

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Reviewing the effect of self-care education through social media on self-care of overweight and obese pregnant women

Protocol summary

Study aim

Reviewing the effect of self-care training through social media -WhatsApp- on self-care of diabetic pregnant women with obesity and overweight

Design

A clinical trial with a control group and an intervention group. Blocked randomization of 4 in a group of 30 blocks on 120 diabetic pregnant women who suffer obesity and overweight to investigate the effect of self-care training through WhatsApp.

Settings and conduct

After explaining the reasons and methods of the research, diabetic pregnant women will be invited to have the research done. Women, after obtaining informed satisfaction and ensuring of confidentiality of their personal information, would enter the study as intervention and control group. Then, the intervention group members will enter the WhatsApp messenger group and receive the educational content on line on even days in forms of video, photo or written text for 10 weeks from the 28th to the 38th week of pregnancy .Women in the control group only receive routine care.

Participants/Inclusion and exclusion criteria

The terms of entering the study: 1. 24-28-week pregnant women whose gestational diabetes has been confirmed by blood sugar test Two hours after taking 75 grams of glucose 2- being literate 3- having a private mobile phone 4- having WhatsApp installed and being able to use it 5- having the ability to attend In face-to-face .meetings and answering questions The terms of NOT entering the study: 1-Mother suffering from chronic diseases and medical conditions requiring taking medicine 2-Existence of high-risk pregnancy in the mother (pregnancy poisoning, twins...) 3-Mother's history of depression and drug addiction (psychoactive drugs, stimulants, alcoholic drinks...).

Intervention groups

Intervention group: self-care training through WhatsApp social network Control group: only routine care

Main outcome variables

Self-care promoting behaviors score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220909055918N1**

Registration date: **2022-11-07, 1401/08/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-07, 1401/08/16**

Update count: **0**

Registration date

2022-11-07, 1401/08/16

Registrant information

Name

Fatemeh Salarkarimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4336 6681

Email address

f.salar.7172@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Reviewing the effect of self-care education through social media on self-care of overweight and obese pregnant women

Public title

Investigating the effect of self-care training through WhatsApp on self-care criteria of diabetic pregnant women.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

1. 24-28-week pregnant women whose gestational diabetes has been confirmed by blood sugar test Two hours after taking 75 grams of glucose. 2. Being literate.3. Having a private mobile phone.4. Having WhatsApp installed and being able to use it.5. Having the ability to attend in face-to-face .meetings and answering questions

Exclusion criteria:**Age**

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The size of sample group is estimated to be 120 people. Sampling is done by using the Block Design Randomization method (30 blocks of 4) and using the table of random numbers. . In general, the samples are divided in a virtual training group and a control group. In total, 60 people are in the intervention group and 60 people are in the control group. Thus, the samples were randomly divided into the intervention group (training through WhatsApp + routine care)and the control group (only routine care). In this way, all possible modes of placement including A: Training via WhatsApp and B: Routine care were considered in blocks of 4 with an allocation ratio of 1:1, and the number of required blocks was determined based on the number of samples. After that, according to the required number of blocks and based on the table of random numbers, the blocks corresponding to each table were listed in order. Finally, as the samples entered the study, each person got a certain letter according to the obtained order .In order to hide the random allocation, the sealed non-transparent envelopes method with random sequence was used. In this method, first, a random sequence is created using a random number table, and based on the sample size of the research(120), 120 matte envelopes (in order to make the content of the envelope unclear) were

prepared. Each of the created random sequences was recorded on a card by a person who was unaware of the goals and topic of the study and the cards were placed in the envelopes, and finally the envelopes were sealed and placed in a box in order. At the time of sampling, the researcher, according to the order in which the qualified participants entered, opened one of the envelopes and the group of that participant was revealed.

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 Jundi Shapur Ahvaz University of Medical Sciences

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Golestan Ave,Golestan Blvd,Ahvaz,KHuzestan province,Iran

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Postal code

61357-15794

Approval date

2022-09-03, 1401/06/12

Ethics committee reference number

IR.AJUMS.REC.1401.232

Health conditions studied**1****Description of health condition studied**

Gestational Diabetes

ICD-10 code

O24.41

ICD-10 code description

Gestational diabetes mellitus in pregnancy

Primary outcomes**1****Description**

Score of self-care

Timepoint

Before and after the intervention

Method of measurement

Diabetes self-care questionnaire

2

Description

Blood sugar

Timepoint

Before and after the intervention

Method of measurement

blood sugar test 2 hours after consuming 75 grams of glucose and fasting blood sugar test

Secondary outcomes

1

Description

Physical activity

Timepoint

Before and after the intervention

Method of measurement

Physical activity questionnaire

2

Description

life style

Timepoint

Before and after the intervention

Method of measurement

Lifestyle questionnaire

3

Description

Weight changes

Timepoint

Before and after the intervention

Method of measurement

Recording weight changes with a scale.

Intervention groups

1

Description

Intervention group: In the beginning, the people who meet the criteria for entering the study will be identified and by using the block randomization method, divided into two groups of 60 people, the control group (face-to-face training) and 60 people in the intervention group (face-to-face training and training through software. Data collection tools in this research includes: demographic information form, blood sugar test checklist, measuring mothers' weight and recording weight changes, international physical activity questionnaire, lifestyle questionnaire and diabetes self-care questionnaire. At the beginning (between 24 and 28 weeks of pregnancy) for the samples of both groups, a checklist of blood sugar tests two hours of taking 75grams glucose and fast blood sugar test will be completed by the researcher. Then, the

demographic information form and Physical activity, lifestyle and self-care questionnaires will be provided to people to complete. Then the total samples, all 120 people, the intervention group (60 people) and the control group (60 people), will receive face-to-face training, which is actually the same routine pregnancy care through health centers until delivery. In addition to face-to-face training provided by health center midwives for the intervention group training will also be provided through the software. A group will be created on the WhatsApp social network and all the intervention group members will be joined to this group, and within 10 weeks (28-38 weeks) on even days, two educational messages will be sent in the form of written text or photos or educational videos into the group. The content provided in the educational messages will be similar to the content of face-to-face training. The content of face-to-face training sessions (routine pregnancy care) and educational messages of the software includes: "training about gestational diabetes and its effects on the mother and the fetus, explanation of self-care methods, nutrition education including foods that a pregnant person should not consume, portion of food and having regular physical activity, benefits of exercise and physical activity during pregnancy, Regular walking, recommended exercises for pregnant women (balanced movements, stretching exercise, Pilates and special classes for pregnancy), how to eat healthily, how to use insulin correctly'. After the completion of the training in two groups (38 weeks of pregnancy), the samples will be asked to perform the fasting blood sugar test and the blood sugar test after two hours of taking 75 grams of glucose and provide the results to the sampling centers. After reviewing the tests, As mentioned, the results will be recorded in the blood sugar test registration checklist by the researcher, and then the questionnaires (physical activity, lifestyle and self-care) will be completed again by both groups and the amount of weight changes will be estimated.

Category

Lifestyle

2

Description

Control group: Routine care of pregnancy

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Health Centers

Full name of responsible person

Ftamah salarkarimi

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person

Zahra Abbaspour
Position
Associate Professor
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

Use of data for research purposes only

When the data will become available and for how long

The access period starts 6 months after the results are
published

To whom data/document is available

Everyone has access to published data

Under which criteria data/document could be used

Raw statistical data will not be published, but statistical
analysis will be available

From where data/document is obtainable

Responsible for clinical trial registration

What processes are involved for a request to access data/document

It will be possible with the permission of the Ethics
Committee and Research Vice-Chancellor of Jundishapur
University of Medical Sciences, Ahwaz

Comments