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

Submission date
31/05/2017

Recruitment status
No longer recruiting

Registration date
02/06/2017

Overall study status
Completed

Last Edited
27/05/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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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 Reseach 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