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DE-PASS Best Evidence Statement (BESt)

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BMJ Open DE-PASS Best Evidence Statement (BESt): modifiable determinants of physical activity and sedentary behaviour in children and adolescents aged 5-19 years-a protocol for systematic review and meta-analysis

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ABSTRACT

Introduction Physical activity among children and adolescents remains insufficient, despite the substantial efforts made by researchers and policymakers. Identifying and furthering our understanding of potential modifiable determinants of physical activity behaviour (PAB) and sedentary behaviour (SB) is crucial for the development of interventions that promote a shift from SB to PAB. The current protocol details the process through which a series of systematic literature reviews and metaanalyses (MAs) will be conducted to produce a bestevidence statement (BESt) and inform policymakers. The overall aim is to identify modifiable determinants that are associated with changes in PAB and SB in children and adolescents (aged 5-19 years) and to quantify their effect on, or association with, PAB/SB. Methods and analysis A search will be performed in MEDLINE, SportDiscus, Web of Science, PsychINFO and Cochrane Central Register of Controlled Trials. Randomised controlled trials (RCTs) and controlled trials (CTs) that investigate the effect of interventions

on PAB/SB and longitudinal studies that investigate the associations between modifiable determinants and PAB/SB at multiple time points will be sought. Risk of bias assessments will be performed using adapted versions of Cochrane's RoB V.2.0 and ROBINS-I tools for RCTs and CTs, respectively, and an adapted version of the National Institute of Health's tool for longitudinal studies. Data will be synthesised narratively and, where possible, MAs will be performed using frequentist and Bayesian statistics. Modifiable determinants will be discussed considering the settings in which they were investigated and the PAB/SB measurement methods used.

Ethics and dissemination No ethical approval is needed as no primary data will be collected. The findings will be disseminated in peer-reviewed publications and academic conferences where possible. The BESt will also be shared with policy makers within the DE-PASS consortium in the first instance.

Systematic review registration CRD42021282874.



STRENGTHS AND LIMITATIONS OF THIS STUDY

- Modifiable determinants will be summarised and described within the settings in which they were investigated to contextualise how they interact with other determinants and subsequently affect physical activity and sedentary behaviour in children and adolescents.
- The body of evidence from high-quality research will be summarised, accounting for differences in study designs, methodological quality and measurement methods of physical activity and sedentary behaviour of children and adolescents.
- Bayesian meta-analysis will be used in addition to frequentist metaanalysis to allow for assessment of the plausibility of the results and provide more nuanced conclusions regarding the effectiveness of physical activity and sedentary behaviour interventions in children and adolescents.
- Modifiable determinants reported in study designs which are not included in the current works may be overlooked and should be investigated in future reviews as they may provide insights into potentially effective interventions.
- ⇒ While our aim is to quantify the effect of modifiable determinants on physical activity and sedentary behaviour of children and adolescents, the analyses of most included studies might not permit the quantification, thus a narrative approach will be adopted.

INTRODUCTION

Physical inactivity among children and adolescents is a global public health issue. Four in five (81%) adolescents across the world do not meet the WHO's physical activity (PA) guidelines. ^{1 2} Physical inactivity is a contributing factor to the high prevalence of cardiovascular, metabolic and bone health-related conditions.³ Reducing levels of physical inactivity from a young age has a positive impact on physical and mental health as children and adolescents transition into adulthood. It is therefore important to promote physical activity behaviour (PAB) and minimise sedentary behaviour (SB) as part of a healthy lifestyle in children and adolescents to mitigate the negative effects of physical inactivity.⁵ In the global action plan on PA 2018-2030, the WHO adopted a target to reduce physical inactivity worldwide by 15% by 2030. To achieve this target, evidence-based policies need to be created and adopted worldwide. Furthermore, the fact that PA guidelines are currently not met in a large proportion of young people points towards a lack of understanding and insufficient translation of the evidence behind what makes children and adolescents physically active into policy and public interventions.⁸ Therefore, a better understanding of the determinants of PAB/SB is a crucial first step in developing interventions that lead to a sustained increase in PAB and reduced SB and a foundation for PA policy development. 10 11 In the current protocol, we refer to 'determinants' of PAB or SB as mechanisms that drive and explain behaviour adaptation in specific contexts. 11 12 We focus on modifiable determinants, signifying those which are malleable and can be altered through interventions, and present opportunities to intervene from public health and policy perspectives. 11 13 Using a rigorous methodology, our goal is to synthesise high-quality evidence on the effectiveness and association of key modifiable

determinants on PAB/SB and produce a Best Evidence Statement (BESt) which can inform future interventions. We also aim to identify the settings for interventions that are most readily translatable to policy.

The current evidence of the effectiveness of modifiable determinants on PAB/SB is fragmented due to considerable variations in the methodologies used and the methodological quality across the available studies, which has contributed to largely inconclusive findings in systematic literature reviews (SLRs) and meta-analyses (MAs). 8-10 13-18 To limit the variations across studies and extract trustworthy evidence, it is important to identify high-quality studies. Factors that contribute to methodological quality include research design and PAB/SB measurement methods. A range of research designs have been applied in existing PA research (eg. cross-sectional, longitudinal, randomised controlled trials (RCTs) and controlled trials (CTs)). Potential causality between modifiable determinants and the outcome measures can be indicated by RCTs and CTs, and well-designed RCTs can minimise bias through randomisation and intention-to-treat analyses. 10 19 20 However, challenges in randomisation of PAB/ SB interventions have been recognised, 21 therefore, CTs might be the next most credible alternative. While RCTs are regarded as the 'gold standard', high-quality longitudinal studies can provide indications of a causal relationship between modifiable determinants and the outcome measures by virtue of the repeated measurements over time.8 Furthermore, RCTs and CTs can be short-lasting and may not capture the prolonged exposures that can be explored in longitudinal follow-ups. 10 Therefore, we consider RCTs, CTs and longitudinal studies to be among the highest quality of evidence appropriate to develop the BESt.

Methods for measurement of PAB/SB contribute to the disparities in the methodologies used between studies. Data obtained from self-report methods are generally considered to be less sensitive to change than data obtained via device-based methods due to recall errors, underestimation/overestimation or interpretation discrepancies. 14 15 22 23 On the one hand, devicebased measurements are deemed to be more sensitive to behaviour change and can detect cognitively salient behaviours, such as time spent in SB.²³ On the other hand, many studies rely on self-report measurements as they are less costly, logistically easier to implement and are more applicable in some domains of behaviour (eg, strength training) than device-based measurements.²³ Given that both device-based and self-report methods present strengths and weaknesses, we consider it methodologically appropriate to include both in BESt, provided that validity and reliability of the instruments are assessed and reported thoroughly in the included studies. However, as previous research has shown low levels of agreement between the two measurement methods, we will conduct separate analyses per method within SLRs and MAs.²⁴

Over the years, PAB/SB measurements have been used to assess different forms of PA, such as structured PA (eg,

physical education), leisure-time PA and active transport PA and different domains where sedentary time is spent, such as screen-based activities (eg, doing homework on computers), leisure-based activities (eg, sitting and reading) and transport-related activities (eg, sitting in a bus). 15 Recently, there has been an increased emphasis on identifying the settings (or contexts) in which PAB/ SB take place and the determinants at work within the settings, so that the settings of the most impactful, modifiable determinants can be targeted when translating research into policy.^{8 25} Answering the questions about what works for whom (children and/or adolescents), why (determinants and their interactions) and when/where (settings) is critical to advance our understanding of the implementation and possible effectiveness of interventions. 26 Therefore, to produce the BESt, we aim to investigate the modifiable determinants in their respective settings in SLRs and MAs so that our results can inform future interventions within settings that speak to policy makers.

The current protocol will be used to produce a series of SLRs and MAs aiming to investigate the effectiveness of modifiable determinants on PAB/SB in children and adolescents using high-quality evidence available. Investigating the modifiable determinants of PAB/SB in their respective settings will help contextualise their modifiability and effect. Therefore, to produce the BESt, it is important to ascertain methodological rigour which is set apart from previous efforts in understanding PAB/ SB determinants in children and adolescents. By considering the settings of the modifiable determinants, our results can readily inform policy makers and future PA interventions.

Objectives

The overarching aim of the proposed SLRs and MAs is to identify modifiable determinants that are associated with changes in PAB and SB in children and adolescents (aged 5–19). Specific aims are:

- To investigate which modifiable determinants of PAB and SB have been targeted in interventions designed to promote PA in children and adolescents in RCTs and CTs.
- To investigate which modifiable determinants are associated with PAB and SB in children and adolescents in longitudinal studies.
- To investigate the strength of the association between such modifiable determinants and PAB/SB in children and adolescents.

METHODS AND ANALYSIS

The current protocol was registered in the International prospective register of systematic reviews (PROSPERO) on 12 October 2021 with the registration number: CRD42021282874. The reporting in the current protocol manuscript was guided by the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols(PRISMA-P).²⁷

The modifiable determinants that have been targeted in all included studies will be listed and analysed narratively in SLRs. Meta-analytic methods will be applied to the data from intervention and longitudinal studies. Analyses will be performed for different categories of studies based on (1) methods for measurement of PAB/SB (eg, self-report, device-based) and (2) age (eg, children aged 5-12 years, adolescents aged 12-19 years) in a series of SLRs and MAs with varying focus. Study settings (eg, school, home, community) will also be identified.

Population

Studies targeting children and adolescents with and without disabilities aged 5-19 years will be included. According to the International Classification of Functioning, Disability and Health (ICF), 28 disability is an umbrella term for impairments, activity limitations and participation restrictions, denoting the negative aspects of the interaction between an individual and that individual's contextual factors. Studies that include children and/or adolescents with any reported ongoing diagnosed medical conditions known to affect PA participation and include patients under treatment on all levels of care will be excluded (eg, studies including patients with cancer or individuals with anterior cruciate ligament injury, or studies where the intervention takes place in a clinical setting). Studies that report data for ages exceeding the specified age range will be excluded, unless data for a subgroup within the eligible mean age can be extracted.

Types of studies

We will include studies examining modifiable PAB/ SB determinants in RCTs, CTs and longitudinal studies. RCTs and CTs that investigate the effectiveness of interventions aiming to promote PA or reduce SB in children and adolescents, should include control groups or other intervention groups, that are matched to the experimental groups, and report preintervention and postintervention measurements of both outcome measures and modifiable determinants. Longitudinal studies should investigate the association between modifiable determinants of PA and PAB/SB in children and adolescents and report measurements of both the modifiable determinants and PAB/SB at least at two time-points. No control groups or comparisons will be required for the longitudinal studies. Length of follow-up or length of intervention in any of the study designs will not be restricted, data will be extracted if reported for participants within the specified age range (5-19 years).

Outcomes

The main outcome measures targeted in the current protocol are PAB and SB. PA is defined as any bodily movement produced by skeletal muscles that requires energy expenditure, thus including any modality of movement at any intensity.² As such, PAB encompasses behaviours of sedentary, light, moderate and vigorous intensity PA and SB includes any waking behaviour characterised by



an energy expenditure of 1.5 METs or lower while sitting, reclining or lying.^{2 29} Therefore, we will categorise PAB into light, moderate and vigorous intensity and SB-based types of activities reported in the included studies. Any of the two types of measurement methods for PAB/SB, including self-report methods (eg, questionnaires, diaries, recall), and device-based methods (eg, accelerometers, pedometers) will be included.²³ Moreover, we target studies which have reported modifiable determinants as secondary measures. Modifiable determinants will be identified based on the context of each study, where manipulation of the determinant is hypothesised to have an effect on PAB/SB. Where possible, we will explore the mediating effect of the modifiable determinants in the changes in PAB/SB by analysing the structural relationship between the modifiable determinants and PAB/SB.

Comparators

The main comparator will include PAB/SB measurement methods. The included studies will comprise those adopting self-report or device-based measures of PAB/SB or both as outcome measures. Self-report and device-based measures will be analysed separately. In studies where both device-based and self-report measures are reported, the data for both measurement methods will be extracted and analysed separately. In addition, to strengthen the BESt, results from the respective measurement methods will be compared with provide further indication of the strength of the evidence yielded from studies, depending on their measurement methods for PAB/SB. Classification of the settings in which the modifiable determinants were targeted will be identified once data have been extracted.

Search strategy

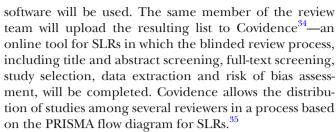
A search will be performed in MEDLINE (Ovid), PsycINFO (EBSCO), Web of Science, Sport Discus and Cochrane Central Register of Controlled Trials (CENTRAL). The piloted search strategy is presented in table 1. The search strategy is built using the main outcome measures of (1) PAB and (2) SB, and synonyms of PAB/SB that are commonly used in PA research; (3) the targeted study designs (ie, RCTs, CTs and longitudinal studies) and related terms; (4) determinant and synonyms that are commonly used in PA research; (5) the targeted population, to identify children and adolescents and synonyms that are commonly used in PAB/SB research; and (6) measurement methods for PAB/SB such as accelerometer or pedometer for device-based methods and diary and activity recall for self-report methods.

For languages other than English, studies will be included if an English version is available, or if a translation can be obtained through members of the review team. We will include studies published from 2010—which was the year when the first global PA guidelines were published by WHO³⁰ and around the time previous SLRs with similar aims were published.^{31 32} Only peerreviewed studies will be included and grey literature such as research reports, working papers, conference proceedings and theses will be excluded during the search and at the initial screening of the studies.

Study records

At the initial screening, records of grey literature and duplicates from the different databases will be excluded. The initial screening will be performed before the start of the blinded review process by one member of the review team. For this, EndNote x9³³—a reference management

Domain	Search terms
Outcome: Physical activity behaviour*	('Physical activ*') OR (exercise) OR (sport*) OR (play) OR (exertion) OR (recreation) OR (training) OR ('motor activit*') OR ('physical performance') OR ('physical movement') OR ('physical effort') OR (exergaming)
OR	
Outcome: Sedentary behaviour*	(sedentar*) OR ('screen time') OR (gaming) OR ('computer use') OR (sitting) OR (inactiv*) OR ('seated posture' OR ((watch* or view*) N/2 (TV or television))
AND	
Target population*	(child*) OR (youth) OR (adolescen*) OR ('young people') OR ('school age*') OR (p?ediatric) OR (juvenile) OR (teen*)
AND	
Study design†	(RCT) OR ('control* trial*') OR (quasi) OR (longitudinal) OR (intervention*) OR (prospective) OR ('follow-up')
OR	
Determinants†	(determinant*) OR (antecedent*) OR (predictor*) OR (mediator*) OR (moderator*) OR (exposure*)
AND	
Measurement methods†	(acceleromet*) OR ('activity profile') OR (recall) OR (diary) OR ('activity monitor*') OR ('heart rate monitor*') OR ('direct observation') OR (actigraph*) OR ('activity track*') OR ('self report*') OR (survey) OR (pedomet*) OR (wearable*)



Several workshops will be held before the commencement of the respective stages (ie, study screening, risk of bias assessments and data extraction) to ensure that all reviewers will be proficient in the procedures and to ensure agreement among them. As the review team consists of 31 members, an online communication tool— Slack³⁶—will be used to maintain communication among the members of the review team throughout the review process to respond to queries and provide updates on the process. A core group of the review team will guide and support the review team members throughout the review process.

Screening process

At title and abstract screening and full-text screening, each study will be screened by two blinded independent reviewers of the review team. Any conflicts between the independent reviewers will be resolved by a third reviewer, who is a member of the core group. An equal number of studies will be distributed among reviewers and random studies are selected by Covidence to be distributed to each reviewer. At the first stage, titles and abstracts will be assessed for eligibility using a prepiloted decision tree based on the inclusion/exclusion criteria expected to be found in either the title or abstract. The full-text version of the studies that remain after title and abstract screening will then be uploaded to Covidence. At the second stage, full texts will be assessed for eligibility using the full inclusion/exclusion criteria. Reasons for exclusion of studies at the full-text stage will be recorded. Following the full-text screening, the included studies will be checked by one reviewer to exclude any duplicate reporting, that is, reporting of the results from the same sample in multiple studies or studies that have been published more than once. For this purpose, study information will be compared between studies, such as authors, study locations and settings, intervention content and design, sample size, demographic information and ethical committee approval number.³⁷ If duplicate reporting is detected among included studies, the reviewers will attempt to identify the main study which was duplicated. If the main study cannot be identified, the study with the longest follow-up or highest number of measurement time points will be selected for inclusion.^{38 39}

Data extraction

A data extraction form will be created in Covidence and piloted ahead of the data extraction stage. The data extraction from each study will be completed by two

independent reviewers. If any information or data are missing, or if clarifications are needed, the corresponding author of the respective studies will be contacted. If a response is not provided before data extraction completes, or if the reporting remains incomplete, the study will be excluded. Following the independent data extraction, the two reviewers will perform a consensus procedure to resolve any conflicts and ascertain the correctness of the extracted data.

The data extracted will include the following items:

- Study/intervention description: study design, brief study intervention description, description of intervention design and content, description of control group activity and study setting.
- Sample information: sample size, sample age (including age by sex), sex (including grouping based on sex; % Male, % Female) and population type (disability/non-disability).
- Outcome measures and modifiable determinants: PAB/SB outcome measurement method type (eg, self-report, device-based) and instrument (eg, Acti-Graph, Youth Activity Profile, 7-day recall), length of device-based PAB/SB measurement (days), days of the week for device-based PAB/SB measurement (weekdays/weekend day), wear-time requirement for device-based PAB/SB measurement, unit of measure for PAB/SB, reported validity and reliability of PAB/ SB measurements, modifiable determinant measurement instruments and their reported validity and reliability.
- Time frames: intervention length (weeks), intervention location (country), number of measurement time points and length of follow-up (weeks).
- Results data: PAB/SB outcome data (mean, measures of variance) and modifiable determinant data (mean, measures of variance).

Risk of bias

Different scales will be used for the assessment of risk of bias depending on the study design of each included study. For RCTs, a modified version of the Cochrane risk of bias tool for randomised trials (RoB V.2.0) will be used. 40 For CTs without randomisation, a modified version of Cochrane's Risk of Bias in Non-randomised Studies-of Interventions (ROBINS-I) will be used. 41 The Cochrane tools, RoB V.2.0 and ROBINS-I, are modified to include an additional domain concerning the bias in measurement of the determinants. For longitudinal studies, an adapted version of the National Institutes of Health quality assessment tool will be used. 42 The adaptation of the latter tool involves the exclusion/addition of items relevant to longitudinal studies, based on the tool used by Kontostoli et al. 43

The two independent reviewers who extract the data from the respective studies will perform the risk of bias assessment to ensure familiarity with the studies. The risk of bias assessment will be completed in forms created in Covidence with the respective risk of bias tools as templates. Following the independent data extraction, the two reviewers will perform a consensus procedure to resolve any conflicts and ascertain the correctness of the assessment.

Data synthesis

Data extraction will yield a data file containing data for the included RCTs, CTs and longitudinal studies, and include populations with and without disabilities. A summary table will be created describing the overall characteristics of the included studies with information on the methods (ie, intervention description for intervention studies/exposure for longitudinal studies), settings, modifiable determinants, sample characteristics (ie, sample size, age) and outcomes (ie, outcome measures, measure type, number of measures, measurement time points). Results of the risk of bias assessment will be reported in a separate table.⁴⁴

Findings will be synthesised narratively to identify and list the modifiable determinants and the settings they were investigated in. Studies for disability and non-disability populations, and studies reporting PAB/SB measured using self-report and device-based methods will be discussed separately. The findings will be discussed considering the different settings and the quality of evidence included in the review.

Most data extracted from the included studies are expected to be continuous. Where possible, meta-analytic methods will be applied. MAs will be performed using both frequentist and Bayesian approaches to statistical inference in JASP statistics software. ⁴⁵ MAs will be performed for intervention studies (RCTs and CTs) to investigate the effect of the interventions on PAB/SB and determinants and for longitudinal studies to investigate the strength of the association between identified modifiable determinants and PAB/SB. For studies including more than one experimental group or modifiable determinant, each will be included in the MAs.

Direct effect will be investigated in frequentist pairwise comparisons, for which the standardised mean difference (SMD) and the 95% CIs will be calculated. We expect the presence of heterogeneity among included studies in each MA due to the nature, settings or types of interventions. Therefore, the MAs will be conducted using random effects models. For intervention studies, the postintervention data will be used to calculate the between-group difference while controlling for baseline differences. For longitudinal studies, the within-group difference will be calculated as control groups are not expected to be included in longitudinal studies. For data interpretation, effect size values of SMD < 0.50 indicate small, $0.50 \le$ SMD < 0.80 indicate medium and SMD ≥ 0.80 indicate large effects. 46 Heterogeneity will be identified using Cochrane's Q, which is based on a χ^2 test using the CI size in relation to the df. Heterogeneity will also be quantified by using I², which represents the degree (in %) of methodological consistency across studies using the χ^2 statistic Q in relation to the df. For interpretation of heterogeneity, $I^2 < 25\%$ indicates low heterogeneity, $25\% < I^2 < 50\%$ indicates moderate heterogeneity and I^2

> 75% indicates high heterogeneity. Benchmarks will be used to give an approximation for the level of heterogeneity—0%–40%: might not be important; 30%–60%: may represent moderate heterogeneity; 50%–90%: may represent substantial heterogeneity; and 75%–100%: considerable heterogeneity. The level for statistical significance will be set to α <0.05.

The Bayesian approach to statistical inference will be applied for the MAs using random effects models. The primary benefits of using Bayesian meta-analysis in addition to frequentist meta-analysis include (1) the ability to include prior knowledge of the effect into a model, updating the existing knowledge as evidence accumulates; (2) the ability to make more nuanced conclusions that expand on a simple presence or absence of support for the hypotheses based on a p value and (3) the ability to assess the plausibility of the results and to make conclusions based on the probability that the results are within a given range. 49 50 For the Bayesian meta-analysis, Gibbs sampling of the Markov Chain Monte Carlo algorithm will be used in JASP. 45 The probability for publication bias will also be calculated using the JASP extension Robust Bayesian Metaanalysis (RoBMA). We will apply RoBMA to conduct stateof-the-art publication bias-adjusted MA.^{51 52} The Bayesian framework will allow for Bayesian model averaging, 49 taking several plausible models into account and alleviating concerns about selecting the right model from the variety of adjustment methods available.⁵³ In addition, RoBMA has several other benefits—it allows researchers to (1) quantify evidence on a continuous scale, including for the null, (2) avoid accumulation bias and (3) ease estimation problems by using prior distributions. We will use the prior specifications⁵¹ and models with the modification of removing the fixed-effects models.

Additionally, the mediation effects of determinants on PAB/SB will be investigated using frequentist meta-analytical structural equation modelling (meta-SEM).⁵⁴ To conduct meta-SEM, the covariance structure of the mediation is required. If this information is not presented in a primary study, the authors will be contacted. We will conduct meta-SEM only when we can extract the required data.

ETHICS AND DISSEMINATION

The current protocol describes the process through which a series of SLRs and MAs will be performed, with the aim to identify modifiable determinants that are (in)effective in influencing PAB and SB in children and adolescents. The findings of the resultant studies will be disseminated in peer-reviewed publications and academic conferences, where possible. Modifiable determinants from studies with different study designs and measured using self-report or device-based methods will be reported separately in different publications. The BESt will also be shared with policymakers within the DE-PASS consortium in the first instance. As no primary data will be collected, no ethical approval is required.



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