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
Kerman
Postal code
7616913555
Phone
+98 913 341 2065
Email
f_mirzaee@kmu.ac.ir
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
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 913 341 2065
Email
f_mirzaee@kmu.ac.ir

Person responsible for scientific 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
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 913 341 2065
Email

f_mirzaee@kmu.ac.ir

Person responsible for updating data

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

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 913 341 2065

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