Alere Wellbeing Inc.

The future intervention trial will test the effects of two approaches to help low-income smokers quit: a Specialized Quitline and Basic Needs navigation. In low-income populations, basic needs like food, housing, personal safety and money for necessities supersede health needs. We have demonstrated in our previous research that among low-income smokers, those with multiple unmet basic needs are significantly less likely to contact a quitline referral they received, and less likely to remember even getting the referral. But when basic needs problems are resolved, the odds of calling a quitline increase. Addressing basic needs should therefore increase low-income smokers' participation in quit smoking programs. However, those programs will have limited effectiveness if they are not made relevant to economically vulnerable populations. Thus proven approaches like quitlines should be more beneficial when they are adapted to the context and life circumstances of the poor.

Using a 2x2 randomized factorial design, we will compare the effects of Standard and Specialized Quitlines with and without a Basic Needs navigator on smoking cessation among 2000 low-income smokers. The primary study outcome is self-reported 7-day point prevalence abstinence at 6-month follow up. All contacts with participants will be by telephone. This statewide field trial will recruit smokers who call United Way 2-1-1 Missouri. Smokers interested in quitting and joining our study will complete a phone survey and then be referred to the standard or specialized Missouri Tobacco Quitline, provided by Alere Wellbeing, Inc. Both 2-1-1 Missouri and Alere Wellbeing, Inc./Optum are research partners in this study. Embedding the study in these practice agencies will accelerate the path to application should our findings support it.

1.4 Specify your research question(s), study aims or hypotheses:

Aim 1: Compare the relative and combined effects of Specialized Quitline services and Basic Needs navigation on use of the Missouri Tobacco Quitline by low-income smokers.

Primary research questions:

A. What proportion of smokers in each study group enrolls in and receives Quitline services?
B. Of those enrolled, does the number of counseling sessions completed vary by study group?
C. Of those enrolled, does use of Quitline services (Print, Text2Stop, WebCoach) vary by study group?

Aim 2: Compare the relative and combined effects of Specialized Quitline services and Basic Needs navigation on quit attempts and abstinence among low-income smokers.

Primary research questions (again, by study group):

A. What proportion report 7-day and 30-day point prevalence abstinence at 3 and 6 months?
B. What proportion report quitting smoking for at least 24 hours (i.e., make a quit attempt)?
C. What proportion report using any pharmacologic cessation aids, like nicotine replacement?

Aim 3: (Dissemination and Implementation Aim) Conduct scalability and economic evaluations to assess the sustainability of the study's referral and intervention approaches.

Primary research question (again, by study group):

A. What are the costs and benefits of each study condition per Quitline referral, per smoker interaction with the Quitline, and per successful quitter from the perspective of Quitline funders and providers?

1.5 Background and significance and/or Preliminary studies related to this project:

There is a greater burden of smoking and smoking-related cancers in low-income populations.

Compared to other Americans, those with lower incomes are more likely to smoke (27.9% prevalence in 2012), have greater nicotine dependence, lower readiness to change, lower self-efficacy for quitting, are less likely to know about and use evidence-based methods to quit smoking, and less likely to quit.11-15; 16-18 Smoking-related cancers disproportionately affect the poor and uninsured and those with less than a high school education.19 Smoking deepens poverty among poor populations.

In addition to the health consequences of smoking, it is increasingly clear that low-income smokers and their families suffer greater financial hardship because of tobacco use. The prioritization of cigarettes over food among low-income smokers has been documented in several studies,20-22 and economic analyses show that poor populations spend a greater percentage of income on cigarettes.23-25 Low-income smokers and their families experience greater financial stress, food insecurity and a reduced standard of living compared to low-income families with no smokers,
and children in these households have increased rates of malnutrition.24,26-29

Effective cessation programs and resources are available but underutilized by low-income smokers.

Low-income adults are less likely to know about and use evidence-based methods to quit smoking.12,30,31 While

most Missouri smokers (77%) report knowing about available cessation services, awareness is lower among low income smokers (68%). Proactive telephone counseling for smoking cessation is an evidence-based intervention1,5,32 that is recommended in both clinical and community practice guidelines.2,5 Tobacco quitlines provide free telephone counseling, NRT, print information resources, and other support services to help smokers quit. Smokers can call a quitline, or through a third party can consent to be contacted by the quitline (e.g., "fax-back" programs).33 During an initial quitline contact, smokers arrange a series of phone counseling sessions to be initiated by the quitline (i.e., proactive counseling) and delivered over 1-3 months around a planned quit date. Quitline users who receive NRT are more likely to complete multiple counseling sessions.34

Studies show 6-month abstinence rates of 12% among quitline users who receive multi-session counseling, and up to 35% when counseling is accompanied by NRT.2,35-38 Yet only 29% of Missouri smokers report using a cessation medication in their last quit attempt, with an even lower rate (23%) among those with no health insurance.31 Because quitlines offer population-wide free access to smoking cessation, they have potential to reach a more diverse cross section of American smokers. However, although 65% of current smokers in a national survey knew about tobacco quitlines, only 9% had called a quitline.39 Studies indicate that the low interest in quitlines is due to smokers' negative perceptions about the service, perceived poor fit of the service, privacy concerns, stigma of using the service and beliefs that they don't need help to quit smoking.40-42

There are unique challenges to promoting smoking cessation in disadvantaged populations. Many low-income smokers have acute needs – no job, inadequate housing, not enough food or money, mental health challenges – that supersede any interest they may have in quitting smoking. It is well established that adults of low socioeconomic status (SES) are less likely to engage in preventive behaviors – including tobacco cessation – than those with higher SES,43 even after adjusting for employment and insurance status.44 One explanation is that people living in poverty have such overwhelming needs in other areas of life, that disease prevention becomes secondary to these priorities.45,46 Our own data collected from Food Stamps clients showed that unmet basic needs are higher among low-income smokers than among low-income non-smokers. Smokers (n=244) were more likely than non-smokers (n=267) to say they would not have enough money for everyday necessities in the next month (51% vs. 41%, $p<.06$) and may not have a place to stay for all of the next month (24% vs. 13%, $p<.01$). In our previous research with low-income 2-1-1 callers, smokers reported more unmet basic needs (M=2.49, SD=1.25) compared to non-smokers (M=2.34, SD=1.24; $p=.015$).

Novel strategies are needed to increase successful smoking cessation among low-income smokers.

Although quitlines are a proven intervention, less is known about how to maximize their use. This is especially true for low-income smokers. For example, while mass media promotional efforts can significantly increase quitline use,47-49 some campaigns to promote smoking cessation and quitline use have been less effective in low-education populations.50 Moreover, time-limited campaigns tend to have short-lived effects.51-53 Effective and sustainable approaches are needed to increase quitline use in low-income populations, like building partnerships with systems that already serve them.32 To date, most efforts to integrate cessation referrals into organizational practice have occurred in health care settings. Lessons learned from these efforts include assuring that: (1) screening and referral is systematic and becomes part of usual care; (2) referrals are made to specialized cessation services, like quitlines; and (3) implementation is monitored carefully and adapted as needed.2,54-56 Additionally, cessation services may be most effective when linked to solutions for smokers' priority problems.45 For example, worksite health promotion studies among blue collar workers show that when employers address workers' most pressing concerns first (e.g., occupational exposure to hazards), workers become more receptive to other health information provided by the employer and are more likely to participate in smoking cessation and other programs.57-59 In our own research with low-income 2-1-1 callers, those who resolved the problem they called about were more likely to contact a health referral for needed prevention services like a mammogram or quitting smoking. Once a problem was resolved, getting additional help from a navigator (vs. no navigator) increased the likelihood of contacting a health referral (45% vs. 27%; $p<.05$).9

Unmet basic needs thwart abilities to address disease prevention and health promotion.

Having unmet basic needs interferes with making behavior changes like quitting smoking. When needs like food, shelter, safety, and money for necessities are unmet, fulfilling them supersedes addressing other life challenges, including modifying unhealthy behaviors.45 This is not simply a matter of prioritization, but also because scarcity captures the mind in ways that diminish one's cognitive capacity to focus on other goals.60 This can lead to short term thinking, poor decision making, and reduced awareness of, attention to, or persistence in pursuing resources toresolve the problem.60-64

Low-income individuals also have less access to resources like money, knowledge, power, social support and broad social networks. Those with greater resources have more opportunity to learn about health risks and treatments and take action to reduce risk and minimize the consequences of disease.65,66 Having transferable resources allows individuals to adapt to changing social and environmental risks. Thus unmet basic needs are especially harmful if allowed to accumulate. Having unmet basic needs is linked to psychological stress, sleep disturbances, physical and mental health problems, and mortality,67-73 and reduces the likelihood of engaging in health promoting behaviors, keeping health care appointments, and using medication as prescribed.74-76

Figure 1 illustrates this process with a proposed pathway from unmet basic needs to health behavior change. The green boxes show where two types of intervention strategies – basic needs interventions (at left) and traditional behavioral interventions (at right) – would typically be delivered. We hypothesize that traditional cognitive behavioral interventions alone will often fail to yield desired results in vulnerable populations because a person's attention, capacity, time, and motivation will have been drained by unmet basic needs. However, when basic needs interventions are also delivered – focused on coping, support, and problem resolution – the odds of health behavior

change occurring should improve. When basic needs are addressed, stress should be reduced or better managed, cognitive bandwidth increased, and ability to attend to, process, and focus on health behaviors increased.
Figure 1. How unmet basic needs undermine health behavior change.
Strong evidence supports this expectation. In well-designed studies, interventions that address basic needs like housing and food have shown beneficial effects on health behaviors, psychological distress, and mental health outcomes like symptoms of anxiety and depression.77-82 Our study will compare the independent and combined effects of two intervention approaches that enhance and extend the traditional behavior-focused approach used by evidence-based tobacco quitlines. The first is an adapted, Specialized Quitline service with heightened attention to contextual conditions in the lives of low-income smokers; the second uses navigators to help low-income smokers address their unmet Basic Needs. Both approaches follow the Institute of Medicine recommendations that social science and behavioral research interventions address individuals' health behaviors as well as the socioenvironmental context in which they live.66,83,84 Specific recommendations included: 1) focusing on social and behavioral determinants of health including economics; 2) using of multiple approaches – one size does not fit all; 3) accounting for the special needs of target groups including social class; and 4) engaging social service and other sectors not traditionally involved in health promotion efforts.

1.6 Literature cited/references (if attaching a grant enter N/A):
Literature cited in attached grant proposal

1.7 Describe EACH of your participant populations
Include description of any control group(s)
Specify the Inclusion/Exclusion criteria for EACH group
Inclusion criteria: All participants will be recruited from UnitedWay 211 Missouri and must be 18 years and older, English speaking, not in crisis, smoke cigarettes every day of the week, planning to quit smoking in the next 30 days, comfortable receiving calls from smoking expert and project team, willing to provide phone numbers to be reached, Missouri resident, and will be a resident Missouri in the next 3 months
Exclusion criteria: pregnant or planning to pregnant in the next 3 months,insurance through employer, currently breastfeeding, currently enrolled in smoking quitline The control group, up to 500 participants, will receive standard quit line services and no basic needs navigator.
The treatment groups, up to 1500 participants, will receive either the standard quit line with basic needs navigation, specialized quit line with no basic needs navigation, or the specialized quit line and basic needs navigation.

1.8 Check all materials/methods that will be used in recruiting participants:
• Telephone script
• Referral
• Medical Records or Other PHI

Attachment Name Category Version Date Attached
211 Quitline Phone
Recruitment:Screening Script.rtf Recruitment Script: Phone 1 12/02/16
211 Phone Consent Script for
Collateral Contacts.rtf Recruitment Script: Phone 1 12/16/16

1.8.a List the individual data elements you will need to access/use from the patient or clinic records to identify potential participants for recruitment
Patient health records will not be accessed. For the interview/questionnaire we are collecting personal, identifiable information i.e name, DOB, and mailing address to receive compensation, insurance status, any existing health conditions as a result of smoking, existing mental health conditions, etc. Please see attachments "Baseline Survey"

1.8.b What is the plan for participant identifiers obtained to identify participants for recruitment?
Identifiers for both those who enroll and those who do not enroll will be retained beyond the period of recruitment and enrollment of participants
• Data analysis/verification

1.8.c Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule?
Yes

1.9 Will you use a screening log or other record that would include information on people who do not consent to participate in the study?
No

1.10 Describe where the consent discussion will occur (check all that apply):
• Private room or area
• By phone

1.11 Participants and/or their legally authorized representative will have (check all that apply to the consent process and explain process in Question 1.12 below):
• As much time as they desire to consider enrolling in the study, including:
An opportunity to thoroughly review the consent materials with knowledgeable members of the research team, and with family and/or friends as appropriate
Sufficient time to have all of their questions answered

1.12 Provide a description of the enrollment and consent process in sequential order and address EACH of the bulleted points
below:

Describe each study population separately including control population
Describe when recruitment and consent materials are used
Indicate how much time individuals will have to consider participation
Use THIRD person active voice. For example, "the principal investigator will identify potential participants, the study coordinator will discuss the study with participants over the telephone and schedule the first study visit, etc..."
Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process
The study population will come from United Way 2-1-1 callers that are Missouri residents who are 18 years and older, have self-identified as smokers. United Way 2-1-1 is not engaged in research activity. United Way 2-1-1 Missouri Information Specialists will identify callers that are English-speaking, not experiencing crisis, 18 years and older, and are cognitively capable of understanding the process and what is being asked. Once callers have been screened by the 2-1-1 Information Specialists using the provided recruitment telephone script, express interest in the study, they will be considered to be interested and potential study participants by 2-1-1. Their contact information will be recorded in a spreadsheet and electronically retrieved by the Washington University (WUSTL) Research team at the close of the recruitment period (end of the business day Monday-Friday over the three year recruitment period). United Way 2-1-1 will NOT do any consenting. They will only invite callers to participate in the research project. When the spreadsheet is received, the participants' information will be entered into a secure database. After which, participants will be contacted by the WUSTL research staff to confirm their interest and eligibility, obtain verbal informed consent, administer the baseline survey, and obtain detailed contact information and preferences. This process will happen in 1-2 business days after the information has been received from United Way 2-1-1. After completing the baseline assessment, participants will be enrolled into quitline services, and wait to be contacted by the quitline (Alere Wellbeing, Inc./Optum) in the next 1-3 business days. During this time, collateral contacts will also be consented to be called during the study if the participants cannot be reached on their primary and secondary numbers provided.
For participants completing the urine test, verbal consent will be obtained over the phone, prior to mailing the testing kit. Participants will be contacted within 1-2 business days of completing the 6-month follow-up survey to consent to the urine test and review instructions. The urine test will be offered to all participants who reported smoking abstinence at 6-month follow-up.
Re-consenting of participants regarding the audio recordings will take place by telephone and documented in their study record. This language has been modified in the updated consent document that has been uploaded.
1.13 Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.
Describe study populations separately if they will be participating in different procedures
DESCRIBE:
Control populations, if applicable
Any randomization, if applicable
What participants will be asked to do/what happens in the study (in sequential order)
The time period over which procedures will occur
Long-term follow-up and how it occurs
The recruitment and study procedures will occur for about 3 years. Participants will be asked to participate in the study for a total of six months that will include completing the quitline coaching sessions which can take 1-4 months, and follow-up at 3 and 6 months; however, they can withdraw from the study at any time. During this time, half of the participants will also asked to work with a Navigator to assist with the basic needs from their initial 2-1-1 call.
The control population will only receive the Standard Quitline (standard of care): Alere's Quit for Life program helps smokers set a quit date within 30 days of enrollment and provides one coaching call before and four carefully timed calls after the quit date to prevent relapse. Calls are scheduled at the smoker's convenience, can be spread over 1-3 months around the quit date, and are adjusted based on the individual's quit success or other needs. Quit coaches try up to five times to reach a smoker for each counseling session. The counseling goal is to increase a smoker's readiness to quit and develop an individually tailored quit plan. In Missouri, Alere provides: (1) up to four sessions of proactive cognitive behavioral counseling by phone from trained quit coaches; (2) access to the same quit coach each call (3) unlimited calls to a toll-free phone number by the smoker and access to Alere's WebCoach® online service and live chat; (4) self help print materials (i.e., "Quit Guide"); (5) tailored motivational emails and/or personal interactive text messages sent throughout the quitting process; and (6) up to 2 weeks of free NRT (patch or gum) for eligible smokers. The quitline also can provide materials for family members to help them support the smoker's quit attempt.
One treatment group will only receive the Specialized Quitline: Very low-income smokers are different from other smokers in important ways not always addressed by standard quitline services. As summarized in Table 2, these differences dictate modifications to counseling protocols, content and personnel. The research team and Alere staff will create and pre-test custom protocols, scripts, prompts and other content to maximize intervention relevance and acceptability to very low-income smokers. RIU coaches who will be delivering the Specialized Quitline services will receive training from clinical quitline staff, the research team and 2-1-1 staff who have extensive experience with the target population. Focus areas for training and distinctive content and protocol for the Specialized Quitline include:
- Health Literacy
- Abstract vs. concrete language
- Lived experience
- Resource constraints.
- Future orientation.
- Getting cigarettes.

• Living situation
• Phone/online access.
The remaining two treatment groups will receive either the Standard or Specialized Quitlines with a Navigator. Navigators will: (1) identify and assess smokers' needs, including the reasons they called 2-1-1; (2) jointly generate solutions to address the needs; (3) develop plans to carry out the solutions, including; (4) help prioritize among multiple needs; (5) identify community resources that could help solve the problem; (6) determine eligibility for services; (7) help smokers access available resources by scheduling appointments and provide appointment reminders; (8) prepare smokers to interact with service agencies and/or act as an advocate on their behalf; (9) provide instrumental support such as arranging transportation; (10) actively intervene to resolve barriers to basic needs solutions; (11) oversee follow-up of problem solving actions; and (12) review progress made towards resolving unmet basic needs and adapt solutions accordingly.
Follow-up: Follow-up at 3 & 6 months. The primary study outcomes are cessation-related. Participants will be asked if they smoked at all in the past 7 days and past 30 days to assess point prevalence abstinence. Those who report any smoking in the past 7 days will be asked if they quit for at least 24 hours since the previous survey and to report on their nicotine dependence measured by the Heaviness of Smoking Index (cigarettes per day; time elapsed between waking and smoking). These items from the Fagerstrom Test of Nicotine Dependence are reliable over time with good predictive validity. All participants will report use of any pharmacologic cessation aids (i.e., NRT, bupropion, Chantix), self-help, or counseling resources they have used since the prior survey. Successful quitters (7 days) will report their confidence in staying quit and all others will report their greatest barriers to cessation (open ended), current motivation (1=very low; 10=very high), and readiness to quit. Follow-up surveys also will assess changes in unmet basic needs (items described in "Baseline") and problem resolution for each reason they called 2-1-1 at enrollment ("When you called 2-1-1 on <date> you asked for help with <problem>. Has that problem been resolved?"). Reactions to the quitline and navigation interventions and staff will be assessed with measures from our previous studies assessing usefulness (e.g., was it helpful?), satisfaction (would you recommend it to others?) user experience (were they easy to talk to?); quit coaches and navigators (similarity, liking, expertise, sincerity, trustworthiness); and intervention appropriateness (relevant to my life and situation, designed for someone like me).
All participants who complete the 6-month follow up survey (estimated N=1200) and report smoking abstinence and no use of nicotine replacement products in the past 7 days (estimated <14% = N<168) will be invited to biochemically assess carbon monoxide levels or cotinine levels. If participants are willing to participate, they will be mailed a urine test to measure their cotinine levels, which is a metabolite of nicotine. The urine test, which can be purchased at any local pharmacy over-the-counter, will be mailed to participants with instructions for sending the results. The study team will not receive any biological samples or testing materials in the mail. Instead, participants will be instructed to send a picture of their results to the study email account and/or phone account. The photo will include only the results: a photo of the dipstick next to the results card. No personal identifiable information will be included in the photo. The results will be linked to the participants study ID via their phone number from which the photo was sent. Consent will be obtained prior to sending the testing kit in the mail via phone script (see attached). Results will be recorded in participants study record. Incentives will be mailed to participants after result has been received by study team.
1.14 Will participants be randomized?
Yes
1.15 Will any of the following be used to collect information from the participant or others?
Screening questions or screening/eligibility questionnaires
Surveys
Questionnaires
Stimuli
Any other written assessments
Yes
Attachment Name Category Version Date Attached
Needs Assessment for Navigator.rtf
Subject Data Collection Instruments 3 03/08/17
Draft Follow-Up Survey.rtf Subject Data Collection Instruments 1 12/16/16
3-month follow-up survey IRB_coronavirus update.rtf
Subject Data Collection Instruments 4 03/09/20
6 Month Follow-Up Survey_coronavirus update.rtf
Subject Data Collection Instruments 8 03/09/20
Final Baseline IRB_coronavirus update.rtf
Subject Data Collection Instruments 5 03/09/20

1.16 Does this project involve creating any audio, video, or photographs?
Yes
1.17 Does the study include any form of deception (e.g., providing participants with false information, misleading information,
or withholding information about certain study procedures)?
Examples:
Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.
Participants will be provided with false information regarding the particular behaviors of interest in the research.
Procedures include a confederate pretending to be another participant in the study.
Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.
Study is designed to introduce a new procedure (or task) that participants are not initially told about.
No
1.18 Indicate any payments or reimbursements to participants (check all that apply)
Gift or Debit Card
1.19 Does this study have a plan to have an individual or committee review combined data from all participants on a periodic
basis (such as summary or aggregate safety and/or efficacy data)?
No
1.20 What have you done to minimize any risks?
• No forseeable risks
• Psychological consultation and/or referrals readily available
1.21 What are the potential benefits related to this project for:
the participant (if any)
benefits to society (if any)
All participants in the study will given the opportunity to stop smoking with a quit coach from the Missouri Tobacco Quitline. Some participants, not all, may receive free Nicotine Replacement Therapy (NRT) as a result of their insurance status.
Participants in the control group will receive standard quitline services that include four quit coaching sessions, as well as a quit guide resource booklet.
Participants in treatment group 1 will receive standard quitline services that include four quit coaching sessions, as well as a quit guide resource booklet. Additionally, participants will be assigned to a Basic Needs Navigator that will assist them in navigating the resources provided to them on their previous 2-1-1 calls and addressing any other basic needs that have since require immediate attention.
Participants in treatment group 2 will receive a specialized quitline that includes four quit coaching sessions and an abbreviated quit guide tailored to the population.
Participants in treatment group 3 will receive a specialized quitline that includes four quit coaching sessions and an abbreviated quit guide tailored to the population. Additionally, participants will be assigned to a Basic Needs Navigator that will assist them in navigating the resources provided to them on their previous 2-1-1 calls and addressing any other basic needs that have since require immediate attention.
This study provides a significant health benefit to participants and their close others who were exposed to smoke. This research will allow us to examine the impact of two strategies for increasing smoking cessation among low income smokers.
The benefits of this study far outweigh the minimal risks of participation. Little published research to date has examined the relative effect of unmet basic needs navigation intervention on smokers' ability to complete quitline counseling, and successfully abstain from smoking for 7 or more days at 3 and 6 months follow-up. If the addition of the basic needs navigator's support significantly improves cessation rates of quitline clients, such supports could become integrated into standard quitline training and service.