Effectiveness of the Let's Move It multilevel school-based intervention on physical activity and sedentary behaviour: A cluster randomised trial

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Abstract

Background: Physical activity (PA) declines in late adolescence, particularly among those with low education. Few trials have tested interventions to decrease sedentary behaviour (SB). No school-based interventions have shown lasting effects on PA or sedentary behaviour (SB) among older adolescents.

Purpose: To examine whether the multi-component *Let's Move It* intervention has an effect on behavioural and clinical outcomes among adolescents after two and 14 months.

Methods: A cluster randomised trial in six school units in vocational education in Finland (*N*=1112) (mean age 18.5 years, range 15-46). The intervention targeted in-class activity opportunities, and students' motivation and self-regulation. Valid (≥4 days, ≥10 hours/d) accelerometer data was obtained from 741 students at baseline, 521 (70.3%) at 2 months, and 406 (54.8%) at 14 months.

Results: No evidence of a significant intervention effect on three co-primary outcomes was found. The intervention arm reduced their total daily SB time by 32 minutes (95% CI -43.2 to -20.8) on weekdays, compared with the control arm's reduction of 8.6 (95% CI -19.5 to 2.3) and engaged in more accelerometer-measured light PA during school time. Few differences were found in secondary outcomes. Fidelity of delivery was relatively good.

Conclusions: Low-dose school-based interventions might not provide sufficient intensity to affect leisure-time activity. Despite a positive outcome on school-time light PA, more comprehensive or intensive environmental changes may be needed to meaningfully improve older adolescents' total activity.

[Trial registration information moved for masked review.]

Keywords: physical activity, sedentary behavior, theory-based intervention, randomized trial, self-determination theory, reasoned action approach, self-regulation

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Background

Physical activity (PA) decreases and sedentary behaviour (SB) increases during adolescence, with most adolescents worldwide currently not meeting recommended activity levels [1]. Inactivity is more prevalent adolescents from a lower socioeconomic status [2]. Effective interventions to improve PA among youth would help prevent non-communicable diseases [3]. Increasing attention has been given to the "gender gap" in PA: on average, girls engage in less PA than boys [4].

On average, school-based interventions have produced minimal effects on accelerometer-measured moderate-to-vigorous physical activity (MVPA), among both boys and girls [5]. Among older adolescents, there is a dearth of research, and none of the few trials have shown long-term effects in PA or SB of school-based interventions [6]. Trials have had low power and other methodological limitations [6]. Regardless, school-based interventions still hold promise [7] as majority of the age-cohort can be conveniently reached where they spend most of their day-time.

Evidence on interventions deployed in school settings seem to support the use of multicomponent strategies, as opposed to classroom-based or environmental strategies only [8]. The current trial attempted to use previous evidence, behavioural science theory, co-creation, and empirical optimisation to develop a whole school system intervention to increase PA and reduce SB. The development aimed to make the intervention acceptable, practicable, effective, cost-effective and disseminable [9,10]. The systematic intervention design has been described in detail [11], as well as the preceding comprehensive research and evidence synthesis [9,11,12]. Activity behaviours by adolescents were identified to be affected by multiple influences on behaviour [13]. Hence, the developed intervention drew on several theories tapping on both quantity and quality of motivation, environmental influences and self-regulation. As the teachers were identified to control a large part of student sedentary environments during weekdays, their in-class behaviour was targeted with an intervention based on the self-determination theory [14], reasoned action approach [15], and habit theory [16]. Evaluation of the teacher intervention showed that those teachers who adopted more behaviour change skills also reported providing more classroom activation for their students [12]. Qualitative evaluation among a subsample of students found that students felt that they received various insights, inspiration, and actual skills for increasing daily activity [17], and that the intervention was highly acceptable, still, many of them reported not taking up PA in their daily lives [18]. Quantitative investigation into the assumed mechanisms of action from self-determination theory [14], reasoned action approach [15], and self-regulation noted that on average, intervention arm students self-reported using more behaviour change techniques post-intervention [19], and showed some positive, yet short-lived, changes in SB-related cognitions [20]. As opposed to the previously published process evaluations, this paper reports the main trial result, i.e. effectiveness of the intervention.

To our knowledge, this is the first major trial in vocational schools.

Intervention fidelity can be defined as the degree to which interventions are put into practice as intended [21,22], and thus plays a crucial role in reliability and validity of intervention research. However, fidelity is often overlooked in behaviour change intervention studies [22], and it is often conceptualised only as fidelity of delivery by the intervention provider [e.g., 23]. However, assessing the extent to which participants receive the intervention, and whether this 'received dose' is associated with outcomes, is also warranted.

This study represents the main outcome evaluation of the intervention, and thus aims to report on the effectiveness of the Let's Move It intervention on changes in students' PA and SB over two months (immediately after the intensive intervention, T3) and 14 months (T4), specifically in the following four co-primary outcome measures: 1) MVPA, as measured by accelerometry and self-report, and 2) Sedentary behaviour (SB) as sedentary time and breaks in sedentary time as measured by accelerometry.

We test the hypothesis that the intervention is effective in increasing or maintaining PA and reducing SB, compared to standard curriculum. We also evaluate the hypothesis that there is a significant difference in change in MVPA specifically among students with low or moderate levels of MVPA at baseline. MVPA was measured with both accelerometry and self-report, due to accelerometers missing certain types of sports (e.g. swimming). To assess SB comprehensively, primary outcomes include both the time spent sitting or lying down and breaks in sedentary time. At the time of trial design, MVPA, SB, and breaking SB had most evidence with regard to health benefits.

Secondary outcomes include other indicators of activity (e.g. light PA, standing), body composition, self-reported fitness, and mental well-being [9]. As accelerometry only encompasses seven days at most on each measurement occasion, it may not be representative of a typical activity. Therefore, eventual changes in body composition (e. g. lean mass) and in self-reported fitness may better reflect sustained levels of activity over several months. Due to well-known differences between weekday and weekend activity [24], we also conduct additional exploratory analyses with weekdays and weekend days separately, as well as school time. Furthermore, we conduct secondary analyses on the effects of gender and dose received.

Methods

Study design and setting

This cluster randomised trial with study assessments conducted at baseline, and 2 and 14 months after the baseline was conducted in six school units in Southern Finland. The trial was reviewed by the ethical committee for gynaecology and obstetrics, paediatrics and psychiatry of The Hospital District of Helsinki and Uusimaa (367/13/03/03/2014) and registered ([Trial registration number moved for masked review.]) when participant recruitment was ongoing. Detailed descriptions of design and recruitment[9] and intervention development [11] have been published.

To determine sample size, we used the power calculation approach by Eldridge and Kerry [25] to define the design effect, by which a sample size derived for a difference in means would be inflated in a 2-level cluster randomised design. We assumed unequal cluster sizes (*M*=17, *SD*=3.83), derived from an internal pilot study. We aimed for at least 1100 participants at baseline, and details (e.g. the ICCs used) are reported in the protocol [9]. The spreadsheet with the syntax used for sample size calculations is available publicly [26].

Vocational education and training (VET) in Finland is designed both for young people without upper secondary qualifications and for adults already in work life. Approximately half of each age cohort obtains vocational degree, and half continues to high school and higher academic education. VET is organised mainly in institutions (on-the-job learning included) or as apprenticeship training. In an institutional setting, a qualification will usually take approximately three years to complete and is free of charge. A vocational qualification gives general eligibility for university of applied science and university studies. The Ministry of Education and Culture prepares VET legislation and steers and supervises the sector. The Ministry also grants the education providers' permits to provide VET.

Participants and recruitment

Figure 1 depicts participant flow. Other papers report details about recruitment [9], baseline associations [27], and findings among teachers [12].

<Figure 1>

Randomisation and allocation

Randomisation was conducted at the school level and the matched school units (with specified educational tracks). Student participants were blind to randomisation. Due to practical reasons [9], assessors were not blind to allocation but all contacts and interactions with the participants were carefully scripted in order to provide identical contacts with control and intervention participants and avoid bias. Research staff handled all communication about the study. Details of various measures taken to reduce risk of bias in this trial are listed in Supplementary file 1.

Intervention

The intervention objective was to increase total PA. The intervention development aimed to assure a good fit with the school curriculum, and teachers and student representatives were involved in the design of the intervention (for details, see [11]). For example, some activities were piloted among a small group of students and then modified based on feedback. The trial participants were not part of the co-design team. Scarce resources and minimal time available for intervention delivery in the school settings were accounted for as key constraints.

The systematic intervention design led to a two-pronged approach (see Figure 2): PA behaviours were targeted through conscious motivational and self-regulation processes in face-to-face student group sessions along with graded, step-wise self-guided experimentation of self-selected PA. A detailed description of the seven group sessions (duration ranged from 45 to 60 minutes),delivered as part of the school curriculum, can be found elsewhere [11]. The description also details how session activities instrumentalised theories, often targeting multiple theoretical constructs simultaneously, e.g. Coping Plan Consultants exercise, where students in small groups were presented with the case of an "inactive adolescent who wants to increase their activity levels", and then prompted the group to brainstorm ideas for this case: this exercise aimed to provide students with practical tips for exercise, build selfefficacy, provide coping planning skills, and supports norms relating to exercise (see description in [10], Table 1). SB was addressed with environmental changes, including physical changes in classrooms (e.g., gym balls as chairs) and teacher-led changes in classroom practices (e.g., increasing breaks in sitting in class). Teacher training, to deliver the SB intervention, was delivered as three 2-hour workshops that aimed to build teachers' motivation, self-regulation and habits toward using classroom practices to reduce student sitting (a detailed description can be found in [12]). Both the student group sessions and the teachers training workshops were delivered by facilitators that were part of the research team. A parallel poster campaign and increased access to other environmental opportunities for PA (e.g., lower-cost participation in neighbourhood sports centres) boosted both approaches.

<Figure 2>

Data collection procedures

The study was conducted in six cohorts. Data in each cohort was collected at four time points: pre-intervention baseline (Time 1, T1), during the intervention after the third group intervention session (T2, intervention arm only), post-intervention at two months (T3), and 14 months (T4) [9] The trial employed methods to enhance quality of measurement (e.g., careful and repeated training of assessors, exchanging assessors between schools). All data were collected during school time at schools. Students filled out the online survey, accelerometers and instructions for its use were distributed to students, and anthropometric measures were taken.

Measures

Behavioural outcomes. PA was measured using accelerometers (Hookie AM 20, Traxmeet Ltd, Espoo, Finland) with a digital triaxial acceleration sensor (ADXL345; Analog Devices, Norwood MA), that has shown to be a valid measurement tool both among adults [28] and young people [29]. Daily average minutes of MVPA, total sedentary time, and breaks were the co-primary accelerometer-measured outcomes. (It should be noted that due to an oversight, also step count was listed in the registration, but this paper is amended to report the four main outcomes as per protocol.) The accelerometers collected and stored the tri-axial raw data in actual acceleration (g-units). The data was analysed in 6 seconds' epoch length. The three PA intensity categories based on metabolic equivalents (MET) were light, moderate and vigorous. Light PA is defined as activity corresponding to 1.5−2.9 MET, moderate activity as 3.0–5.9 MET and vigorous activity to more than 6 MET [30]. According to the definition of SB [31], time spent in sitting and reclining positions are combined to indicate SB, time standing still is analysed separately. Breaks in sedentary time were calculated on the basis of the number of lying/sitting periods ending-up with a clear vertical acceleration. (For more information, see [9]). Participants were requested to wear the accelerometer over the right hip during waking hours, except during shower and other water activities, for seven consecutive days. Daily reminders were texted to consenting students [32]. Student data were included in the analysis if the accelerometer was worn for ≥10 hours on ≥4 days. Weekday school-hours were estimated to occur between 8am-3pm, and for these analyses, the criterion was set of a minimum of five hours during school hours.

Self-reported MVPA assessed the number of days the respondent reported having been active at least 30 minutes during the past week, a part of the NordPAQ measure [33]. For further information on the MVPA measures (accelerometry and questionnaire based), see Supplementary file 2.

Anthropometric data. Body composition, i.e. lean mass and adiposity (fat mass), was measured with Tanita (MC-780MA). Height was recorded to the nearest 0.1 cm using a portable stadiometer. Analyses controlled for height as well as season of measurement due to arm imbalance.

Student characteristics. An online survey assessed sociodemographic characteristics and also other measures not included in the current paper (e.g.,hypothesised psychosocial mediators of intervention effect) (for a full list of measures obtained in the trial, see Table 3 in [9].

Process measures. *Delivery fidelity* was measured with checklists. These listed each intervention activity conducted during the seven face-to-face student group sessions (e.g. “I revisited the most important messages of the current session“, “I presented, prompted and participated in the activity break”, “I highlighted coping planning strategies”). This checklist was answered by the session facilitator that was asked, for each class and each activity, if each intervention activity was “Delivered fully as intended”, “Partly delivered”, or “Not delivered”. *Fidelity of receipt* was here conceptualised as attendance to sessions, by student, this measure was based on a record kept by facilitators. The analyses were conducted by differentiating groups that received at least 50% of the sessions.

Statistical analyses

Longitudinal data were analysed with Linear Mixed Models (LMM) for continuous outcome measures and Generalized Linear Mixed Models (GLMM) for dichotomous outcome measures. These analyses allowed the incorporation of incomplete longitudinal data into the analyses. At baseline [27], the two arms differed in the proportions of the four educational tracks (nurses, IT, business and hotel & catering), and as the educational track was strongly associated with PA, educational track was also controlled for in the analyses. Baseline values of gender, age, educational track, parental SES, and country of birth were modelled as covariates with fixed effects and student group as a covariate with random effect. For outcomes from accelerometer data, accelerometer wear time was used as time-varying covariate. Analyses were conducted for weekdays, weekends, and school time (8am-3pm).

Analyses of the change in MVPA are reported for the whole trial cohort, and for a subsample excluding those displaying high levels of MVPA at baseline. The reason for this is that the intervention components to increase PA were specifically designed for youth with low levels of PA and MVPA (i.e., the programme theory does not hypothesise effectiveness of the intervention for individuals with already high levels of PA), hypothesizing greater gains for those low in PA.[34] For the low vs. high MVPA stratification, a feasible cut-off point was set so that no more than 20% of the trial cohort would be excluded from the analysis. The power analysis in the protocol was performed using this cut-off [9].

Reported p-values are taken from interaction effects between group and time. Subgroup analyses by educational track were conducted as sensitivity analyses to evaluate eventual differential response to intervention. Sensitivity analysis excluding over 20-year-olds and non-Finnish-speakers were also conducted.

Within-group differences between two time points are presented with mean difference and 95% confidence interval. Between-group differences in changes between two time points were analyzed with analysis of covariance using baseline value of outcome as covariate. All the analyses were performed using IBM SPSS software. T tests were used to determine if students who provided data at follow-up differed from those that only provided baseline data on gender, age, and PA level. For all analyses, significance was set at 0.05.

Results

Sample/enrollment

Six school units were recruited to the study, including four municipal and two private schools. Informed signed consent was received from 89.7% of the approached students. Figure 1 outlines the flow of participants. Detailed baseline characteristics of this sample have been reported elsewhere [27].

At baseline, 81.4% of those students who wore an accelerometer provided at least 4 days of valid accelerometer data. At 2 and 14-month follow-ups, 862 and 623 students wore an accelerometer, and 60.4% and 65.2% of them provided at least 4 days of valid accelerometer data. Drop-out was larger in the intervention (T3: 34.1%, T4: 26.3%) than the control arm (T3: 24.7%, T4: 17.9%). Baseline age, gender, or PA level did not predict drop-out, but parental education did: those whose parents only had basic education dropped out (27.9%) more than children of parents with college or equivalent degrees (11.0%) (p=0.002).

Intervention and control arms differed in some background factors: Firstly, parental socioeconomic status was higher in control arm (mother's education level university in intervention arm 13.4%, among controls 20.7%; or unknown: intervention: 29.1%, control 22.7%). Secondly, there were more students born in Finland in the control arm (88%) than the intervention arm (80%), and students whose one or both parents were born in Finland (control 78%, intervention 66%), reflecting the fact that the intervention arm is more ethnically diverse, much of this explained by (mostly parental) refugee backgrounds.

Fidelity

Fidelity of intervention delivery, measured after each session with facilitator checklists of the session components, was high for all groups: all components were either fully or at least partly delivered 97.0 % of the time, on average. Facilitators reported not having delivered at all only 2.7% of the intended activities. The criterion of fidelity of at least 80% was fulfilled for all groups, with eight groups receiving full 100%, and no groups receiving less than 83% of the components. The most commonly omitted components included recap of important messages at the end of session 1 (omitted in 25.0% of the facilitator reports) and at the end of session 2 (21.4%), giving intervention letters to family to the students (20.0%), presenting social media accounts for students at session 3 (18.2 %) or mentioning them at session 6 (13.3%), and showing the group's PA maps at the booster session (12.0%). The most often perfectly delivered (i.e. highest rating) 'active ingredient' components were the feeling cards exercise at session 1 (93.3%), discussion exercise of the Let's Move It principles at session 6 (93.3.%), problem solving at booster session (96%) (See Supplementary file 3.)

Fidelity of receipt, measured as attendance, was adequate: Of the six sessions in the first two months, 67% of intervention arm participants attended at least four.

Co-primary outcomes (accelerometer-measured)

At 2 months, differences between students in the intervention and control arms were not detected in the co-primary outcomes of MVPA or SB on the whole (Supplementary file 4). Table 1 shows that on weekdays, the intervention arm reduced their total daily SB time by 32 minutes (95% CI -43.2 – -20.8) compared with control arm's reduction of only 8.6 (95% CI -19.5–2.3) (p=.047). As for the other activity variables, the only detectable difference between arms was in light physical activity (LPA), with lower LPA among control arm at the 2-month follow-up (between-arm mean difference 9.3 minutes; 95% CI 2.8–15.9) (p=.01). However, there were no differences between arms in any of the activity variables (in absolute minutes) by the 14-month follow-up.

During school hours only (note, also exploratory analyses), changes in LPA and SB were significant (both p<.001), with LPA minutes significantly increasing and SB minutes significantly decreasing by the 2-month follow-up in the intervention arm compared to the control arm (between-arm difference in LPA was 11.2 minutes; 95% CI 6.6–15.8 and in SB -13.6 minutes; 95% CI -21.9– -5.3). The proportional differences between arms' LPA remained at the long-term follow-up (see Figure 3C). It should be noted that the analyses differentiating school time and leisure time, as well as weekdays and weekends were not registered, and were exploratory.

Excluding the 20% with highest MVPA levels at baseline, there were no detectable differences in the outcome variables between arms. Educational track did not show differential response to intervention. Fidelity did not alter the results systematically, but the changes in activity behaviours were slightly better sustained among those who attended at least three of the sessions (compared to non-attendance, SB attendance >50% p = .068. attendance <50% p = .026; LPA attendance >50% p = .005. attendance <50% p = .375).

<Table 1; Table 2>

Secondary outcomes

Between baseline and T4, the proportion of participants self-reporting poor fitness decreased in the intervention arm but increased in the control arm, but the 10.7 %-point difference lost significance after controlling for confounders. No other differences were found. No adverse events or side effects were detected.

Figure 3 visually displays the proportional changes in MVPA, SB (primary outcomes) and LPA (secondary outcome) in both arms. Supplementary tables display analyses without weekday-weekend separation (in accordance with study statistical protocol registration), and without adjustments for confounding variables.

Gender differences

Overall, the intervention seemed to be more effective among girls when compared to boys (see supplementary file). Exploratory analyses indicated that during weekdays, the intervention effect on sedentary time was significant among girls (p = .002) but not boys (p = .492), as well as on LPA (girls p = .003 v. boys p = .764), MVPA (girls p = .045 v boys p = .091) and self-reported MVPA (girls p = .047 v. boys p =.825). The effect on breaks in SB was non-significant among both genders (girls p = .261, boys p = .056).

<Figure 3>

Discussion

This cluster-RCT investigated the effects of a multi-level intervention on student activity behaviours and secondary outcomes. The trial did not find evidence that the intervention was effective in changing the co-primary outcomes of MVPA or SB overall. However, there was a statistically significant increase in LPA during weekdays, and a decrease of SB during school hours, with on average 9 minutes more LPA during weekdays, and 11 minutes more LPA and 14 minutes less SB during school hours. Gender-specific analyses suggested the intervention was more effective among girls. We highlight that the analyses regarding school, weekday and weekend, or analyses by gender, were not pre-registered, but were conducted to achieve better understanding of the trial.

The results align with those from other trials: Most school-based interventions have not been able to show meaningful improvements in accelerometer-measured MVPA [5]. However, increased volume of LPA during school time was observed and it is likely attributable to successful teacher activation of classroom time, as suggested our previous analyses of the teacher behaviour change [12]. Qualitative process evaluation suggested intervention arm students identified several insights regarding MVPA, saying these also inspired them to increase activity [17]. However, the current analyses suggest that these insights or improved motivation were not sufficiently widespread to translate into measurable behaviour during leisure time, especially among boys.

Why did the intervention only influence changes in LPA but not other types of activity? Intervention content may have been more likely to increase LPA to begin with, e.g. with the messages emphasising “starting small” and “any activity is better than nothing”. The decreases in SB and increases in LPA indicate that some SB time has been replaced by LPA. For some analyses, the change in SB is not significant given its high levels to start with in comparison to the total minutes of LPA or MVPA. Besides, as students increased their levels of LPA during school hours, the perceived need to increase PA in general and MVPA in particular, in other settings, may have decreased. The key message that "every little increase in PA counts" seems to have been strongly considered - however, this compensation hypothesis cannot be supported by any data. The LPA finding is among the most robust in this study. It is a positive signal, as LPA has recently been found to produce health benefits [35], and the average addition of about 50 minutes of LPA per during the weekdays may produce significant health outcomes if sustained. Systematic increase in activity, even light intensity, is effective, if sustained over the long term.

The exploratory analyses suggesting that the intervention was more effective among girls, in increasing MVPA and LPA and reducing SB time, are in line with previous evidence indicating school-based intervention effectiveness mostly among girls but not boys [36], although meta-analysis on trials using accelerometry found no more effectiveness among girls than boys [5]. There is some inconclusive data suggesting that for PA, gender-targeted interventions may be slightly more effective than gender neutral [37]. The Let's Move It intervention contained some components potentially more relevant to girls, e. g. addressing pressure for good looks vs. well-being as primary motive for PA. Also, although boys were equally engaged as girls in co-design and feasibility study, and the ADs involved in designing the visuals and slogans of the intervention were men, the development and provider team consisted mostly of women. It is difficult to speculate whether the decisions undertaken by a team of men would have led to an intervention more appealing to boys. It should be noted that gender is confounded with educational track [27].

The results on MVPA give rise to alternative explanations: 1) First, intervention theory, or programme theory (i.e., expectations of how the interventions would bring about its effects) was wrong, and these interventions would not have helped in increasing youth –

especially boys' - PA anyway. Alternatively, 2) the intervention theory (or part of it) was correct but did not bring results due to (a) low fidelity; (b) too small dose (more intensive and longer interventions are more effective [38] as behaviour change is difficult and hardly easy to learn even for the motivated ones within a few contact hours); (c) external disturbances (e.g., co-occurring governmental cuts in school budgets, and major changes in intake criteria including no more requiring language proficiency among new students); and/or (d) too early measurements (effects may become visible only later - the programme teaches skills for behaviour change, which may take longer to assimilate and actually accommodate, and these skills may only be used in early adulthood a few years later. Furthermore, in universal interventions, it is challenging to produce solutions fit to different individuals or subgroups, despite possibilities of tailoring within the intervention. Finally, major changes only occurred within schools, less in other living environments of the students – but daily living arrangements and environments at home and with friends may be more influential. Other evaluation studies [12, 17-20] support the interpretation that many of the intervention elements were supportive of change, but with the exception of the classroom-related changes, the dose was too small. Passive overall life environments, conducive to sustaining previous passive behaviours, can act as deep "valleys" in the behavioural landscape, making change particularly challenging [39]. Further, this intervention aimed to balance between offering sufficiently prepared, behavioural-science based materials and activities (to reduce the burden on school staff), yet allowing for school-specific tailoring. However, more intensive context-specific approach may be called for, to increase effectiveness [40].

Fidelity for some components of the intervention was good and, for others, lower than ideal. A criterion of at least 80% delivery of program components was mainly followed for all groups. However, as this is based on self-report by facilitators, there is the possibility of bias. For MVPA, the programme theory hypothesised relevance of a) getting motivated, b) adopting self-regulatory skills, and c) behavioural experiments (students were encouraged to select and plan some leisure time PA activity). The fidelity of receipt, by adolescents, of motivational and self-regulation sessions was deemed good and adequate (see qualitative analysis of receipt [18]), but the facilitators observed that the engagement level with behavioural experiments and home workout videos was extremely low. The original rationale was that regularly incorporating PA in daily life may be more likely to result in maintenance across time, even outside of school terms, rather than offering PA only within school. A better solution might have been to embed simultaneously a PE class where engagement with the target behaviour could have been done with high fidelity (see e.g. [41]), to strengthen the effect of the motivational, self-regulatory discussion classes. Although social support was highlighted and encouraged in several ways, an even more social network underpinned approach, via e.g. collaborative planning with friends (see also e.g. [42]), may have been more effective, yet more difficult to deliver. With increasing appealing digital - and physically passive - screen activities, PA interventions may have to take into account such competing forces: even a strong motivation for PA may not overpower motivations for alternative fun activities such as gaming and social media [43].

The study has several limitations. First, although recruitment rate was high, suggesting low selection bias, drop-out leaves results open for bias. We had originally estimated to need a post-dropout sample of 704, but the analyses at hand include less than 300 people. Low sample and selective drop-out (by arm) may bias the findings. Also, PA levels may be different if the measurement week was not normal school time (indeed at the final follow-up, many were out of school, on distance learning or an internship). Fourth, although accelerometer data give in general less subjective results than self-reports [44] and was considered a golden standard at the time of trial design, it is somewhat restricted in type of PA. The accelerometer, as a technical device that needs to be worn for measurement to occur, suffers from reliability and validity issues, such as selective non-wear, restricted battery life, malfunction, and non-adherence. We followed internationally accepted procedures by excluding participants with insufficient wear time. Due to restrictions on accelerometer use at work and certain sports (i.e., water or contact sport), there is a risk of missing valuable information on duration and intensity of PA. Also, accelerometer reporting of PA in intervention studies in general has been poor [45], hindering comparison to other similar studies. However, the strengths of accelerometry include precise data on intensity and total volume of PA during short time periods, characteristics inaccessible with self-report: These findings such as number of breaks, light PA minutes, steps, could not have been assessed and researched without the use of accelerometer data.

Finally, the arms differed at baseline on several issues, with the control arm being slightly more affluent and displaying slightly more positive patterns of PA-relevant variables (see also [27]). It is difficult to assess how this might have affected the outcomes of this trial. Balancing control and intervention arms across a variety of measures in a vocational school with different educational tracks, that present a gender imbalance, is a challenging, if not impossible task. In a vocational school context, where student groups are formed based on educational tracks and the consistency of schools (as to educational tracks) varies, it is challenging to create classical cluster-RCTs, compared to e. g. high-schools. Hence, the unique histories of the schools, or their students could have influenced the results. However, we were unable to analyse this due the small number (six) of participating schools and the lack of information on pre-baseline trends. These results are in line with recent calls for systems-level interventions to target multiple socio-ecological levels, and clearly highlight the concerns on the limitations of a classical RCT design [46].

This study has several strengths: It overcomes several methodological weaknesses of previous trials of school-based interventions in this age group [6], with its larger sample size, using various ways to ensure and assess intervention fidelity, and assessing outcomes with accelerometry rather than self-report only. Furthermore, the intervention itself was a result of a careful development process involving stakeholders and co-creation, drawing on several behavioural theories, and the intervention content is transparently and comprehensively reported. Finally, the trial design with mixed-methods data collection enables complementing this main outcome evaluation by process evaluation [e.g. [17,18]. Indeed, on average, school-based PA interventions have not managed to influence accelerometer-measured PA, among boys nor girls [5], but this intervention seems to have caused sustainable changes also in girls' accelerometer-measured activity, which may be remarkable. Further studies should examine this gender difference.

Conclusions

This trial was the first to investigate a multi-level school-based intervention on PA and SB in the vocational school setting. The findings suggest that leisure-time PA or SB may be too challenging, particularly amongst older adolescent boys, to change by a relatively low-intensive school-based intervention, i.e. with a maximum of seven teaching hours with groups. This aligns with findings of school-based trials in also younger age-groups [5]. Despite positive outcomes on school-time SB and light PA, more comprehensive environmental changes may be needed to meaningfully improve total activity among both boys and girls. Recommendations for future research include further high-quality intervention research (see also [47]), with rigorous methodology and transparent reporting of intervention development processes [48] and intervention content and fidelity, using not only outcome but also process evaluations.

List of abbreviations: PA physical activity, SB sedentary behaviour, MVPA moderate to vigorous physical activity, LPA light physical activity, RCT randomized controlled trial, LMM Linear Mixed Model, GLMM Generalized Linear Mixed Model

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Table and figure captions:
Figure 1. Flow diagram.
Figure 2. Overview of the Let's Move It intervention components
Figure 3. Proportional changes in moderate to vigorous physical activity (A),in light physical activity (secondary outcome) (B) and sedentary behaviour during schooltime (C).
Table 1. Intervention effects on primary and secondary activity outcomes
Table 2. Intervention effects on secondary outcomes
Supplementary files:
Supplementary file 1: Reducing risk of bias
Supplementary file 2: Details on methods
Supplementary file 3: Intervention delivery descriptive results
Supplementary file 4: Outcome analyses

Figure 1. Flow diagram

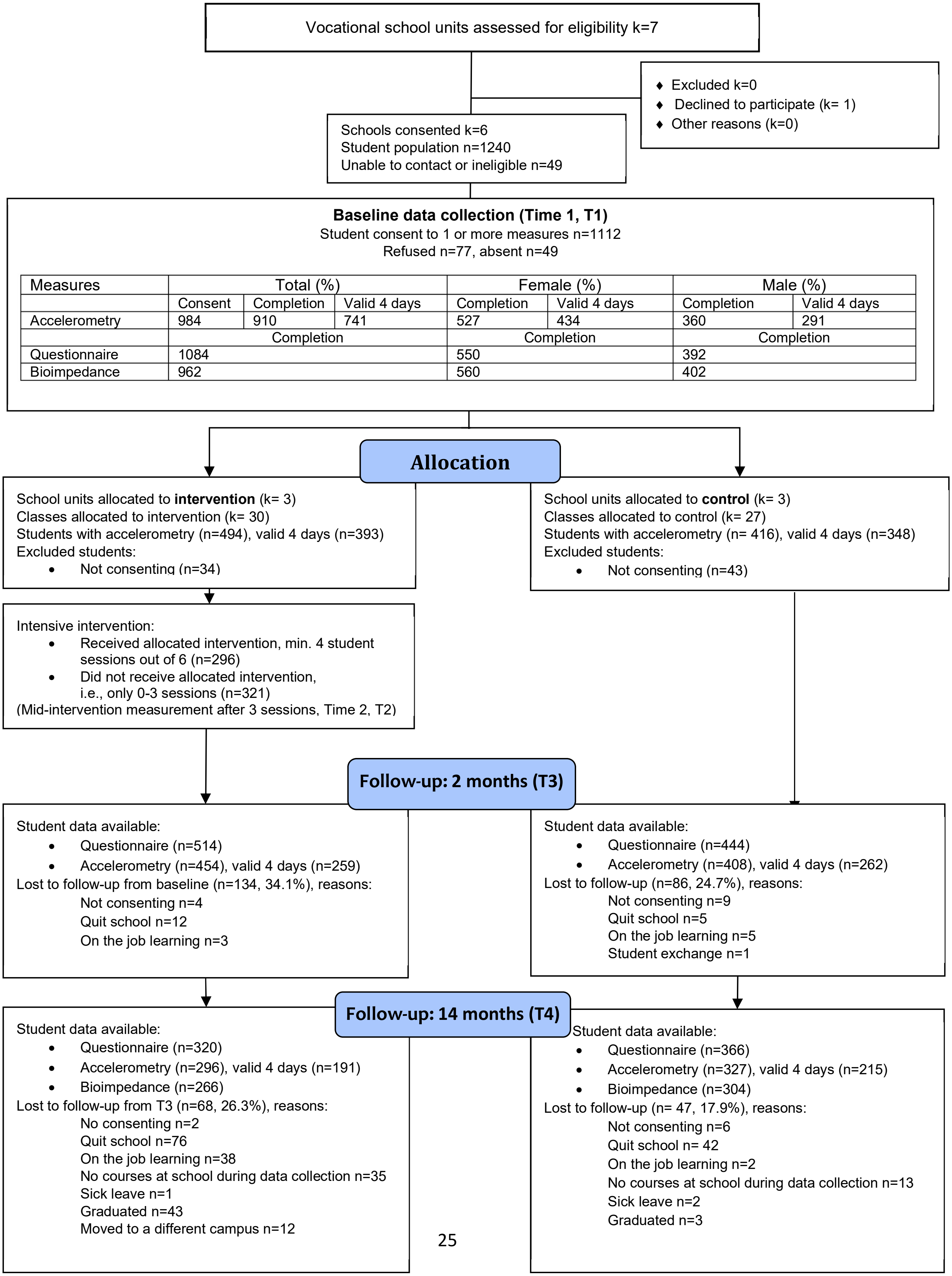


Figure 2. Overview of the Let's Move It intervention components.

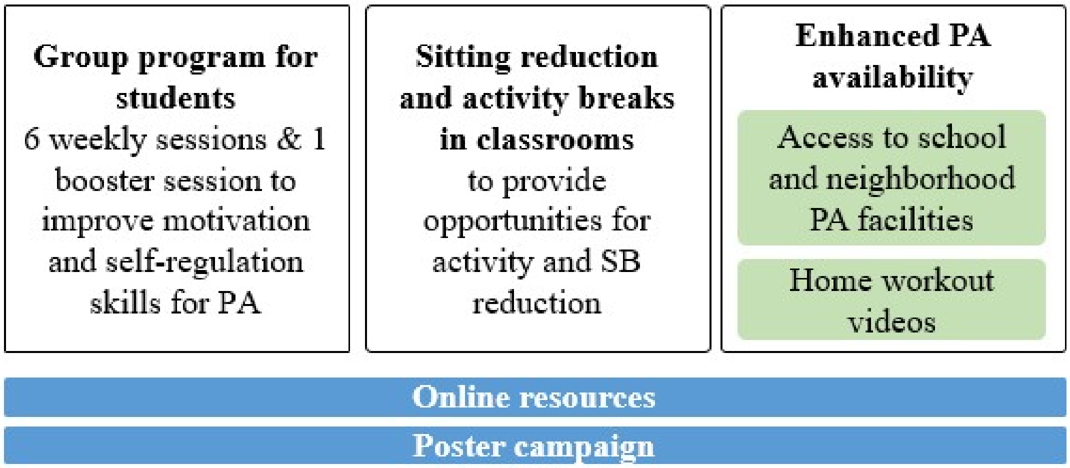
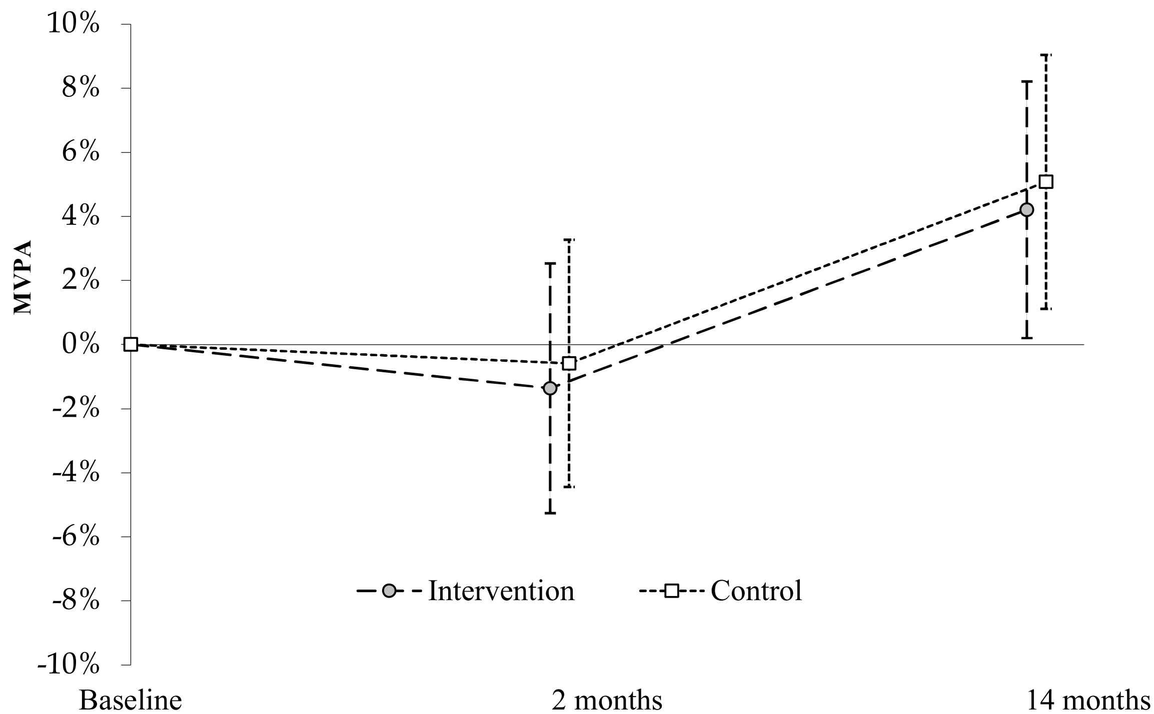
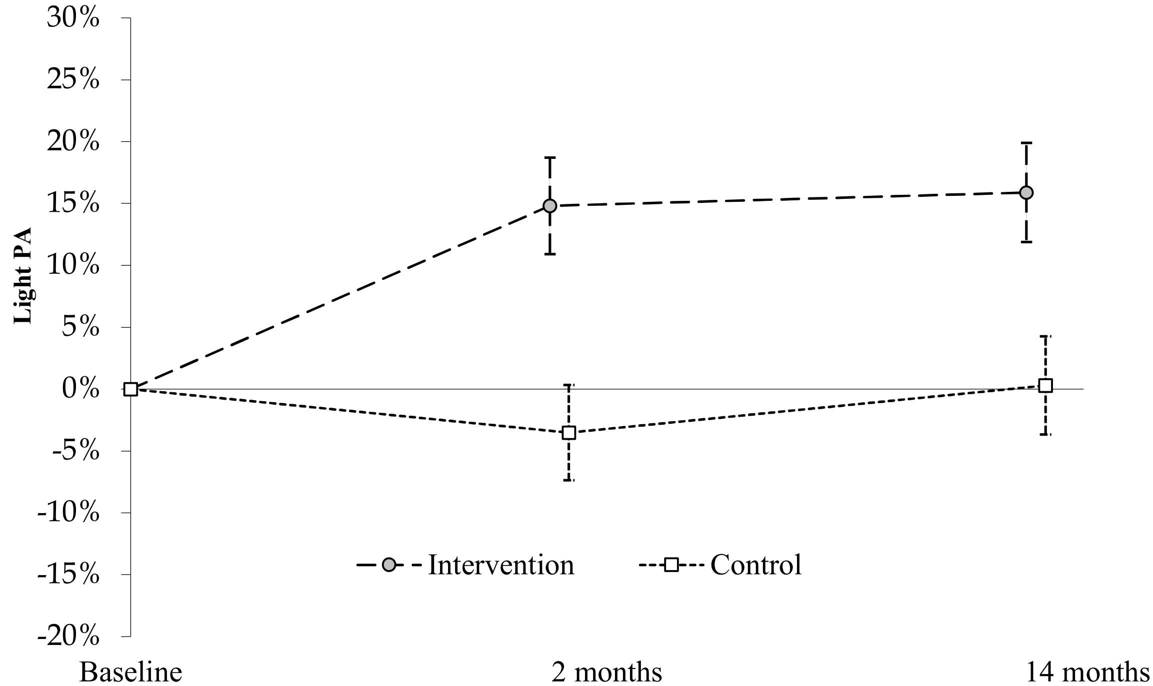


Figure 3. Proportional changes in moderate to vigorous physical activity (A),in light physical activity (secondary outcome) (B) and in sedentary behaviour during school time (secondary outcome) (C).

(3A)



(3B)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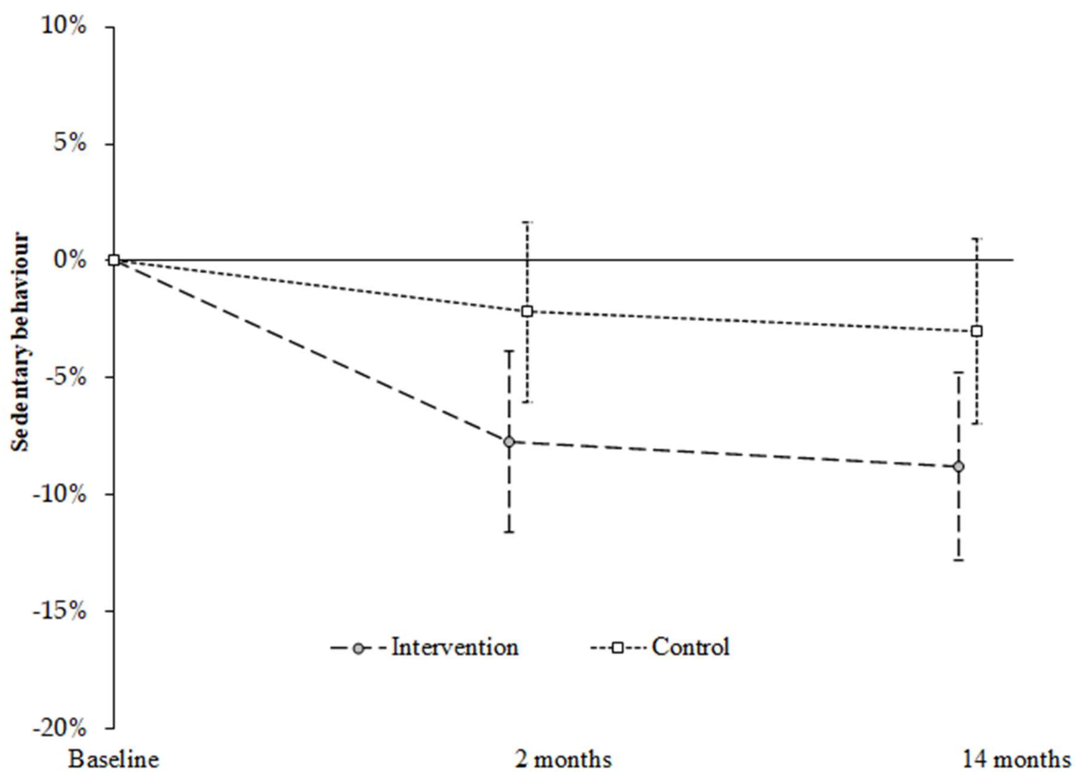
Light PA
Intervention
Control
Baseline
2 months
14 months

(3C)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Sedentary behaviour
Intervention
Control
Baseline
2 months
14 months