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Adolescent substance use prevention

Submission date	Recruitment status	[ ] Prospectively registered
20/11/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/01/2016	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/01/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
It is thought that, in general, students start experimenting with tobacco and alcohol between the ages of 12 and 16. However there is, is yet, no information on when 12 to 16 year old students with intellectual disabilities (ID) start doing the same. Prevention programs, like “Prepared on time”, work well but have not been tested on students with ID. “Prepared on time”, a prevention program based on the attitude-social influence-efficacy model (ASE model), can be used in the 5th and 6th grades of primary schools. It is based on the future behaviour of a person being determined by, and closely related to, their intention. Intention is, in itself, determined by a person’s disadvantages, advantages, social acceptance of and norms, the pressures placed upon them and how much they believe they manage their own lives. The goal of this study was look at tobacco and alcohol use among 1st and 2nd graders in secondary special needs schools and to test the performance of the e-learning program “Prepared on time” for this population.

Who can participate?
Students aged 12-16 with ID.

What does the study involve?
Three schools agree to take part in the study. Two of these schools are randomly allocated to the experimental or control group. For the third school, to ensure groups of equal size, half the children are allocated randomly to the experimental group and half to the control group. In the first week, both the experimental group and the control group are asked to complete a questionnaire. Two weeks after completing the first questionnaire, participants in the experimental group are enrolled in the “Prepared on time” program. Three weeks after working with the program, all children in both groups complete the follow-up questionnaire.

What are the possible benefits and risks of participating?
The benefits for participating in the study include the students having the possibility of trying a new kind of prevention program and the teachers gaining more insight into the tobacco and alcohol use of their students. Risks include students being adversely affected by the intervention itself by getting them interested in tobacco or alcohol use.

Where is the study run from?
Three special education schools in the Netherlands

When is the study starting and how long is it expected to run for?
January 2011 to March 2013

Who is funding the study?
Aveleijn Intellectual Disabilities Services (Borne, The Netherlands)

Who is the main contact?
Mrs Marion Kiewik

Contact information

Type(s)
Scientific

Contact name
Mrs Marion Kiewik

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Grotestraat 260
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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 program on special education schools

Study objectives
1. We assume a lower lifetime prevalence of tobacco and alcohol use among this population in the Netherlands.
2. We assume that the program ‘Prepared on time’ will increase the smoking and drinking knowledge of students with intellectual disabilities (ID). Further, we assume that 'Prepared on time' will influence behavioral determinants, based on the ASE model.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pre-/post intervention design with control group

Primary study design
Interventional

Secondary study design
Pre-/Post intervention design with control group

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Adolescents with mild intellectual disabilities, attending special secondary needs schools.

Interventions
The program “Prepared on time”, developed as a prevention program based on the ASE model, was originally used in the 5th and 6th grade of primary schools. This study was a pilot study among 73 students with a mild intellectual disabilities (ID).

An invitation letter was sent to six schools. Three schools, comprising 73 students, finally agreed to participate. For pragmatic reasons, two schools were assigned by lot to either the experimental and the control. The students in the third school were listwise assigned to either condition in order to create equal size groups, initially resulting in 37 students in the experimental group and 36 students in the control group.

In the first week, both the experimental group and the control group were interviewed to complete a questionnaire. Two weeks after completing the first questionnaire, participants in the experimental group were enrolled in the program. Three weeks after working with the program, both groups were interviewed again to complete the follow-up questionnaire. Finally, 69 students completed both questionnaires (35 students in the experimental group, 34 in the control group).

Intervention Type
Behavioural

Primary outcome measure

1. Alcohol use (lifetime prevalence and onset). Students are asked to indicate retrospectively, how many standard units they consumed in one drinking occasion.
2. Tobacco use (lifetime prevalence and onset).

Both measured with a self-report questionnaire at baseline.

3. Basic socio-demographic information will be available through a teacher-reported and student-reported questionnaire at baseline.
4. Behavioural determinants (Alcohol and tobacco knowledge; Attitude; Modelling; Social Pressure; Intention) were measured at baseline and three weeks after working with the program (follow-up questionnaire).

In the first week, both the experimental group and the control group were asked to complete a questionnaire. Two weeks after completing the first questionnaire, participants in the experimental group were enrolled in the program. Three weeks after working with the program, both groups completed the follow-up questionnaire.

Secondary outcome measures
Feasibility of the e-learning program by asking participants' experiences working with the program (11 questions in the follow-up questionnaire), measured 3 weeks after completion of the e-learning program.

Overall study start date
01/01/2011

Completion date
01/03/2013

Eligibility

Key inclusion criteria
1. Age between 12 - 16
2. Attending Dutch Special needs school, first or second class
3. IQ levels between 50 and 70 according to ICD-10 criteria measured by regular intelligence tests
4. Sufficient communication skills and ability to respond using Likert Scale categories

Participant type(s)
Other

Age group
Child

Lower age limit
12 Years

Upper age limit
16 Years

Sex

Both

Target number of participants
This study was a pre-/post-intervention study with control group among 73 students with a mild ID. An invitation letter was sent to six schools. Three schools, comprising 73 students, finally agreed to participate. For pragmatic reasons, two schools were assigned by lot to either the experimental and the control. The students in the third school were listwise assigned to either condition in order to create equal size groups, initially resulting in 37 students in the experimental group and 36 students in the control group.

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2011

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
VSO "Het Korhoen"
Korhoenstraat 2
Hengelo
Netherlands
7577 PC

Study participating centre
VSO "De Brug"
Burcht 107
Almelo
Netherlands
7608 JD

Study participating centre
Het Meerik VSO (formerly known as "VSO De Huifkar")
Lijsterstraat 117
Enschede
Netherlands
7523 ES

Sponsor information

Organisation
Aveleijn

Sponsor details
Grotestraat 260
Borne
Netherlands
7622 GW

Sponsor type
Other

ROR
https://ror.org/03krr1g45

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Aveleijn Intellectual Disabilities Services (Borne, The Netherlands)

Results and Publications

Publication and dissemination plan
We intend to publish a full article in the special issue of Research in Developmental Disabilities

Intention to publish date
01/03/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Thesis results	14/01/2019	07/01/2022	No	No