Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of nutrition training and physical activity on weight changes and Self-efficacy of Weight Lifestyle for Women with High Body Mass Index in Postpartum Period

Protocol summary

Study aim
Determining the effect of nutrition education and physical activity on weight changes and lifestyle self-efficacy related to weight of women with high body mass index in the postpartum period

Design
Two-group randomized clinical trial with parallel groups, one blind, on 64 patients

Settings and conduct
For sampling, first a Mashhad center is selected, then from among the health centers under its coverage, by accident, using a lottery, one center is considered as the intervention group and the nearest center is considered as the control group.

Participants/Inclusion and exclusion criteria
Obese and overweight women who go to health centers in 6-12 weeks after delivery.

Intervention groups
Obese and overweight women who go to health centers in 6-12 weeks after delivery. Training by the researcher in groups of 5 to 7 people in 4 sessions of 60-60 minutes, once a week in the form of question, group discussion and answer lectures. it is possible. Session 1: Measuring anthropometric indices, completing questionnaires including Clark Weight Lifestyle Self-Efficacy Questionnaire, Physical Activity Index Questionnaire, then training on physical activity and its benefits in the postpartum period and how to use it Is given from the step count. The second, third and fourth sessions of healthy nutrition training focus on four sources of self-efficacy. At the end of the session, an educational booklet on healthy living will be presented. In the intervention group, after completing the training, in the 2nd and 6th weeks, a telephone call is made to follow up the research units. The control group will receive routine care. Maternal weight at the end of weeks 4 and 8 of control, then the mean of weight changes and weight-related lifestyle self-efficacy at the end of week 8 will be compared between the two groups

Main outcome variables
Weight chenges -Weight-Efficacy of Life style

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170606034339N2**
Registration date: **2020-09-08, 1399/06/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-08, 1399/06/18**
Update count: **0**

Registration date
2020-09-08, 1399/06/18

Registrant information

Name
Hoda Naderi

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 76 3537 7297

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naderih931@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of nutrition training and physical activity on weight changes and Self-efficacy of Weight Lifestyle for Women with High Body Mass Index in Postpartum Period

Public title
The effect of education on weight changes and lifestyle self-efficacy of women in the postpartum period
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: have written consent to participate in research; to visit the health center at 6-16 weeks after delivery; have physical activity level poor (score between 20-39) or inactive (score Less than 20); the pre-pregnancy body mass index is between (25-34/9); after delivery body mass index is between (25-34/9).
Exclusion criteria:
Exclusion criteria: do not participate in one of the training sessions; walking has not been done in 3 continuous Sessions or 5 discontinuous sessions; in more than 5 sessions, the number of steps recorded is less than 100-120 steps per minute.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization is done by lottery.
Blinding (investigator's opinion)
Single blinded
Blinding description
Among the health centers under the auspices of the university, one center is randomly selected as the intervention group using a lottery, and the nearest center in terms of distance and similarity in terms of socio-economic context is considered as the control group. The reason for choosing a separate intervention and control center to prevent the dissemination of information between the two groups. In this way, the participants do not know whether they are in the intervention or control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Qaryashi Building, University Street, Mashhad Holy
City
Mashhad
Province
Razavi Khorasan
Postal code
91388-13944
Approval date
2020-06-10, 1399/03/21
Ethics committee reference number
IR.MUMS.NURSE.REC.1399.011

Health conditions studied

1

Description of health condition studied
Overweight and Obesity after childbirth
ICD-10 code
E.66.8
ICD-10 code description
Other obesity

Primary outcomes

1

Description
Weight chenges
Timepoint
Before the intervention, 4 weeks after the intervention, 8 weeks after the intervention
Method of measurement
Scales

2

Description
Weight-Efficacy of Life style
Timepoint
Before intervention, 8 weeks after intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Physical Activity Index
Timepoint
Before the intervention, 8 weeks after the intervention
Method of measurement
Questionnaire

2

Description
Waist to Hip Ratio
Timepoint
Before the intervention, 4 weeks after the intervention, 8 weeks after the intervention
Method of measurement
Meter

3

Description
Hip Circumference
Timepoint
Before the intervention, 4 weeks after the intervention, 8 weeks after the intervention
Method of measurement
Meter

4

Description
Waist Circumference
Timepoint
Before the intervention, 4 weeks after the intervention, 8 weeks after the intervention
Method of measurement
Meter

5

Description
Body Mass Index
Timepoint
Before the intervention, 4 weeks after the intervention, 8 weeks after the intervention
Method of measurement
Scales and Meters

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to the standard care available in health centers, nutrition education with emphasis on four sources of self-efficacy and physical activity with pedometer by the researcher in groups of 5-7 people through lectures, group discussions and questions and answers. It is done in 4 sessions (45-60) minutes with an interval of one week. At the end of the training sessions, a healthy lifestyle booklet with the content of healthy nutrition and physical activity after childbirth will be given to mothers.
Category
Lifestyle

2

Description
Control group: The control group will receive the standard care available in the health centers.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Bandar Abbas Health Center
Full name of responsible person
Hoda Naderi
Street address
Bandar Abbas
City
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Hormozgan
Postal code
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Recruitment center
Name of recruitment center
Bandar Abbas Health Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person
Research Mashhad University of Medical Sciences

Street address
Mashhad, Daneshgah street, Mashhad University of Medical Science

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Maryam Moradi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for scientific inquiries

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Maryam moradi

Position
Associate professor

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Ph.D.

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Person responsible for updating data

Contact

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Mashhad University of Medical Sciences

Full name of responsible person
Hoda Naderi

Position
Master of Midwifery student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Sharing plan

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

Study Protocol
No - There is not 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

All data will be published after the individuals are unidentified

When the data will become available and for how long

Immediately after completing the plan

To whom data/document is available

All the researchers

Under which criteria data/document could be used

People working in health centers

From where data/document is obtainable

Hoda Naderi

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

Initially, an application is submitted via email, then after the email is read, if possible, the data will be provid

Comments