

High schools- High on life Study protocol

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The High schools- High on life intervention – aim and project organization

High schools-High on life is an intervention developed in a collaboration between the Danish Cancer Society's alcohol campaign "High on life" and the National Institute of Public Health, SDU, Denmark and evaluated by the National Institute of Public Health, SDU, Denmark. The aim of the intervention is to reduce alcohol consumption among Danish high school students and thereby contribute to a healthier alcohol culture among young people in Denmark.

The intervention will be implemented and evaluated in the school year 2019-2020

Target group: 1st year high school students in Denmark (≈16 years of age)

Background

Compared to other countries, Denmark has one of the highest levels of drunkenness among adolescents and drinking to intoxication is common even among young teenagers [1]. Among Danish high school students 28% (35% boys and 24% girls) have been binge drinking 4 or more times within the last 30 days and 20% drink above recommended high risk drinking limits of 21 units a week for men and 14 units a week for women [2].

In the short-term alcohol use in adolescence can lead to accidents, conflicts and violence [3, 4]. Excessive alcohol use in the teenage years often tracks into and through adulthood and early drinking onset increases the risk of addiction later in life [5-9]. In the long term, adolescent binge drinking has also been associated with adult physical and mental health and social consequences such as illicit drug use, school dropout and lower adulthood social class, however the existing evidence is of insufficient quality to warrant causal inferences [10, 11].

Previous primary prevention interventions have most often been targeting primary school children with the goal of abstinence or postponed debut age [12]. Educational school programs targeting primary school children have been most effective when they involved teaching skills to refuse peer pressure and drug offers and enhance social and personal competences including problem solving and decision-making skills [12-17]. However, fewer school-based interventions have been targeting High school students.

Interventions targeting older adolescents are mostly American college interventions [18, 19], high risk interventions based on screening and brief motivational interviewing [20, 21] or internet-based personalized normative feedback interventions [22, 23]. The American college literature translates difficultly to the Danish high school setting in which students still live at home with parents, but where alcohol is a strongly integrated part of the Danish high school culture, and where a large group of the students drink excessively [24, 25]. In a European context, the best evidence of effectiveness for alcohol interventions among adolescents is, the intervention project 'the Unplugged program' [26]. The design of 'the Unplugged program' was based on the Comprehensive Social Influence Approach [27, 28], incorporating life skills elements such as social skills, personal skills, knowledge and normative education. Results from a large cross-national study which was carried out in seven European countries showed that exposure to 'the Unplugged program' was associated with a significantly lower prevalence of episodes of drunkenness and marijuana use in the past 30 days in the intervention group 15 months after the completion of the program, compared to the control group [16]. Frequency of alcohol consumption was however not significantly affected by the intervention [29].

Based on the high prevalence levels of excessive drinking in Danish youth, there is an urgent need for intervening among Danish high school students (15-20-year old) to reduce excessive alcohol use and promote a healthy alcohol culture. The aim of the intervention *High schools- High on life* was to develop, implement and evaluate a multi-component high school-based intervention to reduce excessive drinking among high school students.

Research questions:

Can the *High schools- High on life* intervention reduce alcohol consumption among 1st year high school students after one year of intervention?

How does the level of implementation affect the effect?

Which barriers and facilitators are important in relation to the implementation of the intervention at high schools?

Intervention components

The Intervention consists of three main components: school environmental component, school educational components and parental components, which will be elaborated in the following section. Intervention schools are encouraged to deliver all components.

School environmental component: Alcohol policy

A checklist for high schools' development/revision of the alcohol policy was developed with the aim to limit availability of alcohol, help enforcement and communicate clear attitudes to alcohol. The checklist was based on evidence from the national alcohol policies [30, 31] that have shown effect previously and interviews with principals to ensure feasibility. Most initiatives were mandatory to implement; however, some initiatives were optional because of implementation challenges or weaker evidence of impact. Headmasters will receive the checklist and be asked to tick the initiatives they intend to introduce before the new 1st year high school students begin in August 2019. Each school can decide for itself whether they also want to introduce the optional items in the checklist. Headmasters are asked to sign the adapted checklist and return it to the Danish Cancer Society to be published on the project's website. In this way, the checklist can also become a tool for leaders to promote and label their high school as a responsible institution. Headmasters are responsible for implementing and enforcing the new policy.

School educational components

-Web based education for social student committees that organize events where alcohol is sold such as parties, cafés, concerts etc. were developed, alongside with an web-based educational program for the introduction committee welcoming 1st year high school students to the high school.

The purpose of the web-based educational programs to the social student committees and intro committees is to make students aware of their responsibility for developing inclusive events, were students that do not drink also feel welcome, and the fact that they act as role models for their peers. The programs will provide information on national legislation on alcohol at high schools, marketing of alcohol, school alcohol policy, information on drinking peer pressures and social norms for adolescent alcohol use. Further, the programs provide guidance to arrange appealing social events without focusing on alcohol.

Pocket movie campaign

The aim of the Pocket movie campaign is to make students reflect on their alcohol use, and when it is fun and not fun to drink. The campaign aims at promoting a new drinking norm of drinking less. All 1st year high school students will receive one day training on how to make movies using their smartphones and information on how alcohol increases the risk of acute consequences such as conflicts, having sex you regret and getting sick. The day is facilitated by the company Lommefilm A/S. In groups of 4 students, students are encouraged to create a 45 seconds long prevention campaign movie with the message "Drink less- experience more".

Social norms campaign

The social norms campaign aims to promote new social norms of drinking among high school students. It includes posters and videos. In the video campaign 3rd year high school students provide new 1st year students with advices of high school start and encourage them to take it slow and not drink too much. The video will be shared on high schools' websites and Facebook-page and distributed to new 1st year high school students. Through identification with 3rd year students 1st year students are expected to change their expectation of how much they need to drink to fit in. The video campaign will be supported by posters (digital and in print) with the video campaign message, distributed to schools.

Additional posters (digital and in print) guided by the Social Norms Approach [32-34] will be distributed to high schools. *The 'perceptions and beliefs of what is "normal" behavior in the people close to us'* [32] has been identified as a key factor modifying drug use behavior among young adults. It has been shown that adolescents and young adults tend to overestimate drug use in their respective peer group and that these incorrect perceptions are predictive of higher rates of personal drug use [35-37]. Regarding alcohol use, these misperceptions can include both rates of peer alcohol use (*descriptive norms*) and the social acceptability of alcohol use (*injunctive norms*). Students tend to overestimate the frequency and quantity of alcohol consumption of their peers, as well as their peers' acceptability of heavy drinking. The students are then motivated to match their own alcohol consumption to what is an incorrect overestimated perception. Previous social norms interventions have been found to be effective in changing attitudes and knowledge about the norms of alcohol use, and some have been effective in changing behavior [32, 36]. Based on the social norm approach the aim of the posters is to correct misperceptions about the group norm and thereby decrease the social pressure to drink excessively on the individual student. The posters include descriptive and injunctive norms, tailored to each high school, based on the baseline survey.

Parental Components

The aim of the components is to empower parents to talk to their children about alcohol and reach an agreement on their drinking habits. The materials inform parents that their attitudes toward alcohol are associated with how much their children drink (even though their children are now older and have entered high school). Furthermore, the parents will be encouraged and receive guidance on how to discuss alcohol with their child and make agreements. The parental component consists of three separate elements.

- School meeting for parents

At the beginning of the school year, all schools must invite parents of 1st year high school students to a parent meeting, to inform them of the high school's alcohol policy. Parents are encouraged to support high school policies and discuss alcohol with their child.

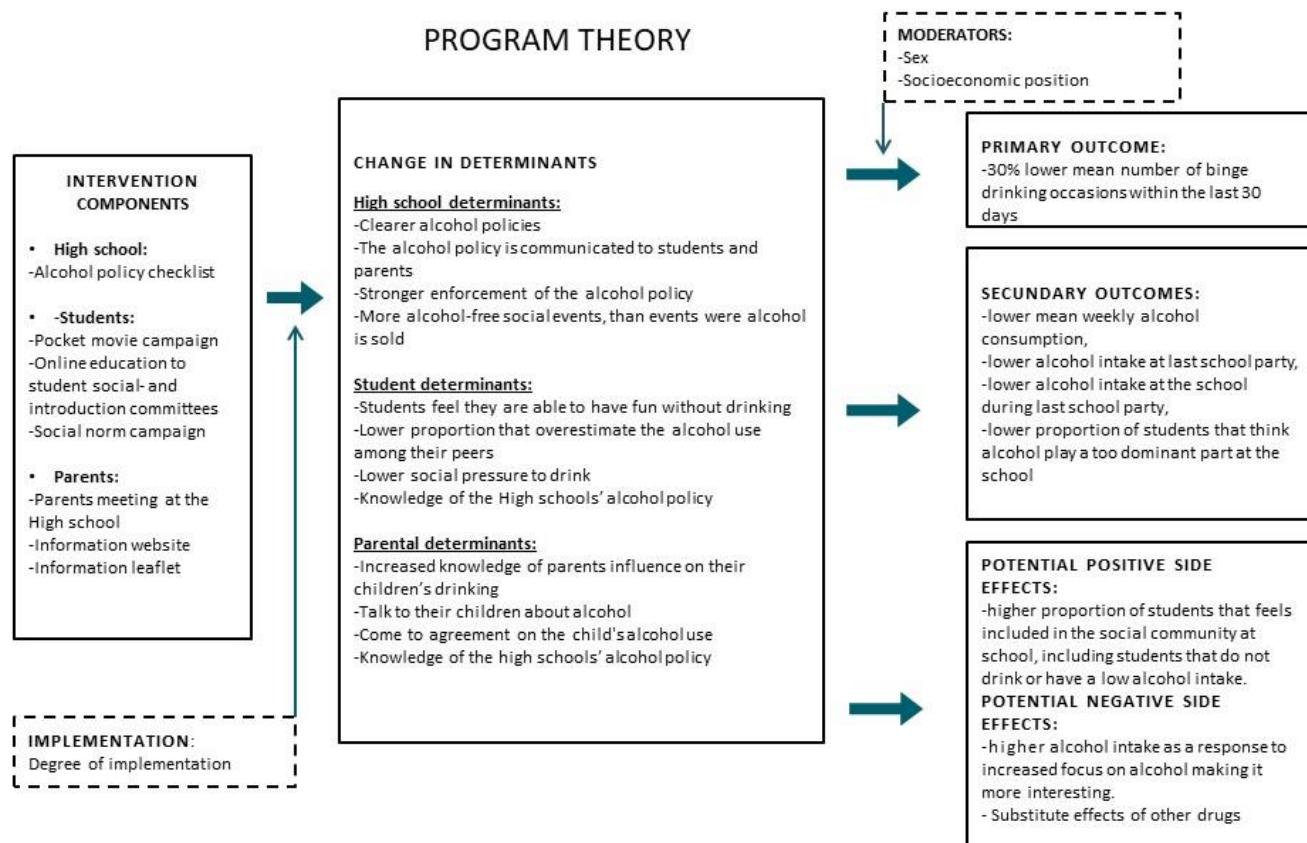
-Parent leaflet

At the parents' meeting, the parents will receive an information leaflet on young people's alcohol consumption and attitudes, and what they can do to prevent excessive alcohol consumption among their children. The Information leaflet will also contain links to the website.

-Website for parents

The information website is designed to provide parents with information on how their attitudes toward alcohol are still important to how much their children drink and give parents the skills to discuss alcohol with their child and make agreements.

Figure 1: Program Theory of the High Schools- High on life intervention



Evaluation design**Effect evaluation**

Intervention effects will be evaluated in a cluster-randomized controlled trial. Based on power calculations, we plan to include a random sample of 16 high schools randomly 1:1 allocated to either intervention or control using stratified covariate-constrained randomization [38]. The randomization process will be stratified on whether the school was an independent general high school or the school is embedded within a broader youth educational institution, and furthermore school information on school size measured by number of students, proportion of parents with high educational level and degree of urbanization will be balanced using the CCR SAS macro [39]. All general high schools were invited to participate in The Danish National Youth Study 2019 (n=150), which served as the baseline for the evaluation of the *High schools High on life* intervention. 53 general high schools participated in The Danish National Youth Study 2019 (response rate: 35%) and were invited to participate in *High schools High on life*. 16 high schools agreed to participate (participation rate: 30%). Main reasons for declining participation was lack of resources or participation in other studies.

Intervention

Intervention high schools will be asked to introduce the intervention components.

Control high schools will be asked to continue business as usual in the intervention period (the school year 2019-2020) and offered the intervention afterwards (in the school year starting in 2020).

Inclusion criteria

- High schools were invited to participate in the study if they participated in the Danish National Youth Study 2019.
- General high schools

Exclusion criteria

- High schools that did not participate in the Danish National Youth Study 2019
- Non-general high school students.
- Students younger than 15 years or older than 25 years of age.

Ethics

Behavioral health prevention interventions are generally not required to notify for etic approval by the Scientific Ethics Committees{Scientific Ethics Committee, 2019 #172}. A query has been sent to the Scientific Ethics Committees for the Capital Region of Denmark (19021957).

According to the Danish Ethic Scientific Committee Act, only health science research projects must be notified to a scientific ethics committee. "Health science research project" is a concept that is defined partly in the committee act itself and partly in the executive order on the law.

Section 2 (1) of the Committee Act has the following definition of a health science research project;

§ 2. For the purposes of this Act:

1) Health science research project: A project involving experiments on live-born human subjects, human germ cells, which are intended to be used for fertilization, human fertilized eggs, embryos and fetuses, tissues, cells and human, fetus, and hereditary components or deceased. This includes clinical trials on medicinal products in humans, cf. No. 2, and clinical testing of medical devices, cf.

Data collection

The student questionnaire is based on items from other studies (e.g. The HBSC Study and the Danish National Youth Study 2014) either transferred without any revision or adapted to the high school setting [40, 41]. A few items will be developed specifically to the *High Schools- High on life* program. The student baseline alcohol questionnaire was tested among 4 high school students (3 girls and 1 boy) and followed by an interview about comprehensiveness, layout etc. The questionnaire was modified according to the students' comments and suggestions. 1st year high school students' response of the Danish National Youth Study 2019 questionnaire will serve as the baseline for the effect evaluation. The Danish National Youth Study 2019 questionnaire took around 45 minutes to answer. All 1st year high school students in intervention and the control schools should answer the follow-up questionnaire. The follow-up questionnaires will only include questions relevant to the intervention and take around 15 minutes to answer. All student questionnaires will be electronic internet-based and answered in class. Baseline data was collected from January to March 2019, while follow-up data will be collected from March to April 2020.

Outcomes

The primary outcome is mean number of binge drinking occasions within the last 30 days. 1st year high school students will be asked "*how many times within the last 30 days have you been drinking 5 or more units of alcohol within one occasion?*". Secondary outcomes are 1) mean weekly alcohol consumption, 2) mean alcohol intake at last school party, 3) mean alcohol intake at the school during

last school party, and 4) proportion of students who think alcohol plays a too dominant part at the school (see Table 1).

Explorative outcomes: a potential positive side effect of the intervention is that a higher proportion of students feels included in the social community at school. We want to look at this among all students and further do a stratified analysis among students who do not drink or have a low alcohol intake (25% lowest quantile in mean weekly alcohol consumption at baseline among students in both interventions and control group). A potential negative side effect of the intervention is a higher alcohol intake among students in the intervention group as a response to increased focus on alcohol, making it more interesting among students in intervention group. We will also study substitute effects by analyzing whether students in the intervention group are more likely to experiment with drugs as compared to students in the control group.

Table 1: Outcomes and mediators

Variable	Question	Type	Units/categories
Primary outcome			
Binge drinking occasions	<i>How many times within the last 30 days have you been drinking 5 or more units of alcohol within one occasion?</i>	Continuous	Occurrences
Secondary outcomes			
Weekly alcohol consumption	<i>How many units of alcohol have you been drinking on each day during the last week?</i>	Continuous	Units of alcohol
Alcohol intake at last school party	<i>How many units of alcohol did you drink at the last high school party you attended?</i>	Continuous	Units of alcohol
Alcohol intake at the school during last school party	<i>How many units of alcohol did you drink at <u>the school</u> during high school party you attended?</i>	Continuous	Units of alcohol
Proportion of 1 st year high school students who think alcohol play a too dominant part at the school	<i>Do you feel that alcohol plays a too dominant part at your high school (e.g.</i>	Binary	Yes/no

*at high school parties, school bars,
introduction trips, study tours etc.)?*

Explorative outcomes

Potential positive side effects

Proportion of 1 st year high school students who feel included in the social community at school	<i>Are you part of the social community at your school?</i>	Binary	Yes, always or yes, sometimes vs. Occasionally or seldom or never
Proportion of 1 st year high school students who feel included in the social community at school among students who do not drink or have a low alcohol intake (25% lowest quantile in mean weekly alcohol consumption among 1 st year students at baseline).	<i>Are you part of the social community at your school?</i>	Binary	Yes, always or Yes, sometimes vs. Occasionally or seldom or never

Potential negative side effect

Weekly alcohol consumption	<i>How many units of alcohol have you been drinking on each of the days during the last week?</i>	Continuous	Units of alcohol
Consumption of drugs.	<i>Have you ever tried to smoke marihuana, weed, or pot?</i>	Binary	Yes/no
	<i>Have you ever tried other drugs than marihuana?</i>	Binary	Yes/no

Mediators (determinants)

A clear alcohol policy	<i>Leader/coordinator questionnaire (questions will be developed)</i>
Alcohol policy communicated to students and parents	<i>Leader questionnaire/coordinator (questions will be developed)</i>
Enforcement of the alcohol policy	<i>Leader questionnaire/coordinator (questions will be developed)</i>

	<i>Student questionnaire:</i> <i>Is it your experience that...</i> <i>Alcohol is sold at most social events at my high school?</i>		
More alcohol-free social events, than events were alcohol is sold	<i>Leader questionnaire/coordinator</i> <i>(questions have not been developed)</i>		
Proportion of 1 st year high school students who overestimate the alcohol use among their peers	<i>At your high school: How many units of alcohol do you think other young people with the same gender and school year as you drank at the last high school party you attended?</i>	Binary	Proportion who think more than average
	<i>Proportion who overestimate the average of the secondary outcome</i> "Mean alcohol intake at the school during last school party"		
Proportion of 1 st year high school students who have felt a social pressure to drink	<i>How often have you experienced any of the situations described below?</i> <i>I have felt a pressure to drink more than I would like to.</i>	Binary	Often or sometimes vs. seldom or never or I never attended a party or anything like that where alcohol was served
Proportion of 1 st year high school students who feel they can have fun without drinking	<i>To what degree do you agree in the following(..)- I can have fun at a party without drinking</i>	Binary	Highly agree or agree vs. neither agree nor disagree or disagree or highly disagree
Proportion of 1 st year high school students who are familiar with the high schools' alcohol policy	<i>Do you know if your high school has an alcohol policy?</i>	binary	Yes, we do, and I know the content vs. Yes, we do but I do not know the content or No, we don't, or I do not know if my high school has an alcohol policy

Proportion of 1 st year high school students who talk to their parents about alcohol	<i>Have you talked to your parents about your use of alcohol?</i>	Binary	Yes, we talk about it regularly vs. Yes, we have talked about it once recently or Yes, we talked about it a long ago or No we have never talked about it.
Proportion of 1 st year high school students who have agreements with their parents on how much they can drink	<i>Do you have agreements with your parents about your alcohol consumption?</i>	Binary	Yes/no

Change in determinants (mediators)

Based on the program theory we expect to see a difference in a range of determinants of excessive drinking between intervention and control high schools, addressed by the multiple intervention components. On the high school level, we expect to find clearer alcohol policies at intervention school, that are communicated to students and parents, stronger enforcement of the alcohol policy, and more alcohol-free social events than events where alcohol is sold, as compared to control schools. At student level, we expect to see a larger proportion of students who feel they can have fun without drinking at intervention schools, compared to control school. Further we expect a smaller proportion who overestimate the alcohol use among their peers and a smaller proportion who have felt a social pressure to drink, at intervention schools as compared to control schools. Additionally, we expect a larger proportion of students who know the high schools' alcohol policy, talk to their parents about alcohol and have rules/agreements with their parents on how much they can drink, among students in intervention schools, as compared to control schools.

Changes in determinants will be evaluated in statistical mediation analysis based on student and leader/coordinator questionnaire.

Sample size calculation

Based on results from the Unplugged program [42], we expect a 30% lower mean number of binge drinking occasions within the last 30 days in the intervention group as compared to the control group at follow-up. Sample size calculation to estimate the number of high schools needed to recruit was performed using the

statistical software STATA v15 using *Sampsii* and *Sampclus*. The average number of binge-drinking episodes within the last 30 days was estimated based on data from the Danish National Youth Study 2014 [41]. In 2014, high school students had an average of 2.94 binge drinking occasions within the last 30 days, with a standard deviation of 2.58, an interclass correlation of 0.034, and an average of 198 enrolled 1st year students per high school (cluster size). Conventional levels of statistical power (0.8) and level of significance (0.05) were used. Under the above assumptions, calculations showed that at least 12 high schools should be recruited for the study to show a 30% reduction in the number of binge-drinking episodes within the last 30 days (6 control schools and 6 intervention school, equivalent to a total of 2,296 students). Due to the risk of loss to follow-up, we aimed at recruiting an additional 30%, corresponding to 16 high schools.

Planned statistical analysis

A blinded version of the data will be used for data analysis. Outcomes will be analyzed after the principle of intention-to-treat including all students in the arm to which they were allocated independently of whether they received (or completed) the intervention as planned. Intention-to-treat analysis will be supplemented by per protocol analysis based on the implementation of intervention components (both on school and individual level). Multi-level models will be used to account for the clustering of students in schools and school classes. General and generalized linear models will be used to study continuous and binary outcomes. If the model assumptions of the general linear model are not fulfilled, transformation of the outcome will be performed. All analyses will be adjusted for sex, parental education level, parental income and baseline level of the outcome, to increase precision. Differential effects of intervention by sex, parental educational level on the primary outcome will be investigated (explorative analyses). We hypothesize that boys may experience stronger intervention effects than girls due to higher initial level of binge drinking [43]. We had no hypotheses of the direction of socioeconomic differences in intervention effects, as previous research has been inconsistent in the direction of intervention effects [44, 45].

If the number of missing outcomes is larger than 10% and the results of the primary outcome is significant, a worst-case scenario will be performed for the primary and secondary outcomes as sensitivity analyses. The missing outcome values in the one group will be imputed with the mean value of the primary or secondary outcome of the other group and vice versa.

The primary outcome will be tested with significance level of 5%. Analyses of the pre-defined secondary outcomes will be analyzed with no p-value adjustment due to multiplicity and the interpretation of these results will be assessed in the light of multiple testing. This means that statistically significant effects will be

interpreted in the context of increased risk of type I error. No significance testing will be performed for the exploratory outcomes.

We will apply mediation analysis to test our program theory and hypothesized assumptions of changes in specific determinants will lead to change in the primary outcome.

Process evaluation

Process evaluation will be based on Grant et al.'s framework for process evaluation of cluster randomized trials of complex interventions and we will combine qualitative and quantitative methods [46].

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