

The Caring Universities Project

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20889

Bron

NTR

Verkorte titel

TBA

Aandoening

stress, mood

Ondersteuning

Primaire sponsor: NA

Overige ondersteuning: The central coordination of the project is done by the Vrije Universiteit Amsterdam. However, every university (Vrije Universiteit Amsterdam, Leiden University, Maastricht University, and Utrecht University) has an equal share in the project. The project is funded by the Vrije Universiteit Amsterdam, Leiden University, Maastricht University, and Utrecht University themselves.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

With regards to the programs the following questionnaires will be used as the primary outcome for both programs:

- The Client Satisfaction Questionnaire (Larsen et al., 1979) (CSQ-8)
- System Usability Scale (Brooke, 1996) (SUS-10)

Toelichting onderzoek

Achtergrond van het onderzoek

Psychological problems are very common among university students. Addressing student mental health and psychosocial problems might be effective in improving students' wellbeing and academic results and decrease study drop-out rates. Universities can be an excellent environment for detecting students at high risk of mental disorders and for applying evidence-based treatment approaches in order to prevent and treat symptoms of common mental disorders or treat them at an early stage. Therefore present study aims to implement two separate evidence-based guided Internet-based self-help programs for university students. The first intervention will be for students with mood-related symptoms. The second intervention will be targeting students with elevated levels of stress. We will evaluate the feasibility and acceptability of these programs by measuring client satisfaction and usability. A secondary goal is to gain an insight into pre-test to post-test differences with regard to mood/stress levels and quality of life. We will also assess the adherence of the students to the program.

Doel van het onderzoek

We anticipate that students who will receive the Internet-based intervention based on their symptoms will have high satisfaction and show high adherence to the program. We also expect to find significant improvements in symptoms of stress /mood and quality life.

Onderzoeksopzet

Data collection will be conducted at pre-program (T0), post-program (T1), and 6 months post-program (T2). We will also collect data by weekly measurements during the program (Tx). For mood program we will collect weekly measurement using Patient Health Questionnaire – 4 items (Kroenke et al., 2009) (PHQ-4) [Tx] and for stress management program, Perceived Stress Scale (PSS-4) will be used for weekly measurements.

Onderzoeksproduct en/of interventie

Guided web-based self-help programs will be offered to the students targeting low mood or elevated levels of stress.

Moodpep:

Colleagues Nadia Garnefski and Vivian Kraaij, both associate professors at the department of

clinical psychology at Leiden University, developed Moodpep, a guided e-health program for students with mood-related symptoms. Moodpep consists of 8 weekly modules (1-2 hrs each) based on Cognitive Behavioral Therapy techniques. In previous research, the online self-help program 'Living positive with HIV', which is identical to Moodpep with regards to its content (some case examples have been changed), has been shown to be effective (with a large effect size) in treating mood-related symptoms in people with HIV (van Luenen et al., 2018). The program includes four main components: 1-behavioral activation, 2-relaxation exercises, 3-changing negative thoughts, 4-goal setting. Participants can work on the program in their own pace, at their own place, in complete anonymity. After every module, a coach will give feedback on the assignments.

Stress management program:

The program is a guided Internet-based stress management program based on Cognitive-Behavioral Therapy (CBT) and Lazarus and Folkman's transactional model of stress (Lazarus & Folkman, 1984). The program consists of five online sessions with duration ranging from 4 to 6 weeks depending on individual progress. Modules cover information about stress and coping strategies, and also several activities to reduce stress levels and increase skills to be able to cope with stressors. Sessions cover psychoeducation about stress, identifying the stressors, stress-inducing thoughts and the consequences of these stressors in one's life, information about coping skills, and how participants can apply the coping skills to everyday life stressors, information, and exercises about cognitive restructuring, and behavioral activation. Optional modules will be offered within the program about assertiveness, maintaining a healthy lifestyle (sleep, overcoming emotional eating, exercise), adaptation to a new culture, procrastination and time management.

Guidance of the programs:

E-coaches will be trained 3rd-year psychology students. E-coaches will provide asynchronous written personalized feedback to each participant through the program platform within 48 hours (counting workdays only) after session completion. The aim of the written feedback is to increase the motivation and adherence of the participants. The estimated time will be approximately 20 minutes per feedback but no more than 30 minutes per session. Participants will also receive automatic reminders to support them in completing the sessions in case of the non-completion of the session. Research team will provide training and supervision for the e-coaches.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria for the guided e-health programs:

- Being fluent in Dutch and/or English
- Being enrolled as a student of the 4 participating universities, namely Vrije Universiteit Amsterdam, Leiden University, Maastricht University, and Utrecht University.
- Being 16 years of age or older
- Having access to a PC or mobile device with internet access
- Having mild to moderate mood related symptoms (Patient Health Questionnaire- 9 (PHQ-9) > 4) or elevated stress (Perceived Stress Scale-10 (PSS-10) > 21) (depending on the program that will be offered.)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Current risk for suicidal behavior (PHQ-9-item-9 ≥ 2 AND G10 ≥ 1 [About how many months in the past 12 did you think about how you might kill yourself or work out a plan of how to kill yourself?] AND G11 ≥ 1 [How likely do you think it is that you will act on this plan in the next 12 months --> somewhat likely or very likely])
- Severe depression (PHQ-9 total score > 20)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 12-06-2020

Aantal proefpersonen: 50

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8686
Ander register	The Executive Board of the Medical Ethics Review Committee VU University Medical Center decided that this study does not fall within the scope of the Medical Research Involving Human Subjects Act (WMO). The study was approved by The Scientific and Ethical Review Board (VCWE) of the Faculty of Behavior & Movement Sciences, VU University Amsterdam. : METC VUmc Source ID: 2020.088; VCWE Source ID: VCWE-2020-076R1

Resultaten