

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 changes -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)

Phone

+98 76 3537 7297

Email address

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 changes

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

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Recruitment center

Name of recruitment center

Bandar Abbas Health Center

Full name of responsible person

Hoda Naderi

Street address

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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

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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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Position

Associate professor

Latest degree

Ph.D.

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Person responsible for updating data

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Master of Midwifery student

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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