## The GOOD Life intervention

Submission date 28/01/2016	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>[X] Protocol</li> </ul>
<b>Registration date</b> 17/02/2016	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 10/03/2023	<b>Condition category</b> Mental and Behavioural Disorders	Individual participant data

#### Plain English summary of protocol

#### Background and study aims

The use of alcohol and other drugs (AOD) among adolescents in Denmark is one of the highest in Europe. Some 34% of Danish pupils aged 15-16 years have already experienced being drunk while an average in Europe for this age group is 17%. Similarly, the percentage of binge drinking i.e. who have consumed five or more drinks at one drinking session, in this age group is high with 38% and 26% for boys and girls, respectively. Improvements in alcohol behaviour have been seen during past few years, but, as the numbers reveal ,not enough to be comparable to other European countries. Long-term, there is a risk that harmful drinking could develop in adulthood, along with alcohol dependency and alcohol related diseases later in life. In other countries social norm marketing has been shown to be an good method of reducing the amount of alcohol young people drink. Social norms are "perception and beliefs of what is normal behaviour in the people close to us" and they are found to be a key factor for modifying drug use. Adolescents in particular tend to overestimate the amount of drugs that other people in their peer group take, leading them to take more drugs themselves. Individuals may overestimate the frequency and quantity of alcohol use (descriptive norms) as well as how acceptable peers feel heavy drinking to be (injunctive norms). Based on social comparison theory individuals are then motivated to match their own alcohol use to this incorrect perception. On the basis of previous studies showing promising results the current study 'The GOOD life' has been developed. The aim is to determine the effectiveness of a basic social norm intervention (programme) in preventing binge drinking and social misperceptions among adolescents 14-16 years old in the Region of Southern Denmark.

#### Who can participate?

The trial will be run in the region of Southern Denmark. All pupils in grade 8 or 9 can participate.

#### What does the study involve?

The schools who confirm participation are randomly allocated to one of two groups. Schools in the intervention group receive a one hour feedback session on the theory of social norms and the difference between true and perceived alcohol consumption amongst pupils. Each school is also given 4-5 posters with various messages selected specifically for that school which are then put up for the duration of the study period. There is also a web-based app where pupils can test their own social misunderstandings. Schools in the control group carry on as usual during the study period but do receive the GOOD life programme after it is complete. All pupils (in both groups of schools) fill out surveys on how much alcohol they drink, whether they have smoked

tobacco or taken drugs and their perceptions on how much their peers drink, smoke or take drugs at the beginning of the study and then again after 4 months.

What are the possible benefits and risks of participating?

The potential benefits are for pupils are correcting misperceptions of peer alcohol and other drug consumption and reduced engagement in risk-behaviour. Potential risks can be feelings of guilt or discomfort related to own alcohol and other drug use.

Where is the study run from? University of Southern Denmark, Unit for Health Promotion Research

When is study starting and how long is it expected to run for? January 2014 to June 2017

Who is funding the study? 1. TrygFonden, Denmark 2. University of Southern Denmark

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

#### Study website

http://sdu.dk/en/Om\_SDU/Institutter\_centre/Ist\_sundhedstjenesteforsk/Forskning /Forskningsenheder/Sundhedsfremme/Forskningsprojekter/detgodeliv

### **Contact information**

**Type(s)** Scientific

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### Additional identifiers

EudraCT/CTIS number

#### **IRAS number**

ClinicalTrials.gov number

Secondary identifying numbers S-20140185

### Study information

#### Scientific Title

Social norms intervention to prevent drug use and its harmful consequences among Danish adolescents: Det gode liv mellem de unge

Acronym TheGOODlife

#### Study objectives

The social norm intervention results in a 20% decrease in binge drinking (5 or more drinks per one occasion) among pupils from intervention schools compared to control schools

**Ethics approval required** Old ethics approval format

#### Ethics approval(s)

De Videnskabsetiske Komitéer for Region Syddanmark (The Regional Committees on Health Research Ethics for Southern Denmark), approved December 15, 2014, S-20140185

**Study design** Cluster randomized controlled trial

**Primary study design** Interventional

Secondary study design Cluster randomised trial

**Study setting(s)** School

**Study type(s)** Prevention

Participant information sheet

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

The use of alcohol and other drugs (AOD) among young people in Denmark.

#### Interventions

The trial is conducted in grades 8 and 9 of public schools in the region of Southern Denmark.

Intervention schools:

All schools receive the same intervention consisting of three intervention components: Normative feedback is given through social norms messages for each school. They are phrased to challenge potential overestimations of peer behaviour and attitude towards alcohol use. The messages are used throughout the three main components of the "The GOOD life" programme. 1. A one-hour feedback session: Schools will receive a class-based feedback session on the theory of social norms and the discrepancy between perceived and true consumption of alcohol. The session is based on interaction and high amount of inclusion of pupils e.g. through a webbased poll, which displays what the class collectively assume to be the truth where after the true data from the baseline data collection are presented.

Posters: Each school will receive 4-5 posters with various selected messages specific for the school. Teachers are asked to hang them up for the remaining period of the intervention.
 Web-app: A web-based element is included, where pupils by using laptops or smartphones can test their social misunderstandings. The app function as the web-poll, but on an individual basis.

#### Control schools:

Do not receive any social norms intervention during the trial period. They receive the feedback sessions and posters for their school after participating in the follow-up survey as incentive to participate.

#### Intervention Type

Behavioural

#### Primary outcome measure

Binge drinking (more than 5 units per one occasion) during the last 30 days measured by baseline survey and follow-up survey after 4 months

#### Secondary outcome measures

- 1. Smoking in the last 30 days
- 2. Marihuana use in the last 30 days
- 3. Perceived alcohol use of peers
- 4. Perceived smoking of peers
- 5. Perceived marihuana use of peers
- 6. Number of alcohol related harms

All secondary outcomes measured by baseline survey and follow-up survey after 4 months.

## Overall study start date 01/01/2014

**Completion date** 30/06/2017

### Eligibility

#### Key inclusion criteria

1. Public schools in the Region of Southern Denmark

2. Pupils in grades 8 or 9

**Participant type(s)** Healthy volunteer **Age group** Child

**Sex** Both

**Target number of participants** 26 clusters (schools) with 1400 participants (pupils)

**Key exclusion criteria** Private schools

**Date of first enrolment** 01/01/2015

Date of final enrolment 31/12/2016

### Locations

**Countries of recruitment** Denmark

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

### Sponsor information

**Organisation** TrygFonden

Sponsor details Hummeltoftevej 49 Virum Denmark 2830 ++45 26 08 00 info@trygfonden.dk

#### Sponsor type

Charity

Website https://www.trygfonden.dk/english

ROR https://ror.org/02rcazp29

### Funder(s)

**Funder type** Research organisation

**Funder Name** TrygFonden

**Funder Name** Syddansk Universitet

Alternative Name(s) University of Southern Denmark, SDU

**Funding Body Type** Private sector organisation

**Funding Body Subtype** Universities (academic only)

**Location** Denmark

### **Results and Publications**

#### Publication and dissemination plan

1. Intervention design article July 2016

2. Baseline findings August 2016

3. Intervention effect article February 2017

#### Intention to publish date

01/03/2017

Individual participant data (IPD) sharing plan

Not provided at time of registration

# **IPD sharing plan summary** Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Basic results</u>		19/10/2018	19/10/2018	No	No
<u>Results article</u>	results	28/10/2018		Yes	No
<u>Protocol article</u>		03/08/2016	10/03/2023	Yes	No
Results article	Qualitative findings	04/05/2020	10/03/2023	Yes	No
<u>Results article</u>	Secondary analysis	28/08/2019	10/03/2023	Yes	No