

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

'INternetbased Social Norms Intervention for substance use prevention for Students'-study

Trial Acronym

INSIST

URL of the trial

<https://www.ispi-studie.de/home.html>

Brief Summary in Lay Language

The main goals of the INSIST-study are:

a.) the development, implementation and evaluation of an internet-based 'social norms'- intervention for

- the reduction of rates of alcohol and tobacco consumption**
- the prevention of the use of cannabis, cocaine and synthetic drugs**
- the prevention of the use of non-prescription medicines**

b.) the evaluation of the effects of the intervention on attitudes towards substance use among university students and on rates of personal substance use. Attitudes toward substance use as well as rates of substance use will be assessed at baseline and 5 months later. In each country, the control group will receive the intervention after the implementation phase is completed in the intervention group.

How does the intervention work? Peers play an important role in the lives of university and college students. An overestimation of rates of substance use in the peer group can be associated with increases in rates of personal substance use. Previous studies indicate that students tend to overestimate consumption rates of legal substances in their peers. Presenting students with a feedback that outlines the gap between misperceived and actual social norms regarding substance use has been shown to be an effective harm reduction method in the U.S. and in Australia. Not much is known about the feasibility and effectiveness of this approach in Germany. The intervention will include a website. On this website, students will complete questionnaires regarding personal and peer substance use. Answers to these questionnaires will be used to develop a 'social norms'-feedback based on possible overestimations of rates of substance use in the peer group.

Brief Summary in Scientific Language

The aims of the INSIST-study are a) to assess and compare self-reported consumption rates of licit and illicit substances among university and college students at eight universities or colleges in four different regions of Germany. b) to examine the feasibility (i.e., understanding, utility and applicability) of a web-

based 'social norms'-intervention in the participating universities, and c) to compare the effects of the e-health intervention on social norms and the consumption of both licit (alcohol, especially binge drinking, tobacco and sedatives) and illicit substances (cannabis, cocaine, synthetic drugs, not prescribed medication, inhalants) among study participants in the intervention vs. the control group over the course of 5 months. The intervention will be delivered via a website. On this website, students will complete questionnaires regarding personal and peer substance use. Answers to these questions will be used to develop a social norms feedback based on possible overestimations of rates of substance use in the peer group. Attitudes toward substance use as well as rates of substance use will be assessed at baseline and 5 months later. In each country, the control group will receive the intervention after 5 months.

Organizational Data

- DRKS-ID: **DRKS00007635**
- Date of Registration in DRKS: **2014/12/17**
- 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.: **6487 , Ethikkommission der Medizinischen Hochschule Hannover**

Secondary IDs

Health condition or Problem studied

- Free text: **SUBSTANZKONSUM**

Interventions/Observational Groups

- **Arm 1: Intervention group: At baseline, attitudes toward licit and illicit substance use will be assessed among university students as well as rates of substance use. The intervention group will receive individualized social norms feedback. The website will remain online during the following 5 months. After five months, a second survey will be conducted and effects of the intervention on social norms and substance use compared to the control group will be assessed.**
- **Arm 2: Control group: At baseline and 5-months follow-up, attitudes toward licit and illicit substance use will be assessed among university students as well as rates of substance use. The control group will receive the intervention after the follow-up questionnaires were completed.**



Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Personal and perceived peer substance use: Personal and perceived social norms regarding substance use will be assessed. These items will be based on existing research and will be tailored to the target population of students. Data will be assessed at baseline and 5 months later using a web-based questionnaire.

Secondary Outcome

Substance use: The use of the following substances will be assessed: Alcoholic beverages (beer, wine, spirits, etc.), tobacco products (cigarettes, chewing tobacco, cigars, etc.), waterpipe tobacco (shisha), cannabis (marijuana, pot, grass, hash, etc.), medication to improve academic performance (e.g. Ritalin) that were not prescribed, synthetic cannabis (spice, etc.), cocaine (coke, crack, etc.), ecstasy, other amphetamine-type stimulants (speed, meth, etc.), sedatives or sleeping pills (diazepam, alprazolam, flunitrazepam, midazolam, stilnoct, etc.) which were not prescribed, hallucinogens (LSD, acid, mushrooms, trips, ketamine, etc.), inhalants (nitrous, glue, petrol, paint thinner, etc.). In addition, binge drinking and polydrug use (alcohol and tobacco, alcohol and any other illicit substances) will be assessed. The choice of substances included will be based on the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST), developed by the World Health Organization. Data will be assessed at baseline and 5 months later using a web-based questionnaire.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Universität, Bielefeld**



- other **Universität, Düsseldorf**
- other **HAW, Hamburg**
- other **MH, Hannover**
- other **Universität, Heidelberg**
- other **Universität, Mannheim**
- other **TU, Dresden**
- other **MLU, Halle Wittenberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/01/15**
- Target Sample Size: **4800**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

students at the participating universities

Exclusion criteria

None

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Bundesministerium für Gesundheit

11055 Berlin

Germany



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11055 Berlin
Germany**

Telephone: [---]*

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E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/08/31**

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.