Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 neighbirhood, 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.

City
Tehran

Province
Tehran

Postal code
1895114478

Phone
+98 21 5585 8228

Email
F.shahabi87@yahoo.com

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

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

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 6105 4124

Email
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

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

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 5585 8228

Email
F.shahabi87@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Sarieh poortaghi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Dr mirkhani (East Nusrat), Tohid Square, Faculty of Nursing and Midwifery

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 61054

Email
Spoortaghi@gmail.com

Person responsible for updating data

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

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

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 5585 8228

Email
F.shahabi87@yahoo.com

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