ISRCTN11768445 https://doi.org/10.1186/ISRCTN11768445

# Does the game VR FestLab improve alcohol resistance skills among adolescents?

| | | |
|---|---|---|
| **Submission date**<br>07/04/2020 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>04/05/2020 | **Overall study status**<br>Completed | |
| **Last Edited**<br>14/03/2022 | **Condition category**<br>Other | |

## Plain English summary of protocol

Background and study aims
Denmark is among the countries with the highest rate of substance abuse in Europe. Alcohol use is a major risk factor for a number of diseases and contributes as a significant factor to homicides, suicides, and motor vehicle fatalities. There is a strong relationship between early onset of drinking and later development of alcohol use disorders. Adolescents who begin drinking at a younger age also tend to have lower self-esteem, be less resistant to peer pressure and display anti-social features. Researchers have developed a Virtual Reality (VR) alcohol prevention programme “VR FestLab” – a gamified drama that unfolds at a teen house party, with a range of storylines, actioned and determined by the user. This study aims to test if a virtual social environment can help young people build their skills to make decisions and say “no” in situations where they may feel that they are subject to peer pressure in relation to alcohol and other drugs.

Who can participate?
Danish-speaking adolescents aged 15-18

What does the study involve?
The VR-based learning tool consists of a computer simulation of a three-dimensional environment that shows a typical party situation for young people. Participants are able to "steer" their own party through intuitive and realistic choices that can be carried out using special electronic equipment. Intended effects of the game “VR FestLab" are increased drinking refusal self-efficacy regards social pressures and a change of alcohol expectancies. The tool will be tested with 420 participants randomly allocated into a VR game play group and an active control group with another commercial game (e.g. Wii). The effect will be measured using a tested questionnaire that includes questions to assess a person's belief in his/her own ability to resist drinking alcohol in social situations and questions measuring the participants' expectations about the positive or negative outcomes of drinking alcohol. In addition, the researchers will investigate user satisfaction, game involvement and gaming experience through both questionnaires and individual interviews.

What are the possible benefits and risks of participating?
The possible benefits of participating in the study for the adolescents are that through this

virtual social environment they can build their skills to make decisions and say “no” in situations where they may feel that they are subject to peer pressure in relation to alcohol and other drugs. There are not identified any possible risks of participating in this study. However, the study will involve collecting health behavior data regarding wellbeing, drinking and smoking behaviour which could be sensitive to disclosure for this age group. Further, the VR FestLab experience portraying a party situation may not be acceptable to adolescents with very strict religious beliefs, where any alcohol use is not permitted.

Where is the study run from?
University of Southern Denmark (Denmark)

When is the study starting and how long is it expected to run for?
June 2019 to May 2021

Who is funding the study?
TrygFonden (Denmark)

Who is the main contact?
Associate professor Christiane Stock
cstock@health.sdu.dk

# Contact information

### Type(s)
Public

### Contact name
Prof Christiane Stock

### ORCID ID
https://orcid.org/0000-0001-9379-3844

### Contact details
Principal Investigator
Unit for Health Promotion Research
Department of Public Health
University of Southern Denmark
Esbjerg
Denmark
6700
+45 (0)65504210
cstock@health.sdu.dk

### Type(s)
Scientific

### Contact name
Prof Christiane Stock

### ORCID ID
https://orcid.org/0000-0001-9379-3844

### Contact details
Principal Investigator
Unit for Health Promotion Research
Department of Public Health
University of Southern Denmark
Esbjerg
Denmark
6700
+45 (0)65504210
cstock@health.sdu.dk

# Additional identifiers

### Protocol serial number
TrygFonden ID 129372

# Study information

### Scientific Title
Does a virtual reality-based game improve alcohol resistance skills among adolescents? A cluster randomised controlled trial

### Acronym
VR FestLab

### Study objectives
Current study hypothesis as of 02/02/2021:

The main hypothesis is that adolescents who experience “VR FestLab" score higher in drinking refusal self-efficacy (DRSQ) at first follow-up compared to those in an active control group. The secondary aim is to test the effects of game to encourage adolescents towards more responsible behaviour in party situations. The hypothesis is that the “VR FestLab" increases awareness of social pressures and creates more realistic outcome expectations and positive role-models for staying in control.

_____

Previous study hypothesis:

The main hypothesis is that adolescents who experience “VR FestLab" score higher in drinking refusal self-efficacy (DRSQ) and drug refusal skill scales compared to those in an active control group.
The secondary aim is to test the effects of game to encourage adolescents towards more responsible behaviour in party situations. The hypothesis is that the “VR FestLab" increases awareness of social pressures and creates more realistic outcome expectations and positive role-models for staying in control.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 20/03/2020, Research Ethics Committee of the University of Southern Denmark (University of Southern Denmark, cc: Nadine Kollmeyer, SDU Research & Innovation Organisation, Cortex Park 26, DK – 5230 Odense M, Denmark; +45 (0)6550 3578 / 9350 7483; nadko@sdu.dk), ref: 20/5348

## Primary study design
Interventional

## Study design
Cluster randomised controlled trial

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
The use of alcohol and other drugs (AOD) among young people in Denmark

## Interventions
Current interventions as of 01/10/2020:
The trial is conducted in grades 9 and 10 of public and boarding schools in the region of Southern Denmark. Randomization will be performed by a statistician by the use of the randomization function in SAS.

Intervention schools:
All classes receive the same intervention consisting of a session where each student will try the virtual reality FestLab game, followed by a group session where the experiences will be discussed.

Control schools:
All classes receive the same intervention consisting of a session where each student will try another VR game (Oculus Quest – First Steps). All classes are offered to try the VR FestLab game after participating in the follow-up survey as an incentive to participate.

The total duration of the intervention itself is approximately 45 minutes.

Previous interventions:
The trial is conducted in grades 9 and 10 of public and boarding schools in the region of Southern Denmark. Randomization will be performed by a statistician by the use of the randomization function in SAS.

Intervention schools:
All classes receive the same intervention consisting of a session where each student will try the virtual reality FestLab game, followed by a group session where the experiences will be discussed.

Control schools:
All classes receive the same intervention consisting of a session where each student will try another VR game (Merry Snowballs). All classes are offered to try the VR FestLab game after participating in the follow-up survey as an incentive to participate.

The total duration of the intervention itself is approximately 45 minutes.

6-8 focus group interviews will be conducted with pupils in the intervention group regards their experiences with VR FestLab. Focus group interviews will be conducted according to individual arrangements with the schools.

## Intervention Type
Device

## Phase
Not Applicable

## Primary outcome(s)
Current primary outcome measure as of 02/02/2021:
1. Resistance towards peer pressure to drink measured by the Social Pressure subscale of the DRSEQ-R at baseline and at first follow up (immediately after the intervention)

---

Previous primary outcome measure:

1. Resistance towards peer pressure to drink measured by the Social Pressure subscale of the DRSEQ-R at baseline, at first follow up (immediately after the intervention), and second follow up (6 weeks follow-up)
2. Drug refusal skills measured using the Brief Assessment Tool for the Life Skills Training Drug-Abuse at baseline, first follow up (immediately after the intervention), and second follow up (6 weeks follow-up)

## Key secondary outcome(s)
Current secondary outcome measures as of 02/02/2021:

All secondary outcome measures (except gameplay experiences) are measured by the baseline survey, first follow up (immediately after the intervention), and second follow up (6 weeks follow-up). Gameplay experiences are measured immediately after the intervention only.

1. Knowledge of blood-alcohol concentration (BAC) measured using questions developed by the research team at baseline, first follow up, and second follow up
2. Communication skills measured using the items concerning knowledge in the Alcohol Misuse Prevention questionnaire at baseline, first follow up, and second follow up
3. Positive role-models measured using questions developed by the research team with inspiration from the Regan Attitudes toward Non-Drinkers Scale (RANDS) at baseline, first follow up, and second follow up
4. Social support willingness measured using questions developed by the research team at baseline, first follow up, and second follow up
5. Outcome expectations measured using Danish “Ungeprofil” [Youth profile] at baseline, first follow up, and second follow up
6. Awareness of social pressures measured using one item of the Susceptibility to Peer Pressure index at baseline, first follow up, and second follow up
7. Gameplay experience (level of engagement, enjoyment and emotional reactions) measured by a scale developed by the research team as well as with the User Experience Questionnaire (UEQ-S) immediately after the intervention (first follow up) only

8. Drug refusal skills measured using the Brief Assessment Tool for the Life Skills Training Drug-Abuse at baseline, first follow up, and second follow up first follow up
9. Resistance towards peer pressure to drink measured by the Social Pressure subscale of the DRSEQ-R at baseline and at second follow-up

6-8 focus group interviews will be conducted with pupils in the intervention group regards their experiences with VR FestLab. Focus group interviews will be conducted according to individual arrangements with the schools.

_____

Previous secondary outcome measures:

All secondary outcome measures (except gameplay experiences) are measured by the baseline survey, first follow up (immediately after the intervention), and second follow up (6 weeks follow-up). Gameplay experiences are measured immediately after the intervention only.

1. Knowledge of blood-alcohol concentration (BAC) measured using questions developed by the research team at baseline, first follow up, and second follow up
2. Communication skills measured using the items concerning knowledge in the Alcohol Misuse Prevention questionnaire at baseline, first follow up, and second follow up
3. Positive role-models measured using questions developed by the research team with inspiration from the Regan Attitudes toward Non-Drinkers Scale (RANDS) at baseline, first follow up, and second follow up
4. Social support willingness measured using questions developed by the research team at baseline, first follow up, and second follow up
5. Outcome expectations measured using Danish “Ungeprofil” [Youth profile] at baseline, first follow up, and second follow up
6. Awareness of social pressures measured using one item of the Susceptibility to Peer Pressure index at baseline, first follow up, and second follow up
7. Gameplay experience (level of engagement, enjoyment and emotional reactions) measured by a scale developed by the research team as well as with the User Experience Questionnaire (UEQ-S) immediately after the intervention (first follow up) only

6-8 focus group interviews will be conducted with pupils in the intervention group regards their experiences with VR FestLab. Focus group interviews will be conducted according to individual arrangements with the schools.

### Completion date
17/05/2021

# Eligibility

### Key inclusion criteria
1. Public primary/elementary schools in the Region of Southern Denmark
2. Students aged 15 – 18
3. Males/females/diverse

### Participant type(s)
Healthy volunteer

**Healthy volunteers allowed**
No

**Age group**
Child

**Lower age limit**
15 Years

**Upper age limit**
18 Years

**Sex**
All

**Total final enrolment**
573

**Key exclusion criteria**
1. Individual students with insufficient knowledge of Danish to understand typical everyday conversations
2. Individual students with special educational needs in mainstream classrooms

**Date of first enrolment**
01/06/2020

**Date of final enrolment**
05/07/2020

# Locations

**Countries of recruitment**
Denmark

**Study participating centre**
**University of Southern Denmark**
Niels Bohrs Vej 9-10
Esbjerg
Denmark
6700

# Sponsor information

**Organisation**
TrygFonden

**ROR**
https://ror.org/02rcazp29

# Funder(s)

**Funder type**
Charity

**Funder Name**
TrygFonden

**Alternative Name(s)**
Tryg Foundation

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
Denmark

# Results and Publications

**Individual participant data (IPD) sharing plan**
For access to the datasets please contact the principal investigator Associate professor Christiane Stock (cstock@health.sdu.dk). The type of data which is available upon request is data from the pre, post and follow-up survey. Data will, after full anonymization, be available after the project is finished, and the effect paper is published. Access criteria for access to the data are that the data can only be used for analysis which is out of scope for the present study. All researchers or students in higher education are eligible for access to the data. Accessed data will be available for statistical analysis and will be accessed by being granted access to a cloud where data is stored. At the beginning of the questionnaire the researchers have specified that all information the participants provide in connection with the questionnaire will be treated confidentially and anonymously. An individual anonymous code will be generated based on background information such as first letter in mother's name, school and month of birth. After the generation of the code these variables will be deleted. The pseudoanonymized data will later be fully anonymized.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| Results article | | 10/03/2022 | 14/03/2022 | Yes | No |
| Other publications | intervention design article | 09/02/2020 | 02/02/2021 | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |