



The effect of confinement on the mental health of individuals during the COVID-19 pandemic: an online survey

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Main Information

Primary registry identifying number

LBCTR2020043459

Protocol number

HDF 1632

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

11/04/2020

Primary sponsor

Hotel Dieu de France hospital

Primary sponsor: Country of origin

Lebanon

Date of registration in primary registry

16/04/2020

Date of registration in national regulatory agency

11/04/2020

Public title

The effect of confinement on the mental health of individuals during the COVID-19 pandemic: an online survey

Acronym

Scientific title

The effect of confinement on the mental health of individuals during the COVID-19 pandemic: an online survey

Acronym

Brief summary of the study: English

This an online survey aiming at screening most common mental disorders occurrence (depression, anxiety, eating disorders and substance use disorders) in the general population of Lebanese individuals under confinement. The study will use 3 screening questionnaires: DASS-21, SCOFF and CAGE-AID in Arabic, English and French. Three groups divided among those who have a minimal, moderate or severe impact of the confinement on their lifestyle will be created and their scores on screening questionnaires will be compared.

Brief summary of the study: Arabic

يهدف هذا الاستطلاع عبر الإنترنت إلى فحص معظم الاضطرابات النفسية الشائعة (الاكتئاب والقلق واضطرابات الأكل واضطرابات تعاطي DASS-21 و SCOFF و CAGE-AID : استبيانات للفحص3المخدرات) في عموم السكان اللبنانيين تحت الحبس. ستستخدم الدراسة باللغات العربية والإنجليزية والفرنسية. سيتم إنشاء ثلاث مجموعات مقسمة بين أولئك الذين لديهم تأثير الحد الأدنى أو المعتدل أو الشديد للحبس على نمط حياتهم ومقارنة درجاتهم في استبيانات الفحص.

Health conditions/problem studied: Specify

Mental Disorders

Interventions: Specify

Online survey dividing participants to three groups according to the level of influence of confinement on their lifestyle





Key inclusion and exclusion criteria: Inclusion criteria

Age > 18 years
Living in Lebanon
Speaking English Arabic or French

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Exclusion criteria

Refusal to participate

Type of study

Observational

Type of intervention

Lifestyle changes

Trial scope

Other

Study design: Allocation

N/A

Study design: Control

N/A

Study design: Purpose

Screening

Study design: Assignment

Parallel

IMP has market authorization

Name of IMP

Type of IMP

Pharmaceutical class

No pharmaceutical class is involved

Therapeutic indication

No indication

Therapeutic benefit

Assessment of confinement impact on mental health

Study model

Cohort

Study model: Specify model

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age maximum

85

Type of intervention: Specify type

N/A

Trial scope: Specify scope

Study design: Masking

N/A

Study phase

1

Study design: Specify purpose

N/A

Study design: Specify assignment

N/A

IMP has market authorization: Specify

Year of authorization

Month of authorization

Study model: Explain model



N/A

Cross-sectional online survey comparing 3 groups

Time perspective

Other

Time perspective: Explain time perspective

Transversal assessing current month's psychological well-being

Time perspective: Specify perspective

N/A

Target follow-up duration

1

Target follow-up duration: Unit

N/A

Number of groups/cohorts

3

Biospecimen retention

None retained

Biospecimen description

N/A

Target sample size

500

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

14/04/2020

Date of study closure: Type

Anticipated

Date of study closure: Date

18/05/2020

Recruitment status

Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan

No

IPD sharing statement description

N/A

Additional data URL

Admin comments

**Trial status**

Approved

Secondary Identifying Numbers

No Numbers

Sources of Monetary or Material Support**Name**

N/A

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Rami Bou Khalil	rami.boukhalil@usj.edu.lb	Lebanon	01615300	rami.boukhalil@u sj.edu.lb	Saint Joseph University
Scientific	Rami Bou Khalil	rami.boukhalil@usj.edu.lb	Lebanon	01615300	rami.boukhalil@u sj.edu.lb	Saint Joseph University

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu de France	Rami Bou Khalil; Ramez Dagher; Ghassan Sleilaty; Sami Richa	Psychiatry and cardiothoracic surgery	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	09/04/2020	Sami Richa	sami.richa@usj.edu.lb	01615300



Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Depression	Depressive episode (F32)	Depression
Anxiety	Anxiety disorder, unspecified (F41.9)	Anxiety

Interventions

Intervention	Description	Keyword
N/A (online survey)	Online survey assessing mental health during the last month	Mental Health; Online survey; Confinement

Primary Outcomes

Name	Time Points	Measure
Mental disorders (Depression; anxiety; eating disorders; substance use disorders)	one month	DASS-21; SCOFF; CAGE-AID

Key Secondary Outcomes

Name	Time Points	Measure
N/A	N/A	N/A



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