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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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 questionaire

Secondary outcomes

1

Description
Self care

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

Method of measurement
Use of questionaire

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.
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3

Recruitment center
Name of recruitment center
Tallish health center (3)
Full name of responsible person
Dr Zohreh Mahmoodi
Street address
Tallish health center (3),Namaz Square, Tallish, Guilan, IR.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Dr Mohammad Noori sepehr
Street address
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
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Web page address

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