Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of the Effectiveness of transition to parenthood programs the Family Foundation(FF) with Couples Care for Parents(CCP) on subjective well-being, marital conflict, and marital satisfaction new parents.

Protocol summary

Study aim
effectiveness of the family foundation education program and the care program for couples to become parents on mental well-being, marital conflicts, and marital satisfaction

Design
A clinical trial with the control group, with parallel groups, randomized, 90 couples

Settings and conduct
The location of the research is Ahvaz city health Center. It is a semi-experimental research of pre-test, post-test, and follow-up study with a control group.

Participants/Inclusion and exclusion criteria
90 couples based on a structured interview and criteria for entering the research, including being pregnant with the first child, mother's pregnancy month from 3 to 6 months, singleton pregnancy, no history of abortion or stillbirth, unwanted pregnancy, age of the couple between 20 and 40 years, education level of minimum diploma, exclusion criteria: physical distance and the decision to separate in couple, physical background (eg, heart disease, thalassemia major, etc.) and mental illnesses (eg, bipolar, depression), drug addiction

Intervention groups
The Family Foundation Program is an example of a global group intervention that lasts several months in the prenatal and postpartum periods. Experimental group 2, in four sessions during the 3rd to 6th month of pregnancy and four sessions after the fifth week. Participating in a parenting couple care program. The parenting couple care program is a relatively short-term structured program (about 12 hours of work per couple over 4-5 months). Control group participants participated in four virtual sessions and they will participate in parenthood preparation programs online.

Main outcome variables
subjective well-being, marital conflicts, and marital satisfaction of couples

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230709058725N1**
Registration date: **2023-11-26, 1402/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-26, 1402/09/05**
Update count: **0**

Registration date
2023-11-26, 1402/09/05

Registrant information

Name
Ali sarvestani

Name of organization / entity
The University of Shahid Chamran

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-05, 1402/08/14

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the Effectiveness of transition to parenthood programs the Family Foundation(FF) with Couples Care for Parents(CCP) on subjective well-being, marital conflict, and marital satisfaction new parents.

Public title

Effect of programs for the transition to parenthood

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

first pregnancy The second trimester of pregnancy The couple's age is between 20 and 40 Minimum education level is diploma Desired pregnancy singleton pregnancy

Exclusion criteria:

Couples who have physical distance and decide to separate. Having physical diseases such as thalassemia and heart Having mental illnesses such as bipolar disorder and acute depression, etc. Having drug addiction

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

In this project, two experimental groups and one control group will be used. In this research project, the sample size of 90 couples has been determined and the method of randomization allocation law will be used to allocate members to each group. This method represents a large block for It is the total sample size, which means that the balance in the number of people assigned to each of the groups will be achieved at the end of the study. For this purpose, a total sample size is first determined, then a group of them is randomly assigned to group A. We will allocate the set to group B and the rest to group c. The unit of randomization is pairwise.

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 shahid chamran university of Ahwaz

Street address

Golestan Blvd., Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

۶۱۳۵۷۸۳۱۵۱

Approval date

2023-11-05, 1402/08/14

Ethics committee reference number

IR.SCU.REC.1402.033

Health conditions studied

1

Description of health condition studied

Couples expecting their first child

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The well-being score of the participants is on the Edinburgh Warwick Mental Well-Being Scale.

Timepoint

pre-test before the intervention (second trimester of pregnancy) and post-test 9 weeks after delivery, follow-up 60 days after the end of the intervention

Method of measurement

Warwick-Edinburg Mental Well-being Scale (WEMWBS)

2

Description

Marital conflict is the score that participants get on the Strauss Conflict Resolution Tactics Scale

Timepoint

pre-test before the intervention (second trimester of pregnancy) and post-test 9 weeks after delivery, follow-up 60 days after the end of the intervention

Method of measurement

Strauss Conflict Resolution Tactics Scale

3

Description

Marital satisfaction is the score obtained by the participants in Mehrabian's marital satisfaction scale

Timepoint

pre-test before the intervention (second trimester of pregnancy) and post-test 9 weeks after delivery, follow-up 60 days after the end of the intervention

Method of measurement

Mehrabian's Marital Satisfaction Scale

Secondary outcomes

1

Description

Mental health

Timepoint

pre-test before the intervention (second trimester of pregnancy) and post-test 9 weeks after delivery, follow-up 60 days after the end of the intervention

Method of measurement

Depression, Anxiety and Stress Questionnaire

Intervention groups

1

Description

Intervention group: This group includes those who are taught the family foundations program. The Family Foundation (FF) program is an example of a global group intervention that lasts several months in the prenatal and postpartum periods.

Category

Prevention

2

Description

Intervention group: This group includes those who are taught to become parents by the care program of couples. The couple care program for parenting is a relatively short-term structured program (about 12 hours of work per couple over 4-5 months).

Category

Prevention

3

Description

Control group: The participants of the control group will participate in four virtual and online parenthood preparation programs.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Ahvaz city

Full name of responsible person

Eshagh Sarvestani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid chamran university

Full name of responsible person

Seyed Abas Razavi

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alisarvestani@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid chamran university

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

Shahid chamran of university

Full name of responsible person

Gholamreza Rajabi

Position

Professor

Latest degree

Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available
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
I will share the details of the educational protocol in the thesis and final paper. Also, in this research, only part of the data is shared, such as general information related to the main variables.پ
When the data will become available and for how long
I will share the protocol of this research before the end of the intervention in the form of articles in reputable journals. Access to data files begins 6 months after publication of results
To whom data/document is available
Data will be available only to researchers working in academic and scientific institutions and medical centers
Under which criteria data/document could be used
Only for scientific exchange among researchers who are interested in this field.
From where data/document is obtainable
To receive the data, contact the researcher via email. 1- Gholamreza Rajabi rajabireza@scu.ac.ir 2- Alisarvestani alisarvestani@yahoo.com
What processes are involved for a request to access data/document
Applicants must send their application to the administrator with the official letter of the university that is in operation. If the executive determines that the purpose of using the documents is to advance and exchange information, he will provide the documents to the applicant. It will be sent to them between one week and two months.
Comments