

Just-in-time delivered planning intervention to reduce alcohol use in adolescents

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|----------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Submission date 31/05/2017 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 02/06/2017 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 27/05/2020 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Interventions to reduce alcohol use typically include several elements such as information on the risks of alcohol consumption, motivation for sensible drinking, or strategies to resist drinking in certain situations. However, the effectiveness of these single intervention elements within comprehensive programs has not been addressed so far, but could give valuable insights for the development of future interventions. Just-in-time interventions provided via mobile devices (i.e., text messages) are intended to help people to make healthy decisions “in the moment”, and thus have a near-future impact. The aim of this study is to test the impact of such just-in-time delivered interventions on alcohol use and binge drinking.

Who can participate?

Adolescents aged 16 or over who binge drink (i.e., who have drunk 4 (female)/5 (male) or more alcoholic drinks on one or more occasion in the last 30 days)

What does the study involve?

On two of their typically indicated drinking days at 5pm, participants are randomly allocated to receive either:

1. An intervention including two text messages: one text message where they choose one of two predetermined if-then plans to practice sensible drinking, and another text message prompt to visualize the chosen plan
2. No intervention

The number of alcoholic drinks they consume in the evening/night is assessed by another text message at 5pm on the following day.

What are the possible benefits and risks of participating?

Alcohol use may be lower after receiving the sensible drinking text message. No risks of participation are expected.

Where is the study run from?

Swiss Research Institute for Public Health and Addiction (Switzerland)

When is the study starting and how long is it expected to run for?

January 2017 to December 2018

Who is funding the study?

1. Swiss Research Institute for Public Health and Addiction (Switzerland)
2. Swiss Federal Office of Public Health (Switzerland)

Who is the main contact?

Dr Severin Haug

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

17.4.11

Study information

Scientific Title

Efficacy of a just-in-time delivered planning intervention to reduce alcohol use in adolescents with hazardous alcohol consumption: a micro-randomized controlled trial

Study objectives

1. Alcohol use on the evening/night will be lower at points in time with digital micro intervention compared to assessment only

2. Binge drinking prevalence on the evening/night will be lower at points in time with digital micro intervention compared to assessment only

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the Faculty of Philosophy at the University of Zurich, 18/04/2017, ref: 17.4.11

Study design

Micro-randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Home

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

Alcohol prevention

Interventions

Participants receive the just-in-time delivered planning intervention to reduce alcohol use on their typically indicated drinking day at 5pm. The study has an AB/BA crossover design, in which each participant receives the intervention and the control in a randomized order. The randomization sequence will be created using computerized random numbers. There is a period of at least 2 weeks between the intervention and control.

Intervention points in time include:

1. Assessment of state of receptivity and state of vulnerability via SMS text message question ("Are you planning to go out or meet with friend this evening?") on the typical individually indicated drinking day at 5pm
2. Confirmation of receptivity and vulnerability by a text message reply ("Yes") from the participant
3. The digital micro intervention where participants can choose one of two predetermined if-then plans to practice sensible drinking via SMS text messaging and another text message prompt to visualize the chosen plan

Control points in time only include 1 and 2.

Follow-up assessments will be conducted 24 hours after the assessment of state of receptivity and vulnerability in both intervention and control points in time.

Intervention Type

Behavioural

Primary outcome measure

Number of alcoholic standard drinks consumed during the previous evening/night, measured via an SMS text message "How many alcoholic drinks did you have last evening/night?" at 24 hours after the assessment of state of receptivity and vulnerability (i.e., at 5pm the following day)

Secondary outcome measures

Binge drinking: consumption of 5 (male) or 4 (female) or more alcoholic standard drinks during the previous evening/night, measured via an SMS text message "How many alcoholic drinks did you have last evening/night?" at 24 hours after the assessment of state of receptivity and vulnerability (i.e., at 5pm the following day)

Overall study start date

01/01/2017

Completion date

31/12/2018

Eligibility**Key inclusion criteria**

1. Ownership of a mobile phone
2. Hazardous alcohol use defined by binge drinking: consumption of 5 (male; female: 4) or more alcoholic standard drinks on one or more occasions within 30 days preceding the baseline assessment
3. Aged 16 or over

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Both

Target number of participants

79

Total final enrolment

136

Key exclusion criteria

1. No alcohol consumption with friends or when going out in the evening
2. Typical drinking time with friends or when going out: in the morning or afternoon
3. Age < 16

Date of first enrolment

22/06/2017

Date of final enrolment

31/10/2018

Locations

Countries of recruitment

Switzerland

Study participating centre

Swiss Research Institute for Public Health and Addiction

Zurich

Switzerland

8031

Sponsor information

Organisation

Swiss Research Institute for Public Health and Addiction

Sponsor details

Konradstrasse 32

Zurich

Switzerland

8031

Sponsor type

University/education

Website

www.isgf.ch

ROR

<https://ror.org/02crff812>

Funder(s)

Funder type

University/education

Funder Name

Swiss Research Institute for Public Health and Addiction

Funder Name

Swiss Federal Office of Public Health

Results and Publications

Publication and dissemination plan

Planned publication in a psychological or medical peer reviewed journal around one year after the overall trial end date.

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Severin Haug (severin.haug@isgf.uzh.ch).

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 26/05/2020 | 27/05/2020 | Yes | No |