

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

the Effect of Self Determination Theory (SDT) based physical activity motivational intervention on happiness and quality of life: A randomized controlled trial

Protocol summary

Summary

Objective: To evaluate the Effect of Self Determination Theory (SDT) based physical activity motivational intervention on happiness and quality of life: A randomized controlled trial. Design: A randomized controlled trial. Setting: 86 women aged 30-45 years, covered by damghan urban health centers. Inclusion criteria: female; Age between 30 to 45 years old; Body Mass Index (BMI)<35; Infertility; Not involving in a routine physical activity programs; Not having any wound and health problem (or being on medicine) which leads to any movement prohibition recommendation; They do not tend to move to another city. Exclusion criteria: Catching a severe illness (psychological or physical) with any medical diagnosis and drug treatment; Unwillingness of the individual to continue the cooperation; Not being able to continue due to the personal reasons. Intervention: At the first meeting, the participants will receive the learning materials and devices (forms and pedometer) with a manual about how to use and keep the pedometer also a training manual according to the educational topics of ministry of health and medical education, and they will be trained to work with pedometer. These people will participate in 8 hours of the designed sessions based on SDT protocol and motivational interviews about physical activity. Control: At the first meeting, the learning materials and devices (forms and pedometer) with a manual about how to use and keep the pedometer also a training manual will be given to participants and they will be trained to work with pedometer. The individuals will participate in 8 hours learning sessions, based on the ministry of health and medical education topics about physical activity including a summary of physical conditions i.e. BMI, and they will receive a list of the learning programs - in process - in the health centers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020223072N1**
Registration date: **2017-01-13, 1395/10/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-13, 1395/10/24

Registrant information

Name

Mohammadreza Ghaneapur

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research and Technology, Tehran University of Medical Sciences

Expected recruitment start date

2016-07-10, 1395/04/20

Expected recruitment end date

2017-01-09, 1395/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the Effect of Self Determination Theory (SDT) based physical activity motivational intervention on happiness and quality of life: A randomized controlled trial

Public title

the Effect of Self Determination Theory (SDT) based physical activity motivational intervention on happiness and quality of life: A randomized controlled trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: female; Age between 30 to 45 years old; Body Mass Index (BMI)<35; Infertility; Not involving in a routine physical activity programs; Not having any wound and health problem (or being on medicine) which leads to any movement prohibition recommendation; They don't tend to move to another city. Exclusion criteria: Catching a severe illness (psychological or physical) with any medical diagnosis and drug treatment ; not being able to continue due to the personal reasons.

Age

From **30 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

By using Firmware of Block Stratified Randomization Ver.6, allocation of samples Will be done in a manner of Randomized Block Desig n.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Vice-chancellor of Research the Technology, Tehran University of Medical Sciences, Pursina Avenue, Tehran, Iran, Islamic Republic Of

City

Tehran

Postal code

1417653761

Approval date

2015-10-27, 1394/08/05

Ethics committee reference number

IR.TUMS.REC.1394.1020

Health conditions studied

1

Description of health condition studied

Physical Activity

ICD-10 code

Z72.3

ICD-10 code description

Lack of physical exercise

Primary outcomes

1

Description

Physical Activity

Timepoint

Before the intervention, one month after the start of intervention and three months later

Method of measurement

Pedometer

Secondary outcomes

1

Description

Happiness

Timepoint

Before the intervention, one month after the start of intervention and three months later

Method of measurement

Oxford Happiness Inventory

2

Description

Quality of Life

Timepoint

Before the intervention, one month after the start of intervention and three months later

Method of measurement

SF-36 Questionaire

Intervention groups

1

Description

Intervention group: At the first meeting, the participants will receive the learning materials and devices (forms and pedometer) with a manual about how to use and keep the pedometer also a training manual according to the educational topics of ministry of health and medical education and they will be trained to work with pedometer. These people will participate in 8 hours of the designed sessions based on Self Determination Theory and motivational interviews about physical activity.

Category

Lifestyle

2

Description

Control group: At the first meeting, the learning materials and devices (forms and pedometer) with a manual about how to use and keep the pedometer also a training manual will be given to participants and they will be trained to work with pedometer. The individuals will participate in 8 hours in learning sessions, based on the ministry of health and medical education topics, about physical activity including a summary of physical conditions i.e. BMI and they will receive a list of the learning programs - in process - in the health centers.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Damghan Health Center

Full name of responsible person

Mohammad Reza Ghaneapur

Street address

Damghan Health Center, Fallahi Avenue, Damghan city, Semnan province, Islamic Republic of Iran

City

Damghan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of Research and Technology, Tehran University of Medical Sciences

Full name of responsible person

Dr. Masud Yunesian

Street address

Vice-chancellor of Research and Technology, Tehran University of Medical Sciences, Pursina street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor of Research and Technology, Tehran 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

Tehran University of Medical Sciences, Department of Health Education and Promotion

Full name of responsible person

Dr. Hassan Eftkhar

Position

Pediatrician, MD, MPH/ Professor

Other areas of specialty/work

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City

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