Document Coversheet

Study Title: PROMIS WOMAN Education Program : ImProving ceRvical Cancer preventiOn Methods Among Muslim AmerIcans WOMEN

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Improving Cervical Cancer Prevention Methods Among Muslim American Women in **Virginia**
VCU INVESTIGATOR: Vanessa Sheppard Ph.D., Professor, Social, and Health Policy Department.

SPONSOR: Geographical Management of Cancer Health Disparities (GMaP) program at the National Cancer Institute (NCI)

ABOUT THIS CONSENT FORM

You are invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**
This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.
Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

The main goal of this study is to help Muslim American women in the United States prevent cervical cancer by creating a program that considers their religious and cultural needs. Building upon previous research, we have adapted educational materials to align with the cultural and religious preferences of Muslim women. To ensure the materials are sensitive to their needs, we collaborated with a focus group and engaged with important community members.
There are two key objectives for this study:

- Test the effectiveness of the adapted program: We anticipate that participants who go through the program will gain improved knowledge and acceptance of cervical cancer prevention. To evaluate the effectiveness, we will conduct surveys before and after the program to measure changes in participants' understanding and attitudes.
- Evaluate the feasibility and acceptability of the adapted program: In addition to educational components, the program will include activities to practice communication skills. We will recruit 20 new participants and conduct a trial to assess whether the program is practical and well-received. This evaluation will consider factors such as enrollment, implementation, engagement, retention, and satisfaction.

By taking into account the unique cultural and religious factors that influence cervical cancer prevention in Muslim American women, this study aims to reduce disparities and improve the health outcomes for this specific population.

Why is this study being done?

The purpose of this research study is to find out more about cervical cancer prevention among Muslim American women. We want to understand why some Muslim women may have lower participation rates in cervical cancer screening and prevention activities. By studying this, we hope to develop an intervention program that is tailored to the religious and cultural needs of Muslim women, and ultimately improve their knowledge and engagement in cervical cancer prevention.

The results of this study will be used to inform healthcare providers, policymakers, and community organizations about effective strategies for promoting cervical cancer prevention among Muslim American women. By understanding the unique cultural and religious factors that influence participation in screening and prevention activities, we can develop targeted interventions that better meet the needs of this population. Ultimately, the findings of this study will contribute to reducing cervical cancer disparities and improving the overall health outcomes of Muslim women.

What will happen if I participate?

If you choose to participate in the Religious and Culturally Tailored Intervention Program for promoting cervical cancer prevention methods among Muslim women in Virginia, here's what will happen:

1- Pre-Surveys: Before the intervention program begins, you will be asked to complete a presurvey. This survey will assess your knowledge and acceptance of cervical cancer screening and prevention. It will take approximately 45 minutes to complete. The survey will be self report and can be accessed online through InSite. The survey link will be sent to you via text message or can be completed at home.

   The survey scales will include:

   - Demographic: This section will collect information about your age, gender, ethnicity, and other relevant demographic factors.
   - Perceived Discrimination: This scale aims to assess your perceptions of discrimination in various contexts.
   - Religious Discrimination: This scale will measure your experiences of religious discrimination.
   - Spiritual Health Locus of Control: This scale will explore your beliefs about the influence of spirituality on health outcomes.

- Modesty: This scale will assess your attitudes towards modesty and its impact on health-seeking behaviors.
- Cervical Cancer Knowledge: This section will evaluate your understanding of cervical cancer, its risk factors, and prevention methods.
- Perceived Risk: This scale will measure your perception of the risk of developing cervical cancer.
- Course of Action: This scale will assess your intention and willingness to engage in cervical cancer screening and prevention activities.
- Self-Efficacy: This scale will explore your confidence in your ability to perform cervical cancer prevention behaviors.
- Attitude about CC Screening: This section will measure your overall attitudes and beliefs about cervical cancer screening.
- HPV Vaccination Acceptability: This scale will assess your attitudes towards the acceptance of HPV vaccination as a preventive measure.

The pre-test survey is an essential part of the study and will take approximately 45 minutes to complete. We will send you the survey as a link via text message, providing you with the flexibility to choose where you would prefer to complete it. You can either complete the survey at home or, if you prefer, inside the Islamic center. Our goal is to accommodate your convenience and ensure that you can participate in a comfortable and familiar environment.

2- The Intervention Program: The program consists of one session; The duration of this session will be approximately two hours. The session is divided into multiple sections, each focusing on different aspects of cervical cancer prevention.

- Section 1: This section will provide you with essential information about cervical cancer, its risk factors, and the importance of early detection and prevention. It will also address common misconceptions and cultural barriers related to cervical cancer screening and prevention among Muslim women. The duration of this session will be approximately two hours.

- Section 2: In this section, you will learn about various cervical cancer screening methods available, such as Pap smears and HPV testing. We will discuss the benefits, limitations, and cultural considerations associated with each screening method. This session will also provide an opportunity for interactive discussions and addressing any questions or concerns you may have. The duration of this session will be approximately two hours.

- Section 3: The focus of this section will be on effective communication skills and strategies for discussing cervical cancer prevention with healthcare providers, family members, and community members. You will learn how to effectively convey the importance of screening and prevention within your cultural and religious context. This session will include role-playing exercises and practical tips to enhance your communication skills.

Following the completion of the education sessions, you will be asked to complete a postsurvey.

3- Post-Surveys: Once you have completed the education sessions, we kindly request your participation in a post-survey. This survey serves as a follow-up to the pre-survey and will evaluate your knowledge and acceptance of cervical cancer screening and prevention, similar to the initial assessment. The survey link will be conveniently sent to you via text message. You can access and complete the survey using the internet, either in the comfort of your home or within the Islamic centers. The post-survey will encompass a range of scales to gather comprehensive data on various aspects related to the study. These scales include:

- Perceived Discrimination: This scale aims to assess your perceptions of discrimination in various contexts.
- Religious Discrimination: This scale will measure your experiences of religious discrimination.
- Spiritual Health Locus of Control: This scale will explore your beliefs about the influence of spirituality on health outcomes.
- Modesty: This scale will assess your attitudes towards modesty and its impact on health-seeking behaviors.
- Cervical Cancer Knowledge: This section will evaluate your understanding of cervical cancer, its risk factors, and prevention methods.
- Perceived Risk: This scale will measure your perception of the risk of developing cervical cancer.
- Course of Action: This scale will assess your intention and willingness to engage in cervical cancer screening and prevention activities.
- Self-Efficacy: This scale will explore your confidence in your ability to perform cervical cancer prevention behaviors.
- Attitude about CC Screening: This section will measure your overall attitudes and beliefs about cervical cancer screening.

- HPV Vaccination Acceptability: This scale will assess your attitudes towards the acceptance of HPV vaccination as a preventive measure.
- General Self-Efficacy Scale (GSES).
- Cervical Cancer Screening Self-Efficacy Scale.

Your valuable input through the post-survey will enable us to assess the impact of the intervention program and further our understanding of cervical cancer prevention among Muslim women. We anticipate that the survey will take approximately 45 minutes to complete.

4- Satisfactory Survey: Following the completion of the education sessions, we kindly request your participation in a Satisfactory Survey. This survey, conducted one week after the session, aims to gather your valuable feedback regarding your experience with the intervention program. The survey will specifically focus on assessing your satisfaction with various aspects, including the sessions themselves, the materials provided, and the overall effectiveness of the program. The Satisfactory Survey will provide an opportunity for you to share your insights on:
   - Your overall experience with the intervention
   - The acceptability of the content covered in the session.
   - Your perception of the delivery of the program

Your feedback will play a crucial role in evaluating the intervention's impact and identifying areas for improvement. We anticipate that the survey will take approximately 30 minutes to complete.

Please note that your participation in this study is voluntary, and you have the right to withdraw at any time without facing any negative consequences. Your insights and feedback are crucial in helping us develop effective interventions that address the specific needs of Muslim women in cervical cancer prevention. If you have any questions or concerns about your participation or the study in general, please feel free to reach out to the study team.

What are the risks and benefits of participating?

A) Risks and Discomforts:

The research team understands that participating in this study may raise concerns about privacy and emotional discomfort. We want to assure you that we have implemented measures to address these potential risks:

- Loss of Privacy: ○ Confidentiality: We prioritize the protection of your personal information. All data collected during the study will be handled with strict confidentiality. Your responses will be anonymized and securely stored, with access limited to authorized members of the research team.

- Data Security: We will use password-protected electronic systems to store and transmit data. Only designated researchers will have access to this information, and appropriate security measures are in place to safeguard your data from unauthorized access.

- Emotional Discomfort: ○ Voluntary Participation: Your participation in this study is entirely voluntary. If at any point during the study you feel uncomfortable or distressed, you have the right to withdraw without any negative consequences.
    - Supportive Environment: The research team is committed to creating a supportive and respectful environment throughout the study. If you encounter any distressing questions or experiences, please inform the research team immediately, and we will provide appropriate support and assistance.

We want to emphasize that your well-being and comfort are of utmost importance to us. If you have any concerns or questions about privacy or emotional discomfort related to this study, please do not hesitate to discuss them with the research team. We are here to address your needs and ensure a positive and safe research experience.

B) **Benefits to You and Others**:

- Direct benefits: While there is no guarantee of direct benefits to you personally, participating in this study may provide the following potential benefits:
    - Knowledge and Awareness: By participating, you will have the opportunity to gain valuable knowledge about cervical cancer prevention, including information about screening methods, risk factors, and preventive measures. This increased awareness can empower you to make informed decisions about your own health and well-being.
    - Culturally Tailored Information and Support: The study aims to provide culturally tailored educational materials and interventions specifically designed for Muslim American women. By participating, you may receive information and support that is aligned with your cultural and religious preferences, addressing the unique needs and concerns of the community.
- Benefits to others: By participating in this study, you will contribute to the broader scientific understanding of cervical cancer prevention among Muslim American women. The information learned from this study has the potential to benefit others by informing the development of interventions and strategies to improve cervical cancer screening rates and reduce disparities within the Muslim-American community and beyond.

It is important to note that the anticipated benefits described here are based on previous research or the goals of the study. Individual benefits may vary, and we cannot guarantee specific outcomes for each participant.

If you have any further questions or concerns about the risks and benefits of participating in this study, please feel free to ask the research team. We are here to provide you with the information you need to make an informed decision about your participation.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

As a participant in the intervention group of this study, you will receive a compensation total of $150 .00 for your time and participation in the education session. The compensation will be provided to you in the form of an e-gift card or physical gift card, based on your preferred choice. Please note that the compensation will be distributed as follows: $75.00 for completing the pre-test survey, and $75.00 for completing the post-test survey.

We will provide a $50.00 gift card for completing the satisfaction survey after the education session.

It is important to be aware that if the total compensation you receive from this study within one calendar year exceeds $600, VCU is required to report these payments to the IRS and provide you with the necessary documentation. It is possible that you may be required to claim the compensation as taxable income. Rest assured that your social security number, which will be NOT collected for payment purposes.
If you have any further questions or concerns about the compensation or payment process, please feel free to ask the research team.

CAN I STOP BEING IN THE STUDY?
You have the right to stop participating in this research study at any time, and your decision to withdraw will not have You have the freedom to discontinue your participation in this research study at any time, and it will not have any negative consequences for your medical care, employment status, or academic standing at VCU or VCU Health. If you are considering or have made the decision to withdraw from the study, we kindly request that you inform the study staff.

In certain situations, the investigator may need to end your participation in the study without seeking your consent. This can happen if the investigator determines it is necessary for your health or safety, if you are deemed ineligible for the study, or if the sponsor decides to halt the study.

If you have any concerns or questions regarding withdrawing from the study or the termination procedures, please don't hesitate to discuss them openly with the study staff. They are available to address any inquiries you may have.

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

We take the protection of your personal information very seriously. VCU has implemented secure research databases and computer systems to ensure the confidentiality and security of your data. Only authorized individuals involved in this study or those with specific research-related responsibilities will have access to these databases.

Identifiable information about you will not be released to individuals or organizations outside of VCU, unless it is explicitly stated in this consent form or required by law. While the results of this research may be shared in presentations or publications, your personal information will remain confidential and will not be disclosed.

In the management, monitoring, and oversight of this study, personal information may be shared with or accessed by authorized representatives from the following organizations:

Rest assured that all individuals and organizations with access to your personal information are bound by strict confidentiality agreements and regulations to ensure the security and privacy of your data.

Certificate of Confidentiality

To ensure the protection of your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). This certificate provides additional safeguards for the confidentiality of your information. With a Certificate of Confidentiality, researchers are able to refuse to disclose your information in legal proceedings, providing an extra layer of protection. However, it's important to note that there are certain situations in which the researchers may be required to disclose your information. It's also important to understand that the researchers cannot prevent you or others, such as a family member, from sharing information about your participation in this research. If you have given permission for an insurer, employer, or any other individual to receive research information, the researchers may not use the Certificate of Confidentiality to withhold that information.

Please be aware that in certain specific circumstances, such as cases of child or elder(women) abuse or neglect, or if there is a risk of harm to yourself or others, the researchers may be obligated to share information about you or your participation in the research project without your consent.

Rest assured that the researchers will take all necessary measures to protect the confidentiality of your information and comply with applicable laws and regulations.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will not be using or accessing any health information from your healthcare records. Therefore, no health information will be used or shared with others during this research.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions, complaints, or concerns about your participation in this research study, please contact the following individuals:

Study Principal Investigator:
Name: Asmaa Namoos (Student) Email: Asmaa.namoos@vcuhealth.org
Phone: 757-768-3512
Address: Virginia Commonwealth University Department of Health Behavior and Policy One Capitol Square, 9th floor 830 E. Main St. Richmond, VA 23298

Study Co-Principal Investigator:
Name: Vanessa Sheppard (Mentor)
Email: Vanessa.Sheppard@vcuhealth.org
Address: Virginia Commonwealth University Department of Health Behavior and Policy One Capitol Square, 9th floor 830 E. Main St. Richmond, VA 23298.

If you have general questions about your rights as a research participant or wish to discuss any issues or concerns related to research, you can contact the **Virginia Commonwealth University Office of Research:**
Virginia Commonwealth University Office of Research 800 East Leigh Street, Suite 3000, Box 980568 Richmond, VA 23298
Phone: (804) 827-2157
Website: https://research.vcu.edu/human-research/hrppirb/research-participants/

Please do not sign this consent form until you have had the opportunity to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have carefully read and reviewed this consent form. I have had all of my questions regarding this study answered to my satisfaction. By signing this consent form, I confirm that I have not waived any of my legal rights or benefits to which I am entitled. My signature indicates that I voluntarily consent to participate in this research study. I understand that I will receive a copy of the consent form for my records.

_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date