

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Assessment the Effect of Sexual Counseling on Sexual Quality of Life in Married Elderly Women

Protocol summary

Study aim

Determine the impact of sexual counseling on the quality of life of married elderly women

Design

A clinical trial was conducted in two groups: control and test, randomized, double blind, with a sample size of 30 people in each test and control group.

Settings and conduct

The location of the municipality's buildings is located in the 6th district of Tehran. After random sampling, two groups of control and test, each group consisting of 30, were determined by the consultant, and the researcher and the participants were not aware of the samples from the two groups, then 4 sessions of the classroom and 4 sessions of telephone counseling The test group is held and the control group does not receive any intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: elderly people who are married; age range 60 to 70 years old; having reading and writing skills; the absence of significant cognitive impairment (such as dementia, Alzheimer's and ...); able to communicate verbally and in an eye; the absence of important life events such as divorce, death of loved ones and ... in a recent month; absence of depression and anxiety disorders; do not take antidepressants and anti-anxiety drugs; failure to receive previous training in sexual matters. Exit criteria: participants' reluctance to continue their research; not attending training sessions more than twice in a row; start cognitive problems during research; start acute visual and acuity hearing problems while conducting research; death.

Intervention groups

The samples are divided into two groups of test and control; for the test group, 4 sessions of the training class and 4 sessions of telephone counseling are conducted and the control group does not receive any intervention.

Main outcome variables

Sexual quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180904040946N1**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-28, 1398/03/07**

Update count: **1**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

Fatemeh Shahabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5585 8228

Email address

f.shahabi87@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the Effect of Sexual Counseling on Sexual Quality of Life in Married Elderly Women

Public title

Effect of Sexual Counseling on Sexual Quality of Life

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly people are married Age range 60 to 70 years old Having reading and writing skills The absence of significant cognitive impairment (such as dementia, Alzheimer's and ...) Able to communicate verbally and in an eye The absence of important life events such as divorce, death of loved ones and ... in a recent month Absence of depression and anxiety disorders Do not take antidepressants and anti-anxiety drugs Failure to receive previous training in sexual matters

Exclusion criteria:

Participants' reluctance to continue their research Not attending training sessions more than twice in a row Start cognitive problems during research Start acute visual and acuity hearing problems while conducting research Death

Age

From **60 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Sample randomization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of the Faculty of Nursing and Midwifery of Tehran

Street address

Dr Mirkhani (East Nursing), Tohid Square, Faculty of Nursing and Midwifery

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-09-04, 1397/06/13

Ethics committee reference number

IR.TUMS.FNM.REC.1397.107

Health conditions studied

1

Description of health condition studied

Quality of Life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual Quality of Life

Timepoint

At the beginning of the study and 3 months after the beginning of Group and Telephone counseling

Method of measurement

Sexual Quality of Women Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention:30 patients were selected randomly as intervention group and completed the demographic questionnaire and sexual quality of life. For the intervention group, four sessions of two-hour weekly one-time group training and four weekly telephone counseling sessions are held once. After one month, the sexual quality of life questionnaire is completed by the intervention group.

Category

Lifestyle

2

Description

Control group: Thirty people are in control group who will not receive any training or counseling.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Town Hall Square District 6 City of Tehran

Full name of responsible person

Fateme shahabi

Street address

1. Vesa shirazi neighborhood, not reaching Fariman street, Bozorg mehr street. 2. Sana'a neighborhood, Third floor, Sha'a'e square, Qa'im street. 3. Fatemi neighborhood: Jahan Ara street, Fifteenth street, The northern side of Qaleh park, Entrance to Ara.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Tehran University of Medical Sciences

Full name of responsible person

Sarieh Poortaghi

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Dr Mirkhani (East Nursing), Tohid Square, Faculty of Nursing and Midwifery

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Spoortaghi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research of Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fateme shahabi

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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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

Article, In the end, the results of the study will be publicly available

When the data will become available and for how long

A year after printing results

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

After correspondence with the research team

From where data/document is obtainable

Fateme shahabi

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

The request has been addressed to Ms. Fatemeh Shahabi then Mrs. Shahabi shared the request with the research team and After the research team agrees, the documentation will be provided by email to the applicant.

Comments