CHInese pRimary school children Physical activity and DietaRy behAviour chanGes InterventiON (CHIRPY DRAGON)

Submission date 09/01/2015	Recruitment status No longer recruiting	[X] Prospectively registered
		Protocol
Registration date	Overall study status	Statistical analysis plan
03/02/2015	Completed	Results
Last Edited	Condition category	Individual participant data
20/01/2015	Nutritional, Metabolic, Endocrine	☐ Record updated in last year

Plain English summary of protocol

Background and study aims

The number of children who are overweight and obese in urban China is increasing rapidly and there is a high likelihood that these problems will persist in adulthood and affect health. Effective interventions to prevent and control childhood obesity are urgently needed. The aim of this study is to test an obesity prevention programme among urban primary school children in Guangzhou (China).

Who can participate?

Students aged 6–7 and their family members, and relevant school staff

What does the study involve?

Children and their family members will be randomly selected from participating schools.

What are the possible benefits and risks of participating?

A benefit is the prevention of obesity and its consequences. Risks were not provided at the time of registration.

Where is the study run from?

Three non-boarding state primary schools in Guangzhou (China)

When is the study starting and how long is it expected to run for? From March 2015 to July 2015

Who is funding the study?
Zhejiang Yong Ning Pharmaceutical Co Ltd

Who is the main contact? Dr Bai Li b.li.3@bham.ac.uk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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Study information

Scientific Title

Development and evaluation of a childhood obesity prevention programme in urban China: a feasibility trial

Acronym

CHIRPY DRAGON

Study objectives

- 1. Are the planned methods for the recruitment of school and participants feasible?
- 2. Is delivery of the developed intervention programmes feasible?
- 3. Are the planned methods and procedures for outcome measures feasible?
- 4. What modifications in intervention components and/or implementation arrangements are needed to maximise the programme's feasibility and acceptability?
- 5. What are the most culturally relevant methods for cost-effectiveness evaluation for a future trial?

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee, 16/12/2014, reference number ERN 14-1440

Study design

Feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Childhood overweight or obesity, related health behaviours and quality of life

Interventions

Four components:

- 1. Improving health knowledge and perception among grandparents or parents and children through:
- 1.1. Interactive learning activities targeting carers
- 1.2. Interactive learning activities targeting children
- 1.3. Cross-generation guizzes targeting both carers and children
- 1.4. Family-wide health behavioural challenges targeting both carers and children
- 2. Improving the nutritional quality and taste of school meals and parental perception about school meals by:
- 2.1. Having a joint monitoring and evaluating system
- 2.2. Demonstrating tested and feasible changes to current menus and preparation methods among kitchen staff
- 3. Providing and encouraging off-campus physical activities that involve both parents and children by:
- 3.1. Demonstrating and practicing family-friendly active fun games
- 3.2. Assigning homework to play the games learnt once a day outside school (this homework will be implemented in coordination with component 1.4.)
- 4. Promoting better implementation of the national requirement for a 1 hour of physical activity on campus each day in schools by:
- 4.1. Facilitating discussion about situation, barriers and opportunities for improvement
- 4. 2. Supporting continuous development of action plan and progress evaluation

Activities in components 1 and 3 will take place once every 2 weeks for a total of three or four sessions in the spring term (family-wide health behavioural challenges will be on a weekly basis); activities in components 2 and 4 will take place mostly on a daily or weekly basis.

Intervention Type

Behavioural

Primary outcome measure

Body-mass index z score at baseline

Secondary outcome measures

- 1. Children's quality of life, assessed with the validated Chinese version of the Pediatric Quality of Life Inventory (4.0) and the validated Chinese version of the Child Health Utility 9D; both will be administered to children face to face by a trained researcher
- 2. Child diet, assessed with an adapted Short Form Food Frequency Questionnaire
- 3. Physical activity, assessed with the Zhiji Energy Monitor UX-02, a translated version of the Day in Life Questionnaire, an adapted version of the Physical Activity Questionnaire for Older Children, and an adapted version of the Godin Leisure-Time Exercise Questionnaire and self-designed questions
- 4. Quality of life of parents and grandparents, assessed with the Chinese version of EQ-5D

The outcome measures will be tested at baseline.

Overall study start date

01/01/2014

Completion date

31/12/2015

Eligibility

Key inclusion criteria

- 1. First year students (aged 6–7) in three non-boarding state primary schools in Guangzhou (China)
- 2. Students' family members
- 3. Relevant school staff

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

123 for testing outcome measures

Key exclusion criteria

Students who are not in year one of the three participating schools and their family members

Date of first enrolment

09/02/2015

Date of final enrolment

20/03/2015

Locations

Countries of recruitment

China

Study participating centre Three non-boarding state primary schools in Guangzhou (China)

Guangzhou China

Sponsor information

Organisation

University of Birmingham

Sponsor details

Edgbaston Birmingham England United Kingdom B15 2TT

Sponsor type

University/education

Website

www.bham.ac.uk

ROR

https://ror.org/03angcq70

Funder(s)

Funder type

Industry

Funder Name

Zhejiang Yong Ning Pharmaceutical Co., Ltd

Results and Publications

Publication and dissemination plan

- 1. Submission of articles reporting on intervention development (methods and results of the theoretical modelling phase and feasibility study) and the protocol for the randomised controlled trial to peer reviewed journals
- 2. Presentation at relevant international conferences
- 3. Preparation of reports in plain Chinese after completion of the feasibility study and dissemination to local authorities, schools, participants' families, and the funder; if required, reports will also be made available in English
- 4. Findings from the study that have implications for other members of the wider community will be publicised through the mass media

Intention to publish date 01/09/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available