Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The effect of integrative counseling based on EX-PLISIT model in women with female orgasmic disorder (FOD)

Protocol summary

Study aim
The effect of integrated consultation based on EX-PLISSIT model on female orgasm disorder

Design
This study is a non-blind randomized clinical trial with a control group. The estimated sample size is 60 individuals divided into two intervention and control groups with simple random allocation.

Settings and conduct
The research environment is Arash Women's Hospital of Tehran University of Medical Sciences. Eligible women will be divided into intervention and control groups after obtaining informed consent by simple randomization. The intervention group will receive integrated sexual counseling for three weeks using the EX-PLISSIT model. The control group will not receive any intervention during the study. The Female orgasm scale will be completed for both groups before, 4, and 8 weeks after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Married women with Being in the permanent and monogamous marital relationship Having at least level of reading and writing literacy Criteria for not the entrance to the study: Having sexual dysfunction being in the treatment process Addiction to narcotic drugs and alcohol Her husband has sexual dysfunction A positive history of unpleasant psychological experiences in the past six months Being in the pregnancy, lactation, and menopause period Having psychological and physical well-known chronic disease that affects sexual function Using drugs that affect sexual function Exclusion criteria: Not willing to continue of the study Absent in the one or more than Therapeutique sessions.

Intervention groups
The intervention group will receive integrative sexual counseling based on the EX-PLISSIT model for three weekly sessions. The control group will no intervention during the study but after that, based on their willing the researcher will educate them.

Main outcome variables
Orgasmic disorder

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160808029255N9**
Registration date: **2019-11-25, 1398/09/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-25, 1398/09/04**
Update count: **0**

Registration date
2019-11-25, 1398/09/04

Registrant information

Name
Raziyeh Maasoumi

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-21, 1398/07/29

Expected recruitment end date
2020-03-09, 1398/12/19

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of integrative counseling based on EX-PLISIT model in women with female orgasmic disorder (FOD)

Public title

The effect of integrative counseling based on EX-PLISIT model in women with female orgasmic disorder (FOD)

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having reading and writing literacy. Age of 18-45 years Having a live husband Married Sexually active Not having other sexual disorders

Exclusion criteria:

Having or positive history of well-known psycho-somatic diseases Using sexually-suppressive drugs Having marital and interpersonal relationships satisfaction Substance abuse Unwillingness to participate in any of the stages of the research and not attending more than one of the intervention sessions

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, individuals will be allocate by simple random method in two groups; intervention and control. It is a technique that chooses individuals for intervention and control groups entirely by chance with no regard to the will of researchers or patients' condition and preference. In this study, simple random allocation will be done by tossing a coin.

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 Tehran University of Medical Sciences

Street address

No. 226, Qods St., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2017-07-22, 1396/04/31

Ethics committee reference number

IR.TUMS.FNM.REC.1396.2940

Health conditions studied

1

Description of health condition studied

Female orgasmic disorder

ICD-10 code

F52.31

ICD-10 code description

Female orgasmic disorder

Primary outcomes

1

Description

Female orgasmic disorder

Timepoint

Before the intervention, 4, 8 weeks after the intervention

Method of measurement

Female orgasm scale

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive individualized integrative sexual counseling by using the EX-PLISSIT model through three sessions during 45 to 60 minutes. The female orgasm scale will be complete before, 4 and 8 weeks after the intervention by sample of intervention group.

Category

Behavior

2

Description

Control group: The control group will not be receive the intervention. The female orgasm scale will be complete before, 4 and 8 weeks after the intervention by sample of control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ruin Tan Arash Hosital

Full name of responsible person

Raziyeh Maasoumi

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Eastern 162th St., Baghdarnia st., Resalat Highway, Tehranpars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Sahraian

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226, Qods St., Keshavarz Blvd

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Raziyeh Maasoumi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sexology, Sexual and Reproductive Health

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Tehran University of Medical Sciences

Full name of responsible person
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Position
Assistant Professor

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Other areas of specialty/work
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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
Not applicable

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Data of the study would be available after unrecognizable process of participants

When the data will become available and for how long
6 months after publications of findings

To whom data/document is available
Data of this research would be available for academic researchers

Under which criteria data/document could be used
Data of this study would be available for same research

From where data/document is obtainable
Dr. Raziyeh Maasoumi

What processes are involved for a request to access data/document
Sending a request by email attendance to the office of corresponding of project presentation the reasons for similarity of two projects studying the proposal by corresponding of project final decision making with corresponding author access of data in office of corresponding author

Comments