Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Effect of cognitive-behavioral counseling based on mind-fullness on weight gain and quality of life of pregnant woman with overweight and obese

Protocol summary

Study aim

determine the effect of cognitive-behavioral counseling based on mind-fullness on weight gain and quality of life of pregnant woman with overweight and obese referring to health care centers of Shahid Sadoughi University of Medical Sciences in Yazd .

Design

This is a parallel clinical trial. Among the patients referring to three health care centers, 60 people were selected based on the criteria for entering and Exit the study and divided into two intervention and control groups according to the random numbers table.

Settings and conduct

This is a parallel clinical trial. Among the patients referring to three health care centers, 60 people were selected based on the criteria for entering and Exit the study and divided into two intervention and control groups according to the random numbers table.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include: aged over 19, BM I(Body mass Index) between 25, 39.9, gestational age 16 to 26 weeks, single pregnancy and low risk, at least the first prenatal care until the 16th week of gestation. Exit criteria include: Experience of stressful events in the last six months , using psychiatric medications last year, , metabolic disorders related to obesity and substance abuse.

Intervention groups

For the intervention group, in addition to receiving routine pregnancy care, 8 sessions of 90 minutes of group counseling will be held on a weekly basis. The control group will receive only routine pregnancy care.

Main outcome variables

In the case of effective cognitive-behavioral counseling based on the mindfulness of changes in weight and quality of life of pregnant women with overweight and obesity, this method of counseling is used to prevent overweight in pregnant women, and to improve their quality of life in the context of the care provided for these groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190316043071N1**
Registration date: **2019-06-24, 1398/04/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-24, 1398/04/03**
Update count: **0**

Registration date

2019-06-24, 1398/04/03

Registrant information

Name

Mozhgan Dehghani mohammad abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3836 3789

Email address

mo.dehghani@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of cognitive-behavioral counseling based on mind-fullness on weight gain and quality of life of pregnant woman with overweight and obese

Public title
Effect of cognitive-behavioral counseling based on mind-fullness on weight gain and quality of life of pregnant woman with overweight and obese referring to health care centers of Shahid Sadoughi University of Medical Sciences in the Yazd.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The inclusion criteria : ages older than 19 years, BMI(Body Mass Index) between 25 and 39.9, gestational age 16 to 26 weeks, singleton pregnancy, low risk pregnancy (no significant medical or obstetric problem before or during pregnancy such as: the history of thyroid disease, gestational diabetes, hypertension, ...), wanted pregnancy and performing the first prenatal care until the 16th week of pregnancy at a health care center
Exclusion criteria:
Exclusion criteria: Experience of stressful events in the past six months, such as the loss of a husband or other relative, the history of psychotherapy over the past year, the development of metabolic disorders associated with obesity, such as diabetes, etc and substance abuse
Age
From **19 years** old
Gender
Female

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The sample size is equivalent to 60 pregnant women who are referred to health care centers. They are randomly assigned to two groups using random numbers. For the intervention group, in addition to receiving routine pregnancy care, 8 sessions of 90 minutes of mind - fullness group counseling will be held on a weekly basis. The control group will receive only routine pregnancy care. At the end of the study, if the counselor wishes to be effective and they desired, mindfulness sessions will be held for the control group. Samples were weighted in each group at the time before intervention, immediately after the end of 8 sessions, one month later. They will also complete the quality of life questionnaire at all three times.
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 Shahid Sadoughi University of Medical Sciences, Yazd
Street address
Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd
City
yazd
Province
Yazd
Postal code
8916877443
Approval date
2019-01-06, 1397/10/16
Ethics committee reference number
IR.SSU.MEDICINE.1397.178

Health conditions studied

1

Description of health condition studied
Weight gain
ICD-10 code
ICD-10 code description

2

Description of health condition studied
quality of life
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Weight gain
Timepoint
Before intervention, after intervention and one month After intervention
Method of measurement
Based on kilograms and using the weight in health centers

2

Description
quality of life
Timepoint
Before Intervention, after intervention and one month after intervention
Method of measurement
Quality of Life questionnaire SF-36

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Behavior

2

Description
Control group:
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Rahmat Abad Health center
Full name of responsible person
Mohammadabadi Dehghani mozhgan
Street address
101Alley, Shahid Dashti Boulevard, Yazd
City
yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3824 1751
Fax
+98 35 3824 9705
Email
mo.dehghani@ssu.ac.ir

2

Recruitment center
Name of recruitment center
Azadshahr Health center
Full name of responsible person
Mohammadabadi Mozhgan
Street address
Mokhaberat Alley-, Second Square,Azadshahr yazd
City
yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3824 1751
Email
m.dehghani2279@yahoo.com

3

Recruitment center
Name of recruitment center
Farabi Health center
Full name of responsible person
Mohammadabadi Mozhgan
Street address
Shahid Dashti Blvd yazd
City
yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3824 1751
Email
m.dehghani2279@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Shahid Sadoughi University of Medical Science
Full name of responsible person
Dr. Amir Houshang Mehrparvar
Street address
Headquarters of Yazd University of Medical Sciences, Bahonar Square, Yazd
City
yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3724 0171
Email
m.dehghani2279@yahoo.com
Grant name
00
Grant code / Reference number
00
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Vice Chancellor for Research of Shahid Sadoughi University of Medical Science

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
Yazd University of Medical Sciences

Full name of responsible person
DehghaniMohammadabadi Mozhgan

Position
A graduate student in midwifery advice

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Nursing Midwifery Faculty, Bou ali Avenue, Thimsar Fallahi Avenue, Safaiyeh, Yazd

City
yazd

Province
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Postal code
8916877443

Phone
+98 38241751

Email
m.dehghani2279@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Azam Khoshbin

Position
Faculty trainer

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Nursing Midwifery Faculty, Bou ali Avenue, Thimsar Fallahi Avenue, Safaiyeh, Yazd.

City
yazd

Province
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+98 35 3824 1751

Email
a.khoshbin@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Mohammadabadi Dehghani Mozhgan

Position
A graduate student in midwifery advice

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Yazd Akhbaran Kashani Alley Sepideh

City
Yazd

Province
Yazd

Postal code
8916877443

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+98 35 3836 3789

Email
m.dehghani2279@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The Whole data is Available After identifying individuals.such as weigh again quality of life

When the data will become available and for how long
6 months after the results were published.

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
The data are available only to rely on the future papers of individuals.

From where data/document is obtainable
E-mail:m.dehghani2279@yahoo.com TEL;09135269522

mozhghan dehghani

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

A maximum of a week after your email is sent or the phone call is called.

Comments