Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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)

Phone

+98 35 3821 0135

Email address

r.alamdaryazdi@stu.ssu.ac.ir

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. 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.

City
Yazd

Province
Yazd

Postal code
8916886938

Phone
+98 35 3822 9007

Email
Sadoghi-hospital@ssu.ac.ir

2

Recruitment center

Name of recruitment center
Shohadaye Kargar Hospital, Yazd

Full name of responsible person
Dr. Vahide Salimi

Street address
Shohaday Kargar Hospitale, Modarres Blvd,Akramieh, Yazd.

City
Yazd

Province
Yazd

Postal code
1457965595

Phone
+98 35 3182 2000

Email
shohadakargar.hos@tamin.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Amin Salehi Abarghoi

Street address
Bahnar Square, Central Organization of Shahid Sadougi University of Medical Sciences, Yazd

City
Yazd

Province
Yazd

Postal code
8916978477

Phone
+98 35 3733 3726

Email
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

Street address
Bu Ali St, Yazd

City
Yazd

Province
Yazd

Postal code
8916877443

Phone
+98 35 1751 3824

Email
farajkhoda_t@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person
Tahmineh Farajkhoda

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Clinical Pshycology

Street address
Bouali ave

City
Yazd

Province
Yazd

Postal code
8916877443

Phone
+98 35 3824 1754

Email
farajkhoda_t@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Tahmineh Faraj Khoda

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Clinical Psychology

Street address
Bu Ali St., Yazd

City
Yazd

Province
Yazd

Postal code
8916877443

Phone
+98 35 3824 1751

Email
farajkhoda_t@yahoo.com

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