

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

STRESS, ANXIETY AND DEPRESSION AMONG PRECLINICAL MEDICAL STUDENTS OF UNIVERSITI PUTRA MALAYSIA AND THE EFFECT OF MINDFULNESS ON DASS-21 SCORES

Protocol summary

Summary

This study is aiming to identify the prevalence of psychological distress among preclinical medical student then it will explore the possible causes of stress by identifying the main stressor factors. Then it will be followed by an intervention program to help the students cope with these stressors in order to decrease, if not eliminate, the psychological distress that they feel. This will make this study a comprehensive approach towards the problem of psychological distress among medical students. The selection of the preclinical students is determined in order to identify the problem at early stages in order to help the students to cope with their future stress in clinical years as the studies showed that the stress levels as persistent throughout the years of medical education as well as in physicians under-training

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050627756N1**

Registration date: **2016-08-14, 1395/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-14, 1395/05/24

Registrant information

Name

Maher Fuad

Name of organization / entity

Universiti Putra Malaysia

Country

Malaysia

Phone

+60 3-8946 6000

Email address

gs33742@mutiara.upm.edu.my

Recruitment status

Recruitment complete

Funding source

The study is funded by initiative RUGS 3 of Universiti Putra Malaysia

Expected recruitment start date

2014-01-18, 1392/10/28

Expected recruitment end date

2014-06-18, 1393/03/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

STRESS, ANXIETY AND DEPRESSION AMONG PRECLINICAL MEDICAL STUDENTS OF UNIVERSITI PUTRA MALAYSIA AND THE EFFECT OF MINDFULNESS ON DASS-21 SCORES

Public title

STRESS, ANXIETY AND DEPRESSION AMONG PRECLINICAL MEDICAL STUDENTS OF UNIVERSITI PUTRA MALAYSIA AND THE EFFECT OF MINDFULNESS ON DASS-21 SCORES

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Students with mild, moderate and high distress scores; Preclinical undergraduate medical students; Willing to participate Exclusion Criteria: Students who do not give their consent to participate in the study; Clinical undergraduate students; Extremely severe distress scores will be referred to

psychiatrist evaluation.

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

A baseline cross sectional study is conducted to determine the students with high stress, anxiety and depression scores

Secondary Ids

empty

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

Research ethics Committee of the Universiti Putra Malaysia (JKEUPM)

Street address

Pejabat Timbalan Naib Canselor (penyediaan dan Inovasi) Universiti Putra Malaysia

City

Serdang

Postal code

43400

Approval date

2013-08-26, 1392/06/04

Ethics committee reference number

UPM/TNCPI/RMC/JKEUPM/1.4.18.1/F1

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

Stress, Anxiety and Depression

ICD-10 code

Z56.3

ICD-10 code description

Stressful work schedule

Primary outcomes**1****Description**

Stress and Anxiety

Timepoint

Baseline and after 8 weeks

Method of measurement

DASS-21 and GHQ-12

Secondary outcomes**1****Description**

Depression

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

PHQ-9, SSKM-20

Intervention groups**1****Description**

The intervention group will receive the One-Day Mindfulness program (ODM) which consist of two sessions (Morning and afternoon sessions) The morning session explains the ABC of stress, anxiety and depression (SAD). It explains the definition, and types. Then the basic mechanism and the benefit of mindfulness will be explained. Students will be trained in Mindful Stretching & Muscle Relaxation as well as a training to anchor attention by labeling their actions and to pay attention to hearing, touching and seeing (HTC Method) the surrounding environment to help them appreciate it. Students are trained also in deep and mindful breathing as well as mindful imagery. The afternoon session included teaching the student on how to apply mindfulness in their daily life in order to Transform their thoughts (especially the negative one) into happy one. The session will involve a movie, a song and the application of mindful STOP technique which enabled the students to access mindfulness anytime and anywhere.

Category

Treatment - Other

2**Description**

The control group is the wait-listed group and they will receive the intervention at the end of the study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Putra Malaysia, faculty of Medicine and Health Sciences

Full name of responsible person

Dr. Maher D. Fuad

Street address

Serdang

City

Serdang

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Putra Malaysia

Full name of responsible person

Associate Prof. Dr. Normala Ibrahim

Street address

Faculty of Medicine and Health Science, University of Putra Malaysia

City

Serdang

Grant name**Grant code / Reference number**

RUGS initiative 3

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

Yes

Title of funding source

University of Putra 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

Universiti Putra Malaysia

Full name of responsible person

Dr. Maher D. Fuad Fuad

Position

PhD candidate

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

PhD Candidate

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty