



Effects of a mindfulness program on the welfare of university students

22/11/2024 08:04:35

Main Information

Primary registry identifying number

LBCTR2023065390

Protocol number

FM446

MOH registration number

-

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Prospective

Type of registration: Justify

N/A

Date of registration in national regulatory agency

21/06/2023

Primary sponsor

Saint Joseph University of Beirut

Primary sponsor: Country of origin

Lebanon

Date of registration in primary registry

19/09/2023

Date of registration in national regulatory agency

21/06/2023

Public title

Effects of a mindfulness program on the welfare of university students

Acronym

-

Scientific title

The effects of a mindfulness program on the reduction of symptoms of anxiety and depression and on the perception of pain and stress in university students

Acronym

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Brief summary of the study: English

The study aims to evaluate the effects of mindfulness through mindfulness sessions administered by a professional to university students in the health field. Thus, it is a question of following the evolution of the symptoms of anxiety and depression of a group adhering to the training of mindfulness compared to a control group, by means of specific questionnaires. The impact of the mindfulness trait on different students will also be studied. In addition, the influence of this training on the perception of pain will be the subject of a test subjecting the various participants to a painful stimulus and recording their responses in two stages, before and after the mindfulness intervention. Finally, the study aims to compare the reaction of students to acute stress before and after the intervention, by inflicting an uncomfortable nerve stimulation in response to arithmetic mental tasks. Some physiological parameters of stress (heart rate, body temperature, skin conductance and salivary cortisol) will be assessed.

Brief summary of the study: Arabic

تهدف الدراسة إلى تقييم تأثيرات اليقظة الذهنية من خلال جلسات اليقظة التي يديرها متخصص لطلاب في المجال الصحي. وبالتالي، فإن الأمر يتعلق بمتابعة تطور أعراض القلق والاكتئاب لدى مجموعة ملتزمة بتدريب اليقظة مقارنة بمجموعة، عن طريق استبيانات محددة. سيتم أيضاً دراسة تأثير سمة اليقظة على الطلاب المختلفين. بالإضافة إلى ذلك، سيكون تأثير هذا التدريب على إدراك الألم موضوع اختبار يُخضع مختلف المشاركين لمحفز مؤلم ويسجل ردودهم على مرحلتين، قبل وبعد تدخل اليقظة. أخيراً، تهدف الدراسة إلى مقارنة تفاعل الطلاب مع القلق الحاد قبل التدخل وبعده، من خلال إحداث تحفيز عصبي غير مريح استجابة للمهام الذهنية الحسابية. سيتم تسجيل بعض العوامل الفسيولوجية للقلق (معدل ضربات القلب ودرجة حرارة الجسم وموصلية الجلد والكورتيزول اللعابي).



**Health conditions/problem studied: Specify**

This study is conducted with healthy young adult volunteers and could reduce their symptoms of anxiety, depression and stress. Moreover, mindfulness can have a positive impact on the perception of stress and pain. Therefore, it could be beneficial to students in the health field.

Interventions: Specify

5-7 mindfulness sessions administered by a professional
Intervention 2: stress test using TENS (transcutaneous electrical nerve stimulation)
Intervention 3: pain induction test using CPT (cold pressor test)

Key inclusion and exclusion criteria: Inclusion criteria

Healthy university students in the health field (aged between 18 and 30 y.o.)

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender**Key inclusion and exclusion criteria: Age minimum**

18

Key inclusion and exclusion criteria: Age maximum

30

Key inclusion and exclusion criteria: Exclusion criteria

Has already followed a mindfulness program
- Suffers from active chronic pain
- Suffers from acute pain at the present moment (wounds, sores, etc.)
- Suffers from uncorrected visual disturbance
- Suffers from psychiatric disorders
- Suffers from a neurological disorder (or other disorder that may alter the perception of pain)
- Substance abuse
- Taking psychiatric drugs or painkillers
- Previous trauma (sexual harassment, explosion, etc.)

Type of study

Interventional

Type of intervention

Lifestyle changes

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope**Study design: Allocation**

Randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Active

Study phase

N/A

Study design: Purpose

Other

Study design: Specify purpose

Improving welfare and quality of life

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization**IMP has market authorization: Specify****Name of IMP****Year of authorization****Month of authorization****Type of IMP**

**Pharmaceutical class**

N/A

Therapeutic indication

stress

Therapeutic benefit

stress, anxiety and pain management

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration**Target follow-up duration: Unit****Number of groups/cohorts****Biospecimen retention**

Samples without DNA

Biospecimen description

saliva

Target sample size

55

Actual enrollment target size

36

Date of first enrollment: Type

Actual

Date of first enrollment: Date

03/07/2023

Date of study closure: Type

Actual

Date of study closure: Date

21/09/2023

Recruitment status

Recruiting

Recruitment status: Specify**Date of completion**

01/12/2023

IPD sharing statement plan

Yes

IPD sharing statement description



.Individual participant data will be available.
2.Individual participant data that underlie the results reported in the article, will be shared after deidentification.
3.Study protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code will be available.
4.The above data will be shared with researchers who provide a methodologically sound proposal.
5.Sharing data could be done for any purpose of analyses.
6.Proposals should be directed to sandra.kobaitermaarawi@usj.edu.lb. To gain access, data requestors will need to sign a data access agreement. Proposals may be submitted up to 36 months following article publication. After that time, data will be available in our university Lab database.

Additional data URL

-

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Saint Joseph University of Beirut	FM446

Sources of Monetary or Material Support

Name
Name - Saint Joseph University of Beirut - Faculty of Medicine and Research Council

Secondary Sponsors

Name
-



Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
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Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Saint Joseph University of Beirut – Faculty of Medicine – Laboratory of Research in Neuroscience	Sandra Kobaiter Maarrawi	Neuroscience	Approved
Saint Joseph University of Beirut – Faculty of Medicine – Laboratory of Research in Neuroscience	Joseph Maarrawi	Neurosurgery	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	13/12/2022	Pr Michel Scheuer	michel.scheuer@usj.edu.lb	00961 1 421 000 ext 2228

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
stress	2-Propanol (T51.2)	stress
anxiety and depression	2-Propanol (T51.2)	anxiety



Interventions

Intervention	Description	Keyword
Mindfulness	focused awareness and non-judgmental acceptance of the present moment	Mindfulness

Primary Outcomes

Name	Time Points	Measure
stress	pre and post intervention	STAI score
pain tolerance	pre and post intervention	cold pressor test – withdrawal duration and pain score

Key Secondary Outcomes

Name	Time Points	Measure
Mindfulness traite	pre and post intervention	FFMQ score
Salivary cortisol	pre and post intervention	ELISA concentration
stress	during tests, pre and post intervention	body temperature
stress	during tests, pre and post intervention	skin conductance
stress	during tests, pre and post intervention	heart rate



Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files