

# Evaluation of two web-based self-help interventions for young adults with risky alcohol use

<b>Submission date</b> 25/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/06/2013	<b>Condition category</b> 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

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

Comparing the efficacy of two web-based self-help interventions for young adults with risky alcohol use a randomised controlled trial

## Study objectives

The modified program with more computer-tailored feedbacks and interactive elements of relapse prevention is more effective than the original version

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The ethics committee of the University of Applied Sciences Magdeburg-Stendal approved the study protocol on 28/10/2010 (ref: AZ 4973-15)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Prevention

## Participant information sheet

Patient information in German can be found at : [https://www.drugcom.de/changeyourdrinking\\_studieninfo.pdf](https://www.drugcom.de/changeyourdrinking_studieninfo.pdf) (german)

## Health condition(s) or problem(s) studied

Risky alcohol use, alcohol abuse or addiction

## Interventions

1. Two versions of a fully automated self-help intervention for adolescents and young adults with risky alcohol use are compared
2. Both versions of change your drinking begin with a self-test (check your drinking), which gives a personalised feedback
3. The aim of change your drinking is to reduce or to drinking
4. In detail, participants should not drink more than 24g/12g (m/f) pure alcohol per day
5. They can even choose to drink less or abstain from drinking
6. After registration participants get access to a drinking diary
7. In the original program the drinking diary can be filled out for 10 days and participants receive a short personalised feedback at the end

8. The modified version lasts 14 days and consists of additional interactive elements:
- 8.1. Participants receive short personalised feedbacks every day and longer feedbacks 7 and 14 days after registration
  - 8.2. Every day participants are advised to reflect their personal risk situations and to develop strategies in order to cope with those situations (relapse prevention)
  - 8.3. Participants are encouraged to reward themselves for achieving their personal goal
  - 8.4. The drinking diary can be extended for additional 14 days, but without personalised feedback
9. The program is open to the general public
10. Eligibility criteria will be checked after completion of the self-test check your drinking
11. Users who do not meet criteria or do not want to participate on the study receive the original version of change your drinking

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

- 1. Alcohol consumption within the last seven days: amount of pure alcohol
- 2. Mean number of drinking days in the past 30 days
- 3. Proportion of subjects drinking within the guidelines: i.e., not drinking more than 24 grams of pure alcohol (men) or 12 grams (women) on any day during the last week
- 4. Proportion of binge drinking within the last seven days: five or more drinks on one occasion
- 5. Mean number of alcohol related problems
- 6. Follow-ups are carried out six weeks and three months after registration

### **Secondary outcome measures**

Satisfaction with the intervention

### **Overall study start date**

01/03/2011

### **Completion date**

31/12/2012

## **Eligibility**

### **Key inclusion criteria**

- 1. Minimum age of 18 years
- 2. Alcohol Use Disorder Identification Test (AUDIT): score of 8 or more
- 3. Last week average daily alcohol consumption of pure alcohol: 24g (males), 12g (females)

### **Participant type(s)**

Patient

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

624

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/03/2011

**Date of final enrolment**

31/12/2012

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

Delphi GmbH

Berlin

Germany

14057

## **Sponsor information**

**Organisation**

Federal Centre for Health Education (BZgA) (Germany)

**Sponsor details**

Ostmerheimer Str. 220

Köln

Germany

51109

**Sponsor type**

Government

**Website**

<http://www.bzga.de>

**ROR**

<https://ror.org/054c9y537>

## Funder(s)

**Funder type**

Government

**Funder Name**

Federal Centre for Health Education (BZgA) (Germany)

**Alternative Name(s)**

Federal Centre for Health Education, BZgA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Germany

## 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?
<a href="#">Results article</a>	results	06/06/2013		Yes	No