Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of self-care counseling versus control group on quality of life in pregnant teenagers: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of self-care counseling versus control group on quality of life in pregnant teenagers

Design
This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Healthcare Centers in Dargazin city on 70 eligible pregnant teenagers. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 13 to 19 years First pregnancy Singleton pregnancy Gestational age of 20 weeks and above Being literate Exclusion criteria: Pregnancy event Presence of background diseases

Intervention groups
Intervention group: Routine care during pregnancy, in addition to individually self-care counseling session for about 45 to 60 minutes a week, one session weekly for four weeks (including measuring the mother's information about self-care, checking the awareness of changes during pregnancy and the effect on the quality of life, helping the mother to express fulfilling desires and needs, teaching self-care in the field of physical, mental, and social health, identifying false beliefs in this field and increasing awareness about self-care, teaching self-care in the field of worries and concerns during pregnancy) Control group: Just routine care during pregnancy

Main outcome variables
Primary outcome: Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N449**
Registration date: **2022-12-09, 1401/09/18**
Registration timing: **prospective**

Last update: **2022-12-09, 1401/09/18**
Update count: **0**

Registration date
2022-12-09, 1401/09/18

Registrant information

Name
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Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-05-22, 1402/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of self-care counseling versus control group on

quality of life in pregnant teenagers: a randomized clinical trial

Public title
Effect of self-care counseling versus control group on quality of life in pregnant teenagers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 13 to 19 years First pregnancy Singleton pregnancy Gestational age of 20 weeks and above Being literate
Exclusion criteria:
Pregnancy event Presence of background diseases
Age
From **13 years** old to **19 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2022-11-17, 1401/08/26
Ethics committee reference number
IR.UMSHA.REC.1401.676

Health conditions studied

1

Description of health condition studied
Quality if life
ICD-10 code
Z73
ICD-10 code description
Problems related to life management difficulty

Primary outcomes

1

Description
Quality of life
Timepoint
Before the intervention and one month after
Method of measurement
Using the pregnancy quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine care during pregnancy, in addition to individually self-care counseling session for about 45 to 60 minutes a week, one session weekly for four weeks (including measuring the mother's information about self-care, checking the awareness of changes during pregnancy and the effect on the quality of life, helping the mother to express fulfilling desires and needs, teaching self-care in the field of physical, mental, and social health, identifying false beliefs in this field and increasing awareness about self-care, teaching self-care in the field of worries and concerns during pregnancy)
Category
Treatment - Other

2

Description
Control group: Just routine care during pregnancy
Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Healthcare Centers in Dargazin city

Full name of responsible person
Faeze Salehi

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

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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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Faeze Salehi

Position
Student of Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available