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Reduction of alcohol use by young adolescents: a randomized trial with four conditions

Submission date	Recruitment status	[ ] Prospectively registered
07/06/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/01/2021	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
50-50110-98-208, NL593, NTR649

Study information

Scientific Title

Reduction of alcohol use by young adolescents: a randomized trial with four conditions

Study objectives
The implementation of the interventions will reduce alcohol use by adolescents under the age of 16, measured by the percentage of binge drinking, the weekly number of drinks and the percentage of adolescents who drink on a weekly basis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Alcohol abuse or addiction

Interventions
The objective of the present study is to determine the effectiveness of two interventions for reducing alcohol use by young adolescents: the renewed alcohol module, developed within the scope of the healthy school and drugs program, based on elements proven effective in the past in previous modules, and a new parent intervention that focuses primarily on influencing the way parents raise their children with respect to alcohol consumption.
The renewed alcohol module consists of four lessons. The parent intervention is introduced during a parent evening at the school. Both interventions will be held in the first year of secondary education.
Schools will be randomly assigned to one of the following four conditions:
1. Regular curriculum
2. Renewed healthy school and drugs alcohol module
3. Parent intervention (PI)
4. Combination of 2 and 3 above

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Over a course of three years, the effectiveness of two interventions for reducing alcohol use by adolescents under the age of 16 is assessed. In particular, we examine the effectiveness of each of the interventions offered separately and simultaneously.
The interventions are targeted at the reduction of alcohol consumption among young adolescents. These objectives will be concretized with the following attainment targets:
1. Reduce the percentage of binge drinking (>5 drinks) by at least 10%
2. Reduce the weekly number of drinks from 10 to 6 drinks
3. Reduce the percentage of adolescents who drink on a weekly basis by 10%

The parent intervention will take place in October 2006, booster sessions at the beginning of each successive school year in 2007 and 2008.
The alcohol module will be run from March to April of the first grade in secondary education in all participating schools in 2007.
Measurements will take place before the first intervention, T0 August to September 2006, and at the beginning of each successive school year; T1 October to November 2007, T2 October to November 2008, T3 October to November 2009.
Students will answer a digital questionnaire in their classroom. Parents will be sent a questionnaire by post.

Secondary outcome measures
We will examine whether the effectiveness of the intervention is dependent upon the particular child, parent or school characteristics (moderator-effects) and whether the effectiveness is mediated by a particular child, parent or school characteristics. In addition, it will be analysed whether the interventions have a simultaneous effect on the reduction of externalising problem behaviour.

Overall study start date
15/04/2006

Completion date
28/02/2010

Eligibility

Key inclusion criteria
Adolescents in the first grade of secondary school

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
5400

Total final enrolment
3490

Key exclusion criteria
Adolescents who do not attend school

Date of first enrolment
15/04/2006

Date of final enrolment
28/02/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Trimbos-Institute - Netherlands Institute of Mental Health and Addiction
Utrecht
Netherlands
3500 AS

Sponsor information

Organisation
University Medical Center Utrecht (UMCU) (The Netherlands)

Sponsor details
P.O. Box 85500
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Sponsor type
University/education

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/10/2009	08/01/2021	Yes	No