Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Maher Fuad
Name of organization / entity
Universiti Putra Malaysia
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Malaysia
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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 (penyedidikan 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

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Person responsible for scientific inquiries

Contact

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Position
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Other areas of specialty/work

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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