

# 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

##### Phone

+603-61265000

##### Email address

hasanah@pahang.uitm.edu.my

##### 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/m<sup>2</sup>; 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/m<sup>2</sup>); 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)

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Level 1-3, Block E9, Complex E, Federal Government 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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**Full name of responsible person**

Siti Munira Yasin

**Position**

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student Phd/ Degree 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*