ISRCTN95279686 https://doi.org/10.1186/ISRCTN95279686

Adolescent substance use prevention

Submission date
01/02/2015

Recruitment status
No longer recruiting

Registration date
10/02/2015

Overall study status
Completed

Last Edited
04/12/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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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Public

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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
-

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