# Effects of a mindfulness program on the welfare of university students

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## 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**