

# Improving breast self-examination practices among rural women using mannequin-based health education by healthcare professionals in Bihar

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<b>Registration date</b> 29/01/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/01/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Breast cancer is the most common cancer among women worldwide, and early detection can significantly improve outcomes. In India, breast cancer is often diagnosed at advanced stages due to delayed detection and limited access to screening services. Breast self-examination (BSE), a simple, non-invasive method, is recommended for early detection, especially in low-resource settings. However, BSE practices remain underutilized in India, particularly in rural areas. This study aims to assess the effectiveness of mannequin-based health education provided by healthcare professionals on the accuracy of breast self-examination practices among women aged 20–45 years in rural Bihar.

### Who can participate?

Women aged 20–45 years residing in selected rural villages of Bihar for at least one year, who are willing to participate and provide informed consent

### What does the study involve?

Participants are divided into two groups: intervention and comparator. All participants undergo a baseline assessment and receive a video demonstration and health talk on breast cancer risk factors and prevention. The intervention group receives mannequin-based BSE training in two sessions: the first at one month and the second at three months after enrollment. The comparator group receives only standard care. Acceptability of the mannequin-based training is assessed in the intervention group immediately after the first session using the Kirkpatrick model. An endline assessment for both groups is conducted six months after enrollment to evaluate BSE practices.

### What are the possible benefits and risks of participating?

Participants in the intervention group may develop correct BSE practices, aiding in early breast cancer detection. Risks are minimal, with slight discomfort possible during mannequin-based training.

Where is the study run from?

The study is being conducted by the Department of Community and Family Medicine, AIIMS Patna, and implemented in villages under the Rural Health Training Centre (RHTC), Naubatpur.

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

Overall study dates are June 2023 to February 2025. The recruitment started in February 2024 and will run until February 2025, with the endline assessment expected to conclude by then.

Who is funding the study?

The study is funded by the Indian Council of Medical Research (ICMR).

Who is the main contact?

Dr Swapnil Singh, Department of Community and Family Medicine, AIIMS Patna, swapnilsinghbaghel02@gmail.com, swapnil11623@aiimspatna.org

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

No-HRD-Head/PGthesis-program/2023-24(68) Dated 27/08/2024

## Study information

### Scientific Title

Effectiveness of mannequin-based health education intervention provided by healthcare professionals on the breast self-examination practices among women aged 20-45 years in rural Bihar: a community-based pragmatic controlled trial

## **Acronym**

EMPOWER

## **Study objectives**

Null hypothesis- Mannequin-based health education intervention provided by healthcare professionals does not increase the correctness of breast self-examination practices among women aged 20-45 years in rural Bihar.

Alternate hypothesis- Mannequin-based health education intervention provided by healthcare professionals significantly increases the correctness of breast self-examination practices among women aged 20-45 years in rural Bihar.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 05/12/2023, Institutional Ethics Committee AIIMS Patna (Phulwarisharif, Patna, 801507, India; +91 0612-2451006; admin@aiimspatna.org), ref: AIIMS/Pat/IEC/PGTh/Jan23/10

## **Study design**

Interventional cluster-randomized unblinded community-based pragmatic controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life, Screening, Efficacy

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

Breast cancer awareness and the accuracy of breast self-examination practices among women aged 20–45 years in rural Bihar

## **Interventions**

The study includes two groups: intervention and comparator. Two out of four villages in the AIIMS Patna field practice area were purposively selected—those farthest apart to minimize contamination. Randomization was then conducted at the village level using the chit system, where chits were drawn to allocate one village to the intervention group and the other to the comparator group.

- Baseline Assessment: All participants will watch a video on breast self-examination (BSE) and receive a health talk on breast cancer risk factors and prevention.
- Intervention Group: Participants will undergo mannequin-based BSE training in two one-on-one sessions: the first at one month and the second at three months post-enrollment, with a detailed demonstration of the BSE steps. Acceptability of the intervention will be assessed in this group immediately after the first session using the Kirkpatrick model.
- Comparator Group: Participants will not receive the mannequin-based training but will continue to receive standard care at the Rural Health and Training Centre (RHTC), Naubatpur.

- Endline Assessment: Both groups will undergo an endline assessment six months post-enrollment.

**Intervention Type**

Behavioural

**Primary outcome(s)**

Correctness of breast self-examination (BSE) practices is measured using a checklist of BSE steps at baseline and at 6 months post-enrollment.

**Key secondary outcome(s)**

Acceptability of mannequin-based BSE training measured using the Kirkpatrick model checklist immediately after the first intervention session in the intervention group.

**Completion date**

28/02/2025

**Eligibility****Key inclusion criteria**

1. Women aged 20-45 years
2. Residing in the selected rural areas for at least 1 year
3. Participants who are willing to participate in the educational intervention and follow-up assessments

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

20 years

**Upper age limit**

45 years

**Sex**

Female

**Key exclusion criteria**

1. Women with a previous history of breast cancer
2. Those who have undergone mastectomy
3. Women with any history of breast lesions Suspected to be benign or cancerous lesions
4. Women who have undergone any training on screening for breast cancer
5. Women who are part of any project related to screening and/or management of breast cancer
6. Women with known psychiatric illnesses (documented/self-reported)

**Date of first enrolment**

05/02/2024

**Date of final enrolment**

31/07/2024

## **Locations**

**Countries of recruitment**

India

**Study participating centre****Maharajganj**

Village- Maharajganj/ Block - Naubatpur/ City- Patna/Bihar India

Patna

India

800007

**Study participating centre****Ajwan**

Village-Ajwan/ Block - Naubatpur/ City- Patna/Bihar India

Patna

India

801109

## **Sponsor information**

**Organisation**

All India Institute of Medical Sciences, Patna

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Indian Council of Medical Research

**Alternative Name(s)**

Indian Council of Medical Research, Government of India, Indian Council of Medical Research (ICMR), New Delhi, ICMROrganisation, , Indian Council of Medical Research, New Delhi, . . . , ICMR, ICMRDELHI, ...

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

India

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Swapnil Singh, swapnilinghbaghel02@gmail.com, swapnil11623@aiimspatna.org. Researchers who provide a methodologically sound proposal may request access. Data will be shared to achieve the aims specified in the approved proposal. To gain access, data requestors must sign a data access agreement.

De-identified individual participant data for primary and secondary outcomes will be available. Only de-identified data related to primary and secondary outcomes will be shared. A Statistical Analysis Plan will be shared. The study protocol will not be shared. Data will be available within three months of a formal request and will remain available for a period of five years.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			29/01/2025	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes