University of Nevada, Reno
Social Behavioral or Educational Research Consent Form

Title of Study: Evaluation of A Family-based Intervention to Improve Pap Test Screening among Under-screened Chinese American Immigrant Women
Principle Investigator: Wei-Chen Tung
Co-Investigators: Michelle Granner, Minggen Lu
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Study ID Number: 1440348
Sponsor: Pending NIH R21

Introduction

You are being invited to participate in a research study. Before you agree to be in the study, read this form carefully. It explains why we are doing the study; and the procedures, risks, discomforts, benefits and precautions involved.

At any time, you may ask one of the researchers to explain anything about the study that you do not understand.

You do not have to be in this study. Your participation is voluntary. If you do not agree to participate, you will receive the care/education you would have received if the study was not taking place.

Take as much time as you need to decide. If you agree now but change your mind, you may quit the study at any time. Just let one of the researchers know you do not want to continue.

Why are we doing this study?

We are doing this study to find out the impact of the involvement of an influential person(s) (e.g., spouse, partners, parents, children, friends) on Pap test screening intention and behaviors, Pap test self-efficacy, and perceived benefits and barriers to Pap test screening among Chinese American immigrant women. These data specific to the impact of the involvement of an influential person(s) on Pap test screening could be used to develop successful cancer prevention programs that target the specific needs of Chinese populations.

Why are we asking you to be in this study?

We are asking you to be in this study because (a) you are a woman aged 21-65; (b) you are a first-generation Chinese American (born in your native country and relocated to the U.S.); (c) you have no previous cervical cancer screening within the past 3 years; (d) you have no total hysterectomy; (e) you have no history of cervical cancer, and (f) you are able to read English, Simple Chinese, or Traditional Chinese.

How many people will be in this study?

We expect to enroll at least 224 participants from Northern Nevada area and San Francisco Bay area.

What will you be asked to do if you agree to be in the study?

If you agree to be in this study, you will be randomly assigned (by chance) to one of two study groups. The participants in one group will identify their accompanying influential person(s) (e.g., spouse, partners, parents,

children, friends) with whom they will be attending the 1.5-2 hour face-to-face education session on cervical cancer and screening. Your accompanying influential person is eligible if they are (a) aged 18 or older and (b) willing to participate in the study. For the other group, only the participants will attend the face-to-face intervention. The structure of the intervention session will be uniform across all participants in both groups. You can choose Chinese or English to participate in the study. The intervention sessions will be audio recorded.

During the first meeting, your will be asked to sign the consent and complete the baseline questionnaire before the intervention. The 2-week and 6-month assessments after the intervention will be conducted through phone calls. The questionnaire consists of three to four parts that take 10-15 minutes to complete including (a) Demographic Questionnaire, (b) Self-efficacy Scale (questions regarding strength of your perceived ability to participate in cervical cancer screening under various circumstances), (c) Perceived Benefits/Barriers Scale (questions regarding your perceptions concerning the benefits of and barriers to cervical cancer screening), and (d) Cervical Cancer Screening Questionnaire (assessment of your source of cervical screening information, satisfaction with the intervention session, and perceived strengths and weaknesses of the intervention). Please see Table illustrating the data collection timeline for each instrument contained within this study. If you report receiving a Pap test after intervention, you will be asked to email or text "Pap Smear Completed Form" with provider information and signature. This form will be provided to you during the face-to-face Intervention.

Timeline and Instruments Utilized in the Study

	Baseline	2 Weeks	6 Months
Demographic	X		
Self-efficacy Scale	X	X	X
Benefits/Barriers Scale	X	X	X
Cervical Screening- Baseline	X		
Cervical Screening- 2-Week		X	
Cervical Screening- 6-Month			X

How long will you be in the study?

The entire study will take about 3 hours of your time; you'll participate for about 6 months.

What are your choices if you do not volunteer to be in this research study?

If you decide not to be in the study, your other choices may include:

- Getting standard education without being in a study.
- Getting a different experimental treatment/educational experience by taking part in another study.

What if you agree to be in the study now, but change your mind later?

You do not have to stay in the study. You may withdraw from the study at any time by leaving the session, and/or not responding or submitting your information.

What if the study changes while you are in it?

If anything about the study changes or if we want to use your information in a different way, we will tell you and ask if you if you want to stay in the study. We will also tell you about any important new information that may affect your willingness to stay in the study.

Is there any way being in this study could be bad for you?

If you participate in this study, there may be some inconvenience to you in spending the time in study intervention and complete the questionnaire. You may feel uncomfortable answering questions, participating in the barriers discussions and education.

What happens if you become injured because of your participation in the study?

In the event that this research activity results in an injury, treatment will be available. This includes first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your health insurance carrier.

Will being in this study help you in any way?

We cannot promise you will benefit from being in this study but you may benefit from the information provided in the intervention, including increase in participants' knowledge of cervical cancer, screening, and available resources in Northern Nevada area and San Francisco Bay area.

Who will pay for the costs of your participation in this research study?

No costs are associated with participation in this study.

Will you be paid for being in this study?

You will receive a $50 gift certificate via email for participating in the intervention and complete the first survey. The accompanying influential person(s) will also receive a $50 gift certificate via email. Extra two $15 electronic gift certificates will be offered for completing two follow-up surveys (one for after 2 weeks and the other for 6 months of the intervention). Additionally, you will be entered in a drawing for one of forty $50 gift certificates if you complete all surveys.

Who will know that you are in in this study and who will have access to the information we collect about you?

The researchers, the University of Nevada, Reno Institutional Review Board, and the National Institute of Health will have access to your study records.

How will we protect your private information and the information we collect about you?

We will treat your identity with professional standards of confidentiality and protect your private information to the extent allowed by law. We will do this by storing your survey responses in a locked cabinet in Dr. Wei-Chen Tung’s office. We will also create a master code list which will be stored securely and separately. After the study closure, paper records and audiotapes will be erased or destroyed. We will not use your name or other information that could identify you in any reports or publications that result from this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Do the researchers have monetary interests tied to this study?

The researchers and/or their families have no monetary interests tied to this study.

Who can you contact if you have questions about the study or want to report an injury?

At any time, if you have questions about this study or wish to report an injury that may be related to your participation in this study, contact Wei-Chen Tung, PhD, RN, FAAN, at (775) 682-7138.

Who can you contact if you want to discuss a problem or complaint about the research or ask about your rights as a research participant?

You may discuss a problem or complaint or ask about your rights as a research participant by calling the University of Nevada, Reno Research Integrity Office at (775) 327-2368. You may also use the online *Contact the Research Integrity Office* form available from the *Contact Us* page of the University's Research Integrity Office website.

Agreement to be in study

If you agree to participate in this study, you must sign this consent form. We will give you a copy of the form to keep.

Participant's Name Printed

Signature of Participant | Date

Signature of Person Obtaining Consent | Date