

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

Submission date 17/11/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/11/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/11/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 below to request a patient information sheet

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 measure

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 behaviour 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

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.

Secondary outcome measures

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 Bodystat 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 Bodystat 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

Overall study start date

10/10/2016

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

Age group

Child

Lower age limit

3 Years

Upper age limit

5 Years

Sex

Both

Target number of participants

Six nurseries will be recruited (3 intervention and 3 control). Only pre-school year children from each nursery will be asked to participate. We aim to recruit 15-20 participants from each nursery, totaling between 90-150 participants..

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

Scotland

United Kingdom

Study participating centre

University of Strathclyde

Physical Activity for Health Group

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Sponsor information

Organisation

University of Strathclyde

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Sponsor type

University/education

ROR

<https://ror.org/00n3w3b69>

Funder(s)

Funder type

Charity

Funder Name

The Cunningham Trust

Results and Publications

Publication and dissemination plan

A protocol paper outlining intervention development and the methodology will be submitted to an international journal for publication in early 2018. Full results of the feasibility RCT will also be submitted for publication in an international journal in the field of public health or physical activity. Prior to any peer-reviewed publication, teachers and parents of children who participated in the study will be provided with a lay summary of the findings.

Intention to publish date

10/10/2019

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?
Protocol article	results	01/10/2018	04/09/2019	Yes	No
Results article		09/11/2019	30/11/2022	Yes	No