Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Investigating the effectiveness of an intervention based on psychosocial support compared to standard care on pregnancy outcomes in adolescent pregnancy.

Protocol summary

Study aim
Evaluation of the effect of a designed intervention based on psychosocial support of pregnant adolescents on the outcome of pregnancy

Design
It is a single blind clinical trial with a control group and a sample size of 84. The study population is adolescent pregnant women who meet the criteria for entering the study. The method of random allocation is block randomization. In order to hide the random allocation, sealed non-transparent envelopes with a random sequence are used.

Settings and conduct
The researcher will go to one of the health centers in the east and west of Ahvaz and will identify eligible mothers to participate in the study. Due to the nature of this study, it will not be possible to blind the researcher and the participant. But the results of the questionnaires will be collected by another person who is not aware of the objectives of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Low-risk singleton pregnancy; Being at the age of 13-19 years old; Gestational age of 12-28 weeks. Non inclusion criteria: Having a known physical or mental illness; Consumption of alcohol and tobacco by the mother

Intervention groups
In the intervention group, participants will receive 4-6 training sessions based on psychosocial support. Depending on the content, the number of sessions may vary. Group sessions of 4 to 10 people will be offered during pregnancy. In the control group, the researcher will provide only routine supportive care.

Main outcome variables
Social support; Pregnancy outcome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190129042544N1**
Registration date: **2023-06-26, 1402/04/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-26, 1402/04/05**
Update count: **0**

Registration date
2023-06-26, 1402/04/05

Registrant information
Name
setareh yousefi
Name of organization / entity
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Iran (Islamic Republic of)
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Email address
yousefi.setareh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-20, 1402/03/30

Expected recruitment end date
2025-06-20, 1404/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effectiveness of an intervention based on psychosocial support compared to standard care on pregnancy outcomes in adolescent pregnancy.

Public title

The impact of psycho-social support interventions on pregnancy outcomes.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to understand and speak Persian Low-risk singleton pregnancy Gestational age 12-28 weeks Being literate in reading and writing Being at the age of 13-19 years old

Exclusion criteria:

Discovering abnormalities in the fetus Having a known physical or mental illness Consumption of alcohol and tobacco by the mother

Age

From **13 years** old to **19 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

"Due to the limited number of teenage pregnant mothers and the nature of the clinical trial, the researcher will refer to health centers in the east and west of Ahvaz to determine eligible and willing mothers to participate in the study. If the desired sample volume is not provided, the researcher will continue to other centers until reaching the desired sample volume. The samples will then be divided into two groups, an intervention group, and a control group, using the random block method. All possible modes of placement of letters A (intervention) and B (control) will be considered in blocks of 6 with an allocation ratio of 1:1. The number of required blocks will be determined based on the number of studied samples. Then, based on the table of random numbers and the number of required blocks, the blocks corresponding to each table number will be listed in order. When the samples enter the study, each person will be assigned a certain letter according to the obtained order. For example, according to the order (AAABBB/ABABAB), the seventh person will be placed in the intervention group (A). To hide the allocation, sequentially numbered sealed envelopes will be used, with the type of intervention written inside. To hide the random allocation, the method of non-transparent sealed envelopes with random sequences will be used. First, a random sequence will be created by a person who is unaware of the goals and subject of the study. Based on the sample size of the research (84 people), 84 opaque envelopes will be prepared. Each of the random sequences created by the person will be recorded on a card, and the cards will be placed in the envelopes in order. Finally, the envelopes will be sealed and placed in a box, which will be kept by the midwife of the center. When the researcher starts sampling, one of the envelopes will be opened based on the order in which the eligible participants entered the study, and the specialized group of that participant will be revealed. Due to the nature of this study, it will not be possible to blind the researcher and the participant. However, the results of the questionnaires will be collected by another person who is not aware of the study's objectives."

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of this study, it will not be possible to blind the researcher and the participant, but the results of the questionnaires will be collected by another person who is not aware of the objectives of the study.

Placebo

Not used

Assignment

Parallel

Other design features

This research is a multi-method mixed study, that is, the data have been collected, analyzed and integrated with each other with qualitative and quantitative approaches during several stages. In the first stage, the psychosocial support needs of pregnant teenagers are explained with the qualitative approach of guided content analysis. In the second stage, formulation of the intervention based on the solutions extracted from the qualitative stage and a review of the texts, prioritization and consensus on the selection of the intervention to promote psychosocial support provided based on the views of the experts using the nominal group method. And after analyzing the quantitative data and qualitatively, their results will be compared and combined.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Ahvaz Jondishapur University of Medical Sciences

Street address

Ahvaz Jondishapur University of Medical Sciences; Golestan street

City

Ahvaz

Province

Khouzestan

Postal code

15794 61357

Approval date
2023-06-03, 1402/03/13
Ethics committee reference number
IR.AJUMS.REC.1402.140

Health conditions studied

1

Description of health condition studied
Social support
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Perceived Stress
ICD-10 code
Z73.3
ICD-10 code description
Stress, not elsewhere classified

3

Description of health condition studied
Depression
ICD-10 code
F53.1
ICD-10 code description
Severe mental and behavioural disorders associated with the puerperium, not elsewhere classified

4

Description of health condition studied
anger expression
ICD-10 code
R45.4
ICD-10 code description
Irritability and anger

Primary outcomes

1

Description
Social support
Timepoint
Before intervention and after the sessions are completed and one month after the intervention
Method of measurement
Vaux social support

2

Description
Spielberger anger expression scale score
Timepoint
Before intervention and after the sessions are completed and one month after the intervention
Method of measurement
Spielberger anger expression scale

3

Description
Depression
Timepoint
Before intervention and after the sessions are completed and one month after the intervention
Method of measurement
Depression Edinburgh EDS

4

Description
Perceived Stress
Timepoint
Before intervention and after the sessions are completed and one month after the intervention
Method of measurement
Perceived Stress Scale

5

Description
Pregnancy outcome in mental health
Timepoint
Before intervention and after the sessions are completed and one month after the intervention
Method of measurement
Perceived Stress Scale-Depression Edinburgh EDS-Spielberger anger expression scale score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, participants will receive 4-6 training sessions based on psychosocial support. Depending on the content, the number of sessions may vary. Group sessions of 4 to 10 people will be offered during pregnancy.
Category
Behavior

2

Description
Control group: In the control group, only routine supportive care will be provided by the researcher.
Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Health care centers under the supervision of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
The Officials of health care centers
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan St. , Ahvaz , Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerkish
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Ahvaz Jundishapur University of Medical Sciences, Golestan St. , Ahvaz ,
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Simin Montazeri
Position
Assistant Professor of Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
starting 9 months after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
with previous agreement with the corresponding author
From where data/document is obtainable
email address:yousefi.setareh@gmail.com
What processes are involved for a request to access data/document
email address: yousefi.setareh@gmail.com
Comments