

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Investigating The effect of educational and Supportive intervention on health performance and general self-efficacy of pregnant adolescents

#### Protocol summary

##### Study aim

Determining the effectiveness of a part of the comprehensive program to improve reproductive health in pregnant teenagers

##### Design

The Clinical Trial has an intervention group and a control group with parallel groups and without blinding, randomization with permutation block (randomized blocks of four) on 136 pregnant teenagers.

##### Settings and conduct

In order to collect data, the clinic of Vali Asr Educational Hospital and Fasa Comprehensive Health Center are used. Training sessions are held in the conference room of the director's office located on the first floor of Vali Asr Hospital. After the registration of the Trial, the patients who meet the criteria for entering the study will be talked to and consent will be obtained from them to participate in the study. Before determining the type of random allocation of people, the questionnaires are completed. Based on four blocks, people are placed in groups A or B, and a training class is held for the intervention group, and the control group receives the routine intervention.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Adolescents 10-19 years old married pregnant primigravida 18-24 weeks of pregnancy Willingness to participate in classes with accompanying attendance exclusion criteria: Having a high-risk pregnancy Experiencing an unfortunate incident within the last three months Having restrictions on physical movement Using medicine for a physical or mental problem

##### Intervention groups

Intervention group: holding six educational class sessions with questions and answers and creating a group on social networks to repeat what was said in the class and answer questions in the presence of pregnant teenagers and their companions and provide certificates for the companions regarding their attendance at the maternity

hospital Control group: routine intervention

##### Main outcome variables

Health Performance General Self-efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230816059157N1**

Registration date: **2023-08-28, 1402/06/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-28, 1402/06/06**

Update count: **0**

##### Registration date

2023-08-28, 1402/06/06

##### Registrant information

##### Name

Firoozeh Nourimand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5333 6950

##### Email address

firozeh.nourimand@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2023-09-21, 1402/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating The effect of educational and Supportive intervention on health performance and general self-efficacy of pregnant adolescents

**Public title**  
Investigating the effect of education and support on improving the reproductive health of pregnant adolescents

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Adolescents 10-19 years old Married Pregnant Primigravida 18-24 weeks of pregnancy Having a health file in the health centers of Fasa and its suburbs Having the ability to speak and understand Persian language Informed consent to participate in research Willingness to participate in classes with accompanying attendance  
**Exclusion criteria:**  
Having a high-risk pregnancy, including diabetes, high blood pressure, and chronic diseases affecting pregnancy such as cardiovascular disease, lung disease, etc., and History or current mental problems Experiencing a catastrophic life event in the past three months Having physical movement restrictions (heart disease, lung disease, incompetent cervix, high-risk multiple pregnancies, continuous bleeding, Placenta Previa after 26 weeks, Gestational blood pressure) Addiction to any kind of drugs, tobacco Receiving special medicine due to a physical or psychological problem

**Age**  
From **10 years** old to **19 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **136**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Permutation block randomization method with blocks of four has been used. We assigned different permutations to numbers 1 to 6 in the following order. 1. AABB 2. ABAB 3. ABBA 4. BBAA 5. BABA 6. BAAB Now, using the table of random numbers, we extracted the numbers from the table, and depending on whether one of the numbers 1 to 6 came, each of the blocks assigned to these numbers was selected until 36 blocks of 4 were selected. If the numbers 0, 7, 8, and 9 came up, we ignored them and continued this order to provide a complete list for the entire sample size.

**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 Shahroud University of Medical Sciences

##### Street address

Shahroud, 7 Tir Square - Shahroud University of Medical Sciences and Health Care Services

##### City

Shahroud

##### Province

Semnan

##### Postal code

۳۶۱۴۷۷۳۹۴۳

#### Approval date

2022-07-30, 1401/05/08

#### Ethics committee reference number

IR.SHMU.REC.1401.105

## Health conditions studied

### 1

#### Description of health condition studied

-

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Health Performance and General Self-efficacy

#### Timepoint

Before the intervention - immediately after the end of the intervention - one month after the intervention

#### Method of measurement

Health practices questionnaire/ General Self-Efficacy Scale (Sherer et al)

## Secondary outcomes

### 1

#### Description

Maternal and newborn outcomes such as high-risk pregnancy, birth weight of the baby, condition of the

baby, type of delivery

### **Timepoint**

immediately after child birth

### **Method of measurement**

High-risk pregnancy (with/without), birth weight (Kg), condition of baby(hospitalization/Rooming in), type of delivery (NVD/cesarean section).

## **Intervention groups**

### 1

#### **Description**

Intervention group: Educational class for pregnant teenagers with companions. The course will be held during 6 sessions of 60-90 minutes by the researcher in the conference hall of Vali Asr Hospital from the 25th week of pregnancy. Session intervals will be one week. The content of the class includes information about pregnancy and childbirth, pregnancy care, the effect of adequate sleep and rest, appropriate physical activity, proper diet, correct health practices, signs and symptoms of pregnancy, and teaching self-care behaviors and Self-efficacy to control distressing symptoms. The material said in the class will be repeated in the virtual network where the pregnant lady and her companion are members.

#### **Category**

Behavior

### 2

#### **Description**

Control group: The control group will receive routine prenatal care

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Comprehensive health center of Fasa city

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

Mrs. Khosravi

##### **Street address**

Fasa- Blvd. Vali Asr- Department of Health

##### **City**

Fasa

##### **Province**

Fars

##### **Postal code**

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##### **Phone**

+98 71 5335 0994

##### **Fax**

##### **Email**

info@fums.ac.ir

##### **Web page address**

<https://www.fums.ac.ir/>

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Vali Asr Hospital Clinic

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

Mrs. Moradi

##### **Street address**

Fasa, Ibn Sina square

##### **City**

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##### **Province**

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##### **Phone**

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##### **Email**

valiasrfasa@fums.ac.ir

##### **Web page address**

[https://vh.fums.ac.ir/contact\\_us](https://vh.fums.ac.ir/contact_us)

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Shahrood University of Medical Sciences

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

Mr. Dr. Emamian

##### **Street address**

Shahrood, 7 Tir Square - Shahrood University of Medical Sciences and Health Care Services

##### **City**

Shahrood

##### **Province**

Semnan

##### **Postal code**

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##### **Phone**

+98 23 3239 5054

##### **Fax**

+98 23 3239 5009

##### **Email**

info@shmu.ac.ir

##### **Web page address**

<https://www.shmu.ac.ir/fa>

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Shahrood 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**  
Shahroud University of Medical Sciences  
**Full name of responsible person**  
Firoozeh Nourimand  
**Position**  
دانشجو  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Reproductive Health  
**Street address**  
Fasa city, Kanarestan Blvd., No. 32, 20 Alley  
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firozeh.nourimand@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahroud University of Medical Sciences  
**Full name of responsible person**  
Shahrabanoo Salehin  
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Assistant professor  
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Ph.D.  
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## Person responsible for updating data

### Contact

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Shahroud University of Medical Sciences  
**Full name of responsible person**  
Firoozeh Nourimand  
**Position**  
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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

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

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

Information on primary and secondary outcomes can be shared

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

The access period starts 6 months after the results are published

### To whom data/document is available

For researchers working in academic and scientific institutions and people participating in research

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

Improving services to promote reproductive health in pregnant teenagers

### From where data/document is obtainable

Mrs. Dr. Shahrabanoo Salehin 09126311433 Shahroud -  
Haft Tir Square - Shahroud University of Medical Sciences  
Postal code: 36147-73943 drbsalehin@gmail.com  
Firoozeh Nourimand 09357149135 Fasa-Kanarestan  
Boulevard, 20 Alley, No. 32 Postal code: 7461858461

firozeh.nourimand@gmail.com

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

Six months after the completion of the plan, we will be

responsive to the mentioned people by calling, emailing, or texting, and the necessary documents will be sent to them via email within seven working days.

**Comments**