

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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

City

Bushehr

Province

Boushehr

Postal code

7518759577

Phone

+98 912 936 2377

Email

aliyeh.rafieei1400@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.

City

Bushehr

Province

Boushehr

Postal code

7518759577

Phone

+98 912 936 2377

Email

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

Ph.D.

Other areas of specialty/work

Medical Education

Street address

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

City

Bushehr

Province

Boushehr

Postal code

7518759577

Phone

+98 77 3345 0187

Email

Farhanazkamali2006@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Boushehr University of Medical Sciences

Full name of responsible person

Farahnaz kamali

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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Email

Farhanazkamali2006@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

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Email

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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