ISRCTN14306707 https://doi.org/10.1186/ISRCTN14306707

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

Submission date
24/01/2025

Recruitment status
No longer recruiting

Registration date
29/01/2025

Overall study status
Completed

Last Edited
08/04/2026

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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, swapnilsinghbaghel02@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Swapnil Singh

ORCID ID
https://orcid.org/0009-0008-0077-6956

Contact details
ESIC Medical College and Hospital campus in Bihta, Patna
Patna, Bihar
India
801103
+91 9755789082
swapnilsinghbaghel02@gmail.com

Additional identifiers

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

Primary study design
Interventional

Study design
Interventional cluster-randomized unblinded community-based pragmatic controlled trial

Study type(s)
Efficacy, Quality of life, Screening

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

Total final enrolment
0

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, swapnilsinghbaghel02@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?
Participant information sheet			29/01/2025	No	Yes