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An intervention to reduce sedentary behaviour, promote physical activity and improve children's health

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Registration date 30/06/2010	**Overall study status** Completed
Last Edited 13/02/2024	**Condition category** Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

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ClinicalTrials.gov number

Secondary identifying numbers
ID533815, ACTRN12609000715279

Study information

Scientific Title
A multi-setting intervention to reduce sedentary behaviour, promote physical activity and improve children's health: a group-randomised controlled trial with 2x2 factorial design

Acronym
Transform-Us!

Study objectives
Theoretical basis of Transform-Us!
Physical activity interventions that base their strategies on behavioural theories are more likely to be effective. The strategies in the proposed intervention will be based on elements of the behavioural theories that have been shown to be effective in encouraging behaviour change in previous research and our own including: Social Cognitive Theory; Behavioural Choice Theory and Ecological Systems Theory. These theories recognise that there are multiple levels of influence on health behaviour including intrapersonal (e.g. awareness, self-efficacy, enjoyment), interpersonal (e.g. parents, siblings, peers, teachers), environmental (e.g. TV in childs bedroom, access to parks/playgrounds), and policy influences (e.g. school physical activity policies and timetables). As previous research has shown consistent differences in physical activity and in some sedentary behaviours (particularly computer use and playing electronic games) by sex, and sex was a significant moderator in the researchers Switch-Play study the intervention will be tailored for boys and girls.

Aim: The primary aim of this study is to determine whether a 2-year, multi-setting behavioural intervention targeting sedentary behaviour (SB-I) and physical activity (PA-I) alone and in combination (SB+PA-I) results in lower rates of sedentary behaviour and higher levels of physical activity among 8-9 year old children compared with current practice.
The secondary aims are to determine the independent and combined effects of SB-I, PA-I and SB+PA-I on childrens metabolic and cardiovascular risk factors for health; identify the mediators (how did the intervention work) and moderators (who did it work for) of the intervention; determine whether changes in behavioural and health outcomes are maintained 12-months post-intervention; and determine whether SB-I, PA-I and SB+PA-I are cost-effective.

Hypotheses:
Over the course of the 2-year intervention and 12-months follow up, in comparison with the control group:
1. Children in the SB-I arm will show reductions in sedentary time during the school day and when at home;
2. Children in the PA-I arm will show increases in their moderate- to vigorous-intensity physical activity levels during recess and lunchtime breaks at school, and increases in their time spent outdoors in the family setting;
3. Children in the SB+PS-I arm will show reductions in their sedentary time during the school day and when at home, and will show increases in their moderate- to vigorous-intensity physical activity levels during recess and lunchtime breaks at school, and increases in their time spent outdoors in the family setting; and
4. Children in the SB-I, PA-I and SB+PA-I arms will have a more favourable metabolic and cardiovascular risk profile.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Deakin University Human Research Ethics Committee, EC 141-2009
2. Victorian Department of Education and Early Childhood Development, 2009_000344
3. The Catholic Education Office, Project Number 1545

Study design
Group randomized controlled 2x2 factorial design trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Health promotion for children focussing on reducing sedentary behaviour, promoting physical activity and reducing metabolic and cardiovascular risk factors.

Interventions
Sedentary behaviour intervention arm (SB-I)
Targeted behaviours: Reducing uninterrupted time spent sitting during school hours will be targeted in the school setting; and discretionary screen-based behaviours (i.e. TV viewing, computer use and electronic games) will be targeted in the family setting. In addition, the key mediators of sedentary behaviour change will be targeted.

School setting
Curriculum-based key learning messages: Key learning messages will be adapted from Switch-Play materials incorporating the principles of behaviour change and delivered by classroom teachers in 18 lessons divided evenly across the intervention. Teachers will be provided with complete lesson plans but encouraged to modify the materials to suit their class and teaching style. The second year of the intervention will reinforce and enhance the lessons from the first year. Key messages will focus on raising awareness; self-monitoring; goal setting and behavioural contracts; social support (team-based activities at school; information and support for parents; homework to do with parents); and feedback and reinforcement (external and intrinsic rewards). All lessons are developed in line with the Victorian Essential Learning Standards for level 3 and 4. Furthermore, children will be encouraged to meet the National Physical Activity Recommendations for Young People of <2hours/day in electronic entertainment media.
Interrupting classroom sitting time: Teachers will modify the delivery of one class lesson per day (30-45 minutes) so children complete the class standing (e.g., classroom activity stations). Teachers will be provided with a suit of standing lesson delivery methods that can be modified

to any class topic. On average, this will result in 150-minutes less sitting per week. In addition, every two-hour classroom teaching block will be interrupted every 30-min with a 2-min guided light-intensity activity break (e.g. standing and passing a ball around). This will equate to a total of six minutes interrupted sitting time every 2 hours. On average, schools have two 2-hr teaching blocks per day so this would result in 60-minutes less sitting time per week. Teachers will be provided with a menu of activities to deliver during the 2-minute breaks.

Family setting
Newsletters: Each year, eight newsletters will be sent home to parents providing tips on reducing their child's sedentary behaviours and project updates. These will reinforce the key learning messages delivered to the students and will help parents reinforce maintaining children's screen-time to a minimum. Newsletters will contain information about ways to reduce their child's screen time, including the effective use of rules (i.e. no TV during mealtimes, restrictions on small screen use).
Homework assignments: Homework tasks will be modified to reduce sitting time while completing them (e.g. complete worksheets while standing at the kitchen bench). Children will be given homework tasks to complete with their parents. For example, to switch off the TV for a whole weekend day and do something with their parent/s (a menu of alternative light-intensity activities will be provided).

Physical activity intervention arm (PA-I)
Targeted behaviours: Increasing/maintaining moderate- to vigorous-intensity physical activity (e. g. active play, organised and non-organised games) during recess and lunch breaks will be targeted in the school setting and time spent outdoors will be targeted in the family setting. The key mediators of change in physical activity will also be targeted.

School setting
Curriculum-based program: As for SB-I, an 18 key learning messages modified from Switch-Play but focusing on increasing physical activity will be delivered over the intervention period. Children will be encouraged to meet the National Physical Activity Recommendations for Young People of 60-minutes moderate-to-vigorous intensity physical activity every day. All lessons are developed in line with the Victorian Essential Learning Standards for level 3 and 4.
Physical activity during recess and lunch breaks: Physical activity will be promoted and encouraged during recess and lunch breaks. Based on a previous intervention,[18] strategies to maintain activity levels during recess and lunch over the intervention will include ensuring availability of sports equipment and teachers to supervise activities; teacher and peer encouragement and support for active games; and signage promoting activity in schools.

Family setting
Newsletters: Eight newsletters per year will be sent home to parents providing project updates and tips on promoting their child's physical activity e.g. information about activities to do at home and in their neighbourhood. Parents will also be directed to the Kinect Australia website and free Infoline, which contain information for parents on ways to engage their child in physical activity at home, ways to be active with their child, as well as identifying places in their neighbourhood they can take their child to play (e.g. quality playgrounds, walking trails, local sports clubs).
Parent and child homework assignments: Homework tasks will be modified to incorporate physical activity and will be encouraged to complete with their parent/s (e.g. go for a walk with their parent/s and write about where they went and what they saw; measurement homework using their stride as the unit of measurement).

Combined sedentary behaviour and physical activity intervention arm (SB+PA-I)
Schools randomised to the combined SB+PA-I intervention arm will receive a blended version of the two interventions, but with the same intervention 'dose'. For example, when children in this arm complete a behavioural contract to switch off the TV, they will be encouraged to participate in physical activity (SB-I children will not be directly encouraged to participate in activity when they switch off their TV). The combined intervention arm will include 18 class lessons, the interruptions to children's classroom sitting time (standing lessons and short breaks) and the promotion of physical activity during recess and lunch breaks.

Control current practice
Schools assigned to the control current practice group will be asked to continue their usual teaching behaviours and will receive all intervention materials at the completion of the program.

Intervention Type
Behavioural

Primary outcome measure
Data collection will occur at baseline, month 12 (mid-intervention), month 24 (post intervention) and month 36 (12-months follow-up). All measures will be taken at each time point except for the blood sample which will only be taken at months 0, 24 and 36.

Physical activity and sedentary behaviour
Physical activity and sedentary behaviour will be objectively-assessed using the uniaxial function with Actigraph Model GT3X accelerometers (http://www.theactigraph.com/). Children will wear the Actigraph on a belt positioned over the right hip during waking hours for eight days at each of the measurement points. Movement count thresholds based on age-specific energy expenditure prediction equations will be applied to the data to calculate the average time spent being sedentary (<1.8 METs), the number of breaks or interruptions to time spent sedentary (defined as >100 counts.min-1), and based on the Freedson age-adjusted equation, time spent in moderate- (3.0-5.9 METs) and vigorous- (>6.0 METs) intensity activity. Accelerometry data from specific times of the day (e.g. after-school hours, during class time) will also be extracted to identify when changes in physical activity or sedentary behaviour occurred.

In addition, a sub-sample of randomly selected children will wear a PAL Technologies (http://www.paltech.plus.com/products.htm) activPAL inclinometer for assessing time spent sitting. Children will wear the activPAL on a belt positioned on their right thigh during waking hours for eight days at each of the measurement points. Using proprietary algorithms, (Intelligent Activity Classification™), the activPAL classifies the children's free-living activity into periods spent sitting, standing and walking. The investigators are assisting in the development of software to interpret and analyse data generated.

Behavioural information on the types of activities in which children participate (not detectable by accelerometry) will be collected by a parental proxy-report version of the validated CLASS questionnaire. Time spent outdoors will be assessed using a previously validated proxy-report measure.

Secondary outcome measures
1. Anthropometry: Height, weight and waist circumference
Height will be measured to the nearest 0.1cm using SECA portable stadiometers (mod 220). Weight will be measured to the nearest 0.1kg using portable electronic Wedderburn Tanita scales. Waist circumference will be measured using a flexible steel tape at the narrowest point

between the bottom rib and the iliac crest, in the midaxillary plane. If there is no obvious narrowing the mid-point between these 2 landmarks will be used.

2. Blood pressure

After a silent two-minute seated rest, children will have their blood pressure measured on their right arm using the OMRON HEM-907 automatic digital blood pressure machine. Three measurements were taken one-minute apart on two occasions (one week apart).

3. Biomarkers

A fasting blood sample will be taken by a commercial pathology company to assess children's cholesterol, high density lipoprotein (HDL) cholesterol, low density lipoprotein (LDL) cholesterol triglycerides, glucose, insulin, C - reactive protein and 25-Hydroxy Vitamin D levels. Biomarkers will be taken at baseline, post-intervention and 12-month follow-up data collection points only.

4. Nutritional intake

Parent proxy-report food/drink frequency questions derived from food items previously identified from the National Nutrition Survey for the target age groups (8-12 years) as important contributors to energy and fat intakes, and thus the energy density of the diet will be included (items include sweet and savoury snacks and high energy drinks). Literature supports the accuracy of parent reports of usual food intakes.

5. Survey measures

Standard demographic and socio-economic information will be collected by parental report.

6. Mediators

Individual, social and environmental influences on children's behaviours will be assessed by parental proxy-report and self-report survey. Children at 8-9 years are able to reliably report their perceptions and feelings about certain activities (e.g. enjoyment, barriers). These measures have been previously developed and have acceptable psychometric properties and predictive validity.

7. Moderators

Sex of child, parental country of birth, parental educational level will be proxy and self-reported.

8. Sociodemographic characteristics

Childs age and sex, family structure (e.g. siblings, number people living in household), parents' age, sex, marital status, educational attainment, postcode, and country of birth will be collected in the parent survey.

9. Confounders

Parents will report the general health status of their child, and the medical history and family risk factors for diabetes and cardiovascular disease risk factors and their own height and weight.

10. Stage of pubertal maturation

Since all children will be aged 8-9 years old at baseline, it is expected that they will all be pre-pubertal and thus the assessment of pubertal status is not considered necessary. However, to account for any potential growth (maturity) effects, growth rates (change in height) will be assessed from the height measurements taken at each assessment time point.

11. Economic Evaluation

The economic evaluation will help answer the question of whether the intervention represents 'value-for-money' (i.e. intervention versus 'current practice' as represented by the control arm) and if so, how it should be implemented (i.e. comparison across intervention arms). The evaluation will address issues of technical efficiency ('how to do it') through assessment of key design features of the interventions and the associated cost drivers, whilst allocative efficiency ('what to do') will be addressed through the modelling of longer term consequences and cost offsets. The primary analyses will use cost-effectiveness analyses to compare net incremental costs measured from a health sector perspective (with a particular focus on government as a 3rd-party funder) to the full set of outcome measures documented in the trial.

Detailed intervention pathway analysis will be used to specify all steps in the intervention and the associated resource use. Unit costs will be sourced from the most accurate sources for the 2010 reference year, and standard discounting will be applied to costs and outcomes. The cost-

effectiveness analysis will measure differential costs between the interventions and C in relation to the outcomes and intervention costs will be assessed as additional expenditure (savings) against C, expressed as an incremental cost-effectiveness ratio. In addition to the trial based evaluation, the BMI units (kg/m2) 'saved' in the target population will be converted into lifetime 'disability-adjusted life years (DALYs) saved' using the ACE-Obesity methodology which will allow cost-effectiveness comparisons of the current intervention with others.

Overall study start date
08/02/2010

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Participants will be children aged 8-9 years and who are attending one of the 20 randomly selected Primary Schools in Metropolitan Melbourne.

Participant type(s)
Learner/student

Age group
Child

Lower age limit
8 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
On ethical grounds, there will be no exclusion criteria for participants; however, potential confounders will be assessed using parent report of their child's health (PedsQL4.0)

Date of first enrolment
08/02/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment

Australia

Study participating centre
221 Burwood Highway
Burwood, Victoria
Australia
3125

Sponsor information

Organisation
National Health and Medical Research Council (NHMRC) (Australia)

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Sponsor type
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https://ror.org/011kf5r70

Funder(s)

Funder type
Government

Funder Name
National Health and Medical Research Council (NHMRC) (Australia) - Project Grant (ref: ID533815)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/10/2011		Yes	No
Interim results article	mid-term results	20/05/2013		Yes	No
Interim results article	Physical activity in school breaks	01/02/2014		Yes	No
Results article	Screen behaviours	01/12/2015		Yes	No
Results article	Sedentary behaviour	07/07/2022	08/07/2022	Yes	No
Results article	Process evaluation	17/09/2022	20/09/2022	Yes	No
Results article		25/11/2022	28/11/2022	Yes	No
Results article	Cost-effectiveness	12/02/2024	13/02/2024	Yes	No