

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 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

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7951336979

##### Phone

+98 76 3537 7297

##### Email

naderih931@mums.ac.ir

### 2

#### 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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##### Province

Hormozgan

##### Postal code

7951336979

##### Phone

+98 76 3537 7297

##### Email

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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

**City**

mashhad

**Province**

Razavi Khorasan

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**Email**

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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

**Street address**

Crossroads Doktora, Ibn-Sina Avenue

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**Person responsible for scientific inquiries**

**Contact**

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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

**Street address**

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Mahshad

**Province**

South Khorasan

**Postal code**

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**Phone**

00985318591511

**Email**

naderih931@mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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

**Street address**

Ibn Sina Street, Doctora intersection

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**Postal code**

79513-36979

**Phone**

+98 76 3537 7297

**Email**

naderih931@mums.ac.ir

**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**