

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

salehifaeze625@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

salehifaeze625@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Batool Khodakarami

Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

zahrabatol2006@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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