

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Effect of health education program based on Transtheoretical model on physical activity level of Ilam's women

Protocol summary

Study aim

The effect of intervention based on transtheoretical model on physical activity level in women in Ilam

Design

Clinical trial with intervention and control group with volume of each group of 45 people

Settings and conduct

After analyzing the data obtained from the pre-test, an appropriate, applicable and informative educational intervention will be designed with an emphasis on the specified areas, and will be implemented with an effective solution. The study location will be health centers.

Participants/Inclusion and exclusion criteria

Inclusion criteria include consent to participate in the study, referring to the Comprehensive Health Services Center (people with active records), age 30-59 years, being in the pre-contemplation or thinking stage in terms of physical activity, and exclusion criteria including movement, unwillingness to continue the study, pregnancy, developing motor-restriction diseases such as rheumatoid arthritis, advanced heart disease with movement restriction, severe diabetic foot ulcer, and medications. This has caused imbalances and dizziness, such as some drugs prescribed in psychiatric disorders and neurological diseases, the absence of 20% and more is proportional to the number of classes held and the questionnaire is filled out.

Intervention groups

For the intervention group, group walking program, use of gym, educational package including pamphlet and poster and use of pedding software are considered. The control group does not receive any training during this period. After the intervention, educational pamphlet will be provided to the control group in order to observe ethical principles.

Main outcome variables

The effect on the level of physical activity in the intervention group, the effect on the level of knowledge

of the intervention group about the importance and benefits of physical activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200910048679N1**

Registration date: **2020-09-28, 1399/07/07**

Registration timing: **retrospective**

Last update: **2020-09-28, 1399/07/07**

Update count: **0**

Registration date

2020-09-28, 1399/07/07

Registrant information

Name

Fatemeh Shirzai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3331 4424

Email address

shirzadi-f@medilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-09-04, 1399/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of health education program based on
Transtheoretical model on physical activity level of Ilam's
women

Public title

Effect of health education program based on
Transtheoretical model on physical activity level of Ilam's
women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Referral to Comprehensive Health Services Center
(people with active records) Age 30-59 years Being in the
pre-contemplation or thinking stage in terms of physical
activity

Exclusion criteria:

Relocate Unwillingness to continue studying Pregnancy
Developing diseases that cause movement limitations,
such as rheumatoid arthritis, advanced heart disease
with movement limitations, severe diabetic foot ulcers
Taking medications that cause imbalance and dizziness,
such as some drugs prescribed in psychiatric disorders
and neurological diseases Absence of 20% and more
proportional to the number of classes held Fill out the
questionnaire

AgeFrom **30 years** old to **59 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

For this purpose, ilam city is divided into two sections
based on geographical location, and then one area is
randomly determined as an intervention zone and one
area as a control zone, in the next step, the sample
framework (list of all comprehensive health centers) is
prepared and randomly two centers are selected as
intervention and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

- Ethics committee of ilam University of Medical
Sciences

Street address

Shahid shirzadi alley, jomhuri prince boulevard

City

Ilam

Province

Ilam

Postal code

69317-63116

Approval date

2019-08-25, 1398/06/03

Ethics committee reference number

IR.MEDILAM.REC.1398.090

Health conditions studied**1****Description of health condition studied**

physical activity

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

physical activity

Timepoint

90day

Method of measurement

International Physical Activity Questionnaire Short
Form, Researcher-made questionnaire

2**Description**

The transtheoretical model and stages of change

Timepoint

90Day

Method of measurement

Researcher-made questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention group was women
aged 30-59 years who referred to health center. After

random selection and obtaining written consent from them, questionnaires will be completed. The educational intervention will be based on the results of the pre-test for cognitive domain including group training using lecture by the researcher in 5 sessions, as well as for behavioral domain, group walking and the use of gym for participants, as well as an educational package containing pamphlets and posters related to physical activity, which will be prepared by the researcher.

Category

Behavior

2

Description

Control group: The control group includes women aged 30-50 years who referred to the health center who have the characteristics of the intervention group. After random selection, pre-test questionnaires will be completed. There is no training for this group. After the end of the research, educational pamphlets are provided to them in order to observe the ethical principles.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز سلامت شهری شماره 6 ایلام

Full name of responsible person

Shirzadi-fatemeh

Street address

Shirzadi Alley Jomh prince boulevard

City

Ilam

Province

Ilam

Postal code

69317-63116

Phone

+98 84 3331 4424

Email

fatemehshirzadi2017@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr. Mohammad Sadegh Abedzadeh

Street address

Pajoos research boulevard, Bangonjab

City

Ilam

Province

Ilam

Postal code

6931763116

Phone

+98 84 3331 4424

Email

fatemehshirzadi2017@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Shirzadi Fatemeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

Shahid Shirzadi Alley, Jomhuri Blvd

City

Ilam

Province

Ilam

Postal code

6931763116

Phone

+98 84 3331 4424

Email

fatemehshirzadi2017@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Shirzadi Fatemeh

Position

Midwife

Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Shahid Shirzdi Alley, Jomhouri Blvd.
City
Ilam
Province
Ilam
Postal code
6931763116
Phone
+98 84 3331 4424
Email
fatemehshirzadi2017@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Shirzadi Fatemeh
Position
Midwife
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Shahid Shirzdi Alley, Jomhouri Blvd
City
Ilam
Province
Ilam
Postal code

6931763116

Phone

+98 84 3331 4424

Email

fatemehshirzadi2017@gmail.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

Individual data and study outcomes

When the data will become available and for how long

6 Months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For research on other age groups

From where data/document is obtainable

fatemehshirzadi2017@gmail.com

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

One month after receiving the email

Comments