

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The impact of individual counseling on quality of life in Women with cyclic mastalgia

Protocol summary

Summary

Objectives: The impact of individual counseling on quality of life in Women with cyclic mastalgia, (2)Design: a controlled clinical trial. Setting and conduct: This study Will be performed on 80 women with cyclic mastalgia in Karaj, who are eligible to enter the study. The McGill Pain Questionnaire and WHO Questionnaire are used to assess quality of life, (3)Setting and conduct: In order to randomize, a two-stage cluster random sampling method will be used to select the centers.This means that the city will be divided into 5 regions and one health center will be selected from each region. Sample individuals will be selected randomly from these centers and using the random allocation method, will be divided into two groups of intervention and control. Before the intervention and one month after the intervention, the questionnaires will be completed by the two groups and the results will be compared with each other, (4) Participants including major eligibility criteria: Inclusion criteria: pain score ≥ 4 ; pain duration >5 days; 20-year interval to premenopausal state; regular menstruation cycle, Exclusion criteria: Pregnancy;lactation; patient with psychological and somatic disease; The history of breast cancer in the patient and her family; Patients who have been treated for breast pain for the last three months; using Hormonal contraceptives, (5) Intervention: individual counseling (6) main outcome measures (variables): quality of life in Women with cyclic mastalgia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100236513N1**

Registration date: **2017-10-26, 1396/08/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-26, 1396/08/04

Registrant information

Name

Solmaz Fakhravar

Name of organization / entity

Qazvin University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3442 5647

Email address

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research - Qazvin University of Medical Science

Expected recruitment start date

2017-09-03, 1396/06/12

Expected recruitment end date

2017-11-03, 1396/08/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of individual counseling on quality of life in Women with cyclic mastalgia

Public title

The impact of individual counseling on quality of life

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pain score ≥ 4 ; pain duration >5 days; 20-year interval to premenopausal state; regular menstruation cycle, Exclusion criteria: Pregnancy;lactation; patient with psychological and somatic disease; The history of breast cancer in the patient and her family; Patients who have been treated for breast pain for the last three months; using Hormonal contraceptives

Age

From **20 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

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 Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Boulevard,Qazvin

City

Qazvin

Postal code**Approval date**

2017-09-02, 1396/06/11

Ethics committee reference number

IR.QUMS.REC.1396.246

Health conditions studied**1****Description of health condition studied**

Cyclic Mastalgia

ICD-10 code

N64.4

ICD-10 code description

Mastodynia

Primary outcomes**1****Description**

Quality of life

Timepoint

Before and one month after intervention

Method of measurement

Mcgill pain questionnaire , WHOQOL BREF questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: at first the Mcgill pain questionnaire and WHO quality of life brief questionnaire to assess the quality of life will be completed in control group. In this group the subjects won't be given counseling and special training. Finally, a month after the last session of the counseling Mcgill pain questionnaire and WHO quality of life brief questionnaire will be completed by subjects and level of quality life will be assessed.

Category

Lifestyle

2**Description**

Intervention group, at first the Mcgill pain questionnaire and WHO quality of life brief questionnaire to assess the quality of life will be completed by intervention group. Then they will be participated in the counseling sessions. Research units participate in consultation meetings that will be 3 sessions of individual counseling with intervals of 2 days. The duration of sessions are 45 to 60 minutes. Finally, a month after the last counseling session level of quality of life will be assessed.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Javadolaemeh Comprehensive health service center

Full name of responsible person

Solmaz Fakhravar

Street address**City**

Karaj

2

Recruitment center

Name of recruitment center

Sabzehparvar Comprehensive health service center

Full name of responsible person

Solmaz Fakhravar

Street address**City**

Karaj

3

Recruitment center

Name of recruitment center

Sesarak bala Comprehensive health service center

Full name of responsible person

Solmaz Fakhravar

Street address**City**

Karaj

4

Recruitment center

Name of recruitment center

Anbari Comprehensive health service center

Full name of responsible person

Solmaz Fakhravar

Street address**City**

Karaj

5

Recruitment center

Name of recruitment center

Emam Hasan Mojtaba Comprehensive health service center

Full name of responsible person

solmaz fakhravar

Street address**City**

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Qazvin University of Medical Sciences

Full name of responsible person

Amir Peymani

Street address

Qazvin University of Medical Sciences, Bahonar Boulevard, Qazvin

City

Qazvin

Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Qazvin University Of Medical Sciences

Full name of responsible person

Solmaz Fakhravar

Position

Masters student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty