

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effect of self care during pregnancy based on Orem's theory on gestational age for women at risk of preterm birth.

Protocol summary

Summary

(1) Objectives: Determine the effect of self care during pregnancy based on Orem's theory on gestational age for women at risk of preterm birth; Determine the gestational age in the intervention group; Determine the gestational age in the control group; Compare the gestational ages in the control group and intervention group. (2) Design: randomized, not blinded, step 2-3 trial. (3) Setting and conduct: population of this study consisted of all pregnant women referred to health centers in Mashhad to receive prenatal care. Sampling is multi-stage. Researcher visit these centers and choose women who are 24-26 weeks. If they be satisfied, they will fill in screening preterm labor questionnaire, depression anxiety stress scale questionnaire DASS21 and physical activity during pregnancy. Then pregnant women who have conditions of entry to this study will choose according to these questionnaires. They will separate to 2 groups, control and intervention. After that according to self care during pregnancy questionnaire, will evaluate educational needs of the intervention group. Then will be taught in 3 times in 3 weeks 45-60min individually and face-to-face and card-style and questions and answers. Then researcher will call them and follow them to 40 week to will be informed of their delivery. Finally researcher will go to hospital where those women will deliver to they fill in self care questionnaire again. (4) Participants including major eligibility criteria: the main criteria for inclusion: gestational age 24-26 weeks; scores 10 or more of 10 from screening questionnaire. the main criteria for exclusion: lack of desire to continue participating in the study; lack of participate in 3 sessions; filling in of incomplete questionnaires. (5) Intervention: intervention group will be taught in 3 times in 3 weeks 45-60min individually and face-to-face and card-style and questions and answers and control group will be gotten routine pregnancy care. (6) main outcome measures (variables): gestational age.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512225659N1**

Registration date: **2016-06-18, 1395/03/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-18, 1395/03/29

Registrant information

Name

Seyedeh Mahboobe Rezaeean

Name of organization / entity

Nursing Midwifery University

Country

Iran (Islamic Republic of)

Phone

+98 51 3502 5294

Email address

rezaeianm922@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Contributing 90 percent of the research budget of contract enforcement and 10 percent of the credit of evidence-based care research center

Expected recruitment start date

2015-12-18, 1394/09/27

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of self care during pregnancy based on Orem's theory on gestational age for women at risk of preterm birth.

Public title
The effect of Orem's self care on gestational age

Purpose
Supportive

Inclusion/Exclusion criteria
The major terms of inclusion criteria: Iranian; living in Mashhad; literate in Persian; having a phone number to call; gestational age 24-26 weeks; scores 10 or more of 10 from screening questionnaire. The major terms of exclusion criteria upon research: studying in a field of medical sciences; problems with speech, hearing or accent which is unable to connect; lack of desire to continue participating in the study; lack of participation in 3 sessions; filling in of incomplete questionnaires

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

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 committees of Mashhad university of medical sciences
Street address
Doctora Junction, Mashhad
City
Mashhad
Postal code
Approval date
2015-10-31, 1394/08/09

Ethics committee reference number

IR.MUMS.REC.1394.448

Health conditions studied

1

Description of health condition studied

Pregnant women at risk of preterm birth

ICD-10 code

z35.0, z35

ICD-10 code description

Supervision of high-risk pregnancy

Primary outcomes

1

Description

Gestational age for women at risk of preterm birth.

Timepoint

delivery

Method of measurement

gestational age

2

Description

The incidence of preterm birth.

Timepoint

delivery

Method of measurement

gestational age

Secondary outcomes

1

Description

The amount of the score of self care of pregnant women at risk for preterm birth.

Timepoint

delivery

Method of measurement

Score of self care questionnaire

Intervention groups

1

Description

self care during pregnancy based on Orem's theory will be taught in 3 times in 3 weeks 45-60min

Category

Prevention

2

Description

Control group: routine pregnancy care

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center number1

Full name of responsible person

Doctor Naser Amini

Street address

66-68 Vakil Abad Street

City

Mashhad

2

Recruitment center

Name of recruitment center

Health center number 5

Full name of responsible person

Doctor Mahdi Hasannegad

Street address

52 Basij, after the Airport Bridge, Basij(Alghadir)
Highway

City

Mashhad

3

Recruitment center

Name of recruitment center

Health center number2

Full name of responsible person

Doctor Ali Asghar Mahmoodi

Street address

Next to Vahdat Park

City

Mashhad

4

Recruitment center

Name of recruitment center

Health center number 3

Full name of responsible person

Street address

24 Akhoond Khorasani

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of
Medical Sciences

Full name of responsible person

Doctor Mohsen Tafaghodi

Street address

Daneshgah Street

City

Mashhad

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, Mashhad 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

Nursing Midwifery University

Full name of responsible person

Seyedeh Mahboobe Rezaeean

Position

Student of Master degree of midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
Nursing Midwifery University
Full name of responsible person
Seyedeh Mahboobe Rezaeean
Position
Student of master degree of midwifery
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rezaeianm922@mums.ac.ir
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