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Targeted school based intervention to improve depressive symptoms among at risk Chilean adolescents

Submission date
28/05/2011

Recruitment status
No longer recruiting

Registration date
29/06/2011

Overall study status
Completed

Last Edited
05/08/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Depression is a major problem among adolescents, especially in those from low-income families. There is an urgent need to develop effective interventions to help adolescents cope with depressive symptoms in resource-poor settings. This must become a priority, especially when it is known that preventing, delaying or early treatment of depression can have profound implications. This study aims to assess the effectiveness of a group psychosocial treatment (group therapy) to improve depressive symptoms.

Who can participate?
Secondary school students (ages 13 to 18) with depressive symptoms

What does the study involve?
Participants are randomly allocated to either the active group or the control group. The intervention group attends eight weekly group therapy sessions, each lasting 45 minutes, delivered by trained psychologists. The control group receives no treatment. Depressive symptoms are assessed at the start of the study and 3 months after the end of the intervention. If any student reports severe depressive symptoms they are referred to a Primary Care Unit for treatment.

What are the possible benefits and risks of participating?
The intervention is unlikely to harm the students and the sessions are closely supervised by a highly trained clinical psychologist.

Where is the study run from?
Universidad de los Andes (Chile)

When is the study starting and how long is it expected to run for?
August 2010 to December 2011

Who is funding the study?
Wellcome Trust (UK) ref: 082584 Z/07/Z

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Targeted school based intervention to improve depressive symptoms among at risk Chilean adolescents: a randomized controlled trial

Study objectives
1. To carry out a randomized controlled trial to evaluate a targeted, school based intervention to improve depressive symptoms among at risk secondary school students at state schools
2. To quantify the effectiveness and cost-effectiveness of this intervention in reducing depressive symptoms among adolescents
3. To assess improvements in levels of functioning as secondary outcome measures and the role of mediating factors such as problem solving skills and dysfunctional negative thoughts

Hypotheses:
1. There will be an absolute difference of 20% between intervention and control groups in recovery rate 3 months after completing the of the intervention
2. Adolescents receiving the intervention will show greater reductions in negative thoughts and improvements in problem solving skills than those in the control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, University of the Andes, Chile (Universidad de los Andes), November 2010

Study design
Single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

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
Depressive symptoms

Interventions
1. The intervention was based on a cognitive-behavioural therapy model, delivered to targeted students in a pre-defined school room
2. The program consisted of 8 weekly sessions each lasting 45 minutes. there was a introductory session, three sessions dealing with thought re-structuring, three sessions of problem solving and one closing session with a revision of the learning and planning for future
3. The intervention was delivered by trained psychologists (facilitators)
4. These workers had a detailed manual specifying key learning points and objectives for each session
5. Facilitators received 2 days of training which covered the identification and management of mental health concerns, group management techniques as well as training to deliver the specific intervention
6. The intervention was fully manualized
7. During the course weekly supervision groups were provided for facilitators
8. Supervisor was a experienced Senior Clinician from the local team
9. She participated in the initial intervention training sessions so that she was familiar and

knowledgeable about the intervention
10. One of the lead applicants offered support and advice to the supervisor when needed

Control group
The control group received nothing other than the normal teaching activities and assessments

Evaluation of opt-in and opt-out recruitment strategies suggested that opt in strategies resulted in lower recruitment rates and healthier participants. Some authors have suggested that opt-out approaches should be the default recruitment strategy for interventions that pose a low risk to participants. The participants in this study were not referred patients, the intervention was low risk, and as such we used an opt-out approach. At the start of the project a letter was sent to the carers of all eligible young people informing them about the study. The letter therefore informed carers that they could opt out of the assessments if they did not wish their child to complete the questionnaires. In addition, written child consent was obtained before completing the questionnaires i.e. dual carer/child consent/assent was required.

Intervention Type
Behavioural

Primary outcome measure
1. Beck Depression Inventory II (BDI-II) was was to assess depressive symptoms and to determine recovery rate: percentage of students included in the study who had lower than 11 points for boys and lower than 16 points for girls 3 months after completing the intervention
2. This is a brief and well-established depression questionnaire translated to different languages and used widely throughout the world
3. It has previously been used among adolescents in Chile and in other Latin-American countries showing good psychometric properties
4. It is self-completed which has the advantage of reducing potential observer bias since it is unlikely that observers will be completely blind to allocation
5. The BDI- II also provides a good measure of the cognitive changes expected to occur with the intervention

Secondary outcome measures
1. Revised Child Anxiety and Depression Scale (RCADS): this is an adaptation of the Spence Child Anxiety Scale (SCAS) and intends to assess symptoms of DSM-defined anxiety disorders and major depression
2. The scale consists of 47 items that on the basis of exploratory factor analysis are allocated to six subscales:
2.1. Social phobia (9 items)
2.2. Panic disorder (9 items)
2.3. Major depressive disorder (10 items)
2.4. Separation anxiety disorder (7 items)
2.5. Generalized anxiety disorder (6 items)
2.6. Obsessive-compulsive disorder (6 items)
3. Items have to be scored on a 4 point scale
4. RCADS subscale scores can be obtained by summing across relevant items
5. We excluded the depression and separation anxiety sub-scales because these were either covered by other scales or irrelevant to students of this age
6. School records of academic performance: we will only use grades obtained through formal testing because these are standardised across schools
7. Other assessments:

7.1. Measures of psychological functioning: Childrens Automatic Thoughts Scale (CATS)This self completed scale assesses a range of negative self statements in children and young people aged 7-16. For each item the child is asked to rate whether they have had a similar thought over the past week. Each item is rated as not at all (scores 0), sometimes (scores 1), fairly often (scores 2), often (scores 3) or all the time (scores 4)
7.2. Confirmatory factor analysis identified 4 distinct but correlated factors relating to thoughts about physical threat, social threat, personal failure and hostility. Internal consistency for the total score was high (Cronbach Alpha=0.95) with acceptable test retest reliability (0.79). The scale has been found to effectively discriminate between a community and clinical sample with the personal failure sub-scale being the strongest predictor of depressive symptoms. The 10 item personal failure sub-scale will be used.
7.3. The Short Form of the Social Problem-Solving Inventory Revised (SPSI-R Short Form)will be used to assess problem-solving dimensions. The SPSI-R Short Form is a 25-item self-report instrument that measures two adaptive problem-solving dimensions (positive problem orientation and rational problem solving) and three dysfunctional dimensions (negative problem orientation, impulsivity/carelessness style, and avoidance style). Each item is rated on a 5-point scale ranging from not at all true of me (0) to extremely true of me 7.4. Alpha coefficients for the subscales range from .72 to .85
7.5. Studies with the Spanish version of the SPSI-R Short Form confirmed its factor structure and obtained adequate alpha coefficients for the five subscales. In the more recent study, alpha coefficients were .55, .73, .66, .70, and .69 for positive orientation, negative orientation, rational solving, impulsivity, and avoidance, respectively.

Overall study start date
01/08/2010

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Adolescents attending Second secondary grade in state schools (ages 13 to 18 years)
2. State schools located in Santiago of Chile
3. Adolescents with depressive symptoms over a cut-off score: in boys > 10 and in girls > 15

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
The total recruitment of participants for the trials was 300 students

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Chile

Study participating centre
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ROR

https://ror.org/03v0qd864

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust (UK) ref: 082584 Z/07/Z

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/08/2016		Yes	No