Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 fating 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
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Malaysia
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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 ≥140 systolic blood pressure and ≥90 diastolic blood pressure; who are fasting blood cholesterol level ≥200mg/dl or medical treatment with lipid abnormalities; who are obese (≥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

Sg. Buloh

2

Recruitment center

Name of recruitment center

Kolej Sains Kesihatan Bersekutu Sg Buloh

Full name of responsible person

Nur-Hasanah Ruslan

Street address

Jalan Hospital

City

SG BULOH

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 Goverment Administration Centre

City

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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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