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The effects of Grubbel - a web-based group course intervention for 15-25 year olds having parents with substance use problems or mental illness

Submission date
30/08/2016

Recruitment status
No longer recruiting

Registration date
31/08/2016

Overall study status
Completed

Last Edited
25/09/2017

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
Depending on how the problem is defined, between 5-20% of all Swedish children grow up with parents who have alcohol problems, which may affect the children negatively. Nine out of ten Swedish municipalities therefore provide resources for support, but less than 2% of these children are reached by this support. Delivering support programs via the internet is a promising strategy. However, web-based programs targeting this at-risk group of children are scarce. Previously, the study team developed a 1.5 hour long web-based self-help program (Alcohol & Coping) which appears to be an effective way to control the adolescent's own alcohol consumption. However, there is a need for a more intense program, and therefore Kopstoring, a comprehensive Dutch psycho-educative (education for people with mental health problems) prevention program, has been adapted to fit the Swedish context. The purpose of the program, in Swedish called Grubbel, is to strengthen protective factors, such as coping skills and mental well-being, prevent the development of mental health disorders, and to reduce alcohol consumption. The aim of this study is to evaluate the effectiveness of Grubbel, at improving coping strategies, mental health status and substance use.

Who can participate?
15-25 year olds who have at least one parent with a substance use problem and/or mental illness.

What does the study involve?
Participants are randomly allocated to one of two study groups. Those in the first group take part in Grubbel. This involves eight weekly online chat meetings lasting for 1.5 hours each, with a final follow up meeting in the ninth week. Each session fosuses on different themes: (1) getting acquainted with the home situation, (2) roles in the family, (3) thoughts and feelings, (4) questions and answers about mental health problems, risky alcohol use, addiction, and heredity, (5) different behaviour patterns, (6) social networks, (7) leading your own life with regards to social networks, and (8) the future. Between each session, participants complete a homework assignment which is discussed in the following session. Each session is moderated by two trained

professionals who have experience working with young people. Those in the second group continue as normal for the duration of the study. At the start of the study and then after 6, 12 and 24 months, participants in both groups complete a number of questionnaires in order to assess their mental health status, alcohol consumption and life satisfaction.

What are the possible benefits and risks of participating?
Participants who receive Grubbel may benefit from improved coping skills and mental wellbeing, which could help prevent them from developing mental health conditions or drinking too much alcohol. There are no notable risks involved with participating in the study.

Where is the study run from?
The study is run from STAD, Centre for Psychiatry Research, Karolinska Institutet & Stockholm Health Care Services and takes place online (Sweden)

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

Who is funding the study?
National Public Health Agency of Sweden (Sweden)

Who is the main contact?
Dr Tobias Elgán
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Study website
http://www.grubbel.nu

Contact information

Type(s)
Public

Contact name
Dr Tobias Elgán

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Contact details
STAD (Stockholm for the prevention of alcohol and drug abuse)
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Norra Stationsgatan 69
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113 64

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1155/2014-6.2

Study information

Scientific Title
A web-based group course intervention for 15-25 year olds having parents with substance use problems or mental illness: a randomized controlled trial to measure the effects with regards to mental health, coping skills, quality of life, and own alcohol consumption

Acronym
Grubbel

Study objectives
In comparison to a control group who receives care as usual, participants in the intervention group will show improved coping skills, reduced symptoms of depression and behavioural problems, improved quality of life, and a reduction in alcohol consumption.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Stockholm, 17/09/2015, ref: 2015/1320-31/5

Study design
Multi-centre two-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Prevention

Participant information sheet
Available in Swedish at http://grubbel.nu/content/tack-för-visat-intresse

Health condition(s) or problem(s) studied
Adolescents with at least one parent with a substance use problem and/or mental illness

Interventions

Participants are randomly allocated into the intervention Grubbel or a control group using an unequal allocation ratio of 1:8. An unrestricted random allocation sequence will be used.

Intervention group: The intervention program Grubbel is a manual-based and well-structured prevention program and consists of eight consecutive weekly online chat-meetings, each meeting lasting 1.5 hours, and a ninth follow-up meeting one week after the last meeting. Each session focus on a particular theme:
1. Getting acquainted with the home situation
2. Roles in the family
3. Thoughts and feelings,
4. Questions and answers about mental health problems, risky alcohol use, addiction, and heredity
5. Different behaviour patterns
6. Social network
7. Leading your own life with regards to social networks
8. The future.

The ninth session is a follow-up session. In between each session, the participants are required to complete a homework assignment that is discussed at the following session. Each meeting is moderated by one or two trained professionals (prevention and social workers, and psychologists from mental health and addiction centres) who have previous experience from working with the target group, and has participated in a two-day Grubbel-course held by our research group.

Control group: Participants receive care as usual for the duration of the study, which involves receiving information about where to find care as usual.

All assessment are conducted using web-based questionnaires reached by hyperlinks sent out to the participants via e-mail. The assessment consists of a baseline measurement (T0) which takes place before randomization and three follow-up measurements after 6 (T1), 12 (T2), and 24 (T3) months.

Intervention Type

Behavioural

Primary outcome measure

1. Depressive symptoms during the past week are measured using the Center for Epidemiological Studies Depression Scale for children (CES-DC) at baseline, 6, 12 and 24 months
2. Coping strategies are measured using the Brief COPE at baseline, 6, 12 and 24 months
3. Quality of life is measured using the World Health Organization's Quality of Life Questionnaire (WHOQOL-BREF) at baseline, 6, 12 and 24 months
4. Alcohol consumption is assessed using the short version of the Alcohol Use Disorders Identification Test (AUDIT-C) at baseline, 6, 12 and 24 months

Secondary outcome measures

1. Overall life satisfaction is measured using the Ladder of Life, asking about the participants' past, present, and future rating of his/her life over a one year perspective at baseline, 6, 12 and 24 months
2. Competencies and behavioural problems are measured using the young person's version of the Youth Self Report List (YSR), which consists of 119 problem behaviour items that form internalizing and externalizing scales at baseline, 6, 12 and 24 months

Overall study start date
14/04/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Adolescents being 15-25 years old
2. Percieve at least one parent to have a substance use problem and/or mental illness
3. Having access to a computer/tablet/mobile phone and the Internet
4. Fluent in Swedish
5. Being able to participate on a weekly basis
6. Provide an e-mail address
7. Having consented to participate

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
140

Key exclusion criteria
1. No easy access to computer and the internet
2. Not sufficiently fluent in Swedish
3. Symptoms of severe depression
4. Suicidal or self-inflicted harm behaviour

Date of first enrolment
14/04/2016

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Sweden

Study participating centre

STAD (Stockholm for the prevention of alcohol and drug abuse)
Centre for Psychiatry Research
Department of Clinical Neuroscience
Karolinska Institutet & Stockholm Health Care Services
Stockholm County Council
Norra Stationsgatan 69
Stockholm
Sweden
113 64

Sponsor information

Organisation
STAD (Stockholm for the prevention of alcohol and drug abuse)

Sponsor details
Centre for Psychiatry Research
Department of Clinical Neuroscience
Karolinska Institutet & Stockholm Health Care Services
Norra Stationsgatan 69
Stockholm
Sweden
11364

Sponsor type
University/education

Website
www.stad.org

Funder(s)

Funder type
Government

Funder Name
National Public Health Agency of Sweden

Results and Publications

Publication and dissemination plan

Publications are planned in high-impact peer reviewed journals around one year after the second and third follow-up.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/09/2016		Yes	No