Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Psychometric Evaluation of the Persian Version of the Fertility Intention Scale among Young Breast Cancer Survivors

Protocol summary

Study aim
"Psychometrics of the Persian Version of the Fertility Intention Scale for Young Breast Cancer Survivors"

Design
First, the questionnaire will be translated by two independent translators, and then a synthesized version will be prepared. Back-translation will be performed by two other translators, and the versions will be compared with the original text. Subsequently, a 10-member expert panel, including nursing faculty, oncology specialists, reproductive health researchers, and a psychometric expert, will evaluate the translated version for clarity, conceptual meaning, and cultural appropriateness, and will approve the pre-final version. Content validity will be assessed using CVR and CVI indices based on the opinions of 10 experts, and face validity will be examined qualitatively and quantitatively through 10 patients and 5 experts. Construct validity will be evaluated using exploratory and confirmatory factor analysis with standard fit indices. The instrument's reliability will be measured using Cronbach's alpha and test-retest (ICC). Finally, after confirming its psychometric properties, the Persian version of the scale will be ready for use in clinical and reproductive health research."

Settings and conduct
Ayatollah Khansari Hospital

Participants/Inclusion and exclusion criteria
Young female breast cancer survivor with confirmed diagnosis by an oncologist. Being of reproductive age (having regular menstruation and not having entered menopause). No severe physical illnesses or psychiatric disorders that could impair the ability to respond (such as dementia or psychotic episodes). Conscious willingness and consent to participate in the study.

Intervention groups
0

Main outcome variables
Fertility Intention Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250421065430N4**
Registration date: **2026-04-20, 1405/01/31**
Registration timing: **prospective**

Last update: **2026-04-20, 1405/01/31**
Update count: **0**

Registration date
2026-04-20, 1405/01/31

Registrant information

Name
Ahmadreza Mozaffari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3276 2768

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-23, 1405/05/01

Expected recruitment end date
2026-07-23, 1405/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Psychometric Evaluation of the Persian Version of the Fertility Intention Scale among Young Breast Cancer Survivors

Public title
Psychometric Evaluation of the Persian Version of the Fertility Intention Scale among Young Breast Cancer Survivors
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Young female breast cancer survivor with confirmed diagnosis by an oncologist. Being of reproductive age (having regular menstruation and not having entered menopause). No severe physical illnesses or psychiatric disorders that could impair the ability to respond (such as dementia or psychotic episodes). Conscious willingness and consent to participate in the study.
Exclusion criteria:
Having a history of treatment or surgery that has led to the complete removal of reproductive organs (e.g., hysterectomy or bilateral oophorectomy). Unwillingness of the participant to continue cooperation at any stage of the research.
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak University of Medical Sciences
Street address
Faculty of Nursing and Midwifery; Arak University of Medical Sciences, Basij square
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2026-04-18, 1405/01/29
Ethics committee reference number
IR.ARAKMU.REC.1405.020

Health conditions studied

1

Description of health condition studied
Fertility Intention
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fertility Intention
Timepoint
"After providing explanations to complete the questionnaire."
Method of measurement
Fertility Intention scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: "This study aims to psychometrically evaluate the Persian version of the Fertility Intention Scale for young female breast cancer survivors. Participants include women who have completed active breast cancer treatment, are in the follow-up phase, and according to the opinion of an oncology specialist, are of reproductive age and possess the cognitive ability and literacy in Persian. The research procedures will follow standard guidelines for translation and cultural adaptation of psychometric instruments. First, the questionnaire will be translated by two independent translators, and then a synthesized version will be prepared. Back-translation will be performed by two other translators, and the versions will be compared with the original text. Subsequently, a 10-member expert panel, including nursing faculty, oncology specialists, reproductive health researchers, and a psychometric expert, will evaluate the translated version for clarity, conceptual meaning, and cultural appropriateness, and will approve the pre-final version. Content validity will be assessed using CVR and CVI indices based on the

opinions of 10 experts, and face validity will be examined qualitatively and quantitatively through 10 patients and 5 experts. Construct validity will be evaluated using exploratory and confirmatory factor analysis with standard fit indices. The instrument's reliability will be measured using Cronbach's alpha and test-retest (ICC). Finally, after confirming its psychometric properties, the Persian version of the scale will be ready for use in clinical and reproductive health research."

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Khansari Hospital
Full name of responsible person
Ahmadreza Mozaffari
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
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Payambare Azam University Complex, Research and Technology Deputy, Arak University of Medical Sciences, Basij square
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Ahmadreza mozaffari
Position
student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
En There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available