Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

InvestigatingThe 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

InvestigatingThe 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

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Recruitment center

Name of recruitment center

Vali Asr Hospital Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mr. Dr. Emamian

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Web page address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

دانشجو

Latest degree

Master

Other areas of specialty/work

Reproductive Health

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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

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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