

Adolescent substance use prevention

Submission date 20/11/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/01/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/01/2022	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

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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Contact details
Grotestraat 260
Borne
Netherlands
7622 GW

Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

12 years

Upper age limit

16 years

Sex

All

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

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Aveleijn Intellectual Disabilities Services (Borne, The Netherlands)

Results and Publications

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