

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Effect of short massage system on self care of pregnant prediabetic women

#### Protocol summary

##### Summary

Objective: Comparison the effect of short massage system with routine education on self-care of pregnant prediabetic women. Design: Parallel randomized clinical trial Randomization: Patients will allocate to two equal groups of routine and short massage system educations according to table of random numbers. Participants including major eligibility criteria: this study will conduct on 100 patients with prediabetes in Ahvaz Imam Khomeini and Gholestan hospitals. Main inclusion criteria include pregnant women in 12-24 weeks of pregnancy which like to participate in the study; having fasting blood glucose 93-125 mg/dl in blood sugar test; lack of observing any specific diet or lack of any specific kind of exercises; ability to response to questions and participate in educational sessions and main exclusion criteria include having any diseases which interfere with study protocol such as mental diseases, myocardial infarction, stroke or drug abuse; lack of participating in educational sessions more than 2 times; lack of responding to short massage systems with a blank text in 2 days. Main outcome: Self-care Intervention: Subjects in control group will receive education through lecture method in 5 sessions during 10 weeks consecutively in recruitment centers. Subjects in intervention group will receive 2 short massage systems every other day during 10 weeks consecutively beside routine education.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016112531082N1**  
Registration date: **2016-12-13, 1395/09/23**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-13, 1395/09/23

##### Registrant information

###### Name

Anis Amani

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3391 0673

###### Email address

abbaspoor-z@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Ahvaz Judishapur University of Medical Sciences

##### Expected recruitment start date

2016-10-09, 1395/07/18

##### Expected recruitment end date

2017-03-02, 1395/12/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of short massage system on self care of pregnant prediabetic women

##### Public title

Comparison the effect of short massage system with routine education on self care of pregnant prediabetic women refereed to Ahvaz health centers

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

Inclusion criteria: pregnant women in 12-24 weeks of pregnancy which like to participate in the study; having fasting blood glucose 93-125 mg/dl in blood sugar test; lack of observing any specific diet or lack of any specific kind of exercises; ability to response to questions and participate in educational sessions. Exclusion criteria: having any diseases which interfere with study protocol such as mental diseases, myocardial infarction, stroke or drug abuse; lack of participating in educational sessions more than 2 times; lack of responding to short massage systems with a blank text in 2 days.

### **Age**

No age limit

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **100**

### **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 Ahwaz Jundishapur University of Medical Sciences

##### **Street address**

Ahwaz Jundishapur University of Medical Sciences, Golestan road, Ahwaz, Khuzestan

##### **City**

Ahwaz

##### **Postal code**

#### **Approval date**

2016-10-08, 1395/07/17

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

IR.AJUMS.REC.1395.440

## **Health conditions studied**

### **1**

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

Prediabetes

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

R73.0

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

Abnormal glucose tolerance test

## **Primary outcomes**

### **1**

#### **Description**

Self-care

#### **Timepoint**

before and after intervention (in 24 weeks of pregnancy)

#### **Method of measurement**

Researcher-made questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Diet

#### **Timepoint**

Before and after intervention (in 24 weeks of pregnancy)

#### **Method of measurement**

Food frequency questionnaire

### **2**

#### **Description**

Exercise

#### **Timepoint**

Before and after intervention (in 24 weeks of pregnancy)

#### **Method of measurement**

International physical activity questionnaire- short form

## **Intervention groups**

### **1**

#### **Description**

Subjects in control group will receive education through lecture method in 5 sessions during 10 weeks consecutively in recruitment centers.

#### **Category**

Prevention

### **2**

#### **Description**

Subjects in intervention group will receive 2 short massage systems every other day during 10 weeks consecutively beside routine education.

#### **Category**

Prevention

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ahvaz Golestan hospital

**Full name of responsible person**

Anis Amani

**Street address**

Golestan hospital, Golestan road, Ahvaz, Khuzestan

**City**

Ahvaz

### 2

#### Recruitment center

**Name of recruitment center**

Ahvaz Imam Khomeini hospital

**Full name of responsible person**

Anis Amani

**Street address**

Emam Khomeini hospital, Ahvaz, Khuzestan

**City**

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Anis Amani

**Street address**

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

**City**

Ahvaz

**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, Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Anis Amani

**Position**

MSc of midwifery

**Other areas of specialty/work****Street address**

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

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+7 7355292

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anis.amani68@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Zahra Abbaspoor

**Position**

PHD of reproductive health

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

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anis.amani68@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*