

Adolescent substance use prevention

Submission date 01/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/02/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/12/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Students begin experimenting with tobacco and alcohol between 11 and 15 years of age. However, there are no data for 11–15-year-old students with intellectual disabilities. Prevention programmes, like Prepared on time, are successful, but their efficacy has not been studied in students with intellectual disabilities. Prepared on time, based on the ASE model, can be used in the fifth and sixth grades of primary schools. The aim in this study is to examine the tobacco and alcohol use among first and second grade students in special needs secondary schools and to undertake a preliminary study to test the e-learning programme in this population.

Who can participate?

Adolescents with intellectual disabilities

What does the study involve?

Five schools will be randomly assigned to two groups, experimental or control. In the first week, children in both the experimental and control groups will be asked to complete a questionnaire. Two weeks after completing the first questionnaire, participants in the experimental group will be enrolled in the programme. Three weeks after working with the programme, both groups will complete a follow-up questionnaire.

What are the possible benefits and risks of participating?

There are no known benefits or risks to participants taking part in this study.

Where is the study run from?

Five special education schools in the Netherlands: OSG Erasmus – Praktijkonderwijs, Bonhoeffer Praktijk Locatie Vlierstraat, Thomas a Kempis College, Praktijkonderwijs Zutphen and De Maat Ommen.

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

From January 2010 to January 2011

Who is funding the study?

Aveleijn Intellectual Disabilities Services (Netherlands)

Who is the main contact?
Ms Marion Kiewik

Contact information

Type(s)
Scientific

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7622 GW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Substance use prevention programme in special education schools: a cluster randomised control trial

Study objectives

1. We assume a high lifetime prevalence of tobacco and alcohol use among adolescents with intellectual disabilities in the Netherlands.
2. We assume that the programme Prepared on time will increase smoking and drinking knowledge of students with intellectual disabilities. Furthermore, we assume that Prepared on time will influence behavioural determinants, based on the attitude-social influence-efficacy (ASE) model. This programme was originally used in the fifth and sixth grades of primary schools.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Boards of the participating schools; approval date and reference not provided at time of registration

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Adolescents with mild intellectual disabilities, attending special secondary needs schools

Interventions

1. This study is a cluster randomised controlled trial among 210 students with a borderline or mild intellectual disabilities to avoid contamination between classes
2. An invitation letter will be sent to eight schools. Five participating schools, comprising 254 students will be divided into 20 classes. For pragmatic reasons, these schools will be randomly assigned to one of two groups, experimental or control, to create comparable and nearly equally sized groups, initially resulting in 111 students in the experimental group and 143 students in the control group.
3. In the first week, both groups will be asked to complete a questionnaire.
4. Two weeks after completing the first questionnaire, participants in the experimental group

will be enrolled in the programme.

5. Three weeks after working with the programme, both groups will complete a follow-up questionnaire.

Intervention Type

Behavioural

Primary outcome measure

1. Alcohol use (lifetime prevalence and onset): students will be asked to indicate retrospectively how many standard units they consume during one drinking occasion.
2. Tobacco use (lifetime prevalence and onset).

Both outcomes will be measured with a self-report questionnaire at baseline. Furthermore, basic sociodemographic information will be available through a teacher-reported and student-reported questionnaire at baseline. Behavioural determinants (alcohol and tobacco knowledge; attitude; self-efficacy; intention; subjective norm) will be measured at baseline and 3 weeks after working with the programme (follow-up questionnaire).

Secondary outcome measures

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Overall study start date

01/06/2009

Completion date

01/01/2011

Eligibility

Key inclusion criteria

1. Age 11–16 years old
2. Attending Dutch Special needs school, first or second grade
3. Intelligence quotient levels of between 50 and 85 according to the International Statistical Classification of Diseases and Related Health Problems 10th Revision
4. Sufficient communication skills and ability to respond using Likert Scale categories

Participant type(s)

Other

Age group

Child

Lower age limit

11 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

210

Key exclusion criteria

Not meeting the inclusion criteria

Date of first enrolment

01/03/2010

Date of final enrolment

01/07/2010

Locations

Countries of recruitment

Netherlands

Study participating centre**OSG Erasmus - Praktijkonderwijs**

Horstlaan 1

Almelo

Netherlands

7602 AM

Study participating centre**Bonhoeffer Praktijk Locatie Vlierstraat**

Vlierstraat 75

Enschede

Netherlands

7544 GG

Study participating centre**Thomas a Kempis College**

Palestrinalaan 915

Zwolle

Netherlands

8031 VA

Study participating centre**Praktijkonderwijs Zutphen**

Paulus Potterstraat 12A

Zutphen

Netherlands
7204 CV

Study participating centre

De Maat Ommen

Baron van Fridaghstraat 137
Ommen
Netherlands
7731 DL

Sponsor information

Organisation

Aveleijn

Sponsor details

Grotestraat 260
Borne
Netherlands
7577 KS

Sponsor type

Other

Website

www.aveleijn.nl

ROR

<https://ror.org/03krr1g45>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Aveleijn Intellectual Disabilities Services (Netherlands)

Results and Publications

Publication and dissemination plan

The plan is to publish a full article in the Journal of Intellectual Disability Research this year.

Intention to publish date

30/06/2015

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	01/03/2016		Yes	No