Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of healthy nutrition training and physical activity with pedometer on weight changes and weight-efficacy of life style woman with high body mass index in postpartum period

Protocol summary

Summary

In this study, two groups, randomized clinical trial that aim of determining the effect of healthy nutrition training and physical activity with Pedometer on weight changes and weight-efficacy of life style woman with high body mass index in postpartum period. Sample size includes 64 obese and overweight women who go to the health center at 6-16 weeks postpartum. For sampling, Mashhad Center No. 2 and No. 3 were selected. The among their subsidiary centers, randomly, four centers are selected as interventions and four centers are selected as controls. The training is carried out by a researcher in groups of 5 to 7. Teaching is a lecture method, a question and answer that takes place in two sessions (90-60) minutes a week, once a week. Session One: Measurement of anthropometric index and body composition, completion of questionnaires including Clark's Weight Lifestyle Self-Efficacy Questionnaire, Physical Activity Indicator Questionnaire, an explanation on how to fill out a checklist of food and daily physical activity, then training Regarding physical activity and its benefits during postpartum period, and the method of using the pedometer is given. Second session: Training on healthy nutrition counseling and people will be taught to choose their food according to the food substitution list At the end of the session, a healthy lifestyle education booklet (with content of physical activity and healthy nutrition advice) will be presented. In the intervention group, after the completion of 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 is monitored in both groups, then the mean weight changes and lifestyle self-efficacy related to weight at the end of week 8 will be compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062834339N1**
Registration date: **2017-08-31, 1396/06/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-31, 1396/06/09

Registrant information

Name
Hoda Naderi
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-01-14, 1395/10/25

Expected recruitment end date

2017-08-16, 1396/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of healthy nutrition training and physical activity with pedometer on weight changes and weight-efficacy of life style woman with high body mass index in postpartum period

Public title
Effect of training on weight changes and self-efficacy of women's lifestyle with high body mass index in postpartum period
Purpose
Prevention
Inclusion/Exclusion 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: 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
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
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
Postal code
Approval date
2016-12-10, 1395/09/20
Ethics committee reference number
IR.MUMS.REC.1395.429

Health conditions studied

1

Description of health condition studied
Overweight and Obesity after childbirth
ICD-10 code
E66.8
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 Composition
Timepoint
Before the intervention, 8 weeks after intervention
Method of measurement
Electrical Impedance Analysis Device

6

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
In the intervention group, in addition to the standard care provided in the Health centers, a healthy nutrition education and physical activity with a pedometer will be held by the researcher in groups of 5 to 7. Teaching is a lecture method, a question and answer that takes place in two sessions (90-60) minutes, once a week. At the end of the training sessions, a healthy lifestyle booklet will be given to the mothers with the content of healthy nutrition and physical activity after childbirth.
Category
Lifestyle

2

Description
The control group will receive standard care in Health centers.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Center No. 2
Full name of responsible person
Hoda Naderi
Street address
Beginning of Boulevard of Unity, next to Wahdat Park, Health Center No. 2
City
Mashhad

2

Recruitment center
Name of recruitment center
Health Center No. 3
Full name of responsible person
Hoda naderi
Street address
Akhund Khorasani Ave. 24
City
Mashhad

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
City
Mashhad
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
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
Faculty of nursing and midwifery of Mashhad
Full name of responsible person
Masoumeh Kordi
Position
Master of midwifery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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