Active Classrooms: A classroom-based intervention to improve the physical activity levels of primary school children.

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------|-----------------------------------------|--------------------------------------------|--|--|
| 10/01/2015 | | [X] Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 19/01/2015 | Completed | [X] Results | | |
| Last Edited | Condition category | [] Individual participant data | | |
| 17/07/2020 | Other | | | |

Plain English summary of protocol

Background and study aims:

The World Health Organisation (WHO) Global Strategy on Diet, Physical Activity and Health recommends that children should participate in at least 60 minutes of moderate to vigorous physical activity (PA) every day. Recent evidence, however, shows that is often not the case. In 2010, WHO identified PA treatments as a key way of increasing the PA levels of children. School has been recognised as a primary place to reach the majority of children and provide PA opportunities for them. However, the inactive nature of lessons carried out in the classroom has been identified as adding to physical inactivity among this age group. The Active Classrooms study aims to design and test a classroom-based treatment that combines physical activity (PA) and school curriculum content. The effects of the treatment on the PA levels of primary school children will be evaluated.

Who can participate?

Children aged 8-11 years in participating primary schools in Munster, Ireland and their teachers.

What does the study involve?

Participating schools are allocated to one of two groups. Teachers in schools in group 1 (intervention group) are provided with training, lesson plans and resources to encourage them to integrate physical activities into English and Maths lessons ('Active Classrooms' lessons). They teach at least one active English lesson and one active Maths lesson each day. Teachers in schools in group 2 (delayed-treatment control group) continue their usual school curriculum. Children's weight, height and degree of physical activity are measured at the beginning of the study. Physical activity measures are repeated after 8 weeks of participating in treatment lessons and 4 months after the beginning of the study. The children's enjoyment of the lessons are also assessed. Teachers opinions on the programme are evaluated using a questionnaire. After all data is collected for the study, teachers in group 2 are offered the 'Active Classrooms' lessons and resources.

What are the possible benefits and risks of participating? Benefits include improved physical activity levels which may be beneficial to the overall health of the participants. There are no risks to participating.

Where is the study run from?
Mary Immaculate College, Limerick and schools in Munster (Ireland)

When is the study starting and how long is it expected to run for? September 2013 to June 2015

Who is funding the study? investigator initiated and funded (Ireland)

Who is the main contact? Rosemarie Martin rgiltenane@gmail.com

Contact information

Type(s)

Public

Contact name

Ms Rosemarie Martin

Contact details

86 Woodhaven, Castletroy Limerick Ireland 00353

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Active Classrooms: An intervention to improve the physical activity levels of primary school children in Ireland, with a primary outcome of minutes in moderate to vigorous physical activity, objectively assessed using accelerometer data and a randomised controlled trial.

Study objectives

It is hypothesised that improvements in moderate to vigorous physical activity levels will be found in children in intervention classrooms, compared to those in control classrooms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Mary Immaculate College Research Ethics Committee, 20/09/2014, ref: A14-006

Study design

This is an interventional multicentre randomised controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Intervention to improve physical activity levels of children in primary schools in Munster, Ireland.

Interventions

Schools are randomised into two groups:

- 1. Intervention group: Participating teachers in intervention schools will receive training and resources to implement 'Active Classrooms' physically active lessons which integrate academic content.
- 2. Delayed-treatment control group: Teachers in delayed-treatment control schools will not receive any training or resources and will continue teaching their usual school curriculum until all data has been collected. After data collection teachers in control schools will be offered the 'Active Classrooms' lessons and resources.

Intervention Type

Behavioural

Primary outcome measure

The primary outcome is change in minutes of MVPA measured using a week of accelerometry (Actigraph) at baseline, post-intervention (week 8) and at 4 months follow-up.

Secondary outcome measures

Secondary outcomes are:

1. Teacher satisfaction with the programme and its implementation measured using

questionnaire data post-intervention (week 8)

2. Student enjoyment of the programme evaluated using a draw and write technique and focus group discussions post-intervention (week 8)

Overall study start date

01/09/2013

Completion date

30/06/2015

Eligibility

Key inclusion criteria

All children aged 8-11 years, in participating schools who provide written informed assent and parental/guardian consent

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

8 Years

Upper age limit

11 Years

Sex

Both

Target number of participants

230 (10 classrooms with approx. 23 children in each)

Total final enrolment

248

Key exclusion criteria

On ethical grounds, there will be no exclusion criteria for participants but potential confounders will be assessed when undertaking measurements, in direct consultation with class teachers /principals.

Date of first enrolment

22/09/2014

Date of final enrolment

21/11/2014

Locations

Countries of recruitment

Ireland

Study participating centre Mary Immaculate College, University of Limerick

South Circular Road Limerick Ireland 00353

Sponsor information

Organisation

Mary immaculate College, University of Limerick

Sponsor details

South Circular Road Limerick Ireland 00353

Sponsor type

University/education

Website

http://www.mic.ul.ie/Pages/default.aspx

ROR

https://ror.org/00a0n9e72

Funder(s)

Funder type

Not defined

Funder Name

investigator initiated and funded (Ireland)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------|----------|--------------|------------|----------------|-----------------|
| <u>Protocol article</u> | protocol | 01/03/2015 | | Yes | No |
| Results article | results | 01/04/2017 | 17/07/2020 | Yes | No |