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Increasing physical activity and healthy behaviours at nursery and at home: ToyBox Scotland

Submission date
17/11/2017

Recruitment status
No longer recruiting

Registration date
22/11/2017

Overall study status
Completed

Last Edited
30/11/2022

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Scotland has some of the highest levels of childhood obesity in Europe. Some of the causes of this are believed to be low levels of physical activity, unhealthy diets and an increased amount of time spent being inactive. Efforts to improve these behaviors in school-aged children have been promising, however studies which have been conducted on younger children are less common. Scientific research has shown that if these behaviours are targeted at an early age, children are more likely to continue such behaviors into adolescence and adulthood, which in turn will help control the rising levels of obesity. Considering this, there is a need to address low levels of physical activity and unhealthy eating habits in Scottish pre-school children, both at nursery and at home. The ToyBox study was a teacher-led nursery-based intervention developed in Europe which ran in six European countries between 2010-2015. ToyBox aimed to target the behaviours that lead to childhood obesity through active games, environmental changes to the classroom and parent-child activities at home. The aim of this current study is to make some changes to the original ToyBox study so that it can be used in Scottish nurseries, and then test out the intervention to see if a larger study can be conducted which will determine whether ToyBox in Scotland can help prevent childhood obesity in young children.

Who can participate?
3-5 year old children attending participating local authority nurseries

What does the study involve?
Children's physical activity, sitting/lying time, and night-time sleep are measured over a seven day period using a small device called an activPAL accelerometer which is attached to the upper leg using medical tape. Children also have their height, weight and body composition measured on the first day of data collection. Body composition is measured using a method called bio-electrical impedance which requires the child to have two sticky electrodes attached to their hands and feet for around 30 seconds. Parents are provided with questionnaires to get information about health behaviours at home. Nurseries are then be randomly allocated to either intervention or control and teachers lead the ToyBox Scotland programme in the intervention nurseries for 18 weeks. The control nurseries continue to run the usual nursery

curriculum. After 14-17 weeks, the research team returns to the nurseries to repeat the data collection procedures. Participation in the intervention involves the children taking part in various teacher-supported games that target physical activity and sitting time. Parents are also provided with materials and games to participate in activities at home with their child to target physical activity, sitting/screen time, eating/snacking and water consumption.

What are the possible risks and benefits of participating?
The results will show if participation in the ToyBox Scotland programme is beneficial to children in terms of increasing physical activity and other health behaviours etc. There is no serious risk involved in participation in the study. Nurseries have their own safety procedures that will be followed at all times during the intervention.

Where is the study run from?
University of Strathclyde (UK)

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

Who is funding the study?
The Cunningham Trust (UK)

Who is the main contact?
Stephen Malden
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
ToyBox Scotland: A feasibility cluster randomised controlled trial of a nursery and home-based intervention to reduce sedentary behaviour and increase physical activity and healthy eating in 3-5 year old children.

Study objectives
It is hypothesized that participation in the intervention will significantly increase physical activity and healthy eating, and reduce sedentary behaviour time in comparison to controls.

As this is a feasibility study, the primary aim is to determine if a full-scale efficacy trial of the adapted Toybox study will be feasible in Scottish nursery settings. This will involve an investigation of the following: Recruitment rates, determining whether participants/nurseries are willing to be randomised, the percentage of participants who complete baseline and follow-up measures, appropriateness and practicality of the methods for obtaining outcome measures, and appropriate parameters for conducting sample size calculations for any future RCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Strathclyde's School of Psychological Sciences and Health ethics committee, 25/10/2017

Study design
Feasibility cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Obesity, sedentary behaviour (at nursery and at home), physical activity (at nursery and at home), sleep (at home), eating/snacking.

Interventions
The ToyBox Scotland intervention has been adapted from the original European Toybox study (http://www.toybox-study.eu/) for use in Scottish nurseries. Six nurseries are selected from a list of 11 nurseries which expressed an interest in participating after a call was sent out by Glasgow City council to all nurseries in the Greater Glasgow area. Nurseries are selected based on location, size, deprivation score (as defined by the Scottish Index of Multiple Deprivation; from the 3 most deprived quintiles 1-3), and if they are not currently involved in any similar programmes to ToyBox Scotland which could contaminate results. Nurseries are then be matched by size, ethnic diversity and deprivation score before each matched pair of nurseries is randomised to either intervention (n=3) or control (n=3) following baseline measurement.

The intervention is delivered by nursery teachers, who are given appropriate training and materials regarding the ToyBox Scotland programme of activities prior to the study commencing. The intervention involves distinct home and nursery-based elements. Teachers

deliver a programme of activities in the form of semi-structured active play/physical activity sessions. The activities are initiated by the teachers, however the children are given the freedom to lead the sessions in their own direction, in keeping with the ethos of the Scottish Curriculum for Excellence which promotes child-led learning. teachers will focus on physical activity for 4 weeks, followed by sedentary behaviour for 4 weeks. This cycle is repeated for the duration of the intervention period (18 weeks). Timing and duration of each session is at the teacher's discretion, however they are asked to aim for at least two sessions per week. One session should total one hour in duration however this can be split up and spread throughout the nursery day in smaller time slots. Environmental changes are also made to the classroom to promote physical activity and interrupt sedentary behaviour. This includes the installation of a "movement corner" where active games are provided, and the removal of chairs from tables so that children will be required to stand at the tables.

Behaviours in the home are targeted through the use of parent-child games and activities which aim to encourage physical activity, outdoor play, controlled screen time and healthy eating /snacking. Teachers provide parents with the materials and instructions when they collect their children from nursery.

The control nurseries receive their usual care in line with the Scottish Curriculum for Excellence.

Baseline data collection is completed in late January/early February 2018. Nursery and home physical activity are measured over seven consecutive days (using the activPAL accelerometer) as will night-time sleep. Anthropometric measures of height, weight, and body composition (as measured by Bioelectrical impedance) will be taken at the nursery on day one of the data collection periods. demographic, dietary and screen time are collected via a parental questionnaire. All measures are repeated between weeks 14-17 of the intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. BMI z-score is measured using standardised methodology at baseline and follow-up (week 14)
2. Nursery and home physical activity are measured using the activPAL accelerometer to be worn at baseline for seven consecutive days and in week 14 of the study again for 7 consecutive days
3. Nursery and home sedentary behaviou are measured using using the activPAL accelerometer to be worn at baseline for seven consecutive days and in week 14 of the study again for 7 consecutive days

A process evaluation will also be conducted throughout intervention implementation and after final data collection to assess intervention fidelity and acceptability, in addition to the identification of any issues which would need to be addressed before any possible effectiveness trial in the future.

Key secondary outcome(s))
Current secondary outcome measures as of 23/04/2018
1. Sleep is measured using the activPAL accelerometer at baseline and follow-up
2. Body composition (bio-electrical impedance) is measured using the Bodyst at 1500 at baseline and follow-up
3. Eating and snacking is measured by parental questionnaire at baseline and follow-up
4. Water consumption is measured by parental questionnaire at baseline and follow-up
5. Screen-time is measured by parental questionnaire at baseline and follow-up

6. Feasibility parameters (including participant recruitment rates, participant attrition rates, questionnaire response rates, standard deviations of outcome measures and intracluster correlation coefficients which will inform the design of a fully-powered cluster RCT)
7. Intervention fidelity will be assessed using practitioner logbooks completed monthly and observation of intervention delivery, involving two sessions of physical activity and sedentary behavior being observed during intervention delivery at each pre-school midway through the intervention

Outcomes 1-6 will be measured at baseline then again 14-17 weeks later at follow up.

Previous secondary outcome measures
1. Sleep is measured using the activPAL accelerometer at baseline and follow-up
2. Body composition (bio-electrical impedance) is measured using the Bodyst at 1500 at baseline and follow-up
3. Eating and snacking is measured by parental questionnaire at baseline and follow-up
4. Water consumption is measured by parental questionnaire at baseline and follow-up
5. Screen-time is measured by parental questionnaire at baseline and follow-up

Completion date
10/09/2018

Eligibility

Key inclusion criteria
1. Male or female
2. Pre-school year/final year children aged 3-5 years old
3. Able to participate in nursery activities
4. Parental consent provided

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
5 years

Sex
All

Total final enrolment
42

Key exclusion criteria
Participants will be excluded if they have a pre-existing condition which could affect their ability to perform the activities involved in ToyBox Scotland. Such conditions include physical disability, bone/joint injury, heart conditions, severe/poorly controlled asthma.

Date of first enrolment
10/12/2017

Date of final enrolment
10/02/2018

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Strathclyde
Physical Activity for Health Group
School of Psychological Sciences and Health
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Sponsor information

Organisation
University of Strathclyde

ROR
https://ror.org/00n3w3b69

Funder(s)

Funder type
Charity

Funder Name

The Cunningham Trust

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Stephen Malden- stephen.malden@strath.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/11/2019	30/11/2022	Yes	No
Protocol article	results	01/10/2018	04/09/2019	Yes	No