

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### **Effectiveness comparison of the Couple CARE (Couple Commitment and Relationship Enhancement) program versus flourishing model PERMA (Positive Emotion, Engagement, Relationships, Meaning, and Accomplishments) in an online method on the quality of the relationship, the relationship of the couple in the disease and the desire to have children again in high-risk pregnancy**

#### **Protocol summary**

##### **Study aim**

Comparing the effectiveness of the Couple CARE program with the PERMA model on the quality of the relationship, the couple's relationship in illness, and the desire to have children again in high-risk pregnancy

##### **Design**

Randomized Controlled Trial in parallel with the control group, random allocation by permutation block method and random concealment, the sample size of 36 couples in each intervention group (total sample size of 72 couples), without blinding

##### **Settings and conduct**

The researcher goes to Shahid Sadouqi and Shahada Kargar Hospital in Yazd city and selects the samples according to available methods. Then the samples are invited and informed consent is obtained. The samples will be randomly assigned to two intervention groups of the Couple CARE program or the PERMA model. The second researcher carries out the psychological intervention under the supervision of the first, third, and fourth researchers.

##### **Participants/Inclusion and exclusion criteria**

Married pregnant women with a live fetus from the beginning of pregnancy to 28 weeks with a doctor's diagnosis of high-risk pregnancy Having a high-risk pregnancy record For couples, the ability to participate in online counseling sessions Having an Android or iOS smartphone Farsi dialect Consent to participate in research Unfavorable score of couple's relationship in illness and having marital relationship

##### **Intervention groups**

The first intervention group will receive the PERMA program in a 90-minute online session once a week for 6

consecutive weeks. The second intervention group (control) will receive the Couple CARE program in a 90-minute online session once a week for 6 consecutive weeks.

##### **Main outcome variables**

Relationship quality, the couple's relationship in illness, and desire to have children again

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20240123060774N1**

Registration date: **2024-03-02, 1402/12/12**

Registration timing: **prospective**

Last update: **2024-03-02, 1402/12/12**

Update count: **0**

##### **Registration date**

2024-03-02, 1402/12/12

##### **Registrant information**

##### **Name**

Romina AlamdarYazdi

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

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##### **Recruitment status**

**Recruitment complete**

## Funding source

### Expected recruitment start date

2024-04-24, 1403/02/05

### Expected recruitment end date

2024-06-25, 1403/04/05

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

## Scientific title

Effectiveness comparison of the Couple CARE (Couple Commitment and Relationship Enhancement) program versus flourishing model PERMA (Positive Emotion, Engagement, Relationships, Meaning, and Accomplishments) in an online method on the quality of the relationship, the relationship of the couple in the disease and the desire to have children again in high-risk pregnancy

## Public title

Couple CARE program and flourishing model PERMA on the quality of the relationship, the relationship of the couple in the disease, and the desire to have children again in high-risk pregnancy

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Married pregnant women with a live fetus from the beginning of pregnancy to 28 weeks with a high-risk pregnancy diagnosis by a doctor and having a high-risk pregnancy record Ability to participate in online counseling sessions for couples Having an Android or iOS smart phone Persian dialect Consent to participate in research Undesirable score of couple relationship in disease Having a marital relationship

### Exclusion criteria:

Self-declaration of the couple or for women, inclusion in the women's medical record of suffering from neuropsychiatric disorders Treated with psychiatric drugs Drug and alcohol addiction Speech/hearing problems Simultaneous participation in other similar studies

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 72

## Randomization (investigator's opinion)

Randomized

## Randomization description

Eligible couples, referring to Shahid Sadouqi Hospital and Shohada Kargar Hospital in Yazd city, are sampled based on the criteria of participating in the study using the

available method. The permutation block method obtains the randomization sequence, considering blocks of size 4, using the site [www.random.org/sequences](http://www.random.org/sequences). Couples are allocated to two intervention groups the Care Program for Couples (CARE) or the PERMA model (PERMA). They are randomly selected (each group has 36 participants). Concealment is done in random allocation so that neither the researcher nor the women nor their spouses know which of the two groups they will be allocated to.

## 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

Research Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

##### Street address

Research and Technology Vice-Chancellor, Imam Reza (AS) Complex, Imam Hossein Square, Yazd

##### City

Yazd

##### Province

Yazd

##### Postal code

8916877443

#### Approval date

2024-02-03, 1402/11/14

#### Ethics committee reference number

IR.SSU.REC.1402.130

## Health conditions studied

### 1

#### Description of health condition studied

High-risk pregnancy

#### ICD-10 code

O09

#### ICD-10 code description

Supervision of high risk pregnancy

## Primary outcomes

### 1

#### Description

The quality of the couple's relationship

## **Timepoint**

Baseline, completion of the intervention in week 6 and completion of the study in week 10

## **Method of measurement**

Questionnaire of the quality of couple relations by Kennedy et al. (2016)

## **Secondary outcomes**

### **1**

#### **Description**

Couple relationship in illness

#### **Timepoint**

Baseline, completion of the intervention in week 6 and completion of the study in week 10

#### **Method of measurement**

Couple Relationship Scale Questionnaire in Illness

### **2**

#### **Description**

The desire to have children again

#### **Timepoint**

Baseline, completion of the intervention in week 6 and completion of the study in week 10

#### **Method of measurement**

With a question on a visual scale between 1-10, "How willing are you to have children again?"

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The intervention is carried out by a senior counseling student in midwifery who has the certificate and skill to perform the intervention under the supervision of the supervisor (reproductive health specialist and clinical psychologist) and the consultant professor (doctorate in nursing). The intervention for the couple is done online in the space of one of the Iranian messengers as a group in 6 sessions of 90 minutes, once a week. The intervention in the first group (PERMA model) includes an introduction of PERMA elements, the first element of PERMA is positive emotions and their role in life, the second element of PERMA is fascination and methods of increasing immersion, the third element of PERMA is meaning and connection with well-being, the fourth element of PERMA is positive relationships and evaluation of the quality of communication, the fifth element of PERMA is achievement/success and its importance in life. Then, the conclusion includes the summation and post-test implementation. For this group, before the start of the intervention, the link to the online counseling sessions in Skyroom will be sent along with the training video on how to use Skyroom and how to complete the questionnaires in the Iranian messenger group. Also, on the day of the meetings, they will be reminded again by sending an SMS about the start of the meetings along with the link related to the meetings. At the beginning of each meeting, a summary of the

materials related to the previous meetings will be reviewed and the assigned tasks related to the previous meeting will be reviewed by the consultant to measure the improvement of the relationship in each meeting. Couples are asked to participate in online counseling discussions and ask questions. The consultant will also ask questions about the topics of the meeting for the participation of more people. Women are asked to share what they learned in the sessions with their husbands and do the exercises with their participation. In case of absence from the video counseling session, the counseling session will be available to the absent person offline. In case of internet interruption or problems in the online holding system, counseling sessions will be held on another day with the coordination of group members. At the end of each session, a summary of the important topics discussed is presented people's questions are answered, and women are asked to do home exercises until the next session.

#### **Category**

Behavior

### **2**

#### **Description**

Control group: The intervention is carried out by a senior counseling student in midwifery who has the certificate and skill to perform the intervention under the supervision of the supervisor (reproductive health specialist and clinical psychologist) and the consultant professor (doctorate in nursing). The intervention for the couple is done online in the space of an Iranian messenger as a group in 6 sessions of 90 minutes, once a week. Intervention in the Couple CARE group (Couple Commitment and Relationship Enhancement) includes an introduction, initiation of self-change, interaction, intimacy, and care, meaning of differences, sexual relations, looking to the future in communication, and evaluating and monitoring the process of changes in the couple relationship. For this group, before the start of the intervention, the link to the online counseling sessions in Skyroom will be sent along with the training video on how to use Skyroom and how to complete the questionnaires in the Iranian messenger group. Also, on the day of the meetings, they will be reminded again by sending an SMS about the start of the meetings along with the link related to the meetings. At the beginning of each meeting, a summary of the materials related to the previous meetings will be reviewed and the assigned tasks related to the previous meeting will be reviewed by the consultant to measure the improvement of the relationship in each meeting. Couples are asked to participate in online counseling discussions and ask questions. The consultant will also ask questions about the topics of the meeting for more participation and involvement of samples in the meeting. Women are asked to share what they learned in the sessions with their husbands and do the exercises with their participation. In case of absence from the video counseling session, the counseling session will be available to the absent person offline. In case of internet interruption or problems in the online holding system, counseling sessions will be held on another day with the

coordination of group members. At the end of each session, a summary of the important topics discussed is presented people's questions are answered, and women are asked to do home exercises until the next session.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

High-risk pregnancy department of Shahid Sadoughi Hospital, Yazd

**Full name of responsible person**

Dr. Hossein Soleimani

**Street address**

Shahid Sadoughi Hospital, Ibn Sina St., Shahid Qandi Blvd, Yazd.

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Sadoghi-hospital@ssu.ac.ir

**2****Recruitment center****Name of recruitment center**

Shohadaye Kargar Hospital, Yazd

**Full name of responsible person**

Dr. Vahide Salimi

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Shohaday Kargar Hospitale, Modarres Blvd, Akramieh, Yazd.

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Amin Salehi Abarghoi

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Bahnar Square, Central Organization of Shahid Sadoughi University of Medical Sciences, Yazd

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abargouei@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Tahmine Faraj Khoda

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Clinical Psychology

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**Other areas of specialty/work**

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**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**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All individual data of the study participants can be shared after de-identification.

**When the data will become available and for how long**

After publishing the results

**To whom data/document is available**

The data will be available to researchers working in academic and scientific institutions, and people in the industry can also apply to receive them.

**Under which criteria data/document could be used**

Scientific Application

**From where data/document is obtainable**

farajkhoda\_t@yahoo.com

**What processes are involved for a request to access data/document**

One week after receiving the applicant's email

**Comments**