

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 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

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Vice chancellor for research of Gonabad University of Medical Sciences

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PhD in nursing education, Assistant Professor

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## Person responsible for updating data

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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*