Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of self care during pregnancy based on Orems 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 Orems 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, step2-3 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 af entry to this study will choose according to these questionnaires.They will seperate to 2 groups, control and intervention. After that according to self care during pregnancy questionnaire, will evaluated 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: **IRCT2015122225659N1**
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 Orems theory on gestational age for women at risk of preterm birth.

Public title
The effect of Orems 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:studing 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 participate 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 Orems theory will be taught in 3 times in 3 weeks 45-60min
Category
Prevention

2

Description
Control group: routine pregnancy care
Category

Prevention

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
Street address
Doctora Crossroad
City
Mashhad
Postal code
Phone
+98 935 819 1097
Fax
Email
rezaeianm922@mums.ac.ir
Web page address

Person responsible for scientific 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
Street address
Doctora Crossroad
City
Mashhad
Postal code

Phone
+98 935 819 1097
Fax
Email
rezaeianm922@mums.ac.ir
Web page address

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
Other areas of specialty/work
Street address
Doctora Crossroad
City
Mashhad
Postal code
Phone
Fax
Email
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