Action 3:30 - Promoting increased children's physical activity through a teaching assistant-led extra-curricular programme.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
05/09/2012		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/09/2012	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
22/09/2015	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims

Many children in the UK do not meet the recommended levels of physical activity. The end of primary school (Year 5 & 6) has been identified as a key period of decline in physical activity among children. After school hours are recognised as an important opportunity for children to increase physical activity. As teaching assistants (TAs) are a resource in all primary schools, an after-school physical activity programme delivered by trained TAs could be a cost-effective method of promoting physical activity to Year 5 and 6 children. Action 3:30 is a study designed to examine the possibility of a new after-school programme to other schools. The programme has three elements. Firstly, we will develop and deliver a training programme (based on the delivery of after-school physical activity sessions) for TAs. Secondly, we will develop a course of 40 session plans that can be used by the TAs to provide after-school activities for Year 5 and 6 children. Thirdly, the course will be delivered by TAs to Year 5 and 6 children. We will supply each school with equipment to deliver the sessions, and pay schools for the supply teaching costs they incur when TAs attend the training. We will also pay TAs their hourly rate to deliver the after-school sessions.

Who can participate?

We aim to recruit 600 year 5/6 pupils (who are physically able to participate in PE lessons) and 40 teaching assistants from 20 schools within Bristol City Council, Bath and North East Somerset Council, and South Gloucestershire Council.

What does the study involve?

To examine the effect of the programme on children, there will be 10 schools that receive the TA training and the after-school sessions, and 10 schools that do not. Schools will be randomly assigned to the respective groups in November 2012. Data will be collected from children participating in Action 3:30 at three time points. Before the after-school club starts (September-October 2012), during the last few weeks that the clubs run (June-July 2013), and 3 months later (September-October 2013). At each time point we will collect the following data:

1. Physical Activity: Children will be asked to wear an accelerometer (a device that measures

physical activity: Children will be asked to wear an accelerometer (a device that measures physical activity levels) for five days. This data will provide information on the amount of time

children are sedentary, and how much time they spend doing moderate and vigorous physical activity.

2. Psychological Factors: Children will be asked to complete questionnaires about their current physical activity patterns and motivation for being physically active. TAs will also be asked to complete questionnaires based on their experience of the project.

What are the possible benefits and risks of participating?

The schools, teaching assistants and pupils that take part will all receive immediate direct benefit. Schools will receive free training for two teaching assistants, which improves the skills of the workforce. Schools will receive £200 of/for physical activity equipment and an Action 3:30 Leaders Manual, with 40 session plans. We anticipate that schools will use these resources not only for year 5/6 pupils, but for the whole school. Teaching assistants will receive expert training and benefit from being paid to deliver the 40 after-school sessions. Pupils from ten schools will receive a free after-school physical activity club for 20 weeks, which aims to improve their motivation for and participation in physical activity. All pupils get to take part in an informative and exciting process of data collection that uses iPods (for questionnaires) and accelerometers (to record physical activity levels). We anticipate few risks directly attached to participating in the Action 3:30 project. As with all physical activity projects, there is a risk of injury to pupils through engagement in physical activity.

Where is the study run from?

The Centre for Exercise, Nutrition and Health Sciences in the School for Policy Studies, at the University of Bristol (UK).

When is the study starting and how long is it expected to run for? April 2012 to August 2014.

Who is funding the study? Medical Research Council (UK).

Who is the main contact? Professor Russell Jago russ.jago@bristol.ac.uk

Study website

http://www.bristol.ac.uk/sps/researchprojectpages/action330/index.html

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

Action 3:30 - Promoting children's physical activity via enhanced after-school leadership. A randomised controlled pilot study.

Study objectives

It is hypothesised that training Teaching Assistants to deliver after-school physical activity sessions will improve children's motivation for and participation in physical activity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Bristol, School for Policy Studies Ethics Committee, 02/04/2012

Study design

Pilot randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Quality of life

Participant information sheet

http://www.bristol.ac.uk/sps/researchprojectpages/action330/objectives/

Health condition(s) or problem(s) studied

Physical activity, sedentary activity

Interventions

40 x 60 minute after-school physical activity sessions, to be delivered twice a week over a 20 week period (between January and June 2013).

Intervention Type

Behavioural

Primary outcome measure

All measures will be assessed at baseline (time 0), at the end of the intervention period (time 1), and 3-4 months after the intervention has ended (time 2). As the present study is a feasibility study, our primary interest is in estimating the recruitment of schools and children, adherence with the allocated intervention, and completeness of data collection for outcomes and costs.

We will record the total number of schools that were invited to take part in Action 3:30. The method of recruitment and the response rate will be documented. Information on the recruitment of TAs to the project will be provided. TAs will be asked to state their primary reason for signing-up to the project. The recruitment rates of pupils will also be recorded. The age and gender of all TA and pupil participants will be documented. Parents of children who do not want to take part will be asked to provide information on why their child decided not to participate. The TAs delivering the after-school sessions in the intervention schools will keep a register of participants at each session.

The most likely primary outcome in a future definitive trial will be accelerometer-determined minutes of MVPA per day. Accelerometers provide accurate and reliable assessments of PA among young people. Participants will wear accelerometers for five days (including two weekend days). The accelerometers will be set to record at 10 second epochs. Periods greater than an hour with zero values will be considered non-wear time and will be removed from the data. Mean minutes of MVPA will be established for weekdays and weekend days using cutpoints developed for children. Accelerometer counts per minute (CPM), an indication of the volume of activity in which the children engage, will be derived. As the intervention is specifically focussed on the after-school period, we will also assess both MVPA and CPM during the after-school period (3:30pm to 8:30pm).

It is envisaged that in a future trial the primary comparison will be at time 1, with this assessment designed to assess the effect of attending the ACTION 3:30 clubs while they are still running. The time 2 assessments would be secondary comparisons designed to establish if there is a longer-term effect once the intervention sessions have ended.

Secondary outcome measures

As it is possible that an increase in PA after-school may reduce the opportunities to engage in screen-viewing we will assess child self-reported screen-viewing at each of the three assessment periods. We will also assess five further self-reported variables which were selected as they may function as potential mediators of behaviour change in a full trial. The five constructs are:

- 1. Autonomous and controlled motivation for PA. This will be measured using items adapted from the Behavioural Regulations for Exercise Questionnaire and some newly developed items.
- 2. Perceived PA-based autonomy, competence & relatedness need satisfaction.
- 3. Perceived enjoyment of PA.
- 4. Self-esteem, measured using the 'general' sub-scale of the Self-description Questionnaire.

5. Maternal and paternal PA support (logistic, modelling & sedentary restriction), measured using the Activity Support Scale.

Height and weight will be assessed in socks and light clothing (shoes, coats and jumpers will be removed and pockets emptied). Height will be measured to the nearest 0.1 cm using a portable SECA stadiometer. Body weight will be assessed to the nearest 0.1kg using a digital SECA scale. Body mass index (BMI = kg/m2) will be calculated and converted to an age and gender-specific BMI standard deviation score (BMI SDS). This information will be collected by Action 3:30 project staff; all staff will be trained to record height and weight according to CDC criteria by the Primary Investigator.

We are unsure of the impact that special educational needs (SEN) will have upon the recruitment and retention of children to the project. Additionally, certain disabilities may affect the collection and analysis of the accelerometry data (for example, wheelchair users). Therefore, we will record whether or not children require SEN provision in relation to physical education. This information will be collected on the parent-completed demographic information form.

Post-intervention qualitative research will be conducted with key stakeholders in some schools. Two focus groups will be conducted with participant children in five purposively-selected intervention schools to explore their opinions of the after-school element of the programme. One TA from each intervention school will be interviewed in order to consider their views of the project (the training and after-school sessions). We will also interview a member of administrative staff at five intervention and five control schools. This information will help us determine the impact Action 3:30 had on the school and identify aspects of the project that need to be improved.

Accurate assessments of the financial expenditure on the development and delivery of RCTs is of great importance to applicants and funding agencies. To provide detailed information on the feasibility of Action 3:30 we will develop a framework for an economic evaluation. All expenditure will be recorded for the various stages of the project (formative work, intervention, analysis, and dissemination). This will provide an accurate reflection of the finances required to develop, implement, and assess the intervention.

Overall study start date 01/04/2012

Completion date 01/08/2014

Eligibility

Key inclusion criteria

- 1. All year 5 and 6 pupils in primary schools within Bristol City Council, Bath and North East Somerset Council, and South Gloucestershire Council who are physically able to participate in PE lessons
- 2. Teaching assistants in primary schools within Bristol City Council, Bath and North East Somerset Council, and South Gloucestershire Council

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

1. 20 primary schools (10 intervention, 10 control) 2. 600 Year 5/6 pupils3. 40 teaching assistants, from 20 primary schools

Key exclusion criteria

- 1. Schools already engaged in a University of Bristol physical activity intervention
- 2. Schools that have less than 30 pupils in Years 5 and 6 combined
- 3. Schools with insufficient space (physical and/or organisational) to accommodate two afterschool sessions per week for 20 weeks

Date of first enrolment

01/04/2012

Date of final enrolment

01/08/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Bristol University

Bristol United Kingdom BS8 1TZ

Sponsor information

Organisation

Bristol University (UK)

Sponsor details

c/o Mrs Anna Brooke Senate House Tyndall Avenue Clifton Bristol England United Kingdom BS8 1TH

Sponsor type

University/education

Website

http://www.bristol.ac.uk/

ROR

https://ror.org/0524sp257

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council [MRC] (UK) ref: MR/J000191/1

Results and Publications

Publication and dissemination plan

Not provided at time of registration

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?
Protocol article	protocol	02/05/2013		Yes	No
Results article	results	11/09/2014		Yes	No
Results article	results	18/02/2015		Yes	No