Web-based screening and brief Intervention for substance using teens

Submission date	Recruitment status	Prospectively registered		
12/06/2012	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/07/2012	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
31/03/2017	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims

Adolescents aged 16 to 18 are at risk of problematic drinking and illegal drug use. While the short- and long-term effects are a major public health concern, current prevention programs targeting alcohol- and other drug-using adolescents are scarce. The aim of this study is to test the effectiveness of a web-based brief intervention aimed at reducing problematic alcohol use and abstaining from illegal drugs among adolescents aged 16 to 18 in Belgium, Germany, Czech Republic and Sweden.

Who can participate?

Adolescents aged 16 to 18 from Sweden, Czech Republic, Belgium and Germany who are tested for and found to be at risk of alcohol and drugs-related problems

What does the study involve?

Participants are randomly allocated to one of two groups. One group receives the web-based intervention, which takes about 10 to 15 minutes. The intervention provides feedback on participants' alcohol and drug use, including the risks, and practical advice to encourage reduced drinking and abstinence from illegal drugs. The other group receives no intervention. Both groups' use of alcohol and drugs is measured at the start of the study and at 3 months follow-up.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from?
University Hospital Hamburg-Eppendorf (Germany)

When is the study starting and how long is it expected to run for? June 2012 to January 2013

Who is funding the study?

- 1. European Commission (EU)
- 2. University Hospital Hamburg-Eppendorf (Germany)
- 3. Laboratory of Social Psychiatry at Prague Psychiatric Center (Czech Republic)

- 4. Stockholm Centre for Psychiatric Research and Education, Stockholm County Council Health Care Provision and Karolinska Institute (Sweden)
- 5. Vereniging voor Alcohol en andere Drugproblemen vzw (VAD) (Belgium)
- 6. Universität Lund, Clinical Alcohol Research, Skane University Hospital (Sweden)

Who is the main contact? Prof Rainer Thomasius thomasius@uke.uni-hamburg.de

Contact information

Type(s)

Scientific

Contact name

Prof Rainer Thomasius

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

JUST/2010/DPIP/AG/0914-30-CE-0379823/00-48

Study information

Scientific Title

Web-based screening and brief Intervention for SubstancE using teens: a randomised controlled trial

Acronym

WISEteens

Study objectives

Adolescents with risky substance use who participate in the WISEteens intervention show lower levels of substance consumption and higher levels of substance reduction and abstinence related cognitions as opposed to those who receive an assessment only.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Hamburg, Chamber of Physicians, Germany, 10/04/2012 ref: PV4087
- 2. Ethics Committee of Prague Psychiatric Centre, Czech Republic, 18/04/2012, ref: 49/12
- 3. The Regional Ethical Review Board Karolinska Institutet, Sweden, ref: nr 2012/462-31/3
- 4. Committee for Medical Ethics, University of Antwerp, Belgium (Comité voor medische ethiek Universiteit Antwerpen), ref: B300201214283

Study design

Two-arm randomized controlled trial study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Prevention of continued risky substance consumption among young persons

Interventions

The overarching goal of the intervention is to encourage reduced alcohol consumption and abstinence of any illicit drugs. The intervention relies on a single session, is fully electronically delivered (automatic) yet interactive. It works with presenting tailored feedback to the participants responses in the earlier assessment (i.e., consumption levels) and provides choice options to react to this feedback. This interactivity simulates a face-to face dialogue, which aims for an empathic style, avoids argumentation, rolls with resistance and aims at creating a dissonance between actual and desired behavior and raising self-efficacy. In these goals, our intervention basically comprises of three components. First, participants will receive personalized feedback on their substance consumption patterns including the associated risks (related to health and other consequences) and comparisons to a normative reference group. Second, participants engage in interactive MI-based exercises that have been proven effective in prompting readiness to change by encouraging the participant to consider the costs and benefits of their current substance use and actual change. Finally, the intervention will include

practical advice concerning alternative behavior in tempting situations, with a focus on peer resistance skills to raise self-efficacy beliefs and implementation intentions. All components will be described in more detail below. Time to complete the intervention is supposed to take 10 to 15 minutes approximately.

The control group will get no intervention. Participants are invited to visit again and participate after the evaluation period of the intervention of 3 months.

Intervention Type

Behavioural

Primary outcome measure

Frequency and quantity of use of alcohol and drugs other than alcohol over a 30 day period, as well as consumption per typical occasion

Secondary outcome measures

- 1. Additional behavioral outcomes including peak drinking quantity
- 2. Frequency of drinking to intoxication and typical weekend-drinking
- 3. Possible changes in substance use related cognitions including attitudes, subjective norms, control/self-efficacy beliefs, implementation intentions, and stages of change
- 4. Moreover the study addresses a number of moderator variables, such as general psychopathology and quality of parent-child relationship

Overall study start date

25/06/2012

Completion date

25/01/2013

Eligibility

Key inclusion criteria

- 1. Age between 16 and 18 years
- 2. A positive screen on the CRAFFT for risky substance use
- 3. Informed consent of the participants
- 4. Access to the internet

Participant type(s)

Patient

Age group

Child

Lower age limit

16 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

n = 800

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

25/06/2012

Date of final enrolment

25/01/2013

Locations

Countries of recruitment

Belgium

Czech Republic

Germany

Sweden

Study participating centre University Hospital Hamburg-Eppendorf

Hamburg Germany 20246

Sponsor information

Organisation

German Center for Addiction Research of Child and Adolescent (Germany)

Sponsor details

Deutsches Zentrum für Suchtfragen des Kindes und Jugendalters (DZSKJ)

University Hospital Hamburg-Eppendorf

Center for Psychosocial Medicine

Martinistrasse 52

Hamburg

Germany

D-20246

Sponsor type

Government

Website

http://www.uke.de/zentren/suchtfragen-kinder-jugend/index.php

Funder(s)

Funder type

Government

Funder Name

European Commission (EU) ref: JUST/2010/DPIP/AG/0914-30-CE-0379823/00-48

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Εвροπεйската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Funder Name

German Centre for Addiction Research in Children and Adolescents, University Medical Centre Hamburg-Eppendorf (Germany)

Funder Name

Laboratory of Social Psychiatry at Prague Psychiatric Center (Czech Republic)

Funder Name

Stockholm Centre for Psychiatric Research and Education, Stockholm County Council Health Care Provision and Karolinska Institute (Sweden)

Funder Name

Vereniging voor Alcohol en andere Drugproblemen vzw (VAD) (Belgium)

Funder Name

Universität Lund, Clinical Alcohol Research, Skane University Hospital (Sweden)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	26/09/2012		Yes	No
Results article	results	24/05/2016		Yes	No