Effects of a mindfulness program on the welfare of university students

14/08/2025 21:56:13

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
-

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 أيضًا 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. أخيرًا ، تهدف الدراسة إلى مقارنة تفاعل الطلاب مع ا 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.kobaitermaarrawi@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
Public	Sandra Kobaiter Maarrawi	USJ	Lebanon	01 421 677	sandra.kobaitermaarrawi@usj.edu.lb	USJ-FM
Scientific	Elsa Rhayem	USJ	Lebanon	76 536 226	elsa.rhayem@net.usj.edu.lb	USJ-FM
Scientific	Antoun Yammine	USJ	Lebanon	71 957 527	antoun.yammine@net.usj.edu.lb	USJ-FM
Scientific	Nay El Hajj	USJ	Lebanon	71 706 646	nay.hajj@net.usj.edu.lb	USJ

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