

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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 Peplave'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)

Phone

+98 51 3840 9472

Email address

goharis941@mums.ac.ir

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

Manzariz@mums.ac.ir

2

Recruitment center

Name of recruitment center

Tumor clinic of Quaem hospital of Mashhad city

Full name of responsible person

Zahra Sadat Manzari

Street address

Quaem hospital, at the first of Ahmad abad Avenue, Dr. Ali shariati square, Mashhad city, North Khorasan province.

City

Mashhadm

Province

Razavi Khorasan

Postal code

9919991766

Phone

+98 51 3840 0000

Email

Manzariz@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Manzari Zahra Sadat

Street address

Faculty of Nursing and Midwifery, Ibn Sina Avenue, Doctora intersection, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1512

Email

Manzariz@mums.ac.ir

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

Street address

Faculty of Nursing and Midwifery, Ibn Sina Avenue,
Doctora intersection

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

+98 51 3859 7313

Email

Goharis941@mums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Sadat Manzari

Position

Deputy School of Nursing and Midwifery, Mashhad

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Ibn Sina Avenue,
Doctora intersection, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

+98 51 3859 7313

Email

Manzariz@mums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Gohari Somayeh

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Ibn Sina Avenue,
Doctora intersection, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

+98 51 3859 7313

Email

Goharis941@mums.ac.ir

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