Effectiveness of the run-a-mile intervention

Submission date	Recruitment status No longer recruiting	Prospectively registered		
27/10/2016		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/12/2016	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
20/08/2020	Nutritional Metabolic Endocrine			

Plain English summary of protocol

Background and study aims

Childhood obesity has become markedly more common in the last 30 years. Recently, a lot of media attention has been focused on a primary school based in Stirling, Scotland they have encouraged all children in all weathers to either walk or run a mile each day. Although the extent of the benefits are yet to be determined, many involved speak of improved fitness levels, cognitive (mental processing) behaviour, improved learning, lower obesity levels and to children feeling much happier. The aim of this study is to evaluate the effectiveness and cost effectiveness of the 'run a mile' program in primary schools in Birmingham.

Who can participate?

Children in school years 3 and 5 attending participating schools

What does the study involve?

Participating schools are randomly allocated to one of two groups. Over the course of one schools year, hildren attending schools in the first group work with their teachers to map out a track within the school grounds and work out how many times they need to complete the track to reach a mile. Every day, at random times, children are encouraged to walk or run this track with the aim of achieving a mile. This aims to make sure all children achieve an extra 15 minutes of exercise each day. Schools in the second group continue as normal for the duration of the study. At the start of the study and again after six and 12 months, children attending schools in both groups have their physical activity levels measured, as well as their weight, academic achievement and mental wellbeing. At the same time, teachers who work at schools in both groups have their wellbeing measured using a questionnaire.

What are the possible benefits and risks of participating?

Pupils and teachers who take part in the program benefit from an extra 15 minutes physical activity every school day. There are no direct risks involved with participating.

Where is the study run from?

The study is run from Services for Education (Health Education Service) and University of Birmingham (Schools of Public Health and Health Economics) and takes place in 40 primary schools in the Birmingham area (UK)

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

Who is funding the study? Birmingham City Council (UK)

Who is the main contact?
Dr Sandra Passmore
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Section 106

Study information

Scientific Title

To evaluate the effectiveness and cost effectiveness of the daily 'run a mile' intervention implemented across primary schools located in Birmingham

Study objectives

The aim of this study is to evaluate the effectiveness and cost effectiveness of the 'run a mile' intervention implemented across primary schools located in Birmingham.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Birmingham Ethics Committee, 22/04/2016, ref: ERN_16-0064

Study design

Pragmatic 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 to request a patient information sheet

Health condition(s) or problem(s) studied

Obesity prevention, physical activity

Interventions

Participating schools are randomised to one of two study arms.

Intervention arm: Children in the schools allocated to the intervention arm will work with their teachers to map out a track within the school grounds and calculate how many laps of the track will be equivalent to a mile. Every day, at random times of the day, all children will be encouraged to walk or run this track with the aim of achieving a mile. The aim is for all children to achieve 15 minutes additional physical activity per day. The schools will also continue with their usual practice so the mile will be additional physical activity. The intervention will run over one academic school year.

Control arm: Children in schools allocated to the control arm continue with their usual practice for the suration of the intervention.

All the schools will be asked to not take on any other health, physical activity related initiatives during the intervention period but also to continue with any that they are currently doing - such as walking to school, gardening, physical activity clubs, bikeability etc.

After 6 and 12 months, pupils in both study arms are weighted and have their body fat measured, as well as completing assessments of physical activity and wellbeing. Teacher wellbeing is also measured at these timepoints.

Intervention Type

Behavioural

Primary outcome measure

- 1. Pupils' weight and height and percentage body fat is measured at baseline, 6 and 12 months
- 2. Health-related quality of life is measured using the Child-Health Utilities 9-Dimensional Instrument at baseline, 6 and 12 months

Secondary outcome measures

Pupils:

- 1. Cardiovascular fitness is measured using the Pupils' Physical bleep test at baseline, 6 and 12 months
- 2. Wellbeing is measured using the Middle Years Development Instrument at baseline, 6 and 12 months
- 3. Education Attainment is measured through a teacher assessment at baseline, 6 and 12 months

Teachers:

Wellbeing is measured using the Warwick Edinburgh Mental Wellbeing Scale at baseline, 6 and 12 months

Overall study start date

01/11/2016

Completion date

31/03/2018

Eligibility

Key inclusion criteria

- 1. Children in school years 3 and 5
- 2. Attending participating schools

Participant type(s)

Other

Age group

Child

Sex

Both

Target number of participants

Cluster randomised trial with 40 clusters with 60 participants in each cluster

Total final enrolment

Key exclusion criteria

- 1. Disability that prevents children from running/walking a mile a day
- 2. Unable to have BMI measured

Date of first enrolment

25/11/2016

Date of final enrolment

31/01/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Health Education Service, Services for Education

Tudor Court Warwick House 10 Edward Street Birmingham United Kingdom B1 2RX

Study participating centre School of Public Health, University of Birmingham

Edgbaston Birmingham United Kingdom B15 2TT

Study participating centre School of Health Economics, University of Birmingham

Edgbaston Birmingham United Kingdom B15 2TT

Sponsor information

Organisation

University of Birmingham

Sponsor details

School of Public Health Birmingham England United Kingdom B5 2TT

Sponsor type

University/education

ROR

https://ror.org/03angcq70

Funder(s)

Funder type

Government

Funder Name

Birmingham City Council

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

31/03/2019

Individual participant data (IPD) sharing plan

For access to trial data contact Dr Sandra Passmore, Sandra.passmore@servicesforeducation.co. uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/01/2018		Yes	No

Results article results 01/04/2020 20/08/2020 Yes No