Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 pamphel and poster and use of pedding software are considered. The control group does not receive any training during this period. After the intervention, educational pamphulette 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

Age
From **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, jomhouri 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 pamphels 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 pamphulettes 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

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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

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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

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Shahid Shirzdi Alley, Jomhouri Blvd

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Phone

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Email

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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
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Person responsible for updating data

Contact
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Full name of responsible person
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Position
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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