

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of a midwife-led group counseling on pregnant women's empowerment and self care in selected Health Centers of Tallish 1396: Based on Orem's self care model.

Protocol summary

Summary

This study aims to investigate the effectiveness of a midwife-led group counseling on pregnant women's empowerment and self care in selected Health Centers of Tallish: Based on Orem's self care model and This is a randomized clinical trial without blinding. The sample size will be 74 prime gravid pregnant women. Inclusion criteria: prime gravid Iranian women; having least literacy; Nulliparity; had no significant medical problem such as Hypertension; Diabetes; Bleeding...; they having tendency and conscious consent to inter the study. and exclusion criteria: Unwillingness to continue participation in the study, having physical and psychological diseases by patient word, they being absent counseling sessions not more than 2 sessions. The primary outcome measure is empowerment and self care.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021627728N4**

Registration date: **2017-04-12, 1396/01/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-12, 1396/01/23

Registrant information

Name

Zohreh Mahmoodi

Name of organization / entity

Nursing&Midwifery faculty

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Alborz University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of a midwife-led group counseling on pregnant women's empowerment and self care in selected Health Centers of Tallish 1396: Based on Orem's self care model.

Public title

The effectiveness of a midwife-led group counseling on pregnant women's empowerment and self care in selected Health Centers of Tallish 1396: Based on Orem's self care model.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: prim gravid Iranian women; having least literacy; Nulliparity; had no significant medical problem such as Hypertension; Diabetes; Bleeding; they having tendency and conscious consent to inter the study. and exclusion criteria: Unwillingness to continue

participation in the study; having physical and psychological diseases by patient word; they being absent counseling sessions not more than 2 sessions.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 74

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Block sampling with random numeral

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Alborz University Of Medical Sciences

Street address

ninth floor, Dara building, north Yasmin, east Pune street, 45 Yards of Golshahr, karaj, IRAN

City

Karaj

Postal code**Approval date**

2017-01-28, 1395/11/09

Ethics committee reference number

Abzums.Rec.1395.145

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

empowerment

ICD-10 code

z36

ICD-10 code description

Antenatal screening

2**Description of health condition studied**

self care

ICD-10 code

Z31.6

ICD-10 code description

General counselling and advice on procreation

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

Empowerment

Timepoint

Before intervention _ Immediately after the intervention
-3 weeks after intervention

Method of measurement

Use of questionnaire

Secondary outcomes**1****Description**

Self care

Timepoint

Before intervention _ Immediately after the intervention
-3 weeks after intervention

Method of measurement

Use of questionnaire

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

In the intervention group hold 6 consultation sessions weekly based on model of Orem with considering booklet of pregnant women cares for Health Ministry .The time of each session is 90 minute. In the control group hold 2 routine consultation sessions+ educational package weekly and The time of each session is 90 minute

Category

Behavior

2**Description**

Control group : They receive routine pregnancy consultation

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tallish health center (1)

Full name of responsible person

Dr Zohreh Mahmoodi

Street address

Tallish health center (1), Rzeghi alley, Shahid Rajaii Street, Tallish, Guilan, IR

City

Tallish

2**Recruitment center****Name of recruitment center**

Tallish health center (2)

Full name of responsible person

Dr Zohreh Mahmoodi

Street address

Tallish health center (2), Danesh amooz Square, Tallish, Guilan, IR.

City

Tallish

3**Recruitment center****Name of recruitment center**

Tallish health center (3)

Full name of responsible person

Dr Zohreh Mahmoodi

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Tallish health center (3), Namaz Square, Tallish, Guilan, IR.

City

Tallish

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Alborz University of Medical Sciences

Full name of responsible person

Dr Mohammad Noori sepehr

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Department of Nursing, Alborz University of Medical Science, Golestan Street, Eshteraki Street, Baghestan, Karaj, IR.

City

Karaj

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Alborz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Alborz University of Medical Sciences

Full name of responsible person

Dr Zohreh Mahmoodi

Position

PhD

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty