# Shaping the Social: Evaluating the effect of a complex intervention to promote wellbeing and educational attainment and reduce substance use among students in Danish vocational schools

Submission date 30/12/2012	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>[X] Protocol</li> </ul>
<b>Registration date</b> 16/01/2013	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 20/09/2018	<b>Condition category</b> Mental and Behavioural Disorders	Individual participant data

#### Plain English summary of protocol

Background and study aims

Only half of all Danish students starting vocational training complete their programme. The largest drop-out occurs during basic training and 4 in 10 of those who drop out do not continue in education within ten years. Little is known of the health status of this particular group, but it is frequently reported that young people with a problematic pattern of substance abuse experience difficulties in completing an education. At vocational schools, improvements in institutionally anchored possibilities for socializing may reduce the risk of dropping out and prevent harmful substance use. Our goal is to develop, implement, and evaluate an intervention that works through changes in the institutional arrangements of vocational colleges. The aim of the study is to assess the effect of a complex intervention on school wellbeing, physical and psychological wellbeing, smoking and school attainment.

#### Who can participate?

The study aims to recruit students aged > 15 years, both boys and girls enrolled in basic vocational training at 10 schools across Denmark from October 2011 - October 2012.

#### What does the study involve?

The intervention works through changes in the institutional arrangements to improve possibilities for socializing and it is tested among students at four vocational schools. The comparison group consists of students at six vocational schools that continue with their usual practice. About 6,400 students answer questionnaires in the beginning of their vocational training and with follow up after about 10 weeks. To avoid non-response bias the data collection is performed at school. Follow-up of non-respondents is by mail, SMS and a letter. In addition, drop-out rates are tracked via national registers.

What are the possible benefits and risks of participating?

We expect the students in the intervention group to get a more consistent, predictable and socially anchored schooling. The school management and teachers at intervention schools need to engage in continuous collaboration with the researchers about the intervention.

Where is the study run from?

The Shaping the Social study has been set up by the Center for Intervention Research in Health Promotion and Disease Prevention, based at the National Institute of Public Health in Denmark, and is part of the Faculty of Health Sciences at the University of Southern Denmark. In collaboration with researchers at Centre for Alcohol and Drug Research at University of Aarhus, Unit for Health Promotion Research at University of Southern Denmark, Department of Psychosocial Research at The Danish Cancer Society and Department of Psychology and Educational Studies based at Roskilde University.

When is study starting and how long is it expected to run for? The study starts in October 2011 and will run to January 2013. However, the study will extend beyond this as we intend to use national registers.

Who is funding the study? The study is funded by Trygfonden, Denmark.

Who is the main contact? Dr Liselotte Ingholt, liin@niph.dk Miss Susan Andersen, sua@niph.dk

**Study website** http://www.cirhp.dk/side.asp?side=8&id=15&ver=uk

# **Contact information**

**Type(s)** Scientific

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# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

# Study information

#### Scientific Title

A controlled trial evaluating the effect of a complex intervention to promote wellbeing and educational attainment and reduce substance use among students in Danish vocational schools

#### Study objectives

The aim of the study is to access the effect of a complex intervention on school wellbeing, physical and psychological wellbeing, smoking and school attainment. The hypotheses:

1. Social and professional communities at the school have a positive impact on students' school well-being

2. Positive school well-being is important to keep students on training

3. Positive school well-being are associated with fewer somatic and psychological symptoms and positively associated with life satisfaction

4. Institutional structures affecting the formation of social communities are important for reducing smoking in school

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The study has been considered by the Danish Ethical Committee and they concluded that formal ethics approval was not required. This project is registered at the Danish Data Protection Agency (Datatilsynet) (ref: 2011-54-1265)

#### Study design

Quasi-experimental design

#### Primary study design

Interventional

#### Secondary study design

Non randomised controlled trial

**Study setting(s)** Other

**Study type(s)** Quality of life

#### Participant information sheet

Not available in web format, please use contact details to request a patient information sheet

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

School wellbeing, physical and psychological wellbeing , smoking and school attainment

#### Interventions

The intervention comprises two areas aimed at:

1. First day at school: Here the programme focuses on activities that welcome new students, such as introduction of the students to the school, the education, the professional standard and the fellow students.

2. Everyday practice: Here the programme focuses on changes in everyday practice to integrate social activities and social ties with professional learning such as morning meetings, scheduled breaks, fewer possibilities for smoking, and a nook for hanging out during breaks.

The intervention programme is a tool to be used by school management and staff to initiate activities in the two areas. For each of the intervention areas, a number of mandatory and optional improvements will be implemented to either modify existing institutional structures or to establish new ones.

Comparison group consists of students at six vocational schools that continue with their usual practice.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

1. School well-being measured at 10 weeks:

1.1 Positive relations with peers measured on items from Health Behaviour in School-aged Children (HBSC) questionnaire (Roberts et al. 2009; Currie et al. 2009).

1.2 Positive relations with teachers (HBSC items)

1.3 Engagement with and positive attitudes toward the school and the profession (based on HBSC questionnaire and new Shaping the Social items)

1.4 Connectedness to school (HBSC item)

2. Self-reported smoking measured at baseline, and at 10 weeks, and self-reported smoking in school measured at 10 weeks.

3. Dropout in basic course assessed by national registers measured at 1 year, also self-reported dropout measured at 10 weeks.

The Shaping the Social intervention is designed to create significant positive changes at followup versus baseline and between groups. School well-being is not measured at baseline because baseline data collection is performed at the first days of the students vocational training.

#### Secondary outcome measures

Secondary outcome measures measured at baseline, and at 10 weeks:

1. Physical and psychological well-being measured on the HBSC Symptom Check List (HBSC-SCL).

2. Loneliness measured on loneliness scale (four response categories)

3. Life satisfaction measured on Cantril Ladder Scale

Predefined unintended outcome measures measured at baseline, and at 10 weeks:

4. Self-reported alcohol consumption.

5. Self-reported drug use (cannabis and other drugs than cannabis (e.g. cocaine, amphetamine, ecstasy, steroids).

We will measure alcohol and drug consumption as side-effects but it is difficult to predict whether they will occur as unintended adverse or positive effects. Increased school wellbeing

has a positive impact on alcohol and drug use. However, the literature also indicate that young people who have an active social life have more drunkenness-oriented drinking patterns and are experimenting more with drugs.

The primary and secondary outcome measures will be analyzed for sub populations defined by implementation level, age, parental socioeconomic status and the education and training programs.

#### Overall study start date

01/10/2011

#### **Completion date**

31/01/2013

# Eligibility

#### Key inclusion criteria

Students (aged > 15 years, either sex) attending the basic course at one of the 10 participating vocational schools in the period between October 2011 to October 2012. The education and training programs consists of a basic and a main course. The following basic education and training programs are included: Building and construction (carpenter, bricklayer, painter, plumber), electrician, data technician, mechanic, food for human (e.g. cook, waiter), media (e.g. graphic designer, web integrator, sign writer), landscaping, farmer, greenhouse gardener.

Participant type(s) Patient

**Age group** Child

Lower age limit 15 Years

**Sex** Both

Target number of participants Approximately 6400 students in total

**Key exclusion criteria** Students following special education programs that lead to a higher degree of education

# Date of first enrolment 01/10/2011

Date of final enrolment 31/01/2013

## Locations

Countries of recruitment

Denmark

**Study participating centre** Øster Farimagsgade 5a, 2. Copenhagen Denmark 1353

### Sponsor information

**Organisation** Tryg Foundation (TrygFonden) (Denmark)

**Sponsor details** Lyngby Hovedgade 4, 2. sal Kgs. Lyngby Denmark 2800

**Sponsor type** Government

**Website** http://www.trygfonden.dk/Om-TrygFonden/In-English

ROR https://ror.org/02rcazp29

# Funder(s)

**Funder type** Government

**Funder Name** Tryg Foundation (TrygFonden) (Denmark)

# **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?
Protocol article	protocol	20/06/2015		Yes	Νο
Results article	results	12/09/2018		Yes	No