Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of "Roy" adaptation model on self concept in primi gravida women

Protocol summary

Summary

The purpose of this study is to examine the effect of intervention based on "Roy" adaptation model on self concept in primi gravida women. Inclusion criteria include: Gestational age between 24 and 28 weeks; first pregnancy (Primi Gravida); lack of experience a stressful event during 6 recent months; not suffering from clinched mental disorders; do not receive other training or caring plan associated with the self concept during the study. Exclusion criteria include: Lack of participation in educations regularly; the occurrence of complications such as eclampsia and preterm labor; the incidence of stressful event for the samples during the study. In this clinical trial, 86 primi gravida women will be selected and Will be placed randomly in both intervention and control groups. At First, maladaptive behaviors by means of questionnaire based on "Roy" pattern will be determined. Training content based on maladaptive behaviors in 6 sessions of 90 minutes during 6 weeks with method of lecture by using of tools like data projector and whiteboard will be provided. During the study, both groups will be received routine prenatal cares, with this difference that educational intervention will be done only in intervention group. Immediately after the training sessions rate of adaptation in two groups will be measured.The main variable is implementation of "Roy" adaptation model that its effect will be evaluated on self concept.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052217800N1**
Registration date: **2014-06-10, 1393/03/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-06-10, 1393/03/20

Registrant information

Name
Samane Najafi
Name of organization / entity
Gonabad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 53 3722 5027
Email address
najafi.s@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Gonabad University of Medical Sciences

Expected recruitment start date

2014-07-21, 1393/04/30

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of "Roy" adaptation model on self concept in primi gravida women

Public title

The effect of educational caring model on self concept of primi gravida women

Purpose

Health service research

Inclusion/Exclusion criteria
Inclusion criteria: Gestational age between 24 and 28 weeks; At least having ability to read and write; First pregnancy (Primi Gravida); Not suffering from pregnancy disease and complications such as eclampsia, Preeclampsia and gestational diabetes; Lack of experience a stressful event during 6 recent months; Living with a spouse; Not suffering from clinched mental disorders; Do not receive other training or caring plan associated with the self concept during the study. Exclusion criteria: No follow up and request to withdraw from the study at any stage; Lack of participation regularly and according to designed training Program; The occurrence of complications such as eclampsia , hemorrhage, rupture of membranes and preterm labor; The incidence of stressful event for the samples during the study.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **86**

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 Committee of Gonabad University of Medical Sciences

Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad

City
Gonabad

Postal code

Approval date
2014-05-21, 1393/02/31

Ethics committee reference number
GMU.REC.1393.7

Health conditions studied

1

Description of health condition studied
pregnancy

ICD-10 code
Z34.0

ICD-10 code description
Supervision of normal first pregnancy

Primary outcomes

1

Description
self concept

Timepoint
Immediately before and after intervention

Method of measurement
Researcher made questionnaire of the survey of adaptation rate in self concept mode based on Roy pattern

Secondary outcomes

1

Description
Adaptation rate in self concept mode

Timepoint
Immediately before and after intervention

Method of measurement
Researcher made questionnaire of the survey of adaptation rate in self concept mode based on Roy pattern

Intervention groups

1

Description
In intervention group, after determining maladaptive behaviors and codification educational plan, training content in 6 sessions of 90 minutes and during 6 weeks with method of lecture by using of tools like data projector, whiteboard, markers and pamphlets will be provided.

Category
Other

2

Description
In control group, only routine prenatal cares will be provided and will not receive any intervention.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Care Centers of Gonabad
Full name of responsible person
Samane Najafi
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad
City
Gonabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Gonabad University of Medical Sciences
Full name of responsible person
Dr. Ali Mohammadpour
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad
City
Gonabad
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 of Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Samane Najafi
Position
MSc. student in nursing education
Other areas of specialty/work
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad
City
Gonabad
Postal code
Phone
+98 53 3722 5027
Fax
Email
Najafi.S@gmu.ac.ir; S.Najafi2012@yahoo.com; SamanehNajafi79@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Vice chancellor for research of Gonabad University of Medical Sciences
Full name of responsible person
Dr. Ali Mohammadpour
Position
PhD in nursing education, Assistant Professor
Other areas of specialty/work
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad
City
Gonabad
Postal code
Phone
+98 53 3725 3884
Fax
Email
Dr.Mohammadpour@gmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Samane Najafi
Position
MSc. student in nursing education
Other areas of specialty/work
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad
City
Gonabad
Postal code
Phone
+98 53 3722 3028
Fax
Email
Najafi.S@gmu.ac.ir; S.Najafi2012@yahoo.com; SamanehNajafi79@yahoo.com
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