Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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)

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Email address
aghababaii@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 Ouestionnaire

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 Ṡcale (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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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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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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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 Aghababii, 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