Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of implementation consultative-supportive plan based on the Peplau nursing model on perceived stress, hope and sleep quality of women in waiting time for result of breast biopsy.

Protocol summary

Study aim

Determining the Impact of Counseling-Supportive Program Based on Hildaard Peplove's Model on Perceived Stress, Hope Level and Sleep Quality in Women During the Expectation of the results of the Breast Biopsy.

Design

The study is a randomized, double-group pre-test and post-test clinical trial with concurrent independent or parallel control (Concurrent Control trial). Random assignment will be based on Permuted-Block Randomization. Due to the lack of a similar study to calculate the sample size, a pilot study will be conducted to determine the sample size.

Settings and conduct

The research population is the women referred to the radiology center of Imam Reza hospital in Mashhad, who is diagnosed with a clinical examination of the breast or imaging, needs to be diagnosed with biopsy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; Ability to read and write in Persian; Having phone access to follow the phone; Suspected of breast cancer and having a mass requiring biopsy. Non inclusion criteria: History of cancer and chronic disease; having a disability (mental, hearing, vision and speech) or having a mental illness; major stressful events in the past six months (death of first degree relatives, severe family members, financial bankruptcy, accident, severe family disputes with the spouse)

Intervention groups

The intervention group will receive consultative-supportive plan based on the Peplau nursing mode that includes two face-to-face sessions and two telephone follow-up sessions, and control group will receive the usual care.

Main outcome variables

The stress level; the hope level; the sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180618040128N1**
Registration date: **2018-10-12, 1397/07/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-12, 1397/07/20**
Update count: **0**

Registration date

2018-10-12, 1397/07/20

Registrant information

Name

Somayeh Gohari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3840 9472

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of implementation consultative-supportive plan based on the Peplau nursing model on perceived stress, hope and sleep quality of women in waiting time for result of breast biopsy.

Public title
The effect of consultative-supportive plan on perceived stress, hope and sleep quality
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Ability to read and write in Persian Having access to phone Suspected of breast cancer and having a mass requiring biopsy
Exclusion criteria:
Cancellation of participation in the study Taking sedatives, antidepressants or anti-anxiety History of cancer and chronic diseases Major stressful events in the past six months (death of first class relatives, severe family members, financial failures, accidents, severe family disputes with the spouse) Disability (mental, hearing, vision and speech) or mental illness
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment will be based on Permuted-Block Randomization. For this purpose, the size of each block will be determined initially. Then the list of blocks will be prepared and numbers will be allocated to them. Then, by selecting random numbers, the allocation list will be specified.
Blinding (investigator's opinion)
Single blinded
Blinding description
The analyst will be unaware of the intervention and control groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Ethics Committee for Biomedical Research
Street address
Thirteenth floor, block A, Central Headquarters of the Ministry of Health and Medical Education, Sima-e-Iran Street, between South Felamak and Zarafshan streets, Ghods Township
City
Tehran
Province
Razavi Khorasan
Postal code
81455618
Approval date
2018-06-30, 1397/04/09
Ethics committee reference number
IR.MUMS.REC.1397.093

Health conditions studied

1

Description of health condition studied
Breast
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Perceived stress
Timepoint
Before the intervention, before receiving the biopsy result and two weeks after receiving the biopsy result
Method of measurement
Cohen Perceived Stress Questionnaire

2

Description
Hope
Timepoint
Before the intervention, before receiving the biopsy result and two weeks after receiving the biopsy result
Method of measurement
Snyder's hope Questionnaire

3

Description
Sleep quality
Timepoint
Before the intervention, before receiving the biopsy result and two weeks after receiving the biopsy result
Method of measurement
Petersburg's Sleep Quality Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A group who will apply a counseling-supportive based on the Peplau model, which includes two face-to-face meetings and two follow-up by telephone. Depending on the patient's needs, the nurse-patient communication sessions take 30 to 40 minutes. The first session is formed by the physician after the client's visit and the confirmation of the need for biopsy so that the nurse, by introducing herself and expressing the research goals, will attract the satisfaction of the patients to participate in the study and give a pre-test. The second meeting is face-to-face communication before biopsy and after that, two telephone follow-up will be made to get results.

Category
Prevention

2

Description
Control group: receives conventional care

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Interventional radiology, Mashhad Imam Reza hospital

Full name of responsible person
Zahra Sadat Manzari

Street address
Holy Imam Reza Hospital, Emam Reza square

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2

Recruitment center

Name of recruitment center
Tumor clinic of Quaem hospital of Mashhad city

Full name of responsible person
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Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Somayeh Gohari

Position
University student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available