

Evaluating the Youth Aware of Mental Health (YAM): a mental health promotion program for schools

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Registration date 27/06/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/06/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Depression, suicide and suicidal behaviours are serious public health concerns in Europe as well as in other parts of the world. The results of a previous European study called "Saving and Empowering Young Lives in Europe" showed that a school-based educational program called YAM (Youth Aware of Mental Health) was effective at preventing incident suicide attempts and severe suicidal ideation among school pupils in ten EU countries. The risk was reduced by about 50% among pupils who received YAM compared to pupils who did not. This study aims to investigate if the YAM program is effective in Sweden. The study will also investigate if the program has other positive benefits to the adolescents such as an increase in knowledge about mental health, increase in help-seeking behaviours, increased self-esteem, increased empathy and classroom climate. Lastly, the study aims to map different facilitators or barriers for a wider range implementation.

Who can participate?

The study is carried out among elementary and junior high schools in Stockholm County, Sweden. The YAM program is intended for both boys and girls in grades 7 and 8 (which normally corresponds to 13-14 years of age, but some pupils may be slightly younger or older). All schools in the County that include this age group are invited to participate in the study, with the exception of those that are very small (less than 20 pupils per grade), specialized, or using a language other than Swedish. All pupils in the 7 and 8 grade are asked to participate, whether or not they have a history of mental health problems.

What does the study involve?

Participating schools are randomly allocated to either deliver the YAM program or to be put on a waiting list. The YAM program is a 5 hour program and is given to pupils in their regular classes by specially trained instructors, and not by the normal school staff. The YAM program increases adolescents' awareness and knowledge of mental health and mental health problems, stress and crises, depression and suicidal thoughts. It teaches them self-help advice, and provides them with information about how and where to seek appropriate help and support if they experience a problem which is too big for them to solve on their own. It also teaches them how to recognize

if a friend has such problems, and what they can do to help. The program is taught through two one-hour lectures, a booklet, information posters, and three different kinds of role plays (1 hour each) where the pupils are actively engaged to discuss different problems (e.g. what to do when they are very stressed, what to do if they are depressed or suicidal, how to help a troubled friend). During the study, participants with active and severe suicidal ideation or with a recent suicide attempt (past 2 weeks) are referred to a licensed psychologist. All participants are followed up during a 12 month period. The data collection is carried out using questionnaires. At the end of the study, all pupils in the waiting list schools also receive YAM.

What are the possible benefits and risks of participating?

Students are likely to benefit from participating in YAM, as they will be better equipped to handle mental health problems in the future. YAM has been found in a previous trial to be effective AT reducing the incidence of suicide attempts and severe suicidal ideation. Moreover, participants with a recent suicide attempt or suicidal ideation in the previous two weeks will be able to seek help from the YAM staff and talk to a licensed psychologist. No risks or side effects of the program have been noted in the previous study.

Where is the study run from?

1. Stockholm County Council Healthcare Services (Sweden)
2. Karolinska Institutet (Sweden)

When is the study starting and how long is it expected to run for?

January 2016 to December 2020

Who is funding the study?

Stockholm County Council (Sweden)

Who is the main contact?

Prof. Danuta Wasserman

Study website

<http://www.sll.se/yam/>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2016/2175-31/5

Study information

Scientific Title

The YAM cluster randomized controlled trial in Stockholm County

Acronym

YAM-Stockholm

Study objectives

The main hypothesis is that the YAM intervention will reduce the incidence of suicide attempts, severe suicidal ideation and depression. Additional hypotheses regard an increase in knowledge about mental health, increase in help-seeking behaviors, increased in self-esteem, increased empathy and classroom climate. The incidence will be assessed at 3 month and 12 month follow-up.

The intervention is a universal prevention program, and the hypothesis regards a preventive effect of the intervention, but not a treatment effect; thus the risk reduction is not expected to be observed in individuals who are already depressed or suicidal at baseline. The intervention has previously been tested in a previous European school-based study (Saving and Empowering

Young Lives in Europe [SEYLE] randomized controlled trial) with positive results in reducing suicidal behaviours. The aim is to test the effects of the YAM Programme among Swedish pupils and to assess potential factors that may mediate the mental health related outcomes.

The study also includes a process evaluation, which aims to follow the implementation process to investigate facilitators and barriers to introducing the intervention program in Swedish schools.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regionala Etikprövningsnämnden i Stockholm (the regional ethics committee in Stockholm), 26 /11/2015, diary number: 2016/2175-31/5

Study design

School-based cluster-randomized controlled trial with a waitlist design, longitudinal with 3 months and 12 month follow-up

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Suicidal behaviour and depression

Interventions

The intervention that is evaluated in this study is the “Youth Aware of Mental health” (YAM) program. YAM is an universal school-based mental health promotion program. It aims to facilitate discussion and reflection about mental health in the classroom. The intervention takes place within the pupil’s normal school classes for the duration of 5 hours in total. The 5 hours are divided into 3 sessions, 1 week apart. In the first session (first week, 2 hours), participants receive a booklet comprised of six themes: Awareness of mental health; Self-help advice; Stress and crisis; Depression and suicidal thoughts; To help a troubled friend; To seek advice and who to contact).

They also partake in an introductory lecture with the same themes, and are engaged in role-play discussions (Theme 1: Dilemmas and choices). In the second session (second week, 2 hours), the pupils are engaged in two roleplays about mental health (Theme 2: Feelings and how to handle

stress and crisis situations; Theme 3: Depression and suicidal thoughts and how to help oneself or a friend). In the third session (third week, 1 hour), the instructors summarize the experiences and hold a closing lecture that can be adapted to specific topics that has been discussed in the class during the previous sessions. Posters are displayed in the classroom or in common places inside the school during the whole three-week period, with the same six themes covered by the booklet, including relevant contact information to help resources. The intervention sessions are led by trained instructors.

Participants are cluster-randomized on the basis of schools to intervention (YAM) and control conditions. Controls are placed in a waiting list to receive YAM after the 12 month follow-up. Participants in the same school are therefore not randomized into different conditions. Blinding is not possible due to the need of scheduling the intervention with the schools.

Questionnaires are used to evaluate the intervention, and to screen for emergency cases (pupils with immediate risk of suicide determined by one of the subscales in the questionnaire). Participant's identities are encrypted in the questionnaire using unique participation codes, which enables data to be connected longitudinally. Participants provide their personal information and contact information in a separate physical document (key of the study) and these are stored securely and separately from the dataset. Researchers do not have access to the key of the study. Only the main project administrator can connect both pieces of information, which will done exclusively when a participant screens positive for suicide risk and is thus identified as an "Emergency case". These emergency cases are contacted by a psychologist who carries out a semi-structured suicide risk assessment, discuss the pupil's life situation, and who can refer him/her to an appropriate source of help (e.g. child and adolescent psychiatry). This emergency intervention is provided to pupils regardless of experimental condition.

Students who receive the emergency intervention are excluded from data analysis. All students that report previous history of suicide attempts and suicidal ideation (prevalent cases) are excluded from the study as well. The analysis of incident cases only is done to evaluate the preventive effects of the intervention and not the treatment effects.

Intervention Type

Other

Primary outcome measure

1. Suicidal behaviors measured with Paykel suicide scale
 2. Depression is measured through Beck's Depression Inventory – Second edition (BDI-II)
- The primary outcomes are evaluated using electronic questionnaires, administered on tablets in classrooms during school hours. The questionnaires are administered at baseline (one week before the intervention is initiated) and at 3 and 12 month follow-up.

Secondary outcome measures

1. Mental health knowledge
2. Self-esteem
3. Empathy and classroom climate

The secondary outcomes are evaluated using electronic questionnaires, administered on tablets in classrooms during school hours. The questionnaires are administered at baseline (one week before the intervention is initiated) and at 3 and 12 month follow-up.

Overall study start date

12/01/2016

Completion date

31/12/2020

Eligibility

Key inclusion criteria

The inclusion criteria apply mainly at the school-level, as all pupils in the target age group in the selected schools are eligible for recruitment. The sample consists of a random sample of elementary schools and junior high schools within Stockholm County and will comprise approximately 10000 pupils

1. All state schools and private schools in Stockholm County that teaches pupils in grade 7 and 8 are eligible for recruitment
2. The school authority agrees to participate
3. Participation in the questionnaire survey requires informed consent (written consent from both parents/guardians is required from pupils under the age of 15 and written consent from pupils over 15 years old)

Participant type(s)

Other

Age group

Child

Sex

Both

Target number of participants

10000

Key exclusion criteria

The exclusion criteria apply mainly at the school-level, as all pupils in the target age group in the selected schools are eligible for recruitment

1. The school is a specialized school
2. The school authority does not agree to participate
3. Schools that have less than 20 pupils per grade
4. Schools where all education/teaching based on a language other than Swedish

Date of first enrolment

09/01/2017

Date of final enrolment

31/12/2019

Locations

Countries of recruitment

Sweden

Study participating centre

**National centre for suicide research and prevention (NASP), Stockholm County Council
Healthcare Services**

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Solna

Sweden

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Study participating centre

National centre for suicide research and prevention (NASP), Karolinska Institutet

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Sponsor information

Organisation

National Centre for Suicide Research and Prevention, Karolinska Institutet

Sponsor details

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Sponsor type

University/education

Website

<https://ki.se/nasp/start>

ROR

<https://ror.org/056d84691>

Funder(s)

Funder type

Government

Funder Name

Stockholms Läns Landsting

Alternative Name(s)

Stockholm County Council

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Results and Publications

Publication and dissemination plan

Publication of the results of the study is planned in high-impact peer reviewed journals. There are no other public documents available for the study.

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

The data will be held at the National Centre for Suicide Research and Prevention at Karolinska Institutet. Participant level data is not expected to be made available because all the gathered information regards minors (age range 13-16). Even if the data is anonymised, it is possible that study subjects might be recognised through information regarding suicide attempts, dates, attended schools etc. Partial datasets including selected variables may be available upon request and after allowance by the ethics committee.

IPD sharing plan summary

Not expected to be made available