

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

Submission date 27/07/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/07/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/08/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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-Universität Erlangen Nürnberg (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

Contact name
Prof Cristina Botella

ORCID ID
<http://orcid.org/0000-0001-8783-6959>

Contact details
Avenida Vicent Sos Baynat S/N
Castellon de la Plana
Spain
12006

Type(s)
Scientific

Contact name
Prof Rosa Maria Baños Rivera

ORCID ID
<http://orcid.org/0000-0003-0626-7665>

Contact details
Avenida Blasco Ibañez 21
Valencia
Spain
46010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 Jaume 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

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 below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2015

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

Age group

Other

Sex

Both

Target number of participants

N= 464: I-CARE group= 232; Control group: 232

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

3012

Study participating centre

Universität Zürich (UZH)

Zürich

Switzerland

8031

Study participating centre
Friedrich-Alexander-Universität Erlangen Nürnberg (FAU)
Erlangen
Germany
91054

Sponsor information

Organisation

Jaume I University

Sponsor details

Avenida Vicent Sos Baynat S/N
Castellon de la Plana
Spain
12006

Sponsor type

University/education

Website

<http://www.uji.es>

ROR

<https://ror.org/02ws1xc11>

Organisation

Universitat de Valencia

Sponsor details

Avenida Blasco Ibañez 21
Valencia
Spain
46010

Sponsor type

University/education

Website

<http://www.uv.es>

Organisation

Clinical Psychology and Psychotherapy, Universitaet Bern

Sponsor details

Fabrikstrasse 8
Bern
Switzerland
3012

Sponsor type

University/education

Organisation

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

Sponsor details

Konradstrasse 32
Zurich
Switzerland
8031

Sponsor type

University/education

Organisation

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

Sponsor details

Nägelsbachstraße 25a
Erlangen
Germany
90152

Sponsor type

University/education

Funder(s)

Funder type

Government

Funder Name

European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκή Επιτροπή, Европейская комиссия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságrol, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

1. Planned publication in a high-impact peer reviewed journal around one year after the overall trial end date
2. Planned periodic dissemination in International and National congress: Botella, C., Baños, R., Herrero Camarano, R., Garcia Palacios, A., Quero, S., Etchemendy, E., Mira, A., & Corno, G. "ICARE-R: Una intervención online para promover la resiliencia en estudiantes universitarios". Poster presentation at III Congreso de Psicología Positiva in collaboration with the Sociedad Española de Psicología Positiva, 20-23 April 2016, Baeza, Spain.

Intention to publish date

30/12/2024

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