

# Breast health education program to promote breast self-examination practice among high-risk Pakistani women

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<b>Registration date</b> 15/08/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/03/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aim

Breast self-examination (BSE) is a cost-effective screening tool for the early detection of breast cancer in low-resource countries such as Pakistan, where health spending is predominantly through out-of-pocket expenditure. Behaviour related to breast cancer screening or diagnosis among high-risk Pakistani women with a family history of breast cancer highlighted limited awareness about breast cancer and BSE as a screening measure for breast cancer. Regular BSE practice among high-risk Pakistani women was also limited. Late presentation of breast cancer patients at stage III or IV is common in all parts of the country and the most delayed cases were among high-risk Pakistani women. BSE practice empowers women. The most important initial step is encouraging women to be actively responsible for their health linked positively with the early identification of breast cancer, which helps to improve the outcomes of treatment as well as increase the five-year survival rate. Pakistani community is a family-bonded culture. Culture-based strategies for improving BSE practice must be undertaken according to cultural values such as family involvement, linguistically appropriate and implemented in a familiar environment where female privacy will be maintained. So, there is a crucial need to develop a culture-based breast health education program targeting high-risk women that aims to enhance knowledge about breast cancer and BSE, foster a positive attitude towards BSE, and encourage family support to promote BSE practice.

### Who can participate?

Adult women aged between 20 and 50 years old with a family history of breast cancer selected from the oncology departments of a tertiary care hospital. One female family member will also be allowed with each participant in the program and will be nominated by the participant.

### What does the study involve?

The program is a nursing intervention, consisting of interactive educational and training activities and a mobile health application. The study participants will be evaluated after 12 weeks of intervention. A structured, validated and adopted questionnaire will be used to assess

BSE practice. During the training portion of the program, nursing instructors and health care professionals who are experts in oncology care (cancer care) will be involved to provide their assistance.

What are the possible benefits and risks of participating?

The study will provide benefits of self-awareness about breast health and is not expected to cause any risk.

Where is the study run from?

Pakistan Ordinance Factory Hospital

When is the study starting and how long is it expected to run for?

February 2024 to November 2024

Who is funding the study?

C2F – The Second Century Fund Chulalongkorn University. The study is part of a Doctoral degree by the Principal Investigator.

Who is the main contact?

Ms Sumaira Naz (Principal Investigator, Ph. D Scholar), info@ionwmc.edu.pk, 6478803136@student.chula.ac.th, sumaira.naz6@gmail.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

The effect of culture-based breast health education program to promote breast self-examination practice among high-risk Pakistani women

### Study objectives

1. Breast self-examination practice score in high-risk adult Pakistani women after participating in a culture-based breast health education program at three months will be higher than before the intervention program.
2. Breast self-examination practice score of high-risk adult Pakistani women in an experimental group who receive culture-based breast health program at three months will be higher than the control group who receive usual care.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 19/07/2024, Institute of Allied Health Sciences, Wah Medical College, Wah Cantt (Quaid Avenue, Taxila, 46000, Pakistan; +92 051-9314387; info@iahswmc.edu.pk), ref: IAHS/WMC /786/008

### Study design

Two-arm parallel-group single-blind study

### Primary study design

Interventional

### Study type(s)

Other

### Health condition(s) or problem(s) studied

Promotion of breast self-examination practice in women with a family history of breast cancer

### Interventions

A two-armed parallel-group study design study will be used to conduct this study. Participants will be randomly assigned into two groups in equal numbers. The program will consist of interactive educational as well as training activities such as PowerPoint presentations, small group discussions, video sharing, training on breast models and simulators for breast self-examination and mHealth application with various infographics such as monthly reminders, and videos on breast self-examination. The program will be run mainly through the principal investigator with the help of a research assistant who is a nurse instructor, and a female oncologist who has experience in this field. The whole intervention will be carried out inside the oncology department in a separate room with all necessary equipment and provide privacy to participants. The baseline assessment of participants who meet the eligibility criteria will be done and after that study participants will be randomly assigned to one experimental group and one control group. Only the principal investigator knows about the random assignment of participants into two arms. The study will be single blind. The experimental group will receive the culture-based breast health education program for 12 weeks (three months). While the control group receives the usual care already available in the hospital. In the 4th and 8th week self-efficacy of participants in the experimental group will be assessed through a self-reported questionnaire to monitor the intervention working. The study participants will be evaluated after 12 weeks of intervention.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Frequency and skill in performing breast self-examination measured using a standardized self-reported practice questionnaire at baseline and week 12

### **Key secondary outcome(s)**

The self-efficacy of participants to perform breast self-examination measured using a standardized self-reported practice questionnaire at weeks 4 and 8 of the intervention

### **Completion date**

29/11/2024

## **Eligibility**

### **Key inclusion criteria**

1. Able to communicate in Urdu (both verbal and written)
2. The female participant's mother has already been diagnosed with breast cancer and is under treatment
3. Access to a smartphone with internet access
4. Female participant living with family
5. One female family member nominated by the participant

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

20 years

**Upper age limit**

50 years

**Sex**

Female

**Total final enrolment**

72

**Key exclusion criteria**

1. Previously participated in a breast awareness program
2. Participate in the program less than 90%
3. Pregnancy

**Date of first enrolment**

19/08/2024

**Date of final enrolment**

30/08/2024

## **Locations**

**Countries of recruitment**

Pakistan

**Study participating centre**

**Pakistan Ordinance Factory Hospital**

Quaid Avenue, barrier no 1.

Wah Cantt, Taxila

Pakistan

46000

## **Sponsor information**

**Organisation**

Chulalongkorn University

**ROR**

<https://ror.org/028wp3y58>

# Funder(s)

## Funder type

University/education

## Funder Name

C2F – The Second Century Fund Chulalongkorn University

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. Data requests can be submitted after article publication as a supplement to results only if required by the journal. Access can be demanded by qualified researchers through the proper approval of the investigators.

## IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other unpublished results</a>			11/03/2025	No	No
<a href="#">Participant information sheet</a>			15/08/2024	No	Yes
<a href="#">Protocol file</a>			15/08/2024	No	No