

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Survey the effect of group base walking program on social physical anxiety and eating disorders risk in elderly woman

Protocol summary

Study aim

Determining the effect of group walking program on social anxiety and risk of eating disorders in elderly women

Design

Clinical trials with control group, cluster random sampling for health care centers and regular samples for selecting 50 samples in this study and divided into two groups. .

Settings and conduct

This is a clinical trial in which two groups of test and control participate. The statistical population includes all young elderly (60 to 74 years old) who will be selected from health centers in Sari and the impact of walking on the social anxiety of the organs and the risk of eating disorders are reviewed.

Participants/Inclusion and exclusion criteria

Entry criteria : 1- Age 74-60 years 2- Interesting and satisfying to participate in the research (obtaining informed consent). 3. Having reading and writing skills 4. Earn score 8 and above the short-term test 5- Earning an independent score from the daily activities of life questionnaire 6. Not having known chronic diseases according to health records 7. Not having a history of acute accidents and events leading to a mental and physical problem within the past month 8. Earn score 20 and above the risk of eating disorder 9) Earn score 15 and above of Social physique Anxiety Scale 10. No history of regular exercise over the past six months 11. No drug use

Intervention groups

Group intervention in group walking sessions, for 8 weeks, weekly 3 sessions, each session is 30 minutes, but there is no intervention in the control group.

Main outcome variables

walking

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180505039538N1**

Registration date: **2018-12-05, 1397/09/14**

Registration timing: **retrospective**

Last update: **2018-12-05, 1397/09/14**

Update count: **0**

Registration date

2018-12-05, 1397/09/14

Registrant information

Name

Sharare Khalili

Name of organization / entity

The university of babol

Country

Iran (Islamic Republic of)

Phone

+98 11 3327 2156

Email address

sh.khalili@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-17, 1395/08/27

Expected recruitment end date

2017-11-18, 1396/08/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of group base walking program on social physical anxiety and eating disorders risk in elderly woman

Public title

Effect of group walking program on social physical anxiety and eating disorders

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 to 74 years
Interests and satisfaction to participate in the research
Have reading and writing skills
Earn score 8 and above the short cognitive test
Earn a score independent of the daily life activity questionnaire
Earn a score independent of the daily life activity questionnaire...
Earn score 15 and above the Social Anxiety Scale

Exclusion criteria:

Cases of known chronic diseases according to health records
Having a history of acute accidents and events has led to a physical and mental problem during the past month
A record of regular sports letters over the past six months
Use special medication

Age

From **60 years** old to **74 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling will be multistage cluster method, so that each one of the 12 health-care centers located in Sari will be considered as a cluster. Then will be taken from clusters, six clusters are randomly selected. The cluster, according to the sample size, is elderly women, based on the list of names. They will be randomly divided into two groups of test and control choosing a number from 1 to 60 randomly, in a such way that odds number in the test group and even number are in the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

7

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ramsar University of Nursing and Midwifery

Street address

University of Nursing and Midwifery-Ramsar

City

Ramsar

Province

Mazandaran

Postal code

4691714141

Approval date

2017-11-18, 1396/08/27

Ethics committee reference number

MUBABOL.HRI.REC.1396.123

Health conditions studied

1

Description of health condition studied

Social physique anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Group walking

Timepoint

Measurement was performed before and immediately after the intervention.

Method of measurement

Daily Life Activity Questionnaire

2

Description

Eating disorder

Timepoint

Measurement was performed before and immediately after the intervention.

Method of measurement

Risk screening test for eating disorder

3

Description

Social physique anxiety

Timepoint

Measurement was performed before and immediately after the intervention.

Method of measurement

Social physique Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group samples will be invited with written invitations, phone calls and SMS to remind attending the walking sessions. The type of intervention is a group walk that will be conducted by the researcher in the Sari Melal Park for eight weeks, three days a week, at a specific time of the day. The duration of each hike session will be 30 minutes. In the final session after the intervention, as a post-test, both social anxiety and eating disorder questionnaires are repeated with face-to-face interviews.

Category

Prevention

2

Description

Control group: The control group, such as the intervention group will fill the questionnaires but will not do any physical activity.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers in Sari

Full name of responsible person

Sharareh Khalili-Hengameh Karimi

Street address

Taleghani-EmamReza blv

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4818955830

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Email

sh.khalili@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Sharareh Khalili

Street address

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City

Sari

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Sharareh khalili-Hengameh karimi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Babol University of Medical Sciences
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Person responsible for updating data

Contact

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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

A portion of the recorded data will be available from statistical samples that help to understand the research topic and its effects

When the data will become available and for how long

Since 2018

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The use of documentation in order to develop research is permitted

From where data/document is obtainable

Ramsar University of Nursing and Midwifery

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

By written request from the university

Comments