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Health network: alcohol in adolescence

Submission date
05/03/2012

Recruitment status
No longer recruiting

Registration date
30/04/2012

Overall study status
Completed

Last Edited
26/02/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
In Germany the number of children and teenagers treated for drinking too much alcohol (acute alcohol intoxication) has more than doubled between 2000 and 2010. This has led to the development of the prevention program “HaLT-Hart am Limit” (“Stop – close to the limit”), which involves offering a counselling session to children and teenagers who are being treated for heavy drinking in emergency departments. The program is currently carried out at more than 140 locations in Germany, but its effectiveness has not been tested. The aim of this study is to test the effectiveness of a brief motivational intervention for heavy drinking children and adolescents in emergency departments.

Who can participate?
Children and adolescents under the age of 18 who are being treated for acute alcohol intoxication in one of the six participating hospitals

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the control group receive treatment as usual, which consists of information on counselling agencies and the recommendation to contact one, and handouts on the negative effects of drinking. Participants in the intervention group receive a counselling session, information on the negative effects of drinking, and information on counselling agencies and the recommendation to contact one. Intervention group parents/caregivers are also offered a counselling session. Participants in the intervention group are also contacted by telephone 6 weeks after leaving hospital for a 5-10 minute booster.

What are the possible benefits and risks of participating?
There are no known risks for participants.

Where is the study run from?
The study takes place in the emergency departments of six hospitals treating children and young adults in the City of Hamburg, Germany.

When is the study starting and how long is it expected to run for?
July 2011 to July 2014

Who is funding the study?
German Federal Ministry of Education and Research (BMBF)

Who is the main contact?
Prof. Rainer Thomasius
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
01KQ1002B

Study information

Scientific Title
Brief motivational intervention in adolescents treated in emergency departments for acute alcohol intoxication: a randomized controlled trial

Study objectives
1. Children and adolescents who receive a manualised brief motivational intervention (BMI) after being treated for alcohol intoxication in an emergency department will reduce their binge-drinking frequency significantly when compared with controls.
2. Children and adolescents who receive a BMI (intervention group) will significantly more often seek for help in the care system than do children and adolescents who do not receive the BMI (control group).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Chamber of Psychotherapists Ethics Committee, Hamburg, Germany, 12/07/2011

Primary study design
Interventional

Study design
Controlled randomized longitudinal cross-sectional trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
At-risk alcohol use in adolescents

Interventions
The study design is a two-group controlled-randomised, longitudinal and cross-sectional trial with post intervention measures and follow-ups at 3 and 6 months.

Intervention group (BMI + TAU)
Participants in the intervention group receive a manualised brief motivational intervention (BMI) which takes 45-minutes and is delivered by trained facilitators before discharge from hospital (one session only). Participants additionally receive information on cooperating youth- and family-oriented counselling agencies combined with the recommendation to contact a counselling agency and handouts on negative effects of alcohol use for children and adolescents which represents treatment as usual (TAU). Parents/caregivers also receive a counselling session in hospital. Participants in the intervention group are being contacted by telephone 6 weeks after hospitalization for a 5 -10 minute booster to enhance motivation to pursue alcohol-related goals as set in hospital. Participants are contacted by telephone 3 and 6 months after hospitalization for follow-up assessment.

Control group (TAU)
Participants in the control group receive treatment as usual (TAU) which consists of information on cooperating youth- and family-oriented counselling agencies combined with the recommendation to contact a counselling agency, and handouts on negative effects of alcohol use in children and adolescents. Participants are contacted by telephone 3 and 6 months after hospitalization for follow-up assessment.

Intervention Type
Behavioural

Primary outcome(s)
1. Binge-drinking frequency past 3 and 6 months
2. Asking for the help in the care system (follow-up treatment/counselling)

Key secondary outcome(s)
1. Negative consequences of alcohol use [Rutgers Alcohol Problem Index (RAPI)]
2. Drug-related risk-behaviour (RAFFT)
3. Alcohol-related risk-behaviour (CRAFFT)
4. Motivation to change
5. Exploratory analysis regarding:
5.1. Characteristics of adolescents and parents who contact the counselling agencies for help on

alcohol problems
5.2. Characteristics of adolescents who reduce or stop their at-risk alcohol consumption patterns with or without the BMI or counselling agencies
6. Measures:
6.1. Vulnerability / protectivity:
6.1.1. SCL-K-9 (short version)
6.1.2. SPS-J
6.1.3. RS-13 (short version)
6.2. Perceived facilitators characteristics
6.2.1. Basic therapeutic skills (short version)
6.2.2. Critical life events
6.2.3. SLE
6.3. Patients treatment satisfaction
6.3.1. ZUF-8
6.4. Social support
6.4.1. FsozU-K14 (short version)
6.5. Parenting style
6.5.1. Alabama Parenting Questionnaire
6.6. Familiy functioning
6.6.1. Familienbögen (FB-S)

Completion date
16/07/2014

Eligibility

Key inclusion criteria
1. Age range up to 17.9 years
2. Treatment in a pediatric emergency department due to acute alcohol intoxication
3. Informed consent given by participant and parent(s)/caregivers
4. Sufficient mental-cognitive receptiveness

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 Years

Sex
All

Total final enrolment
316

Key exclusion criteria
1. Severe injuries as a result of the intoxication
2. Cognitive difficulties or language barriers

Date of first enrolment
16/07/2011

Date of final enrolment
16/01/2014

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Center Hamburg-Eppendorf
Hamburg
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Sponsor information

Organisation
German Federal Ministry of Education and Research [Bundesministerium für Bildung und Forschung] (BMBF) (Germany)

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung (ref: 01KQ1002B)

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

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	results	01/02/2017	26/02/2021	Yes	No
Protocol article	protocol	30/06/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes