Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of the educational program of couple care during pregnancy and postpartum on marital satisfaction, behavioral self-regulation and parenting stress.

Protocol summary

Study aim
Determining the effect of a couples care training program during pregnancy and postpartum on marital satisfaction, behavioral self-regulation, and parenting stress.

Design
RCT on 86 couples. Sampling is convenience and individuals were assigned to intervention and control groups using a four-way block design using the website http://randomization.com/, separately for each hospital.

Settings and conduct
Due to the changes associated with pregnancy and the fathers' lack of familiarity with them, complications will arise. In this RCT in Tehran, after reviewing the inclusion criteria; 86 couples from two hospitals will be placed in intervention and control groups, using a four-block method. The intervention of the six-session couple care program, based on the Halford program, is 16 videos of about five minutes, 14 videos of about 10 minutes, and two videos of about 15 minutes in MP4 format, in a channel on "WhatsApp" and with six phone calls of about 10 minutes, one week after uploading each session. Answering questions is from 9:00-21:00 and answering questions related to exercises will be in a group for women and a group for men on WhatsApp. control group will have a way to communicate with researcher to answer midwifery questions.

Participants/Inclusion and exclusion criteria
Inclusion criteria: gestational age between 24-28 weeks Living with a spouse Healthy singleton fetus Iranian nationality Having minimum literacy Obtaining a score of 3.5 or less on the GHQ12 Exclusion criteria: Polygamy in the couple The man has multiple jobs or goes on long-term missions The mother's chronic diseases or takes psychological medications

Intervention groups
Five prenatal and one postpartum sessions of the couples care program for parents in the intervention group and routine prenatal care in the control group.

Main outcome variables
Marital satisfaction, behavioral self-regulation, parenting stress

General information

Reason for update

Acronym
CCP

IRCT registration information
IRCT registration number: **IRCT20180427039436N17**
Registration date: **2025-05-14, 1404/02/24**
Registration timing: **prospective**

Last update: **2025-05-14, 1404/02/24**
Update count: **0**

Registration date
2025-05-14, 1404/02/24

Registrant information

Name
Leila Amiri Farahani

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
2025-06-10, 1404/03/20

Expected recruitment end date

2026-06-10, 1405/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of the educational program of couple care during pregnancy and postpartum on marital satisfaction, behavioral self-regulation and parenting stress.

Public title

Effect of the educational program of couple care during pregnancy and postpartum

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant mothers with a gestational age between 24-28 weeks Living with a spouse Single pregnancy with a healthy fetus Iranian nationality of the couple Having minimum literacy Obtaining a score of 3.5 and below on the General Health Questionnaire (GHQ), 12 questions

Exclusion criteria:

Polygamy in a couple The man has two or more jobs, or goes on long-term missions during the wife's pregnancy The mother has chronic systemic diseases Use of psychological medications such as anti-anxiety and antidepressants

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning individuals to the intervention and control groups is a four-way block method using the website http://randomization.com/, which is performed separately for each hospital.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Iran university of medical sciences

Street address

Next to Milad Tower., Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2025-04-05, 1404/01/16

Ethics committee reference number

IR.IUMS.REC.1404.047

Health conditions studied

1

Description of health condition studied

Couple communication and parenting

ICD-10 code

Z63.0

ICD-10 code description

Problems in relationship with spouse or partner

Primary outcomes

1

Description

Marital satisfaction

Timepoint

Before the intervention, two weeks, and six weeks postpartum

Method of measurement

ENRICH Marital Satisfaction

2

Description

Behavioral Self-Regulation

Timepoint

Before the intervention, two weeks, and six weeks postpartum

Method of measurement

Behavioral Self-Regulation for Effective Relationships Scale

3

Description

Parental Stress

Timepoint

Two weeks, and six weeks postpartum

Method of measurement

Parental Stress Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: The present study is a clinical trial on 86 pregnant women with gestational age between 24-28 who meet the inclusion criteria and their spouses, after assessing self-report criteria and assessing mental health using a general health questionnaire, up to one to two weeks after delivery. Also, those who have an undesirable level of mental health (score greater than 3.5) at this stage and after completing this questionnaire; will not be included in the sample; but will be referred to a psychologist. Sampling will be carried out after receiving approval from the Ethics Committee of Iran University of Medical Sciences and obtaining informed consent from eligible individuals who wish to participate in the study. Participants include pregnant women and their spouses who have referred to the prenatal clinics of Akbarabadi and Firoozabadi educational and medical centers for pregnancy care between 24-28 weeks. For this purpose, the researcher will be present at the prenatal clinic of Akbarabadi and Firoozabadi educational and medical centers and, after taking the history and checking the eligibility of the individuals to participate in the project, will explain to the eligible pregnant women (and, if present, to their spouses), the purpose of the project, the conditions for participating in the study and its possible benefits and invite the individuals to cooperate. If the husband is not present at the time of the wife's visit, after coordinating with the wife, she will be asked to inform her husband about the project and contact her husband so that the researcher can provide the couple with the necessary information. Finally, the couples' possible questions about this research project will be answered and, with the couples' approval, after obtaining their mobile phone numbers for channel membership, telephone follow-ups, and sending questionnaires, an informed consent file will be sent to the couples. Then, demographic questionnaires, EMS marital satisfaction questionnaire, and behavioral self-regulation scale will be sent to the couples, and the questionnaires of each couple will be coded. Couples will be assigned to intervention and control groups using a four-block randomization method using the https://randomization.com website, which will be separate for each of the Akbarabadi and Firoozabadi educational and medical centers. The sampling ratio from each hospital will be considered proportional to the number of referrals. The intervention plan is a six-session couples care program based on the Halford program, which has been adjusted to suit the needs of Iranian pregnant couples and is presented as five sessions before delivery and one session between the first and second weeks postpartum. The sessions will be in the form of educational videos on a channel that will be created on the social messaging service "WhatsApp" and will be supported by six phone calls. Also, the researcher's username will be mentioned in the channel description section as a means of communication to answer potential questions from couples, so that it will be available to participants. Also, the postpartum session will be sent separately to each couple, given that the time of delivery is unpredictable. The sessions will last approximately 30-40-80-60-20-20 minutes, respectively; which have been prepared by the researcher with the aim of providing educational content for the intervention and will be made available to couples within a specific time frame. The sessions will be provided to couples in the form of 16 videos of approximately five minutes, 14 videos of approximately 10 minutes, and two videos of approximately 15 minutes in MP4 format, appropriate to the topic; because it will increase learning through audio-visual effects. Also, couples can ask their questions directly to the researcher from 9:00 to 21:00. In order to follow up on the viewing and completion of the assignments for each session and to answer any possible questions about the exercises for the next session, a phone call will be made to the couples for approximately 10 minutes one week after the content of each session is uploaded. Based on the results of the conversation with the couples, the couples' active participation in receiving and viewing the training and completing the assignments will be assessed. In this conversation, the couples will be asked about how they viewed the content, the number and frequency of the content viewed, and how the exercises were performed and the results. If the call is not answered, the couples will be sent a message via SMS and on their private page on social media, and a time will be arranged for the conversation soon. Also, a group will be formed on WhatsApp messenger to answer the couples' questions about how to perform each exercise or their questions about the exercises. A group for mothers and another group specifically for their husbands, so that they can easily ask their questions. The men's group will be supported by a male facilitator. The content of the prenatal sessions includes: Session 1: Introduction, the role of couples in life, relationship goals and self-change to achieve them, definition and importance of communication, ability to communicate, correct way to express opinions, and how to have a principled conversation with an appropriate beginning and end. Exercise: Preparing a list of expectations from the relationship and reviewing them, reporting an effective conversation between couples that occurred between sessions; mentioning possible filters of the speaker and listener and how to overcome them. Session 2: Active listening skills, empathy and mutual trust in communication, parenting expectations and changes corresponding to accepting the parenting role. Exercise: Active listening practice with the help of the "floor" technique, as well as developing a change plan corresponding to accepting the parenting role and planning for adapting to changes. Session 3: Baby care including breastfeeding and feeding, disease prevention, body temperature protection, vaccination, paying

attention to warning signs and timely medical attention; affection and care, relationship and sexuality, interaction about sexual relations and misconceptions. Exercise: Make a list of the things your partner has done to provide care for you in the coming week and also make a similar list related to the activities you have done to provide care for your partner. Also talk about current patterns and preferences for lovemaking and sex, and determine what needs to change and plan for change. Session 4: Conflict management and solutions, anger management, stressors, stress management and stressful changes. Exercise: Evaluate the approaches used in conflict management and examine the strengths and weaknesses of the current approach; use the "floor" technique to talk about a point of disagreement between the couple, considering anger and stress management techniques. Session 5: Mutual support of the partner and its methods, social support of families and attention to cultural beliefs. Exercise: A conversation about a hypothetical situation requiring support and conducting a conversation about it and providing feedback and suggestions for improving the way the partner is supported. The content of the postpartum session also includes: Session 6: Focus on maintaining the relationship and marital adjustment, preventing or early identifying problems, drawing a favorable future outlook. Exercise: Choosing a topic of change that will occur in the couple's life in the next one or two years and then brainstorming about its positive and negative consequences. Also, practicing identifying early warning signs of a problem in the relationship. Both groups complete the marital satisfaction and behavioral self-regulation questionnaires in three stages, before the intervention, after the intervention (two weeks after delivery) and one month after the end of the intervention (six weeks after delivery), and the parenting stress questionnaire is completed only in the stages after the intervention (two weeks after delivery) and one month after the end of the intervention (six weeks after delivery). Also, people with high levels of stress or marital dissatisfaction will be referred to a psychologist. Also, after the end of the intervention and completion of the questionnaires (six weeks after delivery), the content provided to the experimental group will also be made available to the control group.

Category

Behavior

2

Description

Control group: Individuals in the control group did not receive this educational program, and merely to motivate them to participate in the project, they will be provided with a way to communicate with the researcher to answer the couples' questions in the field of midwifery.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi Medical Training Center

Full name of responsible person

Elika Abbaszadegan

Street address

In front of Khatamol anbiaa Hospital., Rashid Yasemi Ave., Valiasr Ave., Tehran., Iran

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Email

info@iums.ac.ir

Web page address

https://iums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Leila Amiri Farahani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available