1. STUDY IDENTIFICATION

Brief Title

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

Official Title

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

Study Type

Interventional

2. STUDY STATUS

Record Verification Date

Approved by the Board of the Faculty of Nursing. No. 11/2024 Date June 11, 2024)/NO/ 5/2566
Letter Issued Dated: 18-06-2024

Overall Recruitment Status

Recruiting (Qualitative Part)

Study Start Date

Actual		25/08/2024
Primary Completion Date	Anticipated	25/11/2024
Study Completion Date	Anticipated	31/12/2024

3. SPONSORS/COLLABORATORS

Responsible Party, by Official Title

Principal Investigator

Investigator Name:	Sumaira Naz
Investigator Official Title:	PhD-Scholar (Faculty of Nursing, Chulalongkorn University-Thailand Assistant professor Nursing-ION-Pakistan
Investigator Affiliation:	Faculty of Nursing, Chulalongkorn University-Thailand. Institute of Nursing/Wah Cantt-Taxila-Pakistan
Collaborators (if any):	N/A

4. OVERSIGHT

Human Subjects Review

Human Subjects Protection Review Board Status (select one):	Submitted, Approved
Board Approval Number	No. IAHS/786/008
Board Name	Ethical Review Board
Board Affiliation	IAHS/National university of health sciences, Pakistan
Board Contact	051-9314387

Address: Institute of allied health sciences-Quaid Avenue-Wah Cantt/Taxila-Pakistan

Data Monitoring Committee (select one): Yes

5. STUDY DESCRIPTION

Brief Summary (using lay language)

The focus of the study is to educate high-risk Pakistani women about breast health to promote breast self-examination practice.

Detailed Description

The purpose of the study is to identity knowledge, attitude and self-efficacy of high-risk Pakistani women towards breast self-examination. Secondly to develop breast health education program based on their culture values for education and training of breast self-examination among high-risk women who has the family history of breast cancer. Furthermore, the study will measure the effect of culture-based breast health education on breast self-examination practice and self-efficacy.

6. CONDITIONS AND KEYWORDS

Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study

1. High-risk women having family member (mother) with breast cancer
2. Education and Training of high-risk women to promote breast self-examination practice

Keywords (Breast cancer, breast self-examination practice, knowledge, attitude, self-efficacy, high-risk, culture-based program)

7. STUDY DESIGN (INTERVENTIONAL)

Primary Purpose (select one): Education and training

Study Phase (select one): N/A

Interventional Study Model (select one): Parallel (2-Arms) Intervention/Control Groups

Model Description

A two-arm parallel study design would be used to conduct this current study. The study participants in an intervention group would be compared with that of a control group. Participants would be allocated through random assignments in two groups with equal numbers.

Number of Arms: 2 (Intervention and Control Groups)

Masking Roles, if Masking (select all that apply): high-risk women and Outcome Assessors

Masking Description

The study participants would not be informed of what group they are in. Independent outcome assessors would be utilized for the assessment. Further outcomes assessors and data analysts' would be kept unaware of intervention or group allocations to carry out their assessment after inclusion of participants into the study.

Allocation (select one): Randomized

Enrollment Type (select one): Actual

Number of Subjects: Intervention Group 33

Control Group 33

8. ARMS, GROUPS, AND INTERVENTIONS

Arm 1: Arm Type (select one): Experimental

Arm Title Intervention Group

Arm Description:

A total of 33 participants would be exposed to the training (intervention) randomly.

Arm 2: Arm Type (select one): No Intervention (Control Group)

Arm Title: Control Group

Arm Description:

A sample of 33 study participants would not be exposed to the training and would be kept in the control group. They would be a group who would receive usual care and routine awareness from their health care professionals.

Intervention Type (select one): Behavioral

Intervention Name: Culture-based breast health education Program

Intervention Description:

The program is a nursing intervention, which aims is to enhance breast self-examination practice among high-risk adult women through improving knowledge, attitude, self-efficacy on breast self-examination with their family support based on social cognitive theory and culture identity concept of PEN-3 cultural model. The program will consist of interactive educational as well as training activities and mHealth application with its various infographic. The study participants will be evaluated after 12 weeks of intervention. A structured, validated and adopted questionnaire will be used to assess breast self-examination practice. Assistance of nursing instructors, health care professionals, specialized in oncology care will be taken during the training part of program.

Arm/Interventional Cross-Reference: Arm-1 Intervention Group
Arm-2 Control Group

9. OUTCOME MEASURES

Primary Outcome Measure

Outcome 1: Breast self-examination practice

Title: Breast self-examination practice will be assessed by the standardized self-reported breast self-examination frequency and proficiency of practice questionnaire at baseline and at 12th after the intervention end. This includes questions about frequency and skill to perform breast self-examination. The mean scores will be calculated for the overall participants to find the effectiveness of the program for high-risk women as compared to the control group.

Outcome 2: Self-efficacy of Breast self-examination

Title: Self-efficacy of breast self-examination will be measures through the standardized self- reported questionnaire at baseline, 4th week and 8th week of intervention. This includes the self-confidence of participants to perform breast self-examination.

10. ELIGIBILITY

Sex/Gender: Female

Gender-Based (if any): Only female participants

Gender Eligibility Description

Female aged 20-50 years, with family history of breast cancer (mother with breast cancer).

Age Limits:

Minimum Age:	20-Years
Unit of Time:	Years
Maximum Age:	50 Years
Unit of Time:	Years
Accepts Healthy Volunteers (select one):	Yes

Eligibility Criteria:

- Female participant able to communicate in Urdu (both verbal and written)
- Female Participant mother already diagnosed with breast cancer and under treatment.
- Female Participant has smart phone with internet access.
- Female Participant living with family.
- One female family member nominated by participant.
- Female participant not having pregnancy.

Exclusion Criteria:

- Female previously participated in breast awareness program.
- Female participate in program less than 90%.

11. CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION

Central Contact Person

First Name:	Sumaira
Middle Initial:	--------
Last Name or Official Title:	Naz
Degree:	PhD Nursing Scholar
Phone:	+92 331-8132975
Email:	sumaira.naz6@gmail.com

Central Contact Backup

First Name:	Sureeporn
Middle Initial:	--------
Last Name or Official Title:	Thanasilp
Degree:	PhD Nursing
Phone:	+6622181155
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Overall Study Official 1:

First Name:	Sumaira
Middle Initial:	----------
Last Name:	Naz
Degree:	Ph D Nursing Scholar
Organizational Affiliation:	Faculty of Nursing-Chulalongkorn university-Pakistan
Official's Role (select one):	Study Principal Investigator

Facility Information:

Facility Name:	Pakistan Ordinance Factory Hospital
City:	Wah Cantt/Taxila
State/Province:	Punjab
ZIP/Postal Code:	47010/47080
Country:	Pakistan
Individual Site Status (select one):	Recruiting
Facility Contact Backup:	Clinical Instructor, POF (Pakistan ordinance factory Hospital), Wah Cantt/Taxila -Pakistan
First Name:	Misbah
Middle Initial:	-----
Last Name:	Naureen
Degree:	MSN
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Investigators:

First Name:	Sumaira
Middle Initial:	-------
Last Name	Naz
Degree:	PhD Nursing Scholar
Role (select one):	Site Principal Investigator

12. IPD SHARING STATEMENT

Plan to Share IPD (select one):	Yes
IPD Sharing Plan Description:	Data generated through this study may be provided to qualified researchers. All the information shared will be coded and with prior permission of concerned departments will be obtained.

IPD Sharing Supporting Information Type (select all that apply): Study Protocol, Statistical Analysis Plan, Report

IPD Sharing Time Frame:	Data requests can be submitted after article publication.
IPD Sharing Access Criteria:	Access can be demanded by qualified researchers through proper approval of the investigators.
IPD Sharing URL:	----------

13. REFERENCES

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