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Randomised controlled trial of a school-based intervention to improve the mental health of low-income, secondary school students in Santiago, Chile

Submission date
07/11/2010

Recruitment status
No longer recruiting

Registration date
10/11/2010

Overall study status
Completed

Last Edited
04/09/2013

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
Cluster randomised controlled trial of a school-based intervention to improve the mental health of low-income, secondary school students in Santiago, Chile

Acronym
YPSA

Study objectives
1. Students receiving the intervention will achieve lower scores (difference in mean of at least 0.4 standard deviations) in the depressive questionnaire in comparison to the control group 3 months after completing the course
2. Symptomatic improvements achieved at 3 months will be maintained until the final assessment 12 months after completing the course
3. The intervention will be more effective at 3 and 12 months follow up among students with higher depression scores at baseline
4. Students receiving the intervention will show greater reductions in negative thoughts and improvements in problems solving skills than those in the control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital Clinico Universidad de Chile Ethics Board approved on the 30th June 2008 (ref: 178)

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Intervention:
The intervention will be based on a CBT model delivered to all students in the class during school hours. The programme consists of 11 weekly and 3 booster group sessions each lasting one hour. There is an introductory session, 5 sessions dealing with thought re-structuring, 1 session related to identifying emotions, 3 with problem solving and 1 closing session with a revision of the learning and planning for the future.

Eight trios of trained research workers (psychologists, teachers, social workers, and others) deliver the intervention. These workers will have a detailed manual specifying key learning points and objectives for each session and students will receive a similar but shortened workbook. Methods include didactic sessions; small group and class interactive exercises.

Three additional booster sessions will be delivered at 2, 7, and 9 months after the intervention is completed. Teachers assist with the discipline of the class in special circumstances. Facilitators receive five days of training which cover the identification and management of mental health concerns, group management techniques as well as training to deliver the specific intervention. The intervention is fully manualised. During the course weekly supervision groups will be provided for facilitators.

Control:
The control group will receive nothing other than the normal teaching activities and assessments. At present all classes receive one curricular hour weekly for counselling delivered by their head-teachers. We will advise teachers to put more emphasis on emotional problems for 12 weeks giving more and better information, allowing students to exchange experiences and provide mutual support. If the active intervention proves to be more effective, we will implement the course in all control schools after completion of the trial.

Duration of course: 3 months plus 3 booster sessions in the following 18 months
Duration of follow up: 3 and 12 months after completing intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Beck Depression Inventory at 3 months after completing intervention

Secondary outcome measures
1. Revised Child Anxiety and Depression Scale (RCADS). We will exclude the depression and separation anxiety sub-scales because these are either covered by other scales or irrelevant to students of this age.
2. School records of academic performance: we will only use grades obtained through formal testing because these are standardised across schools

Overall study start date
01/04/2009

Completion date

31/07/2011

Eligibility

Key inclusion criteria
All students will be invited to participate (ages 13 - 15 years, either sex)

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
2634

Key exclusion criteria
Students in either trial arm with severe depressive episodes, according to Beck Dpression Inventory (BDI-II) baseline assessment, but with no marked suicidal ideation will be invited to attend but also encouraged to seek professional advice. Students with marked suicidal ideation at baseline in either group will be referred for a clinical assessment in their primary care clinic. Students admitted to hospital for mental health reasons during the trial and those with serious alcohol/drug use will be advised to continue with their prescribed treatment and in case of doubt will be referred for a clinical assessment.

Date of first enrolment
01/04/2009

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Chile

England

United Kingdom

Study participating centre
Cotham House
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Sponsor information

Organisation
University of Bristol (UK)

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Sponsor type
University/education

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ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 082584)

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?
Protocol article	protocol	19/02/2011		Yes	No
Results article	results	01/11/2013		Yes	No