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BMJ Open Effectiveness of digital primary prevention interventions targeting physical activity, motor skills and nutrition in children aged 3-10 years in the setting of day care and primary school: protocol for a systematic review

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ABSTRACT

Introduction Available evidence points to an association of increased screen time and the availability of digital tools during childhood with negative health outcomes in later life. For many years, public discourse focused on restricting access and use of digital technologies below certain ages. However, little is known about the specific benefit of a responsible use of digital primary prevention in the setting of (early) childhood education. The objective of this evidence synthesis is to investigate the effectiveness of digital primary prevention interventions targeting physical activity, motor skills and/or nutrition in children aged 3-10 years in day-care facilities and (pre-) schools. Methods and analysis We present the rationale and methodological steps of a systematic review in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses procedures. Automated searches will be conducted by applying a pretested search strategy to the databases MEDLINE/PubMed, EMBASE and PsycInfo to identify relevant interventional (randomised controlled trials, controlled trials, crossover trials and pilot and feasibility) and observational (case-control, cohort) studies in English or German, with no date restrictions. The overall search will be complemented by backward, forward and additional hand searches. Two researchers will independently screen titles/abstracts and assess full texts by applying predefined eligibility criteria. Data extraction will be conducted by using a pretested data extraction sheet. The assessment of methodological quality will be performed independently by two review authors using the Critical Appraisals Skills Programme relevant to the study design applied in the given study. Additionally, qualitative content analysis will be conducted to analyse priorities for future research extracted from the discussion sections and conclusions of included studies.

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Strengths and limitations of this study

- ▶ This is the first systematic review assessing the effectiveness of digitally supported primary prevention strategies with a focus on settings of (early) childhood education.
- Although we aim to provide an extensive overview of the research literature, our broad inclusion criteria, with respect to potential interventions and eligible study designs, may lead to challenges when synthesising the research evidence.
- Based on pretesting the search strategy and an initial rough analysis of identified records, we expect to identify both heterogeneous and limited research evidence in this field, which, in consequence, may also limit the extent to which we will be able to provide applicable recommendations for institutionalised prevention strategies.
- The results of this evidence synthesis will provide a rationale for the responsible use of digital prevention measures in (early) childhood educative settings and highlight specific areas of future research.

INTRODUCTION **Background**

Evidence syntheses highlight the complex associations of (early) childhood behaviour and health indicators in (pre-) school children. Adding to the 'traditional' focus on diet and PA, strategies on motor skill acquisition and perceptions of competence in the young are said to pave the way for a supportive spiral of healthy behaviours. 1-5 Despite the promising associations of healthy lifestyles in children, including adequate physical activity (PA)⁶⁻⁹ and nutrition¹⁰ with health benefits and improved quality of life in adulthood, 11 a substantial part of the children population tends to live rather unhealthy lifestyles. As such, results of the German Health Interview and Examination Survey for Children and Adolescents (wave 1) indicate that the rate of kids achieving the WHO recommendation to be physically active at least $60\,\mathrm{min/day^{12\ 13}}$ decreases with increasing age (51.5%, 3–6 years; 31.0%, 7–10 years; 14,8%, 11–13 years). At the same time, low levels of motor coordination were found to be a predictor of low PA levels in the childhood. Improving motor skills, therefore, represents an important starting point to initiate and maintain physical, psychological and social well-being. In the childhood.

The Centers for Disease Control and Prevention (CDC) define stages of children's lives with preschoolers (3 to 5 years) and middle childhood (6–11 years). B Driven by the rapid development of the body, physical abilities and social relationships, 19 this period is considered as the most important to carry out primary prevention. 20 21 In this respect, developmental cascades refer to cumulative consequences of single developments in children, leading to spreading effects across levels, among domains at the same level, and across different systems or generations. Due to these desired early positive and supportive interactions of parents, caregivers, teachers and children, there is a strong need for educational and preventive work in children in order to support knowledge, attitudes and practices. 24

(Pre) schools are considered an exceptional setting to deliver primary prevention interventions. Reasons include an easy access to children whom spend a significant amount of time there as well as structured environments for fostering the implementation of interventions.

However, available systematic reviews are unable to provide definitive guidance on the best school-based strategies for primary prevention to increase PA or healthy nutrition behaviour, for example, to prevent obesity, cancer or cardiovascular diseases. Additionally, studies on behavioural risk factors tend to focus on modifiable behaviours outside of educational settings or, if conducted in schools, focus on educative elements to, for example, improve diet and PA. Furthermore, although the tremendous impact of early learning environments is well known, schools are frequently criticised for not providing children with sufficient equipment at school and inadequately enabling them to acquire the necessary skills and motivation to be active.

Digital technologies have become an essential part of people's lives, affecting even the youngest. While recent evidence suggests that exposure to digital media is increasing, even in preschoolers and toddlers, ³⁸ ³⁹ excessive screen time and media device availability are known to be associated with adiposity, unhealthy diet and decreased quality of life. ^{40–42} For many years, the public discourse focused on restricting access and use of digital technologies below certain ages. ⁴³ ⁴⁴ On the other hand, recent evidence syntheses highlight potential benefits of digital technology applied in prevention. ²⁹ ⁴⁵ Additionally, digitisation and children's affinity

to media holds great potential to think beyond traditional prevention strategies and consider participating children as active recipients. However, the available reviews studying the effectiveness of digital prevention interventions targeting diet and PA in the youth mostly focus on adolescents, Make 49 make no distinction between relevant settings or focus on specific exercise modalities, like active video games. As such, they do not allow to draw generalisable recommendations for the use of specific digitally supported preventive interventions to be used in (pre) school settings.

Objective

The primary objective of this evidence synthesis is to study the effectiveness of digital primary prevention interventions targeting PA, motor skills and/or nutrition in children aged 3–10 years in day-care facilities and (pre) schools.

As a secondary objective, we aim to identify and categorise priorities for future research.

Using the levels of healthcare introduced by Leavell⁵³ and applying them to the field of digital health, we use digital primary prevention to refer to interventions using digital technology to either prevent risk factors or reduce the incidence of disease prepathogenesis.

METHODS AND ANALYSIS

We will conduct a systematic review in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses.⁵⁴ This systematic review has been registered with PROSPERO (the National Institute for Health Research-funded International Prospective Register of Systematic Reviews). The initial search was conducted in spring 2021 and will be updated in autumn 2021.

Search strategy

Extensive automated and manual searches will be performed for the databases MEDLINE/PubMed, EMBASE and Psych-Info. An update of the electronic search will be done prior to submission of the results of the systematic review. Additionally, a hand search will be done in Google Scholar. After completion of title—abstract—screening, the five most relevant journals are searched separately for latest studies. In addition, reference lists of included studies (backward) and those records citing our included studies (forward search) will be searched.

The PICOTS criteria⁵⁵ listed in table 1 were applied to develop the research question, build the search string and define criteria for inclusion and exclusion of the relevant records. The search string applies a combination of five building blocks from the PICOTS scheme, namely, 'population', 'intervention', 'outcome', 'setting' and 'study design' and are found in the online supplemental annex 1. No date restrictions will be applied.



Table 1 PICOT and eligibility criteria		
	Inclusion	Exclusion
Population	Children aged 3–10 years	Animal studies; adolescents >10 years of age; adults; parents; patients with non-lifestyle-associated conditions
Intervention	Digital primary prevention interventions targeting children	No prevention, secondary and tertiary prevention, pharmacological interventions, interventions targeting only on parents or staff (educators, pedagogues, teachers)
Control	To be omitted	
Outcome	Primary outcomes: Physical activity, nutrition behaviour or calorie intake, motoric development/functionality Secondary: BMI, body weight, diabetes risk, other lifestyle associated outcomes	Prevalence; incidence; none of the listed outcomes or no data reported at all
Study design	Intervention studies; RCTs, CTs, crossover-studies, pilot trials, feasibility studies. Observational studies: case-control studies, cohort studies	Other study designs, study protocols, project reports, (systematic) Reviews, meta-analyses
Setting	Kindergarten; day care; pre-school; school, elementary school	Home-or community based; sedentary time; in-/outpatient care
Other	Language: English; German	Other language; no full-text access, conference presentations, abstracts

BMI, body mass index; CT, Controlled Trial; PICOT, Population, Intervention, Comparison, Outcome, Time; RCT, Randomised Controlled Trial.

Eligibility criteria

Types of participants

As illustrated in table 1, relevant records must focus on children from 3 to 10 years. Studies with populations outside of this age range will be included if they provide data on subgroup matching our criteria. We will exclude those studies that primarily targeted parents/families or staff.

Types of interventions

Studies that did not study a digital or digitally supported intervention, address matters of secondary or tertiary prevention and those evaluating pharmacological interventions will be excluded. Studies are eligible if they studied digitally supported primary prevention addressing at least one of the defined outcome domains (PA, motor skills and/or nutrition). Digitally supported interventions encompass interventions, which are exclusively digital (eg, video-based education, active video games) as well as those containing a digital/or digitally supported intervention component (eg, motivational short messages (SMS) as part of a monitoring system). Studies using pedometers will be included if these were part of an intervention and did not exclusively serve as a measurement instrument.

Types of outcome domains

Eligible studies have to include at least one of the following primary outcomes: movement and PA (measured as active time, steps and distance covered as well as movement variety and speed), motor function (eg, one-legged stance, standing long jump), calorie intake (also, energy expenditure). Secondary outcomes include body weight, age-standardised body mass index (BMI-z), diabetes risk reduction, behavioural change/adjustment and other lifestyle-related outcomes.

Types of study designs

We will include both intervention (RCT, CT, pilot trials, feasibility studies) as well as observational studies (casecontrol group design, cohort studies) to assess the effectiveness of digital primary prevention interventions.

Types of settings

Studies have to be conducted in an educational setting relevant to the defined target group (eg, kindergarten, day care, nursery school, (pre) school). As such, homebased interventions and those primarily targeting parents will be excluded.

Identification and selection of studies

All identified records will be exported to endnote and checked for duplicates. Two researchers will independently screen titles/abstracts by applying the eligibility criteria, to delete any irrelevant studies. After consensus is reached, full texts will also be assessed independently by two researchers. During this second stage, reasons for exclusion will be documented and discussed. Any discrepancies about paper eligibility will be resolved by discussion between two independent reviewers or if relevant by consulting a third one.



Data extraction and analysis

Previously used extraction forms and available guidance from Cochrane⁵⁷ were used to develop a preliminary data extraction form. Due to the differing study types, including both intervention and observational studies as well as heterogeneous intervention phenotypes and outcomes, data extraction will be piloted.⁵⁸ The data extraction will be performed by two scientists both in parallel and independently. Subsequent comparison, discussion and calibration will increase the quality of the data extraction to minimise possible errors. The whole data extraction form is found in online supplemental annex 2. Data will be extracted using a predefined data extraction sheet containing the following variables:

- ▶ *Study characteristics*: authors, title, journal, year of publication, objective, study design, randomisation procedure.
- ▶ *Population*: demographics (including age and gender), overall number of participants, number per group, number of groups.
- ▶ *Intervention:* number and description of components, digital component (hardware and software), intervention frequency and duration, setting/modality (eg, classroom, schoolyard), involvement of educational staff and/or parents, targeted (risk) behaviour.
- ▶ *Outcome* and *data analysis*: number of outcomes, outcome domain, measurement, time of measurement, follow-up, analysis of confounder, statistics.
- ▶ *Setting*: geographical area, educational institution.
- ▶ *Implications*: main finding, recommendation for practice, recommendation for future research.

Critical appraisal—methodological quality (risk of bias) assessment

The assessment of methodological quality will be performed independently by two review authors using the Critical Appraisals Skills Programme (CASP) relevant to the study design applied in the given study following available guidance. 59-62 Currently, there is no consensus on which critical appraisal tool to be used for non-randomised trials. ⁵⁹ 60 We will, therefore, apply the CASP tool for RCTs for matching studies in our review as well as the CASP tool for cohort studies for non-randomised intervention studies. Before critically appraising the included studies, a tabular sheet was prepared containing relevant criteria for scoring. The items of the checklist are provided in online supplemental annex 3. Response options include 'yes', 'no' and 'can't tell'. Decisions will be guided by prespecified criteria, which itself were derived from the 'hint' section of the CASP publications ⁶¹ ⁶² and enriched by relevant evidence (online supplemental annex 3). The criteria for critically assessing cohort studies were informed by relevant studies and high-quality reviews. ^{29 36 37 45 63-67} As such, a long list of potential confounders was extracted and afterwards prioritised by the group of authors in order to define a limited number of 'important confounding factors'.

A comprehensive table documenting the critical appraisal including justifications for individual judgements will be provided. Although it is not recommended to use the CASP checklists as scoring systems and CASP is, therefore, limited to objectively compare study quality, we will also use it to provide a reader-friendly summary score and thereby deliver a measure of distinction between studies comparing overall methodological quality.

Data synthesis and statistical analysis

The requirements for conducting a meta-analysis will be assessed focusing on a minimum number of comparable studies (n≥5). ⁶⁸ This decision will be made by consensus between review authors while considering clinical and methodological diversity. ⁵⁵ However, due to the anticipated heterogeneity in terms of (a) populations (age, country, socioeconomic status, etc), (b) interventions (high expected variability of interventions, number of components, complexity, nature of digital component(s), involvement of educational staff) and (c) outcomes (including measurement), (d) settings and (e) study designs, fulfilled requirements for pooling the data are unlikely. As such, the results will be synthesised using both a textual narrative and a tabular approach to account for the expected heterogeneity.

Qualitative analysis of future research needs

Extracted information on implications for future research will be extracted from the discussion sections and conclusions of included studies. To ensure topicality, only included studies published within the past 5 years will be considered. We will perform inductive formation of categories according to Mayring's method of thematic content analysis.⁶⁹ In short, a codebook will be developed containing categories accompanied by descriptions and examples per category. As a first step, the researchers will familiarise themselves with the extracted data (transcripts), and, afterwards, independently identify relevant quotes. In a first iteration, underlying patterns and recurring schemes will be identified within the extracted information, which will then be used to inform categories and subcategories. After discussing and relabelling these categories, examples taken from the extracted information will be added. Coding and categorisation will be discussed among the researchers until consensus could be achieved. Final reporting of results will be in line with the Standards for Reporting Qualitative Research⁷⁰ as well as the consolidated criteria for reporting qualitative research.⁷¹

Patient and public involvement

Patients and the public were neither involved in writing this study protocol nor will they be involved in conducting the review. However, main findings may be prepared for regional/national dissemination in educational settings of early childhood. Additionally, the results of the qualitative analysis of future research needs may be accompanied by an adaptation for pedagogues, researchers and decision-makers.



ETHICS AND DISSEMINATION Ethics approval

Ethics approval is not required for this systematic review of published data.

Dissemination policy

The findings of this study will be disseminated through peer-reviewed publications and both national and international conference presentations. Additionally, main findings of the analysis, especially relevant implications for practice, may be prepared for regional/national dissemination in educational settings of early childhood.

Updates of the review will be conducted, as necessary, to inform and guide practice.

DISCUSSION

Digitisation has become an incremental part of our everyday lives and is increasingly affecting the development of children and youth growing up. However, little seems to be known about the impact of digital technologies on healthy eating/drinking, PA and the variety of movement in children, especially when being applied in the relevant settings of (early) childhood education. ^{30 45 50 51} An evidence-based and responsible implementation of digital primary prevention interventions in these settings may lead to an increased acceptance of educational staff and ultimately lay the foundations of digital interventions being also seen as facilitators of healthy lifestyles for children. 35 It is of vital importance to find out how settings like daycare facilities and primary schools can be adequately equipped, qualified and empowered to effectively and responsibly use digital interventions to support healthy behaviours of children. The anticipated findings may contribute to combining traditionally separated areas of learning/education, healthy development and digital skill promotion. This systematic review, therefore, aims to fill an existing knowledge gap with a high practical relevance by uncovering successful, feasible and effective strategies to be implemented on a largescale and, in parallel, identify critical issues for future research.

Despite the described rationale for conducting the systematic review, important limitations need to be acknowledged. First, due to the expected heterogeneity of studies, in terms of both interventions and study designs, an overall comparison of effective strategies will be demanding. Second, although we pretested the search strategy, it is likely that we may be missing relevant records. A taxonomy was used to develop parts of the search string and decide on categories for data extraction. However, there is no available taxonomy, which may guide the search in the heterogeneous and fast-evolving field of digital prevention strategies. This risk will be minimised by conducting extensive additional hand searches. Additionally, our focus on children aged 3–10 years

may lead to an exclusion of relevant studies with age ranges slightly below or above the defined thresholds. One strategy to limit the risk of losing relevant data is to include studies if they provide data on subgroups matching our eligibility criteria. Based on the conducted piloting of the search strategy, we also expect that searching for studies and study inclusion process will be demanding due to inadequate nonmeaningful titles and low-quality abstracts. We, therefore, anticipate to include a larger number of studies during the screening of titles and abstracts, which, in turn, will increase the workload during full-text assessment. With regards to the intended inferences of our review, we acknowledge that evidence syntheses suggest that sedentary behaviours may have different impacts on different indicators of health.⁷⁴ Due to our focus on digital interventions implemented in educational settings, omitting home-based interventions and those targeting sedentary behaviours of children in general, we may under/overestimate the true impact of the studied interventions.⁷⁵

Besides these known and anticipated limitations of our approach, additional limitations may arise from the qualitative content analysis, applied to analyse practical implications as well as future research needs in our review. As such, this part of the analysis may be influenced by the individual backgrounds and unintended expectations of the authors during the inductive coding process as well as their previous experiences with the overall methodology. To minimise this inherent limitation of qualitative research, we will involve a third coder categorising the quotes and discussing the categories on future research needs.

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Contributors PT, SH and PF conceived and designed the study protocol, wrote the manuscript and pre-tested the search and screening. HB and PEHS provided feedback on the overall study protocol and reviewed the manuscript. All authors reviewed and approved the final version of the manuscript before submission.

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