

Evaluation of "The Healty School and Drugs" (= "De Gezonde School en Genotmiddelen") for elementary schools.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27186

Source

NTR

Health condition

Smoking and drinking (= roken en drinken).

Sponsors and support

Primary sponsor: Radboud University Nijmegen and The Trimbos Institute.

Source(s) of monetary or material Support: The Trimbos Institute and Ministry of Health, Welfare and Sport (= Ministerie van Volksgezondheid, Welzijn en Sport [VWS]).

Intervention

Outcome measures

Primary outcome

The program is based on the ASE model, which is often used for predicting and explaining health behavior, in this case substance use (De Vries et al., 1988). In this study, the focus is on intention to use.

Secondary outcome

Intention is determined by:

1. The attitude towards substance use;
2. The social influence of friends and family to use or not to use substances;
3. The self-efficacy that is experienced in tempting situations (De Vries et al., 2005).

Study description

Background summary

The aim of the study is: To assess the effectiveness of the universal program "The Healthy School and Drugs" (= "De Gezonde School en Genotmiddelen") for elementary schools by conducting a clustered pilot randomized controlled trial including Dutch elementary schools. The outcome will not be direct effects on substance use behavior, but effects on the determinants underlying this behavior: Attitude, social influence, self-efficacy and the intention to use in the future.

Study objective

Children in the intervention conditions will be more likely to have negative attitudes and norms towards smoking and alcohol than children in the control condition.

Study design

Plan:

T1: November 2011;

T2: April 2012.

Intervention

There are two intervention conditions and a control condition. The first intervention includes the use of the two textbooks "Smoking" and "Alcohol". At the end of the intervention, an information evening will be organized by the local Municipal Health Service to involve the parents. For the teachers a manual is available. In the second intervention the students will use the textbook "Alcohol & smoking, another story". Also an evening for parents will be organized. At this evening the children will present what they have learned during the intervention and they will show what they have designed as part of different assignments

described in the manuals. Also for this intervention a manual is available for the teachers. The control condition is characterized by business as usual and does not receive an intervention.

Contacts

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Eligibility criteria

Inclusion criteria

All children in the last two classes of elementary school (= groep 7 en 8) are eligible for participation.

Exclusion criteria

Schools which already participated in 2010-2011 with "The Healthy School and Drugs".

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2011
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion	
Date:	17-05-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2765
NTR-old	NTR2904
Other	Radboud University Nijmegen / METC : 24000417 / ECG30062011

Register

ISRCTN

ID

ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A