

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

Submission date 14/08/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/08/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/03/2025	Condition category 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,
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Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

See study outputs table

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 measure

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

Secondary outcome measures

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

Overall study start date

16/02/2024

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

Age group

Adult

Lower age limit

20 Years

Upper age limit

50 Years

Sex

Female

Target number of participants

100

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

Sponsor details

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Sponsor type

University/education

Website

<https://www.nurs.chula.ac.th/th/>

ROR

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

Funder(s)

Funder type

University/education

Funder Name

C2F – The Second Century Fund Chulalongkorn University

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed journal

Intention to publish date

30/12/2024

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?
Participant information sheet			15/08/2024	No	Yes
Protocol file			15/08/2024	No	No
Other unpublished results			11/03/2025	No	No