

## STUDY DESIGN ARTICLE

# Preventing smoking initiation in adolescents living in vulnerable socioeconomic conditions: Study protocol of the KickAsh!-intervention

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## Abstract

**Aims:** Adolescents living in vulnerable socioeconomic conditions are confronted with tobacco-related health disparities. As school-based interventions appear to be less effective among these youngsters, other approaches are necessary. One promising avenue is youth social work settings that offer sport and recreational activities (SR-settings). SR-settings have been examined as a leveraging context for health promotion, but evidence regarding smoking prevention is currently lacking. **Methods:** This study describes the protocol of a non-randomised cluster controlled trial evaluating a smoking prevention intervention for adolescents. At least 24 SR-settings are needed for the intervention and control group. A mixed-method design will be used. Quantitative measures will be used to assess effectiveness, involving validated questionnaires on smoking initiation behaviour and influencing factors (i.e. attitude, self-efficacy, social influence and risk perception). In addition, feasibility will be assessed with regard to intervention fidelity, dose and reach. Data will be collected at baseline, three and nine months following the intervention. To gain deeper understanding on the impact and underlying processes of the intervention, we will conduct qualitative interviews with users (adolescents) and implementers (youth workers within the SR-settings) of the intervention. **Conclusions: Conducting this trial will offer novel insights into the effectiveness of a smoking prevention intervention designed for adolescents living in vulnerable socioeconomic conditions. A mixed-method design will enable to measure impact, implementation and underlying processes of the intervention. Overall, this design will enhance our understanding on the suitability of SR-settings as contexts for smoking prevention initiatives targeting hard-to-reach youth. This trial is registered on Clinicaltrials.gov: NCT05920772.**

**Keywords:** *Research design, clinical trial protocol, non-randomised controlled trials as topic, smoking, tobacco smoking, adolescent, low socioeconomic status, leisure activities, social work, community-based participatory research*

## Background

Over the years, there has been a noticeable decline in smoking prevalence, attributed to increasing awareness of its health consequences and implementation of robust tobacco control policies [1,2]. Despite this trend, 1.3 billion people worldwide use tobacco products, causing over eight million deaths per year [3]. Moreover, tobacco-related health disparities exist, resulting in a disproportionately higher risk for smoking in certain groups [4–7]. Smoking usually starts

during adolescence, and studies show that inequalities already occur at young ages [5,8–11]. Adolescents living in vulnerable socioeconomic conditions are often exposed to a higher degree of risk factors for smoking behaviour, including pro-smoking norms, being exposed to smokers in the family, living in a community that accepts or even stimulates smoking and having easy access to cigarettes [5,12,13]. In addition, these youngsters generally have lower self-esteem [14–17] and/or lower health literacy [18,19], contributing to the risk of smoking initiation (i.e. the

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transition from being a never-smoker to becoming a regular smoker) early on and later in life [9,10,12,20]. Also, adolescents with a low socioeconomic status (SES) tend to start smoking at a younger age compared with their more affluent counterparts, which is associated with a higher chance of smoking in adulthood [9,20,21]. Therefore, it is crucial to develop interventions that specifically address the initiation of smoking among adolescents living in vulnerable socioeconomic conditions [11]. Additionally, to prevent smoking initiation from happening, it is important to intervene early (i.e. before the first cigarette is smoked and habits are formed). As the mean age to start smoking in Belgium is 16.6 years old [22], interventions would ideally tackle adolescents below that age (e.g. 10 to 15 years old).

Developing smoking prevention interventions is complex, as smoking is the result of multiple influencing factors. Three elements appear pivotal in developing effective interventions. First, theoretical frames may ground those interventions so to be sure the intervention tackles the most important determinants or reasons underlying behaviour. One such frame is the I-Change model, which has been previously used successfully in the context of smoking initiation behaviour [23]. The I-Change model describes behaviour as the result of a person's intentions to change, influenced by one's abilities (e.g. skills, implementation intention plans) and barriers. Intentions are determined by cognitive-motivational factors, such as attitude, self-efficacy and social influence. The model also posits that predisposing factors (e.g. psychological factors such as personality, or biological factors such as gender), awareness (e.g. knowledge or risk perception) and information factors (i.e. the quality of how and which messages are delivered) may influence abilities and motivation to engage in certain behaviour [23].

Second, co-creation offers another promising approach to create effective interventions [24]. Co-creation within health research implies a collaboration between researchers and people from the target population to combine their specific expertise and address a shared health challenge [25,26]. Through this approach, it becomes possible to develop a tailored intervention with a higher probability of adaptation and effectiveness [26–28]. Engaging in co-creation with adolescents living in vulnerable conditions is particularly relevant as it provides researchers with insights in their unique context and environment, allowing to map out their specific needs and characteristics [29,30]. Additionally, interventions developed through collaboration with these adolescents are more likely to be accepted by their peers and could increase engagement and sustainability [31,32]. It also improves empowerment, co-learning and ownership of this target population [29].

Third and last, considering that interventions need to be appealing and tailored to their specific context, it is important to carefully consider the most suitable channels for reaching the target population. For the target group of adolescents, schools are convenient settings to develop and implement health interventions as a large group of youngsters can be reached at once [12,33]. However, adolescents with a low SES appear to be generally less motivated and engaged through these kind of health programmes, which can further exacerbate existing health inequities [34]. Therefore, it appears appropriate to utilise settings that organise low-threshold activities, which can subsequently foster a high level of engagement when working with adolescents living in vulnerable socioeconomic conditions. In light of this, youth social work settings that provide sport and/or recreational activities, hereafter referred to as SR-settings, could be a suitable option [35]. These settings have the potential to create an environment that is both accessible and engaging for adolescents in vulnerable socioeconomic conditions. They aim for empowerment of vulnerable groups by strengthening their social opportunities, have specific attention for the physical and psychosocial well-being of their target group and are usually more accessible since geographical, financial, cultural and social barriers are lifted [36,37]. Moreover, these settings focus on promoting togetherness and group cohesion (community building), increasing self-esteem, developing social skills and stimulating group participation [36,38–40]. This contributes to the uptake of a smoking prevention intervention. When considering implementation of this type of interventions in SR-settings, youth workers and coaches who work in these settings play a significant role. For many youngsters, they are their confidants [6,37] and act as role models [39]. This relationship between youth worker and adolescent is a possible strong base to promote healthy messages and inform and support vulnerable adolescents regarding making healthy decisions [37,39].

To reduce smoking initiation among adolescents living in vulnerable socioeconomic conditions, we developed the KickAsh!-intervention. This intervention builds on three fundamentals: (1) theoretical grounding (i.e. informed by the I-Change model), (2) a co-creative approach (i.e. collaboration with adolescents and youth workers), and (3) the SR-setting for the development and implementation of the intervention. This paper presents the study protocol of a non-randomised cluster controlled trial evaluating the KickAsh!-intervention. This trial aims at determining the intervention's effectiveness by assessing smoking initiation and its related determinants (i.e. attitude, self-efficacy, social influence and risk perception) and environmental factors. Additionally, the trial includes

a process evaluation to study the process of implementation, intervention feasibility, context and mechanisms of impact underlying the intervention. Study design, measurements, outcomes and a data analysis plan will be reported in this paper.

## Method

To develop this protocol paper, the guidelines from the 2013 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) were utilised [41]. A version of the completed SPIRIT checklist is presented in Supplemental Appendix 1 online.

### Study design and randomisation

To study effect and process evaluation of the KickAsh!-intervention, a non-randomised cluster controlled trial will be conducted using a mixed-method design. For the effect evaluation, quantitative data will be collected through questionnaires. For the process evaluation, both quantitative and qualitative data will be collected, using questionnaires as well as focus groups and individual interviews.

The target population of the intervention is adolescents who participate in SR-settings. Participants are clustered in SR-settings. Twenty-four SR-settings will be selected: in 12 SR-settings the intervention will be implemented during three months, 12 comparable SR-settings will serve as control condition. Participating settings will not be randomly assigned to the control or intervention group, as this would impede recruitment and it was already agreed to allocate the organisations who participated in the co-creative developmental phase to the intervention group. During recruitment, an equal allocation of similar organisations will be considered by the research team to allow comparison between the two groups. This is necessary as a lot of variation exists concerning the target group and the objectives and approaches used in these kind of settings. Several variables were identified which, if not considered when matching between intervention and control group, might influence smoking initiation behaviour of adolescents. Therefore, the following variables will be taken into account when matching the SR-settings: the size of the SR-setting (i.e. small/mid-large), offered activities at the setting (i.e. sport/recreational), geographical location of the setting (i.e. urban/rural), percentage of adolescents with a low SES, percentage of adolescents with a migration background and age composition of adolescents. The necessary information and data will be collected by querying the SR-settings concerning these variables.

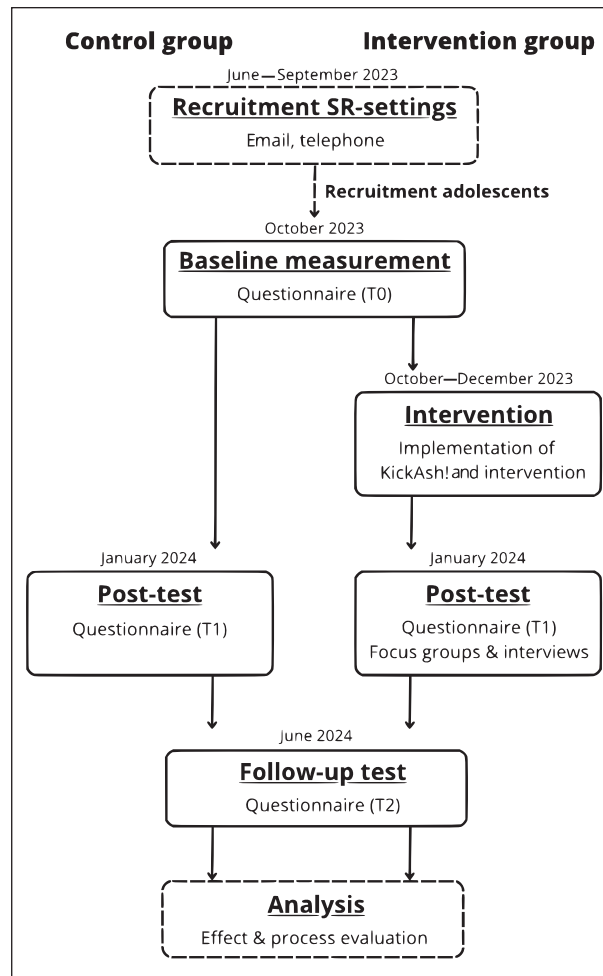


Figure 1. Overview of study progress.

SR-settings = youth social work settings that offer sport and/or recreational activities.

As shown in Figure 1 baseline measurements will be conducted in September 2023 serving as pre-test (T0), followed by three months of intervention implementation. Post-test measurements will be conducted in January 2024 (T1) and follow-up measures in June 2024 (T2).

### Recruitment

A selection of SR-settings in Flanders, Belgium will be invited to participate in the study. Settings will be selected through the official website of the government of Flanders (i.e. desocialekaart.be), which includes an overview of all (health) care offer in Flanders and Brussels. Selection will be based on the activities (i.e. sport or recreational) provided by the SR-setting and their target population (i.e. adolescents living in vulnerable socioeconomic conditions). In addition, several umbrella youth organisations and experts in social

youth work will be contacted as they have a good view on potentially interesting SR-settings. Settings that have already participated in the developmental phase of the intervention will be contacted as well and will immediately be allocated to the intervention group. In total approximately 70 SR-settings are eligible to participate and invited for the study.

Contact details will be searched online. First a recruitment email will be sent to the general email address of the SR-setting or a coordinator if these contact details are available online. If a digital response is not forthcoming, the SR-setting will be contacted by phone. If the setting is interested to participate, an (online) meeting to explain the study in more detail will be organised. Participating SR-settings should be able to reach at least 25 adolescents who are eligible for participation in the study in an intervention period of three months.

If the SR-setting consents to participate, two informal meetings will be organised in this setting to provide information about the study: one for youth workers and one for adolescents from this setting and their parents. Additionally, information letters and consent forms will be provided in different languages for the participants. For those who are not present at this meeting, these letters and forms can also be handed out afterwards.

#### *Ethical considerations and General Data Protection Regulation (GDPR)*

As the participants of this study are minors, signed informed consents are required from both adolescents and their parents or legal guardians (compliant with GDPR-legalisations). However, considering that this research targets adolescents living in vulnerable socioeconomic conditions, receiving informed consents from the parents is inconvenient. After consulting SR-settings, it became evident that establishing contact with parents is challenging. Especially considering the project's focus on the private theme of youngsters' smoking behaviour, often associated with concepts of freedom, autonomy and decision making. Directly involving parents may impede participation of adolescents or even the SR-setting. Indeed, youth workers should adhere to the duty of discretion, as a relationship of trust with their youngsters is extremely important for their work [42]. Therefore, informing parents could result in many adverse effects on the study process and outcomes.

To avoid selection bias before the start of the study, and to ensure that the most vulnerable adolescents will be included as well, the 'active informed consent' of the parents was changed to one of 'public interest'. Yet, this does not imply that participants will not be

informed concerning the processing of their data, the purpose and the design of the study. Comprehensible and accessible information will be provided for both adolescents and their parents through informal meetings in the SR-settings. Adolescents will receive and sign an informed consent letter at the beginning of the study. Participants' privacy will be ensured during data analysis. Only members of the research team will have access to the data. The data-management plan is presented in Supplemental Appendix 2 online.

Ethical approval for this study was given by the Committee of Medical Ethics of the Ghent University Hospital (ONZ-2023-0366) and registered as a clinical trial (Clinicaltrials.govNCT05920772).

#### *Target population*

For this intervention, SR-settings in Flanders (Belgium) will be recruited. To be included in the study, these settings must target adolescents who live in vulnerable socioeconomic conditions. The intervention will be implemented for all adolescents participating in the SR-setting. However, adolescents who will be questioned as a function of the evaluation study should meet the following inclusion criteria:

- Aged between 10 and 15 years old;
- Participate in activities offered by the SR-setting during the implementation period;
- Have sufficient understanding of the Dutch language.

Convenience sampling will be applied to recruit participants for this study at baseline. That is, adolescents who are present at the SR-setting during the T0-collection period will be asked to fill in the questionnaire. The same adolescents will be contacted to fill in the post- and follow-up questionnaire. An incentive will be provided for those who fill in all questionnaires. During data collection, adolescents will always be supported by a researcher or youth worker, who might help by clarifying certain questions. Also, to assure understandability and minimise measurement bias, all questions were pre-checked with adolescents. Youth workers from SR-settings will act as implementers of the intervention. Therefore, they will also be questioned concerning the process evaluation of this study.

#### *Sample size calculations*

A power analysis for clustered samples was executed to calculate the required sample size. For smoking



initiation as primary outcome, it was estimated that 12 settings in each group (assuming an average of 25 adolescents per setting) would provide a minimum of 80% power to detect a small effect size of 0.3 [43–45], accounting for an intracluster correlation coefficient of 0.07 [46]. This means we will need to recruit 24 SR-settings for the evaluation.

#### *KickAsh!-intervention: development, content and implementation*

The general aim of the KickAsh!-intervention is to prevent smoking initiation in adolescents living in vulnerable socioeconomic conditions. For this study, smoking initiation was defined as the phase in which adolescents start experimenting with smoking (from never smoking to smoking maximum once a month), but are not yet regular smokers (smoking at least once a week). This intervention was developed using planning tools from the fields of health promotion and design thinking, that is, the Intervention Mapping Protocol (IMP) [47] and the Double Diamond model (DD-model) [48]. Combining both frameworks seemed relevant for intervention development as their focus is somewhat different and therefore the two approaches complement each other, resulting in a more adequate and effective intervention. In IMP, theory and evidence are used as a base, while the DD-model is more people-driven. Therefore, the I-Change model was used as a theoretical base for the intervention as this model has been previously successfully applied to smoking initiation for the purpose of intervention development [23]. Additionally, a co-creative approach was maintained with adolescents and youth workers to increase tailoring and probability of adaptation. More information concerning the co-creation process will be reported in another paper.

The intervention consists of different components concerning smoking prevention. Most components have a direct influence on smoking initiation by affecting several determinants of adolescents. These components include smoke-free games, mood boards, a smoke-free camp and the Kick some Ash!-challenge. Yet, some components target adolescents by influencing their environment, that is, smoking policy in the organisation and tips and tricks for youth workers. All components are developed using a combination of theoretical methods to change or influence these determinants or environmental factors [47,49–52]. An overview of the components, the influenced determinants or environmental factors and their related methods are presented in Table I.

Youth workers from SR-settings will act as implementers of the intervention. To make the intervention components easily accessible and convenient to its implementers, they were compiled into a digital toolkit in the form of a website. This website will be used only by the implementers. On the website a home page can be found on which youth workers can navigate to four general parts of the toolkit. Each part forms a separate web page on the website covering the different components of the intervention (see Table I). Youth workers can find instructions on how to use the KickAsh!-toolkit and more information about the intervention's aim and development on the first part of the website.

Youth workers will implement all components of the toolkit in their organisation during an intervention period of three months. All necessary materials (both digital and physical) and an implementation plan/timeline will therefore be provided. As SR-settings are very diverse concerning their working methods, youth workers will be given space to make practical adjustments on the materials (without changing the content) to increase suitability for their organisation. Prior to the implementation phase, a meeting with the youth workers from each setting will take place to provide them with all necessary information concerning the study and the KickAsh!-toolkit. In addition, youth workers will receive a digital logbook in which they can keep notes and reflect on the components they implemented (e.g. who was the implementer, number of adolescents present during the activity, barriers/facilitators which occurred during implementation, deviations from the initial implementation plan).

#### *Outcome and measurement instruments*

*Socio-demographics.* General socio-demographic data will be measured during the pre-test, including sex, birth year, birth month, educational year, form of education, migration background, family composition and number of siblings. Presence of the participants in the SR-setting (e.g. daily, weekly, monthly. . .) will be measured as well.

To determine SES of the adolescents, educational level of the parents will be assessed. In addition, two single-item questions will be asked concerning the perceived family financial situation [53] and perceived SES [54].

#### *Effect evaluation*

*Smoking initiation behaviour.* The primary outcome of this study is smoking initiation behaviour. Kremers

Table I. Overview of the intervention and implementation components of the KickAsh!-toolkit.

Intervention/ implementation component	Content	Targeted determinant of adolescent (D)/ environmental factor (EF)	Used theoretical methods [47,49–52]
<i>Home page (part of implementation)</i>			
	- Short introduction video - Navigation through the website	/	/
<i>Toolkit information (part of implementation)</i>			
	- What is it? - How do you use it? - How was it developed? - Who participated?	/	/
<i>Information on how to become a smoke-free organisation</i>			
Smoking policy	- Checklist for mapping out current smoking policy - Tips and tricks to elaborate or improve a smoking policy - Organisations receive a ‘smoke-free label’ when they meet all requirements	Organisation (EF)	Systems change Technical assistance Structural redesign Public commitment
		Policy (EF)	Creating and enforcing laws and regulations
Tips and tricks for youth workers	- Tips for youth workers on how to be a role model concerning smoking prevention - Tips and concrete exercises concerning inoculation theory, the importance of life skills such as assertiveness training and other methods (e.g. planning coping responses) to influence the self-efficacy of youngsters	Social influence (EF)	Modelling Mobilizing social networks Information about others’ approval
		Self-efficacy (D) Skills (D)	Inoculation theory Botvin Life Skills Training Planning coping responses Resistance to social pressure
<i>Smoke-free tools</i>			
Smoke-free games	- Game explanation and needed materials for two smoke-free games: o Tobacco plantation game o Operation smoke free - Youth workers are free to play these games with their youngsters in the existing form or customise them for their organisation	Knowledge (D)	Discussion
		Attitude (D)	Arguments Anticipated regret Cultural similarity
		Risk perception (D)	Consciousness raising
		Subjective norm (EF)	Entertainment education Discussion
Design a smoke-free game	- Guidelines for youth workers on how to make an evidence-based smoke-free game that is customised to their organisation - Possibility to upload the created games on the website	Subject to choice of the youth workers	Subject to choice of the youth workers
Mood boards	- Visual mood boards addressing three themes concerning smoking: o Smoking and health o Smoking and the climate o Smoking and child labour - Mood boards can be placed at different spots in the organisation	Attitude (D)	Arguments Elaboration
		Risk perception (D)	Consciousness raising Personalize risk
		Knowledge (D)	Elaboration Using imagery
Smoke-free camp	- Script for going on a 2–3 day smoking prevention themed camp (includes several components of the toolkit, i.e. the games, mood boards and challenge) - All materials for the camp are provided - This component is optional	Knowledge (D) Risk perception (D) Attitude (D) Social influence (EF) Subjective norm (EF)	Includes methods linked to the relevant components
<i>Kick some Ash!-challenge</i>			
Attend the challenge by creating a smoke-free logo	- Social media challenge - Organisations can attend the challenge by creating a smoke-free logo together with their youngsters - The best logo wins a prize	Risk perception (D)	Consciousness raising
		Attitude (D)	Cultural similarity
		Self-efficacy (D) Skills (D)	Public commitment
		Organisation (EF)	Team building and human relations training
		Subjective norm (EF)	Entertainment education

and colleagues created a model for understanding the developmental process of smoking initiation, integrating both a motivational and a behavioural dimension: the Model of Unplanned Smoking Initiation of Children and Adolescents (MUSICA) [55]. For evaluation studies, it is interesting to consider both dimensions and the different stages they entail, as other approaches might be needed to prevent adolescents in different stages from initiating smoking [56,57]. Smoking initiation will therefore be measured following MUSICA, assessing this behaviour via two questions. First, adolescents will be asked to select the statement that best describes them from a list of nine statements concerning their smoking behaviour. This makes it possible to classify adolescents into the group that best describes their behaviour: never smokers, non-smoking deciders, triers, experimenters, regular smokers and quitters. Subsequently, a similar question will be asked regarding their motivation to smoke in the future, classifying adolescents into committers (firm decision not to start smoking in the future), immotives (do not plan to start smoking, but lack firm decision), progressives (vague plans to start smoking), contemplators (plan to start smoking within six months) and preparers (plan to start smoking within next month) [58]. The results for both questions can be combined, giving a clear view on the stage of smoking initiation of the participating adolescents. Seven stages are distinguished: (1) committed never smokers, (2) immotive never smokers, (3) immotive triers, (4) immotive experimenters, (5) contemplating experimenters, (6) immotive non-smoking deciders and (7) committed non-smoking deciders [55].

In addition, two questions will be addressed concerning smoking frequency (i.e. number of cigarettes smoked) in the past month and in their life [59]. Smoking onset age as well as smoking intention in the future and in the following year will also be questioned [59,60].

*Determinants of smoking initiation.* Based on the I-Change model [23], several determinants will be targeted through the intervention: attitude, self-efficacy, social influence and risk perception (see Table I). Consequently these determinants will be analysed.

Attitude towards smoking will be measured by addressing both perceived advantages and disadvantages. In total, eight items will be assessed: four items for cognitive (dis)advantages of smoking (e.g. it is difficult to stop, it is safe for 1–2 years if you stop afterwards) and four items for emotional (dis)advantages (e.g. makes me look cool, I will regret it). To assess these items adolescents will have to answer the question ‘What do you think about smoking?’ using a five-point Likert answer category range. For example, from

1 ‘it will make me look very cool’ to 5 ‘it will absolutely not make me look cool’. Scales of (dis)advantages of smoking will consist of sum scores.

Self-efficacy will be assessed by six questions measuring the adolescents’ ability to resist smoking in several situations [61], for example, ‘when friends are smoking’, ‘when I am in the setting’, ‘when I am stressed’. Adolescents will have to answer using a five-point Likert scale ranging from 1 ‘very easy not to smoke’ to 5 ‘very difficult not to smoke’. These questions will then be linked to six coping plan items, analysing whether the adolescents have prepared any coping plans for these specific situations. Answers will again be rated on a five-point scale: 1 ‘definitely’ to 5 ‘certainly not’. Sum scores will be calculated for both scales.

Social influence will be measured by assessing subjective norm and perceived social pressure concerning smoking [57,61]. For subjective norm, seven questions will be asked to determine the perceptions of important people in the adolescent’s environment concerning smoking norms. Important others included in this study are friends, best friend, mother, father, siblings, youth workers and youngsters in the SR-setting. A five-point Likert scale will be used. For example: ‘My friends think I should. . .’ 1 ‘definitely smoke’ to 5 ‘definitely not smoke’. Subscales will be constructed for parents (i.e. sum score of father and mother), siblings (i.e. score for siblings), friends (i.e. sum score of friends and best friend) and the SR-setting (i.e. sum scores of youth workers and youngsters in the SR-setting). The social pressure measure consists of seven items, addressing the same important others as the subjective norm measure. Adolescents have to answer whether they ever felt pressure to smoke from these people on a five-point scale, for example, ‘Did you ever feel pressure to smoke from your father?’. The same subscales and sum scores will be constructed as for subjective norm. In addition, the smoking behaviour of environmental actors will be assessed. Adolescents’ perceptions of the number of friends that smoke will be analysed, along with smokers in the family. Perceived smoking behaviour of youth workers and other youngsters present in the relevant SR-setting will be questioned as well.

Last, risk perception will be analysed by assessing susceptibility and severity of smoking initiation. A two-item scale will be used [62]. Adolescents will be asked to answer whether they agree with the following statements: (1) if I smoke now, I am more likely to get lung cancer in the future; (2) I think lung cancer is a serious disease. A five-point Likert scale will be used. Scales of risk perception will consist of sum scores.

*Negative control outcome.* To ensure no confounding bias is present in the results of this study, a negative control outcome will be assessed. Therefore, cycling behaviour for transport will be measured using two items from the International Physical Activity Questionnaire [63]. Adolescents will be asked on how many days in the past week they biked for at least 10 minutes as transportation. In addition, adolescents will have to indicate for how long they biked on such a day. Total Metabolic Equivalent of a Task minutes per week will be calculated.

*Process evaluation.* Process evaluation questions are based on the Medical Research Council (MRC) guidance [64]. MRC distinguishes several key functions of process evaluation and the relations among them. These key functions include more information concerning the implementation (i.e. what is delivered and how), the mechanisms of impact (i.e. in which way does the delivered intervention produce change) and the context. A distinction is made between questions assessed through questionnaires (T0, T1, T2) and through interviews and focus groups (T1).

*Questionnaire.* As mentioned earlier, adolescents' perceptions on smoking behaviour of other adolescents and youth workers who are present in the SR-settings will be measured to evaluate the effect of the intervention. However, these data are also relevant to identify the context in which the participating adolescents are exposed to the intervention. In addition, adolescents will be asked at post-test to indicate which of the intervention components they received and score these components on an agreeableness-, interesting- and/or fun-scale from 1 to 10.

*Focus groups and interviews.* To investigate the implementation process and gain deeper insights into the factors that did or did not produce change, focus groups will be organised with the participating adolescents. At least one focus group per setting will take place with 6–8 adolescents. The following themes will be examined: (1) reach and dose received; (2) general impression concerning the intervention; (3) perceptions regarding the specific intervention components (impressions, experiences and feedback); (4) context; (5) perceived impact and how (effects of the intervention components).

As youth workers who work in the SR-settings serve as the implementers of the intervention, we will include them in the process evaluation as well. Therefore, focus groups will be conducted per setting with all relevant youth workers (i.e. youth workers who carried out the implementation). The interview guide for youth workers will include the

following themes: (1) smoking history; (2) delivered intervention components; (3) intervention fidelity; (4) impression, experiences and feedback concerning the (implementation of) specific intervention components; (5) barriers and facilitators for implementation; (6) perceived mechanisms that did or did not lead to impact; (7) perceived effects of the intervention in adolescents, youth workers, others.

### *Analyses*

Descriptive statistics will be generated for the socio-demographic characteristics of the total sample group (i.e. both intervention group and control group). Intervention effects (i.e. main and interaction effects) will be analysed using generalised linear mixed models (accounting for the clustering of measurements within adolescents within the SR-settings). A drop-out analysis will identify differences in variables between participants with complete and incomplete data. Variables that are found to be related to participant drop-out will be included as covariates in the model. Consequently, the assumption that data are missing at random can be ignored [65]. All statistical analyses will be executed using R-4.3.0 for Windows [66]. Confounders (such as age, sex, SES. . .) will be taken into account during analyses.

Qualitative data from the individual interviews and focus groups will be audio-recorded and transcribed verbatim. Directed qualitative content analysis will be performed for the process evaluation [67]. A deductive approach will be used through predefined codes such as reasons for quitting, intervention acceptability, intervention fidelity, and the like. Data will be coded by two researchers independently. Inter-rated agreement will be calculated using weighted kappa. Inconsistencies will be discussed within the research team until consensus is reached. Qualitative data analysis will be performed using NVivo (Version 14) [68]. The consolidated criteria for reporting qualitative research checklist will be used for good reporting.

### **Discussion**

In this paper, the study protocol for an evaluation of the KickAsh!-intervention is described. This intervention focuses on preventing smoking initiation in adolescents living in vulnerable socioeconomic conditions (10–15 years old) by addressing several determinants on the individual level, including attitude, knowledge, self-efficacy, risk perception, and social influence by youth workers on the environmental level. The intervention itself was developed using three fundamentals: (1) theory-driven approach



(e.g. I-Change model [23]), (2) co-creation with youngsters and youth workers, and (3) being low-threshold and fitted to the context for whom the intervention is meant. SR-settings were used for development and implementation of the intervention, as the literature shows that this might result in higher engagement and higher uptake of the intervention [35,37–40]. Yet, the impact of such an intervention, and particularly whether it is useful in changing smoking initiation behaviour among vulnerable adolescents, is yet to be investigated.

A strength of this study is the thorough evaluation of the effect and process of the intervention, using a mixed-methods design. Over the past few decades, increased attention has been given to the occurrence of ‘black box evaluation’ and how to overcome this. ‘Black box’ refers to approaches focused on intervention outcomes without exploring and trying to understand how and why these were produced [69,70]. Yet, in order to correctly infer an intervention’s impact, one needs to unravel the mechanisms behind effectiveness and conditions through which the effects occur or not [69–71]. This can be accomplished through theory-based evaluation. One such way to perform this kind of evaluation is by using a process evaluation design in addition to the effect evaluation [69].

For example, using SR-settings for this study could possibly entail several implications concerning the implementation of the intervention, which might influence the intervention effects as a consequence. First, participation in SR-settings is not mandatory. This means that adolescents might be only very limitedly exposed to the intervention. Also, a high level of trust exists between youth workers and their youngsters; this could be a potential barrier for youth workers to implement health promoting interventions, such as the KickAsh!-intervention, as this could jeopardise their bond. Last, SR-settings are rather unique and have different ways of elaborating their activities and organisation. This could influence the implementation of the intervention as not all components of the intervention might suit each setting equally well (e.g. playing the smoke-free games in a sports club could be less convenient). These implications emphasise the importance and strength of performing a process evaluation to reveal whether and in which way they have an impact on the intervention effects and how to better take them into account in future research projects.

In this study the MRC framework will be used to create deeper understanding of the processes behind the effects of the KickAsh!-intervention. MRC focuses on recognising the causal assumptions underlying an intervention and the relations

between implementation, mechanisms of change and context [64]. Yet, establishing such evaluation demands a structured and complex action plan in which all relevant actors and different components should be investigated [64,72,73]. Describing this kind of protocol may therefore support future researchers when conducting comparable studies.

Besides the mixed-methods design, another strength of this study is that outcomes will be measured at three different points in time: pre-test, post-test and follow-up, which enables to investigate short- and medium-term effects. A final strength is in using MUSICA [55] as a framework to measure smoking initiation in adolescents. Using this model makes it possible to situate in which behavioural and emotional stage of smoking initiation adolescents are located. This will provide information on which intervention component might be more effective or less effective in which stage, and help us to create better understanding of the intervention processes.

Limitations of this study include that participating SR-settings will not be randomly assigned to the control or the intervention group, which might entail allocation bias [74]. As mentioned before, SR-settings are very unique in their audience, objectives and methods. Therefore, it seems relevant to thoughtfully divide them between intervention and control groups, to ensure an equal allocation of similar organisations and enable comparison between the two groups. Allocation criteria (e.g. activity type, group composition, geographical location. . .) were formulated to ensure this equal allocation. Next, as attending the SR-settings is not mandatory and thus not every adolescent visits the setting at the same time, convenience sampling will be used to recruit adolescents at baseline, which might result in sampling bias [75]. However, this will be taken into account during the recruitment by providing a sufficient period of time (i.e. one month) to fill in the questionnaire, so as to ensure that as many adolescents as possible have the possibility to participate.

Another limitation is that SR-settings whose youth workers and adolescents participated in the co-creation group will be included in the intervention group. This might influence the implementation process and intervention effects of these settings, and consequently this study as well, as participants of the co-creation process might have more knowledge and skills concerning the intervention and smoking (prevention) in general. However, doing this matches the principles and spirit of co-creation and it might be interesting to explore whether there is a stronger effect on smoking initiation in these settings compared with SR-settings who did not participate in the co-creation process. We will strive for recruitment of

a few more settings in the intervention group, to enable exclusion of the co-creation group settings in the analysis if necessary. Also, unlike the intervention, the evaluation design was not developed in a co-creative way. This means that the evaluation methods and strategy might not be completely tailored to the target population and in this way have an impact on the results. For example, involving youth in developing evaluation strategies for other youth could increase credibility and result in collecting more relevant data [76,77]. Still, this decision was made as the co-creation group indicated that they had no need to stay involved in this part of the study, which is a natural process in co-creation [78].

A final limitation is that other substance use and tobacco or nicotine products are not targeted in this study, despite their often found association with cigarette smoking behaviour (e.g. e-cigarette use is longitudinally associated with smoking initiation in adolescents [79]). However, other factors seem to be important to explain, for example, e-cigarette use, suggesting that other methods and strategies might be needed to target this behaviour as well [80].

In conclusion, the results of this trial will provide insights in the effectiveness of the KickAsh!-intervention, a smoking prevention intervention targeting adolescents living in vulnerable socioeconomic conditions. The mixed methods design will enable us to evaluate impact and implementation, as well as underlying processes of the intervention, leading to increased understanding on the usefulness of SR-settings as contexts for smoking prevention initiatives.

#### Author contribution

BD wrote the manuscript. EL, MV, KL and SW provided feedback during the writing process. All authors read and approved the final manuscript.

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The authors have no conflicts of interest to declare.

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#### Supplemental material

Supplemental material for this article is available online.

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