

A web-based coping and alcohol-Intervention program for children of parents with alcohol problems

Submission date 05/12/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/12/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/04/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

It has been estimated that approximately 20% of all Swedish children grow up with parents having alcohol problems, which may result in negative outcomes in these children. Hence, most Swedish municipalities provide resources for support, but at the same time figures show that not even 2% receive support, mainly due to difficulties in identifying and recruiting these children into support programs. Delivering intervention programs to children and adolescents via the Internet seems a promising strategy, but to date, the number of web-based interventions aimed at this target group is very scarce. We have therefore developed a novel internet-delivered therapist-assisted self-help intervention called the web-ICAIP (Individual Coping and Alcohol Intervention Program) for adolescents having parents with alcohol problems. The purpose of the web-ICAIP, which solely takes place on the Internet, is to strengthen adolescents coping behaviour, improve their mental health, and postpone the onset or decrease risky alcohol consumption. The program consists of film-based lectures and stories, various exercises, and personalized feedback.

Who can participate?

The study is open to Swedish-speaking adolescents between 15 and 19 years old who have at least one parent with alcohol problems.

What does the study involve?

Participants will be randomly allocated to an intervention group, with access to the web-ICAIP, or to a waiting list control group, representing treatment as usual. The study will run for six months and assessment consists of online self-administered questionnaires that are to be filled in by the participants at baseline and at two follow-ups (after two and six months following the baseline).

What are the possible benefits and risks of participating?

There may be times where some participants feel discomfort as they are asked to reflect over their own situation. However, it is stressed that the study is anonymous and strictly voluntary, and participants can choose to terminate their involvement at any time. Furthermore, having in

mind the overall aim of the web-ICAIP, participation may result in possible benefits such as improved mental health and coping behaviour, and participants may also postpone their onset of alcohol consumption or decrease their risky alcohol use.

Where is the study run from?

Recruitment will mainly take place at the Drugsmart website (www.drugsmart.com)

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

January 2012 to June 2014

Who is funding the study?

The study has been funded by grants from the Swedish National Institute of Public Health and the Swedish Council for Working Life and Social Research.

Who is the main contact?

Tobias Elgán at STAD, Stockholm Centre for Psychiatric Research and Education, Karolinska Institutet (Sweden).

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Efficacy of a web-based Individual Coping and Alcohol-Intervention Program (web-ICAIP) for children of parents with alcohol problems: A randomized controlled trial

Acronym

Web-ICAIP

Study objectives

The intervention group, who have access to the web-ICAIP, in comparison to the control group, representing treatment as usual, will:

1. Improve their coping behavior
2. Improve their mental health
3. Postpone the onset of alcohol consumption or decrease their risky alcohol consumption

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board, Karolinska Institute, 1 December 2011, ref: 2011/1648-31/5

Study design

Single centre parallel-group single-blinded randomised controlled intervention study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Adolescents having at least one parent with alcohol problems

Interventions

The trial includes two arms. The first one is the waiting list control group, representing treatment as usual, which may include participating in a "face-to-face" support group or being active at self-help forums. The other group is the intervention group which has access to the web-ICAIP which is "locked" during the study period.

The web-ICAIP is derived from the manual-based "face-to-face" Individual Coping and Alcohol Intervention Program (ICAIP). Similar to the original ICAIP intervention, the web-ICAIP is divided into an alcohol and a coping theme, consisting of:

1. Three film-based lectures (each between 8-15 min) concerning alcohol problems within the family
2. One optional film-based lecture related to risky alcohol consumption
3. Four stories, so called readers' letters, which relates to coping and alcohol problems within the family
4. Various exercises related to alcohol and coping behavior
5. Automatic personalized feedback messages
6. Personalized feedback from experts
7. Participants formulate their own action plan for the future

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Current primary outcome measures as of 11/04/2024:

Coping behavior will be measured using a Coping Behavior Scale for children of alcoholics (four-point Likert scale) at baseline and 2 and 6 months following baseline

Previous primary outcome measures:

Study assessment take place at baseline and at 2 and 6 months following baseline.

1. Depressive symptoms will be measured using the Center for Epidemiological Studies Depression Scale (CES-DC) (four-point Likert scales) where a higher total score indicate more depressive symptoms
2. Coping behavior will be measured using a Coping Behavior Scale for children of alcoholics (four-point Likert scales)
3. Alcohol consumption will be measured using the short version of the Alcohol Use Disorders Identification Test (AUDIT-C)
4. Questions will be asked related to whether or not the respondents have ever consumed alcohol to the point that he/she felt intoxicated, and respondents age of onset of drinking and intoxication

Key secondary outcome(s)

Current secondary outcome measures as of 11/04/2024:

The following secondary outcome measures are assessed at baseline and 2 and 6 months following baseline:

1. Depressive symptoms will be measured using the Center for Epidemiological Studies Depression Scale (CES-DC) (four-point Likert scales) where a higher total score indicate more depressive symptoms
2. Alcohol consumption will be measured using the short version of the Alcohol Use Disorders Identification Test (AUDIT-C)
3. Overall life satisfaction will be measured by asking about the participants' past, present, and future rating of his/her life on a ten-point "Ladder of life" representing life status from "worst" to "best" possible life imaginable

Questions will be asked related to whether or not the respondents have ever consumed alcohol to the point that he/she felt intoxicated, and respondents' age of onset of drinking and intoxication

Previous secondary outcome measures:

1. Program adherence will be measured in terms of completed film-based lectures and exercises
2. Overall life satisfaction will be measured by asking about the participants past, present, and future rating of his/her life on a ten-point Ladder of life representing life status from worst to best possible life imaginable

Completion date

30/06/2014

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 11/04/2024:

1. Adolescents being 15-19 years old
2. Have at least one parent with alcohol problems measured by short version of the Children of Alcoholics Screening Test (CAST-6)
3. Approved of informed consent

Previous participant inclusion criteria:

1. Adolescents being 15-19 years old
2. Have at least one alcoholic parent
3. Approved of informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

15 years

Upper age limit

19 years

Sex

All

Total final enrolment

204

Key exclusion criteria

1. No easy access to computer and the Internet
2. Not sufficiently fluent in Swedish
3. Suicidal or self inflicted harm behavior

Date of first enrolment

01/08/2012

Date of final enrolment

31/12/2013

Locations**Countries of recruitment**

Sweden

Study participating centre

STAD, Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet
Norra Stationsgatan 69
Stockholm
Sweden
11364

Sponsor information

Organisation

Stockholm Prevents Alcohol and Drug Problems (STAD) (Sweden)

Funder(s)

Funder type

Government

Funder Name

Swedish National Institute of Public Health (Sweden) ref: HFÅ 2009/133

Funder Name

Swedish Council for Working Life and Social Research (Sweden) ref: 2009-1705

Alternative Name(s)

Swedish Council for Working Life and Social Research, FAS

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/04/2024	11/04/2024	Yes	No
Protocol article	study protocol	16/01/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes