

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Oct 2023

Effect of Pilates and Aerobic Exercise on Quality of Sleep and Fatigue of Girl Students of Dormitory

Protocol summary

Summary

Objectives: The aim of this study is to investigate the effect of Pilates and aerobic exercise on sleep quality and fatigue of female students in residence Method: This study is a semi -experimental and interventional study. Sample includes 120 female students aged 18 to 26 years selected from three residences (Pilates, aerobic exercise and control group). Inclusion criteria include single, Iranian and healthy girls whose their general health were validated before coming to study, aged 18 to 26 years, no history of any regularly physical activities for last 6 months, Body mass index 19/8 to 26, lack of misuse the drug, lack of stressful experiences during the last 3 months. Exclusion criteria include lack of training for three continuous or five non-continuous sessions, lack of tendency to continue cooperation, use of effective foods for sleeping and fatigue such as coffee, espresso and energetic drinks, the occurrence of stressful experiences during the study. Interventions: Pilates exercise will be done for 8 weeks. Sample will exercise in the presence of an instructor and researcher 60 minutes per time, 3 times per week for 8 weeks and aerobic exercise will be done for 8 weeks too. Sample will exercise in the presence of an instructor and researcher 60 minutes per time, 3 times per week for 8 weeks. The control group continued their daily activities. The main outcome variables: Petersburg Quality of Sleep and Fatigue questionnaires will be completed 4 and 8 weeks after beginning intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412282324N15**

Registration date: **2015-06-02, 1394/03/12**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-06-02, 1394/03/12

Registrant information

Name

Maryam Keshavarz

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Iran University of Medical Sciences

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2015-12-06, 1394/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Pilates and Aerobic Exercise on Quality of Sleep and Fatigue of Girl Students of Dormitory

Public title

Pilates and Aerobic Exercise and Quality of Sleep and Fatigue

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria include single, Iranian and healthy girls whose their general health are validated before coming to study, aged 18 to 26 years, no history of any regularly physical activities for last 6 months, Body mass index 19/8 to 26, lack of misuse the drug, lack of stressful experiences during the last 3 months. Exclusion criteria include Lack of training for three continuous or five non-continuous sessions, lack of tendency to continue cooperation, use of effective foods for sleeping and fatigue such as coffee, espresso and energetic drinks, use of effective non-medical methods for fatigue and quality of sleep such as acupressure, use of effective psychiatric drugs for fatigue and quality of sleep during the study such as Floxetine and Citalopram, the occurrence of stressful experiences during the study, marriage during the study.

Age

From **18 years** old to **26 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Commitment of Iran University of Medical Sciences

Street address

Hemat Highway

City

Tehran

Postal code

Approval date

2015-04-06, 1394/01/17

Ethics committee reference number

110427

Health conditions studied

1

Description of health condition studied

Quality of Sleep

ICD-10 code

F51.9

ICD-10 code description

Nonorganic sleep disorder, unspecified

2

Description of health condition studied

Fatigue

ICD-10 code

F48.0

ICD-10 code description

Fatigue Psychogenic (general)

Primary outcomes

1

Description

Quality of Sleep

Timepoint

Before the Intervention, 4 and 8 weeks after Intervention

Method of measurement

Pittsburg Quality of Sleep Inventory

Secondary outcomes

1

Description

Fatigue

Timepoint

Before the Intervention, 4 and, 8 weeks after Intervention

Method of measurement

MFI Fatigue Inventory

Intervention groups

1

Description

The control group continued their daily activities.

Category

Prevention

2

Description

The intervention group 1: Pilates exercise will be done for 8 weeks. After completing initial Quality of Sleep Questionnaires, Fatigue Questionnaires, demographic questionnaires and having inclusion criteria, samples will be trained by instructor and researcher for 8 weeks, 3 times per week, 60 minutes per time. Quality of Sleep questionnaires and fatigue questionnaires will be completed 4 and 8 weeks after starting the intervention.

Category

Prevention

3**Description**

The intervention group 2: Aerobic Exercise will be done for 8 weeks. After completing initial Quality of Sleep Questionnaires, Fatigue Questionnaires, demographic questionnaires and having inclusion criteria, samples will be trained by instructor and researcher for 8 weeks, 3 times per week, 60 minutes per time. Quality of Sleep questionnaires and fatigue questionnaires will be completed 4 and 8 weeks after starting the intervention.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shaghayegh Femal Dorm

Full name of responsible person

Keshavarz Maryam

Street address

Number of 27, Opposite of Torkamanestan St,
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2**Recruitment center****Name of recruitment center**

Amol Femal Dorm

Full name of responsible person

Keshavarz Maryam

Street address

Number of 138, Amol St, Opposite of Pasargad
Hospital, Shariati St.

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3**Recruitment center****Name of recruitment center**

Golestan Femal dorm

Full name of responsible person

Keshavarz Maryam

Street address

School of RehabilitationI, Shahnazari St, Madar Sq.

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Iran University of
Medical Sciences

Full name of responsible person

Dr.Seyed Ali Javad Moosavi

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Hemat Highway

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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, Iran 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**

School Nursing and Midwifery

Full name of responsible person

Ezzati Mosleh Maryam

Position

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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