

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Promoting health literacy about self-care in pregnancy and its effect on self-care in pregnant women referring to Pakdasht Comprehensive health service centers

Protocol summary

Study aim

Aim of the study is determination of the effect of intervention to promote health literacy about self-care in pregnancy on self-care in pregnant women referring to Pakdasht Comprehensive health service centers.

Design

Data collection tools are two researcher made questionnaire about health literacy and self-care in pregnancy.

Settings and conduct

In first stage , questionnaires will be filled in two groups in Pakdasht Comprehensive health service centers. Then an intervention will be planned based on analysis of the data . Intervention consists 4 educational sessions. Duration of each session is 45 minutes and teaching methods will be lecture, group discussion, question and answer, counseling, demonstration. educational materials are a leaf let and an educational film. Intervention will be done only in case group in Pakdasht Comprehensive health service centers. In second stage, one months and three months after intervention, questionnaire will be filled again. Data will be analyzed and compared in two groups.

Participants/Inclusion and exclusion criteria

pregnant women referring to Pakdasht Comprehensive health service centers. inclusion criteria are covered by the studied women at Pakdasht Comprehensive health service centers, pregnant weren't be sick and gestational age of 12 weeks to 24 weeks, and the exclusion criteria are moving and leaving the coverage of the center and Mother's illness.

Intervention groups

Two group (control and case). Intervention consists 4 educational sessions. Duration of each session is 45 minutes and teaching methods will be lecture, group discussion, question and answer, counseling, demonstration. educational materials are a leaf let and

an educational film.

Main outcome variables

health literacy and self-care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030415650N8**

Registration date: **2017-06-01, 1396/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-21, 1397/04/30**

Update count: **1**

Registration date

2017-06-01, 1396/03/11

Registrant information

Name

Mahnaz Solhi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 9928

Email address

solhi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research and Technology, Iran University of medical Sciences

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Promoting health literacy about self-care in pregnancy and its effect on self-care in pregnant women referring to Pakdasht Comprehensive health service centers

Public title
Health promotion about self-care in pregnancy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 En inclusion criteria: The women are covered by Pakdasht Comprehensive health service centers. Mothers weren't ill and their pregnancy age were 12 to 24 weeks.
Exclusion criteria:
 Moved up and be in out of coverage of Pakdasht Comprehensive health service centers Mother's illness pregnancy age were 12 to 24 weeks

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Out of 10 Pakdasht comprehensive health centers, 2 centers were randomly selected. Then, from the two centers, a center was assigned to the control group and another to the intervention group by randomly.

Blinding (investigator's opinion)
Not blinded

Blinding description
Participants in the study were kept blind about dividing in control and case groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Iran University of Medical Sciences
Street address
 Ethics Committee, Vice-chancellor for research and Technology, Iran University of Medical Sciences, near Milad Hospital, Hemmat highway
City
 Tehran
Province
 Tehran
Postal code
 1449614535
Approval date
 2017-04-22, 1396/02/02
Ethics committee reference number
 IR.IUMS.REC. 1395.95-04-27-30279

Health conditions studied

1

Description of health condition studied
Self-care in pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Self-care in pregnancy

Timepoint
Before intervention, one and two months after education

Method of measurement
Resercher made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention in case group: It consists 4 educational sessions. Duration of each session is 45 minutes and teaching methods will be lecture, group discussion, question and answer, counseling, demonstration. educational materials are a leaf let and an educational film. Intervention will be done in Pakdasht Comprehensive health service centers.

Category
Prevention

2

Description

Intervention in control group: No intervention will be done in control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Pakdasht Comprehensive health service centers

Full name of responsible person

Khadijeh Abbasi

Street address

خیابان شهید مطهری

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Pakdasht

Province

Tehran

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3391938561

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Fax

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Email

abbasi86k@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research and Technology, Iran University of medical Sciences

Full name of responsible person

Dr. syyed Ali Javad Moosavi

Street address

Vice-chancellor for research and Technology, Iran University of Medical Sciences, near Milad Hospital, Hemmat highway

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moosavi.j@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for research and Technology, Iran 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

Department of Health Services, School of Health, Iran University of Medical Sciences

Full name of responsible person

Mahnaz Solhi

Position

PhD of Health Education/ Associate Prof.

Latest degree

Ph.D.

Other areas of specialty/work

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School of Health, Iran University of Medical Sciences, near Milad Hospital, Hemmat highway

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Sharing plan

Person responsible for updating data

Contact**Name of organization / entity**

Department of Health Services, School of Health, Iran
University of Medical Sciences

Full name of responsible person

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Latest degree

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Health Promotion

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near Milad Hospital, Hemmat highway

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the confidentiality of the data file of participants
in the study as one of the ethical considerations

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable