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Internet delivered treatment for depression in Colombia

Submission date	Recruitment status	[X] Prospectively registered
26/10/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/07/2015	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Occurrence of depression in Colombia are greatly different from the rates reported in high-income countries. In Colombia, depression is not identified in a large percentage of affected individuals , and they either do not, or simply cannot access treatment. In Colombia there are many barriers to accessing treatment, such as waiting lists, cost of the services, and personal stigma. Treatments given for depression using the internet have been shown to be effective in a large number of studies which have taken place in high-income countries. It is possible that using the internet as a form to give treatment could overcome some of the barriers to accessing treatment that Colombians currently face. However, such internet-based treatments for depression, with or without support, have not been used within a Colombian population before. The objective of the current study is to put in place and evaluate the efficacy of an online treatment, with therapist support, for depression in a student population in Colombia.

Who can participate?
Students at the University Antonio Nariño, Bogotá, Colombia with symptoms of depression . We will aim to recruit 1,200 students to take part in the study.

What does the study involve?
Students will take part in a computerized program consisting of 5 sessions, with therapist support. This will be compared against a group of students who will wait to receive the computerized program - this is the control or waiting list group. The students will receive identical treatment.

What are the possible benefits and risks of participating?
Improvements in depression. There are no known risks of participating in the study.

Where is the study run from?
University Antonio Nariño, Bogotá, Colombia.

When is the study starting and how long is it expected to run for?
We hope to begin recruitment in February 2013 and thereafter the trial for 18 months. The current study will recruit students from 6 different sites (Bogotá, Medellín, Calí, Bucaramanga,

Manizales, and Barranquilla); representative of different regions in Colombia. It will be a staged recruitment, beginning with Bogotá running the trial as outlined and after 12 weeks starting with another site, and so on for the duration of 16 months. At each site our objective is to recruit 200 participants leading to a total sample size of 1,200 participants.

Who is funding the study?
Faculty of psychology, University Antonio Nariño.

Who is the main contact?
Dr Derek Richards
derek.richards@uan.edu.co

Contact information

Type(s)
Scientific

Contact name
Dr Derek Richards

Contact details
Antonio Narino University [Universidad Antonio Narino]
Av 1 de mayo No 13-61
Bogotá
Colombia
-
-
derek.richards@uan.edu.co

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Internet delivered treatment for depression in Colombia: a randomised controlled trial

Acronym
OTDC

Study objectives

Given the presence of elevated levels of psychopathology in the student population of Colombia there is a need for interventions. Current psychological services are overstretched and the presence of such service in Universities in Colombia is scarce. Additionally, many barriers, such as costs, exist that prevent people seeking help when they need it. Colombian students are considered a computer literate group and their attitudes towards technology-delivered interventions is positive. For these and other reasons the study hyothesises that an online intervention for depression treatment may prove useful and demonstrate effectiveness.

Please note that as of 16/08/2012 this record was updated extensively. Changes can be found in the relevant fields with the above update date. Additional changes are as follows:
1. The target number of participants was changed from 200 to 1,200.
2. The overall trial start date was changed from 01/02/2012 to 01/01/2013.
3. The overall trial end date was changed from 01/10/2012 to 01/05/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Antonio Nariño University, 11/11/2011

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Depression

Interventions
Current interventions as of 16/08/2012:
The study is a randomised controlled trial of a computerised cognitive-behaviour therapy (cCBT) program, called !Yo Puedo Sentirme Bien! is a 5-session online delivered cognitive-behavioral therapy program. The program begins with an introduction that includes how the user can navigate the program and the essential features of the program. The introductory module explaines to users the key features of the 'Depression Cycle' and how cognitive-behavioral therapy (CBT) will help a user come to a deeper understanding and equip them with skills and strategies to manage their depression. The course proceeds with a module on behavioral

activation, specifically learning that what one does influences how one feels; the focus is on engaging in pleasurable activities. Following that two further modules focus on the identification and challenging negative automatic thoughts, investigating core beliefs and behaviorally and cognitively challenging those. The program uses a range of different exercises and other interactive applications both to engage the user and help the user learn the different CBT skills and strategies and apply these to their own lives. The final module helps the user plan a management strategy to prevent future relapses and/ or recurrences. All exercises and applications can also be downloaded in paper format for use outside of the program. Each module ends with a summary sheet that can be downloaded and taken away for future reference.

1. An active treatment group
2. A waiting list control.

The active condition consists of 5 modules of cCBT, over 5 weeks, with support from a clinician providing weekly feedback on progress and exercises. The intervention teaches the principles of CBT and also different cognitive and behavioural strategies that participants can learn to help manage their depressive symptoms.

Participants in the waiting list receive access to the treatment at week 6.

The study seeks to observe and evaluate the effect of the treatment on changes in depressive symptoms in participants. Data will be collected at baseline and at the end of treatment, week 6 and at follow-up, week 18 (3-months) and week 30 (6-months).

Previous interventions until 16/08/2012:
The study is a randomised controlled trial of a computerised cognitive-behaviour therapy (cCBT) program, called MindBalance which was initially developed in Ireland and later translated from English to Spanish and further adapted for use in Colombia for the treatment of depression. The trial will be conducted with a student population sample and include two conditions:
1. An active treatment group
2. A waiting list control.

The active condition consists of 6 modules of cCBT, over 6 weeks, with support from a clinician providing weekly feedback on progress and exercises. The intervention teaches the principles of CBT and also different cognitive and behavioural strategies that participants can learn to help manage their depressive symptoms.

Participants in the waiting list receive access to the treatment at week 7.

The study seeks to observe and evaluate the effect of the treatment on changes in depressive symptoms and in general mental health functioning. Data will be collected at baseline and during treatment week 3, at the end of treatment, week 6 and at follow-up weeks 12, 24, and week 32.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Current primary outcome measures as of 16/08/2012:
Depressive symptoms: The Center for Epidemiological Studies Depression scale (CES-D)

Previous primary outcome measures until 16/08/2012:
Depressive symptoms and general mental health functioning

Secondary outcome measures
Current secondary outcome measures as of 16/08/2012:
1. Helpful Aspects of Therapy Form (HAT)
2. Satisfaction with Treatment (SAT)
3. Reasons for dropout

Previous secondary outcome measures until 16/08/2012:
1. The working alliance online
2. Satisfaction with online delivered treatments
3. Helpful and hindering in-session events in online treatments, and reasons for dropout

Overall study start date
01/01/2013

Completion date
01/05/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 16/08/2012:
1. Registered student at the University

Previous inclusion criteria until 16/08/2012
1. Age 18 years and over
2. Depressed as assessed by a score of 14-29 on the Beck Depression Inventory (BDI)
3. Registered student at the University

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,200

Key exclusion criteria

1. Serious suicidal intent
2. Psychotic illness
3. Alcohol or drug abuse
4. Previous diagnosis of a mental disorder
5. Depression preceding or coinciding a diagnosed medical condition

Date of first enrolment
01/02/2013

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
Colombia

Study participating centre
Antonio Narino University [Universidad Antonio Narino]
Bogotá
Colombia
-

Sponsor information

Organisation
Antonio Nariño University [Universidad Antonio Nariño] (Columbia)

Sponsor details
Calle 58 A No. 37-9457
Bogotá
Colombia
-
+57 (1) 278 4826
derek.richards@uan.edu.co

Sponsor type
University/education

Website
http://www.uan.edu.co/

ROR
https://ror.org/014hpw227

Funder(s)

Funder type
University/education

Funder Name
Antonio Nariño University (Columbia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration