

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The effect of sexual counseling educational based on PLISSIT model on clinical skills and sexual dialogue of midwives with postmenopausal women

#### Protocol summary

##### Study aim

This study aims to determine the effect of sexual counseling education with the PLISSIT(Permission, Limited Information, Specific Suggestions, and Intensive Care) model on clinical skills and midwives' dialogue about sex with postmenopausal women.

##### Design

A controlled, parallel-group, single-blind, randomized clinical trial on 232 midwives. R software was used for randomization.

##### Settings and conduct

The present study is a semi-experimental study with a pre-post-test design with a control group, which investigated the effect of sex counseling training on the clinical skills and sexual dialogue of midwives with postmenopausal women. The sample studied in this research was 232 midwives with medical system (midwifery). In this research, the eligible people were divided into two equal intervention and control groups using simple random allocation. After completing the questionnaire of clinical skills and sexual dialogue, the intervention group received two sessions of sexual counseling training. The duration of each session was 5 hours and the control group did not receive any intervention. After the end of the intervention, the questionnaires were completed again by two groups, and the study was single blind, and the data analysts were blind.

##### Participants/Inclusion and exclusion criteria

1. Interest in sexual topics and conversation 2. Employed in public and private centers and have at least 2 years of work experience. 3. Be a member of the medical system organization and have a medical system (midwifery) number. Excluded criteria: 1. An absent session in the workshop. 2. Failure to complete the post-exam

##### Intervention groups

The intervention group received two sessions of sexual

counseling training. The duration of each session was 5 hours and the control group did not receive any intervention

##### Main outcome variables

Clinical Skills And Sexual Dialogue

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170624034722N2**

Registration date: **2023-12-24, 1402/10/03**

Registration timing: **retrospective**

Last update: **2023-12-24, 1402/10/03**

Update count: **0**

##### Registration date

2023-12-24, 1402/10/03

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5177

##### Email address

f\_mirzaee@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-25, 1399/02/06

##### Expected recruitment end date

2020-04-27, 1399/02/08

##### Actual recruitment start date

2020-04-25, 1399/02/06  
**Actual recruitment end date**  
2020-04-27, 1399/02/08  
**Trial completion date**  
2020-04-27, 1399/02/08

**Scientific title**  
The effect of sexual counseling educational based on PLISSIT model on clinical skills and sexual dialogue of midwives with postmenopausal women

**Public title**  
The Effect of Sexual Counseling Educational Based On PLISSIT Model On Clinical Skills And Sexual Dialogue Of Midwives With Postmenopausal Women.

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Be a member of the medical system organization and have a medical system (midwifery) number Interest in discussing sexual topics. Midwifery employer in public and private centers and at least 2-year work experience.  
**Exclusion criteria:**

Missing one session of the training program Failure to fill out the posttest questionnaire.

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  

- Data analyser

**Sample size**  
Target sample size: **232**  
Actual sample size reached: **232**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this research, the eligible samples were randomly selected based on the computerized list of names and included in the study. Then, using R software, the samples were divided into intervention and control groups.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this study, data analysts were blinded during data analysis.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
-

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

##### Street address

Haft-Bagh Highway

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

#### Approval date

2020-02-17, 1398/11/28

#### Ethics committee reference number

IR.KMU.REC.1398.681

## Health conditions studied

### 1

#### Description of health condition studied

clinical skills and sexual dialogue

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

clinical skills and sexual dialogue

#### Timepoint

Immediately after the intervention

#### Method of measurement

Clinical Skills and Sexual Dialogue questionnaires

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

InterventioThis is a pre-post semi experimental study by control group. 232 midwives by the inclusion criteria simply selected randomly from members of Kerman medical council. They were randomly divided into two groups. After completion the Clinical skills and sexual Dialogue questionnaire, the intervention group received two Sexual Counseling educational sessions. The duration of each session was 5 hours.

#### Category

Behavior

## 2

### Description

Control group: They did not receive any intervention

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Organization of Kerman Medical System

##### Full name of responsible person

Firoozeh Mirzaee

##### Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 913 341 2065

##### Email

f\_mirzaee@kmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Abedin Iranpour

##### Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

##### City

Kerman

##### Province

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##### Postal code

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##### Phone

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##### Email

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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

Kerman 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

Kerman University of Medical Sciences

##### Full name of responsible person

Firoozeh Mirzaee

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Midwifery

##### Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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## Person responsible for scientific inquiries

#### Contact

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Kerman University of Medical Sciences

##### Full name of responsible person

Firoozeh Mirzaee

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Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Firoozeh Mirzaee

**Position**

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**Latest degree**

Ph.D.

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**City**

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**Province**

Kerman

**Postal code**

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**Phone**

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**Email**

f\_mirzaee@kmu.ac.ir

## 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**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals.

**When the data will become available and for how long**

6 months after the results are published

**To whom data/document is available**

The data will only be available to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

If there is a reasonable request for data analysis.

**From where data/document is obtainable**

By contacting the following email: f\_mirzaee@kmu.ac.ir

**What processes are involved for a request to access data/document**

After the applicant's reasonable request, the data will be sent to him as soon as possible.

**Comments**