Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of the computer- based training package on quality of life and symptom severity in andropausal men

Protocol summary

Summary

Title: The effect of the computer- based training package on quality of life and symptom severity in andropausal men Primary objectives of the study: To determine the effect of the computer- based training package on quality of life (QoL) and symptom severity in andropausal men Secondary objectives of the study: 1. To determine the prevalence of andropause symptoms in 40-60 year-old employees; 2. To compare the severity of andropause symptoms in male employees aged 40-60 before and after the intervention; 3. To compare QoL in male employees aged 40-60 before and after the intervention. A quasi-experimental study will be conducted to determine the impact of the computer-based training package on QoL and severity of symptoms in andropausal men prior to and 8 weeks after the training in both intervention and control groups. The study population will consist of all 40-60 year-old male employees at Tehran University of Medical Sciences' Faculties. Inclusion criteria: Proficiency in Persian, being emotionally and physically able to answer questions, being married, having at least high school education, having access to computers, being able to work with the computer to the extent that the training package be used, lack of chronic diseases & mental disorders, lack of disability. Exclusion criteria: Unwillingness to participate in the study, incomplete responses to the questionnaire, being affected with a chronic disease and mental disorder during the study. The required sample size for each group was estimated at n=40. To randomly select the faculties of Tehran University of Medical Sciences the names of all the faculties will be written on separate sheets. Then, an intercollegiate draw will take place. After obtaining written consents from all the participants, they will be handed the following: the AMS (Aging Male Symptoms) questionnaire that screens andropause symptoms and assesses their severity; and the SF36 (Short Form 36) questionnaire that determines QoL. After having completed the questionnaire, those with andropause symptoms and those who possess the inclusion criteria will be included in the final study. Computer-based training will be held for the men in the intervention group in the form of 4 sessions over a period of 4 weeks. Two months after the intervention, QoL and symptom severity will be measured in the intervention group. Moreover, both the intervention and control groups will be asked to complete the questionnaires again, two months after the initial test. Finally, the results of the two groups before and after the intervention will be compared with each other. In the end, the control group's participants will too be provided with the training package.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407166777N3**
Registration date: **2014-11-03, 1393/08/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-03, 1393/08/12

Registrant information

Name

Minoo Pakgohar

Name of organization / entity

School of Nursing & Midwifery, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4216

Email address

mpakgohar@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source
Tehran University of Medical Sciences, Vice chancellor for research,

Expected recruitment start date
2014-08-23, 1393/06/01

Expected recruitment end date
2014-10-23, 1393/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of the computer- based training package on quality of life and symptom severity in andropausal men

Public title
The effect of the computer- based training package on quality of life and symptom severity in andropausal men

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Proficiency in Persian, being emotionally and physically able to answer questions, being married, having at least high school education, having access to computers, being able to work with the computer to the extent that the training package be used, lack of chronic diseases & mental disorders, lack of disability. Exclusion criteria: Unwillingness to participate in the study, incomplete responses to the questionnaire, being affected with a chronic disease and mental disorder during the study.

Age
From **53 years** old to **33 years** old

Gender
Male

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
To randomly select the faculties of Tehran University of Medical Sciences the names of all the faculties will be written on separate sheets. Then, an intercollegiate draw will take place.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Bolvarkshavrz, Quds Street

City
Tehran

Postal code

Approval date
2014-07-08, 1393/04/17

Ethics committee reference number
93/130/856/د

Health conditions studied

1

Description of health condition studied
andropause

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality Of Life

Timepoint
Before the experiment, two months after the intervention

Method of measurement
Questionnaire Sf36

2

Description
Symptoms Severity

Timepoint
Before the experiment, two months after the intervention

Method of measurement
AMS Questionnaire

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: Computer-based training will be held for the men in the intervention group in the form of 4 sessions over a period of 4 weeks. Two months after the intervention, QoL and symptom severity will be measured in the intervention group. Moreover, both the intervention and control groups will be asked to complete the questionnaires again, two months after the initial test. Finally, the results of the two groups before and after the intervention will be compared with each other.

Category

Lifestyle

2

Description

Control group: Computer-based training won't be held for the men in the control group. In the control group will be asked to complete the questionnaires again, two months after the initial test. Finally, the results of the two groups before and after the intervention will be compared with each other. In the end, the control group’s participants will too be provided with the training package.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Health, Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Akbari Sari

Street address

Poorsina Street,Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Faculty of Pharmacy, Tehran University of Medical Sciences

Full name of responsible person

Dr Mohamad Sharif Zade

Street address

The old building of the Faculty of Pharmacy, Tehran

City

Tehran

3

Recruitment center

Name of recruitment center

School of Medicine, Tehran University of Medical Sciences

Full name of responsible person

Dr Amirhosein Emami

Street address

Poorsina Street, Ghods Street,Tehran

City

Tehran

4

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Dr Mohamad Bayat

Street address

Kargar Shomali Street, Tehran

City

Tehran

5

Recruitment center

Name of recruitment center

Rehabilitation Faculty, Tehran University of Medical Sciences

Full name of responsible person

Dr Mohamad Akbari

Street address

Enghelab Street, Tehran

City

Tehran

6

Recruitment center

Name of recruitment center

School of Allied Medical Sciences, Tehran University of Medical Sciences

Full name of responsible person

Dr Reza Safdari

Street address

Ghods Street, Enghelab Street,Tehran

City

Tehran

7

Recruitment center

Name of recruitment center

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Dr Mohamad Ali Cheraghi

Street address

Nosrat Street, Tohid Square, Tehran

City

Tehran

8

Recruitment center

Name of recruitment center
Department of Traditional Medicine, Tehran University of Medical Sciences

Full name of responsible person
Dr Mohamadreza Shams Ardakani

Street address
Poorsina Street,Tehran

City
Tehran

9

Recruitment center

Name of recruitment center
Tehran medical technologies, Tehran University of Medical Sciences

Full name of responsible person
Dr Alireza Ahmadian

Street address
Italia Street,Ghods Street, Keshavarz Bolvar, Tehran

City
Tehran

10

Recruitment center

Name of recruitment center
Faculty of Nutrition and Diet, Tehran University of Medical Sciences

Full name of responsible person
Dr Fereydoon Siasi

Street address
Naderi Street

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person
Dr masoud younesian

Street address
Bolvar keshavarz, Ghods 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 for research of 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 univesity of medical science

Full name of responsible person
Elahe afsharnia

Position
Student of Master of Science in Midwifery

Other areas of specialty/work

Street address
Valiasr Square, Damascus street, Tehran

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Minoo pak gohar

Position
Phd of Geronatology

Other areas of specialty/work

Street address
Tohid square, Nosrat street

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Tehran

Postal code

Phone
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Fax

Email
Mpakgohar@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Elahe afsharnia
Position
Student of Master of Science in Midwifery
Other areas of specialty/work
Street address
Damascud street, Tehran
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00
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Elahe.afsharnia@yahoo.com
Web page address

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