Violence and alcohol abuse intervention for Swedish youth – evaluation for evidence-based practice

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/11/2015		☐ Protocol		
Registration date 22/04/2016	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 18/01/2019	Condition category Mental and Behavioural Disorders	Individual participant data		

Plain English summary of protocol

Background and study aims

Mental health problems and alcohol abuse are among the most common causes of morbidity (illness) and mortality (death) in young people. At this age, people also have a greater risk of being a victim of a violent crime (violence victimisation), and the link between violence victimisation and ill-health in youth is well established. To address this situation, screening and treatment for high-risk alcohol drinking and violence victimisation in youth in health care settings have been backed by organisations such as the WHO and the American Academy of Pediatrics. However, despite the recommended guidelines, it has not yet been agreed how this should be performed. The aim of this study is to find out whether a brief program for young people who show high-risk alcohol drinking and/or violence victimisation during a regular visit to a youth health centre in Sweden is effective.

Who can participate?

People aged between 15 and 22, who currently visit a participating Youth Health Centre for counselling.

What does the study involve?

Participants are randomly allocated to one of two groups. Participants in the first group are interviewed about alcohol/drug use and are asked structured questions about whether they have been a victim of violence (mental, physical, sexual or family), in addition to their regular visit with a midwife or social worker. Those who have been a victim of violence are offered further counselling and are referred to appropriate services. Those who have been a victim of violence and show high-risk drinking also receive help for their alcohol related problems. Participants in the second group are also interviewed about their alcohol habits and whether they have been a victim of violence, but only receive the standard visit from a midwife or social worker. After 3, 6 and 12 months, participants in both groups complete a number of questionnaires in order to measure their drinking behaviour and violence victimisation.

What are the possible benefits and risks of participating?

Participants may benefit from being able to identify their problems so that they are able to work

on resolving any issues they may have, either with violence victimisation or risky drinking. There is a risk for victims of violence that talking about it may be distressing, however these participants will be offered further counselling.

Where is the study run from? Four Youth Health Centres in Västernorrland County (Sweden)

When is the study starting and how long is it expected to run for? January 2012 to June 2013

Who is funding the study? Crime Victim Fund (Sweden)

Who is the main contact? Professor Ulf Högberg ulf.hogberg@kbh.uu.se

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Violence and alcohol abuse intervention for Swedish youth – routine enquiry and counselling for violence and Motivational Interviewing for risk drinking in Swedish youth health centres

Study objectives

- 1. The percentage of youths victimized will decrease after routine enquiry and counselling
- 2. The percentage of youths with risk drinking of alcohol will decrease for those having Motivational Interviewing

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board in Umeå, 24/05/2011, ref: 2011-110-31Ö

Study design

Multi-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Screening

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

- 1. Exposure and victimization to violence among young people
- 2. Risk drinking of alcohol among young people

Interventions

The participants, youth visiting four Youth Centers in the County Västernorrland in Sweden, are randomized into the intervention or the control group. A statistician, who was not otherwise involved in the study, generated a random allocation sequence in Blockrand in R version 2.12, and stratified by different youth health centres. Randomization occurred in blocks of eight, using sealed envelopes.

Intervention arm: The intervention arm consists of two main parts. In the first part, a routine enquiry is made about violence exposure within a health dialogue to all participants. Those in need receive counselling from midwife or social worker and receive a referral to social authorities, school/police, guardians or child/adult psychiatrist if deemed necessary. In the second part, participants are screened for alcohol use using the AUDIT-C (3-item alcohol screen). Those identified as engaging in risky drinking receive motivational interviewing (MI) within the

same visit. MI is a goal-oriented, client-centered counseling style for eliciting behavior change by helping clients to recognise their problems and change their behaviour.

Control arm: Participants receive a regular visit from a midwife or social worker but answered the same questions about violence victimization and alcohol/substance use in a pre-structured questionnaire after the visit.

Participants in both groups are reassessed at 3, 6 and 12 months.

Intervention Type

Behavioural

Primary outcome measure

- 1. Violence victimization is measured using the visual analogue score (VAS) at baseline, 3, 6 and 12 months
- 2. Risky alcohol drinking behaviour is measured using the AUDI-C score and Bingedrinking AUIDIT-score at baseline, 3, 6 and 12 months

Secondary outcome measures

- 1. Perceived general health is measured using at baseline, 3, 6 and 12 months
- 2. Somatic pain symptoms are measured using at baseline, 3, 6 and 12 months
- 3. Absence from school/work is measured using at baseline, 3, 6 and 12 months

Overall study start date

01/01/2012

Completion date

31/12/2013

Eligibility

Key inclusion criteria

- 1. Aged between 15 and 22
- 2. Visiting a participating Youth Health Centre, in Västernorrland county (Sweden) for of counselling about sexual and reproductive health, social, psychological or physical problems, or ill-health

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

500 women and 500 men

Key exclusion criteria

- 1. Severe mental disease
- 2. Not going to a regular school due to mental retardation

Date of first enrolment

01/01/2012

Date of final enrolment

10/06/2013

Locations

Countries of recruitment

Sweden

Study participating centre Youth Health Center Sundsvall

Tullgatan 15 Sundsvall Sweden SE-85231

Study participating centre Youth Health Center Sollefteå

Kungsgatan 10 A Sollefteå Sweden SE-88130

Study participating centre Youth Health Center Örnsköldsvik

Bergsgatan 9 Örnsköldsvik Sweden SE-89134

Study participating centre Youth Health Center Kramfors

Limstagatan 5 Kramfors Sweden SE-87230

Sponsor information

Organisation

Uppsala University

Sponsor details

Department of Obstetrics and Gynecology Women's and Children's Health Akademiska sjukhuset Uppsala Sweden SE-751 85 Uppsala

Sponsor type

University/education

ROR

https://ror.org/048a87296

Funder(s)

Funder type

Charity

Funder Name

Crime Victim Fund (Brottsofferfonden)

Results and Publications

Publication and dissemination plan

Planned publication in peer reviewed journals. The study also is included in the PhD Thesis of Dr Anna Palm at Uppsala University.

Intention to publish date

31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2016	18/01/2019	Yes	No
Results article	results	01/01/2020	18/01/2019	Yes	No
Results article	results	01/08/2016	18/01/2019	Yes	No