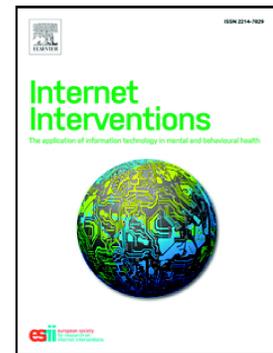


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An Internet based intervention for improving resilience and coping strategies in university students: study protocol for a randomized controlled trial

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Abstract

Background: The literature shows a high prevalence of depression and anxiety in young people. The university represents a change in the lives of students, and is considered a stress factor. Therefore, it is particularly relevant to develop interventions specifically addressed to students and foster supportive environments and resilient communities. As students are “digital natives”, online interventions offer several potential advantages in doing this. This study aims to develop and evaluate the efficacy of an Internet-based intervention (CORE: Cultivating our Resilience), based on the Ryff model of well-being, to promote resilience and coping skills, decrease symptoms of depression and anxiety, and increase overall wellbeing in young people confronting a crucial life event (the university). This paper summarizes the study protocol.

Method: The design of the planned study is a randomized controlled trial. A minimum of 464 participants will be randomly assigned to two conditions: 1) an unguided Internet-based intervention to enhance resilience (N=232); 2) a care-as-usual condition (CAU) (N=232). The primary outcome will be the Connor-Davidson resilience scale. Secondary outcomes will – among others - include other relevant clinical measures, such as anxiety and depressive

symptoms, quality of life, and social support. Outcomes will be assessed 4 and 8 weeks, and 6 and 12-months follow-ups. Intention-to-treat and per-protocol analyses will be performed.

Discussion: The results of this study will contribute to the growing research on Internet-delivered interventions. The expected results may have a major impact on the prevention of mental disorders and possible negative consequences in at-risk populations, such as college students.

Keywords: resilience, well-being, Internet intervention, university students

1 Introduction

Mental health disorders diminish the quality of life of people who suffer from them, and they also increase vulnerability for the development of severe disabling diseases (Mihalopoulos, et al., 2011). Early adulthood represent crucial periods in the development of mental disorders. The literature shows an alarming prevalence of depression and anxiety in young people as university students (Auerbach et al., 2016; Merikangas, et al., 2009). However, care of common mental health disorders (CMHD), such as depression, anxiety, adjustment disorders, or substance use, has primarily included treatment of rather than prevention in most European countries (WHO, 2013), and a shift to more prevention-oriented care has been urged by the European Commission (EC) health policy (WHO, 2013).

Resilience refers to an individual's ability to properly adapt to stress and adversity, to overcome the negative effects of risk exposure, or coping successfully with traumatic experiences. It is also important for maintaining quality of life, emotional well-being, and functional independence. Three resilience models have been identified to explain how promotive factors operate to change the effects of risk factors- compensatory, challenge and protective (Fergus & Zimmerman, 2005). Compensatory model refers to those models where the promotive factor counteracts a risk factor. The challenge model suggest that the risk exposure must be challenging enough to generate a coping response, a exposure to low and high levels of a risk factor are associated to negative effects, but moderate levels are associated to less negative effects. The protective model suggests that a assets or resources reduce the effects of a risk factor.

The transition from adolescence to adulthood represents a high-risk period during which young people are exposed to developing psychological problems (Giedd, Keshavan & Paus, 2008). The university represents a change in the lives of students, and it is considered a stress factor and a heightened risk for psychopathology (Cook, 2007) (e.g., new social relationships and contexts without the support of parents or long-time friends, academic pressure, stress during

exams, social disconnection). Moreover, this stressful situation not only substantially affects students' normal day-to-day activities, but it also has negative consequences such as lower academic achievements, college dropout (Arria et al., 2009; Cook, 2007; Institute for Employment Studies, 2015). Therefore, a preventive intervention offered during this time could reduce the risk of developing a mental disorder and experiencing other negative consequences by enhancing protective factors. Although existing programs designed to promote resilience in young people have demonstrated a decrease in depressive and anxious symptomatology (e.g. Gillham et al., 2007; Stallard, & Buck, 2013), and evidence for these preventive interventions is steadily growing (Das et al., 2016), while literature on this topic is still scarce (Huebner et al., 2009).

A key objective in the promotion of mental health is to propose and deliver interventions that are affordable and available to everyone, the Internet can be an effective medium to deliver mental health interventions (Kazdin, 2015). People can access the web contents of an intervention with little or no cost to the client, with or without minimal assistance from a therapist or other mental health professional (Ashford, Olander, & Ayers, 2016; Griffiths, & Christensen, 2007; Hayward, MacGregor, Peck, & Wilkes, 2007; Kaltenthaler et al., 2006; Mitchell et al., 2010; Muñoz, 2010). In the past decade, web-based interventions have been used to enhance the accessibility and effectiveness of traditional treatments. Global Internet penetration is constantly increasing. The statistic shows that in Europe, 79% of individuals aged 16 to 74 years use the Internet (Eurostat, 2016). Regarding its efficacy, several meta-analyses suggested that web-based programs can be as effective as traditional face-to-face programs, and significantly more effective than control conditions, for a variety of mental health disorders, as depression, anxiety, and adjustment disorders (e.g., Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Botella, Mira, Herrero, García Palacios, & Baños, 2015; Montero-Marín, 2016), health behaviors (e.g., Banos et al., 2015), and the prevention of mental health disorders (Heber et al., 2017; Sander, Rausch, & Baumeister, 2016). Moreover, these interventions are acceptable and

effective across different populations, as child, students and older adults (e.g. Callear, & Christensen, 2010; Ebert et al., 2015; Farrer et al., 2013; Preschl et al., 2012).

Online interventions seems to offer several advantages for the promotion of mental health (Kazdin & Blase, 2011; Christensen & Hickie, 2010). Through its use, existing barriers can be overcome, such as cost, service availability, wait time, transportation, and stigma, thus reducing health care-related disparities. Besides, as young people are immersed in the digital world, internet can be an effective and efficient tools to implement preventive mental health interventions (Baños, Etchemendy, Mira, Riva, Gaggioli, & Botella, 2017). Nevertheless, there are few studies that assessed the effectiveness of web-based preventive intervention to promote psychological well-being and resilience in young people (Baños et al., 2017; Lintvedt et al., 2013; Rose et al., 2013; Bolier et al., 2012; Abbott, Klein, & Ciechomsk, 2008). Although the first results have shown promise, there is a need for more controlled studies based on well-grounded models with long-term follow-ups (Baños, et al., 2017, Leppin., et al., 2014). In this sense, the aim of the present paper is to describe the protocol for a randomized controlled trial that test the efficacy and effectiveness of an online intervention to promote resilience and care as usual in University students.

2 Materials and Methods

2.1 Aim

The aim of the study is to explore the efficacy of a program developed for promoting resilience and coping skills in young people confronting a crucial life event such as the university. The present study is part of the European research project: Integrating Technology into Mental Health Care Delivery in Europe (ICare, N^o 634757; www.icare-online.eu). The main objective of the ICare project is to develop an integrated model of health promotion and risk prevention as well as detection of the most prevalent disorders in Europe. The present study is

one of 7 clinical trials embedded in this European project. Specific hypothesis are that the program CORE will enhance resilience and coping skills, and increase wellbeing.

2.2 Study Design

A multi-country (Spain, Germany, and Switzerland) two-armed single-blind randomized controlled trial (RCT) will be conducted with repeated measures (baseline, 8 weeks, 6 months, and 12 months). Participants that fulfill inclusion and exclusion criteria will be randomized to one of the two study arms in a 1:1 ratio. The randomization will be stratified by platforms (Spanish platform, Germany-Swiss-Austrian platform) and generated according to a permuted block randomization with fixed and concealed block length. Randomization lists will be prepared by ICare Partner WWU (Westfälische Wilhelms-Universität Münster) independently from the study personnel. The two study conditions are: 1) unguided Internet-based intervention for enhancing resilience; 2) care-as-usual condition (CAU). Participants in the intervention condition will receive a 8-week unguided Internet-based prevention program, CORE. Participants in the CAU condition will receive the usual attention at the university, and upon completion of the intervention period, they will receive access to the CORE intervention program.

The study was registered at the ISRCTN registry (ISRCTN13856522), and will be conducted in accordance with the CONSORT 2010 Statement (Moher, Schulz, Altman, & Group, 2001; Moher et al., 2010; Eysenbach & CONSORT-EHEALTH Group, 2011), the CONSORT-EHEALTH guidelines (Eysenbach & CONSORT-EHEALTH Group, 2013) and the SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials) (Chan et al., 2013). Figure 1 shows the study design.

Figure 1: Study Design

2.3 Sample size calculation

Power calculations were taken into consideration to estimate the necessary sample size. Because no information is available about the normality of the Connor-Davidson Resilience Scale (CD-RISC) scores within the targeted population, the CD-RISC scores at post-intervention between CORE and CAU will be compared using a two-sided Mann-Whitney U-Test. So far, there are no data about the effect sizes that can be obtained in Internet-based interventions for the prevention of depression or other common mental health disorders mainly focusing on promoting resilience. However, previous studies on online interventions have shown effect sizes of between .36 and .50 for the reduction of symptoms of depression and between .32 and .42 for the reduction of symptoms of anxiety (e.g., van Straten, Cuijpers & Smits, 2008; Lintvedt et al., 2013; Bolier et al., 2013). At least similar effects on improving resilience is expected. Adopting a conservative approach in relation to these findings, the sample size is based on the smallest effect size detected in previous studies (Cohen's $d = .32$), a significance level of .05, a power of .80, and a dropout rate of 30%, on the primary outcome measure CD-RISC). The planned sample size of 464 participants is sufficient to detect a small effect size (Cohen's $d = .32$). Covariate adjustment for relevant baseline prognostic factors will further increase the power. To ensure recruitment feasibility, five universities (with an estimated number of 170,000 students) will take part in the trial.

2.4 Participants and recruitment

University students with low levels of resilience will be invited to participate.

Inclusion Criteria

- University students with an score one standard deviation below the mean of the sample on the Connor-Davidson Resilience Scale (CD-RISC-25)
- Adequate knowledge to understand and read Spanish or German

- Access to the Internet, and the ability to use a computer.

Exclusion criteria:

- University students with a history of a CMHD in the past 12 months

- University students who are on a waiting list for psychotherapy or are currently or have been in psychotherapeutic treatment within the past 12 months

- Individuals with a current psychotic or bipolar disorder or a history of one.

- Individuals at risk for suicide.

Participants who do not meet the inclusion criteria will be encouraged to seek interventions alternatives better suited to their specific needs.

Recruitment

The study will be advertised online via universities websites: Universitat Jaume I, Castellón, Spain, <https://www.uji.es/>; Universitat of Valencia, Spain, <http://www.uv.es/>; Universität Bern, Switzerland, <http://www.unibe.ch/>; Universität Zürich, Switzerland, <http://www.uzh.ch/>; Technische Universität Dresden, Germany, <https://tu-dresden.de/>. Furthermore, non-professional social-networks (i.e., Facebook and twitter) and advertisements in newspapers will be used. Moreover, posters will be placed in local universities, and an invitation email will be sent to all university students. Individuals interested in participating in the study will be directed to the research website, where they will find further information about the study and what participation entails, as well as an informed consent form. Individuals can request participation through the website and by signing the informed consent form.

2.5 Intervention

CORE Condition

CORE is a 6-week Internet-based prevention program whose main objective is to teach skills and strategies to cope with daily life stressors in order to enhance resilience and coping skills, promote self-empowerment, and increase wellbeing.

The intervention consists of 6 interactive modules designed for weekly sessions (See Table 1).

The therapeutic components of the program are evidence-based techniques selected following the Riff model of well-being (Ryff, 1989; Ryff et al., 2014), and organized in 6 dimensions: Autonomy, Self-Acceptance, Environmental Mastery, Purpose in Life, Positive Relations, and Personal Growth. In addition, each module includes exercises to practice the proposed skills. The program includes multimedia elements: videos, audios, vignettes, images (See Figure 2). Furthermore, it allows the user to keep different records through the PC and Tablet.

CORE will be running on the Minddistrict platform (Minddistrict B.V., Amsterdam, The Netherlands), a web-based eHealth platform. Minddistrict is the technology partner within the ICare project. The Minddistrict platform allows researchers and therapists to produce intervention content and deliver this content to clients. Among the tools that the platform provides, this trial includes the possibility to record daily data in a mobile application, the use of a logical sequence that allows the therapist to deliver specific content related to the answer given by the client (conditional content). Moreover, it ensures secure and encrypted communication between clients and therapist.

Module	Objective
(0) Welcome	Introduction module to the program, with an explanation about the tools and how to use CORE.
(1) <i>Psychoeducation</i>	Explanation of psychological wellbeing and the concept of resilience: <ul style="list-style-type: none"> - Understand the concept of psychological well-being, its most important aspects, and their relevance in life. - Understand the concept of resilience and the importance of training and cultivating it.
(2) <i>Autonomy</i> :	Enhancement of autonomy:

-
- Building my way* - Develop a healthy lifestyle (by pursuing balance in several areas: activity, food, sleep). This lifestyle will allow the person to focus on his/her goals in life.
- Increase psychological well-being by working on the abilities and potentially related to values and goals in life.
- (3) *Mindfulness and self compassion* Training in mindfulness, savoring, and an attitude of self-compassion:
- Learn the meaning of "mindfulness", how to develop this ability, and the benefits that its practice can bring.
 - Learn to distance ourselves from our thoughts and how to handle them.
 - Understand the importance of, recognize, capture, and enjoy the good moments.
 - Develop the skill of kindness and self-care, i.e., the capacity for self-compassion.
- (4) *Overcoming Obstacles* Development of coping strategies to deal with daily difficulties in life:
- Be aware of the importance of facing problems properly.
 - Learn the Problem Solving Technique and how to apply it.
 - Learn the role of our thoughts in the way we feel and how to be flexible in our way of interpreting situations.
- (5) *Connecting to others* Acknowledge the relevance of relationships and how they can be helpful in the construction of well-being:
- Recognize the importance of our social relations.
 - Learn to care for and improve our social relations.
 - Learn to promote quality relationships, which can contribute to maintaining and strengthening resilience.
- (6) *Purpose in life and personal growth* Encourage students to deal with the future with a positive attitude, taking into account what is important for each person and planning the future according to these objectives.
-

Table 1: CORE modules and their objectives**Care as usual condition**

Participants allocated to the control condition will be assessed. Participants will be assessed at baseline, 4 weeks, 8 weeks, and at 6- and 12-month follow-ups. Furthermore, they will receive access to the prevention program by the end of the last follow-up assessment.

Figure 2: CORE: Example of design of a session module on Minddistrict platform**2.6 Data Management**

Data management and monitoring will be provided by the Institute of Biostatistics and Clinical Research (Münster, Germany) for the whole consortium in order to maintain comparable high quality in the conduct of the ICare research projects in trial planning, data management, online monitoring, and analysis.

2.7 Outcomes

Assessments will be conducted online using the Minddistrict platform. The measures used and assessment times in the study are described in Table 2

Primary outcome

The primary outcome is the Connor-Davidson Resilience Scale (CD-RISC; Connor & Davidson, 2003) is a 25-item self-report questionnaire that assesses the ability to cope with stress. Respondents are asked to indicate their level of agreement using a 5-point Likert scale from 0 to 4 (0 = strongly disagree, 4 = strongly agree). Scores range from 0 to 100, with higher scores

reflecting greater resilience. Previous studies have shown that the CD-RISC has good internal consistency (Cronbach alpha above .70) (Yu & Zhang, 2007; Singh & Yu, 2010).

Secondary outcomes

The secondary outcomes are:

Well-Being: The Ryff Scales of Psychological Well-Being - 29 items (PWBS-29; Ryff, 1989) is a theoretically based instrument that specifically focuses on measuring multiple facets of psychological well-being. These facets include six dimensions (i.e., autonomy, environmental mastery, personal growth, positive relations with others, purpose in life, and self-acceptance). The response scale ranges from 1 to 6 (1 = completely disagree, 6 = completely agree). This scale has been shown to have good psychometric properties (e.g., Van Dierendonck, 2004; Diaz et al., 2006).

Depression: The Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001) is a 9-item instrument that can be used to screen and diagnose patients with depressive disorders. The 9 items are scored on a scale from 0 to 3 (0 = not at all, 3 = nearly every day). Total scores range from 0 to 27. Depression severity cut-off points of 5, 10, 15, and 20 represent the thresholds for mild, moderate, moderately severe, and severe depression, respectively. The PHQ-9 has been shown to have good psychometric properties (Wittkamp, Naeije, Schene, Huyser, & van Weert, 2007).

Positive and negative emotionality: Positive and Negative Affect Schedule (PANAS) (Watson, Clark, & Tellegen, 1998). The PANAS consists of 20 items that evaluate two independent dimensions: positive affect (PANAS+) and negative affect (PANAS-). The range for each scale (10 items on each) is from 10 to 50 (Watson, Clark, & Tellegen, 1998). It is a brief, reliable, and valid self-report measure. It has shown excellent convergent and divergent validity (Sandín et al., 1999; Watson, Clark, & Tellegen, 1998).

Anxiety and stress: The Generalized Anxiety Disorder Questionnaire (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006) is a one-dimensional self-administered scale used to detect the presence of the symptoms of Generalized Anxiety Disorder (GAD), as listed in the DSM-IV. The scale does not provide a definitive diagnosis of GAD, but rather it is a rapid, efficient, reliable, and valid instrument for detecting the presence of a common anxiety disorder. Scores range from 0 to 3 (0 = not at all, 3 = nearly every day), and the total score ranges from 0 to 21. Four severity cut-off points (minimal = 0 to 4, mild = 5 to 9, moderate = 10 to 14, serious = 14 to 20) represent the thresholds from minimal to serious general anxiety. The GAD-7 has shown good internal consistency and test-retest reliability, as well as convergent, construct, criterion, procedural, and factorial validity, for the diagnosis of GAD (Spitzer et al., 2006; Löwe et al., 2008).

The Perceived Stress Scale - 4 items (PSS-4; Cohen, Kamarch, & Mermelstein, 1983) is a 4-item self-report questionnaire that assesses the degree to which recent life situations are appraised as stressful (Cohen et al., 1983). The PSS-4 was introduced as a brief version for situations requiring a very short scale or telephone interviews (Cohen & Williamson, 1988). It is rated on a 5-step scale from 1 to 5 (1 = never, 5 = very often). It has been validated in different studies and shown good internal consistency reliability (e.g., Cohen, & Williamson, 1988; Mitchell, Crane, & Kim, 2008).

Self-Esteem: Rosenberg's Self-Esteem Scale (RSE; Rosenberg, 1965) is a 10-item self-report questionnaire that measures global self-esteem by rating both positive and negative feelings about the self (Robins, Hendin, & Trzesniewski, 2001; Rosenberg, 1965). All the items are answered on a 4-point Likert scale format ranging from 1 to 4 (1 = totally disagree, 4 = totally agree). Previous studies have found good internal consistency and test-retest reliability (Gray-Little, Williams, & Hancock, 1997; Robins et al., 2001).

Self-Compassion: The Self-Compassion Scale - Short Form (SCS-SF; Raes, Pommier, Neff, & Van Gucht, 2011) is a shorter version of the original 26-item SCS (Neff, 2003). The original scale was designed to assess overall self-compassion (total score) and 3 facets of this construct: common humanity (SCSCH), mindfulness (SCS-M), and self-kindness (SCS-SK) (Raes et al., 2011). The factor analysis suggested 6 subscales representing positive and negative aspects of each facet, and this was also true for the SCS-SF (Raes et al., 2011). Respondents are asked to indicate how they perceive their actions toward themselves in difficult times using a 5-point Likert-type scale from 1 to 5 (1 = almost never, 5 = almost always). The SCS-SF has adequate reliability and validity (Raes et al., 2011).

Enjoyment: The Enjoyment Orientation Scale (EOS; Hervás, & Vázquez, 2006) assesses the extent to which participants try to be receptive and make an effort to do pleasant things (anticipatory pleasure). It contains 6 items that represent different expressions of this construct (e.g. "I almost always try to enjoy new things every day, no matter how small"), rated on a Likert scale from 1 to 7 (1 = strongly disagree, 7 = strongly agree) (Hervás, Ortiz, Valiente, Cantero, & Vázquez, 2009).

Substance Abuse: The Alcohol Use Disorders Identification Test (AUDIT-C; Bush, Kivlahan, McDonell, Fihn, & Bradley, 1998) is an alcohol screening test that can help to identify patients who are hazardous drinkers or have active alcohol use disorders (including alcohol abuse or dependence). The AUDIT-C is composed of 3 items scored from 0 to 4. Total score ranges from 0 to 12. In men, a score of 4 or more is considered positive alcohol misuse, whereas in women, a score of 3 or more is considered positive. The AUDIT-C has been shown to have good psychometric properties (e.g., Bush et al., 2008; Frank et al., 2008).

Personality: The 10-Item Big Five Inventory (BFI-10; Rammstedt & John, 2007) is a shorter version of the 44-item BFI (John & Srivastava, 1999; John, Donahue, & Kentle, 1991). It is rated on a 5-step scale from 1 to 5 (1 = disagree strongly, 5 = agree strongly). It was developed to

provide a personality inventory for research settings with extreme time constraints. Previous research has shown that the BFI-10 possesses psychometric properties that are comparable in size and structure to those of the full-scale BFI (Rammstedt, & John, 2007).

Economic Evaluation: The Client Service Receipt Inventory (CSRI) was developed to provide information about service utilization and ultimately inform service delivery by collecting retrospective information on service related issues (Chisholm et al., 2000). It is an established tool that has been used in a range of research studies, including in mental health outreach services, community nursing services, and community care of older people and people with challenging behavior. The questionnaire schedule is designed for interviewer/researcher administration with the person receiving the services, assisted by their main caregiver when necessary. The retrospective period is fixed according to the population being investigated and the specific aims of the research. The service receipt section is the core of the CSRI; for each service type, the number and average duration of contacts are recorded and used to summarize particular care packages, illustrate the variety of services used, and determine how resources are allocated.

Program Evaluation: The Credibility and Expectancy Questionnaire (CEQ; Devilly, & Borkovec, 2000) is a 6-item self-report instrument that assesses patients' expectations about treatment. Both factors (credibility and expectancy) have been shown to be stable across different populations, with high internal consistency within each factor (e.g., Devilly, & Borkovec, 2000). The scale consists of 6 questions, with response options rated on a 10-point scale and on a 1-100% scale.

The Client Satisfaction Questionnaire (CSQ; Attkisson, & Greenfield, 1996; Larsen, Attkisson, Hargreaves, & Nguyen, 1979) measures global patient satisfaction with the treatment. It consists of 8 items measured on a 4-point scale, with total scores ranging from 8 to 32. It has very good

internal consistency reliability (e.g., Attkisson, & Greenfield, 1996; Larsen et al., 1979; Roberts, & Attkisson, 1983).

Working Alliance: The Working Alliance Inventory for Technology-Based Interventions (WAI-TECH; Kiluk, Serafini, Frankforter, Nich, & Carroll, 2014) is an 8-item questionnaire that assesses the therapeutic alliance between the technological tool and the patient. The questionnaire covers two dimensions of the working alliance: (1) therapeutic goals and (2) tasks. Respondents are asked to rate their answers on a 5-point Likert scale ranging from 1 to 5 (1 = never, 5 = always). The WAI-TECH has adequate reliability and validity (Kiluk et al., 2014).

Other measures: Other measurements include socio-demographic variables. The following sociodemographic variables will be collected: gender, household size and income, year of birth, marital status, employment status, total population of place of residence, nationality, level of education, and living situation. Other relevant health related variables measures will be assessed, specifically: presence of previous psychological disorders and if a treatment is currently undertaken.

Construct	Questionnaire	S	T0	T1	T2	T3	T4
Demographics	Socio-demographic data	x	-	-	-	-	-
Resilience (Primary outcome)	CD-RISC	x	x	-	X	x	x
Depression severity	PHQ-9	-	x	x	X	x	x
Personality inventory	BFI-10	-	x	-	-	-	-
Anxiety symptoms	GAD-7	-	x	x	X	x	x
Global self-esteem	RSE	-	x	x	X	-	-
Alcohol screening test	AUDIT-C	-	x	x	X	-	-
Positive and negative affect	PANAS	-	x	x	X	x	x

Psychological well-being	PWBS-29	-	x	-	X	x	x
Self-compassion	SCS-SF	-	x	-	X	x	x
Client service receipt inventory	CSRI	-	x	-	X	x	x
Perceived stress	PSS-4	-	x	x	X	x	x
Enjoyment orientation	EOS	-	x	-	X	x	x
Credibility and expectancy of treatment	CEQ	-	x	-	-	-	-
Therapeutic alliance	WAI-TECH	-	-	x	X	-	-
Treatment satisfaction	CSQ	-	-	-	X	-	-

*Assessment times: S – screening, T0 – Baseline, T1 – 4 weeks after the allocation, T2 – 8 weeks after the allocation, T3 – 6 months follow-up, T4 – 12 month follow-up.

Table 2 Study measures, time of assessment, and source of measurement

2.8 Statistical Methods

For the analysis of ICare study data we follow adopted guidelines, e.g. ICH E9 (<http://www.ema.europa.eu/>). The statistical analysis of the primary and secondary outcomes will be described in a statistical analysis plan that will be signed by the study committee and the responsible statistician.

For the primary analysis of the data, including the efficacy analysis, a statistical analysis plan (SAP) has been written. A blinded data review will be performed. Within the blinded data review decision on the multiple imputation strategy and the selection on multivariable models will be taken.

The overall analysis strategy consists of the following steps: (i) Data description, (ii) Analyses of the primary hypothesis (iii) secondary analyses (iv) further exploratory analyses.

Balancing of the randomization will be controlled by appropriate statistical tests of the baseline variables. The study collective will be characterized by descriptive statistical methods such as relative and absolute frequencies, mean, median, standard deviation, and inter-quartile-range (IQR), and appropriate graphics such as histograms, boxplots, and bar charts. Mean and median

will be accompanied by 95%-confidence intervals. All measurement time points (S, T0, T1, T2, T3, T4) will be described separately. All descriptive statistics will be provided for both study arms. Assumptions for the appropriate statistical tests will be checked for normality by histograms, kurtosis, and the Kolmogorov-Smirnov test, sphericity will be checked using the Mauchly Test, (or any of the epsilon corrections in case it cannot be assumed), and the assumption of equality of variance-covariance matrices will be examined with the Box Test and the Levene Test.

Primary confirmatory analysis

The primary null-hypothesis tests whether CORE and CAU do not differ in their distribution of CD-RISC scores, indicated by shifted median CD-RISC scores. We will test this null-hypothesis non-parametrically using a two-sided Mann-Whitney U-Test to answer the confirmatory question for the trial in the intention-to-treat (ITT) sample. The ITT sample comprises all randomized participants who provided the primary outcome measure within the initially assigned study arm. The primary hypothesis will be tested with a preset significance level of 5%. The primary confirmatory analysis will be performed in the SAS software (SAS Inc., Cary, NY, USA). All programming scripts will be validated by a second statistician at the University of Münster.

Sensitivity analyses of the primary analysis

A number of preplanned sensitivity analyses of the primary analysis will be performed. We will analyse the pre-post differences for the primary and all secondary outcomes using two-sided Mann-Whitney-U tests in case of non-normal differences or two-sided paired t-Tests in case of normally distributed differences of the pre-post scores. Also, the primary analysis will be repeated using the per-protocol (PP) sample, i.e. participants without major protocol violations. The primary outcome will also be analyzed within a generalized linear mixed model including covariates as defined within the blinded data review and the study platform (i.e. center). Furthermore, the primary analysis will be repeated as stratified analysis using van-Elteren tests

(stratified Mann-Whitney-U tests) and subgroup analyses. To assess the effect of missing data on the primary analysis the primary outcome will be reanalyzed after a multiple imputation strategy (developed within blinded data review) was applied to the data.

Analysis of secondary outcomes

Secondary outcomes will be compared between groups at individual time points using Student's-T test for unpaired data or the Mann-Whitney U-Test, depending on the normal distribution of scores. Categorical variables will be tested using Fisher's Exact Test or Chi-Squared Tests. The collected longitudinal data will be analyzed using repeated-measures ANOVA or (generalized) linear mixed models (GLMM) with the appropriate link function.

The results of the primary and secondary analyses will be represented by appropriate effect estimates and 95% confidence intervals.

A Multilevel SEM analysis (MSEM) will be carried out, specifically to control for nested data and include potential confounders in the analysis. Time to onset of CMHD will be assessed by Log-rank tests and Cox proportional hazard models. The latter makes it possible to model additional covariates to control for confounding and obtain risk estimates (hazard ratios) for the onset of CMHD. For all multivariate analyses, covariates will be entered as necessary, e.g., baseline characteristics of participants or variables associated with dropout.

All secondary analyses have to be considered exploratory and hypothesis-generating. We will consistently use the nominal significance level of .05 (two-sided) also for exploratory analyses.

Furthermore, a Consensual Qualitative Research (CQR) approach, based on Grounded Theory but specifically designed for clinical content (Hill et al., 2005) will be applied to study the participants' opinions and attitudes about CORE (the online program).

CQR involves asking the participants specific open-ended questions about a topic following the principles specified in the CQR guidelines. Their responses are then coded into themes in a consensual manner by a group of researchers. In these methodology domains, categories and

core ideas are derived from the interactive exchange of a group of coders. In the first place, domains are created by a thorough analysis of the whole content. Next, core ideas incorporate the explicit answers within the domains. Finally, the categories are built. For each instance, discrepancies are resolved within the consensual procedure that this approach entails. The categories are labeled in general if they apply to all cases, typical if they apply to at least half but not all of the participants, and variant if they apply to less than half. This CQR-based qualitative analysis will provide rich information about the participants' opinions and attitudes about the online program, in order to detect possible barriers and analyze possible strategies to overcome them.

3 Discussion

This paper describes CORE, a new Internet-based intervention based on the Ryff model of well-being designed for promoting resilience and coping skills in university students (Ryff, 1989; Ryff et al., 2014; Ryff & Singer, 1996, Ryff et al., 1998), and presents the study protocol to test its efficacy and effectiveness, compared to a CAU condition, using a two-armed RCT. Participants' acceptance of this program will also be studied in order to identify possible implementation barriers for the users.

Considering the high prevalence of emotional problems in young people worldwide (Copeland, Shanahan, Costello, & Angold, 2011) prevention of psychological problems, promotion of resilience and well-being in this age is crucial (Stengård & Appelqvist-Schmidlechner, 2010). The literature shows that mental illness can be prevented in adult and youth populations (Calear & Christensen, 2010; Cuijpers, et al., 2012; Muñoz et al.; 2010; van Zoonen et al., 2014), and that intervening in young people maximizes the benefits of prevention labors (Gladstone, Beardslee, & O'Connor, 2011; O'Connell, Boat, & Warner., 2009).

A key objective of prevention-oriented health care is to propose and deliver interventions that are affordable and available to everyone, the Internet can be an effective medium to deliver mental health interventions. University students, are fully immersed in digital worlds, and their

relationships, activities, tasks and concerns are being defined by ICTs. Therefore, implementing Internet-based interventions can potentially be advantageous, compared to face-to-face interventions (Christensen & Hickie, 2010), among this population.

The strengths of this study are: First, to our knowledge, this would be the first RCT to test an online intervention for enhancing resilience in university students. Second, CORE is a multi-country two-armed simple-blind RCT that will be conducted in three countries (Spain, Germany, and Switzerland) by four research institutions, which will allow good generalization of the results in Europe. Finally, some limitations should be mentioned. First, dropout rates are expected to be high, as reported by previous research (Spek, Cuijpers, Nyklicek, Keyzer, & Pop 2007; Van Ballegooijen et al., 2014). Indeed, dropout rates have been taken into account in the sample size calculation. Second, online mental health interventions also raise some particular ethical issues, such as confidentiality and anonymity and duty of care. For this reason, international guidelines will be followed to address these concerns (Barak et al., 2009; Ritterband, Andersson, Christensen, Carlbring, & Cuijpers, 2006).

4 Conclusion

We present the design of our study aimed to promote resilience among university students. The results of this study will contribute to the growing research on Internet-delivered treatments. If the expected results are obtained, this could be a first step in the implementation of these programs to enhance the resilience and coping skills in a risk populations, as university students, to prevent common mental disorders. Furthermore, we will analyze feasible strategies to implement the program and identify possible implementation barriers for final users, professionals of University counseling services, and University authorities.

Trial Status

Recruitment started in September 2017 in Spain and will continue approximately through January 2018. Follow-up assessments for the remaining patients are expected to be completed by January 2019.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

RH, AM, GC, EE, RB, AGP, and CB designed the study. DDE, MF, TB MPS, DG and CJ contributed significantly to the study design. AM, GC, RH, EE, RB, AGP, and CB wrote the first draft of the manuscript. DDE, MF, TB MPS, DG and CJ revised the manuscript and completed the final draft. All authors contributed feedback, read, and approved the final manuscript.

Ethical Statement

This trial is conducted in compliance with the protocol, the Declaration of Helsinki and good clinical practice. The trial was registered at ISRCTN (ISRCTN13856522). The local ethical commissions in each country provided approval. Data security/confidentiality is guaranteed; all

relevant EU legislation and international texts on privacy are observed and respected. Regarding regulation at international level, starting from the OECD guidelines including the “Guidelines on the protection of privacy and transborder flow of personal data” (1981) and “Guidelines for the security of information systems” (1991/92), the ICare consortium in particular acknowledges heterogeneity in international data protection jurisdiction.

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Highlights

- University students is a risk population for mental disorders
- Resilience is a key concept in the prevention field.
- Online intervention seems a suitable tool for a preventive intervention
- CORE is an online intervention for enhancing resilience and coping skills

ACCEPTED MANUSCRIPT

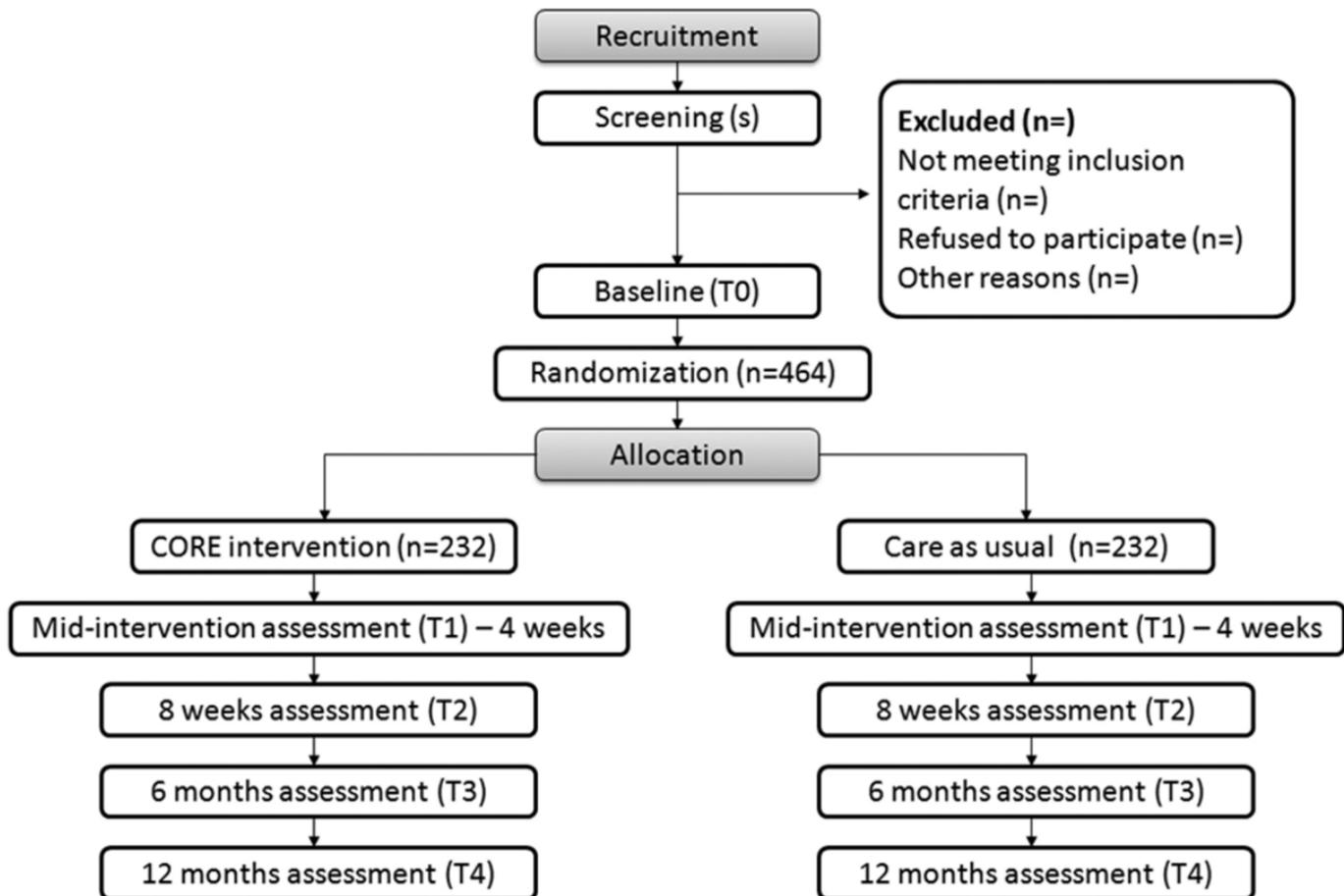


Figure 1

3. ¿Se puede aprender a ser resiliente?

Escuchar

La buena noticia es que todos aquellos elementos que te hacen una persona más resiliente, es decir, fuerte y capaz emocionalmente, se pueden aprender, desarrollar y mejorar. De la misma forma que has aprendido diferentes habilidades en tu vida, también puedes convertirte en una persona resiliente.



Como vimos anteriormente, los problemas, las adversidades, los tiempos difíciles, son parte de la vida. Todo el mundo, en un momento u otro, nos enfrentamos a circunstancias difíciles (la pérdida de un ser querido, un fracaso, un desamor,...), no podemos dejar de tenerlos o escapar de ellos. Lo que sí podemos hacer es prepararnos para hacerles frente de forma adecuada. Ten en cuenta que la resiliencia no es algo estático, bien al contrario, es algo que se va desarrollando a medida que somos capaces de hacer frente a más dificultades. En definitiva es un proceso de aprendizaje continuo.



Figure 2