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ABSTRACT

Introduction In this study, researchers collaborate with children from a deprived neighbourhood in Amsterdam in developing, implementing and evaluating interventions targeting their health behaviours. This Youth Participatory Action Research (YPAR) project focuses on the promotion of physical activity and healthy dietary behaviour.

Methods and analysis This study is a controlled trial using participatory methods to develop interventions together with 9 - 12-year-old children. At four primary schools in a deprived neighbourhood in Amsterdam an 'Action Team' was installed: a group of six to eight children who actively participate as co-researchers in developing, implementing and evaluating interventions. An academic researcher facilitates the participatory process. Four control schools, also located in deprived areas in and around Amsterdam, continue with their regular curriculum and do not participate in the participatory process. For the effect evaluation, physical activity and sedentary behaviour is assessed using: accelerometers and self-reporting; dietary behaviour using self-reporting; and motor fitness (strength, flexibility, coordination, speed, endurance) using the MOPER fitness test. Effectiveness of the interventions will be evaluated by multi-level regression analysis. The process of co-creating interventions and the implemented interventions will be continually evaluated during meetings of the Action Teams and with children participating in the interventions. Empowerment of children is evaluated during focus groups. Summaries and transcripts of meetings are coded and analysed to enrich children's findings.

Discussion Using YPAR methodology with 9 - 12-year-old children is novel and promising based on results with youth.

Ethics and dissemination The Medical Ethics Committee of the VU Medical Center concluded that this protocol does not fall within the scope of the Medical Research Involving Human Subjects Act (2016.366).

Protocol registration The study protocol has been registered at the Dutch trial registration www.trialregister.nl under number TC=6604.

Strengths and limitations of this study :

- This study is the first to combine Youth Participatory Action Research (YPAR) with Intervention Mapping (IM), ensuring that the development interventions are both evidence-based and matching the interests and needs of the specific target group.
- The study design is a controlled trial, which is unique in YPAR.
- This study is embedded in the community involving a multidisciplinary project group. This aids the sustainability of the interventions.
- This study includes an effect evaluation as well as a process evaluation in which the YPAR process and empowerment of youth is evaluated.
- Randomization of schools into the intervention and control group was not possible because of the community approach.

1. INTRODUCTION

The number of children with overweight or obesity is growing worldwide and this public health problem is high on municipal and governmental agendas. This is no different in the Netherlands, where in 2016 on average there were 10.7% of the children between 8 and 12 years old with overweight/obesity [1]. In urban areas such as Amsterdam, the rates exceed the country's average, with prevalence rates of overweight/obesity of 12.8% among 5-year-olds and 20.9% among 10-year olds [2]. Even though the overweight numbers are stabilizing, health inequalities still exist [3]: children with overweight or obesity are not only disproportionately divided geographically, but also across income and ethnic groups [4-6]. Looking at race/ethnicity, children from minority groups show higher overweight/obesity rates than children from a majority group [4 7 8]. For example, in Amsterdam 10.4% of 5-year-old children with a Dutch ethnicity have overweight while this is almost 30% in 10-year-old children with a non-Western background [3]. In relation to income groups, in the Netherlands in the age category 4 - 25-year-olds, 11.2% of the highest income group had overweight, versus 18.0% of the lowest income group [9]. Similarly, in 2017 in Amsterdam 30.1% of the 10-year-old children with a very low socioeconomic status (SES) had overweight, versus 9.8% of the 10-year old children with a very high SES[3]. Importantly, children with overweight are at high risk of remaining overweight and are therefore also at higher risk for chronic illnesses during childhood and in their adult life [10]. This is why prevention of overweight in children is a priority for many health organizations, municipalities and ministries [11 12].

Many interventions have been developed and implemented to tackle childhood obesity, but most show disappointing effects [13 14]. Strikingly, the most affected group of children – i.e. from families with a low SES and from non-Western backgrounds – is most difficult to reach through interventions [15], thereby maintaining or even widening health inequalities [16 17]. One reason why these interventions show low participation and effectiveness in this target group could be because the target group is seldom involved in the development of the interventions [18]. Involving the target group is essential to connect to their needs and interests [19], as this influences the reach and effectiveness of the intervention. Therefore, in the current research project – 'Kids in Action' – children from a deprived neighbourhood are engaged as co-researchers, i.e. applying Youth Participatory Action Research (YPAR). Children not only co-create interventions to improve their lifestyle and that of their peers

and family members, but also collaborate in the implementation and evaluation of these interventions. To structure this process, the systematic Intervention Mapping (IM) methodology is applied alongside YPAR. This combination of IM and YPAR ensures that the co-created interventions are appropriate to the interests and needs of the children, but also build on existing evidence.

1.1. Aims and objectives

The overall aim of the 'Kids in Action' study is to develop, implement and evaluate interventions that stimulate a healthy lifestyle to reduce health inequalities in children from a low SES neighbourhood in collaboration with the children themselves. This study builds on a participatory needs assessment that was conducted in the same neighbourhood [20]. From this needs assessment, two main needs were identified: to improve physical activity and a healthy diet. The organized activities should be offered at a low price and at a nearby location, the education concerning a healthy diet should be organized in a fun and practical manner.

The primary objective of this study is to evaluate whether designing interventions in collaboration with children can lead to interventions that are more effective in improving children's physical activity and dietary behaviour.
The secondary objective of this study is to evaluate the process of combining YPAR with IM. This includes evaluating the effects of participating in the YPAR process on the empowerment of children and the judgement of children and other stakeholders of interventions that were co-developed by their peers.

2. METHODS

The Medical Ethics Committee of the VU University Medical Center approved the protocol and concluded that this protocol does not fall within the scope of the Medical Research Involving Human Subjects Act (2016.366).

2.1. Participatory Action Research

Participatory Action Research (PAR) aims to 'improve health and reduce health inequities' by working together with the community and consequently empowering the community by getting them to improve their own health [21]. Throughout the entire process of developing,

implementing and evaluating interventions, community members are involved as co-researchers and highly valued as experts of their own lives and experiences. At the same time, the community is empowered and experiences more ownership over their lives and livelihood.

This study specifically works together with children in the PAR process. YPAR engages youth as co-researchers in the research process. In this process, children identify problems in their living environment and become empowered to do something about it [22-25]. Children learn research skills so they can participate in research and have shared power over the research- and decision-making processes [23 25 26].

2.2. Patient and public involvement

This study is initiated by academic researchers and a community organization. The municipality advises on the selection of the intervention neighbourhood, to recruit a neighbourhood with high health needs that can benefit from the project. As this study is informed by a participatory needs assessment (see section 1.1) [20], the objectives and outcome measures of this study are determined in collaboration with children, parents and professionals working with children in the neighbourhood. The design of the study and recruitment procedures are decided by the academic researchers. The conduct of the study, the development of interventions and the dissemination of the results to the study participants and other relevant stakeholders, is decided together with the children.

2.3. Participants

The four intervention schools are all situated in one deprived neighbourhood in Amsterdam, where in 2015-2016 over 50% of the residents had a non-Western background, 27% of the 10-year-olds were overweight/obese and in 2014 31% of the children under 18 years old grew up in a household defined as low-income [27-29]. Possible control schools are selected based on similarity in neighbourhood characteristics: overweight/obesity rates, household income and cultural background.

Participants in this study are children from four intervention schools and four control schools in deprived neighbourhoods in Amsterdam, the Netherlands. The intervention schools participate in the YPAR process, including implementing and evaluating the developed interventions. The control schools only participate in the measurements for the effect evaluation.

2.3.1. Recruitment

Following selection of a neighbourhood with high health needs, the intervention schools are contacted by the municipality to inform them about the project and to ask them if they are willing to participate. After the schools agree to participate, the main researcher contacts the schools to give them more information about the project. Control schools in the area of Amsterdam are contacted by the main researcher in a random order via e-mail or telephone until four schools are found that are willing to participate as control schools. Control schools are offered a presentation about the research results after the study is finished.

All 9 - 12-year-old children (i.e. children of the three highest grades in primary school) of the four intervention and four control schools are eligible to participate in the effect measurements of the project. For the YPAR process, children from intervention schools are invited to collaborate with academic researchers in co-researcher groups, named 'Action Teams'. For both the effect measurements and the Action Teams, every year new children can participate as the highest grade leaves the school and new children enter the third-highest grade. All children receive an information letter for themselves and for their parents about the measurements and the Action Team. Attached to the information letters for parents is an informed consent letter that at least one of the parents has to sign if they agree to the participation of their child. At all schools, the researcher explains the project in all classes before handing out the information letters. Children who participate in the measurements and/or in the Action Team receive a small gift.

2.4. Procedures

This section describes the five phases of the 'Kids in Action' project. See Figure 1 for an outline.

Phase 1: Creating partnerships

The first phase consists of creating partnerships with the schools and other stakeholders in the area, such as social workers, organizers of after-school activities and the community centres. Together with these stakeholders, a project group is started that meets every three months to discuss running projects in the neighbourhood and how partners can collaborate. In this phase, an IM expert group is also formed, to advise on how YPAR and IM should be combined. The IM expert group is involved throughout all phases of the study.

Phase 2: Formation of Action Teams

In the second phase of the project, the Action Teams are formed. Each of the Action Teams consists of six to eight children, an academic researcher and a research assistant. Meetings with the principals of the four intervention schools are planned to decide upon recruitment methods for the Action Teams and to schedule the meetings. Subsequently, the Action Teams are formed and a general outline of the meetings is developed. In this phase, the baseline effect measurement (T0) is executed.

Phase 3: Intervention development

In the third phase, the meetings of the Action Teams take place. The meetings with the Action Teams are ideally held biweekly during school hours for one hour. Despite not all schools agreeing to this in the needs assessment, the researchers try to schedule meetings during school hours to raise the children's motivation for participation [20]. If the schools do not agree with this, meetings are held weekly for 45 minutes, followed by a 45-minute sports session [20].

The first three to four meetings are used to verify the data that was gathered in a participatory needs assessment and to decide on determinants that the interventions need to focus on [20]. The rest of the meetings (approximately 10 per year) are used to develop interventions targeting children's physical activity and healthy dietary habits. Throughout these meetings, capacity building takes place to help the children through the process of intervention development. Children learn for example about formulating a research question, different kinds of research methodologies, how to analyse qualitative data, how to translate this data into intervention ideas and practical steps that need to be taken when developing intervention plans. At the end of phase 3, pilots of the first intervention activities are carried out. The Action Teams are also asked to identify 'Champions', i.e. people who can help them with the development and implementation of the pilots. The results of this phase (i.e. the needs assessment, the intervention ideas and results of the pilots) are discussed with the stakeholders in the project group to make sure the interventions become a joint and sustainable effort.

At the end of the year, a focus group with the Action Teams and their peers is held to discuss the feeling of empowerment that the children of the neighbourhood experience as part of the process evaluation.

Phase 4: Implementation and evaluation of interventions

In the beginning of phase 4, new Action Teams are recruited/formed. Children who were in the Action Teams of the previous year can still participate and are approached first. With the new Action Teams, meetings are planned monthly. Champions are involved and asked to participate in the meetings when appropriate. Together with stakeholders from the project group and the Action Teams, the implementation plans are finalized and subsequently the interventions are implemented. Once the interventions are implemented, the meetings are used to evaluate the interventions. If the Action Teams feel the interventions are going well, they are encouraged to develop and implement additional intervention activities that focus on other determinants or a different subgroup [30]. At the end of the year, focus groups are held focusing on empowering children and evaluating interventions. The first effect measurement (T1) is also executed in this phase.

Phase 5: Gradual transfer of responsibilities

In phase 5, responsibilities are gradually transferred to the identified champions. Specific plans are made together with the champions and other stakeholders to continue the interventions and participatory process after this project has ended. The meetings with the (new) Action Teams continue to take place every month, and are used to evaluate and, if necessary, adapt the interventions and discuss new ideas for interventions. The post-intervention effect measurement (T2) is executed in this phase. The study ends in November 2019.

2.5. Measurements

2.5.1. Effect evaluation

The primary outcomes of this study include measures of dietary behaviour, physical activity, sedentary behaviour, self-rated health, and physical fitness. Dietary behaviour, physical activity and screen behaviour is measured by self-report. Additionally, physical activity and sedentary behaviour is measured using an accelerometer. Motor fitness is measured using the MOPER fitness test. In the first school year (T0), questionnaire and accelerometer data are gathered in the period September-October 2016. The fitness tests take place in March-April 2017, 2018 and 2019.

Questionnaire

A questionnaire is developed containing questions on: the number of small (e.g. crisps, nuts, chocolate) and large (e.g. hamburger, fries, pizza) snacks children eat; the number of sugar-sweetened beverages they drink; their sports and outdoor play participation; their attitude towards sports and outdoor play; their screen behaviour; and their self-rated health. The questionnaire is based on validated items from the ENERGY child questionnaire [31], the DOiT questionnaire [32], and the Euroqol [33]. Table 1 presents the questionnaire items, and the validity and reliability of the original items.

The children fill in the questionnaire during school hours, in the presence of a researcher who explains the procedure of completing the questionnaire before handing out the questionnaires. The children are requested to go through the questionnaire section by section, with the researcher giving a short explanation about each section before the participants fill in that specific section. In this way, examples can be given, for example by showing different sizes of soda cans, and all participants finish at the same time. The questionnaire takes approximately 40 minutes to complete.

Data entry of the multiple-choice questions is done through digital scanning and transferred into SPSS by an independent organization. Qualitative data are manually entered in SPSS.

Table 1: Questionnaire items, their origin, and reliability and validity [31-33]

Questionnaire item	Question derived from	Reliability (ICC/k)/Validity (ICC/k)
1.*How many days a week do you drink sugar-sweetened beverages?*	ENERGY child questionnaire	0.71/0.59
2.*On a day you drink sugar-sweetened beverages, how many glasses/small bottles (250ml), cans (330ml) or big bottles (500ml) do you drink*?	Combination ENERGY child questionnaire, DOiT questionnaire	ENERGY Glasses/small bottles (250ml) 0.59/0.24 Cans (330ml) 0.53/0.44 Big bottles (500ml) 0.58/-0.01 DOiT Cartons/small bottles (200ml) 0.74/0.12 Glasses (200ml) 0.45/0.47 Cans (330ml) 0.61/0.24 Bottles (500ml) 0.28/0.17
3.*How many days a week do you drink energy drinks or sports drinks*?	Added based on Q1	
4.*On a day you drink energy drinks or sports drinks, how many small cans/bottles (250ml)or big cans/bottles (500ml) do you drink*?	Added based on Q2	
5.*How many school days per week do you eat sweets?*	DOiT questionnaire (adapted) Original: '*How many days a week do you eat sweets?*'	0.66/0.60
6.*When you eat candy on a school day, how much sweets do you eat?*	DOiT questionnaire	0.71/0.21
7.*How many days in the weekend (Saturday/Sunday) do you eat sweets?*	DOiT questionnaire (adapted) Original: '*How many days a week do you eat sweets?*'	0.66/0.60
8.*When you eat sweets on a day in the weekend, how much candy do you eat?*	DOiT questionnaire	0.73/0.07

9.*How many schooldays per week do you eat snacks?*	DOiT questionnaire (adapted) Original: '*How many days a week do you eat snacks?*'	0.50/-0.11
10.*When you eat snacks on a school day, how many small and large snacks do you eat?*	DOiT questionnaire	Small snacks 0.62/0.13 Large snacks 0.58/-0.08
11.*How many days in the weekend (Saturday/Sunday) do you eat snacks?*	DOiT questionnaire (adapted) Original: '*How many days a week do you eat snacks?*'	0.50/-0.11
12.*When you eat snacks in the weekend (Saturday/Sunday), how many small and large snacks do you eat?*	DOiT questionnaire	Small snacks 0.53/0.44 Large snacks 0.64/0.08
13.*How do you usually travel to school?*	DOiT questionnaire	Not in test-retest study
14.*How long does it take you to get from home to school?*	DOiT questionnaire + ENERGY child questionnaire (adapted) Original: '*If you walk/bike to school, how long does it take you?*'	DOiT Walking 0.65/ zero variance Biking 0.91/0.68 ENERGY Walking 0.70/0.59 Biking 0.81/0.66
15.*What do you usually do when you play outside at school?*	ENERGY child questionnaire	0.80/0.65
16.*I like playing outside*	ENERGY child questionnaire - Adapted from Q20	
17.*I play outside never/1-2 times a week/3-4 times a week/5-6 times a week/every day*	Added	
18.*When you play outside after school, what do you do?*	ENERGY child questionnaire – Adapted from Q15	
19.*When you play outside after school, how long do you play?* (fill in the number of hours per day in table)	Added	
20.*I like playing sports*	ENERGY child questionnaire	0.64/0.09
21.*I play sports often/sometimes/never*	Added	
22a. *Do you participate in sports in your free time?* *22b. How many times per week do you do this sport?* *22c. How many hours per day do you do this sport?* (fill in all sports that you do, the number of times and number of hours per week in the table)	DOiT questionnaire (adapted) Original: 1. '*Do you participate in a sport at a sports club?*' 2. '*How many hours a week do you do this sport?*' 3. '*Do you participate in a second sport at a sports club?*' 4. '*How many hours a week do you do this second sport?*' 5. '*Do you participate in sports outside a sports club?*' 6. '*How many hours a week do you do these sports?*'	1. 0.98/0.86 2. 0.94/0.78 3. 0.79/0.69 4. 0.76/0.96 5. 0.64/0.33 6. 0.64/0.45
23.*About how many hours a day do you usually watch television/DVDs/movies on the tablet or iPad in your free time?* (fill in the number of hours per day in table)	ENERGY child questionnaire (adapted) Original: '*About how many hours a day do you usually watch television in your free time?*' (weekdays and weekend days)	Weekdays 0.67/0.63 Weekend days 0.68/0.56
24.*About how many hours a day do you usually play games on your game computer, iPad, smartphone or surfing on the internet in your free time?* (fill in the number of hours per day in table, weekdays and weekend days)	ENERGY child questionnaire (adapted) Original: '*About how many hours a day do you usually play games on a computer, or use your computer in your free time?* ' (weekdays and weekend days)	Weekdays 0.67/0.35 Weekend days 0.67/0.65
25.*How do you rate your health today?*	Euroqol EQ-5D-Y Dutch	0.83/ -0.51

Accelerometer

Physical activity and sedentary behaviour is objectively assessed by ActiGraph GT3X+ accelerometers. The children receive instructions and the accelerometers from an academic researcher after filling in the questionnaire. Children are asked to wear the small and light-

weight (4.6 x 3.3 x 1.5 cm; 19 grams) accelerometer on the right hip for eight consecutive days during all waking hours except for water-based activities.

The children receive the accelerometer after completing the questionnaire. The children also receive a diary in which the instructions are summarized and they can write down when and why they did not wear the accelerometer, if applicable. Additionally, they are asked to write down the time they went to bed. All children who participate in the questionnaire- and accelerometer measurements receive a small present after returning the accelerometer. Additionally, at each school there is one prize for a participant who wore the accelerometer properly (seven days, at least ten hours) and recorded their data correctly in their diary. Data are downloaded from the accelerometers into the ActiLife programme in 15 second epochs. Accelerometer data is analysed using a customized software programme developed in R. For inclusion in the data analysis, each participant needs a minimum of six days with at least eight valid hours, including at least one weekend day [34]. Data is analysed on total time spent in MVPA and sedentary , and time in bouts spent in MVPA and sedentary.

MOPER

Children's motor fitness is measured using the Motor Performance Test (MOPER). The MOPER tests speed, flexibility, endurance, coordination and strength by means of eight tests [35]. For practical reasons, the arm pull and 12-minute endurance test have been replaced, leading to the following tests: 1) hang as long as possible on a horizontal bar with flexed arms; 2) jump as high as possible from a standing position; 3) run 10x5 meters as fast as possible; 4) reach as far as possible from a sitting position; 5) hand grip strength measured using a dynamometer [36 37](instead of arm pull); 6) lie on their back and lift their extended legs ten times as fast as possible; 7) tap two plates which are 75 cm apart with the preferred hand 50 times as fast as possible; and 8) shuttle run test [38 39](instead of 12-minute endurance test). Children can do tests one and eight once. Tests two and five are executed twice, but when the difference between one and two is more than 10%, a third try is performed. The highest score is used. The other tests are performed twice and the highest score is used. The first seven activities of the MOPER test are executed during one Physical Education (PE) class by the PE teacher together with five or six research assistants. The PE teacher conducts the shuttle run test in a separate PE class. All research assistants and PE teachers are trained by an academic researcher on how the tests should be executed. At the

end of the study, or when children from the highest grade leave the school, the PE teacher anonymously shares the results of the test. Parents receive an information letter with a passive consent form, which should be signed by at least one of the parents if they object to anonymously sharing the fitness test results of their child with the researchers.

2.5.2. Process evaluation

The process evaluation includes the description of the process of co-creating interventions, combining IM and YPAR, and empowerment. The PAR process is continually evaluated in the Action Team meetings, and meetings are optimized in accordance with the evaluation [21]. The academic researcher and research assistant who are part of the Action Teams evaluate after every meeting, using a reflection form consisting of a summary of the meeting, what the setting was like, the group process and a personal reflection [40-42].

The interventions are developed by combining the YPAR and IM methodologies in an iterative process and are continuously evaluated during the meetings of the Action Teams and with the children participating in the interventions. In collaboration with the Action Teams, it is determined how to evaluate the experiences of children with the interventions. The Action Teams can for example interview peers or develop a questionnaire. The goal of these evaluations is to see how their peers perceive the interventions and whether quick adaptations need to be made. At the end of each school year, focus groups are organized with children from both the Action Teams and their peers, as well as champions to reflect upon the implementation of ongoing interventions and on the empowerment process. Empowerment consists of a combination of individual, organizational, and community empowerment [43]. In our research, we mostly focus on the empowerment of children (individual), but this cannot be evaluated without taking the organizational (school) and community empowerment into account [44]. The focus groups consist of two exercises. The first exercise is mainly focused on individual empowerment, evaluating what children have learnt about the process of intervention development, how they see their role, and competences [45 46]. The children can choose an intervention idea which has not been further developed yet. For this intervention they have to make a timeline with all the steps they need to take from coming up with the idea through to implementation. The researchers guide them through questions, for example: in which order do the steps need to be written down?; do they think they can execute this step by themselves?; if not, do they know where

they can get help? [45]. The second exercise evaluates the organizational and community empowerment. In pairs, the children first indicate which changes happened at school or in the community; then they indicate whether children had any influence on the changes; finally, the findings are discussed in a plenary session. Again the researchers ask questions, for example: how do you feel when you have influence on changes in the community/school?; do you think children have enough influence?; would different changes have been made if children had had more influence? The findings of this focus group provide critical understanding of the environment, what children have learnt, to what extent children participate in the organizational setting and community, and what collective action has already been taken [44-46].

Of all hard-copy research data gathered in the PAR meetings, identifiable information is removed and the data are stored in a locked cabinet at the research location until the study is completed. All online data are coded and stored on the VUmc protected drive until five years after the completion date of the study. Hard-copies of the questionnaires and the audio-recordings are also stored at the VUmc until five years after the study is completed. The three researchers on this project, who are also the authors of this paper, are the only ones who have full access to the trial data. Research assistants have limited access to copies of the data.

2.5.3. Sample size calculation

Using a significance level of 0.05 and a power of 0.80, 180 children per group are needed to detect a difference of 0.15SD in the primary outcome variables. With an estimation of 360 eligible children in the intervention group and 360 in the control group, and a response rate of 2/3, 240 children per group participate. Taking into account drop-out, we expect to include data from 180 children per group in the analyses.

2.5.4. Data analysis

Effect evaluation

To test for baseline differences in the dependent variables between control and intervention groups, t-test for continuous variables and chi-square tests for categorical variables are used. Effectiveness of the interventions on dietary behaviour, physical activity, sedentary behaviour, physical fitness and self-rated health is evaluated using multi-level regression

analysis with a 3-level structure (i.e. student, class, school) to adjust for clustering of observations. Analyses are adjusted for age, gender, ethnicity and baseline levels. All statistical analysis is performed in SPSS, using a significance level of $P<0.05$.

Process evaluation

Evaluation of the PAR process and its meetings are mainly performed by the Action Teams themselves. The academic researcher stimulates the children to find patterns and relations in the findings of their own research and assists in interpretation [47]. Children can for example look at the pictures they have taken and write down why they took the picture and what they want to say with the picture. Children can also write down the key issues that come up in the interviews they have conducted and see if they can identify a pattern. By giving children this role in qualitative data analysis, less misinterpretation of data occurs (than would be the case with adults trying to interpret the children's findings).

In addition, all meetings are summarized and include field notes, and key meetings are fully transcribed [40]. The academic researcher analyses these transcripts to enrich the children's findings. When, for example, the children discuss the pictures they have taken, these discussions may also contain valuable information in addition to the pictures and conclusions of the children. All summaries and transcripts are coded in ATLAS.ti by two researchers to improve the reliability of the study. For the entire process evaluation, an elaborate coding scheme is produced through open coding [47]. For specific aspects like the evaluation of an intervention, coding is done separately resulting in its own coding scheme. For evaluations relating to empowerment, closed coding is used as this will be linked to a conceptual model.

3. DISCUSSION

In the Kids in Action project, children are involved throughout the entire research process. This YPAR approach has previously shown promising results for communities in need with respect to researchers' understanding of the community, lowering health disparities, increasing children's skills (e.g. research skills, life skills), critical awareness, involvement and empowerment concerning community action [48-50].

In the Kids in Action project, children will not be involved in the first phase of this study, in which partnerships with other stakeholders in the community have to be set up. This is because creating partnerships can be time-consuming and not very interesting for children,

and we did not want to lower their spirits [30]. The partnerships are important in YPAR for creating support in the community for the study [48 51] and are beneficial in the rest of the research process and outcomes.

A difference between this study and most YPAR studies is that 9 – 12-year-old children are involved as co-researchers, whereas most YPAR studies collaborate with adolescents older than 12 [52]. Younger children can be more easily distracted, have a limited attention span and might need more 'play', all of which should be taken into account when designing the meetings. Meetings should not be too long, should contain fun and playful exercises, and wording should be suitable for the children, while retaining key principles of YPAR. These principles include: sharing power between researchers and children; training children to participate in research and identify needs in their community; teaching children how to become advocates; creating ownership over the process; and creating involvement in establishing change in their community [53]. When all of this is done with care, children between 9 and 12 years old are capable of joining in YPAR research [54-56].

One implication of working with 9 – 12-year-old children is that you often have to collaborate intensively with the schools. This could mean that changes in the planning have to be made beforehand or during the project, based on the schools' preferences, holidays and other reasons for cancelling meetings [30]. Also, the approval and assistance of schools and other community organizations are likely to be needed for implementing the interventions. Because this is a community project, all primary schools in the neighbourhood are included in the intervention and randomization of schools is not possible. However, the inclusion of comparable control schools is a strength of this study as this is seldom included in PAR [57]. Another strength of this study is the combination of YPAR with IM, which makes sure that evidence-based strategies are being applied. As far as we know, this has not been done before.

A challenge for all intervention studies in real life is that other initiatives can also take place in the neighbourhood. This is part of usual care and can take place both in the intervention school and the control school neighbourhoods, and may dilute intervention effects.

AUTHOR'S CONTRIBUTIONS

All authors worked on the design of this study. MA is the coordinating researcher on the

project, coordinating the effect measurements, process evaluation, leading the participatory process and facilitating the Action Teams. TA and MC designed the study. The paper was drafted by MA, with MC and TA providing comments and revisions to drafts. All authors approved the final version.

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STATEMENTS

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The authors declare that they have no competing interests.

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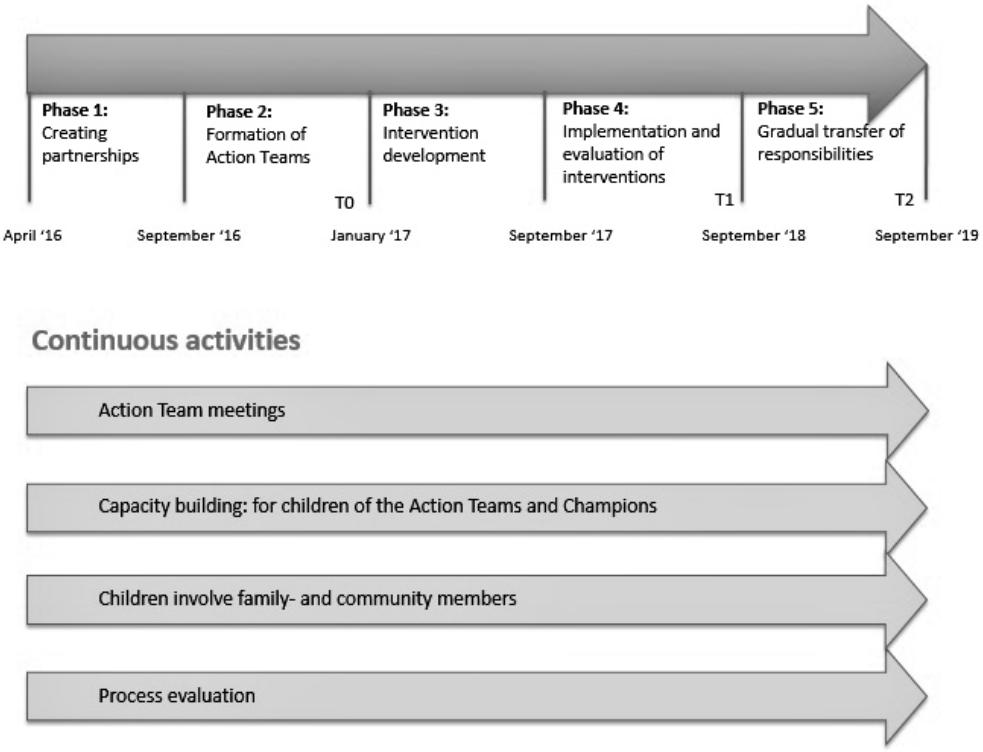
FIGURE AND TABLE TITLES

Figure 1: Outline of the 'Kids in Action' project

Table 1: Questionnaire items, their origin, and reliability and validity



Outline of the 'Kids in Action' project

55x42mm (300 x 300 DPI)

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
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	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
	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)
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
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
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)

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
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)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	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)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
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
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)
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
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

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

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
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
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
	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 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
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
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	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)
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

	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
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
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
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)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
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
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
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
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
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
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
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

*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

Kids in Action: The protocol of a Youth Participatory Action Research project to promote physical activity and dietary behaviour

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Kids in Action: The protocol of a Youth Participatory Action Research project to promote physical activity and dietary behaviour

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Kids in Action: The protocol of a Youth Participatory Action Research project to promote physical activity and dietary behaviour

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ABSTRACT

Introduction In this study, researchers collaborate with children from a deprived neighbourhood in Amsterdam in developing, implementing and evaluating interventions targeting their health behaviours. This Youth Participatory Action Research (YPAR) project focuses on the promotion of physical activity and healthy dietary behaviour.

Methods and analysis This study is a controlled trial using participatory methods to develop interventions together with 9 - 12-year-old children. At four primary schools in a deprived neighbourhood in Amsterdam an 'Action Team' is installed: a group of six to eight children who actively participate as co-researchers in developing, implementing and evaluating interventions. An academic researcher facilitates the participatory process. Four control schools, also located in deprived areas in and around Amsterdam, continue with their regular curriculum and do not participate in the participatory process. For the effect evaluation, physical activity and sedentary behaviour is assessed using: accelerometers and self-reporting; dietary behaviour using self-reporting; and motor fitness (strength, flexibility, coordination, speed, endurance) using the MOPER fitness test. Effectiveness of the interventions is evaluated by multi-level regression analysis. The process of co-creating interventions and the implemented interventions is continually evaluated during meetings of the Action Teams and with children participating in the interventions. Empowerment of children is evaluated during focus groups. Summaries and transcripts of meetings are coded and analysed to enrich children's findings.

Ethics and dissemination The Medical Ethics Committee of the VU Medical Center approved the study protocol (2016.366).

Protocol registration The study protocol has been registered at the Dutch trial registration www.trialregister.nl under number TC=6604.

Strengths and limitations of this study :

- This study is the first to combine Youth Participatory Action Research (YPAR) with Intervention Mapping (IM), ensuring that the development interventions are both evidence-based and matching the interests and needs of the specific target group.
- The study design is a controlled trial, which is unique in YPAR.
- This study is embedded in the community involving a multidisciplinary project group. This aids the sustainability of the interventions.
- This study includes an effect evaluation as well as a process evaluation in which the YPAR process and empowerment of youth is evaluated.
- Randomization of schools into the intervention and control group is not possible because of the community approach.

1. INTRODUCTION

The number of children with overweight or obesity is growing worldwide and this public health problem is high on municipal and governmental agendas. This is no different in the Netherlands, where in 2016 on average there were 10.7% of the children between 8 and 12 years old with overweight/obesity [1]. In urban areas such as Amsterdam, the rates exceed the country's average, with prevalence rates of overweight/obesity of 12.8% among 5-year-olds and 20.9% among 10-year olds [2]. Even though the overweight numbers are stabilizing, health inequalities still exist [3]: children with overweight or obesity are not only disproportionately divided geographically, but also across income and ethnic groups [4-6]. Looking at race/ethnicity, children from minority groups show higher overweight/obesity rates than children from a majority group [4 7 8]. For example, in Amsterdam 10.4% of 5-year-old children with a Dutch ethnicity have overweight while this is almost 30% in 10-year-old children with a non-Western background [3]. In relation to income groups, in the Netherlands in the age category 4 - 25-year-olds, 11.2% of the highest income group had overweight, versus 18.0% of the lowest income group [9]. Similarly, in 2017 in Amsterdam 30.1% of the 10-year-old children with a very low socioeconomic status (SES) had overweight, versus 9.8% of the 10-year old children with a very high SES[3]. Importantly, children with overweight are at high risk of remaining overweight and are therefore also at higher risk for chronic illnesses during childhood and in their adult life [10]. This is why prevention of overweight in children is a priority for many health organizations, municipalities and ministries [11 12].

Many interventions have been developed and implemented to prevent childhood obesity, but most show disappointing effects [13 14]. Pivotal in childhood obesity prevention is improving dietary behaviour, physical activity and sedentary behaviour [15 16], but this is challenging [17-19]. Strikingly, the most affected group of children – i.e. from families with a low SES and from non-Western backgrounds – is most difficult to reach through interventions [20], thereby maintaining or even widening health inequalities [21 22]. One reason why these interventions show low participation and effectiveness in this target group could be because the target group is seldom involved in the development of the interventions [23]. Involving the target group is essential to connect to their needs and interests [24], as this influences the reach and effectiveness of the intervention. Therefore, in the current research project – 'Kids in Action' – children from a deprived neighbourhood are engaged as co-researchers, i.e.

applying Youth Participatory Action Research (YPAR). Children not only co-create interventions to improve their lifestyle and that of their peers and family members, but also collaborate in the implementation and evaluation of these interventions. To structure this process, the systematic Intervention Mapping (IM) methodology is applied alongside YPAR. Through six iterative steps the IM protocol guides health promoters in the development of evidence-based interventions to change behaviour [25 26]. Combining IM and YPAR ensures that the co-created interventions are appropriate to the interests and needs of the children, but also build on existing evidence. The application of IM alongside YPAR is a novel approach which we iteratively shape during this study.

1.1. Aims and objectives

The overall aim of the 'Kids in Action' study (April 2016-November 2019) is to develop, implement and evaluate interventions that stimulate a healthy lifestyle to reduce health inequalities in children from a low SES neighbourhood in collaboration with the children themselves. This study builds on a participatory needs assessment that was conducted in the same neighbourhood [27]. From this needs assessment, two main needs were identified: to improve physical activity and a healthy diet. The organized activities should be offered at a low price and at a nearby location, the education concerning a healthy diet should be organized in a fun and practical manner.

The primary objective of this study is to evaluate whether designing interventions in collaboration with children can lead to interventions that are more effective in improving children's physical activity and dietary behaviour.
The secondary objective of this study is to evaluate the process of combining YPAR with IM. This includes evaluating the effects of participating in the YPAR process on the empowerment of children and the judgement of children and other stakeholders of interventions that were co-developed by their peers.

2. METHODS

The Medical Ethics Committee of the VU University Medical Center approved the study protocol (2016.366).

2.1. Participatory Action Research

Participatory Action Research (PAR) aims to 'improve health and reduce health inequities' by working together with the community and consequently empowering the community by getting them to improve their own health [28]. Throughout the entire process of developing, implementing and evaluating interventions, community members are involved as co-researchers and highly valued as experts of their own lives and experiences. At the same time, the community is empowered and experiences more ownership over their lives and livelihood.

This study specifically works together with children in the PAR process. YPAR engages youth as co-researchers in the research process. In this process, children identify problems in their living environment and become empowered to do something about it [29-32]. Children learn research skills so they can participate in research and have shared power over the research- and decision-making processes [30 32 33].

2.2. Patient and public involvement

This study is initiated by academic researchers and a community organization. The municipality advises on the selection of the intervention neighbourhood, to recruit a neighbourhood with high health needs that can benefit from the project. As this study is informed by a participatory needs assessment (see section 1.1) [27], the objectives and outcome measures of this study are determined in collaboration with children, parents and professionals working with children in the neighbourhood. The design of the study and recruitment procedures are decided by the academic researchers. The conduct of the study, the development of interventions and the dissemination of the results to the study participants and other relevant stakeholders, is decided together with the children.

2.3. Participants

The four intervention schools are all situated in one deprived neighbourhood in Amsterdam, where in 2015-2016 over 50% of the residents had a non-Western background, 27% of the 10-year-olds were overweight/obese and in 2014 31% of the children under 18 years old grew up in a household defined as low-income [34-36]. Potential control schools are selected from different neighbourhoods but with similar characteristics regarding overweight/obesity rates, household income and cultural background.

Participants in this study are children from four intervention schools and four control schools

in deprived neighbourhoods in Amsterdam, the Netherlands. The intervention schools participate in the YPAR process, including implementing and evaluating the developed interventions. The control schools only participate in the measurements for the effect evaluation.

2.3.1. Recruitment

Following selection of a neighbourhood with high health needs, the intervention schools are contacted by the municipality to inform them about the project and to ask them if they are willing to participate. After the schools agree to participate, the main researcher contacts the schools to give them more information about the project. Control schools in the area of Amsterdam are contacted by the main researcher in a random order via e-mail or telephone until four schools are found that are willing to participate as control schools. Control schools are offered a presentation about the research results after the study is finished.

All 9 - 12-year-old children (i.e. children of the three highest grades in primary school) of the four intervention and four control schools are eligible to participate in the effect measurements of the project. For the YPAR process, children from intervention schools are invited to collaborate with academic researchers in co-researcher groups, named 'Action Teams'. At each of the four intervention schools one Action Team is formed. For both the effect measurements and the Action Teams, every year new children can participate as the highest grade leaves the school and new children enter the third-highest grade. All children receive an information letter for themselves and for their parents about the measurements and the Action Team. Attached to the information letters for parents is an informed consent letter that at least one of the parents has to sign if they agree to the participation of their child. At all schools, the researcher explains the project in all classes and encourages children to participate, before handing out the information letters. Children who participate in the measurements and/or in the Action Team receive a small gift.

2.4. Procedures

This section describes the five phases of the 'Kids in Action' project. See Figure 1 for an outline.

Phase 1: Creating partnerships

The first phase consists of creating partnerships with the schools and other stakeholders in

the area, such as social workers, organizers of after-school activities and the community centres. Together with these stakeholders, a project group is started that meets every three months to discuss running projects in the neighbourhood and how partners can collaborate. In this phase, an IM expert group is also formed, to advise on how YPAR and IM should be combined throughout all phases of the study.

Phase 2: Formation of Action Teams

In the second phase of the project, the Action Teams are formed. Each of the Action Teams consists of six to eight children, an academic researcher and a research assistant. Meetings with the principals of the four intervention schools are planned to decide upon recruitment methods for the Action Teams and to schedule the meetings. All interested 9-12-year-old children can sign up for the Action Teams. This approach may lead to bias as only children interested in health may sign up, but limits bias that would occur if teachers select the children for the Action Teams (i.e. only the high-performers might be selected). Subsequently, the Action Teams are formed and a general outline of the meetings is developed. In this phase, the baseline effect measurement (T0) is executed.

Phase 3: Intervention development

In the third phase, the meetings of the Action Teams take place. The meetings with the Action Teams are ideally held biweekly during school hours for one hour. Despite not all schools agreeing to this in the needs assessment, the researchers try to schedule meetings during school hours to raise the children's motivation for participation [27]. If the schools do not agree with this, meetings are held weekly for 45 minutes, followed by a 45-minute sports session [27].

The first three to four meetings are used to verify the data that was gathered in a participatory needs assessment and to decide on determinants that the interventions need to focus on [27]. In the rest of the meetings (approximately 10 per year) we develop interventions together with the children targeting children's physical activity and healthy dietary habits. The type of the interventions (e.g. environmental changes, organisational changes, or educational approaches) is dependent on this collaborative process. Throughout these meetings, capacity building takes place to help the children through the process of intervention development. Children learn for example about formulating a research

question, different kinds of research methodologies, how to analyse qualitative data, how to translate this data into intervention ideas and practical steps that need to be taken when developing intervention plans. At the end of phase 3, pilots of the first intervention activities are carried out. The Action Teams are also asked to identify 'Champions', i.e. people who can help them with the development and implementation of the pilots. A champion is a well-known community member such as a teacher, sports coach or family member. Children discuss who they think is suitable to assist them with a specific intervention and subsequently ask the champions to fulfil this task. The results of this phase (i.e. the needs assessment, the intervention ideas and results of the pilots) are discussed with the stakeholders in the project group to make sure the interventions become a joint and sustainable effort.

At the end of the year, a focus group with the Action Teams and their peers is held to discuss the feeling of empowerment that the children of the neighbourhood experience as part of the process evaluation.

Phase 4: Implementation and evaluation of interventions

In the beginning of phase 4, new Action Teams are recruited/formed. Children who were in the Action Teams of the previous year can still participate and are approached first. With the new Action Teams, meetings are planned monthly. Champions are involved and asked to participate in the meetings when appropriate. Together with stakeholders from the project group and the Action Teams, the implementation plans are finalized and subsequently the interventions are implemented. In order to offer sustainable interventions we looked for partners within the community whose job description aligns with providing the intervention. Depending on the type of intervention, implementers could be dieticians, sports coaches or supermarkets in the community. Once the interventions are implemented, the meetings are used to evaluate the interventions. If the Action Teams feel the interventions are going well, they are encouraged to develop and implement additional intervention activities that focus on other determinants or a different subgroup [37]. At the end of the year, focus groups are held focusing on empowering children and evaluating interventions. The first effect measurement (T1) is also executed in this phase.

Phase 5: Gradual transfer of responsibilities

In phase 5, responsibilities are gradually transferred to the identified champions. Specific plans are made together with the champions and other stakeholders to continue the interventions and participatory process after this project has ended. The meetings with the (new) Action Teams continue to take place every month, and are used to evaluate and, if necessary, adapt the interventions and discuss new ideas for interventions. The post-intervention effect measurement (T2) is executed in this phase. The study ends in November 2019.

2.5. Measurements

2.5.1. Effect evaluation

The primary outcomes of this study include measures of dietary behaviour (consumption of snacks and sugar-sweetened beverages), physical activity (total MVPA time, time spent playing outside, time spent participating in sports), sedentary behaviour (total sedentary time and screen time), self-rated health, and physical fitness. Dietary behaviour, physical activity and screen behaviour is measured by self-report. Additionally, physical activity and sedentary behaviour is measured using an accelerometer. Motor fitness is measured using the MOPER fitness test. In the first school year (T0), questionnaire and accelerometer data are gathered in the period September-October 2016. The fitness tests take place in March-April 2017, 2018 and 2019.

Questionnaire

A questionnaire is developed containing questions on: the number of small (e.g. crisps, nuts, chocolate) and large (e.g. hamburger, fries, pizza) snacks children eat; the number of sugar-sweetened beverages they drink; their sports and outdoor play participation; their attitude towards sports and outdoor play; their screen behaviour; and their self-rated health. The questionnaire is based on validated items from the ENERGY child questionnaire [38], the DOiT questionnaire [39], and the Euroqol [40]. Table 1 presents the questionnaire items, and the validity and reliability of the original items.

The children fill in the questionnaire during school hours, in the presence of a researcher who explains the procedure of completing the questionnaire before handing out the questionnaires. The children are requested to go through the questionnaire section by section, with the researcher giving a short explanation about each section before the

participants fill in that specific section. In this way, examples can be given, for example by showing different sizes of soda cans, and all participants finish at the same time. The questionnaire takes approximately 40 minutes to complete.

Data entry of the multiple-choice questions is done through digital scanning and transferred into SPSS by an independent organization. Qualitative data are manually entered in SPSS.

Table 1: Questionnaire items, their origin, and reliability and validity [38-40]

Questionnaire item	Question derived from	Reliability (ICC/k)/Validity (ICC/k)
1.*How many days a week do you drink sugar-sweetened beverages?*	ENERGY child questionnaire	0.71/0.59
2.*On a day you drink sugar-sweetened beverages, how many glasses/small bottles (250ml), cans (330ml) or big bottles (500ml) do you drink*?	Combination ENERGY child questionnaire, DOiT questionnaire	ENERGY Glasses/small bottles (250ml) 0.59/0.24 Cans (330ml) 0.53/0.44 Big bottles (500ml) 0.58/-0.01 DOiT Cartons/small bottles (200ml) 0.74/0.12 Glasses (200ml) 0.45/0.47 Cans (330ml) 0.61/0.24 Bottles (500ml) 0.28/0.17
3.*How many days a week do you drink energy drinks or sports drinks*?	Added based on Q1	
4.*On a day you drink energy drinks or sports drinks, how many small cans/bottles (250ml)or big cans/bottles (500ml) do you drink*?	Added based on Q2	
5.*How many school days per week do you eat sweets?*	DOiT questionnaire (adapted) Original: '*How many days a week do you eat sweets?*'	0.66/0.60
6.*When you eat candy on a school day, how much sweets do you eat?*	DOiT questionnaire	0.71/0.21
7.*How many days in the weekend (Saturday/Sunday) do you eat sweets?*	DOiT questionnaire (adapted) Original: '*How many days a week do you eat sweets?*'	0.66/0.60
8.*When you eat sweets on a day in the weekend, how much candy do you eat?*	DOiT questionnaire	0.73/0.07
9.*How many schooldays per week do you eat snacks?*	DOiT questionnaire (adapted) Original: '*How many days a week do you eat snacks?*'	0.50/-0.11
10.*When you eat snacks on a school day, how many small and large snacks do you eat?*	DOiT questionnaire	Small snacks 0.62/0.13 Large snacks 0.58/-0.08
11.*How many days in the weekend (Saturday/Sunday) do you eat snacks?*	DOiT questionnaire (adapted) Original: '*How many days a week do you eat snacks?*'	0.50/-0.11
12.*When you eat snacks in the weekend (Saturday/Sunday), how many small and large snacks do you eat?*	DOiT questionnaire	Small snacks 0.53/0.44 Large snacks 0.64/0.08
13.*How do you usually travel to school?*	DOiT questionnaire	Not in test-retest study
14.*How long does it take you to get from home to school?*	DOiT questionnaire + ENERGY child questionnaire (adapted) Original: '*If you walk/bike to school, how long does it take you?*'	DOiT Walking 0.65/ zero variance Biking 0.91/0.68 ENERGY Walking 0.70/0.59 Biking 0.81/0.66
15.*What do you usually do when you play outside at school?*	ENERGY child questionnaire	0.80/0.65
16.*I like playing outside*	ENERGY child questionnaire - Adapted from Q20	
17.*I play outside never/1-2 times a week/3-4 times a week/5-6 times a week/every day*	Added	
18.*When you play outside after school, what do you do?*	ENERGY child questionnaire – Adapted from Q15	

19.*When you play outside after school, how long do you play?* (fill in the number of hours per day in table)	Added	
20.*I like playing sports*	ENERGY child questionnaire	0.64/0.09
21.*I play sports often/sometimes/never*	Added	
22a. *Do you participate in sports in your free time?* *22b. How many times per week do you do this sport?* *22c. How many hours per day do you do this sport?* (fill in all sports that you do, the number of times and number of hours per week in the table)	DOiT questionnaire (adapted) Original: 1. *'Do you participate in a sport at a sports club?'* 2. *'How many hours a week do you do this sport?'* 3. '*Do you participate in a second sport at a sports club?*' 4. '*How many hours a week do you do this second sport*?' 5. '*Do you participate in sports outside a sports club?'* 6. '*How many hours a week do you do these sports?*'	 1. 0.98/0.86 2. 0.94/0.78 3. 0.79/0.69 4. 0.76/0.96 5. 0.64/0.33 6. 0.64/0.45
23.*About how many hours a day do you usually watch television/DVDs/movies on the tablet or iPad in your free time?* (fill in the number of hours per day in table)	ENERGY child questionnaire (adapted) Original: '*About how many hours a day do you usually watch television in your free time?*' (weekdays and weekend days)	Weekdays 0.67/0.63 Weekend days 0.68/0.56
24.*About how many hours a day do you usually play games on your game computer, iPad, smartphone or surfing on the internet in your free time?* (fill in the number of hours per day in table, weekdays and weekend days)	ENERGY child questionnaire (adapted) Original: '*About how many hours a day do you usually play games on a computer, or use your computer in your free time?'* (weekdays and weekend days)	Weekdays 0.67/0.35 Weekend days 0.67/0.65
25.*How do you rate your health today?*	Euroqol EQ-5D-Y Dutch	0.83/ -0.51

Accelerometer

Physical activity and sedentary behaviour is objectively assessed by ActiGraph GT3X+ accelerometers. The children receive instructions and the accelerometers from an academic researcher after filling in the questionnaire. Children are asked to wear the small and light-weight (4.6 x 3.3 x 1.5 cm; 19 grams) accelerometer on the right hip for eight consecutive days during all waking hours except for water-based activities.

The children receive the accelerometer after completing the questionnaire. The children also receive a diary in which the instructions are summarized and they can write down when and why they did not wear the accelerometer, if applicable. Additionally, they are asked to write down the time they went to bed. All children who participate in the questionnaire- and accelerometer measurements receive a small present after returning the accelerometer. Additionally, at each school there is one prize for a participant who wore the accelerometer properly (seven days, at least ten hours) and recorded their data correctly in their diary.

Data are downloaded from the accelerometers into the ActiLife programme in 15 second epochs. Accelerometer data is analysed using a customized software programme developed in R. We select a cut point of 100 counts per minute (cpm) for sedentary behaviour [41 42] and

a cut point of 3000 cpm for MVPA [43]. Non-wear time is defined as a period of ≥60 minutes of consecutive zeros [44]. For inclusion in the data analysis, each participant needs a minimum of six days with at least eight valid hours, including at least one weekend day [44]. Data is analysed on total time spent in MVPA and sedentary, and time in bouts spent in MVPA and sedentary.

MOPER

Children's motor fitness is measured using the Motor Performance Test (MOPER). The MOPER tests speed, flexibility, endurance, coordination and strength by means of eight tests [45]. For practical reasons, the arm pull and 12-minute endurance test have been replaced, leading to the following tests: 1) hang as long as possible on a horizontal bar with flexed arms; 2) jump as high as possible from a standing position; 3) run 10x5 meters as fast as possible; 4) reach as far as possible from a sitting position; 5) hand grip strength measured using a dynamometer [46 47](instead of arm pull); 6) lie on their back and lift their extended legs ten times as fast as possible; 7) tap two plates which are 75 cm apart with the preferred hand 50 times as fast as possible; and 8) shuttle run test [48 49](instead of 12-minute endurance test). Children can do tests one and eight once. Tests two and five are executed twice, but when the difference between one and two is more than 10%, a third try is performed. The highest score is used. The other tests are performed twice and the highest score is used. The first seven activities of the MOPER test are executed during one Physical Education (PE) class by the PE teacher together with five or six research assistants. The PE teacher conducts the shuttle run test in a separate PE class. All research assistants and PE teachers are trained by an academic researcher on how the tests should be executed. At the end of the study, or when children from the highest grade leave the school, the PE teacher anonymously shares the results of the test. Parents receive an information letter with a passive consent form, which should be signed by at least one of the parents if they object to anonymously sharing the fitness test results of their child with the researchers.

2.5.2. Process evaluation

The process evaluation includes the description of the process of co-creating interventions, combining IM and YPAR, and empowerment. The PAR process is continually evaluated in the Action Team meetings, and meetings are optimized in accordance with the evaluation [28]. The

academic researcher and research assistant who are part of the Action Teams evaluate after every meeting, using a reflection form consisting of a summary of the meeting, what the setting was like, the group process and a personal reflection [50-52].

The interventions are developed by combining the YPAR and IM methodologies in an iterative process and are continuously evaluated during the meetings of the Action Teams and with the children participating in the interventions. In collaboration with the Action Teams, it is determined how to evaluate the experiences of children with the interventions. The Action Teams can for example interview peers or develop a questionnaire. The goal of these evaluations is to see how their peers perceive the interventions and whether quick adaptations need to be made. At the end of each school year, focus groups are organized with children from both the Action Teams and their peers, as well as champions to reflect upon the implementation of ongoing interventions and on the empowerment process. Empowerment consists of a combination of individual, organizational, and community empowerment [53]. In our research, we mostly focus on the empowerment of children (individual), but this cannot be evaluated without taking the organizational (school) and community empowerment into account [54]. The focus groups consist of two exercises. The first exercise is mainly focused on individual empowerment, evaluating what children have learnt about the process of intervention development, how they see their role, and competences [55 56]. The children can choose an intervention idea which has not been further developed yet. For this intervention they have to make a timeline with all the steps they need to take from coming up with the idea through to implementation. The researchers guide them through questions, for example: in which order do the steps need to be written down?; do they think they can execute this step by themselves?; if not, do they know where they can get help? [55]. The second exercise evaluates the organizational and community empowerment. In pairs, the children first indicate which changes happened at school or in the community; then they indicate whether children had any influence on the changes; finally, the findings are discussed in a plenary session. Again the researchers ask questions, for example: how do you feel when you have influence on changes in the community/school?; do you think children have enough influence?; would different changes have been made if children had had more influence? The findings of this focus group provide critical understanding of the environment, what children have learnt, to what extent

children participate in the organizational setting and community, and what collective action has already been taken [54-56].

Of all hard-copy research data gathered in the PAR meetings, identifiable information is removed and the data are stored in a locked cabinet at the research location until the study is completed. All online data are coded and stored on the VUmc protected drive until five years after the completion date of the study; data from the questionnaires, accelerometers, MOPER and personal data are saved with encryption. Hard-copies of the questionnaires and the audio-recordings are also stored at the VUmc until five years after the study is completed. The three researchers on this project, who are also the authors of this paper, are the only ones who have full access to the trial data. Research assistants have limited and temporary access to copies of the data.

2.5.3. Sample size calculation

Using a significance level of 0.05 and a power of 0.80, 180 children per group are needed to detect a difference of 0.15SD in the primary outcome variables. Taking into account dropout and clustering of data within schools we aim to include 240 children per group.

2.5.4. Data analysis

Effect evaluation

To test for baseline differences in the dependent variables between control and intervention groups, t-test for continuous variables and chi-square tests for categorical variables are used. Effectiveness of the interventions on dietary behaviour, physical activity, sedentary behaviour, physical fitness and self-rated health is evaluated using multi-level regression analysis with a 3-level structure (i.e. student, class, school) to adjust for clustering of observations. Analyses are adjusted for age, gender, ethnicity and baseline levels. Data are analysed according to the intention-to-treat principle. All statistical analyses are performed in SPSS, using a significance level of $P<0.05$.

Process evaluation

Evaluation of the PAR process and its meetings are mainly performed by the Action Teams themselves. The academic researcher stimulates the children to find patterns and relations in the findings of their own research and assists in interpretation [57]. Children can for example look at the pictures they have taken and write down why they took the picture and what

they want to say with the picture. Children can also write down the key issues that come up in the interviews they have conducted and see if they can identify a pattern. By giving children this role in qualitative data analysis, less misinterpretation of data occurs (than would be the case with adults trying to interpret the children's findings).

In addition, all meetings are summarized and include field notes, and key meetings are fully transcribed [50]. The academic researcher analyses these transcripts to enrich the children's findings. When, for example, the children discuss the pictures they have taken, these discussions may also contain valuable information in addition to the pictures and conclusions of the children. All summaries and transcripts are coded in ATLAS.ti by two researchers to improve the reliability of the study. For the entire process evaluation, an elaborate coding scheme is produced through open coding [57]. For specific aspects like the evaluation of an intervention, coding is done separately resulting in its own coding scheme. For evaluations relating to empowerment, closed coding is used as this will be linked to a conceptual model.

3. DISCUSSION

In the Kids in Action project, children are involved throughout the entire research process. This YPAR approach has previously shown promising results for communities in need with respect to researchers' understanding of the community, lowering health disparities, increasing children's skills (e.g. research skills, life skills), critical awareness, involvement and empowerment concerning community action [58-60].

In the Kids in Action project, children are not involved in the first phase of this study, in which partnerships with other stakeholders in the community have to be set up. This is because creating partnerships can be time-consuming and not very interesting for children, and we do not want to lower their spirits [37]. The partnerships are important in YPAR for creating support in the community for the study [58 61] and are beneficial in the rest of the research process and outcomes.

A difference between this study and most YPAR studies is that 9 – 12-year-old children are involved as co-researchers, whereas most YPAR studies collaborate with adolescents older than 12 [62]. Younger children can be more easily distracted, have a limited attention span and might need more 'play', all of which should be taken into account when designing the meetings. Meetings should not be too long, should contain fun and playful exercises, and wording should be suitable for the children, while retaining key principles of YPAR. These

principles include: sharing power between researchers and children; training children to participate in research and identify needs in their community; teaching children how to become advocates; creating ownership over the process; and creating involvement in establishing change in their community [63]. When all of this is done with care, children between 9 and 12 years old are capable of joining in YPAR research [64-66].

One implication of working with 9 – 12-year-old children is that you often have to collaborate intensively with the schools. This could mean that changes in the planning have to be made beforehand or during the project, based on the schools' preferences, holidays and other reasons for cancelling meetings [37]. Also, the approval and assistance of schools and other community organizations are likely to be needed for implementing the interventions. Because this is a community project, all primary schools in the neighbourhood are included in the intervention and randomization of schools is not possible. However, the inclusion of comparable control schools is a strength of this study as this is seldom included in PAR [67]. Another strength of this study is the combination of YPAR with IM, which makes sure that evidence-based strategies are being applied. As far as we know, this has not been done before.

A challenge for all intervention studies in real life is that other initiatives can also take place in the neighbourhood. This is part of usual care and can take place both in the intervention school and the control school neighbourhoods, and may dilute intervention effects.

AUTHOR'S CONTRIBUTIONS

All authors worked on the design of this study. MA is the coordinating researcher on the project, coordinating the effect measurements, process evaluation, leading the participatory process and facilitating the Action Teams. TA and MC designed the study. The paper was drafted by MA, with MC and TA providing comments and revisions to drafts. All authors approved the final version.

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The authors declare that they have no competing interests.

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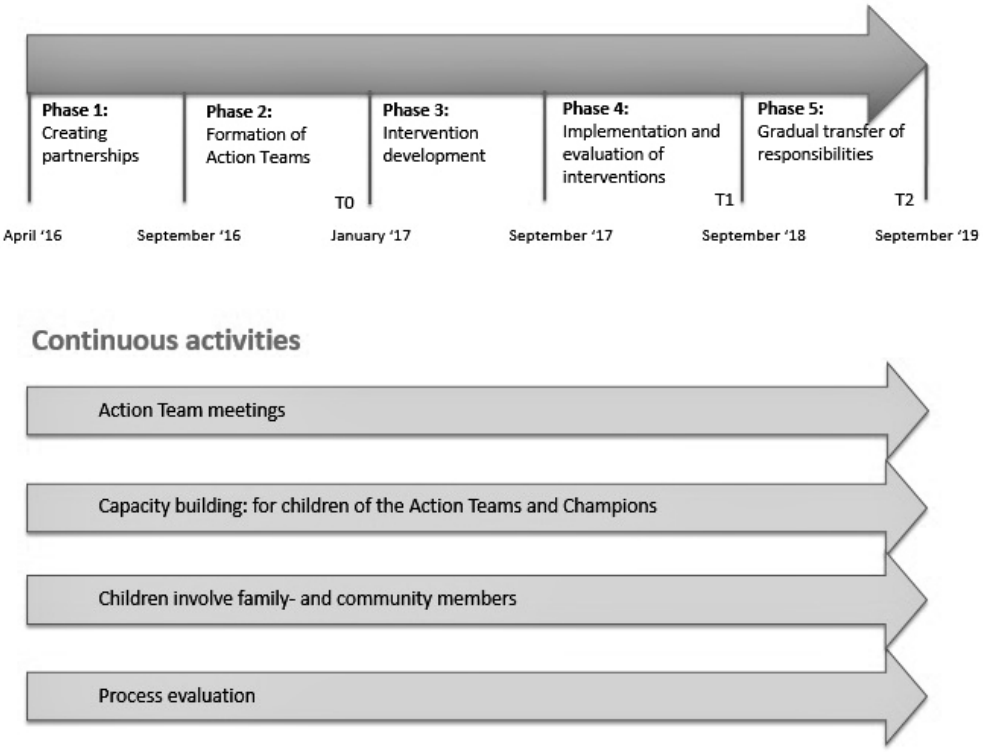
FIGURE LEGEND

Figure 1: Outline of the 'Kids in Action' project



Outline of the 'Kids in Action' project

55x42mm (300 x 300 DPI)

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 – page numbers
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym – page 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry – page 2
	2b	All items from the World Health Organization Trial Registration Data Set – throughout paper
Protocol version	3	Date and version identifier – n/a
Funding	4	Sources and types of financial, material, and other support – page 16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors – page 2 and 16
	5b	Name and contact information for the trial sponsor – page 17
	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 – page 17
	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) – n/a
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 – page 3 and 4
	6b	Explanation for choice of comparators – page 3 and 4
Objectives	7	Specific objectives or hypotheses – page 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) – page 4 and 5

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 – page 5 and 6
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) – page 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered – page 6-9
	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) – n/a
	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 – page 9-14
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) – page 6 and Figure 1
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 – page 14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size – page 6

Methods: Assignment of interventions (for controlled trials) – n/a

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
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
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
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 – 'Measurements', page 9-13
	18b	Plans to promote participant retention and complete follow-up – page 6 – including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols – n/a
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 – page 10-13
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 – page 14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) – page 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) – page 15
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 – n/a
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 – page 2
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) – n/a
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) – page 6
	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 – page 14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site – page 16
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 – page 14
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 – Through collaboration with the local government, the community and local professionals are informed. The sponsor writes a report for the general public.
	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 – n/a
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates – upon request
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.