

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

A comparative study of the effect of personal counseling and home visits on the level of self-care of pregnant mothers

Protocol summary

Study aim

Determining and comparing the effect of personal counseling and home visits on the level of self-care adherence of pregnant mothers

Design

This study was a clinical trial study. Ninety women with first pregnancies, who were single pregnancy and had a gestational age of 26-32 weeks, were randomly divided into three groups of control, first and second experimental groups, according to the inclusion criteria.

Settings and conduct

This study is a clinical trial study conducted in Kermanshah. The target population included women with the first pregnancy referred to health centers in Kermanshah who were in the third trimester of pregnancy (26-32 weeks) and had inclusion criteria. Ninety pregnant women were selected as a cluster from Kermanshah and were randomly divided into two experimental groups and a control group. The first and second experimental groups, in addition to routine care, underwent 5 sessions of individual counseling and 5 sessions of home visits, respectively, and in the control group, only routine care was performed. Mothers in the three groups were assessed before and after the intervention using the Hart Self-Care Adherence Questionnaire.

Participants/Inclusion and exclusion criteria

Resident of Kermanshah; Has a minimum literacy; Willingness to participate in the study; Gestational age between 26-26 weeks; First pregnancy; single pregnancy; No cognitive disorders or mental illness; No pregnancy complications

Intervention groups

The first intervention group, in addition to the routine care of the centers, 5 individual counseling sessions per week, one session 50-60 The second intervention group, in addition to the routine care of the centers, 5 sessions of home visits (weekly for 5 consecutive weeks) Control group, routine care centers

Main outcome variables

Adherence to self-care of pregnant mothers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201202049574N1**

Registration date: **2020-12-29, 1399/10/09**

Registration timing: **retrospective**

Last update: **2020-12-29, 1399/10/09**

Update count: **0**

Registration date

2020-12-29, 1399/10/09

Registrant information

Name

Maryam Sayadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3822 1404

Email address

data6670@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-20, 1399/02/31

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

2020-05-20, 1399/02/31

Actual recruitment end date

2020-09-20, 1399/06/30

Trial completion date

2020-11-21, 1399/09/01

Scientific title

A comparative study of the effect of personal counseling and home visits on the level of self-care of pregnant mothers

Public title

The effect of personal counseling and home visits on the level of self-care of pregnant mothers

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant mothers first pregnancies gestational age of 26-32 weeks singletons pregnancy Being a resident of Kermanshah city Has a minimum of elementary level
Absence of speech and hearing disorders Lack of cognitive impairment or mental illness

Exclusion criteria:

Premature delivery before the end of the study
Complications of pregnancy that cause hospitalization
Reluctance to continue collaborating in research

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a numbered card, the samples were randomly divided into three groups (two test groups and one control group). Initially, three cards with the letters of the English alphabet written on them; Each was placed separately in an envelope. The control group (C), the first test group - counseling (M) and the second test group - home visit (H). The first three participants were then asked to each take one of the envelopes and open the card inside. Based on the letters on the cards, the control (C), the first test (M) and the second test (H) groups were identified. At the end of sampling, the samples were entered into groups in the same way and in the same way.

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 Kermanshah University of Medical Sciences

Street address

Research Deputy, Building No. 2, Shahid Beheshti Boulevard, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2019-05-20, 1398/02/30

Ethics committee reference number

IR.KUMS.REC.1398.196

Health conditions studied**1****Description of health condition studied**

Pregnancy

ICD-10 code

Z34.03

ICD-10 code description

Encounter for supervision of normal first pregnancy, third trimester

Primary outcomes**1****Description**

Hart's Self-Care Adherence Score Questionnaire

Timepoint

Before the intervention and 4 weeks after the last intervention session

Method of measurement

Hart Self-Care Adherence Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: In addition to routine care centers, 5 individual counseling sessions, one session per week

Category

Prevention

2

Description

Intervention group 2: In addition to the routine care of the centers, 5 sessions of home visit, one session per week

Category

Prevention

3

Description

Control group: Routine health care related to pregnancy

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah health centers

Full name of responsible person

Maryam Sayadi

Street address

Midwifery department, Imam Reza hospital, Parstar Blvd., Sorkheh Lijeh

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6742775333

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Maryam Sayyadi

Position

Midwifer

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some of the participants' data will be shared with the
subscriber in the form of dissertation and article reports
after making them unidentifiable.

**When the data will become available and for how
long**

Start of access period from the beginning of 2021

To whom data/document is available

Real people working in academic and scientific
institutions

Under which criteria data/document could be used

Only the results of data analysis mentioned in the
dissertation can be used.

From where data/document is obtainable

Sorkheh Lijeh, Parstar Blvd., Imam Reza Hospital,
Midwifery, Maryam Sayadi

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

A written request or email to Ms. Maryam Sayadi is
sufficient to use the documents.

Comments