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Promoting resilience and coping skills in people at risk of developing adjustment disorders

Submission date
27/07/2016

Registration date
28/07/2016

Last Edited
30/08/2024

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Adjustment disorder (AD) is a type of stress-related condition, in which a person has difficulty coping with, or adjusting to, a particular source of stress. The first year of university can be seen as a stressful situation, due to the increased work load and major life change it represents. It often shares some symptoms with clinical depression, such as feelings of hopelessness, loss of interest in work and activities, and anxiety. People with low resilience (the ability to recover quickly from difficulties) are more likely to develop AD. This study will look at a self-help internet-based program which aims to promote resilience called CORE. The aim of this study is to investigate the effectiveness and cost-effectiveness of the CORE program at improving resilience and wellbeing and reducing levels of depression and anxiety.

Who can participate?
First year university students aged 18 years and over with low resilience levels.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in the CORE program for six weeks. The program includes a range of multimedia, including videos, audios, vignettes and images, as well as educational material designed to enhance resilience and coping skills, to promote self-empowerment and increase wellbeing. Those in the second group do not receive any additional treatment throughout the study period. After the study is over, they are given access to the CORE program. Participants in both groups complete a number of questionnaires at the start of the study and then after 4 weeks, 8 weeks, 6 months and 12 months, to test their resilience levels and mental wellbeing.

What are the possible benefits and risks of participating?
Participants who receive the CORE program may benefit from improved resilience and mental wellbeing. There are no notable risks of participating in this study.

Where is the study run from?
1. Universitat Jaume I (Spain)
2. Universitat de Valencia (Spain)
3. Universitaet Bern (Switzerland)

4. Universität Zürich (Switzerland)
5. Friedrich-Alexander-Imiversitaet Erlangen Nuernberg (Germany)

When is the study starting and how long is it expected to run for?
September 2015 to July 2019

Who is funding the study?
European Commission (Belgium)

Who is the main contact?
1. Professor Cristina Botella (scientific)
2. Professor Rosa Maria Baños Rivera (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ICARE-R2016

Study information

Scientific Title
ICare-R: Integrating Technology into Mental Health Care Delivery in Europe - Resilience Trial

Acronym
ICare-R

Study objectives
The aim of this trial is to develop and test the effectiveness and cost-effectiveness of unguided Internet intervention program for promoting resilience and coping skills in people at risk of developing adjustment disorders (AD), such as students low in resilience confronting a crucial life-event like the first year of university. Specifically aims of the study are:
1. To provide a preventative online intervention for enhancing resilience (ICare-R), for decreasing symptoms of depression and anxiety and for increasing wellbeing
2. To evaluate the effectiveness and acceptability of ICare-R in a randomized controlled trial compared with care as usual (CAU)
3. To analyze feasible strategies to implement ICare-R and to identify possible implementation barriers from final users, professionals of University counseling services and the University authorities

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval Universitat Juame I: Comisión Deontológica de la Universitat Jaume I (Ethical Committee of the Jaume I University), 02/06/2016

Study design
Multi-country randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Adjustment disorders (AD)

Interventions
Participants will be randomized in a 1:1 ratio. Randomization will be stratified according to trial site.

ICare-R condition: Participants allocated to this condition will use a self-help programme named CORE. CORE is a 6-week Internet-based prevention program, which main objective is to teach skills and adaptive strategies to cope with daily life issues in order to enhance resilience and coping skills, to promote self-empowerment and increase wellbeing. CORE provides techniques based on cognitive behaviour therapy and positive psychology strategies (behavioural activation, cognitive restructuring, problem solving, mindfulness, self-compassion, among others). The

program includes several multimedia elements: videos, audios, vignettes, images. Besides, each module includes exercises for practicing the different skills. CORE addresses several important dimensions related with wellbeing: self-acceptance, the establishment of quality ties to other, a sense of autonomy in thought and action, the ability to manage complex environments to suit personal needs and values, the pursuit of meaningful goals and a sense of purpose in life, continued growth and development as a person.

“Care as usual” condition: “ICare-R”-prevention model will be compared to care-as-usual (CAU). Since participants are part of the general population, it is not expected that they have serious mental disorders, but they will be monitored to detect if they engage in treatment (psychotherapy or medication treatment). Upon completion of the intervention period, the participants in the CAU condition will be debriefed about the study, and provided access to the “ICare-R” program intervention program.

Online- and telephone assessments will be conducted at pre- and post-intervention, and at 6- and 12-month follow-up.

Intervention Type
Behavioural

Primary outcome(s)
Resilience capacity is measured using the Connor-Davidson Resilience Scale (CD-RISC 25) at baseline, 8 weeks, 6 months and 12 months

Key secondary outcome(s))
1. Resilience capacity is measured using the Resilience Scale (RS-14) at baseline, 8 weeks, 6 months and 12 months
2. Depressive symptoms Patient Health Questionnaire (PHQ-9) at baseline, 4 weeks, 8 weeks, 6 months and 12 months
3. Personality traits are measured using the 10-Item Big Five Inventory (BFI-10) at baseline, 8 weeks, 6 months and 12 months
4. Anxiety symptoms are measured using the Generalized Anxiety Disorder Questionnaire (GAD-7) at baseline, 4 weeks, 8 weeks, 6 months and 12 months
5. Self-esteem is measured using the Rosenberg's Self-Esteem Scale (RSE) at baseline, 4 and 8 weeks
6. Alcohol use is measured using the Alcohol Use Disorders Identification Test (AUDIT-C) at baseline, 4 and 8 weeks
7. Positive and negative emotions frequency is measured using the Positive and Negative Affect Scale (PANAS) at baseline, 4 weeks, 8 weeks, 6 months and 12 months
8. Wellbeing is measured using the Psychological Wellbeing Ryff (PW-29) at baseline, 8 weeks, 6 months and 12 months
9. Self-compassion is measured using the Self-compassion Scale - Short Form (SCS-SF) at baseline, 8 weeks, 6 months and 12 months
10. Health service utilization is measured using the Client Service Receipt Inventory (CSRI) at baseline, 8 weeks, 6 months and 12 months
11. Stress is measured using the Perceived Stress Scale (PSS) at baseline, 8 weeks, 6 months and 12 months
12. Pleasant orientation is measured using the Enjoyment Orientation Scale (EOS) at baseline, 8 weeks, 6 months and 12 months
13. Expectations of the intervention are measured using the Credibility and Expectancy Questionnaire (CEQ) at baseline, 8 weeks, 6 months and 12 months

14. Alliance with technological intervention is measured using the Working Alliance Inventory (WAI-TECH) at baseline, 8 weeks, 6 months and 12 months
15. . Satisfaction with the intervention is measured using the Client Satisfaction Questionnaire (CSQ) at 8 weeks

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Freshmen university students
2. Scoring one standard deviation below the mean of the sample on the Connor-Davidson Resilience Scale (CD-RISC-25)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Individuals with a history of a Common Mental Disorder in the past 12 months
2. Individuals who are on a waiting list for psychotherapy or are currently or have been in psychotherapeutic treatment within the past 12 months for any kind of mental health problems
3. Individuals with a current or history of a psychotic or bipolar disorder
4. Individuals at risk for suicide

Date of first enrolment
30/09/2016

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
Germany

Spain

Switzerland

Study participating centre
Universitat Jaume I
Castellon de la Plana
Spain
12071

Study participating centre
Universitat de Valencia
Valencia
Spain
46010

Study participating centre
Universitaet Bern (UBERN)
Bern
Switzerland
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Study participating centre
Universität Zürich (UZH)
Zürich
Switzerland
8031

Study participating centre
Friedrich-Alexander-Imiversitaet Erlangen Nuernberg (FAU)
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91054

Sponsor information

Organisation
Jaume I University

ROR
https://ror.org/02ws1xc11

Organisation
Universitat de Valencia

Organisation
Clinical Psychology and Psychotherapy, Universitaet Bern

Organisation
Swiss Research Institute for Public Health and Addictions (ISGF) - Universität Zürich

Organisation
Clinical Psychology and Psychotherapy Friedrich-Alexander University of Erlangen-Nuremberg

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/03/2018	11/05/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes