Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of Training and Counseling based on the Self-management Empowerment Model on Childbearing Motives, Marital Satisfaction and Sexual Satisfaction in Couples

Protocol summary

Study aim

The effect of education and counseling based on the self-management empowerment model on childbearing motives, marital satisfaction and sexual satisfaction in couples.

Design

Clinical trial with test group, control group, without blinding, randomized

Settings and conduct

The target population is couples referring to Bushehr health centers, the research environment of Bushehr Comprehensive Health Centers. The research samples will be selected from the centers (based on the allocation to share sampling that was explained in the sampling section). They will be randomly divided into two control and test groups. Test forms will be designed in Google Doc, informed consent form, demographic information form, and a questionnaire on motives for having children, marital satisfaction, and sexual satisfaction, then a pre-test will be conducted in the test group. and control, intervention is not done in the control group. In the intervention test group, self-management empowerment will be done face-to-face, and then the post-test will be done in both groups, and data analysis will be done using appropriate software.

Participants/Inclusion and exclusion criteria

Inclusion: absence of pregnancy; being married; being Iranian; having informed consent; age 18-40 Years old. Exit criteria: secondary infertility; physical and mental illness; failure to attend more than one training session.

Intervention groups

In the intervention group, four training and consultation sessions based on the self-management empowerment model will be held; after completing the study, the control group will be given a training booklet.

Main outcome variables

1) Childbearing motivation score with childbearing motivation questionnaire 2)Marital satisfaction score with the Enrich Marital Satisfaction Questionnaire 3) Sexual satisfaction score with the Larson Sexual Satisfaction Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220830055827N2**
Registration date: **2023-12-09, 1402/09/18**
Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**
Update count: **0**

Registration date

2023-12-09, 1402/09/18

Registrant information

Name

Farahnaz Kamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3345 0187

Email address

f.kamali@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-10, 1402/09/19

Expected recruitment end date

2023-12-31, 1402/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Training and Counseling based on the Self-management Empowerment Model on Childbearing Motives, Marital Satisfaction and Sexual Satisfaction in Couples

Public title

Investigating the Effect of the Self-management Empowerment Model on Childbearing Motives, Marital Satisfaction and Sexual Satisfaction

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being Literate Being Iranian Being Married Living with a Spouse Age 18-40 Years Not Pregnant Not having a Medical Prohibition for Pregnancy Consent of Wife and Husband to Participate in the Study

Exclusion criteria:

Failure to Participate in more than one Counseling Session Participate in Similar Courses at the Same Time Having Secondary Infertility based on Self-report Physical and Mental Illness in a Person or Spouse based on Self-report

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

First, sampling will be easy and then random allocation will be done in two groups, intervention and control. Blocking will be done using blocks of eight; In this way, the letter A will be assigned to the intervention group and the letter B will be assigned to the control group, and then blocking will be done using Random Allocation software. In each center, sampling will be done in the form of allocation to shares. That is, the number of samples is determined according to the population covered by each center.

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

Ethics Committee of Bushehr University of Medical Sciences

Street address

School of Midwifery Nursing, Bushehr University of Medical Sciences, Salman Farsi St., Bushehr

City

Bushehr

Province

Boushehr

Postal code

7518759577

Approval date

2023-07-11, 1402/04/20

Ethics committee reference number

IR.BPUMS.REC.1402.077

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Childbearing Motivation Score from the Childbearing Motivation Questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and two months after the end of the intervention

Method of measurement

Childbearing Motivation Questionnaire

2

Description

Marital Satisfaction score from Enrich Marital Satisfaction Questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and two months after the end of the intervention

Method of measurement

Enrich Marital Satisfaction Questionnaire

3

Description
Sexual Satisfaction score from Larson's sexual Satisfaction Questionnaire
Timepoint
At the beginning of the study (before the start of the intervention) and two months after the end of the intervention
Method of measurement
Larson sexual Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Training and counseling of the self-management empowerment model in four sixty-minute sessions, In an interview manner, During two weeks, there will be two meetings in person each week. Continue the intervention in the form of telephone follow-up in six weeks and a meeting every week to answer questions.
Category
Behavior

2

Description
Control group: There is no intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
All the clinics of Bushehr city
Full name of responsible person
Farhanaz Kamali
Street address
City level clinics, Bushehr, Bushehr province
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aliyeh.rafiei1400@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Akram Farhadi
Street address
Deputy of research and technology, Bushehr University of Medical Sciences, Salman Farsi St.
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+98 912 936 2377
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ak.farhadi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Boushehr 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
Boushehr University of Medical Sciences
Full name of responsible person
Farhanaz kamali
Position
Assistant professor
Latest degree
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Other areas of specialty/work
Medical Education
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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
Undecided - It is not yet known if there will be a plan to make this available
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