

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of teaching the principles of lifestyle based on the teachings of traditional Iranian medicine on the biological, psychological, and behavioral consequences of the age group of 30 years and older living in rural areas of Ardakan city

Protocol summary

Study aim

Determining the effect of teaching the principles of lifestyle based on the teachings of traditional Iranian medicine on the biological, psychological, and behavioral consequences of the age group of 30 years and older living in rural areas of Ardakan city

Design

One-group clinical trial, before and after the intervention, assigning the number of samples according to the principles of stratified sampling based on the village population, then selecting samples based on systematic sampling

Settings and conduct

After sampling the total population of 30 to 60 years old living in rural areas of Ardakan city at the village health house, in three stages (Before the start, three months later and a year later) information based on blood sampling and completing a questionnaire is collected

Participants/Inclusion and exclusion criteria

1- Permanent resident of Ardakan region 2- Age 30-60 years

Intervention groups

A group that receives lifestyle lessons

Main outcome variables

BMI : LDL Cholesterol: HDL Cholesterol: Tri glyceride :
Fasting blood sugar: HbA1C : Anxiety : Depression: blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211106052973N1**

Registration date: **2022-03-16, 1400/12/25**

Registration timing: **retrospective**

Last update: **2022-03-16, 1400/12/25**

Update count: **0**

Registration date

2022-03-16, 1400/12/25

Registrant information

Name

Seyed Mohammad Javad Nezam al hosseyni ezabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3826 2633

Email address

statisticalgroup@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-07, 1400/09/16

Expected recruitment end date

2022-01-06, 1400/10/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of teaching the principles of lifestyle based on the teachings of traditional Iranian medicine on the biological, psychological, and behavioral consequences of the age group of 30 years and older living in rural areas of Ardakan city

Public title

The effect of teaching lifestyle principles on biological, psychological and behavioral consequences

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Resident of Ardakan region Age 30 to 60 years

Exclusion criteria:

Age under 30 years and over 60 years

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **290**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

No. 11, Dead End 18, Hazrat Abolfazl Alley, Daneshjoo Boulevard

City

Yazd

Province

Yazd

Postal code

8916816651

Approval date

2021-08-31, 1400/06/09

Ethics committee reference number

IR.SSU.REC.1400.125

Health conditions studied

1

Description of health condition studied

Behavioral consequences

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Biological consequences

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Psychological consequences

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

Before training, three months later, one year later

Method of measurement

Intravenous blood test

2

Description

Hb A1c

Timepoint

Before training, three months later, one year later

Method of measurement

Intravenous blood test

3

Description

Cholestrol

Timepoint

Before training, three months later, one year later

Method of measurement

Intravenous blood test

4

Description

triglyceride

Timepoint

Before training, three months later, one year later

Method of measurement

Intravenous blood test

5

Description

Body Mass Index

Timepoint

Before training, three months later, one year later

Method of measurement

Weight with hand scales and height with meters

6**Description**

Hypertention

Timepoint

Before training, three months later, one year later

Method of measurement

Mercury Barometer

7**Description**

Stress and depression

Timepoint

Before training, three months later, one year later

Method of measurement

LSQ questionnaire

Secondary outcomes

empty

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

Intervention group:1- Public call by health workers 2- Referral of villagers to the health house and formation of lifestyle identity card 3- Analysis of individual problems 4- Lifestyle education based on the teachings of Iranian medicine in accordance with the educational content prepared and approved by the Iranian medicine office of the Ministry of Health Two two-hour sessions on the six principles of lifestyle, including eating and drinking in accordance with the mood and eating slowly and avoiding liquids with food, sleep and wakefulness, including the best hours of sleep between 22 and 2 midnight, mood control, status Climate appropriate to the individual's temperament, elimination of waste products from the body and elimination of constipation, exercise and rest appropriate to the individual's temperament by health workers 5- If the lifestyle does not improve and change, refer to a traditional Iranian medicine specialist Educational Content: Lifestyle Factors in Iranian Medicine In this article, the six lifestyle factors that all human beings are exposed to are described as "Six essential principles for a healthy life." The six essential principles are important because everyone deals with them on a daily basis and without them life is impossible. Proper management of these cases has long been the focus of Iranian traditional medicine scientists. These six vital principles are: Air and environment 2. Movement and stillness (exercise and rest) 3. Sleep and wake 4. Eating and drinking 5. Disposal of non-essential materials and preservation of essential materials 6. Note the mental states: The items recommended in this section are taught to maintain health in healthy people

and prevent them from getting sick and are applicable.1.

Air and the environment: One of the most important components of the environment is the air around us. Adapting the body to the ambient air and following the relevant recommendations helps to maintain good health. In other words, it is neither too hot nor too cold, nor too cold or too hot. Moderate weather is suitable for healthy people with a temperament close to moderation. In this air, the body's natural functions are performed completely and correctly, and waste is expelled from the body in a sufficient and timely manner. Warm hot air absorbs blood to the surface of the skin and reddens the skin: but constant contact with Hot weather causes the skin to gradually turn yellow, the person gradually loses weight, and may experience problems such as headaches, drowsiness, and poor digestion. Cold cold air is more beneficial for moderately healthy people than hot air because it tightens the body and clogs its pores, and heat builds up inside the body and digestion improves, appetite increases, and the senses become stronger. B) Pollution Air: Air pollution is the most important issue in air hygiene today. We have all experienced the feeling of being lively and energetic on the beach and in forested and mountainous areas, and conversely, when we live or work in big cities, we are often tired, nervous and depressed. This is the effect of cleanliness and air pollution on us. Polluted air affects organs, including the heart, brain, and liver, and makes them sick. Polluted air causes excessive accumulation of waste and toxic substances in the body and the inability and weakness of the body to excrete them. A set of strategies to combat the effects of air pollution on the body is shown in Table 1-2. Table 1-2: Tips from the experiences of past scientists and modern science research to reduce the effects of air pollution on the body Spend weekends in parks and green spaces Avoid unnecessary travel outside during the hours and days when air pollution is high. Such as garages, terminals, and garbage dumps If you are planning a construction plan for your home, build the house so that the roof is high and if possible the rooms and living room are facing east and the window Have large ones, some facing east and some facing north. Plant trees and flowers around your house. (Pine and oleander trees are not recommended) Avoid smoking in the home environment as well as the use of chemical air fresheners and insecticides Empty the inside or apple and fill it with rose water and put it on indirect heat such as a heater To make the house smell fragrant and eliminate pollution When a family member is infected with a viral disease, pour a cup of vinegar with 18-20 cups of water into a pot and put it on a very low heat to boil continuously. Cut a number of onions, garlic or oranges, each of which was available, in half and place them in the corners of the room and the place of sitting and standing, especially the sleeping place of the family, and every 24 hours. Remove and replace with fresh onions, garlic or oranges. Dietary measures in case of air pollution Preferably use softer meats such as mutton, chicken, partridge, quail and goat. It is better to cook and consume these meats with a little sour ingredients such as sumac, gourd, lemon juice, vinegar or sour pomegranate juice. Avoid

fresh Avoid heavy and slow-digesting foods as much as possible, such as olives, pasta, noodle soup, factory-made foods, fast foods, and ready-made and fried foods. (Eating pasta once with the addition of spices such as mint and thyme is not prohibited.) Avoid constipation. Exercise and activity measures during air pollution o Avoid strenuous physical activity. Swinging and sitting in a moving chair is recommended. Other cases Avoid sleeping for less than 6 hours or more than 10 hours Avoid excessive sexual activity. (Recommended for young and hot-tempered people 2-3 times a week.) In case of psychological stress, use ways to stay calm, such as reciting the Quran and prayers or religious rituals, using pleasant scents and communicating with friends and relatives. get. Avoid exposure to harmful waves, especially computers and mobile phones, as much as possible. If for some reason you are forced to use these devices: Avoid doing unnecessary tasks such as games, etc. Avoid excessive use of mobile phones and spending time in the virtual world • Spend hours exploring nature during the week. In clean, semi-reclining air, take a deep breath and fill your lungs with fresh air. Hold your breath for 5 seconds, then slowly exhale for about ten seconds. Repeat the above command 10 times. • Help others as much as you can. The feeling of satisfaction you get from this work will reduce many of your mental stresses • Know your abilities and do not compare yourself with anyone • Do not focus on negative thoughts and instead look for solutions to deal with Do the things you love, no matter how limited your possibilities. • Make a list of the gifts that God has given you and thank God every day for having them. Leads to sadness and depression.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Tork Abad
Full name of responsible person
Seyed Javad Nezam Al Hosseyni
Street address
at the beginning of the road in front of Ardakan
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2

Recruitment center

Name of recruitment center

Mazree No Health House
Full name of responsible person
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Mazree No
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3

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Shahid Sadoughi Boulevard, University Headquarters
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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

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Seyed Mohammad Javad Nezam Al Hosseyni

Position

Employee

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Monire Seyed Hashemi

Position

specialist

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Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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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/documentAll data is potentially shareable after unidentified
individuals**When the data will become available and for how long**Access period starts 6 months after the results are
published**To whom data/document is available**

The data will be available to the public

Under which criteria data/document could be used

The data will be available to the public

From where data/document is obtainable

Seyed Mohammad Javad Nezam Al Hosseyni

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

Documents will be sent in less than a month after sending the request

Comments