Memorial Sloan Kettering Cancer Center
IRB Number: 16-949 A(12)
Approval date: 17-Nov-2021

Verbal Informed Consent for Clinical Research

Study title for participants: Informing the Adaptation of a CHW Model to Facilitate Lung Cancer Screening for the Chinese community: Pilot RCT

Official study title for internet search on http://www.ClinicalTrials.gov:

Informing the Adaptation of a CHW Model to Facilitate Lung Cancer Screening for Chinese Taxi Drivers

Lead Researcher: Jennifer Leng, MD, MPH, 646-888-8057

Directions for the consenting professional:
- You can attempt to contact the potential participant **only 3 times**.
- Do not leave a voicemail message unless you have received IRB approval to do so.

Introduction

Hello, may I speak with (potential participant's name)?

If NO:
- **Do not** leave your name or number to call back. Say that you will call back another time and ask for a good time to reach the potential participant.

If YES:
- Continue with discussion.

My name is (consenting professional), and I am calling from the Department of Psychiatry and Behavioral Sciences' Immigrant Health and Cancer Disparities Service at Memorial Sloan Kettering Cancer Center. I am contacting you about our research study, "*Informing the Adaptation of a CHW Model to Facilitate Lung Cancer Screening in the Chinese Community: Pilot RCT*." We are asking you to take part in this study because you are a of Chinese descent, Mandarin or Cantonese speaking, age 50 to 80 years old, male, a current or former smoker with a 20-pack year history, will not leave NYC for more than 3 months in the next 12 months, and has not had lung cancer screening (LCS) with low-dose CT (LDCT) in the past 12 months.

This study is being done to test a new community health worker (CHW) program. This program will help support and guide at-risk Chinese community members through shared decision making for lung cancer screening. Shared decision making is a process where a health care worker and a patient work together to make a decision about the patient's medical care.

Would this be a good time to speak with you about this study? Our conversation will take about 15 minutes.

If NO:
- Ask when a better time might be to call and record his/her availability.

- If the potential participant is not interested in hearing more: Thank the potential participant for his/her time and end the call.

If YES:

- Continue with discussion.

Overview of the Consent Discussion

During this call, I will explain the study and its risks and benefits, and we will discuss any questions you have. After that, I will ask if you would like to take part in the study. It is important to know that a research study is completely voluntary. You can choose whether to take part, and you can change your mind at any time. Please take your time to make your decision. If you have questions at any time, please feel free to ask me for more information.

Before continuing:

- [OPTION 1 (if study information sheet was provided):] Do you have the hard copy of the study information sheet available to use as a guide to our discussion?
- [OPTION 2 (if study information sheet was not provided ahead of time):] After our conversation, we will send you a study information sheet that includes key information about this study.

Study Information

The purpose of this study is to test if our Community Health Worker program can help at-risk NYC Chinese community members participate in shared decision making and lung cancer screening (if appropriate) and compare it to the help provided by written materials.

Before you begin the study, you will need to answer some questions to find out if you can be in the study. Once we identify that you can be in the study, we will share full details about the study, and we will try to answer any questions you may have. If you can be in the study and would like to take part in this study, we will ask you for your consent.

If you are eligible and decide to take part in this study, you will be asked to complete an intake form that will ask questions about your background (e.g. driving history, household income), health care access, smoking habits, and medical history including cancer screening history.

After finishing the intake form, you will be randomly assigned to 1 of 2 study groups. Random assignment is like a flip of a coin. This means you have an equal chance of being a part of each group. A team member will let you know which group you were assigned to.

In Group 1, you will get written materials we have developed on lung cancer screening,

In Group 2, a Community Health Worker (CHW) will give you the same written materials. They will also support and guide you through shared decision making and lung cancer screening (if appropriate). Shared decision making is a process where a health care worker and a patient work together to make a decision about the patient's medical care. A community health worker is a trained Mandarin or Cantonese speaking staff member who has learned the health risks of smoking and its connection to lung cancer, positives and negatives of lung cancer screening, signing up for

health insurance, and information in NYC on where to get care and where to get screened. The CH Worker support will include health insurance assistance, finding a doctor, and scheduling appointments for shared decision making and lung cancer screening or general check-ups. If you are currently smoking, CHWs will also give you advice on how to discuss quitting smoking with your doctor and information on smoking cessation (quit smoking) programs. CHWs will regularly contact you by phone (call and/or text) at least once a month (or more often if needed) to complete study surveys and navigation. They may also go together with you to your doctor or lung cancer screening appointment(s) if you wish.

You will participate in the study for about 12 months. If you complete lung cancer screening (LCS) with low-dose CT (LDCT) before the 12-month comes to an end, we will ask you to complete a survey right after you complete the screening and receive your results. The survey will ask you questions about your experience while on study, whether someone talked to you about shared decision making and/or lung cancer screening (LCS), if you completed LCS, and if so, what results and follow-up advice were provided. We will also ask about difficulties you may have faced in getting screening, and for those in the CHW group, we will ask your feedback and satisfaction with the CHW program, what parts you found most or least helpful and suggestions on how to improve it.

You may receive the results of this research study. When results are available, you may request a copy of the overall results from the study staff.

About 50 people will take part in this study.

Do you have any questions about this study so far?

Risks and Benefits

There are both risks and benefits to taking part in this study. If you choose to take part in this study, there is a risk that you may miss time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office. You may be asked sensitive or private questions that you do not usually discuss. You may become stressed by learning about lung cancer health risks that you did not know about before. You may also find out that you have health problems while taking part in this study. We will ask that you tell us about any feelings of stress or medical concerns. Staff will be trained to tell study doctors about this. The study doctor or trained member of the study team will give you referral information to low cost community health centers when necessary. You may ask the study team (lead researcher and research staff) any questions you may have about risks.

You may benefit from taking part in the study by getting lung cancer screening information and medical care at a location near you that you may have not known about before. You may also benefit from knowing that this research may help others. This study may help us find better ways of helping at-risk Chinese community members getting screened for lung cancer.

Participants will be assigned unique identification numbers, which will be used to identify all the data. Study findings will be presented in summary form only, with no reference made to individual participant's data. Any surveys collected as hard copies will be housed in locked file cabinets at MSKCC offices. Generally, screening and study survey data will be collected by trained research staff electronically on tablets directly into a secure web-based database called REDCap. REDCap

(Research Electronic Data Capture) is a data management software system supported by the Clinical Research Administration Office (CRA) at Memorial Sloan Kettering Cancer Center (MSKCC). If the survey was collected via pen and paper the survey data will be entered into the study REDCap database. Access to the REDCap study database will be restricted to trained study staff. Members of the CRA supporting the REDCap software will have access to REDCap projects hosted by MSKCC's servers for the purpose of ensuring the proper functioning of the database and the overall software system.

Alternatives to Participation

If you decide not to take part in this study, you may choose to get information on lung cancer screening from your care team, or you may choose to take part in a different research study if one is available.

Ending Participation

You can decide to stop being part of this study at any time. If you decide to stop, let the study team know as soon as possible. We will not be able to withdraw information about you that has already been used or shared with others.

The study team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. The study doctor may take you off the study if your health changes or new information becomes available, and the study is no longer in your best interest, you do not follow the study rules, or if the study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or the study sponsor, Memorial Sloan Kettering Cancer Center. The study sponsor is the organization that oversees the study.

Conflict of Interest

This study is sponsored by Memorial Sloan Kettering Cancer Center.
The study is funded by the National Cancer Institute.
No potential conflicts of interest have been identified for this study.

Costs of Participation

You will not have to pay for the written material and CHW support.

You and/or your health plan/insurance company will have to pay for all the other costs of shared decision making, lung cancer screening, and any subsequent tests or treatment, if applicable, while you are in this study. These charges include the costs of insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects. The study team can work with you to find a low-cost doctor or lung cancer screening location.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

The study team can help you find the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The study will not pay for medical treatment. We will work with you to find low-cost referrals near you if you need them.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

As a thank you, you will receive $40 after completion of the study intake, and $60 after completion of the study exit survey for a total of $100 for study participation.

Do you have any questions?

Privacy and Security Information

Your privacy is very important to us, so I would like to end by explaining who will have access to your information and how your information will be used.

In the future, any information that identifies you may be removed. Your data may be assigned a unique code, and the list that links the code to your name will be stored separately from your data. Your information may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases related to research. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or social security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

MSK must get your permission before using or sharing your protected health information for research purposes. Your protected health information includes your medical and research records, which could include HIV-related or genetic information.

The main reasons for using or sharing your information are to do the study, to check your health status, and to find out the research results. We also want to make sure the research meets legal and institutional requirements.

Your protected health information may be shared with and used by the following:

- The study's lead researcher and the research team
- People and offices that deal with research oversight, quality assurance, and/or billing, if applicable.
- MSK and the sponsor's research collaborators, business partners, subcontractors and

agent(s) working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study.
  - Once your data is shared, it may not be as well protected as it is at MSK.
  - Your information may also be shared with federal and state agencies, and other domestic or foreign government bodies including:
    - the Office for Human Research Protections of the US Department of Health and Human Services
    - the National Cancer Institute /National Institutes of Health
- Other qualified researchers, approved by Memorial Sloan Kettering Cancer Center, who may receive results that do not identify you

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Your information may be given out, if required by law. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

The study doctors have a Certificate of Confidentiality from the National Institutes of Health for this study. This gives MSK an additional way to protect sensitive information that identifies you in your records if it is requested as part of a legal proceeding. However, MSK may still be required to share some of your medical information if required by law.

If you agree to take part in this study, you give us permission to share your protected health information. If you do not agree to let us share your information, you will not be able to take part in this study.

Contact Information

You can talk to the study team at 917-692-9569 about any questions or concerns that you may have about this study. You may also contact the lead researcher, Dr. Jennifer C. Leng at 646-888-8057. More information about this study may be available at ClinicalTrials.gov.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

Agreement to Participate

Based on our discussion, do you voluntarily agree to participate in this study?

If NO:

- Thank the participant for his/her time. Do not complete the below participant and consenting professional information. Add a note to the medical record/research file indicating that he/she declined to participate.

If YES:

- Continue.

Thank you so much for your time and for agreeing to participate in this study.

Participant Information	
Participant Name	
MRN/Study ID	

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		