

BMJ Open Study protocol for the evaluation of long-term effects of the school-based obesity prevention program Lekker Fit! ('enjoy being fit'): a retrospective, controlled design

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ABSTRACT

Introduction Preventive interventions to reduce overweight and obesity in childhood and adolescence are studied on their effectiveness worldwide. A number with positive results. However, long-term effects of these interventions and their potentially wider influence on well-being and health have been less studied. This study aims to evaluate the long-term effects of a multicomponent intervention in elementary school children targeting individual behaviour as well as environment (Lekker Fit!). The primary outcome is body mass index and the secondary outcomes are waist circumference, weight status, physical fitness, lifestyle, psychosocial health and academic performance.

Methods and analysis In a naturalistic effect evaluation with a retrospective, controlled design adolescents in secondary schools, from intervention and non-intervention elementary schools, will be compared on a wide set of outcome variables. Data will be collected by questionnaires and through anthropometric and fitness measurements by trained physical education teachers and research assistants. Baseline data consist of measurements from the adolescents at the age of 5 years old and are gathered from preventive youth healthcare records, from before the intervention took place. Multilevel regression models will be used and adjusted for baseline measurements and potential confounding variables on the individual and environmental level. Furthermore, propensity scores will be applied.

Ethics and dissemination The study has been approved by the Medical Research Ethics Committee of the Erasmus Medical Centre, Rotterdam, The Netherlands (permission ID: MEC-2020-0644). Study findings will be disseminated in peer-reviewed journals and by conference presentations.

Trial registration number NL8799. Pre-results.

INTRODUCTION

The prevalence of overweight and obesity in children has been a growing health concern for many years worldwide.^{1–3} Recent estimation from the WHO European Childhood

Strengths and limitations of this study

- Studies regarding the sustainability of effects of school-based obesity prevention programmes are needed.
- Effects on a broad set of outcome variables will be assessed.
- A controlled study design will be used with retrospective collection of baseline data and adjustment for the non-randomised design by a range of confounders.
- Study population will be diverse in age, socioeconomic background, ethnic background, grade and school level.

Obesity Surveillance Initiative (COSI) indicates an overweight prevalence of 9%–43% for boys and 5%–43% for girls, with numbers varying across countries.^{4,5} Furthermore, an obesity prevalence of 2%–21% for boys and 1%–19% for girls was reported by the COSI.^{4,5} Although a recent stabilisation in the trend of the overweight and obesity prevalence in children has been demonstrated in high-income countries, the overall prevalence of overweight in childhood remains high.^{2,6} In 2019 in the Netherlands, 12.0% of the children (aged 4–12 years old) were overweight, including 2.0% obese children.⁷ For adolescents (aged 12–16 years old), overweight prevalence was 14.7% of the population, including 1.9% obese adolescents.⁷

Childhood overweight and obesity have been associated with numerous adverse health consequences, like cardiovascular disorders, type 2 diabetes and psychosocial health problems.^{8–13} Furthermore, children with overweight or obesity are at higher risk for obesity in adulthood than their normal weight peers.^{14,15} In addition, individuals with



obesity pose a substantial financial burden on the global healthcare systems as their individual medical costs are 30% higher.¹⁶ The combination of the economic consequences, health consequences and high prevalence warrants the implementation of effective interventions to prevent and reduce overweight and obesity in children.^{6,17}

Physical activity and diet, being factors associated with the development of overweight and obesity,^{18,19} often form important entry points for those interventions. A recent Cochrane review, addressing interventions for the prevention of obesity, reported that combined diet and physical activity interventions do reduce body mass index (BMI) z-scores for children aged 6–12 years old, although the level of evidence is low.²⁰ Schools have been suggested to be the optimal place to deliver the interventions due to continuous contact with children,²¹ and reaching children with a wide range of different backgrounds.²² Two recent reviews provide evidence that school-based interventions are generally effective in the reduction of children's weight gain.^{17,23} However, little is known about the sustainability of effects by obesity prevention interventions as long-term studies are scarce.^{24,25} The authors of the Cochrane review indeed suggest that interventions and strategies to prevent obesity in children should include follow-up measurements over several years.²⁰ Furthermore, the wider effects of school-based interventions including a physical activity component on health and well-being have been less studied, although the association between physical activity and both academic performance^{26,27} and psychosocial health and well-being^{28–30} in children and adolescents have been well documented.

The multicomponent obesity prevention programme Lekker Fit! (translated as 'enjoy being fit'³¹) for schooled children was developed and implemented in 2005 via elementary schools in Rotterdam, the Netherlands, targeting children aged 6–12 years old. The results of a randomised controlled trial (RCT) performed in 2006–2007 demonstrated positive intervention effects on overweight prevalence, waist circumference and aerobic fitness among elementary school children in grades 3–5 after 1 year of intervention.³² The long-term effects of Lekker Fit! (after leaving elementary school) as well as the wider effects on psychosocial health and academic performance have not been studied yet. This knowledge is important to determine whether beneficial effects of Lekker Fit! sustain into adolescence and whether wider effects are present. To the authors' knowledge, no studies are available for the assessment of the long-term effectiveness of multicomponent school-based interventions on a set of outcome variables including weight status, fitness, lifestyle, psychosocial health and academic performance.

Therefore, the main objective of this study is to evaluate the long-term effects of Lekker Fit! on (a) the primary outcome BMI, and (b) the secondary outcomes waist circumference, weight status, physical fitness, lifestyle and lifestyle determinants, psychosocial health and academic performance. In subgroup analysis, we will explore if any encountered effects are different for

gender, socioeconomic status and time since intervention. Moreover, dose–effect associations will be explored if the data provide sufficient variability in the amount of intervention years. Finally, on an exploratory basis, we will investigate the participants' appreciation of the Lekker Fit! intervention and similar components from regular school programmes.

Our hypothesis is that adolescents who have attended a Lekker Fit! elementary school exhibit healthier scores than their peers who have attended a regular elementary school on the set of primary and secondary outcome variables. However, we do not know the relationship between longer follow-up and the intervention effects, due to the scarce literature on the sustainability of such intervention effects into adolescence. Furthermore, we hypothesise that more years of Lekker Fit! intervention on an elementary school leads to better scores on the set of outcome variables, due to the prolonged exposure to this behavioural changing intervention.

METHODS AND ANALYSIS

Lekker Fit! intervention and regular school program

In 2005, to halt the rise in obesity among children, the City of Rotterdam, the Netherlands has developed and implemented the intervention programme Lekker Fit! (translated as 'enjoy being fit').³¹ This programme has been implemented in collaboration with elementary schools in Rotterdam targeting children aged 6–12 years old and at a later stage with day care organisations. In the Dutch school system, children attend elementary school for 8 years (4–12 years old) and start secondary school at age 12. In 2020, about half of all elementary schools (94) in Rotterdam have adopted Lekker Fit! into their education programme.³³

Although the Lekker Fit! programme has no direct focus on reducing overweight, the contribution of the programme to reducing overweight is expected to be the consequence of a healthy diet and active lifestyle. The intervention entails multiple components (table 1). In comparison with regular school programmes, these include an additional third physical education (PE) lesson per week, professional PE teachers instead of regular classroom teachers providing the PE lessons, voluntary additional physical activities outside school hours, the promotion of drinking water and the promotion of a healthy diet and lifestyle.³³

Besides targeting individual behaviours of children, Lekker Fit! targets the obesogenic environment of the children and involves parental engagement.^{31,32} The strategy for behavioural change is mainly based on the theory of planned behaviour (TPB),³¹ while several components of Lekker Fit! are based on specific theories such as social marketing.³⁴ The TPB states that a behaviour is being influenced by the intention towards that behaviour. The intention itself is being influenced by the individual's attitude, social norm and self-efficacy.^{35,36} Lekker Fit! primarily targets children in the socioeconomically

Table 1 Components (and their year of introduction) of the Lekker Fit! intervention on elementary schools in comparison with the regular elementary school programme

Since	Lekker Fit! intervention components	Regular school programme
2005	Three PE lessons per week	Two PE lessons per week
2005	A trained PE teacher provides all the PE lessons and coordinates the implementation of the intervention on school	The classroom teacher provides all the PE lessons
2005	Three 1.5-hour sessions of special themed education per year by the classroom teacher. Themes of special education are healthy diet, physical activity and making healthy choices	Schools are free to use education programmes on specific themes
2005	A PE lesson for several different sports by an external PE teacher, as a first step towards a sportsclub membership (an after school hours component)	Regular schools are given the same non-obligatory opportunity for these PE lessons
2006	The school sports clubs provide four trainings of different sports on a weekly basis (an after school hours component)	Regular schools are given the same non-obligatory opportunity for these trainings
2005	Annual weight and height measurements	–
2007	Additionally the PE teachers monitor the motor development of children in accordance with the Dutch basic protocol for PE	–
2005	An information meeting for parents on annual basis regarding the themes fruit, water, breakfast and physical activity	–
2005	The school dietitian signals overweight and obesity, based on the weight and height measurements, and provides parents with information	–
2012	Extension of the Lekker Fit! intervention to classes 1 and 2 (children aged 4 and 5 years old)	–
2013	The water campaign with community involvement; Children drink water at least two times per day during school hours	–
2013	The ‘enjoy fruit’ component; children only eat fruit or vegetables during their morning break	–
2015	The ‘treats’ component; In the Netherlands it’s a habit that children share treats among their peers on their birthday. This component presents guidelines regarding these birthday treats. Guidelines say that one treat is enough and that a small treat is okay!	–

PE, physical education.

disadvantaged neighbourhoods, because of a higher prevalence of overweight and obesity and therefore a higher risk at metabolic diseases in those neighbourhoods.^{37 38}

Study design

In order to determine the long-term effects of the Lekker Fit! intervention, a naturalistic effect evaluation^{39–41} with a retrospective, controlled design will be conducted

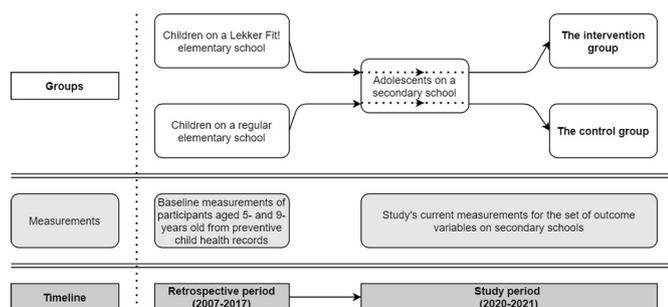


Figure 1 The naturalistic effect evaluation with a retrospective, controlled design of this study.

(figure 1). We will recruit adolescents aged 12–18 years old on secondary schools for participation in the study. This allows for a follow-up period of up to 6 years. Due to the COVID-19 pandemic, a prolonged recruitment and data collection period is applied in this study. The recruitment period ranges from September 2020 up to and including September 2021. The data collection period continues until December 2021.

We will compare the adolescents who attended Lekker Fit! elementary schools—the intervention group—with adolescents who attended regular non-Lekker Fit! elementary schools—the control group. Given the naturalistic non-randomised design, correction for confounding variables will be applied. Correction for available pre-intervention baseline measurements around the age of 5 years old will be applied by obtaining data from the regional preventive youth healthcare provider (CJG Rijnmond). Furthermore, available measurements at the age of 9 years old will be obtained to serve as an additional control measurement. Thus, the set of baseline

data ranges from the period 2007–2017, depending on the current ages of the participating adolescents. Confounding variables and baseline measurements will be described in detail below. We used the Standard Protocol Items: Recommendations for Interventional Trials checklist (online supplemental file 1) to address all recommend items in our study protocol.⁴²

Study population and recruitment

We will include 2218 adolescents aged 12–18 years in this study (see the Power considerations section). We expect to include 20–25 secondary schools in Rotterdam, from neighbourhoods with divergent socioeconomic backgrounds, in this study. They will receive an informative letter to explain the nature, relevance, objectives and measurements of this study. Only after a school has given consent for its participation, will the adolescents in that school be approached for participation in close collaboration with the school. We will recruit adolescents from all different school levels and grades within the age range. The targeted adolescents and their parents will receive an information letter. Additionally, all relevant information about the study will be available on a website (URL: <https://www.rotterdam.nl/onderzoeklekkerfit>). Comprehensive information will be given about all the relevant topics regarding the study and the consequences of participation. Adolescents are asked to give digital informed consent before they are eligible for participation in this study. For the adolescents who are under the age of 16 years old, digital informed consent by one parent will also be obtained in accordance with Dutch legislation.

Lekker fit! intervention group and control group

For all adolescents in this study, their school career (specified per school year) will be obtained from the municipal records in Rotterdam. Specific permission for the collection and coupling of this data will be asked within the digital informed consent forms. Combined with information from the City of Rotterdam about which elementary schools implemented Lekker Fit!, we are able to assign the adolescents to the intervention group or control group. Adolescents who attended elementary schools outside Rotterdam were not exposed to Lekker Fit! and will be assigned to the control group. Children may move between schools and change between the intervention condition and the control condition. Based on the accurate year by year school career data from the municipality, we will be able to determine exposure to Lekker Fit! in years and years since intervention for all adolescents.

New data collection

Participants are asked to complete a digital questionnaire using LimeSurvey software during school hours and to engage in physical measurements during their PE class. LimeSurvey will also be used by the researchers to manage the digital consent forms of participants and parents.

Furthermore, we will collect information about possible confounding variables that might have an influence on the effect of the Lekker Fit! intervention. In this respect, measures for age, gender, ethnic background, household situation and socioeconomic background will be obtained from participants and environmental measures like the presence of a healthy school canteen and the presence of any additional psychosocial or physical interventions on the secondary schools will be collected. All the instruments that will be used for data collection are described within the Measurements section.

Retrospective data collection

Retrospective baseline data will be retrieved from the CJG Rijnmond archives. The CJG Rijnmond is a regional preventive youth healthcare provider for children in the larger Rotterdam area. The CJG Rijnmond invites all children for growth and health monitoring during childhood. Collected baseline data will involve measures of anthropometrics, BMI and psychosocial health data. The data consist of measurements from the participants around the age of 5 years old and 9 years old (figure 1). Baseline data around the age of 5 years old will provide information about participants before the Lekker Fit! intervention is entered (Lekker Fit! starts in grade 3 of elementary school). Baseline data around the age of 9 years old will be obtained as an additional control measurement. Furthermore, the child records consist of information about any additional professional guidance that participating adolescents received for being overweight during childhood.

Measurements

Primary and secondary outcome variables

The primary outcome variable in this study is BMI. The secondary outcome variables in this study are waist circumference, weight status, physical fitness, lifestyle and lifestyle determinants, psychosocial health and academic performance.

Trained PE teachers and research assistants will measure body weight, body length and waist circumference. Body weight will be measured to the nearest 0.1 kg and body length and waist circumference will be measured to the nearest 0.1 cm. A fixed protocol will be used in which the adolescents will be measured (apart from their peers) with light clothing, without shoes. BMI will then be calculated and BMI-for-age z-scores (zBMI) will be determined based on international growth standards for school-aged children and adolescents.^{43 44} Based on BMI-for-age z-scores, adolescents' weight status will be categorised as underweight ($zBMI < -2$), normal weight ($-2 \leq zBMI \leq 1$), overweight ($zBMI > 1$) or obese ($zBMI > 2$) using common cut-offs according to WHO standards.^{43 45} Physical fitness will be measured by the 20m-Shuttle Run test according to a standardised protocol under guidance of the PE teacher in which the outcome will be the number of stages completed.⁴⁶ The 20m-Shuttle Run test

is an acceptable, feasible and reliable method for determination of cardiorespiratory fitness in youth.⁴⁷

The LimeSurvey questionnaire will be used to obtain information on the outcome variables lifestyle and lifestyle determinants, psychosocial health and academic performance. The Short Questionnaire to Assess Health-enhancing physical activity (SQUASH) will be used to assess adherence to physical activity guidelines.⁴⁸ The SQUASH is being used by Dutch government agencies to monitor individuals concerning physical activity guidelines.⁴⁹ The SQUASH was validated using the doubly labelled water method. The SQUASH was found to be a valid self-report tool for measuring physical activity energy expenditure for adolescents.⁴⁹ Furthermore, participants will be asked if they currently have a membership at a sportclub and if they had a sportclub membership during elementary school.

Psychosocial health will be assessed by the Dutch version of the Strengths and Difficulties Questionnaire (SDQ).⁵⁰ The SDQ contains 25 items which are evenly distributed over the domains of emotional symptoms, behavioural problems, hyperactivity/inattention, problems with peers and pro-social behaviour. The SDQ leads to a total score as well as five domain scores. Its Dutch version is classified as a valid and reliable instrument for the first identification of psychosocial problems in adolescents.⁵¹

Determinants of a healthy lifestyle are measured using items based on the TPB.³⁵ Questions are included for healthy behaviours that are promoted by the Lekker Fit! intervention using the guidelines by Ajzen.⁵² The healthy behaviours, for which determinants will be measured, include^{53 54}:

1. 1 hour of moderate intensely exercising every day.
2. Three times per week muscular and bone strengtning exercises.
3. Consciously making healthy choices in diet.
4. Two pieces of fruit every day.
5. 250 g of vegetables every day (approximately four serving spoons).
6. Limiting sugar-sweetened beverage consumption.

Participants are asked to rate their attitude, social norm, self efficacy, intention and actual behaviour (TPB items) towards these standards of healthy behaviour to derive the determinants for a healthy and active lifestyle (example illustrated in table 2).

Academic performance is measured by the question ‘how well is your academic performance as judged by your teacher in comparison with the academic performance of your classmates?’. This item, derived from the International Health Behaviour in School-aged Children Study, was confirmed to be valid and useful to distinguish respondents who get good grades from respondents who do not get good grades.⁵⁵ Furthermore, academic performance will be captured by the school level (preparatory vocational secondary education or senior general secondary education or university preparatory education) of the adolescent.

Possible confounders

Possible confounding variables that we will collect are participant’s current age, gender, ethnic background, household situation, socioeconomic background and professional guidance for overweight during childhood.

Within the questionnaire, the adolescent’s, mother’s and father’s country of birth will be asked. According to Statistics Netherlands, adolescents will be classified for ethnic background based on their mother’s country of birth (to take into consideration the cultural background of the most frequent primary caregiver), unless it is the Netherlands. In that case, adolescents will be classified for ethnic background based on their father’s country of birth (55).

Regarding household situation, we assess whether the participant lives alone, in a two parent or single parent household.

Socioeconomic background will be assessed by questions on parents’ financial difficulties (Did you experience any financial burden in expenses in your household in the last 12 months?) and unemployment payments (Did one of your parents receive an unemployment

Table 2 Example of questions to asses the outcome measure determinants of a healthy and active lifestyle following the guidelines of Ajzen according to the theory of planned behaviour

Healthy behaviour		
Eating two pieces of fruit every day		
TPB items	Question asked	Rating
Attitude	If I eat two pieces of fruit every day for the next 3 months, that would be ...	Bad 1/2/3/4/5/6/7 Good
Perceived norm	Most people who are important to me approve that I eat two fruits every day for the next 3 months	Disagree 1/2/3/4/5/6/7 Agree
Self-efficacy	I am confident that I can eat two pieces of fruit every day for the next 3 months	False 1/2/3/4/5/6/7 True
Intention	I intend to eat two pieces of fruit every day for the next 3 months	Unlikely 1/2/3/4/5/6/7 Likely
Past behaviour	In the past 3 months, I have eaten two pieces of fruit every day	False 1/2/3/4/5/6/7 True

TPB, theory of planned behaviour.

payment in the last 12 months?). Furthermore, socio-economic neighbourhood indicators will be obtained for adolescents based on their postal code and/or elementary schools attended.

Other possible confounding variables that are embedded within the questionnaire include measurements for pubertal development. Pubertal development is measured with the Dutch version of the self-report Pubertal Development Scale.^{56 57} These items are used to determine pubertal status of the participants and will be used to adjust weight status measures. For male participants, questions on pubertal development include growth spurt, body hair, facial hair, voice change and skin changes, whereas for female participants, questions include growth spurt, body hair, breast development, menstruation and skin changes.

On a school level, we will collect the following information from secondary schools:

1. The number of PE lessons per week.
2. The presence of dietetic programmes (for instance a healthy school canteen programme).
3. The presence of preventive mental health and well-being programme (for instance anti-bullying programmes).

Appreciation of the intervention or similar components on regular elementary schools

Within the questionnaire adolescents are asked to evaluate on several components of the Lekker Fit! intervention (or evaluate on similar components in regular elementary schools for the control group). Adolescents are asked to evaluate the quantity and quality of their PE lessons and quality of their PE teachers on elementary school. Furthermore, they are asked to rate their attendance and the quality regarding organised physical activities outside school hours. These items allow us to analyse the subjective experiences of participants during elementary school and allow us to compare appreciation of the Lekker Fit! intervention with the regular school programme.

Power considerations

A statistical a priori power analysis was performed for the estimation of sample size.⁵⁸ With an $\alpha=0.05$, power=0.80 and taking into account the cluster design, we need a sample size of $n=2218$ in total to find an absolute BMI difference of 0.3 kg/m^2 between the intervention and control group.⁵⁸ Hereby assuming an SD of 3.0, clustering within schools accounting for 4% of the variance (Intraclass correlation 0.04), a correlation of 0.75 for baseline and follow-up measurements.⁵⁹ Further assuming a 30% participant loss to non-response, we aim to invite 3169 adolescents for participation in the study.

Statistical analysis

Descriptive statistics will be used to describe the characteristics of the participants in the total study population and separately for the intervention group and the control group. To study the effects of Lekker Fit!, we will use

logistic and linear regression models to evaluate the long-term effects of the Lekker Fit! intervention for all primary and secondary outcome variables. Multilevel analyses will be used to correct for the clustering within secondary schools. The exposure to the Lekker Fit! intervention (intervention/control group) forms the independent variable. All baseline measurements and confounding variables will be added to the models as covariates. Interaction terms for intervention and the variables gender, ethnic background, educational level and time since intervention will be tested. Depending on results, exploratory subgroup analysis will be performed. Moreover, if the data provide sufficient variability in the amount of intervention years for participants, further exploratory analysis will be performed to evaluate possible dose-response associations (using years of intervention exposure). We anticipate that adolescents in the intervention group and control group may differ regarding several baseline characteristics. These baseline characteristics may have had an influence on the chance of receiving the Lekker Fit! intervention or not. Therefore, we will also perform propensity score adjusted comparisons of effects between intervention and control groups, by using propensity scores as a covariate in the model, to account for these possible bias due to the non-randomised design of this naturalistic study. The propensity score will be calculated using a model based on all baseline and confounding variables that will be used as covariates in the analysis on intervention effects. Multiple imputation techniques will be used to handle missing baseline and covariate data.

Patient and public partnership

No participants were involved in the creation and design of this study. A sample of the study population was first involved in this study by testing the questionnaires on quality and feasibility. Individual data may be disseminated to participants who are interested in their personal outcome variables. Participating secondary schools will receive data on school level, which can be used for their school policies. They will be encouraged to share the results with their students.

DISCUSSION

In this article the study protocol for a naturalistic effect evaluation with a retrospective, controlled design is described. The aim of this study is to evaluate the long-term effects of the Lekker Fit! intervention on (a) the primary outcome BMI and (b) the secondary outcomes waist circumference, weight status, physical fitness, lifestyle and lifestyle determinants, psychosocial health and academic performance.

Earlier studies have demonstrated a number of positive intervention effects for the Lekker Fit! intervention.^{32 60} An RCT on the effectiveness of Lekker Fit! was conducted a decade ago.³² Findings included positive intervention effects for weight status, waist circumference and physical fitness for 6–9 years old children in elementary schools,

although no positive effects on BMI were found. The Lekker Fit! intervention programme has been updated with several additional components since then (table 1); among others a water campaign component which incorporated multiple stakeholders in the neighbourhood of the school. The effectiveness of the water campaign was studied in a controlled design and provided evidence for the reduction of children's sugar-sweetened beverages consumption.⁶⁰

Weihrauch-Blüher and colleagues recommended to combine behaviour-oriented intervention programmes, that were found to have only limited effects, with community-oriented components in order to reach sustainable effectiveness of obesity prevention interventions for children and adolescents.⁶¹ The Lekker Fit! intervention is such a multicomponent school-based intervention targeting the individual child and its environment.^{31–33} Lekker Fit! is thereby primarily targeting children in the socioeconomically disadvantaged neighbourhoods, because those children are at higher risk for the development of overweight and obesity.^{37,38}

The recent Cochrane review on obesity prevention interventions included 64 studies on school-based interventions, and 3 studies on school-based interventions with a community element for children aged 6–12 years old.²⁰ They indicate that most of the evidence in their review is based on interventions of 12 months or less. They emphasise that research on long-term effects of completed studies would provide important information on the sustainability of behaviour change and impact on weight.²⁰ Since long-term studies are scarce, little is known about the sustainability of effects^{24,25} or about the determinants that explain whether results are sustainable or not. Furthermore, little is known about the wider benefits that these interventions have on health and well-being of children and adolescents, although associations between physical activity and both academic performance^{26,27} and psychosocial health and well-being^{28–30} in children and adolescents have been reported.

To the authors' knowledge, no studies are yet conducted for the measurement of the long-term effectiveness of multicomponent school-based interventions on the broad set of outcome variables including weight status, fitness, psychosocial health and academic performance. The Lekker Fit! intervention in elementary schools targets children up to 12 years old. As this study includes adolescents aged 12–18 years, long-term effects up to 6 years will be assessed. Additional subgroup analysis will provide insight in the interaction effects between intervention and follow-up length. The current study will therefore contribute to this field of scarce knowledge and expand the insights in the long-term effects of multicomponent school-based interventions and into the sustainability of intervention effects. Adding to this knowledge helps policymakers and intervention developers to decide on further implementation and intervention development.

RCTs are considered the gold standard for effectiveness evaluations of an intervention.⁶² Choosing for a

randomised controlled design, with the length of the follow-up period we employ, would be almost impossible as it would be unethical to withhold schools from implementing an intervention programme that was already proven at least partly effective. The non-randomised design of our study can be regarded as the main limitation. We acknowledge that the assessment of the long-term effects of Lekker Fit! by a naturalistic evaluation design^{39–41} is potentially subject to selection bias, which could arise by the fact that schools are not randomly chosen for implementation of the Lekker Fit! intervention. This limitation is accounted for by using propensity scores in the analysis⁶³ to reduce selection bias. We also acknowledge there are factors that possibly influence our outcome measures besides the Lekker Fit! intervention on elementary school. Therefore, we will include pre-intervention baseline measurements and a broad spectrum of possible confounding variables on the individual and environmental level. The retrospective, controlled design with the application of propensity score analysis we choose seems best suited to overcome this limitation. Further, the self-report for physical activity can be regarded as a limitation. However, the SQUASH questionnaire was found to be a valid self-report tool for measuring physical activity energy expenditure for adolescents and is less costly than direct measurements.⁴⁹ Self-report items may also manifest recall bias. To minimise recall bias for the items in our questionnaire, the items are easy to understand and sometimes provided with additional explanation or relatable examples.

On the other hand, we do not rely on self-report regarding anthropometric measurements or fitness. This can be regarded as a strength. Further, the naturalistic effect evaluation design of this study also allows us to observe subjects in 'a real world' setting instead of in a highly controlled experimental setting. A second strength of this practice-based design is therefore that it provides strong external validity of the results by providing a realistic representation of the 'practice-based' setting.^{39,40} This study hereby measures a broad set of outcome variables for a wide picture of the effects of Lekker Fit! on health in youth. The fact that we include a large sample size of participants with different socioeconomically backgrounds might be considered a strength of this study. It provides us with the opportunity to further generalise our findings to several populations characterised by apparent socioeconomic inequalities.

In conclusion, this paper describes the design of a study to determine the sustained effects of the school-based Lekker Fit! intervention, a multicomponent intervention targeting overweight and physical inactivity in children. This study will provide insight in the long-term intervention effects and will extend insights in a variety of outcome measures including BMI, waist circumference, weight status, physical fitness, lifestyle and lifestyle determinants, psychosocial health and academic performance.

ETHICS AND DISSEMINATION

Ethical statement

The Medical Research Ethics Committee of the Erasmus Medical Centre, Rotterdam, The Netherlands decided that the regulations from the Dutch Medical Research Involving Human Subjects Act (Dutch abbreviation WMO) do not apply to this research protocol. Therefore permission was granted by the committee for the execution of this study and for publications in a later stage of the study (permission ID: MEC-2020-0644). The research proposal has been registered in the Dutch trial register NTR, in which effect-studies are registered that are conducted in the Netherlands.

Dissemination statement

The project team will disseminate the findings from this scientific study by conference presentations and scientific peer-reviewed journals.

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Contributors MSS, HR, FM, MEGW, RB and WJ contributed to the design of the study and the development of the protocol for this study. MSS mainly wrote the manuscript and HR, FM, MEGW, RB and WJ contributed to the manuscript by critical revisions and giving comprehensive feedback on multiple drafts. MSS, HR, FM, MEGW, RB and WJ read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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