

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effects of exercise intervention on tobacco withdrawal symptoms in smokers

Protocol summary

Summary

Objectives:To examine the effects of moderate aerobic exercise on beta-endorphin, adrenalin and TWS during temporary smoking abstinence among sedentary smokers, to measure the correlation effects of beta-endorphin and adrenalin on TWS following moderate aerobic exercise during temporary smoking abstinence among sedentary smokers and to compare the effectiveness of moderate aerobic exercise on beta endorphin, adrenaline and TWS during temporary smoking abstinence. **Design:**This study will be a quasi-experimental study with mixed design repeated measured analysis of variance (ANOVA) . **Setting and conduct:**The study setting and conduct will be done among staffs at Universiti Teknologi MARA Sg Buloh and Kolej Sains Kesihatan Bersekutu Sg. Buloh. Those institution is 1km for each other. **Inclusion and exclusion criteria:** The study consist of screening phase and intervention phase. The purpose of screening phase is to screen for inclusion and exclusion criteria. The major inclusion criteria is (sedentary smoker, smoked 10-20 cigarette per day, at the pre-contemplation stage, aged between 20-45 and healthy. while the major exclusion criteria is smoked less than 10 or more than 20 cigarette per day, have mood and mental disorder and high risk of cardiovascular disease. The participant who are interested to participated in this study will be screened for sedentary status used PAR-Q, Risk Screening, PAR-Q, mental health, drug used, blood pressure, Body mass index (BMI) and fasting blood glucose and cholesterol **Intervention :**Study will be divided into experimental group and control group. The experimental group will be intervene with 30 minutes moderate aerobic exercise for 3 times per week up to 2 months via running on treadmill, while the control group encourage to maintain their sedentary lifestyle and smoking habit for two month. Comparison will be made between these groups at before exercise intervention, after exercise intervention and after 2 weeks of post exercise

intervention. Main outcome measure: The primary outcome is to examine the effects of exercise training on TWS. The measures for this study are TWS, sleep quality, smoking urge, mood, theory of planned behavior, beta endorphin, adrenalin, blood pressure and temperature.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102121543N2**

Registration date: **2016-01-25, 1394/11/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

NUR-HASANAH RUSLAN

Name of organization / entity

UNIVERSITI TEKNOLOGI MARA

Country

Malaysia

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+603-61265000

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Recruitment status

Recruitment complete

Funding source

Malaysia Ministry of Higher Education

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2016-06-30, 1395/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of exercise intervention on tobacco withdrawal symptoms in smokers

Public title

The effects of exercise intervention on tobacco withdrawal symptoms (TWS) in smokers

Purpose

Treatment

Inclusion/Exclusion criteria

inclusions criteria Male smokers;who smoke at least 10 cigarettes per day at least for the past 2 years; who have sedentary lifestyle is determining by use of IPAQ (International Physical Activity Questionnaire) ;aged between 20-45 year old;categorized as low and moderate risks by ACSM recommendations identified by AHA/ACSM ; Preparticipation Screening Questionnaires;who are in the pre-contemplation stage ; who are systolic blood pressure around 90-140 mmHg and diastolic around 60-90mmHg; who are body mass index (BMI) less than 30 kg/m²; who are fasting blood cholesterol not more than 200 mg/dl; who are fasting blood glucose not more than 100mg/dL and who are willing to comply with the study's protocol Exclusion who smoke more than 20 cigarette; who are categorized as high risk by ACSM recommendation ;who have cardiovascular diseases ;who have psychiatry problems or on medication; who face psychotherapy or pharmacotherapy for smoking cessation ; who are depressed ; who are hallucinogens /drug/opioid dependent for the past 6 months; who are on a treatment of anxiety/mood disorder ; who have hypertension \geq 140 systolic blood pressure and \geq 90 diastolic blood pressure; who are fasting blood cholesterol level \geq 200mg/dl or medical treatment with lipid abnormalities; who are obese (\geq 30kg/m²); who have orthopaedic problem ;who take alcohol

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

quasi experimental

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Universiti Teknologi MARA

Street address

Universiti Teknologi MARA (UiTM) Shah Alam

City

Shah Alam

Postal code

40450

Approval date

2015-12-22, 1394/10/01

Ethics committee reference number

600-RMI(5/1/6)

Health conditions studied**1****Description of health condition studied**

smoker and sedentary

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

tobacco withdrawal symptoms

Timepoint

before training, after 2 month training and after 2 weeks of detraining in 12 hours of overnight abstinent

Method of measurement

using Wiscounsin Scale withdrawal symptom (WSWS)questionnaire

2**Description**

irritability

Timepoint

before training, after 2 month training and after 2 weeks of detraining in 12 hours of overnight abstinent

Method of measurement

blood pressure and temperature

3**Description**

quality of sleep

Timepoint

before training, after 2 month training and after 2 weeks of detraining in 12 hours of overnight abstinent

Method of measurement

Pittsburgh Sleep Quality index (PSQI)

4

Description

smoking urge

Timepoint

before training, after 2 month training and after 2 weeks of detraining in 12 hours of overnight abstinent

Method of measurement

question of smoking urge (brief QSU)

5

Description

mood

Timepoint

before training, after 2 month training and after 2 weeks of detraining in 12 hours of overnight abstinent

Method of measurement

profile mood state (POMS)

Secondary outcomes

1

Description

cortisol, adrenalin and beta endorphin

Timepoint

before training, after training and after 2 weeks of detraining

Method of measurement

blood

Intervention groups

1

Description

Intervention group is an exercise training , 3 times per week, for 2 month running on treadmill with moderate intensity (64-77% HR max) and need to maintain smoking habit

Category

Lifestyle

2

Description

control group no exercise but need to maintain their sedentary lifestyle and smoking habit

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Universiti Teknologi MARA, Sg Buloh

Full name of responsible person

Nur-Hasanah Ruslan

Street address

Universiti Teknologi MARA (UiTM) Sg Buloh

City

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2

Recruitment center

Name of recruitment center

Kolej Sains Kesihatan Bersekutu Sg Buloh

Full name of responsible person

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Jalan Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ministry Of Higher Education, Malaysia

Full name of responsible person

Siti Hanum A Rahman (RMC UiTM)

Street address

Level 1-3, Block E9, Complex E, Federal Government Administration Centre

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Putrajaya

Grant name

Grant code / Reference number

FRGS/1/2015/SKK01/UiTM/03/1)

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ministry Of Higher Education, Malaysia

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

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Full name of responsible person

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Position

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student Phd/ Bachelor in Biomedicine, MSc in Sport Science

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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