# Sit-stand desks to reduce sedentary behaviour in 9- to 10-year-olds: the Stand Out in Class pilot cluster RCT

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# **Scientific summary**

# The Stand Out in Class pilot cluster RCT

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# **Scientific summary**

#### **Background**

Sedentary behaviour (sitting and expending < 1.5 metabolic equivalents) is an important and highly prevalent negative health behaviour, accounting for > 70% of wake time ( $\approx$ 10 hours/day) in samples of Bradford primary school children. Adverse associations between sedentary behaviour and cardiometabolic health risk markers have been reported in children. As sedentary children are highly likely to become sedentary adults, the reduction of sedentary time in young people is pertinent for the primary and secondary prevention of chronic diseases that result from excessive sitting in adulthood. Classrooms are conducive to high levels of sitting; therefore, changing the classroom environment through the provision of sit–stand desks appears to be a feasible way of reducing children's sedentary time in the short term. Classroom-based interventions are accessible to all children, providing a suitable environment for targeting health inequalities.

# Aim and objectives

The aim of this study was to undertake a pilot cluster randomised controlled trial of the introduction of sit–stand desks in primary school classrooms, to inform a future definitive trial. The objectives were to:

- 1. establish and refine a recruitment strategy for schools and pupils
- 2. determine attrition in the trial (schools and children)
- 3. determine completion rates for outcome measures (and whether or not these are sufficiently high to provide accurate data in a full trial)
- 4. assess whether or not there are any differences in trial recruitment, retention and acceptability between ethnic groups
- 5. assess the acceptability of randomisation to schools
- 6. assess the acceptability of measurement instruments to teachers, children and parents, including the activPAL (PAL Technologies Ltd, Glasgow, UK) inclinometer as the tool for the measurement of the primary outcome
- 7. assess the acceptability of the intervention to teachers, children, parents and guardians
- 8. monitor any adverse effects, such as musculoskeletal discomfort and/or disruption to the classroom/ learning, to inform the design of a full trial and minimise or eliminate any such effects
- 9. assess intervention fidelity over the intervention period
- 10. derive preliminary estimates of the effect of the intervention on children's total daily sitting time, physical activity, indicators of health (markers of adiposity and blood pressure), cognitive function and academic performance, engagement and behaviour
- 11. estimate the standard deviation of the primary outcome to inform a sample size calculation for a full randomised controlled trial
- 12. determine availability and completeness of economic data and conduct a preliminary assessment of potential cost-effectiveness.

#### **Methods**

#### Design and setting

This was a school-based, pilot, two-armed, cluster randomised controlled trial with economic and process evaluations. Individuals (Year 5 children, aged 9–10 years) were the unit of analysis and schools (clusters) were randomly assigned to one of two conditions: (1) six manually adjustable sit–stand desks incorporated

into the classroom environment (intervention condition) or (2) current practice (control condition). Baseline measurements preceded randomisation and the sit–stand desks were installed into the intervention classrooms following this. An identical set of outcome measurements were taken from all participants approximately 7 months after the baseline measures, at the end of Year 5. The study was conducted in primary schools in Bradford, UK. Bradford was chosen as the study location given its ethnic composition (predominantly South Asian and white British) and high levels of deprivation, health inequalities and childhood morbidity. The setting of this study, therefore, is fundamental in addressing the important issue of health inequalities, in that the intervention will be accessible to all children. In addition, the location enabled us to pilot the intervention under challenging circumstances, meaning that if it proves acceptable it is likely to be transferable to most schools.

#### Sample size

A recruitment target of eight primary schools, each with at least 15 child participants (approximately 50% of a typical class), was set, giving a minimum total sample of 120 participants. This matches the minimum of four clusters per arm recommended for a cluster randomised controlled trial and the minimum sample size exceeds the recommendation for pilot trials.

#### The Stand Out in Class intervention

Six sit-stand desks were placed in one Year 5 classroom (replacing three standard desks sitting six children) in each intervention school for two school terms. The research team supported teachers in the development of a classroom rotation plan to ensure that all children in their class were exposed to the sit-stand desks for at least 1 hour per day, on average, across the week. Stools or chairs remained in the classroom and children were free to choose whether they sat or stood when using the sit-stand desks. Teachers and children in the intervention schools received training, underpinned by theoretical frameworks of behaviour change, on the use of the sit-stand desks. Schools assigned to the control arm were requested to continue with their usual practice and lesson delivery, and no environmental changes were made to their classrooms.

#### Outcome measures and analysis

The primary aim of this pilot study was to establish school and participant recruitment and retention rates, the acceptability of the intervention and proposed outcome measures, intervention fidelity, and the availability and completeness of economic data to inform the development of a definitive trial. Recruitment was assessed by recording the number of schools and pupils approached, and the number agreeing to participate. Retention rates were recorded at follow-up, along with completion rates for a series of proposed outcome measures for use in a full trial [including activPAL-measured sedentary behaviour, physical activity – measured using ActiGraph accelerometers (ActiGraph LLC, Pensacola, FL, USA) – adiposity, blood pressure, cognitive function, musculoskeletal comfort, academic progress, engagement and behaviour]. Preliminary estimates of the effectiveness of the intervention on the proposed primary outcome (change in weekday sitting) were examined to determine whether or not the intervention shows a positive direction of effect. A weighted linear regression model compared the trial arms, weighted by the number of participants followed up in each cluster and adjusted for baseline total daily sitting time on school days and average weekday wear time when awake across baseline and follow-up.

#### Economic evaluation

Within-trial analysis was presented as a cost–consequences analysis of health and education resource use and outcomes collected at baseline and follow-up. A scoping review was conducted to identify candidate models for long-term economic modelling. A candidate model was identified and used to model health costs and health-related quality of life in the two trial arms over a 30-year time horizon. An expected value of perfect information analysis was conducted to inform the upper value of future research to resolve all modelled parameter uncertainty.

#### **Process evaluation**

A series of interviews and focus groups with teachers, children and parents were conducted following the completion of the baseline measures and randomisation to explore the acceptability of the trial procedures, including randomisation and the acceptability of the measurement instruments. The acceptability of the intervention, and children's and teachers' perceptions and experiences of the intervention and outcome measures were determined during the intervention through a further set of interviews (with teachers from the intervention schools) and focus groups (with children from the intervention schools). Intervention fidelity was assessed through a series of classroom observations. Audio-recordings of interviews and focus groups with teachers, children and parents were transcribed verbatim and analysed using thematic analysis.

#### **Results**

#### Recruitment, follow-up and measurement completion rates

Thirty-three per cent of schools approached agreed to participate, and 75% (n = 176) of children within the nominated Year 5 classes of these schools provided parental consent and written assent to participate in the trial evaluation. At the 7-month follow-up, 100% of schools were retained in the study and 97% of children returned for follow-up measures. Completion rates of the various outcome measures ranged from 63% to 97%. There were no observed differences in recruitment, retention or completion rates of the evaluation measures between South Asian and white British children.

#### Preliminary estimates of intervention effectiveness

Although the main aim of this pilot randomised controlled trial was to establish key information around recruitment, acceptability and feasibility of the Stand Out in Class intervention, along with the acceptability and feasibility of a range of outcome measures, preliminary estimates of the effectiveness of the intervention on the proposed primary outcome were examined to determine whether or not the intervention shows a positive direction of effect. As the study was not powered to determine effectiveness, these findings should be treated as preliminary. A weighted linear regression model, after adjustment for mean baseline weekday sitting time and mean wear time across the measurement time points, revealed that children in the intervention group spent less time sitting than children in the control group did at follow-up. The mean difference (weighted by school size) in change in sitting time over the intervention period was –30.6 minutes per day (95% confidence interval –56.42 to –4.84 minutes per day) between groups.

#### Health economics

This study demonstrated that it is feasible to conduct an economic evaluation alongside a cluster randomised controlled trial of a sit–stand desk intervention within the classroom environment. Our preliminary analysis suggested little evidence of an effect in within-trial or extrapolated economic analyses. Based on current evidence and using the most plausible scenarios, the intervention is unlikely to be cost-effective over a 30-year time horizon at a threshold of £30,000 per quality-adjusted life-year. However, 'Stand Out in Class' is typical of broader public health interventions, in that its comparatively small cost and quality-adjusted life-year gain result in an incremental cost-effectiveness ratio that is very sensitive to small changes in intervention cost and effectiveness. Models linking non-health outcomes of changes in sedentary behaviour and physical activity to desirable general outcomes (such as improved attendance, classroom behaviour, progress/attainment) would be valuable to analyse, in helping to understand the importance of the possible non-health benefits of 'Stand Out in Class' and similar interventions. A lack of available evidence has prevented further examination of outcomes outside health at this stage.

#### **Process evaluation**

Findings revealed that the recruitment, randomisation and measurement protocols were acceptable to teachers, children and parents. No themes emerged during the process evaluation to indicate differences in the acceptability of the trial or intervention between different ethnic groups. We found some minor issues with the activPAL monitor, which influenced the length of time the device was worn, including minor discomfort caused by attaching the monitor to the thigh and problems with the device coming loose.

The sit–stand desks were acceptable to teachers, children and parents; however, there were variations in how some elements of the intervention were implemented. There were no reports of musculoskeletal discomfort, classroom disruption or disruptions to learning or behaviour caused by the intervention.

#### **Conclusions**

This pilot study has provided evidence of the acceptability and feasibility of the Stand Out in Class intervention and evaluation measures. Participant recruitment rates exceeded expectations and retention rates at follow-up were high (97%). The majority of evaluation measures were deemed acceptable and important lessons have been learnt on improvements, which should be used in the planning of a definitive trial. All participating schools were committed to the trial and we received widespread engagement and enthusiasm for the intervention from teachers, head teachers, children and parents.

Preliminary quantitative evidence suggests that the intervention may have a positive direction of effect on weekday sitting time, which warrants testing in a definitive cluster randomised controlled trial. Importantly, quantitative and qualitative data from this study suggest that the introduction of sit–stand desks into the classroom environment did not negatively affect classroom behaviour and children's learning. These outcomes are likely to be of key interest to schools considering participating in such interventions and/or adopting these desks in the future. The feasibility findings of the present study, and emerging evidence on the potential health benefits of sit–stand desks, support the need for a definitive trial. Such a trial could provide novel and robust evidence of the longer-term ( $\geq$  12 months) health and education impacts of this intervention. Based on the findings of the present study, the following recommendations for the planning of a definitive trial are made:

- As standing provides a potentially important but small increase in metabolism compared with sitting, this stimulus needs to be applied regularly and over a longer time period than the 4.5 months experienced by the children in the current pilot study. A definitive trial should be conducted over a minimum of 1 academic year and more sit–stand desks should be incorporated into the classroom to (1) make it easier for teachers to rotate children so that they are exposed to the desks and (2) increase the overall dose of the intervention. Such a trial could provide novel and robust evidence on the impact of this intervention on sitting time, markers of health and academic progress.
- Different methods to attach the activPAL accelerometer to children should be examined to improve comfort and compliance with this measure, or alternative measures of objectively classifying children's posture should be examined (e.g. use of the ActiGraph on the thigh could be investigated).
- Efforts should be made to make parental surveys easier to complete and reporting of health-care resource use could be streamlined to minimise reporting and recall bias, for example allowing parents to record health-care incidents in real time by a trial-specific application or website.
- In consultation with head teachers and teachers/assessment co-ordinators via public and patient
  involvement, further consideration should be given to measuring academic progress to identify
  appropriate national curriculum-related or standard assessments used by schools, which will enable
  direct comparison between participating schools. In the absence of consensus over such measures,
  proxies of academic progress, such as attendance and/or in-class behaviour data, which can be
  measured consistently across schools, should be identified in collaboration with head teachers
  and teachers.
- Based on teachers' feedback in the current study, an infographic detailing the benefits of reducing sitting time should be produced in collaboration with teachers for use in a full trial, instead of the teachers' handbook, which was deemed to be too long. The nudge prompts should not be included in a future intervention.
- The cognitive assessment test battery should not be included in a full trial, given the limited evidence surrounding the links between sedentary behaviour and cognitive function in children and because of the inappropriateness of some of the tests used (e.g. the rapid visual information processing task) for this age group.

# **Trial registration**

This trial is registered as ISRCTN12915848.

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