

The CHANGE! (Children's Health, Activity and Nutrition: Get Educated!) Project

Submission date 16/02/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 17/03/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/08/2018	Condition category Other	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CHANGE! Protocol V.1.0

Study information

Scientific Title
The CHANGE! (Children's Health, Activity and Nutrition: Get Educated!) Project: a clustered randomised controlled trial

Acronym

CHANGE!

Study objectives

Participants in the CHANGE! intervention group will accrue more moderate to vigorous physical activity post intervention than the control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Liverpool John Moores Research Ethics Committee approved on 22nd September 2010, reference number 10/ECL/039

Primary study design

Interventional

Study design

Clustered randomised controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Paediatric health, physical activity, exercise science and nutrition disciplines

Interventions

The CHANGE! pilot study is a clustered randomised controlled trial (RCT) investigating the efficacy of a twenty lesson school-based physical activity and healthy eating intervention. CHANGE! is delivered through the Personal and Social Health Education strand of schools curricula and the curriculum resource is supplemented by homework tasks that target family involvement.

Twelve schools from the Wigan Borough in North-West England were recruited to the study, Six randomly assigned using a random number generator to the intervention condition. Randomisation occurred prior to baseline measures. Class teachers from the intervention schools received training in the curriculum resource over two twilight training sessions, and were fully familiarised with the CHANGE! curriculum prior to implementation. CHANGE! consists of 20 lesson plans, including worksheets and other resources. This curriculum resource is supplemented by homework tasks that target family involvement. Control schools will receive the curriculum and training in the following academic year once the study has been completed. Measures were completed for intervention and control groups at baseline and will be repeated post-intervention (20 weeks) and at 30-32 weeks follow up, prior to the school summer holidays.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Levels of habitual physical activity, moderate to vigorous physical activity (MVPA)-outcome measured at baseline and will be repeated post-intervention (20 weeks) and at 30-32 weeks follow up, prior to the school summer holidays.

Key secondary outcome(s)

1. Anthropometrics and body composition
2. Cardiorespiratory fitness
3. Food intake
4. Eating behaviour and knowledge
5. Physical self-perceptions
6. Family nutrition and physical activity
7. Behaviour change
8. Quality of life
9. Cardiometabolic disease risk markers
10. Fundamental movement skills

Outcomes were measured at baseline and will be repeated post-intervention (20 weeks) and at 30-32 weeks follow up, prior to the school summer holidays.

To reduce ionising radiation dosage, DEXA body composition scans will be conducted at baseline and follow-up only.

Completion date

31/07/2011

Eligibility

Key inclusion criteria

Within the twelve participating schools:

1. All year 6 children were invited to take part
2. All children with informed parental consent, participant assent and medical screening were eligible to take part

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Children without parental consent, participant assent or those with a medical condition that precluded them from taking part in the programme

Date of first enrolment

01/10/2010

Date of final enrolment

31/07/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Faculty of Education, Community and Leisure,

Liverpool

United Kingdom

L17 6BD

Sponsor information

Organisation

Liverpool John Moores University (UK)

ROR

<https://ror.org/04zfme737>

Funder(s)

Funder type

University/education

Funder Name

Liverpool John Moores University (UK)

Alternative Name(s)

LJMU

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

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?
Results article	results	29/08/2012		Yes	No
Results article	results	02/07/2013		Yes	No
Results article	results	24/07/2018		Yes	No