Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effectiveness of couple counseling with a motivational interviewing approach on marital quality and satisfaction in women referring to comprehensive health centers in Sari city

Protocol summary

Study aim
Determining the effectiveness of couple counseling with a motivational interviewing approach on marital quality and satisfaction in women referring to comprehensive health centers in Sari city

Design
A randomized clinical trial, with parallel groups, on 70 couples of reproductive age, using block randomization method for randomization.

Settings and conduct
The research setting will include two comprehensive health centers in Sari. One group, as the intervention group, will undergo couples counseling with a motivational interviewing approach in addition to routine care, and one group, as the control group, will only receive routine care for women of reproductive age by gynecologists and midwives at the aforementioned health centers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed written consent, Having at least a fifth grade education, Not smoking or being addicted to drugs, Not taking psychiatric medications, Inclusion criteria: Those who have incompletely answered the questionnaires. The occurrence of unfortunate life events such as the death of relatives and incurable diseases in family members in the last month, Death of spouse

Intervention groups
The intervention group, in addition to routine care, will undergo couple counseling with a motivational interviewing approach in a group setting, for 6 consecutive sessions, each session lasting 60 minutes, and the control group will receive routine care at the aforementioned comprehensive health centers.

Main outcome variables
Marital quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200122046228N7**
Registration date: **2025-03-27, 1404/01/07**
Registration timing: **prospective**

Last update: **2025-03-27, 1404/01/07**
Update count: **0**

Registration date
2025-03-27, 1404/01/07

Registrant information

Name
Fatemeh Nasiri Amiri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-03, 1404/01/14

Expected recruitment end date
2025-06-20, 1404/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of couple counseling with a motivational interviewing approach on marital quality and satisfaction in women referring to comprehensive health centers in Sari city

Public title
Investigating the effectiveness of counseling with a motivational interviewing approach on marital quality and satisfaction in couples with poor marital relationship quality referring to comprehensive health centers in Sari city

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Being married Having lived together for at least one year and a maximum of 20 years Having a stable sexual relationship Not having a spouse with sexual disorders or chronic diseases according to the individual's own statements Not having acute conflict to the extent of being on the verge of divorce Not taking hormone replacement therapy in women and testosterone in men. Not participating in any educational-counseling classes before or during the study Obtaining a score of less than 2.84 on the marital quality of life questionnaire
Exclusion criteria:
The occurrence of unfortunate life events such as the death of relatives and incurable diseases in family members in the last month Death of spouse

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**
More than 1 sample in each individual
Number of samples in each individual: **2**
The samples are in pairs (female and male).

Randomization (investigator's opinion)
Randomized

Randomization description
In this parallel randomized controlled trial study, given that not all individuals enter the study at the same time and that the researchers cannot predict in advance which group each patient entering the study will belong to, the block randomization method will be used to assign each sample to one of the two groups. In order to conceal the random assignment, the codes generated by the software will be placed in opaque envelopes so that it is not clear which group the next person will be placed in. In this study, eligible participants will be allocated to one of the two control and intervention groups in a 1:1 ratio and in blocks of six, according to the block randomization protocol (generated by Random Allocation Software), in such a way that the researcher cannot predict which intervention group the next person will be placed in. The codes will be placed in the opaque envelopes, and with each new person entering the study, the envelope will be opened and the person's belonging to the relevant group will be determined.

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
Health Research Institute Babol University of Medcal Sciences

Street address
Ganj Afrooz St., Babol University of Medical Sciences

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Babol

Province
Mazandaran

Postal code
7176-47745

Approval date
2025-03-11, 1403/12/21

Ethics committee reference number
IR.MUBABOL.HRI.REC.1403.365

Health conditions studied

1

Description of health condition studied
Marital quality

ICD-10 code
F68.8

ICD-10 code description
Other specified disorders of adult personality and behavior

Primary outcomes

1

Description
Marital quality

Timepoint
Before the intervention, two months after the intervention

Method of measurement
Revised Dyadic Adjustment Scales (RDAS) of Sexual Quality of Couples

Secondary outcomes

1

Description
Marital satisfaction
Timepoint
Before the intervention, two months after the intervention
Method of measurement
Enrich Marital Satisfaction Questionnaire

Intervention groups

1

Description
Intervention group: In the intervention group, participants will receive couple counseling using a motivational interviewing approach, in addition to the routine care provided for individuals of reproductive age. Educational sessions will be conducted over six consecutive weeks, each lasting 60 minutes. Specifically, the first, third, and fifth sessions will be held in person, while the remaining sessions will consist of 60 minutes of online counseling conducted weekly via video conferencing on platforms such as WhatsApp and Eitaa.To ensure that participants engage with the material, follow-up calls will be made two days after the content is shared. This will provide the researcher with the opportunity to offer individual counseling to each participant.In-person sessions will also occur individually for 60 minutes in designated rooms at the sampling centers, adhering to guidelines that ensure a conducive counseling environment, including appropriate physical conditions, minimal client traffic, and reduced noise levels.It is important to note that prior to the commencement of this work, the midwifery counseling student will be trained in the motivational interviewing approach under the supervision of a psychology counselor. Following proficiency in this approach and subsequent approval from relevant faculty members, the sampling process will initiate under their guidance. Additionally, weekly telephone supervision will be implemented throughout the duration of the trial.The content of the couple counseling sessions will include principles of couple counseling, stages of change in marital lifestyles and behaviors, ambivalences related to marital adjustment, effective verbal and nonverbal communication strategies to enhance marital quality of life, advantages and disadvantages of changes in marital lifestyles and behaviors, reconstruction techniques, values and goals for improving marital lifestyles and behaviors, temptations to revert to pre-change behaviors, and strategies for preventing relapse.
Category
Lifestyle

2

Description
Control group: The control group will receive routine care for women of reproductive age. Routine care for women in this demographic at a health center typically includes a range of health services and screenings designed to support reproductive health and overall well-being. The main components of this care include:Health Assessments: Comprehensive evaluations that include medical history, physical examinations, and vital sign measurements.Screening Tests: This includes Pap smears for the detection of cervical cancer and precancerous conditions. Mammograms are performed for breast cancer screening, typically for women aged 40 and older.Family Planning Services: Provision of necessary counseling on family planning options.Support and Management for Chronic Conditions: Assistance for women with chronic illnesses that may impact reproductive health, such as diabetes and hypertension.Lifestyle Counseling: Guidance for clients on maintaining a healthy lifestyle, including physical activity, dietary habits, and stress management.Referral Services: Referral to specialists as needed for any identified issues or conditions.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive Health Center No. 11
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Fateme Fallah
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

724136232

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Fatemeh Nasiri-Amiri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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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