Stand Out in Class: reducing sitting in the classroom environment

Submission date 07/09/2016	Recruitment status No longer recruiting	Prospectively registered[X] Protocol
Registration date 09/11/2016	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 06/05/2021	Condition category Other	Individual participant data

Plain English summary of protocol

Background and study aims

Advances in technology and changes to the environment and lifestyles have led to children and adults spending most of their waking hours sitting, and therefore expending low levels of energy. Modern day to day environments (e.g. school classroom, workplace) promote prolonged sitting which has been shown to be bad for health. Primary school age children in Bradford have been found to spend approximately 10 hours per day sitting. This is a concern as prolonged sitting is linked to obesity (being very overweight), high blood pressure and high cholesterol in children. In adults prolonged sitting increases the risk of obesity, heart disease, diabetes and some cancers. Children who sit for long periods are likely to become adults who sit for long periods. Therefore, it is important to encourage reduced sitting time during childhood as this will reduce the risks of many diseases linked to prolonged sitting in adulthood. A typical school classroom encourages prolonged sitting; researchers have found that 70% of a child's time in the classroom is spent sitting. This earlier research has shown desks which change height (sitstand desks) which enable children to switch between sitting and standing in the classroom, are successful in the short term in reducing children's sitting time at school and overall during the school day. However, the acceptability of the long term use of these desks in UK primary schools is unknown. The aim of this research is to assess the acceptability of installing sit-stand desks in primary school classrooms over an 8-month period.

Who can participate?

Year 5 children attending one of the participating primary schools.

What does the study involve?

Participating schools are randomly allocated into one of two groups. In schools in group 1, children continue to sit in their classrooms as normal. In schools in group 2, six sit-stand desks (plus one for the teacher) is placed in one year 5 classroom for 8 months. All pupils use the sit-stand desks at least one hour per day using a rotation plan.

What are the possible benefits and risks of participating? Not provided at time of registration Where is the study run from? Eight primary schools in Bradford

When is the study starting and how long is it expected to run for? February 2016 to May 2018

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact? Dr Stacy Clemes s.a.clemes@lboro.ac.uk

Contact information

Type(s) Scientific

Contact name Dr Stacy Clemes

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 199192

Study information

Scientific Title

Stand Out in Class: restructuring the classroom environment to reduce sedentary behaviour – a pilot cluster randomised controlled trial

Acronym

Stand Out in Class

Study objectives

The primary objective of this research is to undertake a pilot cluster randomised controlled trial (RCT) of the introduction of sit-stand desks in primary school classrooms to inform a future fully-powered definitive trial. No specific hypothesis has been stated as part of this study, as the primary outcome measures relate to trial feasibility and acceptability.

Ethics approval required

Old ethics approval format

Ethics approval(s) Loughborough University Ethical Advisory Committee reference, 17/05/2016, ref: R16-P027

Study design Multi-site cluster randomised controlled trial

Primary study design Interventional

Secondary study design

Cluster randomised trial

Study setting(s) School

Study type(s) Prevention

Participant information sheet Not available in web format

Health condition(s) or problem(s) studied

Reducing sedentary behaviour

Interventions

Participating schools will be randomly allocated into either the intervention group or control group.

Six sit-stand desks (plus 1 for the teacher) will be placed in one Year 5 classroom in each intervention school (n = 4) for approximately 8-months (November/December 2016 – July 2017). These desks have been used successfully over the short term (9 weeks) and have led to reductions in sitting time and increases in movement on school days. In consultation with teachers, the study should ensure that all pupils are exposed to the sit-stand desks for at least one hour/day. The research team will support teachers with the development of a rotation plan for desk use and will recommend the use of naturally occurring breaks during class time (e.g. when moving from one subject or task to another) and the school day (morning break and lunch time) as a time for desk rotation. Stools or chairs will remain and children will be free to choose whether they sit or stand.

Schools assigned to the usual practice control arm (n = 4) will be asked to continue with their usual lesson delivery, no environmental changes will be made to their classrooms. Participants in the control schools (year 5 children) will be asked to complete the same study measurements as

those in the intervention schools, at the same time points. Upon completion of the study, control schools will receive a report summarising their pupils' sitting and physical activity data. They will also receive adapted materials (i.e., a Professional Development Manual provided to teachers in the intervention schools, which excludes references to sit-stand desks) upon completion of all follow-up evaluation measures.

Intervention Type

Behavioural

Primary outcome measure

School hours sitting/standing time, and breaks in sitting – measured using the activPAL3 inclinometer (PAL Technologies Ltd), worn continuously on the anterior aspect of the right thigh for 24 hours/day for seven consecutive days during each measurement period.

Taken at baseline (November/December 2016), prior to randomisation, and at follow-up (June /July 2017).

Secondary outcome measures

Secondary cognitive, behaviour, comfort and self-report outcomes:

1. Total and non-school hours sitting, standing and stepping time - measured using the activPAL3 2. Physical activity - measured using the ActiGraph GT3X+ accelerometer, worn on the hip for 24 hours/day over seven consecutive days

3. Time in bed – measured using a self-report diary for seven days whilst participants wear the activPAL3 and ActiGraph GT3X+

4. Blood pressure - measured using a portable blood pressure digital monitor (Omron 907) with a paediatric cuff after a period (5 minutes) of quiet sitting

5. Height - measured without shoes using a portable stadiometer

6. Body weight - measured without shoes using electronic weighing scales

7. Body mass index - calculated from the child's height and weight

8. Body fat percentage - estimated using Tanita SC-331S BIA body composition scales

Economic outcomes:

1. Paediatric Quality of Life inventory (PEDS-QL) – self-report questionnaire completed by children, assessing health related quality of life.

2. EQ-5D Youth – self-report questionnaire completed by children, assessing perceived health status.

All outcome measures will be taken at baseline (November/December 2016), prior to randomisation, and at follow-up (June/July 2017).

Overall study start date 02/02/2016

Completion date 31/05/2018

Eligibility

Key inclusion criteria

All children within year 5 classes (ages 9 - 10 years) of participating schools

Participant type(s)

Healthy volunteer

Age group Child

Lower age limit 9 Years

Upper age limit

10 Years

Sex Both

Target number of participants

8 clusters (schools), with a minimum of 15 children in each. Total minimum sample: 120

Total final enrolment

176

Key exclusion criteria

1. Children without parental consent for their participation in the evaluation

2. Children who do not give their assent to participate in the evaluation

3. Children with any disabilities or injuries/illnesses that prevent them from going about their usual routine

Date of first enrolment

05/10/2016

Date of final enrolment

30/11/2016

Locations

Countries of recruitment England

United Kingdom

Study participating centre Loughborough University Epinal Way Loughborough United Kingdom LE11 3TU

Study participating centre Bradford Institute for Health Research Temple Bank House Bradford Royal Infirmary Duckworth Lane Bradford United Kingdom BD9 6RJ

Sponsor information

Organisation Loughborough University

Sponsor details Research Office Ashby Road Loughborough England United Kingdom LE11 3TU

Sponsor type University/education

ROR https://ror.org/04vg4w365

Funder(s)

Funder type Government

Funder Name National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type Government organisation

Funding Body Subtype

National government

Location United Kingdom

Results and Publications

Publication and dissemination plan

Intention to publish date

01/02/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Stacy Clemes (S.A.Clemes@lboro.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2018		Yes	No
Other publications	report	01/05/2020	20/08/2020	Yes	No
Results article	results	29/04/2020	20/08/2020	Yes	No
Results article		29/04/2021	06/05/2021	Yes	No