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Trial of a school-based, community-linked peer role model programme to increase physical activity levels in 9-11-year-old girls

Submission date
24/03/2021

Recruitment status
No longer recruiting

Registration date
29/03/2021

Overall study status
Completed

Last Edited
24/01/2022

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Physical activity is important for young people's health and wellbeing, but most young people aren't active enough. Young people in Wales are among the least active worldwide, with less than 20% of 11-16-year-olds meeting current guidelines of being active 60 minutes a day. Studies show that girls tend to become less active than boys by age 10, and that this trend continues into secondary school. The transition to adolescence is a crucial time to support girls to become more active, and help stop the drop in physical activity among those who already are active. The use of 'role models' could play a vital role in inspiring young girls to become or remain physically active. In 2016, researchers developed a primary school-based role model programme with the help of school staff, girls, parents and community physical activity partners. The resulting CHARMING Programme involves weekly taster sessions of different types of physical activity, question and answer opportunities post-session and signposting to community activities. The sessions will be delivered each week by a community provider with peer role models (e.g. older girls from secondary schools) joining in with the sessions. All sessions run after school and are based at the school premises.
A pilot of the programme showed the initial feasibility of the programme, including promising engagement and enjoyment scores. As a result of the pilot, the programme has been refined and is now being piloted on a larger scale.
This study aims to assess the feasibility and acceptability of a school-based community linked role-model programme (i.e. the CHARMING Programme) to increase and sustain physical activity among 9–11-year-old girls.

Who can participate?
All Year 5 girls who are opted in by a parent/carer and provide assent

What does the study involve?
Six primary schools across South Wales will take part in the study. They will then be randomly allocated to either receive the CHARMING programme (four schools) or to continue with normal practice (two schools).
All schools will be asked to enable completion of surveys and activity monitoring at two

timepoints (i.e. baseline and follow up), so that the researchers can compare results and understand the acceptability and feasibility of implementing the CHARMING programme. They will ask schools to facilitate the provision of activity monitors, which the Year 5 girls will wear for 7 days.
For the four schools asked to run the school physical activity role model programme for Year 5 girls the researchers will carry out a process evaluation. This includes two focus groups with a sample of the Year 5 girls who receive the program and one focus group with a sample of Year 5 boys (who don't). The researchers will also carry out a few interviews with parents/carers, school staff and the role models, which will take place remotely. Finally, they will observe two program sessions, looking specifically at program delivery. This will only take place in the selected case study school.

What are the possible benefits and risks of participating?
This study will find out if CHARMING is acceptable to children, parents, school staff and role models. The study will also find out whether it is feasible to recruit peer role models and record economic evaluation data. By demonstrating that CHARMING is feasible and acceptable the researchers would then hope to be able to test the effectiveness of the intervention on increasing and sustaining girls' physical activity levels. The primary risk for participants is the possibility of being injured during a physical activity session. Steps will be taken to reduce the risk of participant injury as with all extracurricular activities delivered on the school premises.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
January 2021 to August 2022

Who is funding the study?
Health and Care Research Wales (UK)

Who is the main contact
Dr Kelly Morgan

Study website
https://decipher.uk.net/portfolio/choosing-active-role-models-to-inspire-girls-charming-cluster-randomised-feasibility-study-of-a-school-based-community-linked-programme-to-increase-physical-activity-levels-in-9-11-year-old-girls/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
CHoosing Active Role Models to INspire Girls (CHARMING): a cluster randomized pilot trial of a school-based, community-linked programme to increase physical activity levels in 9-11-year-old girls

Acronym
CHARMING

Study objectives
This study will assess the feasibility and acceptability of a school-based community linked role-model program to increase and sustain physical activity among 9–11-year-old girls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/02/2021, School of Social Sciences Research Ethics Committee (Cardiff University, Glamorgan Building, King Edward VII Avenue, Cardiff, CF10 3WT, UK; Tel: not available; socsi-ethics@cardiff.ac.uk), ref: SREC- 3892

Study design
Cluster randomized controlled feasibility study

Primary study design

Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Quality of life

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
Physical activity

Interventions
This research will conduct a cluster randomised-controlled feasibility study, with allocation at school-level and an embedded mixed-method process evaluation. The study is designed to collect data to satisfy the reporting guidance and requirements of the CONSORT 2010 extension.

Six secondary schools across South Wales will be identified via the School Health Research Network (SHRN). For each secondary school, one feeder primary school will be purposively selected (i.e. based on free school meal percentage, school size and rurality measures) and using publically available contact details, invited to take part in the study. The researchers will engage with secondary school students as peer role models to support intervention delivery in primary schools receiving the intervention. Each secondary school will be contacted by the SHRN Manager and asked to adopt their usual practices for peer role model identification and selection.

Six primary schools across South Wales will take part in the study. They will then be randomly allocated to receive either:
1. The CHARMING programme (4 schools)
2. Continue with normal practice (2 schools)

The CHARMING study involves weekly taster sessions of different types of physical activity sessions, question and answer opportunities post-session and signposting to community activities. The sessions are delivered once each week to Year 5 girls by a community provider, with peer role models from adjoining secondary schools joining in with the sessions.

The four intervention schools are where the process evaluation will take place. The researchers will conduct interviews and focus groups with Year 5 girls who received the programme, Year 5 boys who did not, school teachers and the peer and community role models (see last page for study timetable).

The majority of the process evaluation research is planned to be conducted in person within the participating primary schools, adhering to COVID-19 regulations. The remainder of the research is planned to be conducted via remote means either by telephone or videocall software.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 27/10/2021:

1. Average daily minutes spent in moderate-to-vigorous physical activity (MVPA) measured using 7-day accelerometer data at baseline and 12-month follow-up

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Previous primary outcome measure as of 10/08/2021:

1. Number of schools and children recruited, randomly allocated and retained at 12-month follow-up measured using recruitment data, attendance registers and interviews.
2. Assessment of the feasibility and acceptability of the evaluation design and methods for a future full-scale trial measured using interviews and focus groups post intervention
3. Assessment of intervention fidelity (delivery) measured using teacher logbooks, attendance registers and session observations during intervention delivery
4. Assessment of intervention acceptability to children (girls and boys), parents, school staff and role models measured through interviews and focus groups post intervention
5. Assessment of the feasibility of conducting an economic evaluation in a future full-scale trial using a pilot cost consequence analysis, testing pupil self-reported outcomes measures (Child Health Utility-9D (CHU-9D) and EQ-5D-Y) post intervention

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Previous primary outcome measure:

Average daily minutes spent in moderate-to-vigorous PA (MVPA) measured using 7-day accelerometer data with children aged 8-10 years

Secondary outcome measures
Current secondary outcome measures as of 27/10/2021:

1. Number of schools and children recruited, randomly allocated, and retained at 12-month follow-up measured using recruitment data, attendance registers, and interviews post-intervention and at 12 months
2. Assessment of the feasibility and acceptability of the evaluation design and methods for a future full-scale trial measured using interviews and focus groups post-intervention
3. Assessment of intervention fidelity (delivery) measured using teacher logbooks, attendance registers, and session observations post-intervention
4. Assessment of intervention acceptability to children (girls and boys), parents, school staff, and role models measured through interviews and focus groups post-intervention
5. Assessment of the feasibility of conducting an economic evaluation in a future full-scale trial using a pilot cost consequence analysis, testing pupil self-reported outcomes measures (Child Health Utility-9D (CHU-9D) and EQ-5D-Y) at baseline and 12 months
6. Assessment of sedentary time and time spent at different physical activity intensities within specific segments (e.g. during the club, after school, or at weekends) measured using 7-day accelerometer data at baseline and 12-month follow-up

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Previous secondary outcome measures as of 10/08/2021:

1. Average daily minutes spent in moderate-to-vigorous physical activity (MVPA) measured using 7-day accelerometer data
2. Assessment of sedentary time and time spent at different physical activity intensities within specific segments (e.g. during the club, after school or at weekends) measured using 7-day accelerometer data at baseline and 12-month follow-up

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Previous secondary outcome measures:

1. Sedentary time and time spent at different PA intensities within specific segments (e.g. after school or at weekends) measured using 7-day accelerometer data at baseline and 12-month follow-up
2. Number of schools and children recruited, randomly allocated and retained at 12-month follow-up, measured using recruitment data, attendance registers and interviews
3. The feasibility and acceptability of the evaluation design and methods for a future full-scale trial measured using interviews and focus groups post intervention
4. Intervention fidelity (delivery) measured using teacher logbooks, attendance registers and session observations during intervention delivery
5. Intervention acceptability to children (girls and boys), parents, school staff and role models measured through interviews and focus groups post intervention
6. The feasibility of conducting an economic evaluation in a future full-scale trial using a pilot cost consequence analysis (using CHU-9D and EQ-5D-Y) post intervention

Overall study start date
01/01/2021

Completion date
31/08/2022

Eligibility

Key inclusion criteria
Main feasibility trial:
All Year 5 girls who are opted in by a parent/carer and provide assent

Participant type(s)
Other

Age group
Child

Sex
Female

Target number of participants
Main feasibility trial: 90 year 5 girls across 6 primary schools. Process evaluation in four intervention school: interviews with 2 school staff, interviews with 2 parents, focus group with 6

year 5 girls, focus group with 6 year 5 boys. interviews with x4 community role models across the four intervention schools and a focus group made up of 1-2 peer role models from each intervention school

Key exclusion criteria
Main feasibility trial:
Children who are not opted in by their parents, or cannot engage in PA due to medical reasons

Date of first enrolment
01/03/2021

Date of final enrolment
04/01/2022

Locations

Countries of recruitment
United Kingdom

Study participating centre
Cardiff Local Authority
United Kingdom
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Sponsor information

Organisation
Cardiff University

Sponsor details
Centre for Development, Evaluation, Complexity and Implementation in Public Health Research (DECIPHer Centre)
1-3 Museum Place
Cardiff
Wales
United Kingdom
CF10 3BD
+44 (0)29 2087 9609
decipher@cardiff.ac.uk

Sponsor type
University/education

Website
http://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers plan to write, submit and publish a protocol paper prior to the end of recruitment.
To ensure that the study outputs are disseminated as widely as possible, the researchers have engaged with key stakeholders such as Public Health Wales, DECIPHer's Young Person Advisory Group 'ALPHA' and Sport Wales and Youth Sports Trust at an early stage and will utilise their networks to further their reach. They will also have another consultation with ALPHA during the course of the study.
Results will be used to decide whether and how to proceed with a full-scale cluster randomized controlled trial to determine the effectiveness of a school-based community-linked role model program.
Key findings will be presented at stakeholder knowledge exchange events. Reports and recommendations will be issued to relevant policy-makers, delivery partners and PA affiliated professionals.
Results will be communicated to the academic community through conferences, pre-existing networks and journal publications.
The researchers will also discuss the dissemination and exploration of their research findings with their funder as the study progresses.

Intention to publish date
31/08/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from PI Morgan (DECIPHer, Cardiff University, Spark, Maindy Road, Cathays, Cardiff, U.K., CF24 4HQ; telephone: +44 (0)2920 870296; email: MorganK22@cardiff.ac.uk). Only anonymised survey and accelerometry data will be available. These data will be made available in this way to other research teams based at academic institutions from 2 years after study completion; allowing time for exclusive use of data by the research team for publication and innovation, prior to making data available for broader usage. Consent for data to be shared in this way will be gained from participants during enrolment to the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/01/2022	05/01/2022	Yes	No