

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Evaluating the effect of Guided Imagery with Music (GIM) on sexual satisfaction and function of women with sexual dysfunction

#### Protocol summary

##### Study aim

Effect of Guided Imagery with music (GIM) on Sexual Satisfaction and Sexual Function of Women with Sexual Dysfunction

##### Design

Three-stage clinical trial in two groups of control and intervention.

##### Settings and conduct

Comprehensive health care centers

##### Participants/Inclusion and exclusion criteria

Married women aged 19-49 years with sexual dysfunction; No history of surgery in participants and their husbands; Having mental and physical health NO Premature menopause; Having a diploma and higher education; Having Iranian citizenship for couples; Women who do not live separately from their husbands at the time of the interview; Not having any known diseases that affect sexual function in participants or their husbands; Not consuming drugs that affect sexual function in participants or their husbands; Women who do not remarry; No history of sexual abuse in any life period based on what they say; At least one year has passed since their marriage; Not receiving any other treatment; Not participating in another clinical trial study similar to the present study; The consent of both couples to participate in the research; Not having experience of severe stress in any couple in recent years; Not being addicted to alcohol, cigarettes, and opioids in participants and their husbands; Not being pregnant and first trimester after delivery Exclusion criteria: Occurrence of psychological and physical problems during the study; Unwillingness to continue collaborating during the study; Doing exercises less than half of the conducted sessions; Oral and anal sex

##### Intervention groups

Intervention is an audio file based on guided imagery with music (GIM) technique, in 30-minutes sessions twice a week for 6 weeks in women of reproductive age with sexual dysfunction. There will be no intervention for the

control group and they will receive routine care.

##### Main outcome variables

Sexual Satisfaction and Sexual Function

#### General information

##### Reason for update

##### Acronym

GIM

##### IRCT registration information

IRCT registration number: **IRCT20190806044460N1**

Registration date: **2020-01-09, 1398/10/19**

Registration timing: **prospective**

Last update: **2020-01-09, 1398/10/19**

Update count: **0**

##### Registration date

2020-01-09, 1398/10/19

##### Registrant information

##### Name

Elahe Mohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3743 4144

##### Email address

elahe13mohammadi@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-09, 1398/11/20

##### Expected recruitment end date

2020-03-05, 1398/12/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the effect of Guided Imagery with Music (GIM) on sexual satisfaction and function of women with sexual dysfunction

**Public title**

Evaluating the effect of Guided Imagery with Music (GIM) on sexual satisfaction and function of women with sexual dysfunction

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Married women aged 19-49 years with sexual dysfunction No history of surgery in participants and their husbands Having mental and physical health NO Premature menopause Having a diploma or higher education Having Iranian citizenship for couples Women who do not live separately from their husbands at the time of the interview Not having any known diseases that affect sexual function in participants or their husbands Not consuming drugs that affect sexual function in participants or their husbands Women who do not remarry No history of sexual abuse in any life period based on what they say At least one year has passed since their marriage Not receiving any other treatment Not participating in another clinical trial study similar to the present study The consent of both couples to participate in the research Not having experience of severe stress in any couples in recent years Not being addicted to alcohol, cigarettes, and opioids in the participants and their husbands Not being pregnant and first trimester after delivery

**Exclusion criteria:**

Occurrence of psychological and physical problems for women during the study Unwillingness to continue collaborating during the study Doing exercises less than half of the conducted sessions Oral and anal sex

**Age**

From **19 years** old to **49 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Selected samples randomly divide into intervention and control groups. In this way, two health centers are randomly selected for intervention group and two centers for control group.

**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 in Research Vice chancellor for research - Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2019-12-04, 1398/09/13

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1398.505

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

Sexual dysfunction

**ICD-10 code**

F52

**ICD-10 code description**

Sexual dysfunction not due to a substance or known physiological condition

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

Sexual function score

**Timepoint**

Before, immediately after the intervention, and one month after the intervention

**Method of measurement**

The Female Sexual Function Index (FSFI)

**2****Description**

Sexual satisfaction score

**Timepoint**

Before, immediately after the intervention, and one month after the intervention

#### Method of measurement

Larson' s Sexual Satisfaction Questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Intervention in the present study will be based on the Guided Imagery with Music (GIM) technique. The intervention will be performed in 30 minutes sessions twice a week for 6 weeks. The first session will be 45-90 minutes in community health center and 11 sessions at home with researcher-made GIM audio file.

##### Category

Treatment - Other

#### 2

##### Description

Control group: There will be no intervention for the control group and they will receive routine care.

##### Category

N/A

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Comprehensive Health Care Centers of Isfahan

###### Full name of responsible person

Dr Reza Khadivi

###### Street address

Isfahan

###### City

Isfahan

###### Province

Isfahan

###### Postal code

۸۱۴۸۶۵۳۳۷۴

###### Phone

+98 31 1677 5199

###### Email

Health@mui.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Esfahan University of Medical Sciences

###### Full name of responsible person

Dr Shaghayegh Haghjoo

###### Street address

Isfahan

###### City

Isfahan

###### Province

Isfahan

###### Postal code

۷۳۴۶۱ -۸۱۷۴۶

###### Phone

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###### Email

research@mui.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

###### Full name of responsible person

Mahshid Abdi Shahshahani

###### Position

Instructor

###### Latest degree

Master

###### Other areas of specialty/work

Midwifery

###### Street address

School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jerib street, Azadi square, Isfahan, Iran.

###### City

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###### Province

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m\_abdi@nm.mui.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mahshid AbdiShahshahani

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Reproductive Health

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Elahe Mohammadi

**Position**

MSc Student of Midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

No. 82 , Dead end 6, Vahdat alley, Imam street

**City**

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**Province**

Isfahan

**Postal code**

8451814313

**Phone**

+98 31 3742 0362

**Email**

elahe13mohammadi@nm.mui.ac.ir

## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

Protocol of study and reporting of study in the form of articles and theses

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

since it released forever

**To whom data/document is available**

everyone

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

No more information

**From where data/document is obtainable**

Library or magazine site where the article is published

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

No special process required

**Comments**