

STUDY PROTOCOL

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Efficacy and mechanisms of an education outside the classroom intervention on pupils' health and education: the MOVEOUT study protocol

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Abstract

Background Education can create better opportunities for health, and vice versa. Using a so-called 'add-in' approach, school-based physical activity (PA) promotion and prevention of sedentary behaviours can increase pupils' wellbeing and learning and, on the longer term, reduce the risk of non-communicable diseases. A PA 'add-in' approach involves integrating PA into teachers' curricular obligations without being an extra burden as opposed to an 'add-on' approach which requires additional operational resources and include activities that do not explicitly contribute towards curricular targets making them less long-term acceptable in a school-based context.

Previous studies investigating education outside the classroom (EOtC) show mutual benefits for both health and education outcomes among children and adolescents. However, the evidence is of mixed quality and questionable certainty, which calls for further investigation. The aim of this study protocol is to describe and discuss the study design and methods to investigate the efficacy and mechanisms of EOtC as a vehicle for health and education. The study investigates the intervention developed and conducted in the TEACHOUT study with updated and strengthened design and measures.

Methods The efficacy of EOtC will be investigated in a cluster randomised waitlist design. Participants will be pupils in ~54 classes, grades 4-10 (ages 10-15 years) in ~30 Danish elementary schools. Fifteen schools will be randomised to the intervention: a two-day EOtC training course targeting teachers followed by the teachers implementing EOtC >5 hours weekly over the course of one school year. Pre- and post-measures of health (PA and wellbeing) and learning (school motivation and academic achievement) will be collected. Investigation of pedagogical and motivational mechanisms will be based on observations of EOtC.

Discussion The updated randomised controlled design will provide firmer evidence for the efficacy and mechanisms of EOtC and provide knowledge about how mutual benefits of health and education can be obtained.

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Trial registration Registered with ClinicalTrials.gov (ID [NCT05237674](https://clinicaltrials.gov/ct2/show/study/NCT05237674)) [University of Copenhagen. MOVEOUT: a Cluster RCT of the Efficacy, Mechanisms, and Mediation of an Education Outside the Classroom Intervention on Adolescents' Physical Activity, 2023], February 14, 2022. Most recently updated on November 23, 2022 (Version 2).

Keywords Learning outside the classroom, Movement integration, Outdoor learning, Outdoor teaching, School-based health promotion, Structural prevention

Background

Health and education are synergistic in multifarious ways. Good health supports wellbeing and the cognitive functions underlying learning over the life course [1]. Vice versa, poor health can interfere negatively with schooling, and informal learning in general, through recurrent absences or difficulties concentrating [2, 3]. Good opportunities for learning, on the other hand, provides the basis for participation and informed lifestyles choices. If either education or health is hampered in early life, this will have incremental impacts for both over the life course. Negative feedback loops in childhood tend to track into in adulthood where individuals with higher education generally have higher earnings (and in extension opportunities for healthier foods and living conditions), are more likely to be employed, and to take up positions with fewer risks and physical strains than individuals with lower levels of education [4]. The interconnectedness of health and education calls for coordinated solutions for which efficient and sustainable early-life interventions that can support both health and education in tandem are a necessity. Health and education synergies can be maximised through intersectoral actions, but these actions require a sensitivity towards the core goals, processes, and mandates of the settings through which the actions are implemented. In this protocol, we outline one such approach and describe the methods planned to investigate the efficacy and mechanism of an intervention.

Schools are considered key settings for promoting children and adolescents' health and education, as they spend a large amount of their waking hours at school [5, 6], and because children and adolescents from all socioeconomic and cultural backgrounds can be reached [5]. However, school-based intervention requires an integration of the associated activities within the core goals, processes, and mandates of schools for successful and sustainable implementation [7]. This is particularly pertinent given the current education milieu in which schools and teachers face external top-down pressures to improve academic standards and improve wellbeing among pupils [8]. This means that there is a need for teaching activities and learning experiences that simultaneously improve pupils' learning, wellbeing, and health.

Increased physical activity (PA) and decreased sedentary time reduces the risk of non-communicable diseases, such as cardiovascular diseases, diabetes, and

morbidity over time [9]. Positive effects are also seen on wellbeing, cognitive functioning [10], and academic achievement during childhood [11]. European adolescents are far from reaching the PA guidelines, and activity levels decline with increasing age [12]. Furthermore, the decreasing levels of wellbeing and rise of mental health problems among adolescents has increased during the recent years [13]. Various attempts have been made to increase PA during school hours, e.g., through extracurricular activities such as active brain breaks or time slots allocated for movement activities [14, 15]. However, these approaches are often disconnected from school objectives, require additional manpower, or increasing workload for existing personnel and is not considered a primary objective by the teachers, which in many cases cause a low degree of implementation [16]. In contrast, 'add-in' approaches that integrate PA within primary pedagogical and didactical purposes have shown to achieve better adherence [7]. Education outside the classroom (EOtC) is be such an approach [17, 18].

EOtC has received widespread attention in the face of COVID-19 as a means to reduce school-based transmission [19]. Recent evidence suggests that EOtC in general, and perhaps even more so when conducted in nature, holds benefits for health and wellbeing [20–22]. Pupils have been observed to engage in more PA during EOtC compared to usual classroom-based teaching [23–25] as well as report higher school wellbeing [26, 27], school motivation [28], and academic achievement [29]. Therefore EOtC has been characterised [17, 18] as an intersectoral [30] and integrated 'win-win' opportunity for both health and education sectors, i.e., an 'add-in' approach to school-based PA promotion [7].

In EOtC, teaching sessions are relocated from the classroom to, for example, public open spaces, societal institutions, or outdoor spaces on school property. Examples include the use of the properties in the local neighbourhood to teach geometry (e.g., identifying square or triangular objects), writing poems in and about the city, investigating local history in the neighbourhood, doing STEM education at science centers, or learning about biological and chemical processes through school gardening [31]. The aim of EOtC is to promote learning and wellbeing through practical exercises and the use of one's body and senses in authentic

situations [32, 33]. EOtC often involves teaching activities that require active transportation to and around places outside the school buildings. EOtC is further characterised by the pedagogical and didactical elements of pupil-led approaches, collaborative, action-centred, experiential, inquiry-based and thematic, play-based learning processes, and movement [34, 35]. EOtC involves outdoor teaching explicitly aligned with and contributing to teachers' obligations [17, 21, 34], often in a cross-curricular approach.

The pedagogical approaches that underpin EOtC are thought to stimulate investigative behaviours based on pupils' curiosities alone or in groups, and thereby foster experiences with autonomy as well as relatedness. Tangible and practical work allows an experience of being competent in other fields than, e.g., reading and writing. EOtC pedagogy thus aligns with Self-Determination Theory's (SDT) [36, 37] perspective on motivation and wellbeing [36] in enabling experiences of autonomy and a sense of competency in close relations with teachers and peers [38–40]. SDT is one of the leading wellbeing and motivation theories in the world and widely used in the context of education [41, 42]. SDT represents a broad framework for the study of human motivation, flourishing, and wellbeing. At the centre of the theory is the individual's basic psychological need for *autonomy*, *competence*, and *relatedness*, which when fulfilled has been shown to result in wellbeing and the most self-determined forms of motivation [43–45]. SDT's usefulness for EOtC interventions was confirmed in the so-called TEACHOUT study [28, 38] and has also been used as a central theory to explain the benefits of EOtC in other studies [46, 47].

The TEACHOUT study was conducted in the school year 2014–2015 [38]. The study was a quasi-experimental investigation of the associations of EOtC with PA, wellbeing, and learning among pupils in grades 3–6 in Danish public schools. The study was the first large-scale quantitative multi-outcome investigation of EOtC, and a trailblazer study in its field [21, 48]. The TEACHOUT intervention included a two-day training course for teachers followed by them implementing EOtC at least five hours a week, divided in 1–2 weekly sessions, for one school year [49]. The study showed that regular practice of EOtC was positively associated with device-based measured PA, with the boys seeming to accrue more moderate-to-vigorous PA (MVPA) and girls more light PA (LPA) [23, 24]. The TEACHOUT study also showed positive effects on pro-social behaviour [26] and in-class social relations [27], motivation for school [28], and reading competence [29]. However, this previous research on effects of EOtC has methodological limitations that need to be addressed. PA was only measured once during the intervention, making the design of the PA evaluation cross-sectional and unable to exclude

influences of extraneous impacts on outcomes. This made it impossible to ascertain whether it was EOtC itself that led to improvements in PA over and above the usual practices in the schools. In addition, the study sample did not allow for investigation of subsamples of pupils, e.g., pupils with overweight or inactive girls, who might attain different benefits of EOtC. Furthermore, the collected data did not allow for investigation of compensatory movement behaviours outside the school day [50] or potential adverse effects (e.g., subgroups who do not feel comfortable or safe outside). Furthermore, there is a need for investigation of which pedagogical and didactical elements of the EOtC that mediate and moderate potential effects.

Therefore, on the foundation of both the merits and limitations of the original TEACHOUT study, this study protocol describes the MOVEOUT study. The MOVEOUT study will provide a more robust and reliable evaluation of the potentials and mechanisms of EOtC. Evidence from MOVEOUT will allow formulation of guidelines for practice and policy with details about the pedagogical and didactical elements of EOtC, which need to be emphasised in the ongoing expansion of EOtC.

Aims

This study protocol outlines the design and methods of the MOVEOUT study. The objectives of the MOVEOUT study are to investigate the efficacy and mechanisms of the *TEACHOUT* intervention [49] (hereafter, the intervention) on Danish grade 4–10 pupils' (aged 10–16 years) school-based and overall PA behaviours, school motivation, wellbeing, and academic achievement over the course of one school year in comparison to the schools' usual practice. The schools' usual practice typically involves indoor classroom-based activities. The intervention is the same well-described and manualised EOtC intervention that was investigated in the abovementioned quasi-experimental study, TEACHOUT [49]. See the MOVEOUT study Theory of Change, Fig. 1.

Sub-studies and hypotheses

The study objectives will be reached through two sub-studies – an efficacy and a mechanism study – testing six main hypotheses, which are illustrated in Figure 2.

Sub-study 1

Effects of EOtC (see full pre-registered protocol for H1 and H2 ([51])).

H1 Pupils in the intervention group will retain higher PA intensities compared to the control group, specifically a) more MVPA, b) more LPA, and c) less SED time (referred to in the following only as PA intensities).

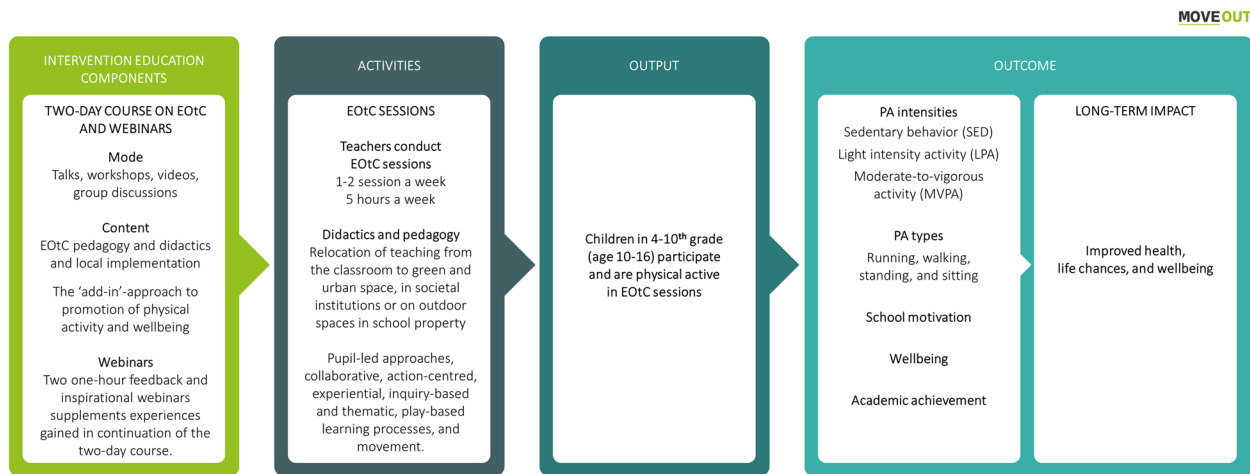
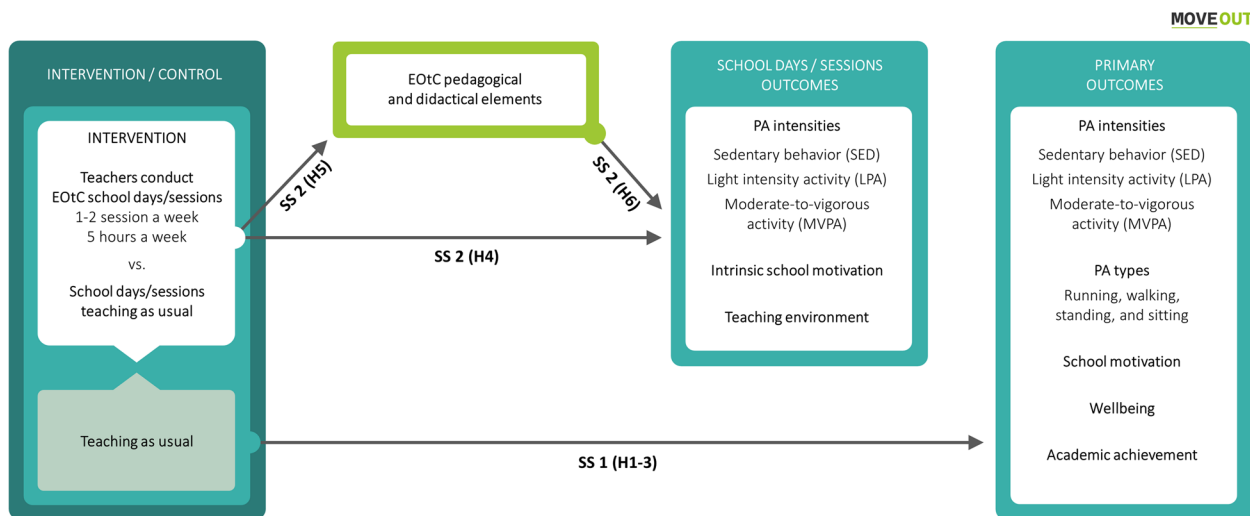


Fig. 1 The MOVEOUT study theory of change



Note. SS, Sub-Study.

Fig. 2 Illustrations of the hypotheses of the two sub-studies

H2 Pupils in the intervention group will retain a) more running, b) more walking, c) more standing, and d) less sitting time compared to the control group.

H3 Pupils in the intervention group will achieve higher school motivation, wellbeing, and academic achievement compared to the control group.

Sub-study 2

Mechanisms of EOTC. The unit of analysis is schooldays or sessions.

H4 EOTC schooldays or sessions will be associated with higher PA intensities, higher levels of intrinsic motivation, and more positive perceptions of the

teaching environment compared to usual schooldays or sessions.

H5 The pedagogical and didactical elements during EOTC sessions will be different from the pedagogical and didactical elements during usual sessions.

H6 The expected association between EOTC and PA intensities, intrinsic motivation, and perceptions of the teaching environment will be mediated by the pedagogical and didactical elements of the EOTC sessions.

Methods

The following paragraphs outlines the methods of the MOVEOUT study in accordance with the SPIRIT (Standard Protocol Items: Recommendations for Inter-ventional Trials) guidelines [52]. Recruitment, data

collection, and intervention training was commenced prior to publication of the protocol (but after registration to ClinicalTrials), and parts of the sections pertaining to past events are therefore written in past tense below.

The MOVEOUT study is a cluster-randomised trial with randomisation occurring at school level. Elementary schools with one or more classes enrolled was randomly assigned to the intervention or control groups. The intervention consisted of a two-day training course on EOtC given to schoolteachers followed by the teachers applying EOtC for at least five hours a week with their class, in 1–2 weekly sessions for one school year. The training course was supplemented by two one-hour inspirational webinars during the first half of the school year (see TIDieR checklist for more detailed description [49]). The schools assigned to the control group will continue their teaching as usual for one school year upon which they will also receive the intervention. See timeline of enrolment, allocation, intervention, and data collection according to SPIRIT in Table 1 and Fig. 3.

Setting and context

The study is conducted in Denmark in typical Danish elementary schools (for 6- to 16-year-old children). Regular

practice of EOtC has increased markedly in Denmark within the last twenty years with at least 19.5% of all schools reporting EOtC in some of their classes in 2019 [53].

During the COVID-pandemic, Denmark was among the first European countries to reopen schools by allowing teaching in primary school classes to take place outdoors [54]. This fostered a further boom in schools and teachers seeking supportive guidelines for outdoor classroom management and ideas of EOtC [55]. In response, various educational actors and organisations developed and offered the needed knowledge, extending the general supply of freely available materials, e.g., Children & Nature – Denmark [56].

Recruitment and participants

We aimed to recruit ~ 54 classes (~ 81 teachers) from 30 Danish general (non-special need) education elementary schools; on average 1.8 classes per school, 1–2 teachers and 21 pupils per class, with a total of 1.134 pupils aged 10–16 years (see Fig. 3). Pupils with noteworthy health problems, reported by their parents or legal guardian, teachers, or investigators will be excluded from the analyses.

Schools in municipalities with larger proportions of citizens with lower levels of education than the average for

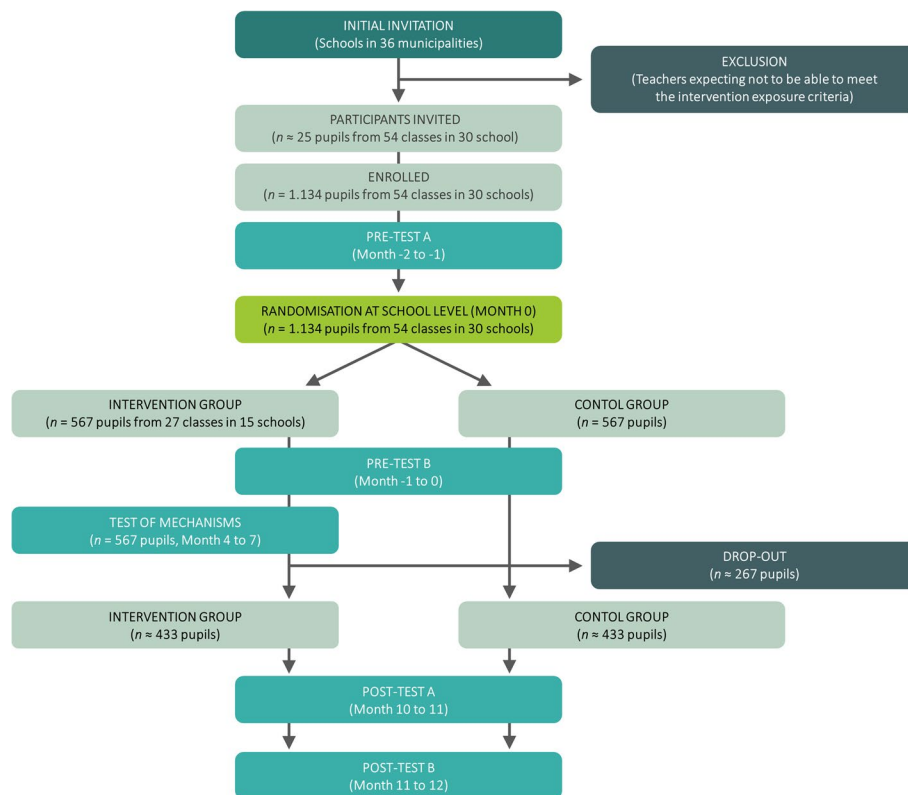


Fig. 3 Participation allocation flowchart of the MOVEOUT study according to SPIRIT

the region were strategically invited for enrolment in the study. Schools located in the Capital Region and Region Zealand were invited to begin with. Thereafter, schools in Region of Southern Denmark were invited, and finally invitations were distributed nationally via teacher networks. School classes were not allowed to be involved in other school development or research projects.

Recruitment and enrolment started around two years before the implementation of the intervention and continued until randomisation (month - 18 to 0, see Table 1). Teachers were recruited via both municipal school directors and direct contact to local school principals. Municipalities and schools were initially contacted via e-mail and non-responders were then

Table 1 Participant timeline according to SPIRIT

	STUDY PERIOD							
	Enrolment	Pre-test A	Pre-test B	Allocation	Implementation			Close-out
					Post-test A	Post-test B		
Time point	-18 mo.	-2 mo.	-1 mo.	0 mo.	4 mo.	10 mo.	11 mo.	14 mo.
ENROLMENT	x							
Eligibility screen	x							
Informed consent	x							
Allocation (cluster)				x				
INTERVENTIONS								
Two-day training course				x				
Two one-hour inspirational webinars					x			
Applying EOtC > five hours pr. week in 1–2 weekly sessions					x	x	x	x
MEASUREMENTS								
<i>Participants</i>								
Pupil socioeconomic status (parent survey)	x							
Pupil health status (parent survey)	x							
Implementer descriptives (teacher survey)	x							
<i>Pre- and post-measures</i>								
PA behaviours (pupil device based, seven days)		x	x			x	x	
School motivation (pupil questionnaire)			x				x	
Wellbeing (pupil questionnaire)			x				x	
Academic achievement (pupil tests)			x				x	
<i>School days/sessions measures (two EOtC and two non-EOtC schooldays, IG only)</i>								
PA behaviours (pupil device based, session)					x			
School motivation (pupil survey, school day)					x			
Learning environment (pupil survey, school day)					x			
Didactical and pedagogical elements (observation, school day)					x			
<i>Implementation</i>								
Degree and characteristics of the EOtC (teacher questionnaire, weekly)					x	x	x	x
Adaption, acceptability, and local supportive structures (teacher interview, IG only)						x		
<i>Background descriptive measures</i>								
Socioeconomic status (survey, parent/legal guardian)		x						
Child health status (survey, parent/legal guardian)		x						
Teacher's previous work and EOtC experience (survey)			x					

EOtC Education outside the classroom, IG Intervention group. Mo Month(s), PA Physical activity

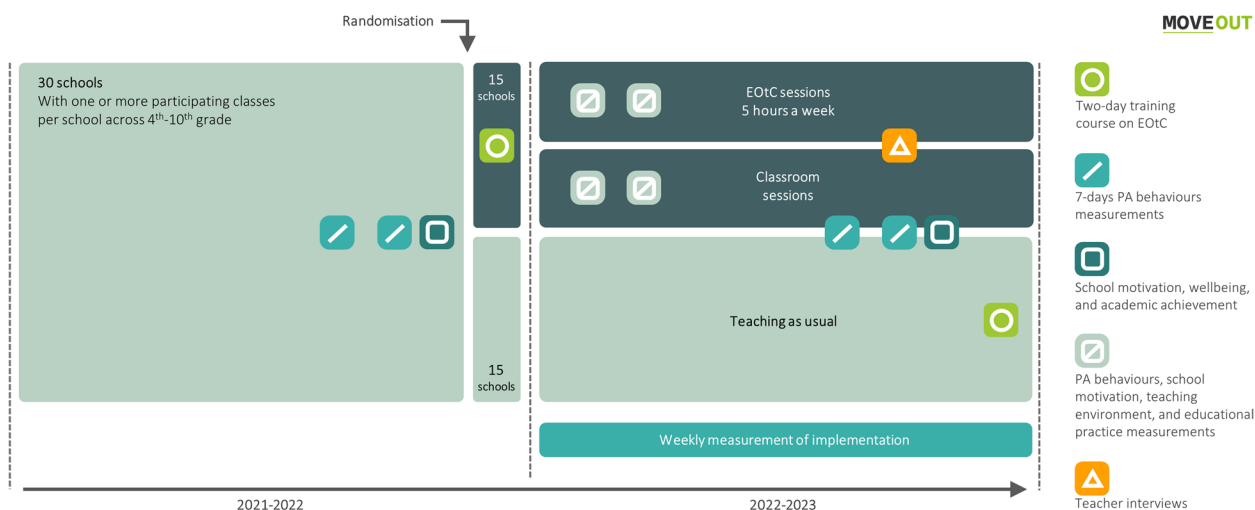


Fig. 4 The MOVEOUT study design

contacted via telephone. Online information meetings were held with school principals and teachers. Participating teachers informed the parents and were provided with written material available in Danish and English, and supplementary video material introducing the study (see Supplementary Information, Additional files 1, 3, and 4). Parents were given a letter with additional information about the study’s rationales and background, and an analogue consent form. The recruitment process was supported by general information on the MOVEOUT study project website (www.moveoutstudy.dk) [57].

Intervention

The intervention is based on the TEACHOUT intervention [49]. It is comprised of a two-day training course (13 h in total) on EOtC for teachers who afterwards implement EOtC in 1–2 weekly sessions, a total of at least five hours per week, for one schoolyear (in this study, August 2022 to June 2023, Month 4 to 14, see Fig. 4). The EOtC sessions in the schools are delivered by one or more of the teachers across different school subjects in various places and settings outside the school buildings.

The course was structured to provide the teachers with knowledge and understanding of the theory and practice of EOtC. The course was taught by expert EOtC teachers and teacher education specialists and included theoretical lectures, supplemented by illustrative examples in workshops and videos, and plenum discussions on local implementation. The training course took place on the 28th and 29th of April 2022 (after randomisation, Month 0, see Table 1). The course was supplemented by two one-hour inspirational webinars during the first half of the school year

(in this study, in September and November 2022, i.e., during Month 4 to 9, see Table 1).

Teachers in the control group received the two-day training course on EOtC in April 2023, close to the end of the intervention group implementation closeout; however, early enough for them to use the course content in their planning of the following school year. Also, they will receive the two one-hour inspirational webinars in the autumn 2023.

Randomisation

Randomisation was performed by PE and MB on 1st of April 2022 (Month 0, see Fig. 4), and was made public on YouTube (see Supplementary Information, Additional file 1). Immediately after, the enrolled schools and teachers were informed by e-mail about the result of the randomisation process.

To ensure a balanced representation of grade levels across the intervention and control groups, stratified block randomisation in a 1:1 ratio was used (i.e., schools with participating classes in grade 4–6 and schools with classes 7–10 were randomised block wise in RStudio using the ‘dplyr’ and ‘readxl’ packages).

Due to the type of the intervention, it was not possible to blind the participants to group allocation. However, allocation levels will be coded before analyses and the analysts will not be informed about the codes before the final analyses have been performed.

Sub-study 1: effects of EOtC

Design

Effects of EOtC will be measured in a between-subjects design. PA measurements pre- and post-intervention will be collected in two intervals each (Test A and B) to

account for seasonal variations. Data collection of the first PA pre-intervention measure commenced before randomisation and continued until just before randomisation (Pre-test A, Month -2 to -1, see Table 1). The second PA pre-measure was collected after randomisation and before the implementation of the intervention (Pre-test B, Month -1 to 0). School motivation, wellbeing, and academic achievement were measured at pre-test B.

The first PA post-measure data collection will commence during the end of the school year (Post-test A, Month 10 to 11, see Table 1). The second PA post-measure data collection will be assessed immediately before finalisation of the intervention (Post-test B, Month 11 to 12, see Table 1). School motivation, wellbeing, and academic achievement will be measured at post-test B.

Outcome measures

School-based and overall PA behaviours will be measured with Axivity[®] AX3 accelerometers (see full pre-registered study description of the investigation of PA behaviours [51]). All acceleration data will be processed in Matlab (Version 9.9.0 R2020b, Mathworks Inc., Natick, Massachusetts, US), which includes resampling, generating ActiGraph counts [58], identification of non-wear, and summarising the subjects' time spent in different PA intensity domains and with types of PA behaviour as running, walking, standing, and sitting. Non-wear periods is identified from both acceleration and temperature using the method described in the study by Rasmussen et al. [59]. Pupils should have valid data from at least one pre-intervention PA measurement.

School motivation is measured using the Academic Self-Regulation Questionnaire (SRQ-A) [60]. The SRQ-A is a domain-specific 32-item self-report questionnaire developed for measuring the level of autonomy relative to doing different types of schoolwork among pupils in late primary and lower-secondary school. In this study, the items from the homework domain are omitted as not every school in Denmark uses homework.

Wellbeing will be measured using two different scales, the overall score from the KIDSCREEN-27 questionnaire and the pro-social behaviour scale of the Strengths and Difficulties Questionnaire (SDQ). KIDSCREEN-27 is the 27-item version of the KIDSCREEN Health-Related Quality of Life (HRQoL) questionnaire which measures the subjective health, wellbeing, and health-related quality of life of children aged 8–18 years [61]. The pro-social behaviour scale of the SDQ measures resources and functioning in terms of social skills and competences of children aged 11–17 years

[62, 63], although high reliability was reported for use in pupils aged 10 years in a similar EOTC intervention study [26].

Academic achievement will be measured with two scales measuring reading competence and math skills. Reading competence will be measured with the validated age-adapted text reading test (Tekstlæseprøve, Grade 3–7; Tekstforståelse Udsagn A [Text comprehension Statement A], Grade 8–10) by Hogrefe [64]. Math skills will be measured with the validated age-adapted mathematical basic skills test (MG, Matematik Grunlæggende [Mathematics Basics]) by Hogrefe [65].

Sample size

Three classes were expected to drop-out during the intervention as per observations in the TEACHOUT study [38]. We further expected a sample size reduction by approximately 20% of the pupils due to drop-out and invalid accelerometer data (equivalent to four pupils per class). We expected an analytical sample of ~30 schools, ~51 classes, and ~867 pupils in total. The expected analytical sample allows 95% power to identify a small to medium effect size using a one tailed test (Cohen's $d=0.374$ 95% CI [0.187,0.561]). Calculations accounted for intraclass correlations (ICC) derived from the TEACHOUT dataset of 0.046 within classes and 0.035 within schools. Power calculations were conducted using R package PowerUpR [66].

Statistical analyses

Estimation of intervention effects (H1, H2, and H3 of Sub-study 1) will be computed using a 'per-protocol' analysis [67]. All classes in the intervention group not adhering to the classification of 'regular EOTC' (an average of >150 min of weekly EOTC over the school year) and all classes in control group practicing too high amount of EOTC (average of >150 min of weekly EOTC over the school year) will be excluded. These analyses will be complemented with sensitivity analyses, following the principle of 'intention-to-treat' [67] which will include all schools in the analyses irrespective of their adherence to the intervention or control condition.

Linear mixed models (LMM) will be used to analyse how post-test scores varies as a function of whether the pupils were assigned to the intervention or the control group while taking into account pre-test scores, sex, age, and random effects of classes and schools. Please, see the H1 and H2 pre-registration for further information on the pre-processing steps and statistical modelling used for these data [51]. The base model used to assess H3 (effects on school motivation, wellbeing, and academic achievement) will include baseline as a covariate and school and class ID as random factor, and

group allocation as the fixed effect of primary interest. Follow-up stepwise modelling will be used to investigate the contribution of previously shown confounders, i.e. primarily the number of weekly EOTC sessions [26], age, and sex [23, 68, 69], to the base models. All sub-studies will be reported following the CONSORT statements and flowchart [70].

Sub-study 2: mechanisms of EOTC

Design

We will investigate the mechanisms of EOTC in a within-subjects design. Pupils in the intervention group will have their PA intensities measured during two randomly chosen EOTC and two usual school days in the first half of the implementation period (Month 4 to 7, see Table 1). The pupils will answer a school motivation and learning environment questionnaire at the end of each day. The pedagogical and didactical elements will be observed during sessions.

Outcome measures

PA intensities will be measured with wrist mounted Axivity® AX3 accelerometers during school sessions and data will be processed as in Sub-study 1.

Motivation for the teaching activities will be measured at pupil-level with the Interest/Enjoyment (3-items), Perceived Choice/autonomy (3-items), and Perceived Competence (3-items) sub-scales of the Intrinsic Motivation Inventory (IMI) [71]. The IMI is an activity-specific measure for intrinsic motivation and basic needs satisfaction [36, 72] specially designed to be distributed immediately after an activity. Experiences of Relatedness was measured with three items inspired by the relatedness subscales of the Basic Psychological Need Satisfaction Scales, Basic Psychological Need Satisfaction and Frustration Scale (BPNSNF) [73] and Psychological Need States in Sport-Scale (PNSS-S) [74].

Learning environment perception will be measured at pupil level with the Learning Rating Scale (LRS) [75]. LRS is a 4-item scale answered on a 10 cm visual analogue scale and assesses the pupils' perceptions of how much they learn at school, how well they are getting along, and how well the teaching methods fit them.

Pedagogical and didactical elements will be quantified with an adapted version of the elementary school teaching practice observation scheme, Einblicknahme in die Lehr- und Lernsituation [76], using items 1–35 of the Danish version [77]. The observation scheme includes five pedagogical and didactical themes including class management; recognition and motivation; structure and consolidation; autonomy and participation; and differentiation. The scheme will be supplemented by six

EOTC-specific [32, 35] and two lesson movement integration items [78, 79], as well as measures of what type of place the teaching takes place outside the school buildings [39]. These eight items will be used as a sixth theme to measure action-centred, experiential, inquiry-based, play-based learning processes theorised to pertain in particular to EOTC.

Statistical analyses

PA intensities during EOTC and usual school sessions will be analysed in three LMM's with sessions as unit of analysis to investigate each PA intensity (i.e., MVPA, LPA, and sedentary time) as a function of whether the pupils have taken part of a EOTC or usual school session (H4). The base model will include school days, nested in observations nested in pupils, nested in school class as random factors, and EOTC/usual sessions as the fixed effect.

Differences in pedagogical and didactical practice will be analysed in six LMM's (H5, one for each of the elements) with sessions as unit of analyses to investigate pedagogical and didactical practice as a function of the degree to which the practice occurred during a EOTC or usual session. The base model will include school days, nested in school class as random factor, and EOTC/usual sessions as the fixed effect. With school days as unit of analysis, two LMM's (H5) will be used to analyse how school motivation and learning environment perceptions vary as a function of whether the pupils have taken part of a EOTC or usual school days. The base model will include observations in pupils, nested in school classes as random factors, and EOTC/usual school day as the fixed effect.

Follow-up stepwise modelling will be used to investigate if previously shown confounders, i.e., length of EOTC sessions [26], age, and gender [23, 68, 69], will improve the PA intensity, school motivation, and learning environment perception base models.

The mechanisms of EOTC (H6) will be analysed in individual secondary structural equation models (SEM) for each of the three proximal outcomes, i.e., session PA, school motivation, and learning environment perception. In all three models, EOTC/usual schooldays or session will be included and the types of EOTC pedagogy applied in the session or schooldays will be investigated as mediators [80].

Evaluation of implementation

Design

Adherence to the intervention will be investigated in a repeated design with weekly monitoring of EOTC practised during the intervention in the intervention group and control group (Month 4 to Month 14, see Table 1). Quality of delivery, variations, facilitating and limiting

contextual factors at school, local, and municipality level, and teachers' acceptability of the intervention will be investigated through semi structured interviews [81] with intervention group teachers taking place in the second half of the implementation period (Month 10, see Table 1).

Outcome measures

Monitoring of the intervention, namely the degree and the characteristics of the EOtC implementation, will be measured with a short self-report teacher questionnaire distributed weekly to teachers by SMS every Friday during the implementation period. In the previous TEACHOUT study, non-intended EOtC implementation in the control group was found to be 1.64 h a week [39]. The questionnaire assesses the amount, place, mode of transportation, and school subjects used during EOtC sessions. The questionnaire is based upon the existing and validated EOtC implementation monitoring tool from the TEACHOUT study [38, 39].

Background descriptive measures

Perceived child health status and data on socioeconomic status (parents' or legal guardian's education level and occupational status) will be collected using the Danish Occupational Social Class Measurement [82] with the pupils' parents (or legal guardian) (Month -2, see Table 1).

Quantitative data about teachers previous work experience and previous experience with their use of EOtC will be collected from the intervention and control group teachers (Month 0, see Table 1).

Data processing

All analyses will be processed in either RStudio or IBM® SPSS® Statistics with the level of statistical significance for all tests set to <0.05 .

Trial status

Recruitment and enrolment were initiated two years before the implementation of the intervention and continued until randomisation (Month -18 to 0, see Table 1). The trial is progressing according to the time plan.

Discussion

EOtC holds promise for improved health and education if implemented regularly and extensively. The threshold, if there is one, for 'how much' EOtC is required for health and education gains is uncertain, but previous experience and findings point to five hours a week as a minimum. However, this current understanding of EOtC rests on findings from previous studies (e.g. [24,

27, 29]) with inherent risks of bias. The MOVEOUT study investigates the effects of the intervention developed and conducted in the TEACHOUT study [38] with updated and strengthened design and measures. The foremost strengths and limitations of the MOVEOUT study are discussed below.

The MOVEOUT study aims to reach more solid conclusions of the effects and mechanisms of EOtC using randomised group allocation, quantification of the pedagogical and didactical elements that are posited to carry effects, and extensive monitoring. The study will not only be able to confirm or disconfirm previous assertions relating to EOtC, but also contribute to a deeper understanding of the so-called active ingredients. Pending the findings, the combination of these data sources provides considerable prescriptive potential for practice and policy.

The use of randomisation will minimise any influences on effect measures of teachers' having different initial interest in and abilities for EOtC. It can be expected that being randomised to do what you as a teacher have hoped for when signing up for the study, i.e., being assigned to the intervention group, may affect pupil outcomes positively. It may also be that the teachers ending in the control group may not refrain from using EOtC. Therefore, the collected weekly monitoring data about EOtC practise among all classes in the project is important data to include in the analysis.

The MOVEOUT study enables an effect evaluation of EOtC-induced PA behaviours by having pre-intervention measures of PA in order to adjust post-intervention PA for baseline PA. We further use two pre-intervention and measures and two post-intervention measures to account for impacts of seasonal changes in weather. Such a design is seldom applied in the studies investigating the influence of comparable interventions on PA [21, 83], and will provide a more valid analysis of the intervention effect that the previous study on the effects of EOtC on PA [23].

Effectiveness and efficacy studies of educational interventions often fail to report whether and how the intervention was monitored [84, 85]. Such a lack of monitoring is also evident in outdoor activity programs [86] and is a general limitation for outdoor learning programs [87]. Lack of intervention monitoring, leads to a 'black box' approach to intervention studies, where implementation is not evaluated [88]. In the MOVEOUT study, such an approach is avoided by combining the quantitative monitoring with on-site observation on school days involving EOtC sessions and usual schooldays. Combined with school day specific assessment of PA and school motivation and learning environment perceptions, monitoring and observations enable an investigation of key mechanisms of EOtC.

Abbreviations

BMI	Body Mass Index
EoTC	Education outside the classroom
EUR	Euro currency
HRQoL	Health-Related Quality of Life
LPA	Light-intensity physical activity
MI	Movement integration
MVPA	Moderate-to-vigorous physical activity
PA	Physical activity
RCT	Randomised Controlled Trial
SDQ	Strengths and Difficulty Questionnaire
SDT	Self-Determination Theory
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SRQ-A	Academic Self-Regulation Questionnaire

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12889-023-16618-3>.

Additional file 1: Table SA1. The MOVEOUT study video materials.

Additional file 2. MOVEOUT SPIRIT 2013 Checklist: Section, item number, and manuscript page number.

Additional file 3. Information about the project and the processing of data (parents).

Additional file 4. Information about the project and the processing of data (teachers).

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Authors' contributions

PE, MB and PB conceptualised the overall study design, with support by CDK, LM, and GN. MB, PE, and KB further developed the Sub-study 2 study design. JB planned all PA data processing. PSM designed and organised the efficacy study data collection, supported by PE and MB. MB, LM, and PE drafted the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

Anonymised participant-level data can be made available upon reasonable request to the corresponding author, such as verification of the research results. To comply with the European General Data Protection Regulation, and to accommodate article 10 of the Danish Act on Data Protection anonymised participant-level data will be made available on the Open Science Framework five years after the main publication of this study (link available in the reference list [51]).

Declarations

Ethics approval and consent to participate

The MOVEOUT study was reviewed by the Regional Committee on Health Research Ethics, Capital Region (ID: 21062006) and deemed not eligible to undergo ethics review (documentation available on the Open Science Framework, under subheading Files (link available in the reference list [51]). By Danish law, only biomedical research projects or projects that include risks for participants need to have their ethics evaluated by a Regional Ethics Board. All other non-biomedical research projects can not apply for formal ethical approval. The MOVEOUT study was evaluated by University of Copenhagen

internal ethics committee, The Research Ethics Committee for SCIENCE and SUND (ID 504–0292/21-5000), which concluded that the project was compliant with appropriate Danish and International standards and guidelines for research ethics (documentation available on the Open Science Framework (see link above)). Informed consent was obtained from all the participants or their legal guardians. The MOVEOUT study was pre-registered at clinicaltrials.gov (NCT05237674). All data and other personal information are collected is processed in accordance with the Danish Data Protection Act. Teachers and classes will each receive a separately reimbursement equivalent to 200 EUR in recognition of their contribution. Trail data documents will be available on request.

Consent for publication

Not applicable.

Competing interests

MB and KB are board members of the NGO, The Danish Education Outside the Classroom Association (UdeskoleNet). All other authors declare that they have no competing interests.

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