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Emotion regulation as the stepping stone for youth mental health: testing the efficacy of the prevention program 'Boostcamp'

Submission date
08/05/2017

Recruitment status
No longer recruiting

Registration date
13/06/2017

Overall study status
Completed

Last Edited
23/07/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The transition from childhood into adolescence is a time of development, which involves physical, mental, emotional challenges. These developments often coincide with issues such as stronger reactions and vulnerability to developing mental health problems. Studies have shown that at least 15-20% of adolescents suffer from mental health issues. Boost Camp is a new universal prevention program which aims to stimulate the use of emotion regulation strategies, improve adolescent mental health, lower risk for developing mental health problems during the stressful life period of school transition, and increasing mental health knowledge while decreasing stigmatization (negative associations). The aim of this study is to find out whether delivering this program to adolescents can help improve their mental health and emotion regulation.

Who can participate?
Adolescents in their first year of secondary school.

What does the study involve?
Participating schools are randomly allocated to one of two groups. Those in the first group continue as normal for the duration of the study. Those in the second group take part in the Boost Camp program. This involves learning and practicing emotional awareness, acceptance, relaxation, distraction, cognitive reappraisal and problem solving through exercises, both as individuals and in groups. Participants fill out questionnaires about mental health and emotion regulation four times through the first year of high school. This happens during school time and under the supervision of the classroom teacher and someone of the department.

What are the possible benefits and risks of participating?
Participating in the study can be beneficial for the participating schools, because they can receive an overall report of the results about the mental health status of their students. The classes who participate gain a class photo-shoot as a reward for their commitment. There are no significant risks involved with participating. Although participation requires time and investment from management board, teachers and their students.

Where is the study run from?
Six schools located in Flanders (Belgium)

When is the study starting and how long is it expected to run for?
April 2016 to May 2018

Who is funding the study?
Research Foundation Flanders (Belgium)

Who is the main contact?
1. Miss Brenda Volkaert (public)
2. Miss Laura White (scientific)

Contact information

Type(s)
Public

Contact name
Miss Brenda Volkaert

ORCID ID
http://orcid.org/0000-0002-9550-8653

Contact details
Ghent University
Henri Dunantlaan 2
Ghent
Belgium
9000

Type(s)
Scientific

Contact name
Miss Laura Wante

Contact details
Ghent University
Henri Dunantlaan 2
Gent
Belgium
9000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0E9217N

Study information

Scientific Title
Evaluating efficacy of a school-based transdiagnostic adolescent mental health prevention program, targeting emotion regulation: a randomised controlled trial

Study objectives
Compared to adolescents in the control group, adolescents in the Boost Camp group will show better mental health and more adaptive emotion regulation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Emotion Regulation (ER)

Interventions
When schools agree to participate, they are randomly assigned to the controle or the intervention condition. In this way, randomisation is clustered since the participating classes of one and the same school are always in the same condition.

Intervention group: Students from schools in the intervention group receive an school-based adolescent training, named 'Boostcamp'. This is a group training for adolescents who are making the transition from primary to secondary school and focuses on improving ER and social skills. The program consists of three different parts:

1. An information moment in which the program is explained and written informed consent will be collected
2. A two-day ‘immersion’ training program
3. Two booster sessions over the subsequent three months of the first semester.
The training is organized at the beginning of secondary school. During two full days, youngsters learn about adaptive ER strategies, social skills, and how to use them in challenging emotional and social situations. The trainers or employees or students of our department, with at least a bachelor's degree in psychology and are coached and guided by the two main investigators who are also trained clinical psychologists.

Control group: Students from schools in the control condition are asked to fill out all the self report questionnaires just like students in the experimental condition and on the same time. However, the control condition do not participate in the two-way training program or the boostersessions.

There are two follow-up measurements: one at the end of the first semester (December 2017) and one at the end of the second semester (May 2018). Both assessments include the same questionnaires as at the baseline.
The students in the experimental condition receive two ‘boostersessions’, in which they repeat the learned theory and skills of the Boostcamp and get opportunities to practice with lifelong situations under the supervision of trainer. These Boostersessions take place before and between the two follow-up moments (at the end of December and at the end of March).

Intervention Type
Behavioural

Primary outcome measure
1. Adolescent mental health is assessed using the Youth Self Report (YSR), Positive and Negative Affect Schedule for Children (PANAS-C), Children’s Depression Inventory (CDI), Compententie Belevingsschaal voor Adolescenten (CBSA), and KIDSCREEN-10 HRQoL for Children and Adolescents (KIDSCREEN-10) at baseline, 8 weeks and 6 months
2. Emotion regulation is assessed using the FEEL-KJ questionnaire, the emotion regulation skills questionnaire (ERSQ) and he subscale 'Emotional Awareness' of the Difficulties in Emotion Regulation Scale (DERS) at baseline, 8 weeks and 6 months. The positive and negative affect (PANAS-C), depression (CDI), emotion regulation skills (ERSQ) and Global Self Worth (CBSA) are assessed immediatly after the two days training (in the last hour of the training).

Secondary outcome measures
1. Mental health knowledge and stigma is measured using qualitative questions at baseline, 8 weeks and 6 months
2. School absenteeism and academic achievement are measured by the school through the whole school year as usual and will be delivered to the investigator after the last questionnaires

Overall study start date
25/04/2016

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Aged 10 - 14 years
2. In the first year of secondary school
3. In a participating class

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
10 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
Six schools (3 control, 3 intervention), 14 classes (7 control, 7 intervention), 280 students (140 control, 140 intervention)

Key exclusion criteria
Not meeting inclusion criteria.

Date of first enrolment
01/02/2017

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
Belgium

Study participating centre
Leiepoort campus Sint-Hendrik
Guido Gezellelaan 105
Deinze
Belgium
9800

Study participating centre

VTI
Leon Declercqstraat 1
Deinze
Belgium
9800

Study participating centre
Koninklijk Atheneum Erasmus Deinze
Volhardingslaan 11
Deinze
Belgium
9800

Study participating centre
Ten Doorn
Zuidmoerstraat 125
Eeklo
Belgium
9900

Study participating centre
Mariagaard
9230, Oosterzelesteenweg 80
Wetteren
Belgium
9230

Sponsor information

Organisation
Ghent University

Sponsor details
Henri Dunantlaan 2
Ghent
Belgium
9000

Sponsor type
University/education

Website
ugent.be

ROR
https://ror.org/00cv9y106

Funder(s)

Funder type
Government

Funder Name
Fonds Wetenschappelijk Onderzoek

Alternative Name(s)
Research Foundation Flanders, Flemish Research Foundation, FWO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Belgium

Results and Publications

Publication and dissemination plan
The intention is to submit a protocol paper of the study before the first assessment take place (September 2017) and an article get published after one year of the overall trial and date in a high-impact peer reviewed journal.

Intention to publish date
31/05/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	21/07/2018	Yes	No