

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 Judishapur 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 Judishapur 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

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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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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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