

The effect of a one hour bout of games-based activity on adolescent cardiovascular health

Submission date 04/09/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/09/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/11/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Children in the United Kingdom are becoming increasingly inactive, with less than 50 % meeting the recommended guidelines for physical activity (60 min a day). With this behaviour children are presenting with risk factors linked to cardiovascular disease and type 2 diabetes, which may lead to the early-onset of such conditions. To prevent the development of risk factors in children it is important successful interventions be determined. Inflammation is one of the main risk factors associated with cardiovascular disease. A one hour bout of exercise has been suggested to cause an anti-inflammatory response that may reduce inflammation; however, this response is yet to be investigated in children. In addition, it is important when assessing the effect of exercise for health, that the type of exercise be attractive to the audience so that the decline in physical activity levels in young people is reversed. Previously, endurance based exercise has been investigated however this is not deemed attractive to children. Therefore, games-based activity is a key interest of our research

group as this is replicative of the type of activity they naturally undertake and is deemed to be fun and attractive. Thus, the aim of the present study was to investigate the effect of one hour games-based exercise (basketball) on inflammation in children and examine the impact of exercise on blood sugar levels.

Who can participate?

Children aged 10 to 12

What does the study involve?

All children complete two trials, one included the one hour of basketball and the other was a rested control trial. Participants arrive to school rested and fasted and had a baseline fingertip blood sample taken. Participants then either rest or complete one hour of games-based activity. Further fingertip blood samples are taken immediately post-exercise and 1, 2 and 3 hours post-exercise. A final fingertip blood sample is taken the next morning. Blood samples are taken at the same time points during the rested trial for direct comparisons. These are analyzed for inflammatory markers. As an additional outcome of the study, all children consume a packed lunch (chicken sandwich, baked crisps and an apple) and blood sugar and insulin responses to this meal are observed in each trial to determine the effect of exercise.

What are the possible benefits and risks of participating?

Participants may benefit from exercise. There are no direct risks however participant's may experience discomfort when providing blood samples.

Where is the study run from?

The Chellaston School (UK)

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

January 2015 to August 2017

Who is funding the study?

Nottingham Trent University (UK)

Who is the main contact?

Miss Karah Dring

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Contact information

Type(s)

Public

Contact name

Miss Karah Dring

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

417

Study information

Scientific Title

Inflammatory, glycaemic and insulinaemic response to an acute bout of high intensity, intermittent games-based activity in adolescents

Study objectives

The aim of this study is to test the hypothesis that an acute bout of high intensity intermittent games-based activity stimulates an anti-inflammatory response for up to 24 h post-exercise, and that the glycaemic and insulinaemic response to a standardised meal is attenuated post-exercise.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Nottingham Trent University Human Ethical Review Committee, 12/04/2015, ref: 417

Study design

A randomised, order balanced, crossover design, which was not blinded due to the completion of exercise in one of the trials.

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

See additional files.

Health condition(s) or problem(s) studied

Cardio-metabolic health

Interventions

The intervention assesses the effect of an acute bout of 60-min of games-based activity (basketball) on the inflammatory, glycaemic and insulinaemic responses in adolescents when compared against a randomised control trial.

Participants are randomised using a order balanced (block sequence ABBA allocation), cross over design. Participants arrived to school at 8.30 am after resting for 24 hour prior and fasted from 9 pm the previous evening with only water allowed ad libitum. Heart rate monitors are fitted to the children upon arrival. A baseline capillary blood sample is taken and then a standardised breakfast is consumed (1.5 g carbohydrate per kilogram body mass in the form of cornflakes, toast and butter).

During the exercise trial a 60-min basketball session is delivered by an experienced coach 45-min post breakfast. Heart rate is monitored throughout the session. Capillary blood samples are subsequently taken immediately, 1 hour, 2 hour and 3 hours post-exercise. In addition, to assess glycaemic and insulinaemic responses post-exercise a standardised lunch (1.5 g carbohydrate per kilogram body mass in the form of chicken sandwiches, baked crisps and an apple) was consumed 1 h post-exercise. Further capillary blood samples are taken at 30 minute, 60 minute

(2 h post-exercise) and 120 minute (3 h post-exercise) following lunch. Participants are instructed to rest for the remainder of the day as a final capillary blood sample was to be taken the following morning to assess inflammation and insulin sensitivity. The children arrive to school the next morning fasted from 9 pm the previous evening, had a capillary blood sample taken and were then fed a breakfast buffet before returning to lessons.

During the rested control trial participants complete the same experimental protocol as outlined above but without the 60-minute of games-based activity. The children are taught sports science related topics throughout the day to ensure they are remained seated during this trial, as this is replicative of a standard school day within the UK. Heart rate is monitored to ensure the children were consistently rested throughout the day.

Intervention Type

Behavioural

Primary outcome measure

Inflammatory cytokines are measured acutely using a flow cytometer (Beckman Coulter Gallios™) specific multiplex bead assay (AimPlex™ multiplex assay, YSL Bioprocess Development Company, Pomona, USA) at baseline, immediately, 1 h, 2h and 3 h post-exercise. A final measurement was taken the following morning 24 h post-exercise to assess inflammatory mediators.

Secondary outcome measures

1. Blood glucose concentration is measured using a commercially available assay (GOD/PAP method, GL364, Randox, Ireland) at baseline, immediately and 1 h post-exercise (30 min following this participants consumed of a standardised lunch), then 30 min, 60 min and 120 min post lunch. A final blood sample was taken the following morning 24 h post-exercise to assess blood glucose.

2. Plasma insulin is measured using a commercially available ELISA (Mercodia Ltd, Sweden) at baseline, immediately and 1 h post-exercise (30 min following this participants consumed of a standardised lunch), then 30 min, 60 min and 120 min post lunch. A final blood sample was taken the following morning 24 h post-exercise to assess plasma insulin.

Overall study start date

20/01/2015

Completion date

17/08/2017

Eligibility

Key inclusion criteria

1. Male and female participants
2. Aged 10-12 years
3. Healthy and free of non-communicable diseases.

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

10 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

40

Total final enrolment

39

Key exclusion criteria

Non-communicable diseases that may alter rested inflammatory cytokines.

Date of first enrolment

01/09/2015

Date of final enrolment

30/11/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The Chellaston School

Derby

United Kingdom

DE73 5UB

Sponsor information

Organisation

Nottingham Trent University

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/04xyxjd90>

Funder(s)

Funder type

University/education

Funder Name

Nottingham Trent University

Results and Publications

Publication and dissemination plan

Our research group plan to publish this paper in a high-impact factor, peer reviewed journal.

Intention to publish date

30/06/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Miss Karah Dring, Karah.dring@ntu.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2019	22/11/2019	Yes	No