

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

93/130/856/5

## Health conditions studied

### 1

**Description of health condition studied**

andropause

**ICD-10 code**

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**ICD-10 code description**

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## 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**

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**Timepoint**

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**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**

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**Grant code / Reference number**

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**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

**City**

Tehran

**Postal code****Phone**

+98 910 576 2775

**Fax****Email**

Elahe.afsharnia@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Minoos pak gohar

**Position**

Phd of Gerontology

**Other areas of specialty/work****Street address**

Tohid square, Nosrat street

**City**

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**Postal code****Phone**

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**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

**City**

Tehran

**Postal code****Phone**

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**Fax****Email**

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*