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Complete List of Authors:	Ram, Bina; Imperial College London, Primary Care and Public Health Foley, Kimberley; Imperial College London, Primary Care and Public Health van Sluijs, Esther; University of Cambridge School of Clinical Medicine, MRC Epidemiology Unit Hargreaves, Dougal; Imperial College London, Mohn Centre for Children's Health and Wellbeing; Imperial College London, Primary Care and Public Health Viner, Russell; UCL Institute of child health, Population, policy and practice research programme Saxena, Sonia; Imperial College London, Primary Care and Public Health
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Developing a core outcome set for physical activity interventions in primary schools: a modified-Delphi study

Bina Ram,*[1] Kimberley A Foley,[1] Esther MF van Sluijs,[2] Dougal S Hargreaves,[1,3] Russell Viner,[4] Sonia Saxena[1]

[1]Department of Primary Care and Public Health, Imperial College London, London, UK

[2]MRC Epidemiology Unit School of Clinical Medicine, Cambridge Biomedical Campus, University of Cambridge, Cambridge, UK

[3]Mohn Centre for Children's Health and Wellbeing, Imperial College London, School of Public Health, London, UK

[4]Population, Policy and Practice Research Programme, UCL Great Ormond Street Institute of Child Health, London, UK

*Corresponding author: Dr Bina Ram | b.ram@imperial.ac.uk | 020 875940979 | @DrBinaRam

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ABSTRACT

Objectives To develop a core outcome set for physical activity interventions in primary schools.

Design Modified-Delphi.

Setting UK and international.

Participants 104 participants from four stakeholder groups (educators, public health professionals, health researchers, parents); 16 children (aged 8-9 years) from one London primary school.

Interventions Physical activity interventions.

Methods A four-stage process: (1) outcomes extracted from relevant studies identified from an umbrella review, and a focus group; (2) list of outcomes produced and domains established; (3) stakeholders completed a 2-round Delphi survey by rating (Round 1) and re-rating (Round 2) each outcome on a 9-point Likert scale from 'not important' to 'critical'; a ≥70% participant threshold identified the outcomes rated 'critical' to measure, and outcomes important to children were identified through a workshop; (4) a stakeholder meeting to achieve consensus of the outcomes to include in the core outcome set.

Results A list of 50 outcomes was produced and three domains established: 'physical activity and health' (16 outcomes), 'social and emotional health' (22 outcomes), and 'educational performance' (12 outcomes). 104 participants completed survey Round 1; 65 participants (80% UK based) completed both rounds. Thirteen outcomes met the threshold; children identified 8 outcomes. Fourteen outcomes achieved consensus to produce the core outcome set; five outcomes for physical activity and health (diet [varied and balanced], energy, fitness, intensity of physical activity, sleep [number of hours]); seven for social and emotional

health (anxiety, depression, enjoyment, happiness, self-esteem, stress, wellbeing); and two outcomes for educational performance (concentration, focus).

Conclusions We have developed the first core outcome set for physical activity interventions in primary schools in consultation with those interested in the development and application of an agreed standardised sets of outcomes. Future studies including these outcomes will reduce heterogeneity across studies.

Registration Core Outcome Measures in Effectiveness Trials (COMET) Initiative: 1322.

Keywords Core outcome set, physical activity, interventions, primary schools, modified-Delphi

ARTICLE SUMMARY

Strengths and limitations of this study

- First core outcome set developed for physical activity interventions in primary schools
- Developed in consultation with participants from key stakeholder groups
- Uses robust methodology as recommended by the Core Outcome Measures in Effectiveness in Trials (COMET) Initiative
- Unbalanced number of participants in each stakeholder group
- Low representation of international participants may limit the use to UK schools only

INTRODUCTION

Increasing children's physical activity is a global health goal given the vast evidence showing benefits on physical, social, mental, and cognitive health outcomes.[1] Health behaviours may become embedded in childhood; providing opportunities for children to engage in physical activities during the primary school years, may lead to physically active lifestyles and improved health during adolescence and adulthood.[2] Many governments support the need for increased physical activity promotion in schools.[3] The World Health Organisation (WHO) recommends that schools should organise and promote opportunities for children to regularly participate in physical activities.[4]

Furthermore, school settings have the potential to reach all children across society[5, 6] including those living in poverty, potentially contributing towards reducing the gap in physical activity among children.[7, 8]

With the recommendation of physical activity promotion in schools, many physical activity interventions are implemented in schools and are adopted globally. These interventions vary in design; some integrate additional physical education classes alongside compulsory physical education lessons,[9] some incorporate 10 minutes of physical activity into every school day,[10] others implement classroom movement breaks[11] or active mile interventions.[12, 13]

There is considerable evidence showing the benefits of physical activity interventions in schools successfully increasing children's fitness,[14-17] and reducing sedentary time[18, 19] There is also increasing evidence of improvements to children's social, emotional, and cognitive outcomes.[20-23] However, due to the heterogeneity of the outcomes assessed

across studies, definitive conclusions are challenging.[20, 22] For example, to assess children's emotional health, one study may measure children's 'happiness', whilst another may measure 'depression'. Both these outcomes are conceptually different and difficult to compare. In 2013, a Cochrane review of 44 randomised control trials of physical activity interventions in schools for children aged 6 to 18 years found considerable variations in the outcomes measured, and the results could not be synthesised to establish intervention effects.[24] The review was updated in 2021; the authors concluded that due to the variability of results, heterogeneity and risk of bias across studies, the impacts of physical activity interventions in schools have shown small effects. These interventions may show small improvements to children's physical fitness but have little or no impact on other outcomes such as Body Mass Index.[25]

Synthesising results from studies are likely to be of interest to a number of key groups including public health professionals, teachers, parents, health care researchers, and policy makers. However, many of the outcomes measured in existing studies, although important to measure, may vary in relevance to specific groups. For example, body mass index (BMI) is a frequently measured outcome from which important conclusions have been identified.[26, 27] BMI may be considered highly important to health care practitioners but may not be considered as important to teachers who may instead place higher importance on cognitive outcomes. Lack of consultation with key groups when deciding which outcomes to measure in studies limits the relevance of findings to specific groups and may has possibly led to differences of outcomes measured across studies, thus preventing comparisons.

A Core Outcome Set (COS) is an agreed set of standardised outcomes in a specific research area that are recommended to measure and report.[28] These sets should be developed in consultation with those who are interested in the development and application of an agreed set of outcomes.[29] The COS should be viewed as a minimum to measure and does not restrict additional outcomes of interest to be assessed. COS's were originally developed for clinical trials but are increasingly being used in other study designs, e.g., in observational studies by practitioners and researchers to conduct their own assessments of interventions.[28] To our knowledge, there is not a COS for physical activity interventions in primary schools. Therefore the development of a COS (the aim of this study), would contribute to this field of research by identifying the key outcomes to be studied, allowing for evidence synthesis to better understand the impact of physical activity interventions in schools on children's health.

METHODS

Design

The protocol for this work has been published (Supplemental File 1);[30] it was developed in accordance with the Core Outcome Measures in Effectiveness Trials (COMET) criteria.[29] Our study was prospectively registered with COMET (registration number 1322).[31] We used a modified-Delphi method consisting of four-stages to develop the COS (Figure 1). First, we extracted outcomes from relevant studies identified through an umbrella review and through a focus group with our Steering Committee (our Steering Committee includes health professionals, health researchers, academics, and sports representatives from organisations such as Sport England and The Daily Mile Foundation). Second, after de-duplication and combining similar outcomes we created a long list and established domains determined by the outcomes. Third, we recruited participants from four key stakeholder groups (educators,

health researchers, public health professionals, and parents of children aged from 5 to 11 years) to complete a two-round Delphi survey. We also obtained children's views of what is important to them through a workshop. Fourth, we held a stakeholder meeting to achieve consensus on the outcomes to be included in the COS. We report the study following the Core Outcome Set–STAndards for Reporting: The COS-STAR checklist (Supplemental File 2).[32]

Stage 1: Extraction of outcomes

For the umbrella review, we searched six databases (MEDLINE, EMBASE, PsycINFO, CINAHL, CENTRAL and the Cochrane Database of Systematic Reviews). Keywords used for the search were 'school', 'physical activity', 'exercise', 'physical education', 'fitness', 'energy expenditure' and adapted to use database specific filters, i.e., subject headings or medical subject headings (MeSH). Reviews were limited to systematic reviews, meta-analyses or meta-syntheses, and those published between 1990 and 2019. Single relevant studies from these reviews were identified from which the outcomes extracted. We also held a focus group with our Steering Committee and used a nominal group technique to brainstorm outcomes and rate importance of them to extract further outcomes that may not have been captured in our literature review.

Stage 2: List of outcomes and establishing domains

We removed duplicate outcomes and merged those that were closely related, for example, outcomes of 'light physical activity', 'moderate physical activity', and 'vigorous physical activity' were combined into 'intensity of physical activity', to create a long list of outcomes. Definitions were generated for each outcome based on those provided by authors of the relevant studies and discussions with our Steering Committee. Guided by the outcomes and

definitions, we established relevant domains by grouping similar outcomes that captured a broader concept.

Stage 3: Stakeholder recruitment, Delphi surveys and children's workshop

The purpose of the Delphi surveys was to identify which outcomes, from the long list we produced, were considered the most important to measure across key stakeholder groups.

Stakeholder recruitment

Through emails to our public health research and practitioner networks, and through snowballing and social media, we recruited participants from four key stakeholder groups (educators [teachers, head teachers, school governors], health researchers, public health professionals, and parents of primary school-aged children). These key stakeholder groups were agreed among our Steering Group of those that would be the most interested in the development and implementation of an agreed set of outcomes to enhance this field of research. An information leaflet was made available to participants which included an electronic link to the Round 1 Delphi survey and study contact details. Through the Round 1 survey link, we obtained consent for participation, followed by participants registering their details (name and email address) and indicating which of the four stakeholder groups they identified with.

Delphi surveys

Using DelphiManager software,[33] we listed the outcomes with definitions by each domain in a Delphi survey conducted over two rounds (Round 1 took place during June 2020, and Round 2 in August 2020). Using the pre-defined Delphi Survey guidelines[33] we asked participants to rate the importance of each outcome using a 9-point Likert scale ranging from 'not important to measure' to 'critical to measure' in Round 1. A rating of 10 could be indicated if participants felt they were unable to score an outcome. Ratings were grouped

into three categories: 'not important to measure' (ratings of 1, 2, or 3); 'important but not critical to measure' (ratings of 4, 5,or 6); and 'critical to measure' (ratings of 7, 8 or 9). In addition, participants were asked to suggest any other outcomes that they felt were not captured. In line with our protocol, if more than two individual participants suggested the same additional outcome, this would be included in Round 2 for all participants to rate. For ratings in Round 2, participants were provided with feedback of Round 1 ratings categorised by stakeholder group, and an option to re-rate their initial ratings based on this feedback. Participants were sent three email reminders to complete Round 1; those who rated all outcomes in Round 1 were invited to complete Round 2. The criteria for outcomes considered most important to measure for each domain after Round 2 were defined *a priori,* ≥70% of all participants rating an outcome 'critical' and 15% or less rating it 'not important'.[30] None of the outcomes were removed between rounds.

Children's workshop

We recruited primary school children to take part in a workshop in December 2020 with consent obtained from parents via the school. Due to Covid-19, our access to schools was restricted. We partnered with one primary school in Greater London, UK. Guided by the list of outcomes, we engaged the children in a series of activities and discussions on physical activity and elicited the children's views on what they thought was important to measure.

Stage 4: Stakeholder meeting

Participants who completed both survey rounds were invited to attend the stakeholder meeting in December 2020. Due to Covid-19 restrictions, the meeting was held virtually using the Zoom platform and we adapted the voting method (70%/15% threshold) as described in our protocol. Instead, to achieve consensus on the outcomes to be included in the COS, we led discussions around the ratings of outcomes in the Delphi surveys and

children's views. We used the Zoom chat function for participants to indicate the most important outcomes and further discussion to agree the outcomes to be included in the COS.

PATIENT AND PUBLIC INVOLVEMENT

We have consulted with professional and public representatives within our Steering Committee and as part of The Daily Mile Research Advisory Group. Both groups include public health professionals, health researchers, academic researchers, and representatives from The Daily Mile Foundation, Sport England, London Marathon, and London Sport. Our COS has been developed in consultation with educators, health researchers, public health professionals, parents and children through focus groups and workshops. We will widely advertise our COS through those involved in the development, and also to child public health policy makers through our research networks.

RESULTS

Stage 1: Extraction of outcomes

Our umbrella review identified 53 relevant papers (Supplemental File 3). Seventy-three individual studies were extracted from which 82 outcomes were identified. The Steering Committee focus group identified 34 outcomes.

Stage 2: List of outcomes and establishing domains

The final list consisted of 50 outcomes (Table 1) representing three domains: (1) physical activity and health (16 outcomes); (2) social and emotional health (22 outcomes); and (3) educational performance (12 outcomes) . Two outcomes, 'sleep' and 'diet' were included in two domains as authors agreed that these outcomes in particular could be both a 'physical

activity and health' and a 'social and emotional health' outcome. For example, sleep defined as number of hours slept as recommended for children was included in the physical activity and health domain, whilst sleep times/ patterns/broken sleep was included in the social and emotional health domain. Similarly for the outcome of diet, eating well-balanced meals was included in the physical activity and health domain whilst appetite was included in the social and emotional health domain (see Table 1 for definitions).

242 **Table 1. List of 50 outcomes and their definitions by domain**

Outcome	Definition
Domain 1: Physical activity and health	
Active travel	To get to and from school, for example, walking, public transport i.e., train/tube/bus (do not include car, van, motorcycle), cycling, scooter
Bioimpedance	Weight, height, body mass index (BMI) body fat, body mass, waist circumference
Blood lipids	Fatty substances found in the blood (i.e., cholesterol, triglycerides) which increase the risk of heart attack
Blood pressure	The force at which your heart pumps blood around your body and the resistance to the blood flow in the blood vessels
Diet	Varied and balanced diet including fruit and vegetables
Energy levels / expenditure	The amount of energy needed to carry out physical functions such as breathing, exercising or digesting food
Fitness	Being fit and healthy for optimal health and overall wellbeing
Heart rate	Number of beats per minutes (BPM) to establish normal resting heart rate, high or low heart rate
Intensity of physical activity	Includes light activity (i.e., taking a stroll); moderate activity (i.e., cycling / swimming at regular pace, sweeping, washing windows); and vigorous activity (i.e., aerobics, running, fast cycling or swimming, climbing stairs)
Leisure time activity	Time spent in activity for leisure during the day (i.e., walking in the park, playing sports with friends/family)
Motor skills	Skills that require using large muscles of the arms/legs/torso, i.e., standing, walking, going up and down stairs, running, swimming, jumping, skipping, swimming, leaping, kicking
Musculoskeletal	Bone strength, bone mineral density
Peak oxygen intake	The maximal rate at which oxygen can be used by the body during maximal work
Sedentary time	Time spent sitting at desk, reading, sitting or lying down to watch television
Sleep	Between approximately 10 to 12 hours per night
Step counts	Number of steps taken in a day
Domain 2: Social and emotional health	
Anxiety	Persistent feeling of worry, fear or nervousness
Appetite	Eating well and regularly

Body awareness	The ability to recognize one's body moves helping to understand how to relate to objects and people at home, at school and outdoors
Body image	The perception one has of their physical self
Depression	Feeling persistently sad for more than a few days
Empowerment	Feeling a sense of becoming stronger and more confident
Enjoyment	Taking pleasure in doing something
Happiness	Feeling a sense of joy and contentment

Table 1. continued

Mood	A state of mind or a feeling such as happy, sad, cheerful or angry
Peer support	Using one's own experiences to help others
Resilience	The ability to recover quickly from difficulties
Satisfaction	A sense of fulfilling a need, desire or appetite
Self-confidence	A feeling of trust in one's abilities, qualities, and judgment
Self-efficacy	A person's belief of their capacity to perform behaviours necessary to produce specific performance attainments
Self-esteem	A factor that influences people's choices and decisions which results in them either taking or not taking care of themselves and explore their full potential
Self-expression	The communication of one's personality, feelings, or opinions
Self-perception	Attitudes towards own preferences and behaviour
Sickness	Feeling unwell, nauseous, dizzy
Sleep patterns	Sleep patterns /achieving less than recommended (10-12 hours) / broken sleep
Social interaction	An exchange between two or more people
Stress	Feeling under pressure or threatened
Wellbeing	Feeling well, happy, healthy and ability to manage stress
Domain 3: Educational performance	
Academic performance	Measurement of a child's achievement over a range of academic subjects

Attention	Taking notice of someone or something
Classroom behaviour	How children are acting in the classroom in response to what is going on or present around them
Cognitive development / function	How children think, explore and figure things out
Concentration	Ability to focus on task
Engagement	The degree of attention, curiosity, interest, optimism, and passion that children show when they are learning or being taught
Executive functioning	A set of mental skills including working memory, flexible thinking, and self-control to apply to everyday learning, work, and daily life
Focus	Ability to concentrate and not easily distracted
Maths	The study of numbers, shapes and patterns
Reading	A cognitive process that involves decoding symbols to arrive at meaning, the primary purpose of which is to understand the text
Working memory / inhibition	A cognitive system with a limited capacity that can hold information temporarily and is important for reasoning, decision-making and behaviour
Writing	A form of communication to express language using symbols; being able to understand grammar, punctuation, spelling, and vocabulary

Stage 3: Stakeholder recruitment, Delphi surveys and children's workshop

Stakeholder recruitment

A total of 104 participants consented and registered their details. Ninety (87%) completed Round 1 in full of whom 65 (72%) also completed Round 2 in full. The 65 participants included 16 (25%) educators, 24 (37%) researchers, 13 (20%) public health professionals, and 12 (18%) parents, and represented 9 countries: UK (80%), Brazil (6%), Korea (5%), Australia, France, Netherlands, Romania, Spain, and Taiwan (all 2%).

Delphi surveys

Thirteen outcomes met the ≥70% participant critical threshold: sleep (number of hours), and diet (varied and balanced) in 'physical activity and health'; happiness, wellbeing, anxiety, self-esteem, depression, self-confidence, enjoyment, and stress in 'social and emotional health'; and concentration, attention, and focus in 'educational performance' (Table 2). In Round 1, a further 29 outcomes were suggested, but after internal discussions, it was agreed that 16 of the suggestions overlapped with the outcomes that were listed in the survey, and the remaining 13 were proposed by only one participant and therefore not carried forward to Round 2. Mean Round 1 ratings between participants completing Round 2 were similar to those who did not complete Round 2 (6.33, SD 2.08 vs 6.48, SD 1.95 respectively) suggesting those who did not complete Round 2 would have scored similarly to those who did.

Table 2. Percentage of all participants' critical ratings after Delphi survey Round 2

Domain	Outcome	% of participants rating outcomes critical
Physical activity and health	Active travel	51%
	Bioimpedance	26%
	Blood lipids	14%

	Blood pressure	14%
	Diet (varied and balanced)*	71%*
	Energy	26%
	Fitness	60%
	Heart rate	17%
	Intensity of physical activity	63%
	Leisure time activity	62%
	Motor skills	46%
	Musculoskeletal	20%
	Oxygen peak intake	9%
	Sedentary time	63%
	Sleep (number of hours)*	85%*
	Step counts	23%

Table 2. Continued

Social and emotional health	Anxiety	78%*
	Appetite	42%
	Body awareness	46%
	Body image	66%
	Depression	74%
	Empowerment	42%
	Enjoyment	74%*
	Happiness	85%*
	Mood	51%
	Peer support	46%
	Resilience	55%
	Satisfaction	46%
	Self-confidence	74%*
	Self-efficacy	68%
	Self-esteem	75%*
	Self-expression	34%
	Self-perception	51%
	Sickness	40%
	Sleep patterns	69%
	Social interaction	65%
	Stress	72%*
	Wellbeing	85%*

	Academic performance	57%
	Attention	74%*
	Classroom behaviour	68%
	Cognition	54%
	Concentration	75%*
Educational performance	Engagement	69%
	Executive functioning	46%
	Focus	72%*
	Maths	55%
	Memory	48%
	Reading	51%
	Writing	48%

*Outcomes that meet the threshold (≥70% participant agreement of 'critical' ratings)

Children's workshop

Sixteen children aged 8 to 9 years took part in the workshop; 50% girls; 13% Caucasian, 56% Asian, and 31% Black; 6% had Special Educational Needs and 75% had English as a second language. The children identified eight outcomes important to measure: five in 'physical activity and health' (energy, fitness, heart rate, muscle strength, and weight), and three in 'social and emotional health' (happiness, mood, and stress). Interestingly, children did not associate physical activity with any educational performance related outcomes.

Stage 4: Stakeholder meeting

Thirteen participants attended (2 educators, 2 parents and 9 researchers). Participants expressed that they had expected more outcomes under the domain of physical activity and health to be rated critical, i.e., intensity of physical activity which had been rated critical by 63% (Table 2). Through discussion, agreement was reached that this outcome is important to measure be able to assess sustainability of physical activity interventions in schools. After review of the outcomes identified critical in the survey and the outcomes considered important to children, six outcomes were dropped and the additional outcome of intensity of

physical activity was included (Supplemental File 4). Therefore, a total of 14 outcomes reached consensus for the COS: diet (varied and balanced), fitness, intensity of physical activity, and sleep (number of hours) in the physical activity and health domain; anxiety, depression, enjoyment, happiness, self-esteem, stress, and wellbeing in social and emotional health domain; and concentration, and focus in the domain of educational performance (Table 3). We sent the agreed set of outcomes for review to the stakeholders unable to attend the meeting. The wider group approved the COS.

Table 3. Core outcome set for physical activity interventions in primary schools

Domain	Outcome
Physical activity and health	Diet (varied and balanced)
	Energy
	Fitness
	Intensity of physical activity
	Sleep (number of hours)
Social and emotional health	Anxiety
	Depression
	Enjoyment
	Happiness
	Self-esteem
	Stress
	Wellbeing
Educational performance	Concentration
	Focus

Discussion

We have developed the first COS for physical activity interventions in primary schools. By using robust consensus methods and multi-disciplinary stakeholder groups, we have achieved consensus on the outcomes considered important to measure. Implementation of

this COS in future studies will reduce heterogeneity between studies allowing for evidence synthesis and will also be relevant to wider audiences.

During the consensus meeting, it was noted that the survey identified only two outcomes (sleep and diet) in the domain of physical activity and health as critical to measure whilst the outcomes 'physical activity intensity' and 'fitness' did not meet the threshold. Outcomes that may fit under these concepts include heart rate, blood lipids, blood pressure and peak oxygen intake which are more commonly studied but these did not meet the critical threshold in our survey. This potentially reflects the heterogeneity across studies of the outcomes that should be measured under broader concepts.

In the studies identified from our umbrella review, we found that from a total of 82 unique outcomes, 9 outcomes related to mental health, 23 outcomes related to educational performance/cognition and 50 outcomes related to physical health. However, all our stakeholders placed more importance on assessing children's social and emotional health outcomes. Our Delphi surveys and consensus methods bought to the forefront the importance of considering potential effects of physical activity interventions on children's social and emotional health, and 50% of all outcomes in our COS were in this domain. This indicates a shift in focus from measuring physiological outcomes and towards measuring mental health when assessing physical activity interventions in primary schools. This further supports the need for a COS in this field as our study has provided a better understanding that to achieve better overall health and wellbeing in children, both physical and mental health are equally important to measure.

Functional precursors of performance-related outcomes (concentration, attention, and focus) met the critical threshold than actual educational attainment outcomes of reading, writing, and maths which are more commonly assessed in previous studies and by schools. A possible explanation for this is that to improve educational attainment, physical activity interventions need to help to improve cognition (i.e., concentration, focus). These interventions may therefore have an indirect effect on improving reading, writing and maths by improving cognition.

Although we are not aware of another COS that specifically evaluates interventions aimed at increasing children's physical activity in primary schools or other settings such as in the community, there are several existing frameworks for assessing these interventions. A systematic review by Cassar et al. (2019) identified 14 frameworks applied across 27 papers[34] which included RE-AIM,[35] Ecological framework for understanding effective implementation,[36] Multilevel implementation quality framework,[37] and A Conceptual Framework for Implementation.[38] The review found that the frameworks were predominantly used for interpreting results and analyses rather than being used as a planning tool for outcomes to be measured or for understanding results.[34] Another review by Damschroder et al. (2009) also found little evidence that frameworks for school-based physical activity interventions were used to guide the data collection.[39] Findings from these reviews imply that the frameworks to assess these interventions provide little emphasis on the planning of what should be measured and perhaps explains the heterogeneity of outcomes measured to date. COS's should be used to inform the choice of outcomes[40] and our COS contributes to an important gap in these frameworks and can add to them by providing a guide on the minimum set of outcomes to measure in future studies of physical

activity interventions in primary schools. It is important to note however that the existing research from physical activity intervention studies has enabled important findings of outcomes that are more commonly measured such as BMI [41] and physical activity[42] and have allowed for a better understanding of the impacts of these interventions on these outcomes. But any COS's currently being developed are mainly centred around childhood obesity [43-45] which is complex; tackling childhood obesity requires comprehensive, multicomponent strategies. Our COS, focussed on physical activity in primary schools, should be considered as part of a set of tools for wider improvement of health in primary schools.

Our study's strengths include we have developed the first COS for physical activity interventions in primary schools, to our knowledge, and used robust methodology as recommended by the COMET to capture a wide range of outcomes to reach consensus. Our inclusion of participants from four key stakeholder groups representing nine countries, as well as incorporating views of children, ensures the relevance of outcomes to measure for the target population. We also ensured that the domains were not pre-determined. We instead established the domains led by the list of outcomes and their definitions thus avoiding any researcher bias. However, there are limitations to our study. As we recruited participants through several methods including advertising on our research network websites and through snowballing, we are not aware of how many potential participants were targeted for our research and did not participate. Although our participants represented nine countries, most were UK based. The educators and health researcher stakeholder groups included participants from five countries whilst participants from two countries represented the public health professional and parent groups. All stakeholder groups had a UK

participant representation between 71% and 95%. The outcomes identified from our umbrella review were not limited to UK based studies, but the lower proportion of participants representing other countries and in each stakeholder group, may have prevented the identification of other outcomes that may be more relevant. Other countries and cultures may differ in the importance placed on physical activity in schools and may focus on other aspects such as educational attainment. This may bias our COS towards outcomes relevant to UK audiences. Some of the definitions of the outcomes overlapped or may have been interpreted with wider meanings which was not explored in our stakeholder meeting. Covid-19 restrictions limited our reach to primary schools and year groups to target for our workshops; children from different year groups may have considered additional or fewer outcomes important. The development of our COS during the Covid-19 pandemic may have influenced our findings. It has been widely reported that school closures and restrictions have reduced opportunities for children to be physically active and has increased poorer mental health.[46, 47] This may perhaps explain the higher number of outcomes in the domain of social and emotional health that met the threshold in our surveys. Finally, it may be challenging for future studies to include all 14 outcomes identfied in our COS. However, as our outcomes have been grouped into three main domains, researchers may choose to include the outcomes within the domain of interest.

The development of our COS is timely; several interventions that have been implemented in schools in recent year may have stopped due to Covid-19. These interventions are likely to resume and may be more important to assess now due the negative impacts the pandemic has had on children's physical activity and mental health. Our COS would be relevant to future studies assessing the impact of physical activity interventions in primary schools such

as The Daily Mile, a popular active mile intervention reaching 1 in 5 state-funded primary schools in England,[48] and recommended by England's National Obesity Plan.[49] Despite its reach, the evidence of its impact remains limited or inconsistent.[50-53]

Our COS would benefit from identifying the best assessment tools to measure the outcomes that are readily available to those implementing physical activity interventions in schools. COMET suggests that a COS use should first aim to establish which outcomes are important to measure, and then aim to identify which assessment tools would be the most accessible for end users.[54] There is a low uptake of COS's in randomised control trials due to lack of recommendations of valid measures, lack of involvement of key stakeholders, and those implementing or assessing interventions not being aware of a COS in their field of research.[54] Our next step is to identify assessment tools that are readily available to measure the outcomes in our COS. Recommendations of assessment tools would further enhance the quality and consistency of results in studies using our COS.

Prevention and public health approaches in early life to reduce health inequalities and improve health of the whole population may be a better investment than treating disease in the population that generally arises later in life.[55, 56] The robust processes that we have applied in this study could be repeated to inform an adolescent (young people aged 12 to 17 years) focussed COS. Physical activity is low among the secondary school population[57] and poorer mental health is also increasing among this age group.[58] We recommend that our COS is included as part of a wider set of tools and frameworks that should be developed to standardise the outcomes to measure other areas of children and young people's health

such as weight and nutrition.[59] This would allow for improved health to continue during adolescence and adulthood.

Conclusion

Our COS identifies the outcomes that are most important to measure for studies of physical activity interventions in primary schools. Next, we aim to identify the assessment tools to measure these outcomes. Wide use of our COS in future studies will reduce heterogeneity allowing for evidence synthesis to better understand intervention effects on children's health and cognition during the primary school years.

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Competing Interests

SS and BR received funding from The Daily Mile Foundation. SS, BR, and KF are members of The Daily Mile Research Advisory Group. All other authors declare no competing interests.

Author Contributions

KF, SS and BR conceived and designed the study. BR and KF designed study materials. BR was responsible for managing all components of the study including recruitment, data

collection and analyses. SS, EvS, DH and RV advised on the project. BR wrote the first draft of the manuscript. All authors contributed to redrafts and approved the final manuscript.

Ethics and Consent

This study was approved by Imperial College London Research Ethics Committee (19IC5428). All participants provided informed consent to take part in the development of this COS and individual responses have remained anonymous. Those named under the acknowledgements have provided consent for their names to be published.

Data Sharing

The data are stored at Imperial College London and will be made available upon request by email to the corresponding author.

Disclaimer

The funders had no role in the analyses or results of this study. The views expressed in this publication are those of the authors and not necessarily those of the NIHR School for Public Health Research, NIHR Northwest London Applied Research Collaboration, the Department of Health and Social Care, Department for Education, or The Daily Mile Foundation.

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Figures

Figure 1. Process for developing a core outcome set

Supplementary Material

Supplemental File 1. Study Protocol

Supplemental File 2. COS-STAR Reporting Checklist

Supplemental File 3. List of the 53 papers identified from the umbrella review

Supplemental File 4. Outcomes included and dropped after review

ORCiD

Bina Ram	0000-0003-0023-1573
Kimberley A Foley	0000-0003-3664-8100
Esther MF van Sluijs	0000-0001-9141-9082
Dougal S Hargreaves	0000-0003-0722-9847
Russell Viner	0000-0003-3047-2247
Sonia Saxena	0000-0003-3787-2083

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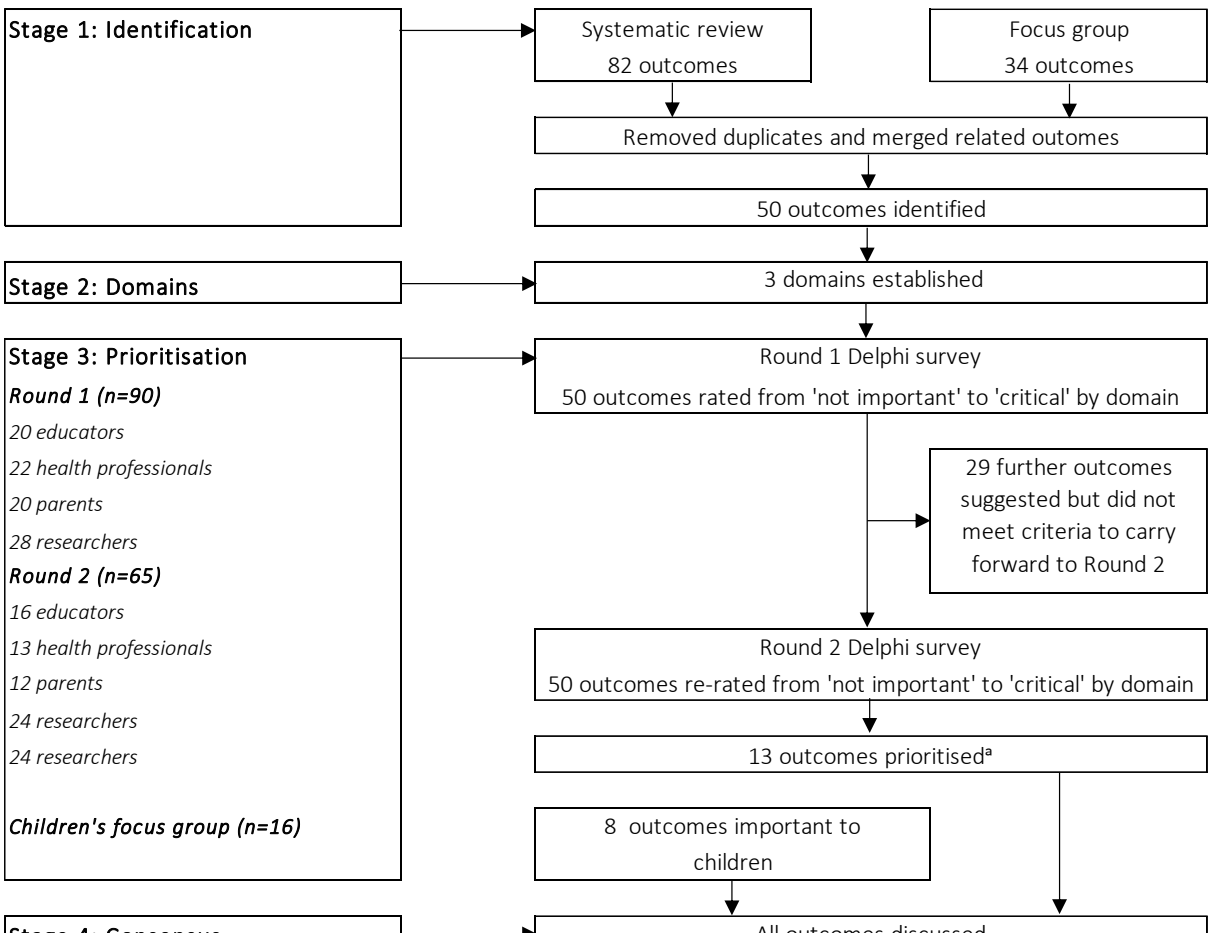
Figure 1. Process for developing a core outcome set for physical activity interventions in primary schools



Open access Protocol

BMJ Open

Protocol for developing a core outcome set for evaluating school-based physical activity interventions in primary schools

Kimberley A Foley ,[1] Tishya Venkatraman ,[1] Bina Ram ,[1] Louisa Ells ,[2] Esther van Sluijs ,[3] Dougal S Hargreaves ,[1] Felix Greaves ,[1,4] Mansour Taghavi Azar Sharabiani ,[1] Russell M Viner ,[5] Alex Bottle ,[1] Sonia Saxena [1]

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[1]Department of Primary Care and Public Health, Imperial College London, London, UK
[2]Centre for Public Health Research, Teesside University, Middlesbrough, UK
[3]MRC Epidemiology Unit, University of Cambridge, Cambridge, UK
[4]Science and Strategic Information, Public Health England, London, UK
[5]Population, Policy and Practice Research Programme, UCL Institute of Child Health, London, UK

Correspondence to
Professor Sonia Saxena;
s.saxena@imperial.ac.uk

ABSTRACT

Introduction Primary school-based physical activity interventions, such as The Daily Mile initiative, have the potential to increase children's physical activity levels over time, which is associated with a variety of health benefits. Comparing interventions or combining results of several studies of a single intervention is challenging because previous studies have examined different outcomes or used different measures that are not feasible or relevant for researchers in school settings. The development and implementation of a core outcome set (COS) for primary school-based physical activity interventions would ensure outcomes important to those involved in implementing and evaluating interventions are standardised.

Methods and analysis Our aim is to develop a COS for studies of school-based physical activity interventions. We will achieve this by undertaking a four-stage process:(1) identify a list of outcomes assessed in studies through a systematic review of international literature; (2) establish domains from these outcomes to produce questionnaire items; (3) prioritise outcomes through a two-stage Delphi survey with four key stakeholder groups (researchers, public health professionals, educators and parents), where stakeholders rate the importance of each outcome on a 9-point Likert scale (consensus that the outcomes should be included in the COS will be determined as 70% or more of all stakeholders scoring the outcome 7%–9% and 15% or less scoring 1 to 3); (4) achieve consensus on a final COS in face-to-face meetings with a sample of stakeholders and primary school children.

Ethics and dissemination We have received ethical approval from Imperial College London (ref: 19IC5428). The results of this study will be disseminated via conference presentations/public health meetings, peer-reviewed publications and through appropriate media channels.

Trial registration number Core Outcome Measures in Effectiveness Trials Initiative (COMET) number: 1322.

Strengths and limitations of this study

- To our knowledge, this will be the first core outcome set developed to evaluate school-based physical activity interventions in primary schools, which will improve evidence synthesis in this field.
- The study will use a robust four-stage process including a modified Delphi technique, to incorporate multidisciplinary stakeholder perspectives, including researchers, public health professionals, educators (ie, head teachers, teachers and school governors), parents and primary school children.
- The stakeholders are drawn from an international pool and a systematic literature review of international literature.
- A limitation of this study is that primary school children are considered too young to participate in the Delphi survey rounds. To ensure we capture children's perspectives, we will conduct a separate face-to-face meeting and their views will be considered at the final stage.

INTRODUCTION

Regular physical activity in children and young people is associated with physical and mental health benefits including musculoskeletal fitness and lower risk of depression, obesity and diabetes.[1 2] A growing evidence base also suggests physical activity improves sleep duration, cognition[3] and academic performance.[4 5] Hence, current guidelines from the WHO recommend 60 minutes of moderate-to-vigorous physical activity every day for children.[6] However, in high-income countries, only one in five children and young people are meeting these physical activity targets.[7] Several school-based physical activity (SBPA) interventions have been developed and implemented to increase children's activity levels. A Cochrane review of 44 randomised controlled trials of SBPA interventions for children aged 6–18 years found nine different outcome domains and concluded that additional research on the long-term impact of these interventions is needed.[8]

Active mile initiatives, such as The Daily Mile, which involves 15 minutes of self-paced physical activity,[9] are encouraged by governments of several European countries. Policy

makers in the United Kingdom (UK) are now promoting and incentivising their implementation in primary schools (children aged 4–11 years).[10] However, the evidence base of their effectiveness is limited. Previous studies, although promising, have been small scale, and examine different outcomes using different measuring tools that are not practical for follow-up over long periods (eg, physical activity measured by accelerometers which only capture a specific period of physical activity pattern).[11 12] It is also unclear which outcomes are most relevant for those involved in implementing and evaluating interventions.

A core outcome set (COSs) is an agreed standardised set of outcomes indicating what should be reported.[13] The outcomes must be measurable and relevant for researchers and other key stakeholders. Core outcome sets were originally developed for clinical trials, but increasingly been developed and used in other areas.[14] A COS specifies a minimum set of outcomes assessed in all studies, but is flexible to allow the inclusion of additional outcomes into any particular study.[13] To our knowledge, there is not a COS that exists for the evaluation of primary school-based physical activity interventions. Therefore, there is a need to develop a COS to ensure that the same outcomes are being measured to allow for the direct comparison of school-based physical activity interventions across studies.

AIMS AND OBJECTIVES

The aim of this study is to identify a COS for primary school-based physical activity interventions over time. This study will focus on what should be measured, and we will assess 'how' to measure each core outcome.

Study objectives include:

1. To develop a list of potential outcomes relevant to evaluating primary school-based physical activity interventions over time.
2. To prioritise outcomes of whole-school physical activity important to relevant stakeholders including professionals and researchers.
3. To achieve consensus on a minimum set of relevant outcomes for primary school-based physical activity interventions (ie, COS).

METHODS

Steering group

We have formed a steering group for this project, including healthcare professionals and researchers to guide the development of this COS. We have recruited members representing different disciples and expertise including health professionals and researchers with methodological expertise in epidemiology, statistics and consensus methods. We have also identified a study management group within the steering committee to conduct day-to-day management of the study. We consulted with this committee to identify core principles that we should apply when identifying our set of core outcomes. This group determined that outcomes should be feasible for use in large-scale studies and should be both valid and reliable.

Modified Delphi

The study design uses a modified Delphi technique (the RAND/UCLA appropriateness method) to identify a set of core outcomes.[15] This technique has previously been used in the development of a COS across a variety of clinical and research contexts.[16 17] The modified Delphi process involves four stages:

1. Identifying a list of outcomes from systematic literature reviews.
2. Reduction of the list into domains for questionnaire items.
3. Prioritisation through a Delphi survey involving two rounds of questionnaires and incorporation of additional outcomes nominated by stakeholders
4. Face-to-face consensus meetings to agree a final core set with stakeholders.

Stage 1: systematic literature review

We will conduct a comprehensive umbrella review of systematic reviews and meta-analyses to identify a list of outcomes relevant to school-based physical activity interventions. The process of this systematic review has been registered with PROSPERO (CRD42019146621).[18] To identify reviews, we will search MEDLINE, EMBASE, CINAHL, CENTRAL, PsycINFO and the Cochrane Database of Systematic Reviews, restricting our search to include English language only and articles published since 1990. A detailed search strategy for each database is included in online supplementary appendix A. We will also aim to include relevant papers from the grey literature and in particular, we will review the Standard Evaluation Framework for Physical Activity Interventions[19] and the DAPA (diet, anthropometry, and physical activity) measurement toolkit.[20]

We will compile studies in EndNote software and remove duplicates. Two authors will independently conduct title/abstract screening to identify eligible systematic reviews or meta-analyses. Disagreements will be resolved by discussion, or as needed, by discussion with a third author. Title and abstract screening will be followed by full-text screening. For inclusion, eligible reviews will describe physical activity interventions or processes targeted at primary school children (aged 4–11 years). All types of study designs will be included. We will exclude any studies that are not in English, focus primarily on adolescents or young adults or those that are aimed at a particular subpopulation of children as these studies would not be generalisable to the whole school population. We will use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to document the number of articles included and excluded during the searches.[21]

Once the systematic reviews are identified, we will conduct a quality assessment of the reviews using the Critical Appraisal Skills Programme (CASP)[22] tool; low-quality reviews will be excluded. We will search the included studies

from each review. As we are interested in studying physical activity interventions delivered in a 'real-world' setting, we will apply additional eligibility criteria to the studies selected from within each review. Eligible studies must include a longitudinal study design (as they may include more relevant outcomes of interest) but we will not limit the duration of the intervention, and outcomes must be applicable to primary school children (approximately 4–11 years). In addition, we will limit studies to those conducted in the last three decades. To ensure we capture all relevant papers, we will identify additional relevant studies by screening the reference list for each eligible study included. Again, this search will be performed by two study authors with disagreements resolved by discussion or through consultation with a third author.

Outcomes will be identified from the methods and results section of each paper. For each outcome, the following data will be extracted: study characteristics (eg, author(s), year, country and sample size), study population (eg, number of participants, target age, ethnic groups), how the outcomes were defined, the time points for measurement and intervention duration, the measurement tool used and whether it was validated, any reliability information (eg, test–retest reliability), and any methods used to enhance quality of outcome measurement (eg, measured twice). If the tool was validated, we will record details of the population used for validation (eg, age and country of children). All data extraction will be completed by one study author but 10% of the papers will be done by a second author to check consistency. Disagreements will be resolved by discussion or by consultation with a third author, as required.

Stage 2: establishing domains for questionnaire items

The domains for questionnaire items will be established by grouping similar outcomes that capture a broader concept.[23 24] Domains will be identified independently by two researchers and a small number of stakeholders in discussion with a third senior researcher if there are discrepancies. The shortlisted domains will form candidate outcomes as questionnaire items in plain English for all stakeholder groups. The questionnaire will be designed and piloted with input from lay representatives to ensure its understanding and acceptability.

Stage 3: prioritisation of outcomes through a Delphi survey

Delphi Survey: round 1

The first round of the modified Delphi process will involve surveying stakeholders to prioritise each of the outcomes identified from the literature search through an anonymous Delphi survey. The advantages of this method include the low costs and avoidance of influence from strong voices in group-based decision-making. Following guidance in the literature,[25] we aim to recruit approximately 60 participants; around 15 members each representing four key stakeholder groups: (1) researchers, (2) health professionals, (3) educators, that is, school teachers, head teachers, school governors, and (4) parents. By ensuring heterogeneity in overall group composition it may help to identify outcomes that would be otherwise overlooked.[13 26 27] Through our research networks, colleagues and through public health social media platforms, we will create a sampling frame of potential stakeholders to invite. In addition, we will ensure that teachers, head teachers, and school governors represent schools that are and are not taking part in SBPA interventions. We will use snowballing methods to identify further panel members and we aim to include adult panel members with a range of expertise and from different countries who are able to write and understand English. Due to the complexity of the survey rounds, we felt it would be inappropriate to include primary school children at this stage of the COS development. Instead we will include children aged 7–11 years in a face-to-face meeting (stage 4) to learn about what is important to them, and ensure their views are represented in this study. This age range reflects the age of children in primary school where children have an understanding of the improtance of physical activity.

We will invite each potential panel member by email to participate in this study. We will obtain informed consent from all participants who agree to take part, and provide them with information about the entire Delphi process and the importance of participating in all rounds of the study.[27] Recruitment of panel members will continue until we have a minimum of 12 and a maximum of 20 from each stakeholder group.[25]

We will send each participant a survey by email which they will be asked to complete within 3 weeks of receipt. Participants will be required to rate the importance of each outcome using a 9-point Likert scale ranging from 0 'not that important' to 9 'critical'. They will also be asked to suggest any additional outcomes not included in survey. All surveys will be completed online. We will send two reminder emails to encourage responses (one at the end of week 2 and one at the end of week 3 allowing for one more week to complete the survey).

All survey results will be reviewed to identify missing data, possible outliers and the range of response options used. For each outcome, the distribution of scores will be generated and the median score calculated. We will calculate these separately for each stakeholder group.

Additional outcomes suggested by at least two participants will be reviewed by the study team. If there is disagreement about whether a new suggested outcome is unique that cannot be resolved by discussion, they will consult with a third team member. New outcomes will be added to the survey for round 2 of the Delphi. All outcomes included in round 1 of the survey will be retained for the second round of the Delphi survey.

Delphi survey: round 2

We will contact all participants who complete round 1 of the survey to complete round 2. The round 2 survey will include feedback from round 1 showing their scores compared with other participants in their own stakeholder group and other groups.[28] In the round 2 survey,

we will ask participants to re-rate the importance of each outcome and any new outcomes. After this round, we will conduct analyses to determine consensus. Consensus that the outcome should be included in the COS will be determined as 70% or more of all panel members scoring the outcome 7%–9% and 15% or less scoring 1%–3%. Consensus that the outcome should NOT be included in the COS will be 70% or more of all panel members scoring the outcome 1%–3% and 15% or less scoring 7%–9%.[14] We will divide the outcomes list into three groups: consensus that it should be included in the COS, consensus that it should be excluded and no consensus reached. Outcomes that reach consensus for inclusion and those where no consensus was reached will be retained for discussion during the face-to-face meeting.

Stage 4: consensus meeting to agree a final core outcome set

The fourth stage of this Delphi process will consist of two face-to-face meetings to obtain consensus on the final core set. We will conduct one meeting with adult stakeholders, and a separate meeting with children. The meeting with children will be first and informed by the results of the Delphi survey. Through a day of activities and discussions led by a trained facilitator, we will learn about which outcomes are important to the children. Recruitment of children for the face-to-face meeting will involve an invitation letter sent to parents identified through the educators and parents (in the UK) participating in the questionnaire rounds. A child information leaflet will be also be included. We aim to include approximately 10–15 children aged from 7 to 11 years per school, inviting a minimum of two and a maximum of four schools. In total, we aim to include 20–60 children. Written parental consent and child assent will be obtained. As the meeting with children will involve a number of activities, it will not be possible to include children from other countries. However, the children will be recruited from UK schools representing those from urban and rural, and from deprived and non-deprived areas.

For the adult stakeholder meeting, a representative sample from each stakeholder group who have completed both rounds of the survey will be invited to attend. We aim to recruit at least one international member for each stakeholder group to join the face-to-face meeting. The meeting will be run by an independent facilitator who has experience of participatory research and one of the study researchers. We will present the results of the Delphi survey to the adult stakeholders invited to attend the face-to-face meeting (including at least one international participant representing each stakeholder group). We will present the ratings for each outcome from the Delphi surveys for each stakeholder group and overall alongside the outcomes deemed important to the children. Each stakeholder group will be asked to discuss the outcomes retained after survey round 2 and present their views back to the whole group. After the discussions, each participant will be issued with a unique keypad and asked to vote each outcome as 'include', 'exclude' or 'unsure'. All voting will be done simultaneously and individually without conferring. All participants will view the results of voting. Outcomes that are equivocal will be discussed as a group and each panel member will have a second chance to vote on these outcomes. The results will be compiled, and consensus ratings determined using the 70/15 criteria described earlier. The final list will be presented to the group for final discussion and comments. All items prioritised by the stakeholders from stage 4 will be included in the final COS for use in research in high-income countries.

Patient and public involvement

We obtained public involvement input from The Daily Mile Foundation and from participants of The Daily Mile Stakeholder Group. We obtained feedback and input on recruitment methods for research participants, incentives for survey participation and written and verbal feedback on recruitment materials. We will obtain further PPI input on the development and piloting of the Delphi survey.

PARTICIPANT CONSENT AND DISSEMINATION

We will obtain written consent from all adult stakeholders, and written parental consent and child assent for children to take part in the face-to-face meeting. All survey rounds will be conducted anonymously; participants will not be told who the other respondents are or what their specific responses were. Participants' contact information (names and emails) will be retained in accordance with Imperial College London's data collection, retention and storage policies. During the face-to-face meeting, participants will be aware of who the other panel members are, but where possible, individual responses will remain anonymous. To limit any adverse impact on school children during the face-to-face meeting, we will aim to make the materials and activities during the meeting interactive and enjoyable. The results of this study will be shared in conference presentations, public health meetings, and via appropriate media channels. We will publish the process of developing the COS in a peer-reviewed journal, and also publish the COS as a technical operating manual for relevant audiences. This study has also been registered with COMET and an update of the study results will be published on their website.

Twitter Alex Bottle @DrAlexBottle and Sonia Saxena @SoniaKSaxena

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Contributors KAF, SS and TV conceived and designed this study with input from BR, LJE, EvS, DSH, FG, MTAS, RMV and AB. KAF drafted the article with critical revision provided by SS, BR, LJE, EvS, DSH, FG and MTAS. All authors approved the final version.

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Patient consent for publication Not required.

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ORCID iDs
Kimberley A Foley http://orcid.org/0000-0003-3664-8100
Tishya Venkatraman https://orcid.org/0000-0001-6171-2384
Bina Ram https://orcid.org/0000-0003-0023-1573
Louisa Ells https://orcid.org/0000-0003-0559-4832
Esther van Sluijs https://orcid.org/0000-0001-9141-9082
Dougal S Hargreaves https://orcid.org/0000-0003-0722-9847
Felix Greaves https://orcid.org/0000-0001-9393-3122
Mansour Taghavi Azar Sharabiani http://orcid.org/0000-0003-3808-277X
Russell M Viner http://orcid.org/0000-0003-3047-2247
Alex Bottle https://orcid.org/0000-0001-9978-2011
Sonia Saxena http://orcid.org/0000-0003-3787-2083

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Supplemental File 2. Core Outcome Set–STAndards for Reporting: The COS-STAR checklist

SECTION/TOPIC	ITEM No.	CHECKLIST ITEM	REPORTED ON PAGE NUMBER
TITLE/ABSTRACT			
Title	1a	Identify in the title that the paper reports the development of a COS	1
Abstract	1b	Provide a structured summary	2
INTRODUCTION			
Background and Objectives	2a	Describe the background and explain the rationale for developing the COS.	4
	2b	Describe the specific objectives with reference to developing a COS.	5
Scope	3a	Describe the health condition(s) and population(s) covered by the COS.	5
	3b	Describe the intervention(s) covered by the COS.	4/5
	3c	Describe the setting(s) in which the COS is to be applied.	5
METHODS			
Protocol/Registry Entry	4	Indicate where the COS development protocol can be accessed, if available, and/or the study registration details.	5
Participants	5	Describe the rationale for stakeholder groups involved in the COS development process, eligibility criteria for participants from each group, and a description of how the individuals involved were identified.	6
Information Sources	6a	Describe the information sources used to identify an initial list of outcomes.	6
	6b	Describe how outcomes were dropped/combined, with reasons (if applicable).	6
Consensus Process	7	Describe how the consensus process was undertaken.	7
Outcome Scoring	8	Describe how outcomes were scored and how scores were summarised.	7
Consensus Definition	9a	Describe the consensus definition.	7
	9b	Describe the procedure for determining how outcomes were included or excluded from consideration during the consensus process.	7
Ethics and Consent	10	Provide a statement regarding the ethics and consent issues for the study.	18
RESULTS			
Protocol Deviations	11	Describe any changes from the protocol (if applicable), with reasons, and describe what impact these changes have on the results.	7
Participants	12	Present data on the number and relevant characteristics of the people involved at all stages of COS development.	11

Outcomes	13a	List all outcomes considered at the start of the consensus process.	9/10
	13b	Describe any new outcomes introduced and any outcomes dropped, with reasons, during the consensus process.	11
COS	14	List the outcomes in the final COS.	13
DISCUSSION			
Limitations	15	Discuss any limitations in the COS development process.	15/16
Conclusions	16	Provide an interpretation of the final COS in the context of other evidence, and implications for future research.	14/15
OTHER INFORMATION			
Funding	17	Describe sources of funding/role of funders.	18/19
Conflicts of Interest	18	Describe any conflicts of interest within the study team and how these were managed.	18

From: Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Devane D, et al. (2016) Core Outcome Set–STAndards for Reporting: The COS-STAR Statement. PLoS Med 13(10): e1002148. https://doi.org/10.1371/journal.pmed.1002148

Supplemental File 3. List of 53 papers identified from the umbrella review

	Authors	Year	Title	Journal	Vol	Issue
1	Alvarez-Bueno, C., Pesce, C., Cavero-Redondo, I., Sanchez-Lopez, M., Garrido-Miguel, M., Martinez-Vizcaino, V.	2017	Academic achievement and physical activity: A meta-analysis	Pediatrics	140	6
2	Amani, M., Djazayery, A., Majdzadeh, R., Taghdisi, M. H., Jazayeri, S.	2015	Effect of school-based interventions to control childhood obesity: A review of reviews	International Journal of Preventive Medicine		
3	Barbosa Filho, V. C., Minatto, G., Mota, J. Silva, K. S., de Campos, W., Lopes, A. D. S.	2016	Promoting physical activity for children and adolescents in low- and middle-income countries: An umbrella systematic review. A review on promoting physical activity in LMIC	Preventive Medicine	88	
4	Barr-Anderson, D. J., Auyoung, M., Whitt-Glover, M. C., Glenn, B. A., Yancey, A. K.	2011	Integration of short bouts of physical activity into organizational routine: A systematic review of the literature	American Journal of Preventive Medicine	40	1
5	Bedard, C., St John, L., Bremer, E., Graham, J. D., Cairney, J.	2019	A systematic review and meta-analysis on the effects of physically active classrooms on educational and enjoyment outcomes in school age children	PLoS ONE	14	6
6	Bleich, S. N., Vercammen, K. A., Zatz, L. Y. Frelier, J. M., Ebbeling, C. B., Peeters, A.	2018	Interventions to prevent global childhood overweight and obesity: a systematic review	The Lancet Diabetes and Endocrinology	6	4
7	Borde, R., Smith, J. J., Sutherland, R., Nathan, N., Lubans, D. R.	2017	Methodological considerations and impact of school-based interventions on objectively measured physical activity in adolescents: a systematic review and meta-analysis	Obesity Reviews	18	4
8	Brown, T., Moore, T. H. M., Hooper, L., Gao, Y., Zayegh, A., Ijaz, S., Elwenspoek, M., Foxen, S. C., Magee, L., O'Malley, C. et al.,	2019	Interventions for preventing obesity in children	Cochrane Database of Systematic Reviews		7

Supplemental File 2. continued

9	Brown, T., Summerbell, C.	2009	Systematic review of school-based interventions that focus on changing dietary intake and physical activity levels to prevent childhood obesity: An update to the obesity guidance produced by the National Institute for Health and Clinical Excellence	Obesity Reviews	10	1
10	Burns, Ryan D., Brusseau, Timothy A., Fu, You	2018	Moderators of School-Based Physical Activity Interventions on Cardiorespiratory Endurance in Primary School-Aged Children: A Meta-Regression	International Journal of environmental research and public health	15	8
11	Burns, R. D., Fu, Y., Podlog, L. W.	2017	School-based physical activity interventions and physical activity enjoyment: A meta-analysis	Preventive Medicine	103	
12	Cai, L., Wu, Y., Cheskin, L. J., Wilson, R. F., Wang, Y.	2014	Effect of childhood obesity prevention programmes on blood lipids: A systematic review and meta-analysis	Obesity Reviews	15	12
13	Campbell, K., Waters, E., O'Meara, S., Kelly, S., Summerbell, C	2002	Interventions for preventing obesity in children	Cochrane database of systematic reviews (Online)		2
14	Cesa, C. C., Sbruzzi, G., Ribeiro, R. A., Barbiero, S. M., de Oliveira Petkowicz, R., Eibel, B., Machado, N. B., Marques, R. D. V. Tortato, G., dos Santos, T. J., Leiria, C., Schaan, B. D., Pellanda, L. C.	2014	Physical activity and cardiovascular risk factors in children: Meta-analysis of randomized clinical trials	Preventive Medicine	69	
15	Daly-Smith, AJ., Zwolinsky, S., McKenna, J., Tomporowski, PD., Defeyter, MA., Manley, A.	2018	Systematic review of acute physically active learning and classroom movement breaks on children's physical activity, cognition, academic performance and classroom behaviour: understanding critical design features	BMJ open sport & exercise medicine	4	1
16	de Greeff, J. W., Bosker, R. J., Oosterlaan, J., Visscher, C., Hartman, E.	2018	Effects of physical activity on executive functions, attention and academic performance in preadolescent children: a meta-analysis	Journal of Science and Medicine in Sport	21	5

Supplemental File 2. continued

17	Dobbins, M., Husson, H., Decorby, K., Larocca, R. L.	2013	School-based physical activity programs for promoting physical activity and fitness in children and adolescents aged 6 to 18	Cochrane Database of Systematic Reviews		2
18	Donnelly, J. E., Hillman, C. H., Castelli, D., Etnier, J. L., Lee, S., Tomporowski, P., Lambourne, K., Szabo-Reed, A. N.	2016	Physical Activity, Fitness, Cognitive Function, and Academic Achievement in Children: A Systematic Review	Medicine and science in sports and exercise	48	6
19	Engel, A. C., Broderick, C. R., van Doorn, N., Hardy, L. L., Parmenter, B. J.	2018	Exploring the Relationship Between Fundamental Motor Skill Interventions and Physical Activity Levels in Children: A Systematic Review and Meta-analysis	Sports medicine	48	8
20	Errisuriz, V. L., Golaszewski, N. M., Born, K., Bartholomew, J. B.	2018	Systematic review of physical education-based physical activity interventions among elementary school children	The Journal of Primary Prevention		
21	Feng, L., Wei, D. M., Lin, S. T., Maddison, R., Ni Mhurchu, C., Jiang, Y., Gao, Y., Wang, H. J.	2017	Systematic review and meta-analysis of school-based obesity interventions in mainland China	PLoS ONE	12	9
22	Friedrich, R. R., Schuch, I., Wagner, M. B.	2012	Effect of interventions on the body mass index of school-age students	Revista de Saude Publica	46	3
23	Guerra, P. H., Nobre, M. R. C., da Silveira, J. A. C., de Aguiar Carrazedo Taddei, J. A.	2013	The effect of school-based physical activity interventions on body mass index: A meta-analysis of randomized trials	Clinics	68	9
24	Harris, K. C., Kuramoto, L. K., Schulzer, M., Retallack, J. E.	2009	Effect of school-based physical activity interventions on body mass index in children: A meta-analysis	CMAJ	180	7
25	Hung, L. S., Tidwell, D. K., Hall, M. E., Lee, M. L., Briley, C. A., Hunt, B. P.	2015	A meta-analysis of school-based obesity prevention programs demonstrates limited efficacy of decreasing childhood obesity	Nutrition Research	35	3
26	Johnstone, A., Hughes, A. R., Martin, A., Reilly, J. J.	2018	Utilising active play interventions to promote physical activity and improve fundamental movement skills in children: a systematic review and meta-analysis	BMC public health	18	1

Supplemental File 2. continued

27	Jones, M., Defever, E., Letsinger, A., Steele, J., Mackintosh, K. A.	2019	A mixed-studies systematic review and meta-analysis of school-based interventions to promote physical activity and/or reduce sedentary time in children	Journal of Sport and Health Science		
28	Kriemler, S., Meyer, U., Martin, E., van Sluijs, E. M., Andersen, L. B., Martin, B. W.	2011	Effect of school-based interventions on physical activity and fitness in children and adolescents: a review of reviews and systematic update	British journal of sports medicine	45	11
29	Kropski, J. A., Keckley, P. H., Jensen, G. L.	2008	School-based obesity prevention programs: An evidence-based review	Obesity	16	5
30	Lai, S. K., Costigan, S. A., Morgan, P. J., Lubans, D. R., Stodden, D. F., Salmon, J., Barnett, L. M.	2014	Do school-based interventions focusing on physical activity, fitness, or fundamental movement skill competency produce a sustained impact in these outcomes in children and adolescents? A systematic review of follow-up studies	Sports medicine	44	1
31	Lavelle, H. V., MacKay, D. F., Pell, J. P.	2012	Systematic review and meta-analysis of school-based interventions to reduce body mass index	Journal of Public Health	34	3
32	Love, R., Adams, J., van Sluijs, E. M. F.	2019	Are school-based physical activity interventions effective and equitable? A meta-analysis of cluster randomized controlled trials with accelerometer-assessed activity	Obesity Reviews	20	6
33	Lubans, D., Richards, J., Hillman, C., Faulkner, G., Beauchamp, M., Nilsson, M., Kelly, P., Smith, J., Raine, L., Biddle, S.	2016	Physical activity for cognitive and mental health in youth: A systematic review of mechanisms	Pediatrics	138	3
34	McDonald, SM., Clennin, MN., Pate, RR.	2018	Specific Strategies for Promotion of Physical Activity in Kids-Which Ones Work? A Systematic Review of the Literature	American journal of lifestyle medicine	12	1
35	Mei, H., Xing, Y., Xie, S., Guo, S., Li, Y., Guo, B., Zhang, J.	2016	The impact of long-term school-based physical activity interventions on body mass index of primary school children - a meta-analysis of randomized controlled trials	BMC public health	16	

Supplemental File 2. continued

36	Minatto, G., Barbosa Filho, V. C., Berria, J., Petroski, E. L.	2016	School-Based Interventions to Improve Cardiorespiratory Fitness in Adolescents: Systematic Review with Meta-analysis	Sports medicine	46	9
37	Mura, G., Rocha, N. B. F., Helmich, I., Budde, H., Machado, S., Wegner, M., Nardi, A. E., Arias-Carrion, O., Vellante, M., Baum, A., Guicciardi, M., Patten, S. B., Carta, M. G.	2015	Physical activity interventions in schools for improving lifestyle in European countries	Clinical Practice and Epidemiology in Mental Health	11	Supplement 1
38	Norris, E., Shelton, N., Dunsmuir, S., Duke-Williams, O., Stamatakis, E.	2015	Physically active lessons as physical activity and educational interventions: A systematic review of methods and results	Preventive Medicine	72	
39	Pozuelo-Carrascosa, D. P., Cavero-Redondo, I., Herraiz-Adillo, A., Diez-Fernandez, A., Sanchez-Lopez, M., Martinez-Vizcaino, V.	2018	School-based exercise programs and cardiometabolic risk factors: A meta-analysis	Pediatrics	142	5
40	Pozuelo-Carrascosa, D. P., Garcia-Hermoso, A., Alvarez-Bueno, C., Sanchez-Lopez, M., Martinez-Vizcaino, V.	2018	Effectiveness of school-based physical activity programmes on cardiorespiratory fitness in children: a meta-analysis of randomised controlled trials	British journal of sports medicine	52	19
41	Ribeiro, I. C., Parra, D. C., Hoehner, C. M., Soares, J., Torres, A., Pratt, M., Legetic, B., Malta, D. C., Matsudo, V., Ramos, L. R., Simoes, E. J., Brownson, R. C.	2010	School-based physical education programs: evidence-based physical activity interventions for youth in Latin America	Global health promotion	17	2
42	Saraf, DS., Nongkynrih, BP., Chandrakant, SG., Sanjeev, KS., Bela, K., Suresh, K., Krishnan, A.	2012	A systematic review of school-based interventions to prevent risk factors associated with noncommunicable diseases	Asia-Pacific Journal of Public Health	24	5
43	Shirley, K., Rutfield, R., Hall, N., Fedor, N., McCaughey, V. K., Zajac, K.	2015	Combinations of obesity prevention strategies in US elementary schools: a critical review	The journal of primary prevention	36	1
44	Sullivan, R. A., Kuzel, A. H., Vaandering, M. E., Chen, W.	2017	The Association of Physical Activity and Academic Behavior: A Systematic Review	The Journal of school health	87	5

Supplemental File 2. continued

45	Summerbell, C. D., Waters, E., Edmunds, L. D., Kelly, S., Brown, T., Campbell, K. J.	2005	Interventions for preventing obesity in children	Cochrane database of systematic reviews (Online)		3
46	Sun, C., Pezic, A., Tikellis, G., Ponsonby, A. L., Wake, M., Carlin, J. B., Cleland, V., Dwyer, T.	2013	Effects of school-based interventions for direct delivery of physical activity on fitness and cardiometabolic markers in children and adolescents: A systematic review of randomized controlled trials	Obesity Reviews	14	10
47	Uijtdewilligen, L., Waters, C. N., Muller-Riemenschneider, F., Lim, Y. W.	2016	Preventing childhood obesity in Asia: an overview of intervention programmes	Obesity Reviews	17	11
48	Van Sluijs, E. M. F., McMinn, A. M., Griffin, S. J.	2007	Effectiveness of interventions to promote physical activity in children and adolescents: Systematic review of controlled trials	British Medical Journal	335	7622
49	Verrotti, A., Penta, L., Zenzeri, L., Agostinelli, S., De Feo, P.	2014	Childhood obesity: prevention and strategies of intervention. A systematic review of school-based interventions in primary schools	Molecular Diagnosis and Therapy	37	12
50	Verstraeten, R., Roberfroid, D., Lachat, C., Leroy, J. L., Holdsworth, M., Maes, L., Kolsteren, P. W.	2012	Effectiveness of preventive school-based obesity interventions in low- and middle-income countries: A systematic review	American Journal of Clinical Nutrition	96	2
51	Wang, Y., Wu, Y., Wilson, RF., Bleich, S., Cheskin, L., Weston, C., Showell, N., Fawole, O., Lau, B., Segal, J	2013	Childhood Obesity Prevention Programs: Comparative Effectiveness Review and Meta-Analysis	Agency for Healthcare Research and Quality (US)		
52	Waters, E., de Silva-Sanigorski, A., Burford, B. J., Brown, T., Campbell, K. J., Gao, Y., Armstrong, R., Prosser, L., Summerbell, C. D.	2011	Interventions for preventing obesity in children	Cochrane Database of Systematic Reviews		12
53	Watson, A., Timperio, A., Brown, H., Best, K., Hesketh, K. D.	2017	Effect of classroom-based physical activity interventions on academic and physical activity outcomes: A systematic review and meta-analysis	International Journal of Behavioral Nutrition and Physical Activity	14	1

Supplemental File 4. Stakeholder meeting: outcomes included and dropped after review of the Delphi survey results and children's views

Domain	Outcome	Included/dropped for final core outcome set
Physical activity and health	Diet (varied and balanced)[1]	Kept
	Energy[2]	Kept
	Fitness[2]	Kept
	Heart rate[2]	Dropped
	Weight[2]	Dropped
	Muscle strength[2]	Dropped
	Sleep (number of hours)[1]	Kept
	Intensity of physical activity	*Included after discussion*
Social and emotional health	Anxiety[1]	Kept
	Depression[1]	Kept
	Enjoyment[1]	Kept
	Happiness[1,2]	Kept
	Mood[2]	Dropped
	Self-confidence[1]	Dropped
	Self-esteem[1]	Kept
	Stress[1,2]	Kept
	Wellbeing[1]	Kept
Educational performance	Attention[1]	Dropped
	Concentration[1]	Kept
	Focus[1]	Kept

[1]Outcomes that met the threshold criteria in the Delphi survey

[2]Outcomes identified important by children

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Developing a core outcome set for physical activity interventions in primary schools: a modified-Delphi study

Bina Ram,*[1] Kimberley A Foley,[1] Esther MF van Sluijs,[2] Dougal S Hargreaves,[1,3] Russell Viner,[4] Sonia Saxena[1]

[1]Department of Primary Care and Public Health, Imperial College London, London, UK

[2]MRC Epidemiology Unit School of Clinical Medicine, Cambridge Biomedical Campus, University of Cambridge, Cambridge, UK

[3]Mohn Centre for Children's Health and Wellbeing, Imperial College London, School of Public Health, London, UK

[4]Population, Policy and Practice Research Programme, UCL Great Ormond Street Institute of Child Health, London, UK

*Corresponding author: Dr Bina Ram | b.ram@imperial.ac.uk | 020 875940979 | @DrBinaRam

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ABSTRACT

Objectives To develop a core outcome set for physical activity interventions in primary schools.

Design Modified-Delphi.

Setting UK and international.

Participants 104 participants from four stakeholder groups (educators, public health professionals, health researchers, parents); 16 children (aged 8-9 years) from one London primary school.

Interventions Physical activity interventions.

Methods Four-stage process: (1) outcomes extracted from relevant studies identified from an umbrella review, and a focus group; (2) list of outcomes produced and domains established; (3) stakeholders completed a 2-round Delphi survey by rating (Round 1) and re-rating (Round 2) each outcome on a 9-point Likert scale from 'not important' to 'critical'; a ≥70% participant threshold identified the outcomes rated 'critical' to measure, and outcomes important to children were identified through a workshop; (4) a stakeholder meeting to achieve consensus of the outcomes to include in the core outcome set.

Results Seventy-four studies were extracted from 53 reviews. A list of 50 outcomes was produced and three domains established: 'physical activity and health' (16 outcomes), 'social and emotional health' (22 outcomes), and 'educational performance' (12 outcomes). 104 participants completed survey Round 1; 65 participants completed both rounds. Thirteen outcomes met the threshold; children identified 8 outcomes. Fourteen outcomes achieved consensus to produce the core outcome set; five outcomes for physical activity and health (diet [varied and balanced], energy, fitness, intensity of physical activity, sleep [number of hours]); seven for social and emotional health (anxiety, depression, enjoyment, happiness,

self-esteem, stress, wellbeing); and two outcomes for educational performance (concentration, focus).

Conclusions We have developed the first core outcome set for physical activity interventions in primary schools in consultation with those interested in the development and application of an agreed standardised set of outcomes. Future studies including these outcomes will reduce heterogeneity across studies.

Registration Core Outcome Measures in Effectiveness Trials (COMET) Initiative:1322.

Keywords Core outcome set, physical activity, interventions, primary schools, modified-Delphi

ARTICLE SUMMARY

Strengths and limitations of this study

- First core outcome set developed for physical activity interventions in primary schools
- Developed in consultation with participants from key stakeholder groups
- Uses robust methodology as recommended by the Core Outcome Measures in Effectiveness in Trials (COMET) Initiative
- Unbalanced number of participants in each stakeholder group
- Low representation of international participants may limit the use to UK schools only

INTRODUCTION

Increasing children's physical activity is a global health goal given the vast evidence showing benefits on physical, social, mental, and cognitive health outcomes.[1] Health behaviours may become embedded in childhood; providing opportunities for children to engage in physical activities during the primary school years, may lead to physically active lifestyles and improved health during adolescence and adulthood.[2] Many governments support the need for increased physical activity promotion in schools.[3] The World Health Organisation (WHO) recommends that schools should organise and promote opportunities for children to regularly participate in physical activities.[4]

School settings are ideal as they have the potential to reach the majority of children across society[5, 6] including those living in poverty. Socio-economic inequalities have been associated with moderate, and vigorous physical activity and may contribute to widening health inequalities.[7] Targeting schools therefore could help towards reducing the gap in physical activity among children.[7, 8] As a result of governments and the WHO recommendations of physical activity promotion and engagement in schools, there are many physical activity interventions that are implemented. However, the interventions vary in design. Some interventions integrate additional physical education classes alongside compulsory physical education lessons,[9] whilst some may incorporate 10 minutes of physical activity into every school day.[10] There are also others which implement classroom movement breaks[11] or active mile interventions.[12, 13]

There is considerable evidence showing the benefits of physical activity interventions in schools successfully increasing children's fitness,[14-17] and reducing sedentary time[18, 19] There is also increasing evidence of improvements to children's social, emotional, and

cognitive outcomes.[20-23] However, due to the heterogeneity of the outcomes assessed across studies, definitive conclusions are challenging.[20, 22] For example, to assess children's emotional health, one study may measure children's 'happiness', whilst another may measure 'depression'. Both these outcomes are conceptually different and difficult to compare. In 2013, a Cochrane review of 44 randomised control trials of physical activity interventions in schools for children aged 6 to 18 years found considerable variations in the outcomes measured, and the results could not be synthesised to establish intervention effects.[24] The review was updated in 2021; the authors concluded that due to the variability of results, heterogeneity and risk of bias across studies, the impacts of physical activity interventions in schools have shown small effects. These interventions may show small improvements to children's physical fitness but have little or no impact on other outcomes such as Body Mass Index (BMI).[25]

Synthesising results from studies are likely to be of interest to a number of key groups including public health professionals, teachers, parents, health care researchers, and policy makers. However, many of the outcomes measured in existing studies, although important to measure, may vary in relevance to specific groups. For example, (BMI) is a frequently measured outcome from which important conclusions have been identified.[26, 27] BMI may be considered highly important to health care practitioners but may not be considered as important to teachers who may instead place higher importance on cognitive outcomes. Lack of consultation with key groups when deciding which outcomes to measure in studies limits the relevance of findings to specific groups and may has possibly led to differences of outcomes measured across studies, thus preventing comparisons.

A Core Outcome Set (COS) is an agreed set of standardised outcomes in a specific research area that are recommended to measure and report.[28] These sets should be developed in consultation with those who are interested in the development and application of an agreed set of outcomes.[29] The COS should be viewed as a minimum to measure and does not restrict additional outcomes of interest to be assessed. COS's were originally developed for clinical trials but are increasingly being used in other study designs, e.g., in observational studies by practitioners and researchers to conduct their own assessments of interventions.[28] To our knowledge, there is not a COS for physical activity interventions in primary schools. Therefore the development of a COS (the aim of this study), would contribute to this field of research by identifying the key outcomes to be studied, allowing for evidence synthesis to better understand the impact of physical activity interventions in schools on children's health.

METHODS

Design

The protocol for this work has been published (Supplemental File 1);[30] it was developed in accordance with the Core Outcome Measures in Effectiveness Trials (COMET) criteria.[29] Our study was prospectively registered with COMET (registration number 1322).[31] We used a modified-Delphi method consisting of four-stages to develop the COS (Figure 1). First, we extracted outcomes and how they had been defined/described by the authors of relevant studies identified through an umbrella review and through a focus group with our Steering Committee (our Steering Committee includes health professionals, health researchers, academics, and sports representatives from organisations such as Sport England and The Daily Mile Foundation). Second, after de-duplication and combining similar outcomes we created a long list and established domains determined by the outcomes.

Third, we recruited participants from four key stakeholder groups (educators, health researchers, public health professionals, and parents of children aged from 5 to 11 years) to complete a two-round Delphi survey. We also obtained children's views of what is important to them through a workshop. Fourth, we held a stakeholder meeting to achieve consensus on the outcomes to be included in the COS. We report the study following the Core Outcome Set–STAndards for Reporting: The COS-STAR checklist (Supplemental File 2).[32]

Stage 1: Extraction of outcomes

For the umbrella review, we searched six databases (MEDLINE, EMBASE, PsycINFO, CINAHL, CENTRAL and the Cochrane Database of Systematic Reviews). Keywords used for the search were 'school', 'physical activity', 'exercise', 'physical education', 'fitness', 'energy expenditure' and adapted to use database specific filters, i.e., subject headings or medical subject headings (MeSH). Reviews were limited to systematic reviews, meta-analyses or meta-syntheses, and those published between 1990 and 2019. Single relevant studies from these reviews were identified from which the outcomes extracted. We also held a focus group with our Steering Committee and used a nominal group technique to brainstorm outcomes and rate their importance to extract further outcomes that may not have been captured in our literature review. Descriptions of each outcome were guided by the published literature and discussions with our Steering Group.

Stage 2: List of outcomes and establishing domains

We removed duplicate outcomes and merged those that were closely related, for example, outcomes of 'light physical activity', 'moderate physical activity', and 'vigorous physical activity' were combined into 'intensity of physical activity', to create a long list of outcomes. Descriptions were generated for each outcome based on those provided by authors of the

relevant studies and discussions with our Steering Committee. Guided by the outcomes and descriptions, we established relevant domains by grouping similar outcomes that captured a broader concept.

Stage 3: Stakeholder recruitment, Delphi surveys and children's workshop

The purpose of the Delphi surveys was to identify which outcomes, from the long list we produced, were considered the most important to measure across key stakeholder groups.

Stakeholder recruitment

Through emails to our public health research and practitioner networks, and through snowballing and social media, we recruited participants from four key stakeholder groups (educators [teachers, head teachers, school governors], health researchers, public health professionals, and parents of primary school-aged children). These key stakeholder groups were agreed among our Steering Group of those that would be the most interested in the development and implementation of an agreed set of outcomes to enhance this field of research. An information leaflet was made available to participants which included an electronic link to the Round 1 Delphi survey and study contact details. Through the Round 1 survey link, we obtained consent for participation, followed by participants registering their details (name and email address) and indicating which of the four stakeholder groups they identified with.

Delphi surveys

Using DelphiManager software,[33] we listed the outcomes with their descriptions by each domain in a Delphi survey conducted over two rounds (Round 1 took place during June 2020, and Round 2 in August 2020). Using the pre-defined Delphi Survey guidelines[33] we asked participants to rate the importance of each outcome using a 9-point Likert scale ranging from 'not important to measure' to 'critical to measure' in Round 1. A rating of 10

could be indicated if participants felt they were unable to score an outcome. Ratings were grouped into three categories: 'not important to measure' (ratings of 1, 2, or 3); 'important but not critical to measure' (ratings of 4, 5,or 6); and 'critical to measure' (ratings of 7, 8 or 9). In addition, participants were asked to suggest any other outcomes that they felt were not captured. In line with our protocol, if more than two individual participants suggested the same additional outcome, this would be included in Round 2 for all participants to rate. For ratings in Round 2, participants were provided with feedback of Round 1 ratings categorised by stakeholder group, and an option to re-rate their initial ratings based on this feedback. Participants were sent three email reminders to complete Round 1; those who rated all outcomes in Round 1 were invited to complete Round 2. The criteria for outcomes considered most important to measure for each domain after Round 2 were defined *a priori,* ≥70% of all participants rating an outcome 'critical' and 15% or less rating it 'not important'.[30] None of the outcomes were removed between rounds.

Children's workshop

We recruited primary school children to take part in a workshop in December 2020 with consent obtained from parents via the school. Due to Covid-19, our access to schools was restricted. We partnered with one primary school in Greater London, UK. Guided by the list of outcomes, we engaged the children in a series of activities and discussions on physical activity and elicited the children's views on what they thought was important to measure.

Stage 4: Stakeholder meeting

Participants who completed both survey rounds were invited to attend the stakeholder meeting in December 2020. Due to Covid-19 restrictions, the meeting was held virtually using the Zoom platform and we adapted the voting method (70%/15% threshold) as described in our protocol. Instead, to achieve consensus on the outcomes to be included in

the COS, we led discussions around the ratings of outcomes in the Delphi surveys and children's views. We used the Zoom chat function for participants to indicate the most important outcomes and further discussion to agree the outcomes to be included in the COS.

PATIENT AND PUBLIC INVOLVEMENT

We have consulted with professional and public representatives within our Steering Committee and as part of The Daily Mile Research Advisory Group. Both groups include public health professionals, health researchers, academic researchers, and representatives from The Daily Mile Foundation, Sport England, London Marathon, and London Sport. Our COS has been developed in consultation with educators, health researchers, public health professionals, parents and children through focus groups and workshops. We will widely advertise our COS through those involved in the development, and also to child public health policy makers through our research networks.

RESULTS

Stage 1: Extraction of outcomes

Our umbrella review identified 53 relevant papers from which 74 individual studies were extracted (Supplemental File 3); around 181 outcomes were identified from these studies. However, we identified variations across studies of how the outcomes were defined or described if at all. The Steering Committee focus group identified 34 outcomes. We created the description for each outcome guided by the literature and from discussions with our Steering Group.

Stage 2: List of outcomes and establishing domains

The final list consisted of 50 outcomes (Table 1) representing three domains: (1) physical activity and health (16 outcomes); (2) social and emotional health (22 outcomes); and (3) educational performance (12 outcomes) . Two outcomes, 'sleep' and 'diet' were included in two domains as authors agreed that these outcomes in particular could be both a 'physical activity and health' and a 'social and emotional health' outcome. For example, sleep defined as number of hours slept as recommended for children was included in the physical activity and health domain, whilst sleep times/ patterns/broken sleep was included in the social and emotional health domain. Similarly for the outcome of diet, eating well-balanced meals was included in the physical activity and health domain whilst appetite was included in the social and emotional health domain (see Table 1 for descriptions).

247 Table 1. List of 50 outcomes and their descriptions by domain, and the number of studies from which the outcomes were extracted

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Domain	Outcomes measured	Description[1]	Studies[2]
1: Physical activity and health	Active travel	To get to and from school, for example, walking, public transport i.e., train/tube/bus (do not include car, van, motorcycle), cycling, scooter	FG*
	Anthropometry[a]	Weight, height, body mass index (BMI) body fat, body mass, waist circumference	34
	Blood lipids	Fatty substances found in the blood (i.e., cholesterol, triglycerides) which increase the risk of heart attack	2
	Blood pressure	The force at which your heart pumps blood around your body and the resistance to the blood flow in the blood vessels	2
	Diet	Varied and balanced diet including fruit and vegetables	FG*
	Energy levels / expenditure	The amount of energy needed to carry out physical functions such as breathing, exercising or digesting food	5
	Fitness	Being fit and healthy for optimal health and overall wellbeing	16
	Heart rate	Number of beats per minutes (BPM) to establish normal resting heart rate, high or low heart rate	5
	Intensity of physical activity	Includes light activity (i.e., taking a stroll); moderate activity (i.e., cycling / swimming at regular pace, sweeping, washing windows); and vigorous activity (i.e., aerobics, running, fast cycling, climbing stairs)	42
	Leisure time activity	Time spent in activity for leisure during the day (i.e., walking in the park, playing sports with friends/family)	FG*
	Motor skills	Skills that require using large muscles of the arms/legs/torso, i.e., standing, walking, going up and down stairs, running, swimming, jumping, skipping, leaping, kicking	8
	Musculoskeletal	Bone strength, bone mineral density, muscle[b]	8
	Peak oxygen intake	The maximal rate at which oxygen can be used by the body during maximal work	1
	Sedentary time	Time spent sitting at desk, reading, sitting or lying down to watch television	7
	Sleep	Between approximately 10 to 12 hours per night	FG*
	Step counts	Number of steps taken in a day	13
2:	Anxiety	Persistent feeling of worry, fear or nervousness	FG*

Social and emotional	Appetite	Eating well and regularly	FG*
	Body awareness	The ability to recognize one's body moves helping to understand how to relate to objects and people at home, at school and outdoors	1
	Body image	The perception one has of their physical self	1
	Depression	Feeling persistently sad for more than a few days	FG*
	Empowerment	Feeling a sense of becoming stronger and more confident	FG*
	Enjoyment	Taking pleasure in doing something	3
	Happiness	Feeling a sense of joy and contentment	FG*

Table 1 continued

	Mood	A state of mind or a feeling such as happy, sad, cheerful or angry	FG*
	Peer support	Using one's own experiences to help others	1
	Resilience	The ability to recover quickly from difficulties	FG*
	Satisfaction	A sense of fulfilling a need, desire or appetite	FG*
	Self-confidence	A feeling of trust in one's abilities, qualities, and judgment	FG*
	Self-efficacy	A person's belief of their capacity to perform behaviours necessary to produce specific performance attainments	2
	Self-esteem	A factor that influences people's choices and decisions which results in them either taking or not taking care of themselves and explore their full potential	1
	Self-expression	The communication of one's personality, feelings, or opinions	FG*
	Self-perception	Attitudes towards own preferences and behaviour	1
	Sickness	Feeling unwell, nauseous, dizzy	FG*
	Sleep patterns	Sleep patterns /achieving less than recommended (10-12 hours) / broken sleep	FG*
	Social interaction	An exchange between two or more people	FG*
	Stress	Feeling under pressure or threatened	FG*

	Wellbeing	Feeling well, happy, healthy and ability to manage stress	FG*
3: Educational performance	Academic performance	Measurement of a child's achievement over a range of academic subjects	20
	Attention	Taking notice of someone or something	6
	Classroom behaviour	How children are acting in the classroom in response to what is going on or present around them	15
	Cognitive development / function	How children think, explore and figure things out	6
	Concentration	Ability to focus on task	16
	Engagement	The degree of attention, curiosity, interest, optimism, and passion that children show when they are learning or being taught	5
	Executive functioning	A set of mental skills including working memory, flexible thinking, and self-control to apply to everyday learning, work, and daily life	4
	Focus	Ability to concentrate and not easily distracted	16
	Maths	The study of numbers, shapes and patterns	16
	Reading	A cognitive process that involves decoding symbols to arrive at meaning, the primary purpose of which is to understand the text	8

Table 1 continued

	Working memory / inhibition	A cognitive system with a limited capacity that can hold information temporarily and is important for reasoning, decision-making and behaviour	6
	Writing	A form of communication to express language using symbols; being able to understand grammar, punctuation, spelling, and vocabulary	5

[1]Descriptions were guided by the published literature and our Steering Group.

[2]From the 74 studies identified from the 53 relevant reviews

*FG = outcome identified by our Focus Group (Steering Group)

[a]Anthropometry was presented as 'Bio-impedance' to participants. Changed to 'Anthropometry' based on reviewer suggestions.

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[b]'Muscle' was not included in the original description presented to participants . This was added based on reviewer suggestions.

Stage 3: Stakeholder recruitment, Delphi surveys and children's workshop

Stakeholder recruitment

A total of 104 participants consented and registered their details. Ninety (87%) completed Round 1 in full of whom 65 (72%) also completed Round 2 in full. The 65 participants included 16 (25%) educators, 24 (37%) researchers, 13 (20%) public health professionals, and 12 (18%) parents, and represented 9 countries: UK (80%), Brazil (6%), Korea (5%), Australia, France, Netherlands, Romania, Spain, and Taiwan (all 2%).

Delphi surveys

Thirteen outcomes met the ≥70% participant critical threshold: sleep (number of hours), and diet (varied and balanced) in 'physical activity and health'; happiness, wellbeing, anxiety, self-esteem, depression, self-confidence, enjoyment, and stress in 'social and emotional health'; and concentration, attention, and focus in 'educational performance' (Table 2). In Round 1, a further 29 outcomes were suggested, but after internal discussions, it was agreed that 16 of the suggestions overlapped with the outcomes that were listed in the survey, and the remaining 13 were proposed by only one participant and therefore not carried forward to Round 2. Mean Round 1 ratings between participants completing Round 2 were similar to those who did not complete Round 2 (6.33, SD 2.08 vs 6.48, SD 1.95 respectively) suggesting those who did not complete Round 2 would have scored similarly to those who did.

Table 2. Outcomes rated 'not important' and 'critical' to measure after Delphi survey Round 2 (n=60)

Domain	Outcome	% of participants rating outcomes 'not important'	% of participants rating outcomes 'critical'
1.	Active travel	3%	51%

	Anthropometry[1]	15%	26%
	Blood lipids	32%	14%
	Blood pressure	28%	14%
	Diet (varied and balanced)*	3%	71%*
	Energy	8%	26%
	Fitness	0%	60%
	Heart rate	20%	17%
	Intensity of physical activity	3%	63%
	Leisure time activity	3%	62%
	Motor skills	8%	46%
	Musculoskeletal	12%	20%
	Oxygen peak intake	29%	9%
	Sedentary time	3%	63%
h y	Sleep (number of hours)*	3%	85%*
	Step counts	12%	23%

278 **Table 2. Continued**

	Anxiety*	0%	78%*
	Appetite	8%	42%
	Body awareness	2%	46%
	Body image	2%	66%
	Depression	3%	74%
	Empowerment	2%	42%
	Enjoyment*	0%	74%*
	Happiness*	0%	85%*
	Mood	0%	51%
	Peer support	0%	46%
	Resilience	3%	55%
	Satisfaction	2%	46%
	Self-confidence*	0%	74%*
	Self-efficacy	2%	68%
	Self-esteem*	0%	75%*
	Self-expression	8%	34%
	Self-perception	2%	51%
	Sickness	12%	40%
	Sleep patterns	3%	69%
	Social interaction	0%	65%
	Stress	0%	72%*
2. Social and emotional health	Wellbeing*	0%	85%*

3. Educational performance	Academic performance	2%	57%
	Attention*	0*	74%*
	Classroom behaviour	2%	68%
	Cognition	2%	54%
	Concentration*	0%	75%*
	Engagement	0%	69%
	Executive functioning	2%	46%
	Focus*	3%	72%*
	Maths	8%	55%
	Memory	2%	48%
	Reading	8%	51%
	Writing	8%	48%

*Ratings that met the threshold (≤15% agreement of the outcome rated 'not important' and >70% agreement of the outcome rated 'critical' to measure.

[1] Anthropometry was presented as 'Bio-impedance' to the participants. This was changed based on reviewer comments.

Children's workshop

Sixteen children aged 8 to 9 years took part in the workshop; 50% girls; 13% Caucasian, 56% Asian, and 31% Black; 6% had Special Educational Needs and 75% had English as a second language. The children identified eight outcomes important to measure: five in 'physical activity and health' (energy, fitness, heart rate, muscle strength, and weight), and three in 'social and emotional health' (happiness, mood, and stress). Interestingly, children did not associate physical activity with any educational performance related outcomes.

Stage 4: Stakeholder meeting

Thirteen participants attended (2 educators, 2 parents and 9 researchers). Participants expressed that they had expected more outcomes under the domain of physical activity and health to be rated critical, i.e., intensity of physical activity which had been rated critical by 63% (Table 2). Through discussion, agreement was reached that this outcome is important to measure be able to assess sustainability of physical activity interventions in schools. After

review of the outcomes identified critical in the survey and the outcomes considered important to children, six outcomes were dropped and the additional outcome of intensity of physical activity was included (Supplemental File 4). Therefore, a total of 14 outcomes reached consensus for the COS: diet (varied and balanced), fitness, intensity of physical activity, and sleep (number of hours) in the physical activity and health domain; anxiety, depression, enjoyment, happiness, self-esteem, stress, and wellbeing in social and emotional health domain; and concentration, and focus in the domain of educational performance (Table 3). We sent the agreed set of outcomes for review to the stakeholders unable to attend the meeting. The wider group approved the COS.

Table 3. Core outcome set for physical activity interventions in primary schools

Domain	Outcome
Physical activity and health	Diet (varied and balanced)
	Energy
	Fitness
	Intensity of physical activity
	Sleep (number of hours)
Social and emotional health	Anxiety
	Depression
	Enjoyment
	Happiness
	Self-esteem
	Stress
	Wellbeing
Educational performance	Concentration
	Focus

DISCUSSION

We have developed the first COS for physical activity interventions in primary schools. By using robust consensus methods and multi-disciplinary stakeholder groups, we have

achieved consensus on the outcomes considered important to measure. Implementation of this COS in future studies will reduce heterogeneity between studies allowing for evidence synthesis and will also be relevant to wider audiences.

During the consensus meeting, it was noted that the survey identified only two outcomes (sleep and diet) in the domain of physical activity and health as critical to measure whilst the outcomes 'physical activity intensity' and 'fitness' did not meet the threshold. Outcomes that may fit under this domain include moderate physical activity, vigorous physical activity, moderate to vigorous physical activity and heart rate, which are more commonly studied but these did not meet the critical threshold in our survey. This potentially reflects the heterogeneity across studies of the outcomes that should be measured under broader concepts. As discussed in our consensus meeting, the underrepresentation of outcomes rated critically important in the physical activity domain may have been due to the specificity of outcomes listed. For example researchers agree that physical activity should be measured but do not agree on which specific outcome to measure. This would explain the wide variation of physical activity outcomes that were identified from the published literature. Physical activity can have many benefits beyond measuring its impact on particular health or clinical outcomes. Therefore our participants agreed that measuring physical activity is important and should be included.

In the published literature, we found only 10 studies which measured outcomes that related to mental health, yet all our stakeholders placed critical importance on many of the outcomes under the domain of social and emotional health. These findings may be explained by the growing awareness of poor mental health in children and the growing evidence base of

associations between increased physical and better mental health. The importance placed on mental health perhaps indicates a shift in focus from measuring physiological outcomes and towards measuring mental health when assessing physical activity interventions in primary schools. This may allow health professionals/researchers/teachers/parents to be able tackle better mental health in childhood which may lead to better mental health in adolescence and adulthood. These findings further support the need for a COS in this field. Our study has provided a better understanding that to achieve better overall health and wellbeing in children, both physical and mental health are important to measure. Functional precursors of performance-related outcomes (concentration, attention, and focus) met the critical threshold than actual educational attainment outcomes of reading, writing, and maths which are more commonly assessed in previous studies and by schools. A possible explanation for this is that to improve educational attainment, physical activity interventions need to help to improve cognition (i.e., concentration, focus). These interventions may therefore have an indirect effect on improving reading, writing and maths by improving cognition. Schools provide children with learning a range of subjects. However, if increased physical activity in schools enhance children's learning by improving their physical and mental health, this will likely increase the acceptability of physical activity interventions in schools. This may therefore generate a greater interest from schools to implement these interventions.

Although we are not aware of another COS that specifically evaluates interventions aimed at increasing children's physical activity in primary schools or other settings such as in the community, there are several existing frameworks for assessing these interventions. A systematic review by Cassar et al. (2019) identified 14 frameworks applied across 27

papers[34] which included RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance),[35] Ecological framework for understanding effective implementation,[36] Multilevel implementation quality framework,[37] and A Conceptual Framework for Implementation.[38] The review found that the frameworks were primarily used for interpreting results and analyses rather than being used as a planning tool for outcomes to be measured or for understanding results.[34] Another review by Damschroder et al. (2009) also found little evidence that frameworks for school-based physical activity interventions were used to guide the data collection.[39] Findings from these reviews imply that the frameworks to assess these interventions provide little emphasis on the planning of what should be measured and perhaps explains the heterogeneity of outcomes measured to date. A study by McKay and colleagues (2019), prioritised a list of frameworks to improve the quality and consistency of implementing interventions to ensure that interventions are effectively delivered to achieve population level benefits.[40] COS's should be used to inform the choice of outcomes[41] and our COS contributes to an important gap in these frameworks and can add to them by providing a guide on the minimum set of outcomes to measure in future studies of physical activity interventions in primary schools. It is important to note however that the existing research from physical activity intervention studies has enabled important findings of outcomes that are more commonly measured such as BMI [42] and physical activity[43] and have allowed for a better understanding of the impacts of these interventions on these outcomes. But any COS's currently being developed are mainly centred around childhood obesity [44-46] which is complex; tackling childhood obesity requires comprehensive, multicomponent strategies. Developing COS's require the need to consider the aims and scale of the intervention, the population groups being targeted, and the needs of the stakeholders. Our COS, focussed on physical activity interventions in

primary schools, developed in consultation with those who would benefit the most to better understand intervention effects, should be considered as part of a set of tools for wider improvement of health in primary schools.

Our study's strengths include we have developed the first COS for physical activity interventions in primary schools, to our knowledge, and used robust methodology as recommended by the COMET to capture a wide range of outcomes to reach consensus. Our inclusion of participants from four key stakeholder groups representing nine countries, as well as incorporating views of children, ensures the relevance of outcomes to measure for the target population. We also ensured that the domains were not pre-determined. We instead established the domains led by the list of outcomes and their descriptions thus avoiding any researcher bias. However, there are limitations to our study. The descriptions of each outcome were guided by the published literature. We had found variations in how the outcomes were described across studies. This resulted in our descriptions for each outcome either being a definition, suggestion, implying a positively directed relationship, or a combination of these. Further research is needed to identify neutral descriptions of outcomes. The low attendance of participants in our consensus meeting which did not include a representation for the educators stakeholder group, may have possibly limited further discussions of the outcomes that should be included in the COS. However, the final list of outcomes was circulated to all the participants who completed both rounds of the Delphi survey and an opportunity to comment further was provided before the final outcome set was agreed. As we recruited participants through several methods including advertising on our research network websites and through snowballing, we are not aware of how many potential participants were targeted for our research and did not participate. Although our

participants represented nine countries, most were UK based. The educators and health researcher stakeholder groups included participants from five countries whilst participants from two countries represented the public health professional and parent groups. All stakeholder groups had a UK participant representation between 71% and 95%. The outcomes identified from our umbrella review were not limited to UK based studies, but the lower proportion of participants representing other countries and in each stakeholder group, may have prevented the identification of other outcomes that may be more relevant. Other countries and cultures may differ in the importance placed on physical activity in schools and may focus on other aspects such as educational attainment. This may bias our COS towards outcomes relevant to UK audiences. Covid-19 restrictions limited our reach to primary schools and year groups to target for our workshops; children from different year groups may have considered additional or fewer outcomes important. In addition, our representation of children with English as a second language was much higher (75%) than the average number of children with English as a second language in London primary schools (48%).[47] The development of our COS during the Covid-19 pandemic may have influenced our findings. It has been widely reported that school closures and restrictions have reduced opportunities for children to be physically active and has increased poorer mental health.[48, 49] This may perhaps explain the higher number of outcomes in the domain of social and emotional health that met the threshold in our surveys. Finally, it may be challenging for future studies to include all 14 outcomes identified in our COS. However, as our outcomes have been grouped into three main domains, researchers may choose to include the outcomes within the domain of interest.

The development of our COS is timely; several interventions that have been implemented in schools in recent year may have stopped due to Covid-19. These interventions are likely to resume and may be more important to assess now due the negative impacts the pandemic has had on children's physical activity and mental health. Our COS would be relevant to future studies assessing the impact of physical activity interventions in primary schools such as The Daily Mile, a popular active mile intervention reaching 1 in 5 state-funded primary schools in England,[50] and recommended by England's National Obesity Plan.[51] Despite its reach, the evidence of its impact remains limited or inconsistent.[52-55]

Our COS would benefit from identifying the best assessment tools to measure the outcomes that are readily available to those implementing physical activity interventions in schools. COMET suggests that a COS use should first aim to establish which outcomes are important to measure, and then aim to identify which assessment tools would be the most accessible for end users.[56] There is a low uptake of COS's in randomised control trials due to lack of recommendations of valid measures, lack of involvement of key stakeholders, and those implementing or assessing interventions not being aware of a COS in their field of research.[56] Our next step is to identify assessment tools that are readily available to measure the outcomes in our COS. Recommendations of assessment tools would further enhance the quality and consistency of results in studies using our COS.

Prevention and public health approaches in early life to reduce health inequalities and improve health of the whole population may be a better investment than treating disease in the population that generally arises later in life.[57, 58] The robust processes that we have applied in this study could be repeated to inform an adolescent (young people aged 12 to 17

years) focussed COS. Physical activity is low among the secondary school population[59] and poorer mental health is also increasing among this age group.[60] We recommend that our COS is included as part of a wider set of tools and frameworks that should be developed to standardise the outcomes to measure other areas of children and young people's health such as weight and nutrition.[61] This would allow for improved health to continue during adolescence and adulthood.

CONCLUSION

Our COS identifies the outcomes that are most important to measure for studies of physical activity interventions in primary schools. Next, we aim to identify the assessment tools to measure these outcomes. Wide use of our COS in future studies will reduce heterogeneity allowing for evidence synthesis to better understand intervention effects on children's health and cognition during the primary school years.

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Competing Interests

SS and BR received funding from The Daily Mile Foundation. SS, BR, and KF are members of The Daily Mile Research Advisory Group. All other authors declare no competing interests.

Author Contributions

KF, SS and BR conceived and designed the study. BR and KF designed study materials. BR was responsible for managing all components of the study including recruitment, data

collection and analyses. SS, EvS, DH and RV advised on the project. BR wrote the first draft of the manuscript. All authors contributed to redrafts and approved the final manuscript.

Ethics and Consent

This study was approved by Imperial College London Research Ethics Committee (19IC5428). All participants provided informed consent to take part in the development of this COS and individual responses have remained anonymous. Those named under the acknowledgements have provided consent for their names to be published.

Data Sharing

The data are stored at Imperial College London and will be made available upon request by email to the corresponding author.

Disclaimer

The funders had no role in the analyses or results of this study. The views expressed in this publication are those of the authors and not necessarily those of the NIHR School for Public Health Research, NIHR Northwest London Applied Research Collaboration, the Department of Health and Social Care, Department for Education, or The Daily Mile Foundation.

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Figures

Figure 1. Process for developing a core outcome set

Supplementary Material

Supplemental File 1. Study Protocol

Supplemental File 2. COS-STAR Reporting Checklist

Supplemental File 3. List of the 74 studies extracted from the relevant reviews

Supplemental File 4. Outcomes included and dropped after review

ORCiD

Bina Ram	0000-0003-0023-1573
Kimberley A Foley	0000-0003-3664-8100
Esther MF van Sluijs	0000-0001-9141-9082
Dougal S Hargreaves	0000-0003-0722-9847
Russell Viner	0000-0003-3047-2247
Sonia Saxena	0000-0003-3787-2083

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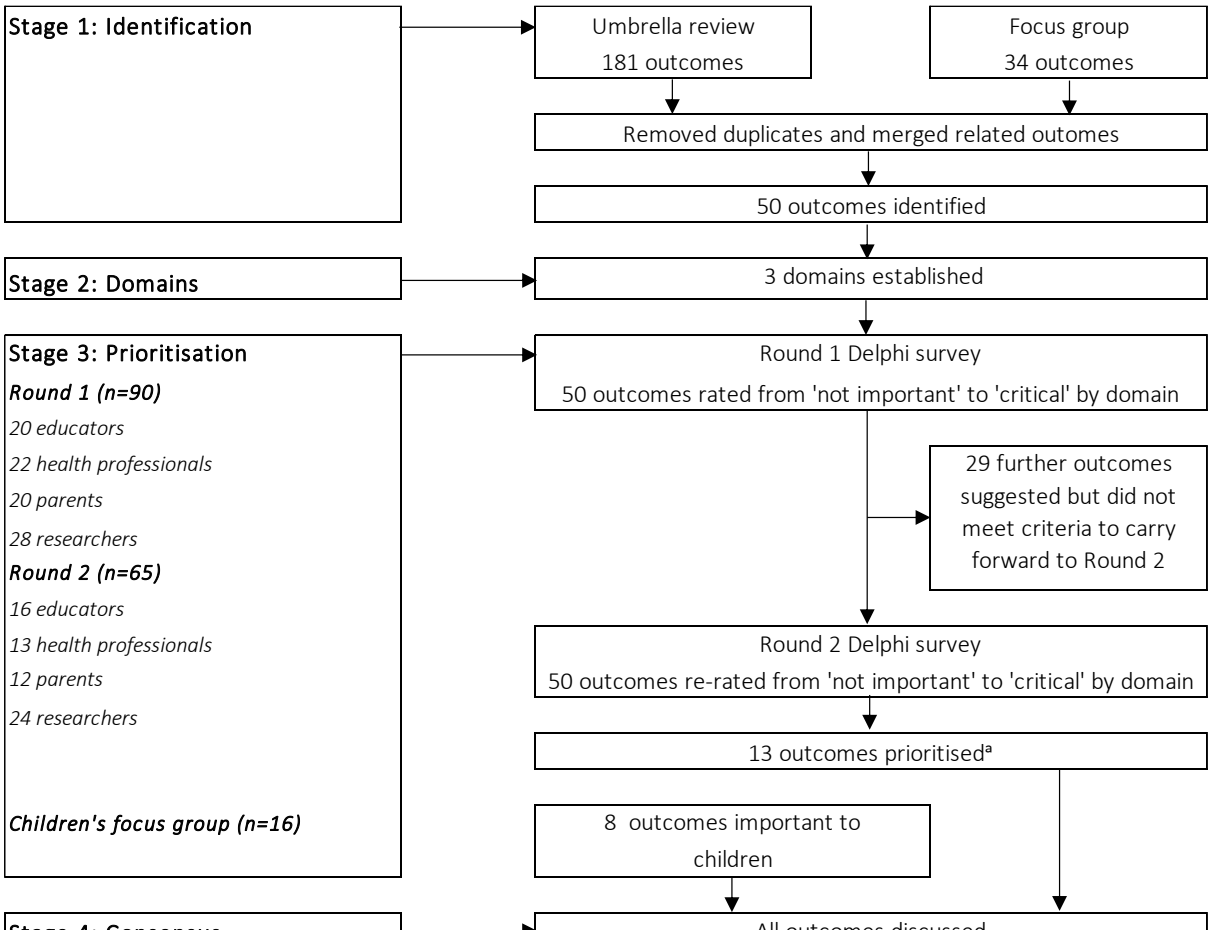
Figure 1. Process for developing a core outcome set for physical activity interventions in primary schools



Open access Protocol

BMJ Open

Protocol for developing a core outcome set for evaluating school-based physical activity interventions in primary schools

Kimberley A Foley ,[1] Tishya Venkatraman ,[1] Bina Ram ,[1] Louisa Ells ,[2] Esther van Sluijs ,[3] Dougal S Hargreaves ,[1] Felix Greaves ,[1,4] Mansour Taghavi Azar Sharabiani ,[1] Russell M Viner ,[5] Alex Bottle ,[1] Sonia Saxena [1]

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[1]Department of Primary Care and Public Health, Imperial College London, London, UK
[2]Centre for Public Health Research, Teesside University, Middlesbrough, UK
[3]MRC Epidemiology Unit, University of Cambridge, Cambridge, UK
[4]Science and Strategic Information, Public Health England, London, UK
[5]Population, Policy and Practice Research Programme, UCL Institute of Child Health, London, UK

Correspondence to
Professor Sonia Saxena;
s.saxena@imperial.ac.uk

ABSTRACT

Introduction Primary school-based physical activity interventions, such as The Daily Mile initiative, have the potential to increase children's physical activity levels over time, which is associated with a variety of health benefits. Comparing interventions or combining results of several studies of a single intervention is challenging because previous studies have examined different outcomes or used different measures that are not feasible or relevant for researchers in school settings. The development and implementation of a core outcome set (COS) for primary school-based physical activity interventions would ensure outcomes important to those involved in implementing and evaluating interventions are standardised.

Methods and analysis Our aim is to develop a COS for studies of school-based physical activity interventions. We will achieve this by undertaking a four-stage process:(1) identify a list of outcomes assessed in studies through a systematic review of international literature; (2) establish domains from these outcomes to produce questionnaire items; (3) prioritise outcomes through a two-stage Delphi survey with four key stakeholder groups (researchers, public health professionals, educators and parents), where stakeholders rate the importance of each outcome on a 9-point Likert scale (consensus that the outcomes should be included in the COS will be determined as 70% or more of all stakeholders scoring the outcome 7%–9% and 15% or less scoring 1 to 3); (4) achieve consensus on a final COS in face-to-face meetings with a sample of stakeholders and primary school children.

Ethics and dissemination We have received ethical approval from Imperial College London (ref: 19IC5428). The results of this study will be disseminated via conference presentations/public health meetings, peer-reviewed publications and through appropriate media channels.

Trial registration number Core Outcome Measures in Effectiveness Trials Initiative (COMET) number: 1322.

Strengths and limitations of this study

- To our knowledge, this will be the first core outcome set developed to evaluate school-based physical activity interventions in primary schools, which will improve evidence synthesis in this field.
- The study will use a robust four-stage process including a modified Delphi technique, to incorporate multidisciplinary stakeholder perspectives, including researchers, public health professionals, educators (ie, head teachers, teachers and school governors), parents and primary school children.
- The stakeholders are drawn from an international pool and a systematic literature review of international literature.
- A limitation of this study is that primary school children are considered too young to participate in the Delphi survey rounds. To ensure we capture children's perspectives, we will conduct a separate face-to-face meeting and their views will be considered at the final stage.

INTRODUCTION

Regular physical activity in children and young people is associated with physical and mental health benefits including musculoskeletal fitness and lower risk of depression, obesity and diabetes.[1 2] A growing evidence base also suggests physical activity improves sleep duration, cognition[3] and academic performance.[4 5] Hence, current guidelines from the WHO recommend 60 minutes of moderate-to-vigorous physical activity every day for children.[6] However, in high-income countries, only one in five children and young people are meeting these physical activity targets.[7] Several school-based physical activity (SBPA) interventions have been developed and implemented to increase children's activity levels. A Cochrane review of 44 randomised controlled trials of SBPA interventions for children aged 6–18 years found nine different outcome domains and concluded that additional research on the long-term impact of these interventions is needed.[8]

Active mile initiatives, such as The Daily Mile, which involves 15 minutes of self-paced physical activity,[9] are encouraged by governments of several European countries. Policy

makers in the United Kingdom (UK) are now promoting and incentivising their implementation in primary schools (children aged 4–11 years).[10] However, the evidence base of their effectiveness is limited. Previous studies, although promising, have been small scale, and examine different outcomes using different measuring tools that are not practical for follow-up over long periods (eg, physical activity measured by accelerometers which only capture a specific period of physical activity pattern).[11 12] It is also unclear which outcomes are most relevant for those involved in implementing and evaluating interventions.

A core outcome set (COSs) is an agreed standardised set of outcomes indicating what should be reported.[13] The outcomes must be measurable and relevant for researchers and other key stakeholders. Core outcome sets were originally developed for clinical trials, but increasingly been developed and used in other areas.[14] A COS specifies a minimum set of outcomes assessed in all studies, but is flexible to allow the inclusion of additional outcomes into any particular study.[13] To our knowledge, there is not a COS that exists for the evaluation of primary school-based physical activity interventions. Therefore, there is a need to develop a COS to ensure that the same outcomes are being measured to allow for the direct comparison of school-based physical activity interventions across studies.

AIMS AND OBJECTIVES

The aim of this study is to identify a COS for primary school-based physical activity interventions over time. This study will focus on what should be measured, and we will assess 'how' to measure each core outcome.

Study objectives include:

1. To develop a list of potential outcomes relevant to evaluating primary school-based physical activity interventions over time.
2. To prioritise outcomes of whole-school physical activity important to relevant stakeholders including professionals and researchers.
3. To achieve consensus on a minimum set of relevant outcomes for primary school-based physical activity interventions (ie, COS).

METHODS

Steering group

We have formed a steering group for this project, including healthcare professionals and researchers to guide the development of this COS. We have recruited members representing different disciples and expertise including health professionals and researchers with methodological expertise in epidemiology, statistics and consensus methods. We have also identified a study management group within the steering committee to conduct day-to-day management of the study. We consulted with this committee to identify core principles that we should apply when identifying our set of core outcomes. This group determined that outcomes should be feasible for use in large-scale studies and should be both valid and reliable.

Modified Delphi

The study design uses a modified Delphi technique (the RAND/UCLA appropriateness method) to identify a set of core outcomes.[15] This technique has previously been used in the development of a COS across a variety of clinical and research contexts.[16 17] The modified Delphi process involves four stages:

1. Identifying a list of outcomes from systematic literature reviews.
2. Reduction of the list into domains for questionnaire items.
3. Prioritisation through a Delphi survey involving two rounds of questionnaires and incorporation of additional outcomes nominated by stakeholders
4. Face-to-face consensus meetings to agree a final core set with stakeholders.

Stage 1: systematic literature review

We will conduct a comprehensive umbrella review of systematic reviews and meta-analyses to identify a list of outcomes relevant to school-based physical activity interventions. The process of this systematic review has been registered with PROSPERO (CRD42019146621).[18] To identify reviews, we will search MEDLINE, EMBASE, CINAHL, CENTRAL, PsycINFO and the Cochrane Database of Systematic Reviews, restricting our search to include English language only and articles published since 1990. A detailed search strategy for each database is included in online supplementary appendix A. We will also aim to include relevant papers from the grey literature and in particular, we will review the Standard Evaluation Framework for Physical Activity Interventions[19] and the DAPA (diet, anthropometry, and physical activity) measurement toolkit.[20]

We will compile studies in EndNote software and remove duplicates. Two authors will independently conduct title/abstract screening to identify eligible systematic reviews or meta-analyses. Disagreements will be resolved by discussion, or as needed, by discussion with a third author. Title and abstract screening will be followed by full-text screening. For inclusion, eligible reviews will describe physical activity interventions or processes targeted at primary school children (aged 4–11 years). All types of study designs will be included. We will exclude any studies that are not in English, focus primarily on adolescents or young adults or those that are aimed at a particular subpopulation of children as these studies would not be generalisable to the whole school population. We will use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to document the number of articles included and excluded during the searches.[21]

Once the systematic reviews are identified, we will conduct a quality assessment of the reviews using the Critical Appraisal Skills Programme (CASP)[22] tool; low-quality reviews will be excluded. We will search the included studies

from each review. As we are interested in studying physical activity interventions delivered in a 'real-world' setting, we will apply additional eligibility criteria to the studies selected from within each review. Eligible studies must include a longitudinal study design (as they may include more relevant outcomes of interest) but we will not limit the duration of the intervention, and outcomes must be applicable to primary school children (approximately 4–11 years). In addition, we will limit studies to those conducted in the last three decades. To ensure we capture all relevant papers, we will identify additional relevant studies by screening the reference list for each eligible study included. Again, this search will be performed by two study authors with disagreements resolved by discussion or through consultation with a third author.

Outcomes will be identified from the methods and results section of each paper. For each outcome, the following data will be extracted: study characteristics (eg, author(s), year, country and sample size), study population (eg, number of participants, target age, ethnic groups), how the outcomes were defined, the time points for measurement and intervention duration, the measurement tool used and whether it was validated, any reliability information (eg, test–retest reliability), and any methods used to enhance quality of outcome measurement (eg, measured twice). If the tool was validated, we will record details of the population used for validation (eg, age and country of children). All data extraction will be completed by one study author but 10% of the papers will be done by a second author to check consistency. Disagreements will be resolved by discussion or by consultation with a third author, as required.

Stage 2: establishing domains for questionnaire items

The domains for questionnaire items will be established by grouping similar outcomes that capture a broader concept.[23 24] Domains will be identified independently by two researchers and a small number of stakeholders in discussion with a third senior researcher if there are discrepancies. The shortlisted domains will form candidate outcomes as questionnaire items in plain English for all stakeholder groups. The questionnaire will be designed and piloted with input from lay representatives to ensure its understanding and acceptability.

Stage 3: prioritisation of outcomes through a Delphi survey

Delphi Survey: round 1

The first round of the modified Delphi process will involve surveying stakeholders to prioritise each of the outcomes identified from the literature search through an anonymous Delphi survey. The advantages of this method include the low costs and avoidance of influence from strong voices in group-based decision-making. Following guidance in the literature,[25] we aim to recruit approximately 60 participants; around 15 members each representing four key stakeholder groups: (1) researchers, (2) health professionals, (3) educators, that is, school teachers, head teachers, school governors, and (4) parents. By ensuring heterogeneity in overall group composition it may help to identify outcomes that would be otherwise overlooked.[13 26 27] Through our research networks, colleagues and through public health social media platforms, we will create a sampling frame of potential stakeholders to invite. In addition, we will ensure that teachers, head teachers, and school governors represent schools that are and are not taking part in SBPA interventions. We will use snowballing methods to identify further panel members and we aim to include adult panel members with a range of expertise and from different countries who are able to write and understand English. Due to the complexity of the survey rounds, we felt it would be inappropriate to include primary school children at this stage of the COS development. Instead we will include children aged 7–11 years in a face-to-face meeting (stage 4) to learn about what is important to them, and ensure their views are represented in this study. This age range reflects the age of children in primary school where children have an understanding of the improtance of physical activity.

We will invite each potential panel member by email to participate in this study. We will obtain informed consent from all participants who agree to take part, and provide them with information about the entire Delphi process and the importance of participating in all rounds of the study.[27] Recruitment of panel members will continue until we have a minimum of 12 and a maximum of 20 from each stakeholder group.[25]

We will send each participant a survey by email which they will be asked to complete within 3 weeks of receipt. Participants will be required to rate the importance of each outcome using a 9-point Likert scale ranging from 0 'not that important' to 9 'critical'. They will also be asked to suggest any additional outcomes not included in survey. All surveys will be completed online. We will send two reminder emails to encourage responses (one at the end of week 2 and one at the end of week 3 allowing for one more week to complete the survey).

All survey results will be reviewed to identify missing data, possible outliers and the range of response options used. For each outcome, the distribution of scores will be generated and the median score calculated. We will calculate these separately for each stakeholder group.

Additional outcomes suggested by at least two participants will be reviewed by the study team. If there is disagreement about whether a new suggested outcome is unique that cannot be resolved by discussion, they will consult with a third team member. New outcomes will be added to the survey for round 2 of the Delphi. All outcomes included in round 1 of the survey will be retained for the second round of the Delphi survey.

Delphi survey: round 2

We will contact all participants who complete round 1 of the survey to complete round 2. The round 2 survey will include feedback from round 1 showing their scores compared with other participants in their own stakeholder group and other groups.[28] In the round 2 survey,

we will ask participants to re-rate the importance of each outcome and any new outcomes. After this round, we will conduct analyses to determine consensus. Consensus that the outcome should be included in the COS will be determined as 70% or more of all panel members scoring the outcome 7%–9% and 15% or less scoring 1%–3%. Consensus that the outcome should NOT be included in the COS will be 70% or more of all panel members scoring the outcome 1%–3% and 15% or less scoring 7%–9%.[14] We will divide the outcomes list into three groups: consensus that it should be included in the COS, consensus that it should be excluded and no consensus reached. Outcomes that reach consensus for inclusion and those where no consensus was reached will be retained for discussion during the face-to-face meeting.

Stage 4: consensus meeting to agree a final core outcome set

The fourth stage of this Delphi process will consist of two face-to-face meetings to obtain consensus on the final core set. We will conduct one meeting with adult stakeholders, and a separate meeting with children. The meeting with children will be first and informed by the results of the Delphi survey. Through a day of activities and discussions led by a trained facilitator, we will learn about which outcomes are important to the children. Recruitment of children for the face-to-face meeting will involve an invitation letter sent to parents identified through the educators and parents (in the UK) participating in the questionnaire rounds. A child information leaflet will be also be included. We aim to include approximately 10–15 children aged from 7 to 11 years per school, inviting a minimum of two and a maximum of four schools. In total, we aim to include 20–60 children. Written parental consent and child assent will be obtained. As the meeting with children will involve a number of activities, it will not be possible to include children from other countries. However, the children will be recruited from UK schools representing those from urban and rural, and from deprived and non-deprived areas.

For the adult stakeholder meeting, a representative sample from each stakeholder group who have completed both rounds of the survey will be invited to attend. We aim to recruit at least one international member for each stakeholder group to join the face-to-face meeting. The meeting will be run by an independent facilitator who has experience of participatory research and one of the study researchers. We will present the results of the Delphi survey to the adult stakeholders invited to attend the face-to-face meeting (including at least one international participant representing each stakeholder group). We will present the ratings for each outcome from the Delphi surveys for each stakeholder group and overall alongside the outcomes deemed important to the children. Each stakeholder group will be asked to discuss the outcomes retained after survey round 2 and present their views back to the whole group. After the discussions, each participant will be issued with a unique keypad and asked to vote each outcome as 'include', 'exclude' or 'unsure'. All voting will be done simultaneously and individually without conferring. All participants will view the results of voting. Outcomes that are equivocal will be discussed as a group and each panel member will have a second chance to vote on these outcomes. The results will be compiled, and consensus ratings determined using the 70/15 criteria described earlier. The final list will be presented to the group for final discussion and comments. All items prioritised by the stakeholders from stage 4 will be included in the final COS for use in research in high-income countries.

Patient and public involvement

We obtained public involvement input from The Daily Mile Foundation and from participants of The Daily Mile Stakeholder Group. We obtained feedback and input on recruitment methods for research participants, incentives for survey participation and written and verbal feedback on recruitment materials. We will obtain further PPI input on the development and piloting of the Delphi survey.

PARTICIPANT CONSENT AND DISSEMINATION

We will obtain written consent from all adult stakeholders, and written parental consent and child assent for children to take part in the face-to-face meeting. All survey rounds will be conducted anonymously; participants will not be told who the other respondents are or what their specific responses were. Participants' contact information (names and emails) will be retained in accordance with Imperial College London's data collection, retention and storage policies. During the face-to-face meeting, participants will be aware of who the other panel members are, but where possible, individual responses will remain anonymous. To limit any adverse impact on school children during the face-to-face meeting, we will aim to make the materials and activities during the meeting interactive and enjoyable. The results of this study will be shared in conference presentations, public health meetings, and via appropriate media channels. We will publish the process of developing the COS in a peer-reviewed journal, and also publish the COS as a technical operating manual for relevant audiences. This study has also been registered with COMET and an update of the study results will be published on their website.

Twitter Alex Bottle @DrAlexBottle and Sonia Saxena @SoniaKSaxena

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Patient consent for publication Not required.

Ethics approval This study has received ethics approval from the Imperial College Research Ethics Committee (reference: 19IC5428).

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ORCID iDs
Kimberley A Foley http://orcid.org/0000-0003-3664-8100
Tishya Venkatraman https://orcid.org/0000-0001-6171-2384
Bina Ram https://orcid.org/0000-0003-0023-1573
Louisa Ells https://orcid.org/0000-0003-0559-4832
Esther van Sluijs https://orcid.org/0000-0001-9141-9082
Dougal S Hargreaves https://orcid.org/0000-0003-0722-9847
Felix Greaves https://orcid.org/0000-0001-9393-3122
Mansour Taghavi Azar Sharabiani http://orcid.org/0000-0003-3808-277X
Russell M Viner http://orcid.org/0000-0003-3047-2247
Alex Bottle https://orcid.org/0000-0001-9978-2011
Sonia Saxena http://orcid.org/0000-0003-3787-2083

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Supplemental File 2. Core Outcome Set–STAndards for Reporting: The COS-STAR checklist

SECTION/TOPIC	ITEM No.	CHECKLIST ITEM	REPORTED ON PAGE NUMBER
TITLE/ABSTRACT			
Title	1a	Identify in the title that the paper reports the development of a COS	1
Abstract	1b	Provide a structured summary	2
INTRODUCTION			
Background and Objectives	2a	Describe the background and explain the rationale for developing the COS.	4/5
	2b	Describe the specific objectives with reference to developing a COS.	5
Scope	3a	Describe the health condition(s) and population(s) covered by the COS.	5
	3b	Describe the intervention(s) covered by the COS.	4
	3c	Describe the setting(s) in which the COS is to be applied.	4/5
METHODS			
Protocol/Registry Entry	4	Indicate where the COS development protocol can be accessed, if available, and/or the study registration details.	5
Participants	5	Describe the rationale for stakeholder groups involved in the COS development process, eligibility criteria for participants from each group, and a description of how the individuals involved were identified.	6
Information Sources	6a	Describe the information sources used to identify an initial list of outcomes.	6
	6b	Describe how outcomes were dropped/combined, with reasons (if applicable).	6
Consensus Process	7	Describe how the consensus process was undertaken.	7
Outcome Scoring	8	Describe how outcomes were scored and how scores were summarised.	7
Consensus Definition	9a	Describe the consensus definition.	7
	9b	Describe the procedure for determining how outcomes were included or excluded from consideration during the consensus process.	6/7
Ethics and Consent	10	Provide a statement regarding the ethics and consent issues for the study.	20
RESULTS			
Protocol Deviations	11	Describe any changes from the protocol (if applicable), with reasons, and describe what impact these changes have on the results.	7
Participants	12	Present data on the number and relevant characteristics of the people involved at all stages of COS development.	11

Outcomes	13a	List all outcomes considered at the start of the consensus process.	9/10/11
	13b	Describe any new outcomes introduced and any outcomes dropped, with reasons, during the consensus process.	12
COS	14	List the outcomes in the final COS.	14
DISCUSSION			
Limitations	15	Discuss any limitations in the COS development process.	17/18
Conclusions	16	Provide an interpretation of the final COS in the context of other evidence, and implications for future research.	16
OTHER INFORMATION			
Funding	17	Describe sources of funding/role of funders.	20
Conflicts of Interest	18	Describe any conflicts of interest within the study team and how these were managed.	20

From: Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Devane D, et al. (2016) Core Outcome Set–STAndards for Reporting: The COS-STAR Statement. PLoS Med 13(10): e1002148. https://doi.org/10.1371/journal.pmed.1002148

Supplemental File 3. List of 74 studies extracted from the relevant reviews

	Author(s)	Year	Title	Journal
1	Ahamed Y., MacDonald H., Reed K., Naylor PJ,. Liu-Ambrose T., and McKay H.	2007	School-based physical activity does not compromise children's academic performance	Psychology and Behavioural Strategies (39(2):371-6)
2	Bryant ES., Duncan MJ., Birch SL., and James RS.	2016	Can fundamental movement skill mastery be increased via a six-week physical activity intervention to have positive effects on physical activity and physical self-perception?	Sports (16(4))
3	Cradock AL., Barrett JL., Carter J., McHugh A., Sproul J., Russon ET., et al.	2014	Impact of the Boston active school day policy to promote physical activity among children	American Journal of Health Promotion (28(3))
4	Crova C., Struzzolino I., Marchetti R., Masci I., Vannozzi G., Forte R., et al.	2014	Cognitive challenging physical activity benefits executive function in overweight children	Journal of Sports Science (32(3), 201-211)
5	Dalziell A., Boyle J., and Mutrie N.	2015	Better movers and thinkers (BMT): an exploratory study of innovative approach to physical education	Europe's Journal of Psychology (11(4), 722–741)
6	de Greef JW., Hartman E., Mullender-Wijnsma MJ., Bosker RJ., Doolard S., and Visscher C.	2016	Long-term effects of physically active academic lessons on physical fitness and executive functions in primary school children	Health Education Research (31:2), 185-194)
7	Donnelly JE., Greene JL., Gibson CA., Smith BK., Washburn RA., Sullivan DK., et al.	2009	Physical activity across the curriculum (PAAC): a randomised controlled trial to promote physical activity and diminish overweight and obesity in elementary school children	Preventative Medicine (49, 336-341)
8	Donnelly JE., Hillman CH., Greene JL., Hansen DM., Gibsone CA., Sullivan DK., et al.	2017	Physical activity and academic achievement across the curriculum: Results from a 3 year cluster randomised trial	Preventative Medicine (99, 140-145)
9	Drummy C., Murtagh EM., McKee DP., Breslin G., Davision GW., and Murphy MH.	2016	The effect of a classroom activity break on physical activity levels and adiposity in primary school children	Journal of Paediatrics and Child Health (52, 745–749)
10	Duncan MJ., Al-Nakeeb Y., and Nevill AM.	2009	Effects of a six-week circuit training intervention on body esteem and body mass index in British Primary school children	Body Image (6, 216-220)
11	Erwin H., Fedewa A, and Ahn S.	2013	Student Academic Performance Outcomes of a Classroom Physical Activity Intervention: A Pilot Study	International Electronic Journal of Elementary Education (5(2), 109-124)

Supplemental File 3 continued

12	Erwin HE., Beighle A., Morgan, CF., and Noland M.	2011	Effect of a low-cost, teacher-directed classroom intervention on elementary students physical activity	Journal of School Health (81(8), 455-461)
13	Erwin HE., Abel MG., Beighle A., and Beets MW.	2011	Promoting children's health through physically active math classes: a pilot study	Health Promotion Practice (12(2), 244-251)
14	Faigenbaum AD., Bush JA., McLoone RP., Kreckel MC., Farrell A., Ratamess NA., et al.	2015	Benefits of strength and skill based training during primary school and physical education	Journal of Strength and Conditioning Research (29(5), 1255-1262)
15	Fairclough SJ., McGrane B., Sanders G., Taylor S., Owen M., and Curry W.	2016	A non-equivalent group pilot trial of a school-based physical activity and fitness intervention for 10-11 year old English children: born to move	BMC Public Health (16:861)
16	Fedewa Al, Ahn S, and Erwin H.	2015	A randomised control design investigating the effects of classroom based physical activity on children's fluid intelligence and achievement	School Psychology International (36(2) 135-153)
17	Gallotta MC., Emerenziani GP., Iazzoni S., Meucci M., Baldari C., and Guidetti L.	2015	Impacts of coordinative training on normal weight and overweight/obese children's attentional performance	Frontiers in Human Neuroscience (9:577)
18	Goh, TL.	2017	Children's physical activity and on task behaviour following active academic lessons	Quest (69:2, 177-186)
19	Grieco LA., Jowers EM., Errisuriz VL., and Bartholomew JB.	2016	Physically active vs sedentary academic lessons: two exploratory studies	Preventative Medicine (89, 98-103)
20	Grieco LA., Jowers EM., Errisuriz VL., and Bartholomew JB.	2009	Physically active lessons and time on task: the moderating effect of body mass index	Medicine & Science in Sports & Exercise (41(10):1921-6)
21	Have M., Nielson JH., Ernst MT., Geji AK., Fredens K., Grontved A., et al.	2018	Classroom based physical activity improves children's math achievement- a randomised controlled trial	PLoS ONE (13:12)
22	Hill L., Williams JHG., Aucott L., Milne J., Thomson J., Greig J., et al.	2010	Exercising attention within the classroom	Developmental Medicine & Child Neurology (52(10):929-34)
23	Howie EK., Beets MW., and Pate RP.	2014	Acute classroom exercise breaks improve on task behaviour in 4th and 5th grade students: a dose-response	Mental Health and Physical Activity (7, 65-71)
24	Howie EK., Schatz J., and Pate RP.	2015	Acute effects of classroom exercise breaks on executive function and math performance: a dose response study	Research Quarterly for Exercise and Sport (86:3, 217-224)

Supplemental File 3 continued

25	Hraste M., Giorgio AD., Jelaska PM., Padulo J., and Granic I.	2018	When mathematics meets physical activity in the school aged child: The effects of an integrated motor and cognitive approach to learning geometry	PLoS ONE (13(8))
26	Klakk H., Chinapaw M., Heidemann M., Anderson LB., and Wedderkopp N.	2013	Effect of four additional physical education lessons on body composition in children aged 8- 13 years- a prospective study during two school years	BMC Pediatrics (13:170)
27	Lazaar N., Aucouturier J., Ratel S., Rance M., Meyer M., and Duche P.	2007	Effect of physical activity intervention on body composition in young children: influence of body mass index status and gender	Acta Pædiatrica (96, 1315–1320)
28	Li YP., Hu XQ., Schouten EG., Liu AL., Du SM., Li LZ., et al.	2010	Report on childhood obesity in China: effects and sustainability of physical activity intervention on body composition of Chinese youth	Biomedical and Environmental Sciences (23, 180-187)
29	Liu A., Hu X., Ma G, Cui Z., Pan Y., Chang S., et al.	2008	Evaluation of a classroom based physical activity promoting programme	Obesity Reviews (9 (Suppl. 1), 130–134)
30	Lucertini F., Spazzafumo L., De Lillo F., Centonze D., Valentini M., and Federici A.	2012	Effectiveness of professionally-guided physical education on fitness outcomes of primary school children	European Journal of Sports Science (13:5, 582-590)
31	Lucht M., and Heidig S.	2013	Applying HOPSCOTCH as an exer-learning game in English Lessons: two exploratory studies	Education Tech Research Dev (61: 762-792)
32	Ma JK., Le Mare L., and Gurd BJ.	2014	Classroom-based high intensity interval activity improves off-task behaviour in primary school students	Applied Physiology, Nutrition, and Metabolism (39: 1332-1337)
33	Ma JK., Le Mare L., and Gurd BJ.	2015	Four minutes of in-class high-intensity interval activity improves selective attention in 9 to 11 year olds	Applied Physiology, Nutrition, and Metabolism (40: 238-244)
34	Macdonald HM., Kontulainen SA., Khan KM., and McKay HA.	2007	Is a School-Based Physical Activity Intervention Effective for Increasing Tibial Bone Strength in Boys and Girls?	Journal of Bone and Mineral Research (22:3, 434-446)
35	Maeda JK., and Randall LM.	2003	Can academic success come from five minutes of physical activity?	Brock Education Journal (13:1)
36	Magnusson KT., Sigurgeirsson I., Sveinsson T., and Johannsson E.	2011	Assessment of a 2 year school based physical activity intervention among 7-9 year old children	International Journal of Behavioural Nutrition and Physical Activity (8:138)

Supplemental File 3 continued

37	Mahar MT., Murphy SK., Rowe DA., Golden J., Shields TA., and Raedeke TD.	2006	Effects of a classroom based program on physical activity and on-task behaviour	Medicine & Science in Sports & Exercise (38:12, 2086-2094)
38	Mavilidi MF., Lubans DR., Eather N., Morgan PJ and Riley N.	2018	Preliminary efficacy and feasibility of "Thinking While Moving in English": A program with physical activity integrated into primary school English lessons	Children (5:109)
39	McKay HA., MacLean L., Petiit M., Mackelvie-O'Brien K., Janssen P., Beck T., et al.	2005	"Bounce at the Bell": a novel program of short bouts of exercise improves proximal femur bone mass in early prepubertal children	Br J Sports Med (39: 521-526)
40	McKenzie T., Nader PR., Strikmiller PK., Yang M., Stone EJ., Perry CL., et al.	1996	School physical education: Effect of the child and adolescent trial for cardiovascular health	Preventative Medicine (25, 423-431)
41	Mead T., Scibora L., Gardner J., and Dunn S.	2016	The impact of stability balls, activity breaks, and a sedentary classroom on standardised math scores	The Physical Educator (73, 433-449)
42	Miller A., Christensen E., Eather N., Gray S., Sproule J., Keay J., et al.	2016	Can physical education and physical activity outcomes be developed simultaneously using a game-centred approach?	European Physical Education Review (22(1), 113-133)
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Supplemental File 3 continued

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Supplemental File 3 continued

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Supplemental File 3 continued

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Supplemental File 4. Stakeholder meeting: outcomes included and dropped after review of the Delphi survey results and children's views

Domain	Outcome	Included/dropped for final core outcome set
Physical activity and health	Diet (varied and balanced)[1]	Kept
	Energy[2]	Kept
	Fitness[2]	Kept
	Heart rate[2]	Dropped
	Weight[2]	Dropped
	Muscle strength[2]	Dropped
	Sleep (number of hours)[1]	Kept
	Intensity of physical activity	*Included after discussion*
Social and emotional health	Anxiety[1]	Kept
	Depression[1]	Kept
	Enjoyment[1]	Kept
	Happiness[1,2]	Kept
	Mood[2]	Dropped
	Self-confidence[1]	Dropped
	Self-esteem[1]	Kept
	Stress[1,2]	Kept
	Wellbeing[1]	Kept
Educational performance	Attention[1]	Dropped
	Concentration[1]	Kept
	Focus[1]	Kept

[1]Outcomes that met the threshold criteria in the Delphi survey

[2]Outcomes identified important by children