Is the 'Let's Move It' school-based intervention effective in increasing physical activity and reducing sedentary behaviour among older adolescents?

Statistical analysis plan		
rticipant data		

Plain English summary of protocol

Background and study aims

Physical inactivity is a health risk, and is especially common among people with less education. Studies have shown that levels of physical activity tend to decline in adolescence. This study examines whether the Let's Move It program, developed for vocational schools and especially adolescents with low physical activity, is effective and cost-effective at increasing (or preventing the decline in) physical activity and reducing passive time. The focus is especially on the youth that display low levels of physical activity at the start of the study.

Who can participate?

Students and teachers at six schools in Southern Finland.

What does the study involve?

Schools are matched into pairs and are randomly allocated to either receive the intervention or continue teaching as usual. In the intervention schools, students attend six weekly group sessions to increase physical activity, classroom sitting time is reduced by activity breaks and light equipment, and opportunities for exercise are increased (e.g., via community partnerships, access to school facilities). The intervention also includes a poster campaign and a website.

What are the possible benefits and risks of participating? Not provided at time of registration.

Where is the study run from? Six schools in Southern Finland

When is the study starting and how long is it expected to run for? January 2015 to May 2017

Who is funding the study? Ministry of Education and Culture (Finland) Ministry of Social Affairs and Health (Finland)

Who is the main contact? Dr Nelli Hankonen Ms Elisa Kaaja Mr Matti Heino

Study website

blogs.helsinki.fi/letsmoveit

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Cluster-randomized trial of a school-based multilevel intervention to increase physical activity and reduce sedentary behaviour among older adolescents in vocational secondary schools: 'Let's Move It'

Study objectives

We hypothesize that the intervention is effective in increasing physical activity and reducing sedentary behaviour, compared to control group, among girls and boys, both immediately and one year after the intensive intervention (i.e., 2 and 14 months from baseline). Specifically, as the trial was designed especially for adolescents with low physical activity at baseline, we expect to detect a significant difference in change in physical activity and sedentary behaviour among low-active participants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Helsinki and Uusimaa Hospital District, decision number 367/13/03/03/2014

Study design

Cluster-randomized parallel-group 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, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Physical activity and sedentary behaviour

Interventions

The design is a cluster-randomised parallel group trial, with school as the unit of randomization, with a no-intervention (standard curriculum/teaching as usual) control group and one intervention arm.

The Let's Move It (LMI) intervention objectives are to increase total physical activity, more specifically: increase moderate-to-vigorous PA (MVPA), decrease time spent in sedentary activities, and introduce more breaks in sitting/lying. The intervention targets Capability, Opportunity and Motivation (COM-B model) to these behaviors, delivered as:

- 1. Six intracurricular group sessions
- 2. Activity breaks and sitting reduction practices in classrooms
- 3. Increased opportunities for PA.

Behavioural science theories (e.g. self-determination theory and self-regulation theory) informed the design of intervention content. More specific description of each follows:

- 1. Trained facilitators in group sessions as part of health education or a similar course included in the school curriculum, and partly using the Internet. The face-to-face intervention consists of six interactive group sessions, ranging from 45 to 60 minutes each, which have been designed to target social cognitive antecedents of motivation and capability. The program includes behaviour change techniques (BCTs) supporting the change of self-determined motivation but also the progress from motivation to goal setting and self-regulation. The website and workbook contains additional materials.
- 2. The classroom sitting reduction involves decreasing passive time in classrooms by providing equipment for light-intensity activity, and by training teachers to use active teaching methods and introduce activity breaks during class. The intervention includes behaviour change techniques to support maintenance of changes, drawing from habit theory, as well as the self-determination theory.
- 3. Enhanced access to PA opportunities include maximising access to existing school PA facilities and increasing collaboration with community sporting groups and/or organisations to provide salient opportunities for students as well as reduced price deals (for leisure-time PA). Also, students are provided with online exercise videos to guide home-based workout tailored to low-active youth and not requiring gear. All activities are supported by internet resources as well as a poster campaign, designed based on Pre-Phase results with an advertisement agency. The intervention pertains to both the class cluster level (LMI sessions, teacher-led activity breaks in classes) and individual level (tailored goals and action plans), as well as school cluster level (poster campaign, teachers workshop and PA equipment, school intervention team).

Intervention Type

Behavioural

Primary outcome measure

Changes in students' physical activity and sedentary behaviour over two months (post-intervention) and 14 months (long-term follow-up), specifically in the following co-primary outcome measures:

- 1. Moderate-to-vigorous physical activity as measured by 7-day accelerometry
- 2. Proportion of (and breaks in) passive time (sitting and lying) as measured by 7-day accelerometry
- 3. Step count, as measured by 7-day accelerometry
- 4. Self-reported physical activity (as measured by questionnaire)

Secondary outcome measures

Students: fat mass and muscle mass (as measured by bioimpedance), BMI, self-reported fitness, symptoms (e.g. neck and shoulder pain), and hypothesized mediators (e.g. autonomous physical activity motivation, intention, outcome expectations, behaviour change technique use), observed teacher sitting reduction behaviours, symptoms, etc).

Teachers: self-reported sitting reduction activities, hypothesized mediators for behaviour change (e.g., motivation, outcome expectancies, habit, behaviour change technique use), observed student behaviour, support from organization, etc).

Overall study start date

01/01/2015

Completion date

31/05/2017

Eligibility

Key inclusion criteria

The study will comprise 6 school units in Southern Finland. In the vocational schools within the study region that meet the eligibility criteria, we will invite an equal number of student groups, with the requirement of having the Health Education course catered in the first or second study period after baseline measurement, or a possibility of locating the six Let's Move It (LMI) student sessions elsewhere in the curriculum. Willing students and teachers are included in the trial.

- 1. Classes of vocational students in the study year 1 or 2 that can be given 6 sessions of LMI sessions as part of standard curriculum
- 2. Students in the class and/or attending the class teaching sessions
- 3. Core class or vocational class teachers whose classes involve a large amount of sitting or static /burdening work positions
- 4. All students of the included classes participate in the LMI sessions, i.e., the voluntariness involves participation in the research measurements
- 5. Students of all ages will be invited to take part in the study, but subgroup analyses will be run for those aged 15-19 years at baseline

Participant type(s)

Healthy volunteer

Age group

Child

Sex

Both

Target number of participants

1000

Total final enrolment

1166

Key exclusion criteria

Classes:

- 1. Insufficient knowledge of the Finnish language to take part in group interventions and use written materials (i.e., preparatory classes for new immigrants)
- 2. Classes comprised primarily of adult-age students
- 3. Classes catering for students with severe physical and mental disabilities

Students:

1. Physical condition hindering taking part in PA or bioimpedance measurement (e.g., pregnancy)

Date of first enrolment

09/01/2015

Date of final enrolment

24/03/2016

Locations

Countries of recruitment

Finland

Study participating centre 6 vocational school units

Helsinki, Espoo Finland 00550

Sponsor information

Organisation

University of Helsinki (Finland)

Sponsor details

Department of Social Research Unioninkatu 37 PO Box 54 Helsinki Finland 00014

Sponsor type

University/education

Website

www.helsinki.fi

ROR

https://ror.org/040af2s02

Funder(s)

Funder type

Government

Funder Name

Opetus- ja Kulttuuriministeriö

Alternative Name(s)

Ministry of Education and Culture, Finland

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Finland

Funder Name

Ministry of Social Affairs and Health (Finland)

Results and Publications

Publication and dissemination plan

Intention to publish date

31/05/2017

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details protocol	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/05/2016		Yes	No
Results article		25/07/2019	16/02/2023	Yes	No
Other publications		24/09/2024	04/02/2025	Yes	No