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Evaluation of a school-based mental health program

Submission date	Recruitment status	[ ] Prospectively registered
30/03/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/04/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/04/2015	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Depression or persistent feelings of sadness and hopelessness lowers the quality of life in adolescents. Depression can also block progress in learning and development of social and emotional skills. In recent times there has been a big increase in Swedish adolescents reporting feeling depressed or experiencing stress. Preventing depression in adolescents can both lessen individual suffering and lower the costs (financial and social) associated with the disorder. Treatments aimed at preventing depression or depressed feelings in adolescents are being used more and more within the school system. This is often in the form of group-based programs led by school nurses, school social workers or teachers. An example of such a program used frequently in Sweden today is called Depression in Swedish Adolescents (DISA). Group participants don't have to have depression so it's a universal prevention program. DISA involves ten structured 1.5 hour group sessions held once a week. The groups have around ten participants and are led by group leaders trained in the DISA method. DISA is usually used with girls in grade 8 (age 14). The aim of this study is to see whether interventions using DISA work well in preventing depression in adolescents, both boys and girls, and to also see what the health-economic benefits of the program might be.

Who can participate?
Male and female students in grade 8 (Sweden).

What does the study involve?
Participants are divided into two groups: students who attend DISA-program meetings which are held during school hours, and students who attend school as usual. The program is held on school premises and is carried out by trained and experienced DISA tutors who are school nurses, school social workers or teachers. Participants complete survey questionnaires which are given at different times during the course of the study. All participants also have both group and individual interviews.

What are the possible benefits and risks of participating?
A benefit of participating is that it will help provide information on whether a universal depression prevention program in schools can help lower the number of adolescents suffering from depression.

Where is the study run from?
Schools in six municipalities in southern Sweden.

When is the study starting and how long is it expected to run for?
March 2012 to June 2018

Who is funding the study?
Kristianstad University (Sweden)

Who is the main contact?
Pernilla Garmy (Sweden)
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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
Preventing mental disorders in adolescents with school based systematic interventions: an effectiveness study in a school setting

Study objectives

DISA originates from a program developed in the US called the Coping With Stress course (CWS) which was directed at teenagers (boys and girls), especially those with evidence of depressive symptoms. CWS was found to be effective in the US however no study has been carried out to see whether the Swedish DISA-program is effective in Sweden. Health-economic evaluations of school based programs aimed at preventing depression in adolescents in Sweden have been lacking thus far, and both the National Board of Health and Welfare and the Swedish Council on Health Technology Assessment have called for such studies. Thus, the the aim of this study is to examine whether the mental health program DISA is feasible and promotes well-being and mental health in adolescents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Lund University, 15/08/2012, ref: 2012/462

Study design
Quasi-experimental longitudinal design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
School

Study type(s)
Prevention

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
School based DISA-program (a cognitive behavioral, manual based, program)

Intervention Type
Behavioural

Primary outcome measure
Depressive symptoms and health related quality of life:
1. Survey at three time-points: baseline, 3 and 12 months, with follow-up at 2, 3, and 4 years. Survey questionnaires concern depression, anxiety, sleep, salutogenic health and quality of life (Center for Epidemiologic Studies Depression Scale (CES-D), Spence Children's Anxiety Scale (SCAS) and EQ-5D™, Salutogenic Health Indicator Scale (SHIS), Insomnia Severity Index, respectively) and are distributed to 300 adolescents belonging to the intervention group, and to

300 belonging to the control group
1.1 Aim: investigate whether DISA is effective in preventing depression in adolescents
2. Focus group interviews with those leading the sessions and with the adolescents participating in them
2.1 Aim: to determine how both those leading the sessions and the adolescents participating in them viewed DISA
3. Interviews with the adolescents
3.1 Aim: learn how the adolescents experienced their participation in DISA
4. Health economic evaluation
4.1 Aim: study the cost effectiveness of DISA

Secondary outcome measures
1. Feasibility and cost-effectiveness

Overall study start date
01/03/2012

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. At baseline the participants are students in grade 8 (aged ~14)

Participant type(s)
Mixed

Age group
Child

Lower age limit
14 Years

Sex
Both

Target number of participants
1500

Key exclusion criteria
No exclusion criteria

Date of first enrolment
01/09/2012

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Kristianstad University
Department of Health and Society
Kristianstad
Sweden
291 88

Study participating centre
Lund University
Centre for Primary Health Care Reserach
Lund
Sweden

Sponsor information

Organisation
Kristianstad University

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Sponsor type
University/education

Website
www.hkr.se

ROR
https://ror.org/00tkrft03

Funder(s)

Funder type
University/education

Funder Name
Kristianstad University

Results and Publications

Publication and dissemination plan
We want to publish data in 2015 - 2018 (findings from the 1 year follow-up can be published in 2015, findings from the 2, 3 and 4 year follow-up can be published 2016-2018).

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request