

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

A randomized controlled trial of effect of PLISSIT and Sexual Health models on women sexual problems

Protocol summary

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Summary

A single-blind, randomized controlled clinical trial will be conducted between August 2012 and March 2013. The aim of this study is to compare the effect of «PLISSIT model» with «Sexual Health model» in women with sexual problems in Tehran, Iran. Eighty-four women aged 20-45 years with history of sexual problem will be randomly allocated to receive either PLISSIT model intervention or Sexual Health model. The main outcome of the study, sexual function and sexual distress, will be measured respectively, with the Brief Index of Sexual Function for Women (BISF_W) and Female Sexual Distress Scale_ Revised (FSDS_R) questionnaires, at base line, 2.5 and 7 months post -intervention

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206099975N1**

Registration date: **2012-09-11, 1391/06/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-11, 1391/06/21

Registrant information

Name

Farnaz Farnam

Name of organization / entity

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Phone

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Email address

Scientific title

A randomized controlled trial of effect of PLISSIT and Sexual Health models on women sexual problems

Public title

Effect of PLISSIT therapeutic model and Sexual Health model on women's sexual problems

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of problem during the last 2 months, distress score > 11 , healthy women age 20 to 45 years, married and having an intact marriage.

Exclusion criteria: alcohol and other form of drug abuse, severe mental disorder such as depression and anxiety, chronic/acute medical disorders that affect on sexuality such as diabetes and heart disease

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization Scheme: A total of 84 women with history of sexual problems who meet the eligibility criteria, will be randomized into one of the groups. Subjects will be randomized according to a preexisting list produced by the computer program. First group will receive PLISSIT model and Sexual Health model will be implemented for the second group. Both groups will participate in six sessions. All enrolled subjects will be assessed for demographic characteristics, medical history, sexual function and sexual stress

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Third floor, Building number 4, Hezar jarib St., Isfahan University of Medical Sciences

City

Isfahan

Postal code

8144503500

Approval date

2012-05-27, 1391/03/07

Ethics committee reference number

391026

Health conditions studied

1

Description of health condition studied

Sexual problems

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

Sexual distress

Timepoint

At baseline, 2 and 4 months post-intervention

Method of measurement

Female Sexual Distress Scale_Revised (FSDS_R)

2

Description

Sexual function

Timepoint

At baseline, 2.5 and 7 months post- intervention

Method of measurement

Brief Index of Sexual Function for Women (BISF_W)

Secondary outcomes

empty

Intervention groups

1

Description

PLISSIT model (Permission, Limited Information, Specific Suggestions, Intensive Therapy) : The subjects in this group will receive five 60- minute therapy sessions. Sessions 1, 2, 3, 4 and 5 are all adapted from the PLISSIT treatment model including four therapeutic stages. St1: Permission; client freely talks about her sexual concerns. Permission also is given to those non-problematic sexual behaviors which subject has already experienced. St2: Limited Information; therapist provides patient with limited information about the given problem. St3: Specific Suggestions; specific recommendations are offered enabling patient to manage her sexual problems. The fourth stage: Intensive Therapy; psycho-sexual therapy is performed by the researcher or Co-I psychiatrist. All subjects will be provided the five therapy sessions even if they might not need to receive intensive therapy. Researcher will be in contact with the subjects regularly to avoid missing follow up as well as addressing their concerns related to the therapy. Interventions for the subjects will be free of charge.

Category

Treatment - Other

2

Description

Sexual Health model: Second group will receive the gold-standard educational-based sexual health model. This Model includes 10 key components posited to be essential aspects of healthy human sexuality such as talking about sex, culture and sexual identity, sexual anatomy and functioning, sexual health care and safer sex, challenges to sexual health, body image, masturbation and fantasy, positive sexuality, intimacy

and relationships, and spirituality. In this group subjects will attend in the five 60-minute group education sessions. Up to 10 women will be participating in each session.

Category

Treatment - Other

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

Imam Khomeyni Hospital

Full name of responsible person

Farnaz Farnam

Street address

Family Health Clinic - Imam Khomeyni Hospital

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Peyman Adibi; Vice-Chancellor for Research

Street address

Third floor, Building number 4, Hezar jarib St., Isfahan University of Medical Sciences

City

Isfahan

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, Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

Farnaz Farnam

Position

PhD candidate in Reproductive Health

Other areas of specialty/work**Street address**

Faculty of nursing and midwifery, Isfahan University of Medical Sciences

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences, Isfahan University of Medical Sciences, Tehran University of

Full name of responsible person

Farnaz Farnam, Mohsen Janghorban, Effate Merghati

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PhD candidate in Reproductive Health, Professor, Assistant Professor

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Full name of responsible person

Farnaz Farnam

Position

PhD candidate in Reproductive Health

Other areas of specialty/work**Street address**

Faculty of nursing and midwifery- Isfahan University of Medical Sciences

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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