

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of self care counseling on self care practice and health locus of control belief in pregnant women aged 35 years or more in the test and control groups

Protocol summary

Study aim

Determining the effect of self care counseling on the self care practice and health locus of control belief in pregnant women aged 35 years or older referring to Hamadan health centers

Design

In this study, at first 100 pregnant women aged 35 years or over with inclusion criteria were selected convenience sampling and then they were randomly divided into two test and control groups.

Settings and conduct

Type of research: The present study is a semi-experimental two-group (test and control) with pre-test and post-test design. Research area: All Health Centers in Hamadan city. The population of the study included all pregnant women aged 35 or over who will be referred to Hamadan Health Centers. The research sample consists of a group of people in the research community who have criteria for entry into the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes: Pregnant women with 35 years or more; having no underlying illnesses; single pregnancy; gestational age more than 24 weeks; have primary and higher literacy. Exclusion criteria includes: - Having no complete health based on medical records.

Intervention groups

Participants will be divided into test and control groups. In the test group, 4 consecutive 2-hour counseling sessions will be done. There will be no intervention in the control group.

Main outcome variables

Self care practice

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120821010635N3**

Registration date: **2017-12-28, 1396/10/07**

Registration timing: **prospective**

Last update: **2017-12-28, 1396/10/07**

Update count: **0**

Registration date

2017-12-28, 1396/10/07

Registrant information

Name

Soodabeh Aghababaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

aghababaei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Hamadan Medical University

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2019-01-19, 1397/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self care counseling on self care practice

and health locus of control belief in pregnant women aged 35 years or more in the test and control groups

Public title

The effect of self care counseling on self care practice and health locus of control belief in pregnant women aged 35 years or older

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria includes: Pregnant women with 35 years or more; having no underlying illnesses; single pregnancy; gestational age more than 24 weeks; Have primary and higher literacy.

Exclusion criteria:

Exclusion criteria includes: Having not complete health based on medical records.

Age

From **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the participants at first will be selected by simple sampling method and then will be divided randomly into control and experimental groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics committee of University of Hamadan Medical Sciences

Street address

University of Hamadan Medical Sciences, Shahid Fahmideh Ave, Hamadan, Iran.

City

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Postal code

65178-3-8698

Approval date

2017-10-14, 1396/07/22

Ethics committee reference number

IR.UMSHA.REC.1396.484

Health conditions studied

1

Description of health condition studied

Self care

ICD-10 code

Z40- Z54

ICD-10 code description

Persons encountering health services for specific procedures and health care

Primary outcomes

1

Description

Self care score

Timepoint

At the beginning of the study (before the intervention) and 30 days after the end of the intervention.

Method of measurement

Use the Health Practice Questionnaire

2

Description

Health Locus of Control score

Timepoint

At the beginning of the study (before the intervention) and 30 days after the end of the intervention.

Method of measurement

Use the Health Locus of Control Scale (HLC)

Secondary outcomes

empty

Intervention groups

1

Description

"Test group": The counseling schedule will take place in the form of GATHER, so that after greetings and establishing a good relationship with mothers and greeting (G), asking the mothers open questions about themselves to help them think and reflect on the subject of the study. Give references to the wishes and needs and help mothers express their feelings and beliefs and get information about the risk of pregnancy and its complications (A) and provide the necessary explanation (T). Second session (45-60 minutes): To help the research units to increase the information about self-care during pregnancy and how to control health by

emphasizing its internal aspect, counseling in La The ground will be presented. Identify the negative thoughts and misconceptions about health. Help (H) The third session (45-60 minutes): During this session, while reviewing the topics of the previous sessions and answering the questions, counseling on self-care during pregnancy and your individual role in health care. Educational pamphlets and educational explanations (E), scheduling for a visit to mothers, determining the next visit, if necessary, and explaining to the mother about follow-up times and weekly contacts (R). There will be no intervention in the control group.

Category

Lifestyle

2

Description

"Control group": There will be no intervention in the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Hamadan Medical Sciences

Full name of responsible person

Soodabeh Aghababaei

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University of Hamadan Medical Sciences, Shahid Fahmideh Ave, Hamadan, Iran.

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aghababaii@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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University of Hamadan Medical Sciences, Shahid Fahmideh Ave, Hamadan, Iran.

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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

Soodabeh Aghababaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Name of organization / entity

University of Hamadan Medical Sciences

Full name of responsible person

Soodabeh Aghababaei

Position

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Latest degree

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Web page address**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

In this research, after the initial permission of individuals
and their unidentified, research data will be shared.

When the data will become available and for how long

The data will be shared after the statistical analysis from
the second half of 1397.

To whom data/document is available

Data will be shared by researchers in relevant fields.

Under which criteria data/document could be used

Any use of data will be subject to obtaining permission
from Hamadan University of Medical Sciences.

From where data/document is obtainable

Responsive name is Dr. Soodabeh Aghababaii, Faculty
Member of University of Hamadan Medical Sciences. E-
mail: aghababaii@yahoo.com

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

Data will be available upon notification of the
respondent.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

University of Hamadan Medical Sciences

Full name of responsible person

Soodabeh Aghababaei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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