

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The impact of intervention based in PLISSIT model on sexual function and sexual quality of life of Middle-aged women

Protocol summary

Study aim

Determining the Effect of PLISSIT-based Intervention on Sexual Function and Gender Quality of Life in Middle-aged Women

Design

The purpose of this study was to determine the effect of PLISSIT-based intervention on sexual function and sexual quality of life in middle-aged women. This trial is conducted on 100 middle-aged women who are 50 in the group and 50 in the control group. Entry criteria include ages 40-60, married, non-marital, non-physical illness Or psychological and willingness to participate in the study. The intervention is based on the advice of the PLISSITmodel in the 40-60 minute sessions and there is no consultation in the control group. Sexual fitness status was evaluated by FSFI questionnaire and women's sexual quality of life by SQOL-F questionnaire before, after and one month after the intervention. Then, the results or appropriate statistical tests are analyzed and analyzed

Settings and conduct

Tehran, Sampling is carried out in selected centers of Tehran and available in sampling.

Participants/Inclusion and exclusion criteria

Women aged 40-60 and married

Intervention groups

Women aged 40-60 and married

Main outcome variables

sexual function sexual quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181205041853N1**

Registration date: **2018-12-17, 1397/09/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-17, 1397/09/26**

Update count: **0**

Registration date

2018-12-17, 1397/09/26

Registrant information

Name

Naeimeh Shariatifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

Email address

n.shariatifar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of intervention based in PLISSIT model on sexual function and sexual quality of life of Middle-aged women

Public title

The impact of intervention based in PLISSIT model on sexual function and sexual quality of life of Middle-aged women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

40-60 years old married

Exclusion criteria:

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

simple

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shaihid Beheshti of Medical Sciences

Street address

Ayatollah Taleghani Hospital, Shahid Chamran highway, Yemen street

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-07-01, 1396/04/10

Ethics committee reference number

IR.SBMU.PHNM.1396.776

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

Timepoint

Before, after the intervention and one month later

Method of measurement

FSFI questionnaire

Secondary outcomes

1

Description

Quality of sexual life

Timepoint

Before, after the intervention and one month later

Method of measurement

SQOL-F questionnaire

Intervention groups

1

Description

Intervention group: Women aged 40-60 years who receive counseling based on the PLISSIT model in middle-aged women. Sexual performance and sexual quality of life will be measured before intervention, after and 1 month after intervention.

Category

Treatment - Other

2

Description

Control group: Middle-aged women between the ages of 40-60 have not received counseling. Sexual performance and sexual quality of life will be measured before intervention, after and 1 month after intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected Centers of Tehran

Full name of responsible person

Naeimeh Shariatifar

Street address

Dep of Midwifery ,School of Nursing and Midwifery ,Shahid Beheshti University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mahrokh Dolatian

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Naeimeh Shariatifar

Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Associate Professor

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Ph.D.

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

Midwifery

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available