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Development of a core outcome set for school-based intervention studies on preventing childhood overweight and obesity: study protocol

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ABSTRACT

Introduction Prevention of childhood overweight is an important health priority. Evidence synthesis from studies evaluating school-based overweight preventive interventions is hampered by the wealth of different outcomes across studies. Therefore, consensus on a core set of outcomes for school-based overweight prevention studies is needed. *This paper presents the protocol for the development of a core outcome set (COS) for school-based intervention studies aimed at childhood overweight prevention.*

Methods and analysis First, a scoping review will be performed to identify outcomes included in studies evaluating school-based overweight prevention interventions in 6–12 year-old children. Additionally, child focus groups will be organised in three countries to list the outcomes children consider important in school-based interventions. Next, an expert panel will identify all unique outcomes (eg, body composition) from the results of the scoping review and focus groups, ruling out how outcomes were defined and measured (eg, body mass index, body fat). In the next phase, a group of international stakeholders will participate in a Delphi study in which they will rate all unique outcomes on a 9-point Likert scale over three rounds to reach consensus on a COS. Participants will include healthcare professionals, policymakers, teachers, school leaders and parents of 6–12 year-olds. All rated outcomes will be presented to stakeholders in two online consensus meetings.

Ethics and dissemination The Medical Ethics Committee of the VU Medical Center approved the child focus group study in the Netherlands (nr. 2020.071) and the Delphi study—including the consensus meeting (nr. 2022.0295). Other sites will obtain ethics approval for focus groups in their country. The University of Strathclyde School of Psychological Sciences ethics committee approved the Delphi study—including consensus meeting (nr. 72.27.04.2022 .A). The final COS will be disseminated through the diverse networks of all authors and participants.

Trial registration number This COS initiative is registered with the Core Outcome Measures in Effectiveness initiative (registration nr. 971).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The international character is an important strength of this study: we work together with experts and steering group members from different countries and stakeholders will participate from many countries.
⇒ A limitation is that the children cannot participate in the Delphi study the same way that adult stakeholders can due to language and understanding barriers.
⇒ A strength is that we take the perspective of the children into account via child focus group interviews and a child consensus meeting.
⇒ Another strength is that we will carefully identify unique outcomes, ruling out how outcomes are defined and measured.

INTRODUCTION

The prevalence of childhood overweight (including obesity) has persistently increased worldwide during the last decades, both in high-income countries and low-to-middle-income countries.[1] These trends are worrisome as overweight can have a negative effect on both physical and mental health of children.[2] In addition, overweight has the tendency to track into adulthood.[3] In a sample of 532 Norwegian adolescents, 6 out of 10 children with overweight at age 5–7 also had overweight at age 15–17.[4] Therefore, prevention of overweight and obesity in childhood is an international public health priority.

The causes of childhood overweight are complex and include among others poor diet and insufficient physical activity[5–8] that are heavily dictated by familial and environmental influences. Therefore, hundreds of interventions stimulating a healthy diet, sufficient physical activity and limiting sedentary behaviours in children have been developed and tested over many years.[9–11] Schools have

been routinely used as a setting for overweight prevention, due to being able to reach most children and the variety of opportunities for interventions throughout the day (eg, the journey to and from school, during school, recess and after school programmes).[12] Moreover, the school setting provides an infrastructure where interventions can be implemented to positively influence children's health behaviours.[13–15]

Previous meta-analyses pooling the results of school-based overweight prevention interventions showed that interventions were in general effective in reducing body mass index (BMI) indices, despite inconsistencies between individual studies.[16] Strikingly, in all meta-analyses a considerable number of studies testing the effects of a school-based overweight prevention intervention could not be included because the required outcome was not provided. For example, Waters *et al*[17] indicated that 12 of the 39 intervention studies did not provide appropriate BMI or BMIz (age and sex standardised BMI) data for inclusion in the meta-analysis and Liu *et al*[18] excluded 66 of 456 studies that lacked data on objectively measured anthropometry. Another difficulty relates to the range and type of outcomes provided to physical activity and diet. Physical activity is, for example, measured and reported as steps per day, accelerations, total minutes of physical activity on weekdays or weekend days while food intake is, for example, measured and reported as daily number of meals, vegetable selection or intake of energy-dense snacks. Consequently, the results of meta-analyses on these (specific) topics should be carefully interpreted as many studies might not have provided the required outcome and therefore were not included.

To improve evidence synthesis and maximise scientific gain from all published studies testing a school-based overweight prevention intervention, it is crucial to develop and use an agreed set of key outcomes to be measured and reported in all future school-based intervention studies aimed at prevention of childhood overweight and obesity.[19–21] This is known as a core outcome set (COS) and includes outcomes that are relevant and important to key stakeholders including patients and those involved in decision-making.[22] When studies always include this minimum set of outcomes in their reporting the heterogeneity in reported outcomes between studies will be reduced. This study presents the protocol for the development of a COS for school-based intervention studies targeting to prevent childhood overweight and obesity.

METHODS AND ANALYSIS

This COS initiative was registered in January 2017 with the Core Outcome Measures in Effectiveness (COMET) initiative.[23] We followed the Core Outcome Set-STAndards for Development[24], Core Outcome Set-STAndards for Reporting (COS-STAR[25]) and Core Outcome Set-STAndardised Protocol items[26] (see online supplemental file 1) for developing and reporting this COS. This section describes the four phases in the COS development using an international, online Delphi study, following guidelines for best practice for COS development.[22 24–26] Figure 1 presents an overview of the four phases.

A project steering committee was formed to guide the different phases of the COS development, consisting of healthcare professionals, researchers and COS experts. The working group consists of researchers in the field of childhood overweight prevention and is responsible for the process of establishing the COS. If necessary, the working group will be expanded with members in other countries to accommodate the further phases of the protocol. An expert panel has been formed to identify unique outcomes based on the results of the scoping review and focus groups with children, ruling out how outcomes were defined and measured. For example, BMI and muscle mass reflect how body composition is defined and measured, while total activity time and number of steps reflect how physical activity is defined and measured. The expert panel consists of researchers and healthcare professionals from the Netherlands with expertise on prevention of childhood overweight, including measures of dietary intake, physical activity, sleep, sedentary behaviour and psychological outcomes. Expert panel members (n=5) have been recruited via email from the network of the researchers from the Netherlands.

Phase 1: identification of outcomes

We will identify outcomes currently used in studies evaluating a school-based intervention aimed at preventing overweight and obesity in children by performing a scoping review (phase 1a). Additionally, in different countries around the world, we will organise focus groups with children to identify outcomes that children perceive as relevant and important (phase 1b).

Phase 1a: identification of outcomes through scoping review

A scoping review will be performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis statement[27] and the 'Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews' checklist.[28] The scoping review is registered in Open Science Frameworks (registration DOI 10.17605/OSF.IO/AQTYU).

We will search four databases (PubMed, Embase, Cochrane and PsycINFO) including search terms related to children (eg, child, youth), overweight and obesity (eg, body weight, adiposity), prevention (eg, health promotion), school-based and (randomised) controlled trials (eg, clinical trial, non-randomised). Studies will be included if they: (i) evaluate school-based interventions aimed at the prevention of overweight and/or obesity; (ii) include children aged on average between 6 and 12 years, both at baseline as well as at follow-up measurement; (iii) use a controlled design (randomised or non-randomised). We defined a school-based intervention as any intervention delivering at least one intervention

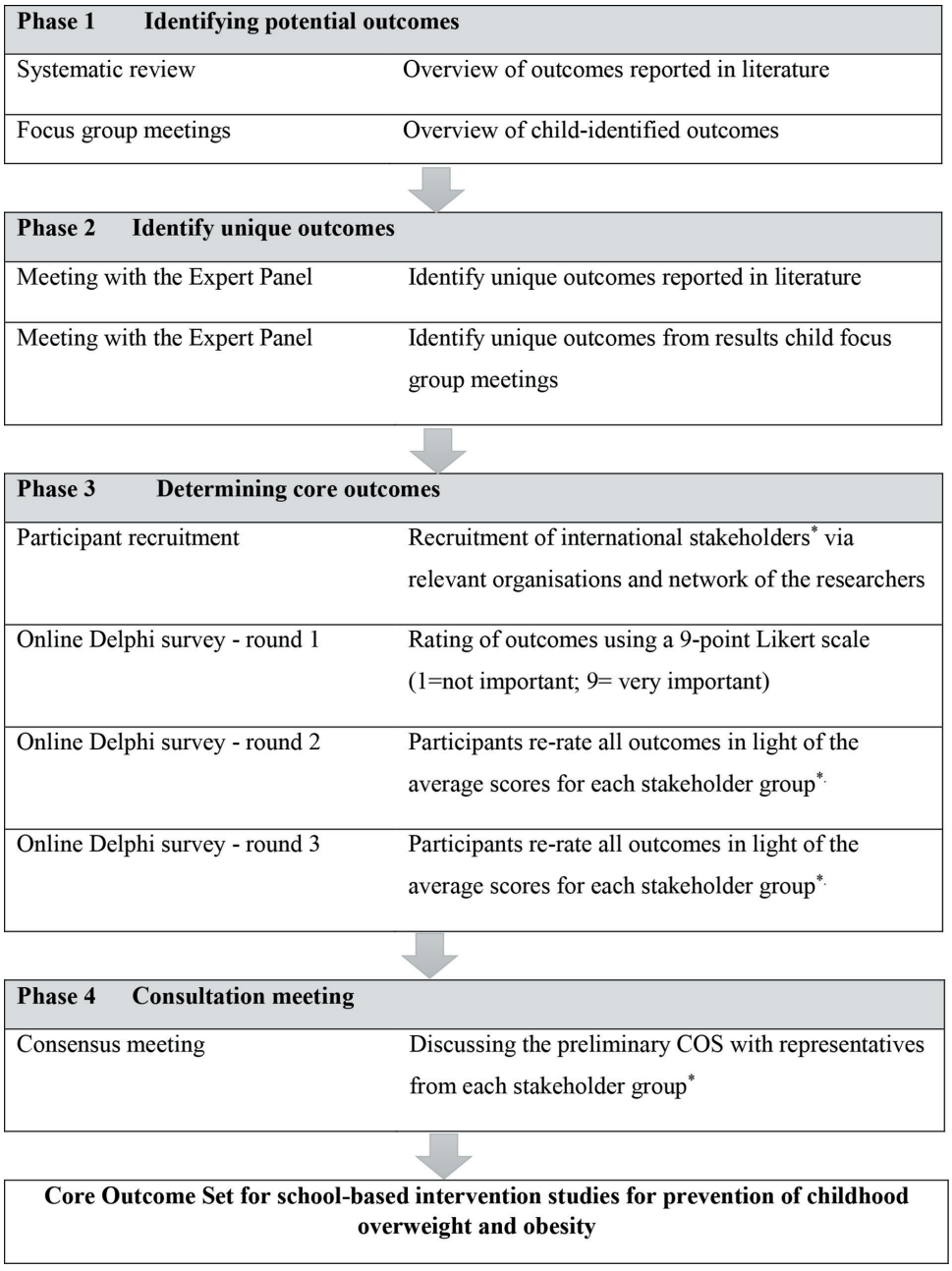

Figure 1 Overview of COS development process. Developing a core outcome set (COS) for school-based intervention studies for prevention of childhood overweight and obesity. * Stakeholder groups are: (1) Healthcare professionals in the field of childhood overweight (eg, paediatricians, dieticians); (2) policymakers (eg, (local) government); (3) teachers and school leaders (eg, teachers, management staff); (4) researchers working in the field of childhood obesity prevention; (5) parents of children aged 6–12 years.

component in the primary school setting. Only full-text studies published in the English language in a peer-reviewed journal will be included.

First, two reviewers will independently check all identified titles and abstracts to establish potentially relevant studies. Disagreement between reviewers will be resolved through discussion. Second, all full-text papers will independently be screened by two reviewers to determine whether inclusion criteria are met, whenever necessary a third reviewer will be consulted. Disagreement between reviewers will be resolved through consensus.

Subsequently, two reviewers will independently extract relevant data from the included studies using a standardised data extraction sheet (see online supplemental file 2). Information will be extracted regarding: study design, study population, intervention characteristics, reported outcomes and measurement tools. Disagreement will be resolved through discussion with a third reviewer. Results will include all unique outcomes, and a frequency table of the most reported outcomes, sorted per outcome domain. This list of unique outcomes will be presented to the expert panel (see phase 2).

Phase 1b: identification of outcome through focus groups with children

To prevent potential language and understanding barriers, the COS-STAR method recommends separate, in person or virtual focus group interviews when involving children.[25] Therefore, in phase 1b, children's opinions on which outcomes they consider relevant in school-based intervention studies will be explored using focus group interviews, in the Child Opinions in a COS study. We will not discuss overweight or obesity directly with the children, but children will be asked to think about intervention programmes that aim to improve children's health behaviours, such as diet, physical activity and sleep. Additionally, we will explain to children that they can think about which outcomes they think are important for primary school children in general, emphasising that they do not need to relate this to themselves.

Children will be recruited via schools, community groups or researcher networks. Children and their parents/caretakers will be informed about the project via an information letter, that they will receive either in person or via email. Children can sign up for the focus groups by sending an email to the research team (or their parents can do this for them). Written informed consent will be obtained from children and one of their parents/caretakers prior to the focus group session. We will conduct focus group interviews with 9–12 year-old children, as children from the age of 9 have adequate reading and writing skills and are cognitively able to understand the topic under study. The focus groups sessions will start with an animation video showing a variety of children that participate in a school-based intervention programme targeting their health behaviours. The animation video will be pilot tested with children. This animation video has been developed using the Vyond animation software by the Creative Team at Leicester Diabetes Centre. LWdV, DH and TMA developed the storyboard (ie, what a frame/scene should contain and what the accompanying voiceover will say) and animation were fitted around this. Voiceovers in English and Dutch were provided by DH and LWdV. The animations will be used as a stimulus for child focus groups and will be especially useful for online groups. The animation will explain the concepts related to potential relevant outcomes of intervention programmes targeting health behaviours, by providing examples of different types of intervention programmes and explaining that all sorts of information can be collected to find out if an intervention programme works (if it changes anything in the lives of children). Using this animation video will minimise translation differences between countries.[29] Children will be asked to think about which outcomes they would consider important for the children from the animation video, which will be discussed using example programmes that aim to improve children's health behaviours such as diet, physical activity and sleep. Focus group sessions will be organised online (using Microsoft Teams) and will use a digital whiteboard (Google Jamboard) to facilitate interactions during these meetings.[30] Children will then decide on the importance of all outcomes mentioned in their focus group session, using the traffic light system where a red score corresponds with score 1–3 (not important) on a 9-point Likert scale, orange with score 4–6 (important) and green with score 7–9 (very important).[24 25 31 32] For both tasks (brainstorming and prioritising), children are requested to first think about this topic individually and subsequently share their ideas and opinions in the group.

We aim to organise three focus groups including 4–6 children per group in at least three countries, selected via the network of the researchers, spread globally, that is, including at least 12 children in each country. This number is an experience-based estimation of the number of children needed for data saturation[33] and with the appropriate size and composition of focus groups should ensure data adequacy. Ethical approval will be obtained for this phase in all participating countries, from the institute to which the researcher responsible for organising focus groups in each specific countries is affiliated. At this moment, the countries that have already confirmed participation are Canada, UK and the Netherlands.

The results of the focus groups will include a list of all unique outcomes identified by children in the various focus groups (in the different countries), and a frequency table of the most frequently reported outcomes. The list of unique child-identified outcomes will be sorted by outcome domain. This list of child-identified outcomes will be presented to the expert panel (phase 2).

Phase 2: outcome identification

The expert panel will identify unique outcomes underlying the results from the scoping review and the child focus groups. This list of unique outcomes will be sorted by outcome domain, coherent with the taxonomy proposed by Dodd *et al*.[34] An independent facilitator experienced in COS development (IG) will guide the meetings. In multiple rounds and separate for each outcome domain (eg, physiological outcomes), the experts will identify the unique outcome (eg, body composition; physical activity) by ruling out how outcomes were defined and measured (eg, fat mass, BMI; total activity time, number of steps). Alternatively, experts can classify outcomes as 'not an outcome', for example, when outcomes reflect an interpretation (eg, healthy eating index) or an adherence-related outcome (eg, presence of classroom materials). This process will continue until consensus is reached, that is, when all results are assigned to a unique outcome or classified as 'not an outcome'.

The result of this phase is a comprehensive list of unique outcomes that will be presented to participants in the Delphi study (phase 3).

Phase 3: Delphi study

A Delphi study is a group facilitation technique that combines the opinions of stakeholders to obtain consensus via multiple structured questionnaires (rounds).[20] To ensure uptake of this COS in future research, it is

important that outcomes are relevant and meaningful to intervention participants (ie, primary school-aged children), their parents, healthcare professionals, teachers and school leaders, policymakers and researchers.[19 35] Therefore, all relevant stakeholders from different countries around the world will participate in the international online Delphi study.[20 36] Before running the Delphi study (phase 3b), we will identify Delphi participants from all relevant stakeholder groups (phase 3a).

Phase 3A: identifying Delphi participants

Stakeholders will be considered eligible for the Delphi study if they have been involved in school-based interventions aimed at the prevention of childhood overweight (eg, experience with planning, delivery or implementing (parts of) an intervention) and/or have in-depth professional knowledge of relevant outcomes in this field. Relevant stakeholder groups will include: (1) healthcare professionals in the field of childhood overweight (eg, school nurses, dieticians, psychologists); (2) policymakers and decision-makers (eg, (local) government); (3) teachers and school leaders; (4) researchers working in a field related to childhood obesity prevention; (5) parents of children aged 6–12 years. Stakeholders must provide informed consent to participate.

During the first survey we will ask the participants if they consider themselves eligible to participate and to what stakeholder group(s) they belong. We aim to recruit at least 25 participants in each of the five key stakeholder groups, with a minimum of five stakeholders per group per country, and expect a 9%–24% dropout over three Delphi rounds.[37] Participants will be recruited in at least three countries using multiple approaches (including social media), including: (1) corresponding authors of all included school-based overweight prevention studies in our scoping review; (2) members of relevant organisations/networks, including Online Progressive Engagement Networks international family, Ensemble, Prévenons l'Obesité Des Enfants international network, European Association for the Study of Obesity (EASO); for example, EASO Childhood Obesity Task Force, EASO Patient council, WHO, International Pediatric Association, European Paediatric Society, national paediatric societies, Make Mothers Matter international and UNICEF; national and international teacher and school leader organisations; (3) contacts via the international network of the project members. A snowballing method will be applied in all approaches, asking participants to forward the invitation letter to relevant stakeholders. To facilitate the participant recruitment, 'ambassadors' with unique and strong networks will be identified in each of the participating countries and requested to help recruit participants from different stakeholder groups locally. Participants will be invited by personalised emails to increase retention of participants between rounds.

Phase 3b: running the Delphi study

The Delphi study will be developed using the online Delphi Manager software (COMET Initiative, UK,[38]; and pilot-tested by the steering committee. During the pilot-testing, the steering committee will also critically reflect on the comprehensibility of the Delphi study, including the definitions of all outcomes. All participants will receive a link to the Delphi study by email. Outcomes will be presented in domains, which will be displayed in random order. The order of domains will be the same for all participants and will persist throughout all Delphi rounds. Outcomes within each domain will be presented in alphabetic order. Participants will have 1 month to complete a round. In the first round, participants will be asked to rate the outcomes as identified in phase two. Participants will be asked to rank each outcome on a 9-point Likert scale ranging from 1 'the outcome is not important at all' to 9 'the outcome is crucial'. Additionally, participants can add outcomes when they feel a crucial outcome is missing. To complete the survey, participants have to rate all outcomes so we will minimise missing data by not allowing partial completion within each participant. However, there is also the option for participants to 'save for later' and some participants may not return. In line with advice we will include responses from participants who saved their of scoring 80% or more of the items. Participants will receive weekly reminders via email if they have not responded during the month before closure of the first round. After closing the first round, a meeting with the expert panel will be organised to check whether additional suggested outcomes fall under the previously identified outcomes. The median score and distribution graphs of the rated outcomes are calculated per stakeholder group after each round to determine whether consensus (see below for consensus definition) on core outcomes is reached, using IBM SPSS statistics V.26. To accelerate the process of scoring outcomes,[39] outcomes for which consensus is already obtained in round one will only be presented in round two to inform the participants, but will not be included for scoring in the survey again. Where possible these outcome will be presented in the introductory text for round two but if the list is long, an embedded link will be used instead.

All participants who complete the first round are invited to participate in round two, which will be 1 month after completing the first round. Participants will receive the feedback from the first round, including their own score for each outcome and the median score and distribution graphs per stakeholder group. Participants will be asked to rerate all outcomes—including any new outcomes—on a 9-point Likert scale. Similar to the first round, participants will receive weekly (personalised) reminders when they have not yet finished the survey during the month before closure of the second round. Similar to the first round, analyses will be conducted to determine whether consensus (see below for consensus definition) on core outcomes is reached. As we expect that three rounds are needed to reach consensus on all outcomes,

Table 1 Description and definition of consensus on whether an outcome should be included in a core outcome set*

Consensus classification	Description	Definition
Consensus 'in'	Consensus that outcome should be included in the core outcome set.	70% or more participants rating as 7–9 AND <15% participants rating as 1–3.
Consensus 'out'	Consensus that outcome should not be included in the core outcomes set.	70% or more participants rating as 1–3 AND <15% of participants rating as 7–9.
No consensus	Uncertainty about importance of outcome.	Anything else.

*Definition of consensus from the Core Outcome Set-STAndards for Reporting guidelines.[25]

all participants who complete the second round will be invited to participate in round three (1 month after completing round two). In this third round participants will rerate all outcomes for which no consensus is reached in round two, using the same procedures as round two. If consensus is not reached within three rounds, we will consult the steering committee to decide whether a fourth round is necessary before the consensus meeting.

According to the Grading of Recommendations Assessment, Development and Evaluation approach using the Delphi method,[24 25 31] an outcome with a score of 1, 2 or 3 is defined as consensus 'out', score 4, 5 and 6 are defined as 'no consensus' and a score of 7, 8 or 9 is defined as consensus 'in', or 'core'. Table 1 summarises the descriptions and definitions whether an outcome should be included in the COS for school-based intervention studies on preventing childhood overweight and obesity.[25] Defined a priori, consensus is reached when 70% of the participants in each stakeholder group agree an outcome is 'core' and less than 15% of each stakeholder group indicate that the outcome is not important. Consensus on not including the outcome in the core outcome set is reached when 70% of the participants in each stakeholder group agree an outcome is 'not important' and less than 15% of each stakeholder group indicate that the outcome should be a 'core' outcome. If no consensus is reached in the online Delphi study, the outcome will be discussed during a consensus meeting.

Phase 4: consensus meeting

The outcomes of the online Delphi study for which no consensus was reached will be presented to stakeholders during two consultation meetings: one with children and one with adult stakeholders. Both meetings will be organised online to facilitate participation of stakeholders from different countries. The outcomes for which consensus was reached will be presented during these meetings. In case 'consensus in' was reached for too many outcomes (making the COS unfeasible to implement), these outcomes will be also discussed in an attempt to narrow down the number of core outcomes. First, we will organise a meeting with children to reach consensus on their perspectives on core outcomes. Participants in this meeting are preferably children with the same age and from the same area as the children who participated in the focus group meetings. Children will be recruited using the same approach and criteria as the child focus group study (see phase 1b). We aim to include three to five children in the child consensus meeting. Similar to the child focus groups, we will use the traffic light system to guide children in the decision on whether an outcome is 'core' (green light) or 'not core' (red light). Consensus requires a majority of children present at the meeting. The second consultation meeting will be organised with adult stakeholders. All participants who completed the online Delphi study will be invited to this consensus meeting. We aim to include at least three participants from each stakeholder group. During this consensus meeting, participants will be asked to rate the importance of the outcomes on a 9-point Likert scale. Consensus 'in' requires a majority of 70% of stakeholders present at the meeting. Outcomes for which participants do not reach consensus during the consensus meeting will remain grouped as 'no consensus'. The results of the meetings will be combined and a final score obtained. When necessary, for example, when children and adult stakeholders disagree on outcomes they consider 'core', we will conduct an extra round of consensus meetings (one with children and one with adult stakeholders). Outcomes for which children and adult stakeholders do not reach consensus will be grouped as 'no consensus'.

Subsequently, a report will be written on the final COS for school-based intervention studies for preventing childhood overweight and obesity and the results of the findings will be disseminated through the networks of the current COS working group and all Delphi participants. Dissemination activities will include a press release, translations of the final COS in various languages and social media promotion (eg, Twitter, LinkedIn). To stimulate the uptake of this COS, we will ask all participants in the final Delphi round to recommend one network they consider important for disseminating the final COS. The next step after establishing the COS on 'what to measure', is establishing consensus on which measurement instruments to use for measuring each outcome in a COS on 'how to measure'.[40]

Patient and public involvement

This study is initiated and designed by academic researchers. Children will be involved in child focus

groups where they provide their opinion on which outcomes are important to them. These child-indicated outcomes will be entered in the Delphi study. Children will also be involved in pilot testing the explanation video used in the focus group meetings. Various stakeholders will be involved in the Delphi study including teachers and school leaders, healthcare professionals, policymakers and parents of 6–12 year-olds, in which they will indicate the outcomes that are important to them. Children and other stakeholders will be recruited by researchers. The dissemination of the study to relevant stakeholders will be decided in cooperation with children and other relevant stakeholders.

Ethics and dissemination

The Medical Ethics Committee of the VU Medical Center has approved the protocol for the child focus groups in The Netherlands (nr. 2020.071) and the Delphi study—including the consensus meeting (nr. 2022.0295). The University of Strathclyde School of Psychological Sciences ethics committee approved the Delphi study—including the Delphi study (nr. 72.27.04.2022.A). All other sites undertaking child focus groups will obtain ethics approval for the researcher's own local institution. All participants (including one parents of child-participants) will provide consent before participating, using an online consent form. The final COS will be disseminated through the network of all authors and all participants.

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Competing interests None declared.

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

Patient consent for publication Not applicable.

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