

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The comparison of the effect of training to group discussion method with the multimedia package on the learning and nutritional status in pregnant women

#### Protocol summary

##### Summary

The purpose of this study is to the comparison of the effect of training to group discussion method with the multimedia package on the learning and nutritional status in pregnant women. Inclusion criteria: gestational age between 6 to 10 weeks; having the possibilities of using multimedia package in the home and lack of experience a stressful event during 2 recent months. 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 and the incidence of stressful event for the samples during the study. For this clinical trial 180 pregnant women will be selected by using quota sampling technique from Gonabad and Mashhad cities. Participants randomly into three groups multimedia package, group discussion and control will be assigned. After obtaining informed consent, the questionnaires will be completed in three groups. For mothers in multimedia group will be loaned a DVD about nutrition during pregnancy for 2 weeks. People in group discussion were divided into 8 groups of 8 to 12 members and will be taught by group discussion method over three 90 minute sessions. During the study, all three groups will be received routine prenatal cares, with this difference that educational intervention will be done only in groups of multimedia package and group discussion. One month after the intervention, the questionnaires will be completed in three groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016091117800N3**

Registration date: **2016-10-11, 1395/07/20**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-10-11, 1395/07/20

##### 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, Gonabad university of medical sciences

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2016-12-21, 1395/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of the effect of training to group discussion method with the multimedia package on the learning and nutritional status in pregnant women

##### Public title

The comparison of training to group discussion method with the multimedia package

ص/1145/92

## **Purpose**

Health service research

## **Inclusion/Exclusion criteria**

Inclusion criteria: gestational age between 6 to 10 weeks; do not receive other training or caring plan associated with the nutrition in pregnancy during the study; having the possibilities of using multimedia package in the home; having ability to read and write; lack of experience a stressful event during 2 recent months. Exclusion criteria: having the severe pica for a particular food; certain diseases with than once from educational session's special medical regimen, no follow up and request to withdraw from the study at any stage; lack of participation regularly and according to designed training Program; the incidence of stressful event for the samples during the study.

## **Age**

From **18 years** old to **35 years** old

## **Gender**

Female

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **180**

## **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, Khorasan Razavi, Iran, Islamic Republic Of.

##### **City**

Gonabad

##### **Postal code**

#### **Approval date**

2013-08-06, 1392/05/15

#### **Ethics committee reference number**

## **Health conditions studied**

### 1

#### **Description of health condition studied**

The comparison of the training to group discussion method with the multimedia package on the learning and nutritional status in pregnant women

#### **ICD-10 code**

Z34.0

#### **ICD-10 code description**

Supervision of normal first pregnancy

## **Primary outcomes**

### 1

#### **Description**

The learning

#### **Timepoint**

Immediately before intervention and one month after intervention

#### **Method of measurement**

The researcher made questionnaire for the survey of the learning in three cognitive, affective and psychomotor domains and "Kolb" learning style questionnaire.

## **Secondary outcomes**

### 1

#### **Description**

Nutritional status

#### **Timepoint**

Immediately before intervention and one month after intervention

#### **Method of measurement**

Food frequency instrument

## **Intervention groups**

### 1

#### **Description**

The intervention group consisted of two groups multimedia package and discussion groups. For mothers in multimedia group will be loaned a DVD about nutrition during pregnancy for 2 weeks. People in group discussion were divided into 8 groups of 8-12 members and will be taught by group discussion method over three 90-minute sessions.

#### **Category**

Lifestyle

### 2

#### **Description**

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

**Category**  
Lifestyle

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Health care centers of Gonabad and Mashhad cities

**Full name of responsible person**

Samane Najafi

**Street address**

Gonabad university of medical sciences, next to the Asian road, Gonabad, Khorasan Razavi, Iran, Islamic Republic Of.

**City**

Gonabad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, 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, Khorasan Razavi, Iran, Islamic Republic Of.

**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, 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 in nursing education

### Other areas of specialty/work

### Street address

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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Najafi.S@gmu.ac.ir;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*