

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

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ABSTRACT

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

Design Modified-Delphi study.

Setting The UK and international.

Participants 104 participants from four stakeholder groups (educators, public health professionals, health researchers, parents); 16 children (aged 8–9 years) from 1 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 two-round Delphi survey by rating (Round 1) and re-rating (Round 2) each outcome on a nine-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; and (4) a stakeholder meeting to achieve consensus of the outcomes to include in the COS.

Results In total, 74 studies were extracted from 53 reviews. A list of 50 outcomes was produced and three domains were 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. In total, 13 outcomes met the threshold; children identified 8 outcomes. Fourteen outcomes achieved consensus to produce the COS: five outcomes for physical activity and health (diet (varied and balanced), energy, fitness, intensity of physical activity, sleep (number of hours)); seven outcomes for social and emotional health (anxiety, depression, enjoyment, happiness, self-esteem, stress, well-being); and two outcomes for educational performance (concentration, focus).

Conclusions We have developed the first COS 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.

Trial registration number Core Outcome Measures in Effectiveness Trials Initiative registration number 1322; Results.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is the first study to develop a core outcome set (COS) for physical activity interventions in primary schools.
- ⇒ The COS has been developed in consultation with participants from key stakeholder groups.
- ⇒ This study uses robust methodology as recommended by the Core Outcome Measures in Effectiveness in Trials Initiative.
- ⇒ There were an unbalanced number of participants in each stakeholder group.
- ⇒ The low representation of international participants may limit the use of this COS 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 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. Socioeconomic inequalities have been associated with moderate and vigorous physical activities 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

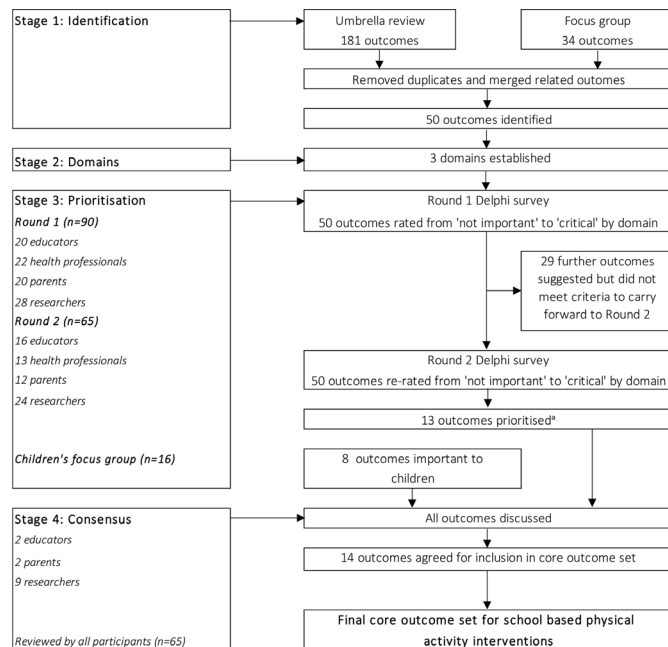


Figure 1 Process for developing a core outcome set for physical activity interventions in primary schools.

vary in design. Some interventions integrate additional physical education classes alongside compulsory physical education lessons,⁹ while some may incorporate 10 min of physical activity into every school day.¹⁰ There are also others which implement classroom movement breaks¹¹ 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', while 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 6–18 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, healthcare researchers and policymakers. 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 healthcare 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 have 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 is 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. COSs were originally developed for clinical trials but are increasingly being used in other study designs, for example, 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 in online supplemental file 1³⁰; it was developed in accordance with the Core Outcome Measures in Effectiveness Trials (COMET) criteria²⁹ and prospectively registered accordingly.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 deduplication 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 COS-STAndards for Reporting check-list (online 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' and 'energy expenditure' and adapted to use database specific filters, that is, subject headings or medical subject headings. Reviews were limited to systematic reviews, meta-analyses or meta-syntheses and those published between 1990 and 2019. 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). Through discussions with our steering group, we identified the key stakeholder groups 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 predefined Delphi survey guidelines,³³ we asked participants to rate the importance of each outcome using a nine-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 rerate 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, $\geq 70\%$ 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 policymakers through our research networks.

RESULTS

Stage 1: extraction of outcomes

Our umbrella review identified 53 relevant papers from which 74 individual studies were extracted (online 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, while 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, while appetite was included in the social and emotional health domain (see table 1 for descriptions).

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: the UK (80%), Brazil (6%) and Korea (5%), Australia, France, the Netherlands, Romania, Spain and Taiwan (2%).

Delphi surveys

In total, 13 outcomes met the >70% participant critical threshold: sleep (number of hours) and diet (varied

and balanced) in 'physical activity and health'; happiness, well-being, 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 of participants completing both Rounds were similar to those who completed Round 1 but 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.

Children's workshop

In total, 16 children aged 8–9 years took part in the workshop, of which 50% were girls; 13% were Caucasian, 56% were Asian and 31% were 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

In total, 13 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, that is, 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 to 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 (online 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 well-being 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.

DISCUSSION

We have developed the first COS for physical activity interventions in primary schools. By using robust consensus

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

Domain	Outcomes measured	Description*	Studies†	
1: Physical activity and health	Active travel	To get to and from school, for example, walking, public transport, that is, train/tube/bus (do not include car, van, motorcycle), cycling and scooter	FG‡	
	Anthropometry§	Weight, height, body mass index body fat, body mass and waist circumference	34	
	Blood lipids	Fatty substances found in the blood (ie, 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 well-being	16	
	Heart rate	Number of beats per minute to establish normal resting heart rate, high or low heart rate	5	
	Intensity of physical activity	Includes light activity (ie, taking a stroll); moderate activity (ie, cycling/swimming at regular pace, sweeping, washing windows); and vigorous activity (ie, aerobics, running, fast cycling, climbing stairs)	42	
	Leisure time activity	Time spent in activity for leisure during the day (ie, walking in the park, playing sports with friends/family)	FG‡	
	Motor skills	Skills that require using large muscles of the arms/legs/torso, that is, standing, walking, going up and down stairs, running, swimming, jumping, skipping, leaping and kicking	8	
	Musculoskeletal	Bone strength, bone mineral density and muscle¶	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	
2: Social and emotional health	Sleep	Between approximately 10–12 hours per night	FG‡	
	Step counts	Number of steps taken in a day	13	
	Anxiety	Persistent feeling of worry, fear or nervousness	FG‡	
	Appetite	Eating well and regularly	FG*	
	Body awareness	The ability to recognise 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‡	
				Continued

Table 1 Continued

Domain	Outcomes measured	Description*	Studies†
	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 judgement	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 and 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‡
	Well-being	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
	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

*Descriptions were guided by the published literature and our steering group.

†From the 74 studies identified from the 53 relevant reviews.

‡FG=outcome identified by our focus group (steering group).

§Anthropometry was presented as 'bioimpedance' to participants, changed to 'anthropometry' based on reviewer suggestions.

¶Muscle was not included in the original description presented to participants. This was added based on reviewer suggestions.

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

Domain	Outcome	Participants rating outcomes 'not important' %	Participants rating outcomes 'critical' %
1. Physical activity and health	Active travel	3	51
	Anthropometry*	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
	Sleep (number of hours)†	3	85†
	Step counts	12	23
	2. Social and emotional health	Anxiety†	0
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†	
Well-being†	0	85†	

Continued

Table 2 Continued

Domain	Outcome	Participants rating outcomes 'not important' %	Participants rating outcomes 'critical' %
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

*Anthropometry was presented as 'bioimpedance' to the participants. This was changed based on reviewer comments.
 †Ratings that met the threshold ($\leq 15\%$ agreement of the outcome rated 'not important' and $>70\%$ agreement of the outcome rated 'critical' to measure).

methods and multidisciplinary 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

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
Educational performance	Well-being
	Concentration
	Focus



the domain of physical activity and health as critical to measure, while 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 under-representation 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 it. 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 well-being 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 (ie, 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 enhances 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*³⁴ identified 14 frameworks applied across 27 papers³⁴ which included reach, effectiveness, adoption, implementation and maintenance framework,³⁵ ecological framework for understanding effective implementation,³⁶ multilevel implementation quality framework³⁷ 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*³⁹ 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 explain the heterogeneity of outcomes measured to date. A study by McKay *et al*⁴⁰ 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 COSs should be used to inform the choice of outcomes⁴¹ 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 BMI⁴² and physical activity⁴³ and have allowed for a better understanding of the impacts of these interventions on these outcomes. But any COSs currently being developed are mainly centred around childhood obesity⁴⁴⁻⁴⁶ which is complex; tackling childhood obesity requires comprehensive, multicomponent strategies. Developing COSs 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, focused on physical activity interventions in primary schools and 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 predetermined. 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, while 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 to 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 one in five 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 COSs 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 12–17 years) focused COS. Physical activity is low among the secondary school population⁵⁹ 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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Contributors KAF, SS and BR conceived and designed the study. BR and KAF designed study materials. BR was responsible for managing all components of the study including recruitment, data collection and analyses. SS, EvS, DSH and RMV advised on the project. BR wrote the first draft of the manuscript. All authors contributed to re-drafts and approved the final manuscript. The guarantor (SS) accepts full responsibility for the finished work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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Supplemental File 1. Study Protocol

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Protocol

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

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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.

INTRODUCTION

Regular physical activity in children and young people is associated with physical and mental health benefits including musculo-skeletal fitness and lower risk of depression, obesity and diabetes.^{1 2} A growing evidence base also suggests physical activity improves

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.

sleep duration, cognition³ 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

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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 disciplines 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 Interventions¹⁹ 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 importance 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,

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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.

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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.

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

Provenance and peer review Not commissioned; externally peer reviewed.

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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	Dalziel 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 AI, 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)
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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
	<i>Intensity of physical activity</i>	<i>Included after discussion</i>
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

¹Outcomes that met the threshold criteria in the Delphi survey

²Outcomes identified important by children