

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 4372 8627

##### Email address

a-sarvestani@stu.scu.ac.ir

#### 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**

Khuzestan

**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

**Street address**

Golestan Blvd., Ahvaz., Iran

#### **City**

Ahvaz

#### **Province**

Khuzestan

#### **Postal code**

6135783151

#### **Phone**

+98 61 3336 7008

#### **Email**

Alisarvestani@yahoo.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Shahid chamran university

##### **Full name of responsible person**

Seyed Abas Razavi

##### **Street address**

Golestan Blvd., Ahvaz, Iran

##### **City**

Ahvaz

##### **Province**

Khuzestan

##### **Postal code**

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##### **Phone**

+98 61 3322 6600

##### **Email**

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**

Psychology

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**Contact**

**Name of organization / entity**

Shahid chamran university

**Full name of responsible person**

Gholamreza Rajabi

**Position**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

SHahid chamran university

**Full name of responsible person**

Gholamreza Rajabi

**Position**

Professor

**Latest degree**

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**Email**

rajabireza@scu.ac.ir

**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**