

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of psychological preparation on patient's anxiety level before taking biopsy from breast in women referred to Ahvaz Golestan Hospital

Protocol summary

Study aim

Aim was evaluation effect of psychological preparation on patient's anxiety level before taking biopsy from breast in women referred to Ahvaz Golestan Hospital.

Design

This assessment is a clinical trial in Phase 3, patients who had a breast biopsy indications considered as the study group. In this study, 62 cases who meet the inclusion criteria will be selected. Patients will be divided into two groups, with 31 case in the intervention group and 31 cases in the control group nonrandomly, patients' anxiety status was evaluated and compared before and after the intervention.

Settings and conduct

This study was performed as a clinical trial in Ahvaz Golestan Hospital, also the study was not blind and not randomized.

Participants/Inclusion and exclusion criteria

Inclusion criteria included as conversational language persian, ability to communicate verbally, no previous history of breast biopsy, having conscious satisfaction, and exclusion criteria included as history of major psychiatric disorder and obvious physical problem

Intervention groups

For the intervention group, 2 to 3 hours before the biopsy, a psychiatric preparation was performed by a psychiatric assistant, also for the duration of the intervention for the case group, neutral materials (properties of fruits and vegetables) prepared in the form of pamphlets were given to the control group for study and no other intervention was performed.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200919048764N1**

Registration date: **2020-10-14, 1399/07/23**

Registration timing: **retrospective**

Last update: **2020-10-14, 1399/07/23**

Update count: **0**

Registration date

2020-10-14, 1399/07/23

Registrant information

Name

Sajedeh Zarif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3232 3051

Email address

sajedehzarif95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-30, 1398/04/09

Expected recruitment end date

2020-04-28, 1399/02/09

Actual recruitment start date

2019-06-30, 1398/04/09

Actual recruitment end date

2020-04-28, 1399/02/09

Trial completion date

2020-04-28, 1399/02/09

Scientific title

The effect of psychological preparation on patient's anxiety level before taking biopsy from breast in women referred to Ahvaz Golestan Hospital

Public title

The effect of psychological preparation on patient's anxiety level before taking biopsy from breast

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Conversational language Persian Ability to communicate verbally No previous history of breast biopsy Having conscious satisfaction

Exclusion criteria:

History of major psychiatric disorder Obvious physical problem

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **62**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jondishapur University of Medical Sciences

Street address

1579461357, olom pezeshki Blvd, Ahvaz, Khuzestan

City

Ahvaz

Province

Khuzestan

Postal code

1579461357

Approval date

2019-09-27, 1398/07/05

Ethics committee reference number

IR.AJUMS.REC.1398.476

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Timepoint

Method of measurement

2

Description

State anxiety

Timepoint

Before and after the intervention

Method of measurement

Spiel Berger overt and covert anxiety questionnaire

3

Description

Trait anxiety

Timepoint

Before and after the intervention

Method of measurement

Spiel Berger overt and covert anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, 2 to 3 hours before the biopsy, a psychiatric preparation was performed by a psychiatric assistant.

Category

Prevention

2

Description

Control group: For the duration of the intervention for the case group, neutral materials (properties of fruits and vegetables) prepared in the form of pamphlets were given to the control group for study and no other intervention was performed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Masoumeh Nazari Nasab

Street address

6135733118, Golestan Hospital, Golestan Alley,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Korosh Zare

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Masoumeh Nazari Nasab

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Position

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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