

# 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

(SBUMs) , Vali Asr street, Niayesh HW Cross Section,  
Tehran, Tehran province , Iran

**City**

Teharn

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 8865 5366

**Email**

n.shariatifar@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Mahrokh Dolatian

**Street address**

Dep of Midwifery ,School of Nursing and Midwifery  
,Shahid Beheshti University of Medical Sciences  
(SBUMs) , Vali Asr street, Niayesh HW Cross Section,  
Tehran, Tehran province , Iran

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**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 8865 5366

**Email**

mhdolatian@gmail.com

**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

**Street address**

Dep of Midwifery ,School of Nursing and Midwifery  
,Shahid Beheshti University of Medical Sciences  
(SBUMs) , Vali Asr street, Niayesh HW Cross Section,  
Tehran, Tehran province , Iran

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**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 8865 5366

**Email**

n.shariatifar@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Zohreh keshavarz

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

PHD of Reproductive Health

**Street address**

Dep of Midwifery ,School of Nursing and Midwifery  
,Shahid Beheshti University of Medical Sciences  
(SBUMs) , Vali Asr street, Niayesh HW Cross Section,  
Tehran, Tehran province , Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 8865 5366

**Email**

keshavarzzohre@yahoo.com

## Person responsible for updating data

**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

**Street address**

Dep of Midwifery ,School of Nursing and Midwifery  
,Shahid Beheshti University of Medical Sciences  
(SBUMs) , Vali Asr street, Niayesh HW Cross Section,  
Tehran, Tehran province , Iran

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**Province**

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**Postal code**

1985717443

**Phone**

+98 21 8865 5363

**Email**

n.shariatifar@gmail.com

**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