

Investigation of the effectiveness and cost-effectiveness of the 'Girls Active' intervention

Submission date 06/01/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/02/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Young people in the UK are not as physically active as they should be. Girls tend to do less physical activity than boys, especially as they progress to secondary school. To address this and encourage girls to be more physically active both inside and outside of school, the Youth Sport Trust has developed a programme called 'Girls Active'. 'Girls Active' provides training, resources and support for teachers to give them the skills to change the way they deliver physical activity, sport and PE, and encourages girls themselves to act as positive role models for others. We want to evaluate how effective 'Girls Active' is at increasing physical activity and whether the programme is value for money.

Who can participate?

We will recruit 20 schools in Leicester, Leicestershire and Rutland. Within these schools all girls aged 11-14 years will be eligible to take part, but only 80 girls in each school will be randomly selected to participate in the evaluation.

What does the study involve?

Half of the schools will receive 'Girls Active' and the other half will carry on with their usual practice until the end of the study. A team of researchers (with current enhanced DBS clearance) will visit each school to complete the measurements. The girls' physical activity levels will be measured using a wrist worn physical activity monitor for 7 days. Participating girls will complete questionnaires about their lifestyle and feelings towards physical activity, sport and PE. They will also have physical measurements taken (height, weight and % body fat). We will also ask the teachers to complete a questionnaire about their school's facilities, PE classes and lunchtime and after school activity sessions. We will carry out all of these measurements just before the schools receive the 'Girls Active' project (baseline) and then again 7 and 14 months after the first measurements (follow-up).

What are the possible benefits and risks of participating?

If we show that 'Girls Active' increases physical activity levels in girls, it could be made available to other secondary schools in the UK. It could lead to teenage girls becoming more active,

healthier and staying active when they are adults. Any potential risk of participating in this evaluation will be minimised by only using female researchers to take the physical measurements and not showing the participating girls their values.

Where is the study run from?

Diabetes Research Centre, Leicester General Hospital (UK).

When is the study starting and how long is it expected to run for?

From February 2015 to January 2017.

Who is funding the study?

National Institute for Health Research (UK).

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A cluster randomised controlled trial to investigate the effectiveness and cost-effectiveness of the 'Girls Active' intervention

Acronym

Girls Active

Study objectives

Despite the health benefits of physical activity, data from the UK suggests that a large proportion of adolescents do not meet the recommended levels of moderate-to-vigorous physical activity (MVPA). This is particularly evident in girls, who are less active than boys across all ages and display a faster rate of decline in physical activity throughout adolescence. Furthermore, a large drop in the proportion of girls meeting MVPA guidelines occurs during and following the transition to secondary school (age 11+). 'Girls Active' has been developed by the Youth Sport Trust to target the lower participation rates observed in adolescent girls, specifically aged 11-14 years. This study will evaluate the effectiveness and cost-effectiveness of the 'Girls Active' intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

College of Medicine and Biological Sciences Research Ethics Committee, University of Leicester, 12/12/2014, ref: mlh31-fa761

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Quality of life

Participant information sheet**Health condition(s) or problem(s) studied**

Physical activity

Interventions

This study will recruit 20 schools within Leicester, Leicestershire and Rutland. At each school a random sample of ~80 Key Stage 3 girls (aged 11-14 years) will be selected to take part in the evaluation measures. Baseline visit will record height, weight and percentage body fat. Participants will be asked to complete lifestyle questionnaires and wear a wrist worn accelerometer for the 8 days following the study visit.

Once the baseline measurements are complete in all 20 schools an independent statistician will randomise half of the schools to the intervention condition (to receive Girls Active) and half to usual care (the control) condition based on school size and proportion of BME pupils.

The measurement session described above will then be repeated at 7 and 14 months.

Process evaluation will also be undertaken with lead teachers and the girls involved in the Girls Active intervention throughout the length of the evaluation. This will involve asking teachers to complete questionnaires on school physical activity, sport and PE provision, and tracking Girls Active delivery.

Intervention Type

Behavioural

Primary outcome measure

A significant difference in mean minutes of moderate to vigorous activity between the intervention and the control group, measured by accelerometer at 14 months after baseline assessment.

Secondary outcome measures

1. A change in the following outcomes 7 and 14 months after baseline assessment:
 - 1.1. Increase in objectively measured total volume of physical activity (accelerometer counts /days)
 - 1.2. Increase in the proportion of girls meeting MVPA guidelines (objectively measured)
 - 1.3. Increase in objectively measured MVPA at 7 months
 - 1.4. Reduction in time spent sedentary (objectively measured and self-reported)
 - 1.5. Reduction in measures of adiposity (body mass index, percentile, percent body fat)
 - 1.6. Improvement in psychological factors that may mediate physical activity participation
2. A full cost effectiveness and cost-consequence analysis of the 'Girls Active' programme
3. A process evaluation of intervention implementation

Overall study start date

01/02/2015

Completion date

31/01/2017

Eligibility**Key inclusion criteria**

School inclusion criteria:

1. Government-funded secondary school within Leicester, Leicestershire and Rutland
2. Schools with at least 80 Key Stage 3 girls

Pupil inclusion criteria:

1. Key Stage 3 girls (must be aged 11, 12, 13 or 14 years)

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

11 Years

Upper age limit

14 Years

Sex

Female

Target number of participants

1600

Total final enrolment

1752

Key exclusion criteria

School exclusion criteria:

1. Private or independent schools and designated special needs schools
2. Schools that do not have any Key Stage 3 pupils

Pupil exclusion criteria:

1. Girls outside of the targeted age range
2. Parent opt-out consent returned

Date of first enrolment

01/02/2015

Date of final enrolment

31/03/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Diabetes Research Centre

Leicester General Hospital

Leicester

United Kingdom

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Sponsor information

Organisation

The University of Leicester

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/04h699437>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	process evaluation	04/06/2015		Yes	No
Results article		25/04/2018		Yes	No
Results article		16/08/2019	19/08/2019	Yes	No
Other publications		29/08/2019	30/08/2019	Yes	No
Results article		01/02/2019	09/02/2023	Yes	No