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Complete List of Authors:	Pisinger, Veronica; Syddansk Universitet, Hoffmann, Sofie; Syddansk Universitet Rosing, Johanne; Syddansk Universitet Det Sundhedsvidenskabelige Fakultet Grønbæk, Morten; University of Southern Denmark, National Institute of Public Health Tolstrup, Janne; Syddansk Universitet Thygesen, Lau; Syddansk Universitet, Krølner, Rikke; Syddansk Universitet
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‘High schools High on life’: Study protocol for an intervention to reduce excessive drinking in Danish high schools

Veronica Sofie Clara Pisinger[1], Sofie Have Hoffmann[1], Johanne Aviaja Rosing[1], Morten Klöcker Grønbæk[1], Janne Schurmann Tolstrup[1], Lau Caspar Thygesen[1], Rikke Fredenslund Krølner[1]

Author Affiliations:

[1]National Institute of Public Health, University of Southern Denmark, Studiestræde 6, Copenhagen, Denmark

Correspondence to: Veronica Pisinger E-mail: vepi@sdu.dk Telephone +45 6570 7777, National Institute of Public Health, University of Southern Denmark, Studiestræde 6, DK-1455 Copenhagen K

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Abstract

Introduction: This paper describes the evaluation design of the 'High schools High on life' intervention; a school-based intervention to reduce excessive drinking among high school students in Denmark. The intervention includes a school environmental component to limit access to alcohol at school, a school-educational component to change social norms around alcohol among 1st year students and a parental component addressing parents' knowledge and attitudes towards alcohol.

Methods/Design: The study will employ a cluster-randomized controlled study design and will include a random sample of 16 high schools randomly allocated 1:1 to either intervention or control group. Target group: 1st year high school students. Timeline: Baseline survey: January to March 2019, collected as part of the Danish National Youth Study 2019. Delivery of intervention: April 2019 to March 2020. Follow-up survey: April to May 2020. Primary outcome measure: 30% reduction in mean number of binge-drinking episodes (five or more alcoholic drinks on one occasion) within the last 30 days. Secondary outcome measures: proportion of students who drink alcohol, mean weekly alcohol consumption, alcohol intake at last school party, alcohol intake at the school during last school party, proportion of students who agree to be able to have fun at a party without drinking, and the proportion of students who think alcohol plays a too dominant part at the school. Implementation will be monitored through process evaluation.

Ethics and Dissemination: The Scientific Ethics Committees for the Capital Region of Denmark has declared that the trial is not subject to notification (jnr. 19021957). The study is registered at the Research an Innovation Office at University of Southern Denmark (ref: 10.314) allowing collection of personal data. Results will be published in peer-reviewed journals.

Trial registration: The trial is registered 29th March 2019 prior to randomization at clinicaltrials.gov (Protocol Record 15/4155_2).

Keywords: alcohol; school; intervention; adolescents; social norms; parents; school environment

Strengths and Limitations of this study

- The 'High schools High on life' intervention will provide insights into effective strategies to reduce excessive alcohol consumption among adolescents. Specifically, in a Danish context were excessive drinking is the norm.

- The study will provide knowledge on implementation processes, and intervention effects among different subgroups, and contribute to the literature on cultural changes in alcohol use in educational institutions.

- A longer follow-up period may be required than originally anticipated, to cause and measure cultural changes within high schools.

Introduction

Alcohol is associated with an increased risk of more than 60 alcohol-related diseases (1) and is estimated to be the leading cause of death among 15-24 year-olds, worldwide (2). Binge drinking (consumption of 5 or more alcoholic drinks on one occasion) is common among adolescents in most western countries, and Danish adolescents have one of the highest levels of drunkenness worldwide (3). The age of drinking onset has increased within the last 30 years (4, 5), however, when young Danes begin high school their alcohol consumption often escalates (6, 7). During high school start, students meet new people, join new peer groups, and attend social events at the high school and outside the school where drinking is the focal point. These experiences contribute to the formation of perceived norms about high school alcohol consumption. Among Danish high school students (15-20-year-olds), 28 % (35 % boys and 24 % girls) have been binge drinking 4 or more times within the last 30 days, and 20 % drink above the Danish Board of Health's high risk drinking limits for adults (21 units a week for men and 14 units a week for women) (8).

In the short-term, alcohol use in adolescence can lead to injuries, homicide, suicide, violence, criminal activity, poor health and risky sexual behavior (9). Furthermore, 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 (10-14).

Beside structural prevention strategies, such as limiting availability through increases in prices and a high minimum purchasing age, interventions in the school setting has been proposed to be one of the most feasible strategies to tackle substance use disorders among adolescents (15). Numerous school-based substance abuse prevention programs have been developed to postpone debut age or reduce use of substances in young adolescents. However, effects of the programs have been mixed (16-18). A systematic review of school-based drug-prevention programs showed that the most effective programs used interactive delivery methods, used peer leaders and focused on affecting peer norms (19). Interventions targeting older adolescents (15-20-year old) are mostly American college interventions (20, 21), high risk interventions based on screening and brief motivational interviewing (22, 23) or web-based personalized normative feedback interventions (24, 25). Systematic reviews suggest that college-based interventions that include educational intervention strategies such as personalized feedback, moderation strategies (on how to avoid drinking too much), expectancy challenge (challenge expectancies of when it is fun and not fun to drink), identification of risky situations, and goal setting are effective in reducing alcohol-related behavior issues among adolescents (18). However, evidence from the American college literature is difficult to transfer to the Danish high school setting, in which alcohol is easily accessible. In Denmark, alcohol is a strongly integrated part of the school culture, and a large group of the students drink excessively with the purpose of intoxication (26, 27). Danish students, in all ages, are allowed to drink and buy alcohol at high

school parties, because high school parties are perceived to be private parties, at which the national age limits of being served or purchasing alcohol (respectively 18 years and 16 years) is not enforced (26). It can be hypothesized that educational strategies cannot stand alone in Denmark and should be combined with school environmental strategies targeting physical, structural, social, and cultural environment for drinking at schools. However, we have not been able to identify previous studies using a multicomponent approach. There is thus a lack of interventions targeting high school students excessive drinking focusing on environmental strategies and social norms approaches to effectively reduce adolescent binge drinking.

The overall aim of the 'High schools High on life' study is to implement and evaluate a multi-component high school-based intervention to reduce excessive drinking among high school students. The aim of this study protocol is to describe the effect and process evaluation design of the 'High schools High on life' intervention.

Research questions of the effect and process evaluation study:

- Can the 'High schools High on life' intervention reduce binge drinking (primary outcome) among 1st year high school students?
- Can the 'High schools High on life' intervention lead to a lower mean weekly alcohol consumption, a lower alcohol intake at last school party, lower alcohol intake at the school during last school party, and lower proportion of students who think alcohol plays a too dominant part at the school (secondary outcomes) among 1st year high school students?
- Does the 'High schools High on life' intervention lead to intended positive side effects?
- Does the 'High schools High on life' intervention lead to any unintended negative side effects?
- Is the effect of the 'High schools High on life' intervention on the primary outcome preceded by changes in the determinants (mediators)?
- Is there a different effect of the 'High schools High on life' intervention among girls vs. boys, or students with high SEP vs. low SEP?
- How does the implementation fidelity affect the effect of 'High schools High on life' intervention?
- Which factors are important in relation to the implementation of the intervention at high schools?

Intervention

The intervention 'High schools High on life' was developed in collaboration between researchers, at the Centre for Intervention Research at the National Institute of Public Health, University of Southern Denmark and staff from Section for Cancer Prevention and Information, the Danish Cancer Society.

The 'High schools High on life' intervention builds on a socio-ecological framework which

recognizes that adolescents' drinking behavior is determined by a wide range of interacting factors on multiple levels (28). The multi-component intervention targeting incoming 1st year high school students includes a school environmental component addressing school alcohol policies and norms, a school educational component addressing students' social norms around alcohol and a parental component addressing parents' knowledge and attitudes towards alcohol. The intervention will be delivered in the school year 2019-2020.

The 'High schools High on life' components

In the following af short description of the main intervention components and mechanisms of change will be described and illustrated (figure 1). A comprehensive description of the intervention components and development of the intervention is published elsewhere (ref intervention development study).

School environmental component

The school environmental intervention component is designed to restructure the physical and social school environment by limiting availability of alcohol at schools, creating a clear alcohol policy to be communicated to students, personnel and parents, and to facilitate implementation and enforcement of the school alcohol policy and create social activities not focusing on alcohol. The component consisted of an alcohol policy checklist to guide the school management's development of the school alcohol policy and web-based educations directed at the student social and introduction committees to motivate and guide student members to arrange social activities for their fellow students not focusing on alcohol.

School educational component

The school educational component is designed to change social norms around alcohol among 1st year students by correcting misperception on rates of peer alcohol use (*behavioral norms*) and the social acceptability of alcohol use (*injunctive norms*), making students reflect on their own alcohol use, and when they perceive it as fun and not fun to drink (29). Further, a pocket movie campaign in which the students promote the ideal of drinking less and experiencing more, inspired by induced compliance theory and a social norms campaign guided by the social norms approach, is included (30, 31). As a voluntary element schools could host (and receive support for) an alcohol-free morning party to give students an experience of partying without drinking.

Parental component

The parental component is designed to encourage parents of 1st year students to talk to their child about

alcohol and come to a mutual agreement regarding the child's drinking habits. The parental component consists of three separate elements: 1) an information meeting at the school in the beginning of the school year, where the parents are introduced to the school policy, encouraged to support it and discuss alcohol with their child, 2) an information folder about high school students' alcohol use and attitudes, and what parents can do to prevent heavy drinking among their children, and 3) a website which aims to promote skill training among parents in discussing alcohol with the child.

Figure 1: Program Theory of 'High schools High on life'.

Methods and Analysis

Study Design

Intervention effects will be evaluated in a two-armed cluster-randomized controlled trial. Baseline information will be derived 1st year students' responses from the Danish National Youth Study 2019, collected from 14 January to 30 March 2019 and follow-up information will be collected from a questionnaire to 1st year students in April to May 2020. The trial is registered prior to randomization at clinicaltrials.org (Protocol Record 15/4155_2). Intervention schools will be asked to introduce the 'High schools High on life' intervention components. Control schools will be asked to continue business as usual in the intervention period (April 2019 – March 2020) and will be offered the intervention afterwards (in the school year starting August 2020). A timeline of the evaluation process is provided in figure 2. The study is considered to be an effectiveness trial as schools will be responsible for the implementation of the intervention. Researchers will however monitor and support the implementation at each school by frequent phone calls, observations at the school, newsletters and e-mail reminders to local coordinators.

Figure 2: Timeline of the evaluation process

Inclusion criteria

-High schools which have previously participated in the Danish National Youth Study 2019.
-Institutions offering general high school examination
-Students older than 15 years of age or younger than 25 years of age

Recruitment

High school will be recruited from participating high schools in The Danish National Youth Study 2019, 1st year students' responses to this survey will serve as the baseline study for the evaluation of the 'High

schools High on life' intervention. A total of 50 general high schools participated in The Danish National Youth Study 2019 (participation proportion: 33%) and will be invited to participate in 'High schools High on life'. High schools will receive an e-mail invitation to the research project and those who do not respond within two workdays will receive a phone call from the research group to describe the aim of the project in more detail.

Sampling

Participating high schools will be randomly allocated 1:1 to either intervention or control using stratified covariate-constrained randomization (32). The randomization will be stratified on whether the school was an independent general high school or embedded within a broader youth educational institution, school size measured by total number of general high school students, proportion of parents with high educational level and degree of urbanization. Information on parental educational level and degree of urbanization was derived from the Danish National Youth Study 2014, and for institutions that did not participate in 2014 information was based on municipality information. The CCR SAS macro was used to balance these variables in the intervention and control schools (33). If schools accept to participate, students are automatically enrolled and assigned to the intervention group the school is randomized to by the project group (figure 3).

Figure 3: Flowchart of expected number of participating schools and students

Data collection

The student baseline questionnaire was 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 (36, 37). A few items were developed specifically to the 'High Schools High on life' intervention. The questionnaire was tested among four high school students (3 girls and 1 boy) and followed by single interviews about comprehensiveness, layout etc. The questionnaire was modified according to the students' comments and suggestions. The Danish National Youth Study 2019 questionnaire took around 45 minutes to answer. All 1st year high school students in intervention and control schools will be asked to answer a study-specific follow-up questionnaire. The follow-up questionnaires will only include questions relevant to the intervention, and take around 15 minutes to answer, as school managers specifically demanded short surveys not to compromise on teaching hours. All student questionnaires will be web-based and answered in the classroom. Table 1 outlines questions answered in the student baseline questionnaire that will be repeated in the follow-up questionnaire (in a similar or modified version).

Researchers will monitor and support the implementation and try to prevent school drop out by frequent phone calls, visits, newsletters and e-mail reminders to local coordinators at schools.

Outcomes

The primary outcome is mean number of binge drinking episodes 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?"*. Mean number of binge drinking episodes within the last 30 days were chosen as the primary outcome of the intervention as 1) binge drinking is associated with increased risk injuries in adolescence and on the long term a wide range of diseases (38), 2) episodes of binge drinking is a global measure of risky alcohol use (38) and 3) episodes of binge drinking is a broad measure of risky drinking patterns, that also take into account possible substitute effects e.g. if the alcohol intake moves to outside the school setting. 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 (table 1).

Explorative outcomes: intended positive side effects: higher proportion of students feels included in the social community at school, including 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). Unintended negative side effects: higher weekly alcohol intake among students in the intervention group as a response to increased focus on alcohol or a substitution effect where a higher proportion of student in the intervention group have tried marihuana, weed, pot, or other drugs.

Change in determinants (mediators)

As outlined in the program theory (figure 1), we expect to see a difference between intervention and control high schools at follow-up in a range of determinants of excessive drinking addressed by the multiple intervention components. At the high school level, we expect clearer alcohol policies, reduced availability of alcohol, communication of the policy to students and parents, stronger enforcement of the alcohol policy, and more alcohol-free social events at intervention schools compared to control schools. At the student level, we expect larger proportions of students at intervention schools compared to control schools who feel they can have fun without drinking, who are familiar with the high schools' alcohol policy, who talk to their parents about alcohol, and who have rules/agreements with their parents on how much they can drink. Additionally, we expect smaller proportions of

students who overestimates the alcohol use among their peers and who has felt a social pressure to drink at intervention schools compared to control schools. These variables and their operationalization are presented in table 1.

Table 1: Outcomes and mediators

Variable	Question	Type	Units/categories
Primary outcome			
Binge drinking episodes	*How many times within the last 30 days have you been drinking 5 or more units of alcohol within one occasion?*	Continuous	Episodes
Secondary outcomes			
Weekly alcohol consumption	*How many units of alcohol have you been drinking on each day during the last week?*	Continuous	Units of alcohol
Alcohol intake at last school party	*How many units of alcohol did you drink at the last high school party you attended?*	Continuous	Units of alcohol
Alcohol intake at the school during last school party	*How many units of alcohol did you drink at the school during the last high school party you attended?*	Continuous	Units of alcohol
Proportion of 1st year high school students who think alcohol plays a too dominant role at the school	*Do you feel that alcohol plays a too dominant role at your high school (e.g. at high school parties, school bars, introduction trips, study tours, the general conversation etc.)?*	Binary	Yes/no
Explorative outcomes			
Intended positive side effects			
Proportion of 1st year high school students who feel included in the social community at school	*Are you part of the social community at your school?*	Binary	Yes, always or yes, sometimes vs. occasionally or seldom or never

Proportion of 1st year high school students who feel included in the social community at school in the total student population and among students who do not drink or have a low alcohol intake (25% lowest quantile in mean weekly alcohol consumption among 1st year students at baseline).	*Are you part of the social community at your school?*	Binary	Yes, always or yes, sometimes vs. occasionally or seldom or never
Unintended negative side effect			
Weekly alcohol consumption	*How many units of alcohol have you been drinking on each of the days during the last week?*	Continuous	Units of alcohol
Consumption of drugs.	*Have you ever tried to smoke marihuana, weed, or pot?*	Binary	Yes/no
	Have you ever tried other drugs than marihuana?	Binary	Yes/no
School party attendance	*Have you ever attended a school party?*	Binary	Yes/no
Mediators (determinants)			
A clear alcohol policy	*Manager/coordinator questionnaire (questions will be developed for follow-up)*		
Alcohol policy communicated to students and parents	*Manager/coordinator questionnaire (questions will be developed for follow-up)*		
Enforcement of the alcohol policy	*Manager/coordinator questionnaire (questions will be developed for follow-up)*		
	Student questionnaire: *Is it your experience that…* *-Alcohol is sold at most social events at your high school?*	Binary	Highly agree or agree vs. 'neither agree nor disagree' or disagree or highly disagree

	-Students are denied entrance to school parties or sent home if they are visibly drunk? *-Nobody drinks alcohol on introduction trips?* *-Nobody drinks alcohol on study trips?* *-Invitations to school parties do not encourage heavy drinking?*		
More alcohol-free social events, than events where alcohol is sold	*Manager/coordinator questionnaire (questions will be developed for follow-up)*		
Proportion of 1st year high school students who overestimate the alcohol use among their peers	*At your high school: How many units of alcohol do you think other young people of the same gender and school year as you drank at the last high school party you attended?*	Binary	*Proportion who overestimates their peers' mean alcohol intake at the school during last school party*
Proportion of 1st year high school students who have felt a social pressure to drink	*How often have you experienced any of the situations described below?* *I have felt a pressure to drink more that I would like to.*	Binary	Often or sometimes vs. seldom or never
Proportion of 1st year high school students who feel they can have fun without drinking	*To which degree do you agree in the following(..)- I can have fun at a party without drinking*	Binary	Highly agree or agree vs. 'neither agree nor disagree' or disagree or highly disagree
Proportion of 1st year high school students who are familiar with the high schools' alcohol policy	*Do you know if your high school has an alcohol policy?*	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 1st year high school students who talk to their parents about alcohol	*Have you talked to your parents about your use of alcohol?*	Binary	Yes, we talk about it regularly vs. yes, we have talked about it once, recently or yes, we talked about it a long time ago or no, we have never talked about it.
Proportion of 1st year high school students who have agreements with their parents on how much they are allowed to drink	*Do you have agreements with your parents about your alcohol consumption?*	*Binary*	*Yes/no*

Planned statistical analysis

A blinded version of the data will be used for data analysis. In the primary analysis, outcomes will be analyzed after the intention-to-treat principle 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 taking the implementation dose of intervention components into account (both at the school and the 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. Non-responses will be handled by weighting based on socio-democratic variables such as sex, parents' socioeconomic position and school region. As the baseline population is different from the follow-up population, all analyses will be adjusted for school level information on baseline outcome level, sex, parental education level and parental income, whether the school was an independent general high school or embedded within a broader youth educational institution, school size measured by total number of general high school students, and degree of urbanization to increase precision. If the number of missing outcomes is larger than ten percent 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 five percent. 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. No significance testing will be performed for the exploratory outcomes.

Differential effects of intervention on the primary outcome by sex and parental educational level will be investigated by stratification (explorative analyses). We hypothesize that boys may experience stronger intervention effects than girls due to higher initial level of binge drinking (39). We have no hypotheses of the direction of socioeconomic differences in intervention effects, as previous research has been inconsistent in the direction of intervention effects in different socio-economic groups (40, 41).
We will apply mediation analysis to test our program theory and hypothesized assumptions of whether changes in specific determinants will lead to changes in the primary outcome (42).

Sample size calculation

Prior to the study, a sample size calculation was performed using the statistical software STATA v15 applying *Sampsi* and *Sampclus* to assess number of high schools and students needed to recruit to evaluate the effects of the intervention. Based on results from the Unplugged program (43), a previous school-based substance abuse prevention program among junior high school students (12-14 year-olds) which has been tested in a large cross-national study in seven European countries, we expected a 30% lower mean number of binge drinking episodes within the last 30 days in the intervention group as compared to the control group at follow-up. The average number of binge-drinking episodes within the last 30 days was estimated based on data from the Danish National Youth Study 2014 (37) with an average of 198 enrolled 1st-year students per high school (cluster size). In 2014, high school students had an average of 2.94 binge drinking episodes within the last 30 days, with a standard deviation of 2.58, and an intraclass correlation of 0.034. Conventional levels of statistical power (0.8) and level of significance (0.05) were used. Under the assumptions above, 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 (six control schools and six intervention schools, equivalent to a total of 2,296 students). Due to the risk of loss to follow-up, we aimed at recruiting an additional 30% of schools, corresponding to 16 high schools and 3,168 students. Flowchart of expected number of participating schools and students is presented in figure 2.

Process evaluation

We will perform a process evaluation study in order to explore and assess the implementation process and explain the effect or lack of effect of the intervention. The process evaluation will be inspired by a six step protocol for systematic process evaluation developed by Aarestrup et al. 2014 (44), Grant et al.'s framework for process evaluation of cluster randomized trials of complex interventions (45) and the factors identified by Durlak and DuPre that effects implementation (46). We will combine qualitative and

quantitative methods to gain information on 1) the dose, quality and participant responsiveness of the intervention delivered to school coordinators, parents and the student social- and introduction committees, 2) the dose, quality and student responsiveness of the intervention delivered from school coordinators, parents and social- and introduction committees to 1st year students, 3) factors affecting implementation (community factors, provider characteristics, innovation characteristics, organizational capacity and training and technical assistance) and 4) contamination at intervention and control schools.

Qualitative methods

Qualitative data will be collected at intervention schools continuously throughout the implementation period including 1) participant observations of the parent information meeting and students' engagement with the web-based education programs 2) interviews with school coordinators (in person and via telephone), 3) focus group interviews with 1st year students and members of the student social- and introduction committees and 4) log of email and telephone communication between the research team and school coordinators.

Quantitative methods

Quantitative data will be collected at follow up (April to May 2020) at intervention- and control schools using student questionnaires and school coordinator telephone interviews. This data will provide information on the intervention dose delivered to school coordinators, the social- and introduction committees, parents and 1st year students, school context and contamination at both intervention and control schools. Website track records will contribute with information on parental use of the High schools High on life website.

Patient and Public involvement

No patient involved.

Ethics and dissemination of results

Ethics

In Denmark, behavioral health promotion interventions are generally not required to notify for ethic approval by the Scientific Ethics Committees (34). The Scientific Ethics Committee for the Capital Region of Denmark has declared that the trial is not subject to notification (jnr. 19021957). The study is registered at the Research an Innovation Office at University of Southern Denmark (ref: 10.314) allowing collection of personal data. When inviting the high schools to participate, school managers received written information

about the study. Students were informed that participation was voluntary, that their information would be used for research purposes only and treated confidentially. Research has been inconclusive regarding the existence of a substitution effect between alcohol and cannabis (35). Possible, unintended negative side effects of the intervention, such as shifting to other drugs as replacement for diminished alcohol use, increased alcohol use due to increased attention to the subject, or other side effects will be monitored in the process evaluation. No other ethical concerns were identified.

Dissemination of results

The trial results will be communicated to other researchers in peer-reviewed journals and scientific conferences. Furthermore, they will be disseminated o the public, schools and public health practitioners through press releases, school health profiles to all participating schools based on questionnaire data and conferences for schools and municipalities working with alcohol prevention.

Discussion

The 'High schools High on life' intervention aims at providing important insights into effective strategies to reduce excessive alcohol consumption among adolescents. Further the study, aims at providing knowledge on implementation processes, and intervention effects among different subgroups, and contribute to the literature on cultural changes in educational institutions.

Trials are expensive and recruitment of schools to research projects can be challenging, it is therefore important to use research data efficiently (47). The recruitment to the intervention was based on existing baseline data which represents an efficient use of data and gives a unique opportunity to study selection bias in participation. However, schools that did not participate in the Danish National Youth Study 2019 (67%) were not invited to participate in the evaluation of the 'High schools High on life' intervention. This reduced the number of high schools that was invited to participate and may reproduce selection bias from the Danish National Youth Study 2019.

Schools will mainly deliver the intervention components themselves. The implementation of the intervention components will be followed closely to support and learn from the implementation processes. The project groups' efforts to secure full implementation will be described thoroughly in the process evaluation as it is important to know the schools' specific need for implementation support for future scale up of the intervention.

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Declarations

Authors' Contribution

MG and JST concepted the original idea of the study. VP wrote the first draft of the manuscript. JAR wrote the first draft of the process evaluation section. LCT, RFK and JST advised the evaluation design and statistical analysis. All authors read, revised and approved the final manuscript.

Ethics approval and consent to participate

In Denmark, behavioral health promotion interventions are generally not required to notify for ethic approval by the Scientific Ethics Committees (34). The Scientific Ethics Committees for the Capital Region of Denmark has declared that the trial is not subject to notification (jnr. 19021957). The study is registered at the Research an Innovation Office at University of Southern Denmark (ref: 10.314) allowing collection of personal data. When inviting the high schools to participate, school managers received written information about the study. For all data collection methods, responders were informed about the aim of the study, that participation was voluntary, that their information would be used for research purposes only and treated confidentially. In the written introduction the electronic questionnaires, responders were asked to agree that they have received information about the study and the use of their data for research and content to participate. Participants could skip questions they did not wish to answer. For the qualitative data collection content to participate was verbal. According to Danish law children can give content based on their maturity and children of the age of 13 years and above can give consent to use of their personal data.

Consent for publication

Not Applicable.

Availability of data and material

The datasets generated and analyzed during the current study are not publicly available due to sensitivity of the data but are available from the corresponding author on reasonable request.

Competing interest

The Danish Cancer Society developed intervention materials based on an ongoing campaign. The Danish Cancer Society had no influence on the study design, data analysis or interpretation of data.

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Trial Sponsor Contact: Anne Mette Bak. The Danish Cancer Society, grants, Strandboulevarden 49, 2100 Copenhagen, Denmark phone: +45 35257257

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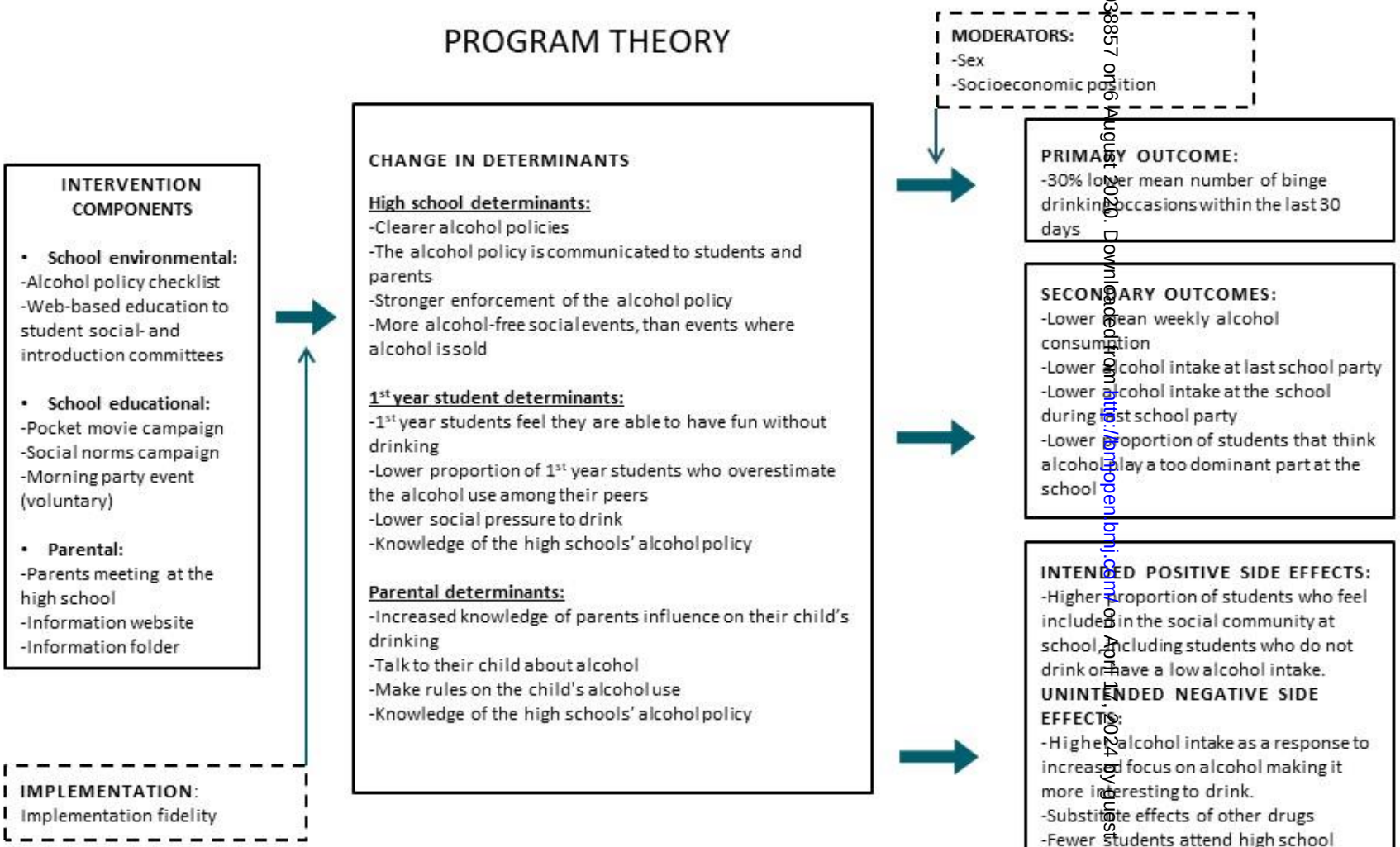

Figure 1: Program Theory of 'High schools High on life'.

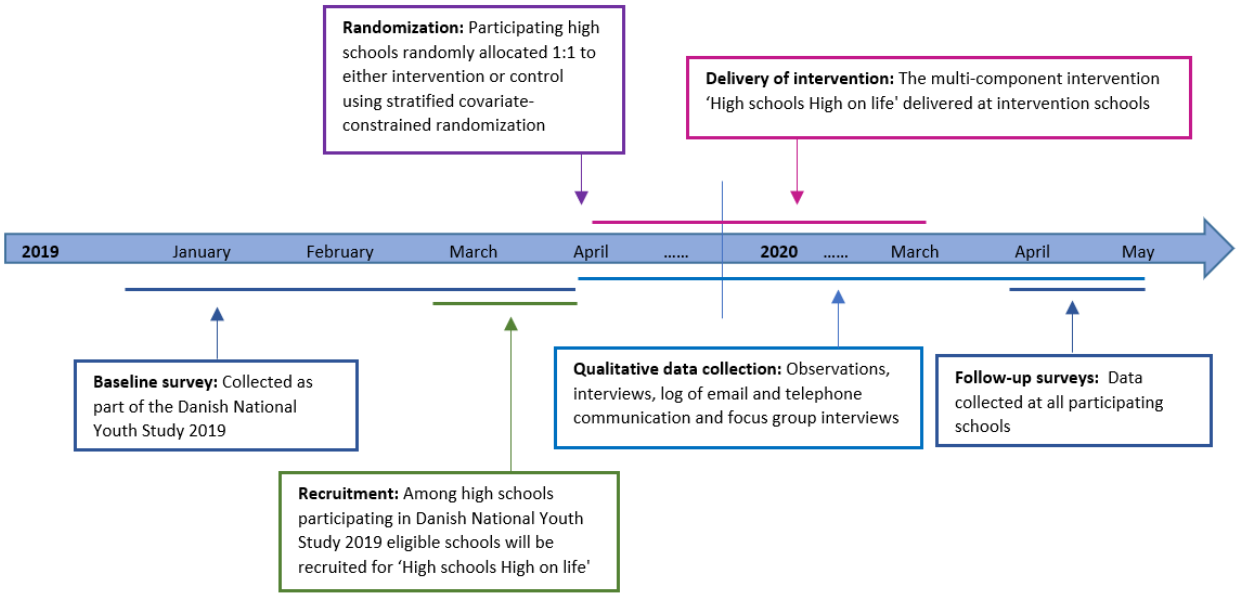

Figure 2: Timeline of the evaluation process

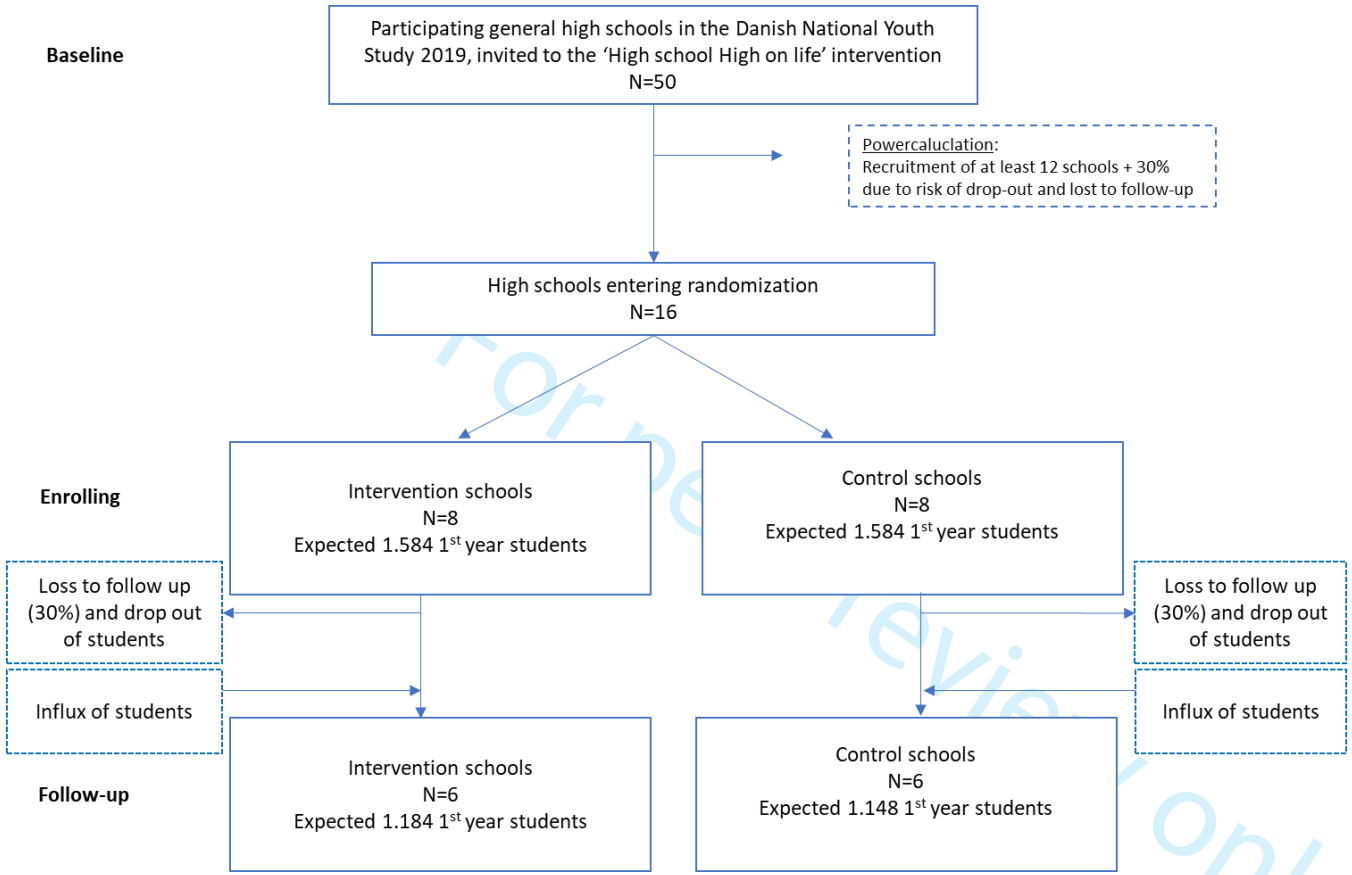

Figure 3: Flowchart of expected number of participating schools and students

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Adressed in study protocol
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Titel page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Titel page
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	Titel page
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Titel page and Declarations: Authors contribution
	5b	Name and contact information for the trial sponsor	Declarations: Funding
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Declarations: Funding and Competing interests

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Declarations: Authors contribution
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Background
	6b	Explanation for choice of comparators	Study design
Objectives	7	Specific objectives or hypotheses	Background: research questions
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Study design and sampling
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Study design
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Inclusion criteria

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Intervention and the ‘High schools High on life’ components Development article also submitted to BMC Public Health
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Study design
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Outcomes and Change in determinants
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Study design

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Sample size calculation
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Recruitment
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Sampling
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Sampling
Implementatio n	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Sampling
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Planned statistical analysis

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Data collection
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Data collection
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	N/A
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Planned Statistical analysis
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Planned Statistical analysis

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Planned Statistical analysis
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Planned Statistical analysis
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Trial registration
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Ethics
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Ethics
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Declarations: Competing interests
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Declaration: Availability of data and material
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Dissemination of results
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Declarations: Availability of data and material
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Ethics
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Study protocol for a cluster-randomized controlled trial testing the effectiveness of the High schools High on life' intervention on reducing excessive drinking in Danish high schools

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Study protocol for a cluster-randomized controlled trial testing the effectiveness of the High schools High on life' intervention on reducing excessive drinking in Danish high schools

Veronica Sofie Clara Pisinger[1], Sofie Have Hoffmann[1], Johanne Aviaja Rosing[1], Morten Klöcker Grønbæk[1], Janne Schurmann Tolstrup[1], Lau Caspar Thygesen[1], Rikke Fredenslund Krølner[1]

Author Affiliations:

[1]National Institute of Public Health, University of Southern Denmark, Studiestræde 6, Copenhagen, Denmark

Correspondence to: Veronica Pisinger E-mail: vepi@sdu.dk Telephone +45 6570 7777, National Institute of Public Health, University of Southern Denmark, Studiestræde 6, DK-1455 Copenhagen K

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Abstract

Introduction: This paper describes the evaluation design of the 'High schools High on life' intervention; a school-based intervention to reduce excessive drinking among high school students in Denmark. The intervention includes a school environmental component to limit access to alcohol at school, a school-educational component to change social norms around alcohol among 1st year students and a parental component addressing parents' knowledge and attitudes towards alcohol.

Methods/Design: The study will employ a cluster-randomized controlled study design and will include a random sample of 16 high schools randomly allocated 1:1 to either intervention or control group. Target group: 1st year high school students. Timeline: Baseline survey: January to March 2019, collected as part of the Danish National Youth Study 2019. Delivery of intervention: April 2019 to March 2020. Follow-up survey: April to May 2020. Primary outcome measure: 30% reduction in mean number of binge-drinking episodes (five or more alcoholic drinks on one occasion) within the last 30 days. Secondary outcome measures: proportion of students who drink alcohol, mean weekly alcohol consumption, alcohol intake at last school party, alcohol intake at the school during last school party, proportion of students who agree to be able to have fun at a party without drinking, and the proportion of students who think alcohol plays a too dominant part at the school. Implementation will be monitored through process evaluation.

Ethics and Dissemination: The Scientific Ethics Committees for the Capital Region of Denmark has declared that the trial is not subject to notification (jnr. 19021957). The study is registered at the Research an Innovation Office at University of Southern Denmark (ref: 10.314) allowing collection of personal data. Results will be published in peer-reviewed journals.

Trial registration: The trial is registered 29th March 2019 prior to randomization at clinicaltrials.gov (Protocol Record NCT03906500).

Keywords: alcohol; school; intervention; adolescents; social norms; parents; school environment

Strengths and Limitations of this study

- The study will test the effect of the 'High schools High on life' intervention in a cluster randomized controlled trial in a real-life setting.

-The 'High schools High on life' intervention will provide insights into effective strategies to reduce excessive alcohol consumption among Danish adolescents, where excessive drinking is the norm.

- The study will provide knowledge on implementation processes, and intervention effects among different subgroups, and contribute to the literature on cultural changes in alcohol use in educational institutions.

- A longer follow-up period may be required than originally anticipated, to cause and measure cultural changes within high schools.

Introduction

Alcohol is associated with an increased risk of more than 60 alcohol-related diseases (1) and is estimated to be the leading risk factor for death among 15-24 year-olds, worldwide (2). Binge drinking (in Denmark defined as consumption of 5 or more alcoholic drinks (12 grams of pure alcohol) on one occasion) is common among adolescents in most western countries, and Danish adolescents have one of the highest levels of drunkenness worldwide (3). The age of drinking onset has increased within the last 30 years (4, 5), however, when young Danes begin high school their alcohol consumption often escalates (6, 7). During high school start, students meet new people, join new peer groups, and attend social events at the high school and outside the school where drinking is the focal point. These experiences contribute to the formation of perceived norms about high school alcohol consumption. Among Danish high school students (15-20-year-olds), 28 % (35 % boys and 24 % girls) have been binge drinking 4 or more times within the last 30 days, and 20 % drink above the Danish Board of Health's high risk drinking limits for adults (21 units a week for men and 14 units a week for women) (8).

In the short-term, alcohol use in adolescence can lead to injuries, homicide, suicide, violence, criminal activity, poor health and risky sexual behavior (9). Furthermore, excessive alcohol use in the teenage years often tracks into and through adulthood, and early drinking onset increases the risk of high alcohol consumption and alcohol dependence later in life (10-14).

Beside structural prevention strategies, such as limiting availability through increases in prices and a high minimum purchasing age, interventions in the school setting has been proposed to be one of the most feasible strategies to tackle substance use disorders among adolescents (15). Numerous school-based substance abuse prevention programs have been developed to postpone debut age or reduce use of substances in young adolescents. However, effects of the programs have been mixed (16-18). A systematic review of school-based drug-prevention programs showed that the most effective programs used interactive delivery methods, used peer leaders and focused on affecting peer norms (19). Interventions targeting older adolescents (15-20-year old) are mostly American college interventions (20, 21), high risk interventions based on screening and brief motivational interviewing (22, 23) or web-based personalized normative feedback interventions (24, 25). Systematic reviews suggest that college-based interventions that include educational intervention strategies such as personalized feedback, moderation strategies (on how to avoid drinking too much), expectancy challenge (challenge expectancies of when it is fun and not fun to drink), identification of risky situations, and goal setting are effective in reducing alcohol-related behavior issues among adolescents (18). However, evidence from the American college literature is difficult to transfer to the Danish high school setting, in which alcohol is easily accessible. In Denmark, alcohol is a strongly integrated part of the school culture, and a large group of the students drink excessively with the

purpose of intoxication (26, 27). Danish students, in all ages, are allowed to drink and buy alcohol at high school parties, because high school parties are perceived to be private parties, at which the national age limits of being served or purchasing alcohol (respectively 18 years and 16 years) is not enforced (26). It can be hypothesized that educational strategies cannot stand alone in Denmark and should be combined with school environmental strategies targeting physical, structural, social, and cultural environment for drinking at schools. However, we have not been able to identify previous studies using a multicomponent approach. There is thus a lack of interventions targeting high school students excessive drinking focusing on environmental strategies and social norms approaches to effectively reduce adolescent binge drinking.

The overall aim of the 'High schools High on life' study is to implement and evaluate a multi-component high school-based intervention to reduce excessive drinking among high school students. The aim of this study protocol is to describe the effect and process evaluation design of the 'High schools High on life' intervention.

Hypothesis and research questions of the effect and process evaluation study:

We hypothesize that the 'High schools High on life' intervention will create a 30% reduction in binge drinking episodes within the last 30 days (primary outcome) among 1st year high school students (age 15-17 years) at intervention schools compared to control schools. Furthermore, the following research questions will be addressed:

- Can the 'High schools High on life' intervention lead to a lower mean weekly alcohol consumption, a lower alcohol intake at last school party, lower alcohol intake at the school during last school party, and lower proportion of students who think alcohol plays a too dominant part at the school (secondary outcomes) among 1st year high school students at intervention schools compared to control schools?
- Does the 'High schools High on life' intervention lead to intended positive side effects among 1st year high school students at intervention schools?
- Does the 'High schools High on life' intervention lead to any unintended negative side effects among 1st year high school students at intervention schools?
- Is the effect of the 'High schools High on life' intervention on the primary outcome preceded by changes in the determinants (mediators) at intervention schools?
- Is there a different effect of the 'High schools High on life' intervention among girls vs. boys, or students with high SEP vs. low SEP at intervention schools?

- How does the implementation fidelity affect the effect of 'High schools High on life' intervention at intervention schools?
- Which factors are important in relation to the implementation of the intervention at intervention schools?

Intervention

The 'High schools High on life' intervention builds on a socio-ecological framework which recognizes that adolescents' drinking behavior is determined by a wide range of interacting factors on multiple levels (28). The multi-component intervention targeting incoming 1st year high school students includes a school environmental component addressing school alcohol policies and norms, a school educational component addressing students' social norms around alcohol and a parental component addressing parents' knowledge and attitudes towards alcohol. The intervention will be delivered in the school year 2019-2020.

The 'High schools High on life' components

The intervention 'High schools High on life' was developed in collaboration between researchers, at the Centre for Intervention Research at the National Institute of Public Health, University of Southern Denmark and staff from Section for Cancer Prevention and Information, the Danish Cancer Society in close consultation with school staff, pupils and parents. The development of the intervention was guided and inspired by the planning steps of the Intervention Mapping protocol ,the Behavior change wheel, Behavior change techniques and theories, the best available evidence new empirical studies of contextual factors influencing students' alcohol intake in the Danish high school setting and experiences and ongoing local and national initiatives and campaigns targeting students' alcohol consumption at Danish high schools (29-32). s. In the following a short description of the main intervention components and mechanisms of change will be described and illustrated (figure 1). A comprehensive description of the intervention components and development of the intervention will be described elsewhere.

School environmental component

The school environmental intervention component is designed to restructure the physical and social school environment by limiting availability of alcohol at schools, creating a clear alcohol policy to be communicated to students, personnel and parents, and to facilitate implementation and enforcement of the school alcohol policy and create social activities not focusing on alcohol. The component consisted of an alcohol policy checklist to guide the school management's development of the school alcohol policy and

web-based educations directed at the student social and introduction committees to motivate and guide student members to arrange social activities for their fellow students not focusing on alcohol.

School educational component

The school educational component is designed to change social norms around alcohol among 1st year students by correcting misperception on rates of peer alcohol use (*behavioral norms*) and the social acceptability of alcohol use (*injunctive norms*), making students reflect on their own alcohol use, and when they perceive it as fun and not fun to drink (33). Further, a pocket movie campaign in which the students promote the ideal of drinking less and experiencing more, inspired by induced compliance theory and a social norms campaign guided by the social norms approach, is included (34, 35). As a voluntary element schools could host (and receive support for) an alcohol-free morning party to give students an experience of partying without drinking.

Parental component

The parental component is designed to encourage parents of 1st year students to talk to their child about alcohol and come to a mutual agreement regarding the child's drinking habits. The parental component consists of three separate elements: 1) an information meeting at the school in the beginning of the school year, where the parents are introduced to the school policy, encouraged to support it and discuss alcohol with their child, 2) an information folder about high school students' alcohol use and attitudes, and what parents can do to prevent heavy drinking among their children, and 3) a website which aims to promote skill training among parents in discussing alcohol with the child.

Figure 1: Program Theory of 'High schools High on life'.

Methods and Analysis

Study Design

Intervention effects will be evaluated in a two-armed cluster-randomized controlled trial. Baseline information will be derived 1st year students' responses from the Danish National Youth Study 2019, collected from 14 January to 30 March 2019 and follow-up information will be collected from a questionnaire to 1st year students in April to May 2020. The trial is registered prior to randomization at clinicaltrials.org (Protocol Record 15/4155_2). Intervention schools will be asked to introduce the 'High schools High on life' intervention components. Control schools will be asked to continue business as usual in the intervention period (April 2019 – March 2020) and will be offered the intervention afterwards (in the school year starting August 2020). A timeline of the evaluation process is provided in figure 2. The study is

considered to be an effectiveness trial as schools will be responsible for the implementation of the intervention. Researchers will however monitor and support the implementation at each school by frequent phone calls, observations at the school, newsletters and e-mail reminders to local coordinators.

Figure 2: Timeline of the evaluation process

Inclusion criteria

-High schools which have previously participated in the Danish National Youth Study 2019.

-Institutions offering general high school examination

-1st year high school students

Recruitment

High school will be recruited from participating high schools in The Danish National Youth Study 2019, 1st year students' responses to this survey will serve as the baseline study for the evaluation of the 'High schools High on life' intervention. A total of 50 general high schools participated in The Danish National Youth Study 2019 (participation proportion: 33%) and will be invited to participate in 'High schools High on life'. High schools will receive an e-mail invitation to the research project and those who do not respond within two workdays will receive a phone call from the research group to describe the aim of the project in more detail.

Sampling

Participating high schools will be randomly allocated 1:1 to either intervention or control using stratified covariate-constrained randomization (36). The randomization will be stratified on whether the school was an independent general high school or embedded within a broader youth educational institution, school size measured by total number of general high school students, proportion of parents with high educational level and degree of urbanization. Information on parental educational level and degree of urbanization was derived from the Danish National Youth Study 2014, and for institutions that did not participate in 2014 information was based on municipality information. The CCR SAS macro was used to balance these variables in the intervention and control schools (37). If schools accept to participate, students are automatically enrolled and assigned to the intervention group the school is randomized to by the project group (figure 3).

Figure 3: Flowchart of expected number of participating schools and students

Data collection

The student baseline questionnaire was 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 (38, 39). A few items were developed specifically to the 'High Schools High on life' intervention. The questionnaire was tested among four high school students (3 girls and 1 boy) and followed by single interviews about comprehensiveness, layout etc. The questionnaire was modified according to the students' comments and suggestions. The Danish National Youth Study 2019 questionnaire took around 45 minutes to answer. All 1st year high school students in intervention and control schools will be asked to answer a study-specific follow-up questionnaire. The follow-up questionnaires will only include questions relevant to the intervention, and take around 15 minutes to answer, as school managers specifically demanded short surveys not to compromise on teaching hours. All student questionnaires will be web-based and answered in the classroom. Table 1 outlines questions answered in the student baseline questionnaire that will be repeated in the follow-up questionnaire (in a similar or modified version). Researchers will monitor and support the implementation and try to prevent school drop out by frequent phone calls, visits, newsletters and e-mail reminders to local coordinators at schools.

Outcomes

The primary outcome is mean number of binge drinking episodes 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?"(39)*. Mean number of binge drinking episodes within the last 30 days were chosen as the primary outcome of the intervention as 1) binge drinking is associated with increased risk injuries in adolescence and on the long term a wide range of diseases (40), 2) episodes of binge drinking is a global measure of risky alcohol use (40) and 3) episodes of binge drinking is a broad measure of risky drinking patterns, that also take into account possible substitute effects e.g. if the alcohol intake moves to outside the school setting. Secondary outcomes are 1) mean weekly alcohol consumption (39), 2) mean alcohol intake at last school party (39), 3) mean alcohol intake at the school during last school party (39), and 4) proportion of students who think alcohol plays a too dominant part at the school (table 1).

Explorative outcomes: intended positive side effects: higher proportion of students feels included in the social community at school, including 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). Unintended negative side effects: higher weekly

alcohol intake among students in the intervention group as a response to increased focus on alcohol or a substitution effect where a higher proportion of student in the intervention group have tried marihuana, weed, pot, or other drugs.

Change in determinants (mediators)

As outlined in the program theory (figure 1), we expect to see a difference between intervention and control high schools at follow-up in a range of determinants of excessive drinking addressed by the multiple intervention components. At the high school level, we expect clearer alcohol policies, reduced availability of alcohol, communication of the policy to students and parents, stronger enforcement of the alcohol policy, and more alcohol-free social events at intervention schools compared to control schools. At the student level, we expect larger proportions of students at intervention schools compared to control schools who feel they can have fun without drinking, who are familiar with the high schools' alcohol policy, who talk to their parents about alcohol, and who have rules/agreements with their parents on how much they can drink. Additionally, we expect smaller proportions of students who overestimates the alcohol use among their peers and who has felt a social pressure to drink at intervention schools compared to control schools. These variables and their operationalization are presented in table 1.

Table 1: Outcomes and mediators

Variable	Question	Type	Units/categories
Primary outcome			
Binge drinking episodes	*Student questionnaire: How many times within the last 30 days have you been drinking 5 or more units of alcohol within one occasion?*	Continuous	Episodes
Secondary outcomes			
Weekly alcohol consumption	*Student questionnaire: How many units of alcohol have you been drinking on each day during the last week?*	Continuous	Units of alcohol
Alcohol intake at last school party	*Student questionnaire: How many units of alcohol did you drink at the last high school party you attended?*	Continuous	Units of alcohol

Alcohol intake at the school during last school party	*Student questionnaire: How many units of alcohol did you drink at the school during the last high school party you attended?*	Continuous	Units of alcohol
Proportion of 1st year high school students who think alcohol plays a too dominant role at the school	*Student questionnaire: Do you feel that alcohol plays a too dominant role at your high school (e.g. at high school parties, school bars, introduction trips, study tours, the general conversation etc.)?*	Binary	Yes/no
Explorative outcomes			
Intended positive side effects			
Proportion of 1st year high school students who feel included in the social community at school	*Student questionnaire: Are you part of the social community at your school?*	Binary	Yes, always or yes, sometimes vs. occasionally or seldom or never
Proportion of 1st year high school students who feel included in the social community at school in the total student population and among students who do not drink or have a low alcohol intake (25% lowest quantile in mean weekly alcohol consumption among 1st year students at baseline).	*Student questionnaire: Are you part of the social community at your school?*	Binary	Yes, always or yes, sometimes vs. occasionally or seldom or never
Unintended negative side effect			
Weekly alcohol consumption	*Student questionnaire: How many units of alcohol have you been drinking on each of the days during the last week?*	Continuous	Units of alcohol
Consumption of drugs.	*Student questionnaire: Have you ever tried to smoke marihuana, weed, or pot?*	Binary	Yes/no

	Student questionnaire: Have you ever tried other drugs than marihuana?	Binary	Yes/no
School party attendance	*Student questionnaire: Have you ever attended a school party?*	Binary	Yes/no
Mediators (determinants)			
A clear alcohol policy	*Manager/coordinator questionnaire: In this school year (2019/2020): Did you introduce a new or change your alcohol policy?*	Binary	'Yes, we made changes in our alcohol policy' or 'Yes, we introduced a new alcohol policy' vs. 'No, we do not have an alcohol policy' or 'No, we have not changed our alcohol policy'
Alcohol policy communicated to students and parents	*Manager/coordinator questionnaire: In this school year (2019/2020): Was the alcohol policy communicated to parents of 1st year students?* *Manager/coordinator questionnaire:* *In this school year (2019/2020): Was the alcohol policy communicated to students?*	Binary Categorical	'Yes, at a parent meeting' or 'Yes, written information' vs. No Yes, all students were informed Yes, all 1st year students were informed Yes, student committees were informed No
Enforcement of the alcohol policy	*Student questionnaire:* *Is it your experience that…* *-Alcohol is sold at most social events at your high school?* *-Students are denied entrance to school parties or sent home if they are visibly drunk?*	Binary	Highly agree or agree vs. 'neither agree nor disagree' or disagree or highly disagree

	-Nobody drinks alcohol on introduction trips? *-Nobody drinks alcohol on study trips?* *-Invitations to school parties do not encourage heavy drinking?*		
More alcohol-free social events, than events where alcohol is sold	*Alcohol policy checklist reported by school principals* *Student questionnaire:* Alcohol is sold at most social events outside school hours at my high school	Binary	Yes/no Highly agree or agree vs. 'neither agree nor disagree' or disagree or highly disagree
Proportion of 1st year high school students who overestimate the alcohol use among their peers	*Student questionnaire: At your high school: How many units of alcohol do you think other young people of the same gender and school year as you drank at the last high school party you attended?*	Binary	*Proportion who overestimates their peers' mean alcohol intake at the school during last school party*
Proportion of 1st year high school students who have felt a social pressure to drink	*Student questionnaire: How often have you experienced any of the situations described below?* *I have felt a pressure to drink more that I would like to.*	Binary	Often or sometimes vs. seldom or never
Proportion of 1st year high school students who feel they can have fun without drinking	*Student questionnaire: To which degree do you agree in the following(..)- I can have fun at a party without drinking*	Binary	Highly agree or agree vs. 'neither agree nor disagree' or disagree or highly disagree
Proportion of 1st year high school students who are familiar with the high schools' alcohol policy	*Student questionnaire: Do you know if your high school has an alcohol policy?*	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 1st year high school students who talk to their parents about alcohol	*Student questionnaire: Have you talked to your parents about your use of alcohol?*	Binary	Yes, we talk about it regularly vs. yes, we have talked about it once, recently or yes, we talked about it a long time ago or no, we have never talked about it.
Proportion of 1st year high school students who have agreements with their parents on how much they are allowed to drink	*Student questionnaire: Do you have agreements with your parents about your alcohol consumption?*	*Binary*	*Yes/no*

Planned statistical analysis

A blinded version of the data will be used for data analysis. In the primary analysis, outcomes will be analyzed after the intention-to-treat principle 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 taking the implementation dose of intervention components into account (both at the school and the individual level). Dose delivered will be measured in the coordinator questionnaire and by observations and will be defined as the number of intervention components delivered as planned) and dose received will be measured in the student questionnaire. and will be defined as the number of intervention components received as planned. 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. Non-responses will be handled by weighting based on socio-democratic variables such as sex, parents' socioeconomic position and school region. As the baseline population is different from the follow-up population, all analyses will be adjusted for school level information on baseline outcome level, sex, parental education level and parental income, whether the school was an independent general high school or embedded within a broader youth educational institution, school size measured by total number of general high school students, and degree of urbanization to increase precision. If the number of missing outcomes is larger than ten percent 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 five percent. 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. No significance testing will be performed for the exploratory outcomes.

Differential effects of intervention on the primary outcome by sex and parental educational level will be investigated by stratification (explorative analyses). We hypothesize that boys may experience stronger intervention effects than girls due to higher initial level of binge drinking (41). We have no hypotheses of the direction of socioeconomic differences in intervention effects, as previous research has been inconsistent in the direction of intervention effects in different socio-economic groups (42, 43).
We will apply mediation analysis to test our program theory and hypothesized assumptions of whether changes in specific determinants will lead to changes in the primary outcome (44).

Sample size calculation

Prior to the study, a sample size calculation was performed using the statistical software STATA v15 applying *Sampsi* and *Sampclus* to assess number of high schools and students needed to recruit to evaluate the effects of the intervention. Based on results from the Unplugged program (45), a previous school-based substance abuse prevention program among junior high school students (12-14 year-olds) which has been tested in a large cross-national study in seven European countries, we expected a 30% lower mean number of binge drinking episodes within the last 30 days in the intervention group as compared to the control group at follow-up. The average number of binge-drinking episodes within the last 30 days was estimated based on data from the Danish National Youth Study 2014 (39) with an average of 198 enrolled 1st-year students per high school (cluster size). In 2014, high school students had an average of 2.94 binge drinking episodes within the last 30 days, with a standard deviation of 2.58, and an intraclass correlation of 0.034. Conventional levels of statistical power (0.8) and level of significance (0.05) were used. Under the assumptions above, 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 (six control schools and six intervention schools, equivalent to a total of 2,296 students). Due to the risk of loss to follow-up, we aimed at recruiting an additional 30% of schools, corresponding to 16 high schools and 3,168 students. Flowchart of expected number of participating schools and students is presented in figure 2.

Process evaluation

We will perform a process evaluation study in order to explore and assess the implementation process and

explain the effect or lack of effect of the intervention. The process evaluation will be inspired by a six step protocol for systematic process evaluation developed by Aarestrup et al. 2014 (46), Grant et al.'s framework for process evaluation of cluster randomized trials of complex interventions (47) and the factors identified by Durlak and DuPre that effects implementation (48). We will combine qualitative and quantitative methods to gain information on 1) the dose, quality and participant responsiveness of the intervention delivered to school coordinators, parents and the student social- and introduction committees, 2) the dose, quality and student responsiveness of the intervention delivered from school coordinators, parents and social- and introduction committees to 1st year students, 3) factors affecting implementation (community factors, provider characteristics, innovation characteristics, organizational capacity and training and technical assistance) and 4) contamination at intervention and control schools.

Qualitative methods

Qualitative data will be collected at intervention schools continuously throughout the implementation period including 1) participant observations of the parent information meeting and students' engagement with the web-based education programs 2) interviews with school coordinators (in person and via telephone), 3) focus group interviews with 1st year students and members of the student social- and introduction committees and 4) log of email and telephone communication between the research team and school coordinators.

Quantitative methods

Quantitative data will be collected at follow up (April to May 2020) at intervention- and control schools using student questionnaires and school coordinator telephone interviews. This data will provide information on the intervention dose delivered to school coordinators, the social- and introduction committees, parents and 1st year students, school context and contamination at both intervention and control schools. Website track records will contribute with information on parental use of the High schools High on life website.

Patient and Public involvement

No patient involved.

Ethics and dissemination of results

Ethics

In Denmark, behavioral health promotion interventions are generally not required to notify for ethic

approval by the Scientific Ethics Committees (49). The Scientific Ethics Committee for the Capital Region of Denmark has declared that the trial is not subject to notification (jnr. 19021957). The study is registered at the Research an Innovation Office at University of Southern Denmark (ref: 10.314) allowing collection of personal data. When inviting the high schools to participate, school managers received written information about the study. Students were informed that participation was voluntary, that their information would be used for research purposes only and treated confidentially. Research has been inconclusive regarding the existence of a substitution effect between alcohol and cannabis (50). Possible, unintended negative side effects of the intervention, such as shifting to other drugs as replacement for diminished alcohol use, increased alcohol use due to increased attention to the subject, or other side effects will be monitored in the process evaluation. No other ethical concerns were identified.

Dissemination of results

The trial results will be communicated to other researchers in peer-reviewed journals and scientific conferences. Furthermore, they will be disseminated o the public, schools and public health practitioners through press releases, school health profiles to all participating schools based on questionnaire data and conferences for schools and municipalities working with alcohol prevention.

Discussion

The 'High schools High on life' intervention aims at providing important insights into effective strategies to reduce excessive alcohol consumption among adolescents. Further the study, aims at providing knowledge on implementation processes, and intervention effects among different subgroups, and contribute to the literature on cultural changes in educational institutions.

Trials are expensive and recruitment of schools to research projects can be challenging, it is therefore important to use research data efficiently (51). The recruitment to the intervention was based on existing baseline data which represents an efficient use of data and gives a unique opportunity to study selection bias in participation. However, schools that did not participate in the Danish National Youth Study 2019 (67%) were not invited to participate in the evaluation of the 'High schools High on life' intervention. This reduced the number of high schools that was invited to participate and may reproduce selection bias from the Danish National Youth Study 2019.

Schools will mainly deliver the intervention components themselves. The implementation of the intervention components will be followed closely to support and learn from the implementation processes. The project groups' efforts to secure full implementation will be described thoroughly in the

process evaluation as it is important to know the schools' specific need for implementation support for future scale up of the intervention.

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Declarations

Authors' Contribution

MG and JST concepted the original idea of the study. VP wrote the first draft of the manuscript in collaboration with SHH. JAR wrote the first draft of the process evaluation section. LCT, RFK and JST advised the evaluation design and statistical analysis. All authors read, revised and approved the final manuscript.

Ethics approval and consent to participate

In Denmark, behavioral health promotion interventions are generally not required to notify for ethic approval by the Scientific Ethics Committees (49). The Scientific Ethics Committees for the Capital Region of Denmark has declared that the trial is not subject to notification (jnr. 19021957). The study is registered at the Research an Innovation Office at University of Southern Denmark (ref: 10.314) allowing collection of personal data. When inviting the high schools to participate, school managers received written information about the study. For all data collection methods, responders were informed about the aim of the study, that participation was voluntary, that their information would be used for research purposes only and treated confidentially. In the written introduction the electronic questionnaires, responders were asked to agree that they have received information about the study and the use of their data for research and content to participate. Participants could skip questions they did not wish to answer. For the qualitative data collection content to participate was verbal. According to Danish law children can give content based on their maturity and children of the age of 13 years and above can give consent to use of their personal data.

Consent for publication

Not Applicable.

Availability of data and material

The datasets generated and analyzed during the current study are not publicly available due to sensitivity of the data but are available from the corresponding author on reasonable request.

Competing interest

The Danish Cancer Society developed intervention materials based on an ongoing campaign. The Danish Cancer Society had no influence on the study design, data analysis or interpretation of data.

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Trial Sponsor Contact: Anne Mette Bak. The Danish Cancer Society, grants, Strandboulevarden 49, 2100 Copenhagen, Denmark phone: +45 35257257

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The 'High schools High on life' project group would like to thank all high schools, students, teachers, and school managers who helped designing the intervention.

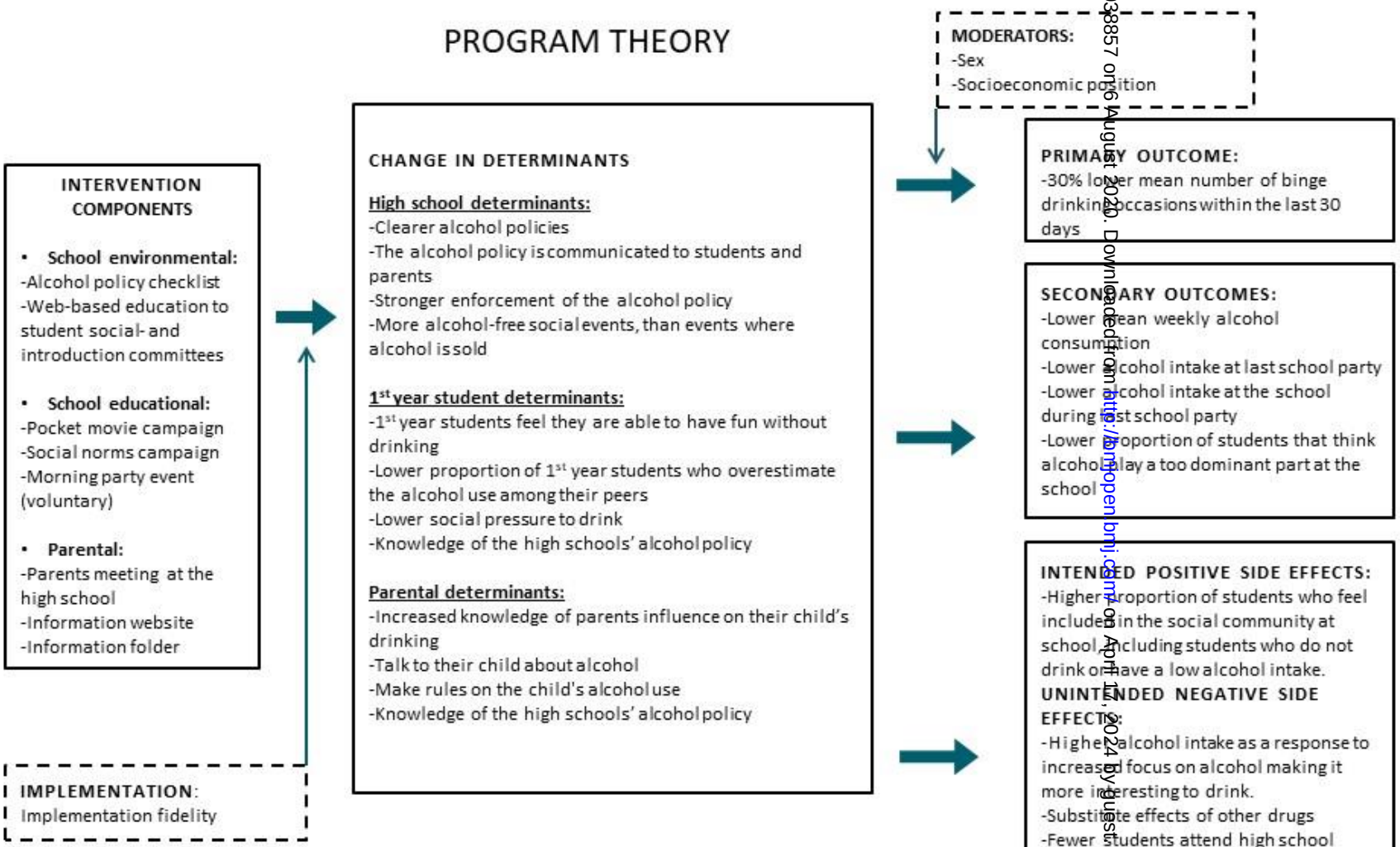

Figure 1: Program Theory of 'High schools High on life'.

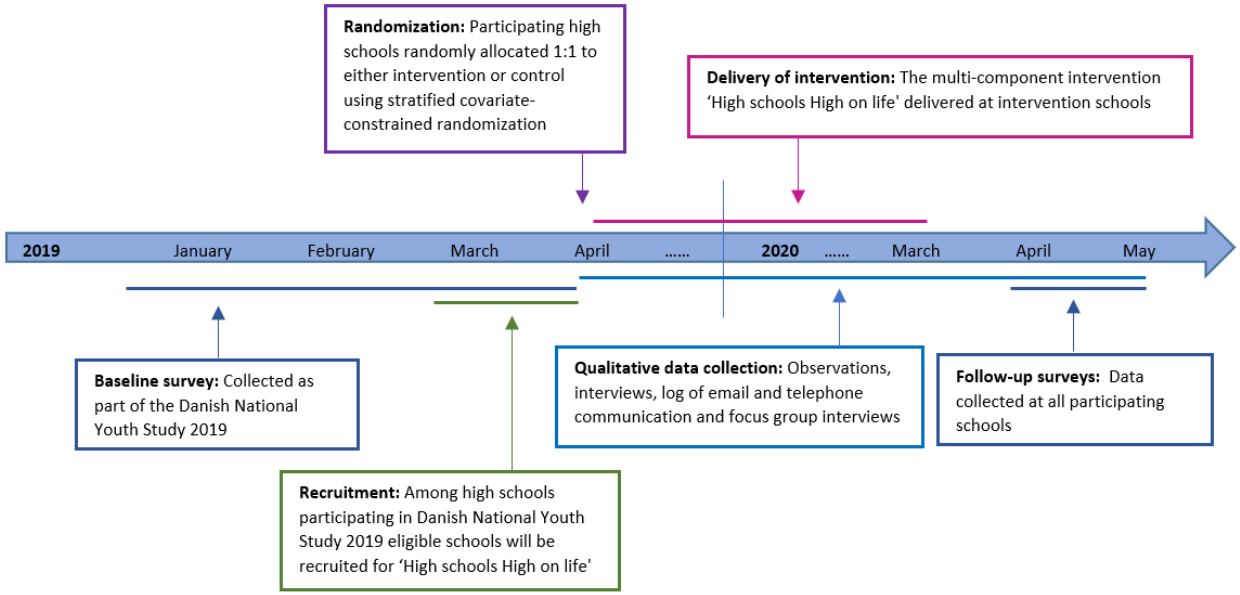

Figure 2: Timeline of the evaluation process

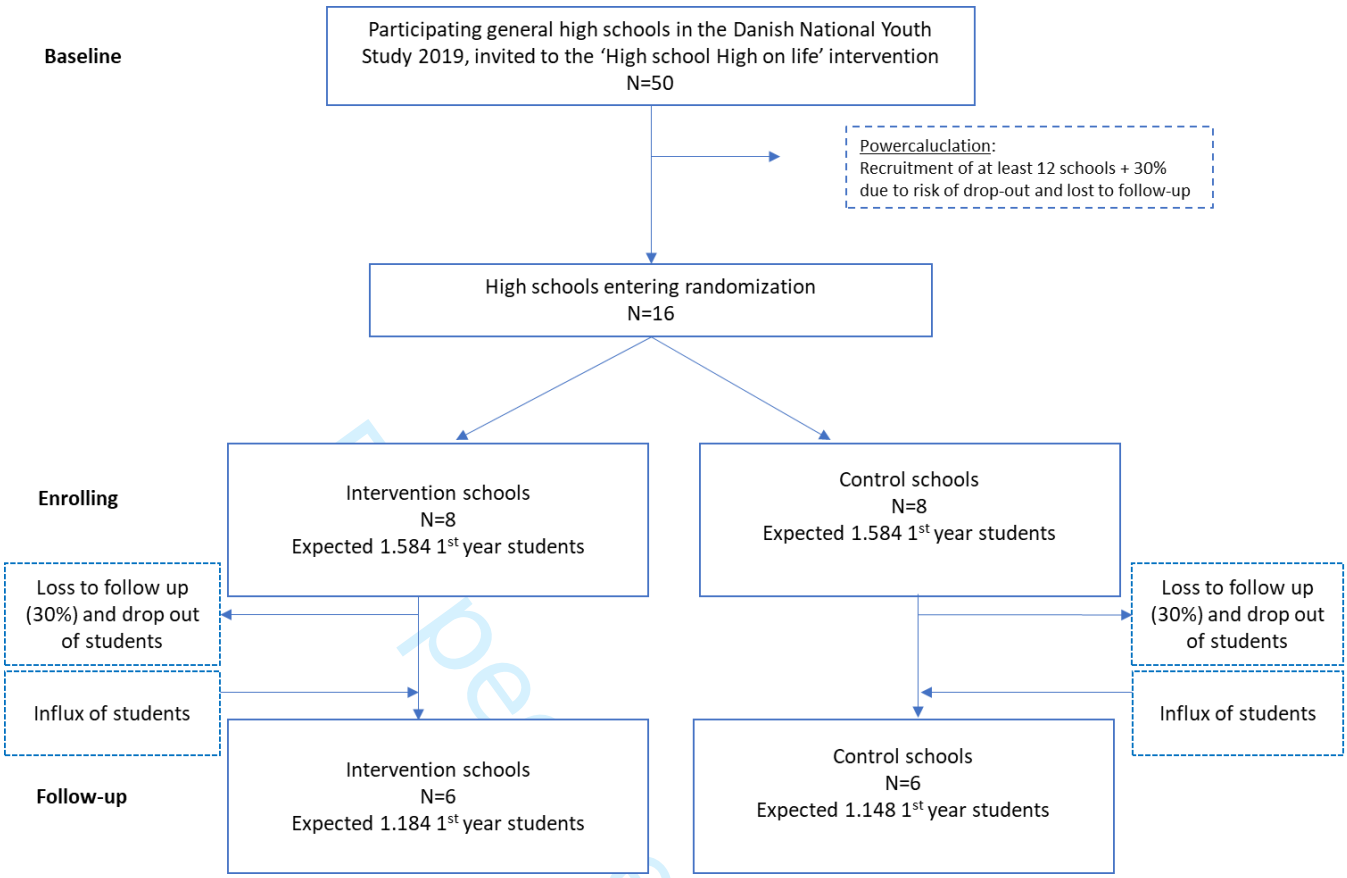

Figure 3: Flowchart of expected number of participating schools and students

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Adressed in study protocol
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Titel page (p.1)
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Titel page (p.1)
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	Titel page (p.1)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Titel page (p.1) and Declarations: Authors contribution (p.20)
	5b	Name and contact information for the trial sponsor	Declarations: Funding (p.21)
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Declarations: Funding (p.21) and Competing interests (p.20)

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Declarations: Authors contribution (p.20)
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Introduction (p.4-6)
	6b	Explanation for choice of comparators	Study design (p.7)
Objectives	7	Specific objectives or hypotheses	Background: research questions (p.4)
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Study design and sampling (p.7 and 8))
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Study design (p.7)
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Inclusion criteria (p.8)

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Intervention and the 'High schools High on life' components (p.5-7) Development article also submitted to BMC Public Health
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Study design (p.7)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Outcomes and Change in determinants (p.9-10)
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Study design (p.7)

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Sample size calculation (p.14)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Recruitment (p.7)
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Sampling (p.8)
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Sampling (p.8)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Sampling (p.8)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Planned statistical analysis (p.13-14)

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Data collection (p.8)
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Data collection (p.8)
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	N/A
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Planned Statistical analysis (p.13-14)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Planned Statistical analysis (p.13-14)

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Planned Statistical analysis (p.13-14)
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Planned Statistical analysis (p.13-14)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics (p.15-16)

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Trial registration (p.2)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Ethics (p.15-16)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Ethics (p.15-16)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Declarations: Competing interests (p.20)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Declaration: Availability of data and material (p.20)
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Dissemination of results (p.16)
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Declarations: Availability of data and material (p.20)
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Ethics (p.15-16)
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.