

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Clinical trial to evaluate the efficacy of short-term treatment for unconsummated marriage for sexual satisfaction

#### Protocol summary

##### Summary

The aim of this study is to evaluate the efficacy of short-term treatment on unconsummated marriage as an experimental clinical trial with pre- and post-test. The target population will be 44 couples with the history of unconsummated marriage referred to the super specialty clinic of Tooloo in Rasht; they will be selected by administering the sexual satisfaction questionnaires to them and a clinical interview by a psychiatrist according to the diagnostic criteria of Diagnostic and Statistical Manual of Mental Disorders (DSM-5). The minimum test scores for inclusion in the research will be ranged from 0 to 27 for men and from 0 to 36 for women. The couples with history of unconsummated marriage that the origin of their disease is not medical condition will be recruited by observation inclusion and exclusion criteria for the study by convenience sampling after obtaining the informed consent. Exclusion criteria would be any history of smoking; alcohol consumption or high body mass index. The treatment will be conducted during 5 sessions with the interval of one week. During the treatment, the skills including easy talking about sex, relaxation of genital muscles, cognitive restructuring, desensitization of anxiety will be taught. The efficacy obtained from the sexual satisfaction questionnaire will be evaluated one month later. The score above 28 for men and above 37 for women will confirm the efficacy of treatment.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2016103021965N3**

Registration date: **2017-01-20, 1395/11/01**

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

Last update:

Update count: **0**

##### Registration date

2017-01-20, 1395/11/01

##### Registrant information

###### Name

Homa Zarrabi

###### Name of organization / entity

Guilan University of Medical Sciences, «Kavosh »  
Cognitive Behaviour Sciences and Addiction Research

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3366 6268

###### Email address

shafakavosh@gums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

University Of Medical Sciences Guilan, Vice chancellor for research

##### Expected recruitment start date

2016-06-20, 1395/03/31

##### Expected recruitment end date

2017-06-21, 1396/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial to evaluate the efficacy of short-term treatment for unconsummated marriage for sexual satisfaction

##### Public title

Clinical trial to evaluate the efficacy of short-term treatment for unconsummated marriage for sexual

satisfaction

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: The couples with history of unconsummated marriage according to the diagnostic criteria of Diagnostic and Statistical Manual of Mental Disorders(DSM-5); obtaining score between 0-27 for men and between 0-36 for women by the sexual satisfaction questionnaire; the participants would included in study if they have 18-64 years old without medical conditions; Exclusion criteria: psychiatric disorders; medicals consumption affecting sexual physiology; drugs or alcohol consumption, smoking cigarette and high body mass.

**Age**  
From **18 years** old to **64 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **44**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**  
-

## Secondary Ids

1

**Registry name**  
-

**Secondary trial Id**  
-

**Registration date**  
empty

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**  
Ethics committee of Guilan University of Medical Sciences

**Street address**  
Shahid Beheshti Blvd, Opposite to the Sepah bank, Above Iran Radiator Representation. Building Of Assistance Research and Technology, Rasht, Iran

**City**  
Rasht

**Postal code**  
4193893345

**Approval date**  
2016-06-14, 1395/03/25

**Ethics committee reference number**  
IR.GUMS.REC.1395.76

## Health conditions studied

1

**Description of health condition studied**  
unconsummated marriage

**ICD-10 code**  
F52

**ICD-10 code description**  
Loss of sexual desire is the principal problem and is not secondary to other sexual difficulties, such as erectile failure or dyspareunia . Frigidity, Hypoactive sexual desire disorder

## Primary outcomes

1

**Description**  
sexual satisfaction

**Timepoint**  
before the treatment and one month after the treatment

**Method of measurement**  
sexual satisfaction questionnaire

## Secondary outcomes

1

**Description**  
-

**Timepoint**  
-

**Method of measurement**  
-

## Intervention groups

1

**Description**  
Intervention group: The treatment is conducted in five 45-minute sessions with one week interval and the skills of feeling comfortable to talk about sex the release of genital muscles cognitive restructuring and desensitization of anxiety will be taught.

**Category**  
Treatment - Other

## Recruitment centers

1

#### Recruitment center

**Name of recruitment center**

Tooloo Specialty and Subspecialty of Psychiatry Clinic of Rasht

**Full name of responsible person**

Dr kiomars Najafi

**Street address**

Shabnam alley, Golsar Crossroads, Opposite to the Municipal of Area (3), Rasht, Iran

**City**

Rasht

#### Sponsors / Funding sources

1

##### Sponsor

**Name of organization / entity**

University Of Medical Sceinces Guilan, Vice chancellor for research

**Full name of responsible person**

Dr Rasool Tabari

**Street address**

Shahid Beheshti Blvd, Opposite to the Sepah Bank, above Iran Radiator Representation, Rasht, Iran

**City**

Rasht

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

University Of Medical Sceinces Guilan, Vice chancellor for research

**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**

Guilan University Of Medical Sciences

**Full name of responsible person**

Dr Kiomars Najafi

**Position**

Psychiatrist, Assistant Professor

**Other areas of specialty/work**

**Street address**

15 khordad avenue, Shafa Hospital, Rasht, Iran

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41939-55599

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#### Person responsible for scientific inquiries

##### Contact

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**Full name of responsible person**

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**Position**

Assistant professor

**Other areas of specialty/work**

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#### Person responsible for updating data

##### Contact

**Name of organization / entity**

Guilan University Of Medical Sciences

**Full name of responsible person**

Mona Musaie

**Position**

Master Of science in Psychology

**Other areas of specialty/work**

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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*