Trial Description

Title

Primary Prevention of Smoking and Drinking in Young People: Nine year follow-up of two cluster-randomized school based drug prevention trials

Trial Acronym

PSD

URL of the trial

[---]*

Brief Summary in Lay Language

For many years school-based programs aimed at preventing substance use and misuse have been implemented and evaluated. While there is evidence that some of these programs have positive short-term and mid-term effects, little is known about their long-term effectiveness. Aim of the current study is to investigate the long-term effects of two German universal school-based prevention programs, „Be Smart - Don't Start” and „Aktion Glasklar”. Starting in 2006, two studies have been conducted in which students who took part in one of the programs were compared with students who received education as usual. The classes were randomly assigned to the groups. Taken together, a total of 5,176 7th graders from 289 classes and 114 schools could be surveyed at baseline in both studies. The results indicate that participation in „Be Smart - Don't Start” and „Aktion Glasklar” might affect smoking and alcohol use positively in the short term. Nine years after the baseline assessment, the samples of the two original studies shall be contacted and surveyed again. Findings of the current study will help to fill the research gap regarding the potential of school-based programs to sustainably influence cigarette and alcohol use up to early adulthood.

Brief Summary in Scientific Language

Background and study aims:
For many years school-based programs aimed at preventing substance use and misuse have been implemented and evaluated. Current evidence suggests that certain generic psychosocial and developmental prevention programs might be particularly effective (Cochrane Database Syst Rev. 2013;4:CD001293; Cochrane Database Syst Rev. 2011:CD009113). However, empirical evidence on the long-term effects is not yet uniquely convincing (Tob Induc Dis. 2009;5:7). This study aims to examine the long-term effects of two German universal school-based prevention programs nine years after their implementation.

Interventions:
The prevention programs are „Be Smart - Don't Start” and „Aktion Glasklar”. „Be Smart - Don't Start” is conceptualized for implementation in schools with a focus on targeting students aged 11-14. Participating classes commit themselves by contract management to stay smokefree for up to six months. Students in
these classes report regularly on whether or not they have smoked. At the end of the competition period successful classes can win attractive prizes in a lottery. „Aktion Glasklar“ is an information and awareness-raising campaign on alcohol which targets adolescents. It consists of booklets for students and parents, teaching materials and a quiz. The teaching materials cover topics such as statutory regulations, marketing, peer pressure and social norms with regard to alcohol.

Methods:
For each of the programs, „Be Smart - Don't Start“ and „Aktion Glasklar“, a two-arm cluster-randomized trial („intervention“ vs. „education as usual“) with schools as the unit of randomization was conducted between 2006 and 2008. Students of the respective intervention group participated either in „Be Smart - Don't Start“ (November 2006 - April 2007) or in „Aktion Glasklar“ (March - May 2006). The students of the respective control group received education as usual. Taken together, a total of 5,176 7th graders from 289 classes and 114 schools could be surveyed at baseline in both studies. Data suggested short term effects of the prevention programs on smoking (J Epidemiol Community Health 2012;66:334-41) and binge drinking (Addiction 2009;104:402-12).

Nine years after the baseline assessment, the samples of the two original studies shall be contacted and surveyed again. The former participants are now young adults aged between 20 and 22. They will be contacted via their former schools. In Germany, schools have to hold class lists with personal data including names and addresses of students for a number of years. Schools that agree to participate in the follow-up trial will be asked to send a postal package containing all relevant study materials to the parents of the former students. In addition to filling in a paper-pencil version of the questionnaire the participants also have the opportunity to use an online platform. In both cases, the survey will be conducted anonymously. To permit a linking between the baseline and long-term surveys a seven-digit individual code generated by the students in the original studies will be used. The code does not allow drawing any conclusions on the personal data of the participants.

Organizational Data

- **DRKS-ID**: **DRKS00007857**
- **Date of Registration in DRKS**: **2015/03/03**
- **Date of Registration in Partner Registry or other Primary Registry**: [---]*
- **Investigator Sponsored/Initiated Trial (IST/IIT)**: **yes**
- **Ethics Approval/Approval of the Ethics Committee**: **Approved**
  - **(leading) Ethics Committee Nr.**: **RH_122014**, Ethikkommission der Deutschen Gesellschaft für Psychologie e.V.

Secondary IDs

**Health condition or Problem studied**
ICD10: F10 - Mental and behavioural disorders due to use of alcohol
ICD10: F17 - Mental and behavioural disorders due to use of tobacco
Free text: Tobacco and alcohol use

Interventions/Observational Groups

- Arm 1: Participation in one of the school-based prevention programs, „Be Smart - Don't Start“ and „Aktion Glasklar“ in 2006 and 2007 within the original studies; within the current study, no intervention takes place.
- Arm 2: No participation in one of the two school-based substance use prevention programs (i.e., education as usual) within the original studies; within the current study, no intervention takes place.

Characteristics

- Study Type: Non-interventional
- Study Type Non-Interventional: Observational study
- Allocation: Randomized controlled trial
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Control group receives no treatment
- Purpose: Prevention
- Assignment: Parallel
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

Primary Outcome

Frequency and quantity of past and current cigarette and alcohol use at long-term follow-up 9 years after baseline

Secondary Outcome

Current cannabis use, (emotional and physical) health (reference: Individual questionnaire 2014 of the German Socio-Economic Panel Study; SOEP)

Countries of recruitment

- DE Germany
**Locations of Recruitment**

- other **Schulen in Sachsen-Anhalt und Schleswig-Holstein**

**Recruitment**

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/04/01**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

**Inclusion Criteria**

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

**Additional Inclusion Criteria**

- Participation in one of the original studies in 2006

**Exclusion criteria**

- No participation in one of the original studies in 2006

**Addresses**

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Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2016/04/30

Trial Publications, Results and other documents
