

## **Information Sheet**

### **Study Participants 20Years of Age or Older**

**Information Sheet consists of 2 parts:**

**Part 1 Information sheet for study participants**

**Part 2 Participant research consent form**

#### **Part 1**

**Research project title:** “The effect of culture-based breast health education program on breast self-examination practice among high-risk adult Pakistani women”.

**Principal Investigator:** Ms. Sumaira Naz

Institute:

Faculty of Nursing, Chulalongkorn University Thailand

Institute of Nursing, Wah medical college, Wah Cantt. Pakistan

Research Funding: Sponsor (Faculty of nursing, Chulalongkorn University, Bangkok. Thailand

Funding: Second century fund (c2f)

#### **Description:**

You are being invited to take part in this study because you are fulfilling the eligibility criteria of this study (having age of 20-50 years, your mother is suffering from breast cancer, living with family, having a smart phone with internet access, not having pregnancy, willing to participate, and able to read and write urdu language).

Before you decide to take part in this study, please take your time in reading this information sheet to make sure that you understand what you will be asked to do as part of this study. You are welcome to discuss this study with your mother or family member that you know and trust before you make your decision. If you have any questions regarding this study, please feel free to ask the researcher. Again, your decision making to take part in this study is completely

voluntary. You can refuse to take part in this study or withdraw from this study at any time without giving a reason.

### **What is this study about?**

Breast self-examination Practice is women act of physical and visual examination of the breasts just after menstruation or at the same time each month to detect any abnormalities. Despite the advancement in the screening measures for early detection of breast cancer, awareness about screening measures such as breast self-examination which is one of cost-effective measure for early detection is significantly low specially in high-risk Pakistani women. This study will address this gap and improve knowledge, attitude and self-efficacy towards breast cancer and breast self-examination. Specifically, the research seeks to investigate whether participation in the program leads to significant improvements in breast self-examination practice among high-risk Pakistani women before and after receiving the program.

### **Study design**

The study design will be a Randomized controlled trial with two-group (the pretest-posttest design), a single-prospective blinded randomized controlled trial having equal allocation to the one experimental group and one control group.

### **Participant Responsibilities**

If you agree to take part in this study, for the control group participants you will perform only pre-post testing and will not receive any intervention but receive standard education already available in hospitals. You will be asked to fill out the 11 items questionnaire named “The breast self-examination frequency and proficiency of practice questionnaire” two times. However, you will be provided with education material such as detailed educational material after finishing intervention (after three month) with experimental group. Completing the questionnaire may take around 10 minutes.

Experimental group participants will receive educational intervention in three sessions of 30-40 minutes each. Different teaching activities will be used during interactive teaching (such as lecture method using power point presentation, small group discussion and Video sharing, skill training by demonstration on breast model by researcher and demonstration by participants,

mHealth app installation) to promote breast self-examination practice. You will be asked to fill out the 11 items questionnaire named “The breast self-examination frequency and proficiency of practice questionnaire” before the start of educational intervention and after finishing it. Completing the questionnaire may take around 5-10 minutes. And also fill breast self-examination self-efficacy questionnaire before the start, at the 4<sup>th</sup> and 8<sup>th</sup> weeks of intervention. It will take only 5/10 minutes.

### **Duration that you will join in this study**

You will be in the study for twelve weeks (first week for 2 hours), 4<sup>th</sup> week for 30 minutes), 8<sup>th</sup> week for 30 minutes, and 12<sup>th</sup> weeks 30 minutes).

### **Possible risks or uncomfortable events from this study and how the study will minimize or avoid these risks**

There will be no risk associated with participation in this study because the researcher sets out to gather information based on self-administered questionnaire. However, experimental group participants may have to spend extra time to attend educational sessions that may not be enjoyable. To avoid it, the researcher will make the educational sessions more interactive by using different techniques. Moreover, you may have fewer private or working hours. And the duration of three months could be burden, but multiple activities of program will help to maintain regular breast self-examination practice. You could refuse or withdraw from the study.

### **Anticipated benefits to study participants**

There will be no direct benefit to the participants. Most important of all, this study will provide benefits for those who will be confident to make positive changes in their behavior such as doing regular breast self-examination practice every month and identify any change at an early stage. If you are withdrawn from this study before the completion of intervention, you might not get the complete information regarding this awareness program which will also help you to maintain behaviour through reminder.

### **Data Protection and Confidentiality**

All information collected about you in this study will be collected on documents. This information will be kept confidential from those who are not allowed to access this information.

Only researcher will have access to your information. However, the Research Ethics Committee and the persons with the authority to oversee this study may access your information to review study information and the research process. You have a legal right to access your personal information.

Data collection will be divided into two parts: Information for the study and personal information that identifies you only by a code. Any data collected from you for this study will only be identified by code and stored with the researcher. This data will be destroyed 03 years after the study is completed and the study findings have been published. While the data is being stored, there may be a need to confirm the accuracy of the information or to repeat the analysis to confirm validity of the findings.

### **How will your information be used and whom will it be shared with?**

The study data presented as a summary without reference to you or anything that will identify you. However, some journals may require that individual data be included in public databases for other researchers to access. Please be assured that any data shared will not have individual identifiers or links to you.

### **Cost or compensation from participating in the study**

The study provides no payment or compensation for your participation.

If you have questions about this study, please contact:

Research contact person (s)

1. Ms. Sumaira Naz

Assistant Professor Nursing

Institute of Nursing, Wah medical College,

Quaid Avenue, Wah Cantt. Punjab

Contact # 0331-8132975

Info@ionwmc.edu.pk

Are there conflicts of interest associated with this study? [ ] Yes [  ] No.

## **Part-2**

### **Consent Form**

I am asking you to participate in a research study. This form is designed to give you information about this study. I will describe this study to you and answer any of your questions.

Project Title: Effects of Culture-based Breast Health Education Program On Breast Self-Examination Practice Among High Risk Adult Pakistani Women: A Randomized Controlled Trial

Principal Investigator: Ms. Sumaira Naz

Institute of nursing/Wah medical college, Wah Cantt

+923318132975, Sumaira.naz6@gmail.com

This study gives breast health promoting educational and training sessions among high-risk women in Rawalpindi district, Punjab to promote Breast self-examination practice. The program will be according to our culture values such as only female researcher with female assistant will give training, training will be in private place and on breast model for developing knowledge related to Breast cancer & Breast self-examination, with your mother/family member presence and enhance you skill to do correct breast self-examination which ultimately improves BSE practice and a mobile application will also be given to you which remind you and improve your skill at home, which you can only use by yourself. Every month I will ask about your performance and how you feel after doing breast self-examination. The duration of this training will be three months. I do not anticipate any risks from participating in this research. Infact you will get benefits for yourself. This study will help you to take care of yourself. There will be no recording of this training. Your personal information will never be shared with anyone. Your Privacy is our priority. You can leave this training at any time, it's all up to your decision.

Statement of Consent

I have read the above information and have received answers to any questions I asked. I consent to take part in the study.

Participant Signature

Date

Family member signature \_\_\_\_\_ Date \_\_\_\_\_

Signature of person obtaining consent \_\_\_\_\_ Date \_\_\_\_\_

This consent form will be kept by the researcher for at least three years beyond the end of the study.