

Can we learn to manage stress?

Submission date 04/12/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/12/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/01/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

University students make up a category of people who are particularly vulnerable to stress. They are prone to having stress-related issues such as anxiety, depression, eating problems, consumption of psychoactive substances, and sleep disorders. These rates are higher in terms of mental health problems than declared in the general population. Online application studies in this field are being developed to treat several problems, such as panic disorder, depression, anxiety, insomnia, post traumatic stress, social phobia and behavioural problems. Stress management is one of the applications that has been suggested to help diverse population groups. The aim of this study is to test the efficiency of an online stress management program on university students.

Who can participate?

French university students aged between 18 and 30 years who have access to the internet.

What does the study involve?

Participants are randomly allocated into one of the two groups. Those in the first group receive the online stress management program. Participants are invited to visit the website once a week and to spend at least 20 minutes on it for four weeks. They could visit the page for longer or more frequently if they wished. Those in the second group continue as normal for the duration of the study. Participants in both groups complete a number of questionnaires to measure their stress levels and mental health at the start of the study and one week after the end of the program and after three months.

What are the possible benefits and risks of participating?

Participants may benefit from improvement in levels of self-esteem and perceived stress. There are no notable risks involved with participating.

Where is the study run from?

Université Paris Nanterre (France)

When is study starting and how long is it expected to run for?

November 2015 to June 2016

Who is funding the study?
Scientific Interest Group "Jeu et société" (France)

Who is the main contact?
Dalia Saleh
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Study website
<https://sites.google.com/site/stressetudiantsuniversitaires/home>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Online stress management: An experimental study carried out on university students

Study objectives
This aim of this study is to investigate the efficiency of an online stress management program.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Committee of the Psychological Science and Learning Science department at the University of Paris Ouest Nanterre La Défense, UFR SPE (Department of Psychology and Education), 18/11/2014
2. CNIL (National commission of computing and freedom), 18/11/2014, ref: 1811031 v 0

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Stress

Interventions

Participants are randomised to one of two groups using SPSS random sample software.

Intervention group: Participants receive the "I'm managing my stress" program. This involves four sessions spread over one month, each 20 minutes long, including psycho-education, practical exercises and one to two weekly activities that the participant is asked to complete (prescription of tasks, as is customary in cognitive-behavioural techniques). The goal is for the students to learn easy techniques to help them face stressing situations in a better way.

Control group: Participants continue as usual and are given the opportunity to receive the intervention program after the study ends.

Participants in both groups complete a battery of questionnaires at baseline (pre-intervention), one week post-intervention and again after three months.

Intervention Type

Behavioural

Primary outcome measure

1. Stress is assessed by the Perceived Stress Scale (PSS-10) at baseline, 1 week post-intervention and 3 months post-intervention

2. Self-esteem is measured using the Rosenberg Self-Esteem Scale (RSES) at baseline, 1 week post-intervention and 3 months post-intervention
3. Psychological distress is measured using the 28-item General Health Questionnaire (GHQ-28) at baseline, 1 week post-intervention and 3 months post-intervention

Secondary outcome measures

Satisfaction in studies is assessed using the 5-item version of (ESDE) at baseline, 1 week post-intervention and 3 months post-intervention.

Overall study start date

01/11/2015

Completion date

06/06/2016

Eligibility

Key inclusion criteria

1. French university students
2. Mastery of the French language
3. Aged between 18 and 30 years
4. Having an e-mail address and access to the Internet

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Upper age limit

30 Years

Sex

Both

Target number of participants

128

Key exclusion criteria

Aged under 18 or over 30 years

Date of first enrolment

01/11/2015

Date of final enrolment

10/01/2016

Locations

Countries of recruitment

France

Study participating centre

Université Paris Nanterre

200 Avenue de la République

Nanterre

France

92001

Sponsor information

Organisation

Université Paris Nanterre

Sponsor details

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Sponsor type

University/education

Website

<http://www.u-paris10.fr/>

ROR

<https://ror.org/013bkhk48>

Funder(s)

Funder type

Research organisation

Funder Name

Scientific Interest Group "Jeu et société"

Results and Publications

Publication and dissemination plan

Planned publication in either PLOS One or BMC in Psychiatry.

Intention to publish date

31/07/2017

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/09/2018		Yes	No
Protocol (other)		05/09/2018	04/01/2024	No	No