

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Sexual Satisfaction after Psychosexual Counselling in Women with Cyclic Mastalgia: An Intervention Study based on the PLISSIT Model

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

Evaluating the effect of psychosexual counselling based on the PLISSIT model on sexual satisfaction in women with periodic mastalgia

Last update: **2019-01-07, 1397/10/17**

Update count: **0**

#### Registration date

2019-01-07, 1397/10/17

#### Design

In this clinical trial, subjects are randomly assigned to one of two groups: the experimental group receiving the intervention, and the control receiving the conventional treatment. The sample size is considered to be 90 (45 patients in each group). To evaluate the efficacy of the study, questionnaires will be completed by all patients before and after the intervention.

#### Registrant information

##### Name

Fatemeh Ghodsi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3293 5402

##### Email address

f.ghodsi@qums.ac.ir

#### Settings and conduct

In this study, subjects are randomly selected from one "Comprehensive Urban Health Center" from each four different regions of Qazvin City; Northwest, Northeast, Southwest and Southeast plus a "Breast Hospital Clinic".

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

inclusion criteria: cyclic breast pain Minimum age of 20 years old regular menstrual periods Married Exclusion criteria: pregnancy menopause Lactation physical or mental illness breast cancer Medical treatment hormonal methods for contraception

#### Expected recruitment start date

2018-09-23, 1397/07/01

#### Expected recruitment end date

2019-02-19, 1397/11/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Intervention groups

The intervention will be individual counselling based on the PLISSIT model. Consultation for the intervention group will be carried out in at least four sessions. Sessions take place on a weekly basis and each lasts for 90 minutes. The control group will receive routine care.

#### Trial completion date

empty

#### Main outcome variables

Sexual satisfaction, sexual distress

#### Scientific title

Sexual Satisfaction after Psychosexual Counselling in Women with Cyclic Mastalgia: An Intervention Study based on the PLISSIT Model

#### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180826040862N1**

Registration date: **2019-01-07, 1397/10/17**

#### Public title

The Effect of Sex Counseling on Sexual Satisfaction in Women with Cyclic breast pain

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Breast pain of four or above based on the visual analogue scale pain which lasts more than five days according to the Cardiff Breast Clinic. At least 20 years old Having regular menstrual periods Being Married and having regular sex No menopause

### Exclusion criteria:

pregnancy Lactation Having physical or mental illness (self-declaration) Family or personal history of breast cancer Drug Administration for treating breast pain in the last three months Using hormonal methods for contraception

## Age

From **20 years** old to **55 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The assignment of women with cyclic mastalgia into groups of intervention and control follows the method of simple randomization. According to this method, in each treatment center, a pool with letters of either A or B kept within sealed envelopes will be considered. The number of envelopes matches the number of subjects in the study. Envelopes will be drawn from the pool without replacement by each subject who enters the study.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

This study consists of two groups with one group receiving the intervention.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of qazvin University of Medical Sciences

##### Street address

Shahid Bahonar Blvd

##### City

Qazvin

## Province

Qazvin

## Postal code

34199-15315

## Approval date

2018-09-25, 1397/07/03

## Ethics committee reference number

IR.QUMS.REC.1397.138

## Health conditions studied

### 1

#### Description of health condition studied

Cyclic Mastalgia, Sexual Satisfaction

#### ICD-10 code

N64.4

#### ICD-10 code description

Mastodynia

## Primary outcomes

### 1

#### Description

Sexual satisfaction

#### Timepoint

Before the intervention - one month after the intervention - three months after the intervention

#### Method of measurement

Larson Sexual Satisfaction Questionnaire

## Secondary outcomes

### 1

#### Description

Sex Distress

#### Timepoint

Before the intervention- one month after the intervention - three months after the intervention

#### Method of measurement

Sexual Distress Dissolved Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: First, questionnaires will be completed by patients. This then will be followed by four one to one in-person counselling sessions. Sessions take place on a weekly basis and each lasts for 90 minutes. According to the PLISSIT model, sessions are summarised as follows: Session 1: Patient administration. During this session, the history of breast pain and sexual discomforts of the patient will be recorded. Session 2: Patient will receive a brief anatomical and physiological summary of limbs and breast. Session 3: Explicit recommendations. At this session, consultation on specific concerns such as

fundamental sexual related concepts and training on specific sexual attitudes and practices and various forms of sexual stimulation will be provided. Mental health screening will also be conducted at this session. Session 4: Referral for comprehensive treatment: After a careful evaluation of the patient's performance during the previous meetings, the patient will be referred if it was concluded that she requires more specialist psychosexual counselling in areas such as male sexual dysfunctions and psychological disorders. Patients will be asked to fill the questionnaires after the intervention completion and also three months after the final counselling session.

### **Category**

Rehabilitation

## **2**

### **Description**

Control group: First, patients are asked to complete the questionnaire. Patients in this group will receive the current standard treatment for Mastalgia. The investigator will not provide the routine treatment. After completing counselling sessions for the intervention group, the control group will be asked to complete the questionnaire simultaneously. If the PLISSIT method outperforms the current standard treatment, after finishing the study, for ethical considerations, patients in the control group will also be introduced to the psychosexual counselling sessions by the investigator.

### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Educational and therapeutic center of the Velayat

##### **Full name of responsible person**

Fatemeh Ghodsi

##### **Street address**

22 bahman

##### **City**

Qazvin

##### **Province**

Qazvin

##### **Postal code**

3471976161

##### **Phone**

+98 28 3379 0620

##### **Email**

hosvelayat.qums@yahoo.com

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Health Center No. 5 (Valiasr)

##### **Full name of responsible person**

Fatemeh Ghodsi

##### **Street address**

Shahid beheshti

##### **City**

Qazvin

##### **Province**

Qazvin

##### **Postal code**

3415633956

##### **Phone**

+98 28 3334 5057

##### **Email**

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### **3**

#### **Recruitment center**

##### **Name of recruitment center**

Health Center No. 12 (Taghavi)

##### **Full name of responsible person**

Fatemeh Ghodsi

##### **Street address**

Dehkhoda Square. Minoder area.

##### **City**

Qazvin

##### **Province**

Qazvin

##### **Postal code**

3471749839

##### **Phone**

+98 28 3378 3300

##### **Email**

infobhc@qums.ac.ir

### **4**

#### **Recruitment center**

##### **Name of recruitment center**

Health Center No. 11 (Shahid bolandian)

##### **Full name of responsible person**

Fatemeh Ghodsi

##### **Street address**

End of University Street

##### **City**

Qazvin

##### **Province**

Qazvin

##### **Postal code**

3414763111

##### **Phone**

+98 28 3365 2972

##### **Email**

infobhc@qums.ac.ir

### **5**

#### **Recruitment center**

##### **Name of recruitment center**

Health Center No.2 (shohada)

##### **Full name of responsible person**

Fatemeh Ghodsi

##### **Street address**

Shohada street

##### **City**

Qazvin  
**Province**  
Qazvin  
**Postal code**  
3418737531  
**Phone**  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
fatemeh ghodsi  
**Street address**  
Bahonar  
**City**  
Qazvin  
**Province**  
Qazvin  
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1531534199  
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info@qums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Qazvin University of Medical Sciences  
**Proportion provided by this source**  
10  
**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**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Ghodsi  
**Position**  
Student of MSc in midwifery counseling  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**

Midwifery  
**Street address**  
unit 27, Ofogh 8 Building, 10th alley, Ferdowsi Avenue, Sadoghi Avenue  
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Ghoush  
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3716888976  
**Phone**  
+98 25 3293 5402  
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## Person responsible for scientific inquiries

#### Contact

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

#### Contact

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**Province**

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+98 25 3293 5402  
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## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Yes - There is a plan to make this available

### **Statistical Analysis Plan**

Yes - There is a plan to make this available

### **Informed Consent Form**

Yes - There is a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

Yes - There is a plan to make this available

### **Data Dictionary**

Yes - There is a plan to make this available

### **Title and more details about the data/document**

All data from questionnaires is able to be shared (without the names of the samples).

### **When the data will become available and for how long**

Six months after the publication of the results in the official journals

### **To whom data/document is available**

All researchers working in educational and industrial institutions can apply for it.

### **Under which criteria data/document could be used**

If our documentation prevents repetition of a similar study. If our documentation makes progress in a research process.

### **From where data/document is obtainable**

The main implementer of the project: Fatemeh Ghodsi  
Address: unit 27, Ofogh 8 Building, 10th alley, Ferdowsi Avenue, Sadoghi Avenue  
Tell:00989338678004 email: F.ghodsi@qums.ac.ir , fatimaghodsi@gmail.com

### **What processes are involved for a request to access data/document**

It is necessary for the applicant to provide a complete introduction of his or her identity and to explain clearly why his request is necessary. After consultation with other administrators, in particular the supervisor, the requested files will be sent.

### **Comments**