

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

Submission date 07/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/06/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 08/01/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

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

Utrecht

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3508 GA

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