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Chinese primary school children physical activity and dietary behaviour changes intervention (CHIRPY DRAGON Study)

Submission date
19/08/2015

Recruitment status
No longer recruiting

Registration date
25/08/2015

Overall study status
Completed

Last Edited
12/09/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
The number of overweight and obese children in cities in China is rapidly increasing, and it is highly likely that these problems will continue into adulthood, leading to serious health problems. Effective ways of preventing and controlling levels of childhood obesity are urgently needed, and a good place to start is with young children who are starting school. An obesity intervention programme including diet changes and exercise was previously tested in children from three schools (http://www.isrctn.com/ISRCTN13619480). The aim of this study is to find out whether implementing this obesity intervention programme across a larger number of schools in Guangzhou city (China) will be cost-effective and successful in tackling the childhood obesity problem.

Who can participate?
Children in their first year of primary school in Guangzhou city (China), their family members and relevant school staff.

What does the study involve?
Forty schools in Guangzhou city in China are selected to take part in the study. These schools are then randomly placed into one of two groups. For schools in the first group (control group) no additional programmes are added to the existing care offered. For schools in the second group (intervention group) the intervention programme will be brought in. The intervention programme consists of four main parts: interactive learning activities to help children and their family members learn more about healthy living, making the meals offered in the schools more healthy and taste better, teaching children and their family members good ways to exercise at home, and finally ensuring that children have to have one hour of physical activity at school every day. The BMI of the children is measured at the start of the study and after one year to compare the amounts of overweight children at both the control and intervention schools.

What are the possible benefits and risks of participating?
Benefits of participating include improved knowledge and parenting/caring skills of parents, grandparents and teachers, as well as improved diet and physical activity habits in children. The

stud also promotes quality family time, which is a potential benefit. There are no notable risks in participating.

Where is the study run from?
Participating primary schools in Guangzhou (China)

When is the study starting and how long is it expected to run for?
July 2015 to December 2018

Who is funding the study?
Zhejiang Yong Ning Pharmaceutical Co., Ltd (China)

Who is the main contact?
Dr Bai Li

Contact information

Type(s)
Scientific

Contact name
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Study information

Scientific Title
Developing and evaluating a theoretically based childhood obesity prevention programme in urban China - A cluster randomised control trial

Acronym
CHIRPY DRAGON

Study objectives
The study will seek to address the following research questions:
1. How effective is the intervention package in preventing overweight and obesity in children, compared to usual practice?
2. For how long do any observed effects persist, after active intervention has ceased?
3. What is the incremental cost associated with supplying the obesity prevention intervention?
4. What is the incremental benefit associated with supplying the obesity prevention intervention?

5. What is the incremental cost-effectiveness ratio of supplying the obesity prevention intervention?
6. How effective is the intervention package in improving diet and increasing physical activity, compared to usual practice?
7. What is the effect of the intervention on quality of life?
8. Is there a trend in difference in outcomes by sex, social class or baseline BMI?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee, 02/03/2015, ref: ERN_14-1440.

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Childhood overweight/obesity, related health behaviours and quality of life

Interventions
40 urban, non-boarding state primary schools in Guangzhou are selected and randomly assigned into the control arm or the intervention arm. All children who are taking part in the trial will undergo baseline and follow-up measures. Follow-up assessments will take place immediately following the delivery of intervention, and 12 months after the intervention. In addition, parents of participating children will be invited to complete questionnaires at both baseline and follow ups.

For schools in the control arm, no additional programmes are added to the existing care offered by the schools.

The intervention arm consists of four key components:
1. Improving health knowledge and behaviours among grandparents/parents and children through interactive learning activities
1.1. Interactive learning workshops targeting carers (parents and grandparents)
1.2. Interactive learning workshops targeting children
1.3. Cross-generation quizzes involving both carers and children
1.4. A range of family-wide health behavioural challenges (with self evaluation) , targeting children and their family members

2. Improving the nutritional quality & taste of school meals through
2.1. Introducing feasible school meal improvement objectives (developed by Chinese nutrition experts, child obesity researchers and school catering workers; and tested in the feasibility trial) to catering staff who are responsible for producing meals at intervention schools
2.2. Regular evaluations/monitoring and providing constructive feedback

3. Increasing the level of physical activity outside campus through:
3.1. Family friendly games learned and practiced at schools (attended by both the children and their fathers or mothers)
3.2. Assigning activity home work to all families (i.e. playing the games learnt at school or doing any non-sedentary activities or sports that involve both the child and his/her parents outside school)
3.3. Completing self-evaluation fun card (this element will be implemented in coordination with component 1's 'family-wide health behavioural challenges').

4. Improving the implementation of the national requirement for 'One-Hour Physical Activity On Campus Each Day' in intervention schools through
4.1. Facilitating an initial school internal stakeholders meeting (led by trained project assistants, attended by school leaders, PE teachers, class head teachers and student representatives) on current situation, barriers and opportunities for improvement (where specific improvement objectives and action plan will be agreed)
4.2. Regular and continuous evaluations/monitoring (by school staff and project assistants)
4.3. Giving monthly constructive feedback (by project assistants) to school stakeholders and setting new objectives and action plan (jointly) for the following month over each follow up meeting.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome meaures:
The difference in BMI z-scores (standardised deviation scores) between control and intervention schools at the first follow up, taking into account clustering, baseline levels and other relevant co-variates.

Previous primary outcome measures:
1. The difference in BMI z-scores (standardised deviation scores) between control and intervention schools at the first follow up, taking into account clustering, baseline levels and other relevant co-variates.
2. Comparing the percentage of children categorised as overweight and obese in control compared to intervention schools.

Key secondary outcome(s)
Current secondary outcome measures as of 01/11/2017:
Secondary outcomes are either binary (e.g. physically active vs. inactive), or continuous (e.g. energy expenditure), and therefore either logistic or linear link functions will be used, with transformations where appropriate to accommodate any non-normality. All model assumptions will be checked, goodness of fit explored and models selected using step wise procedures and analysis of deviance. Anthropometric measures (including percentage of overweight and obesity as defined by the WHO 2007 Growth Charts, waist circumference and body fatness).

1. Dietary Assessment: Parents questionnaire and child diary, where several self designed and adapted validated (University of Leeds SFFQ; Day in Life Questionnaire) questionnaires are included.
2. Physical Activity Assessment: Through parents questionnaire, child questionnaire and child diary, self designed questions and adapt validated (Godin Leisure-Time Exercise Questionnaire; Day in Life Questionnaire and PAQ-C) tools will be used to measure physical activity and

sedentary behaviours of participating children. Additionally, a validated objective method (GENEActiv Original) will be used to assess physical activity and sedentary behaviours of the children.
3. Process Evaluation: To understand intervention fidelity as well as participants and facilitators' barriers and facilitators. These will include focus groups and personal interviews with representatives of participants and programme facilitators. Programme facilitators will also be asked to complete a log book on participant attendance, withdrawals, and note any changes or adaptations that they had to make to any sessions, and known reasons.
4. Economic Evaluation: Comparisons will be made between the situation of supplying the intervention package and a situation where no intervention is in existence (i.e. usual current practice). The primary analysis will estimate the cost per Quality-Adjusted Life Year (QALY) using outcomes measured using the CHU9D instrument, a paediatric utility-based QoL measure validated in a Chinese population. The economic evaluation will be conducted from both a public and a societal perspective. The public sector perspective will only include costs linked to delivery of the intervention alongside the average QALY impact on the children; the societal perspective will broaden the framework to include household expenditure and intervention effect on parents and other household adult members. To facilitate this broader perspective, QALYs for parents and other adult household members will be estimated using data collected from the EQ5D instrument. Costs and outcomes will be combined using incremental cost effectiveness ratio (ICER) and expressed as cost per QALY gained. A secondary analysis will conduct a cost-effectiveness analysis using BMI z scores as the outcome in line with the clinical evaluation. The incremental cost-effectiveness ratio for the intervention versus usual practice will thus be 'cost per change in BMI z score'.

Previous secondary outcome measures:
Secondary outcomes are either binary (e.g. physically active vs. inactive), or continuous (e.g. energy expenditure), and therefore either logistic or linear link functions will be used, with transformations where appropriate to accommodate any non-normality. All model assumptions will be checked, goodness of fit explored and models selected using step wise procedures and analysis of deviance.

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4. Economic Evaluation: Comparisons between the situation of supplying the intervention package and a situation where no intervention is in existence (i.e. usual current practice) to estimate the cost per Quality-Adjusted Life Year (QALY) using outcomes measured using the CHU9D instrument, a paediatric utility-based QoL measure validated in a Chinese population.

Completion date
31/12/2018

Eligibility

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

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
1641

Key exclusion criteria
Children:
1. Not from randomly selected schools
2. No parental consent given

Date of first enrolment
01/09/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
China

Study participating centre
Participating primary schools in Guangzhou, China
China
n/a

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Industry

Funder Name
Zhejiang Yong Ning Pharmaceutical Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
Data are available upon request by contacting the first author but are not publicly available due to our ethical permissions. Re-analysis and secondary analysis will need to be within the original remit of the research question and will need to be approved by the research team in advance of sharing the dataset.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/11/2019	27/11/2019	Yes	No
Protocol article		01/12/2017		Yes	No
Other publications	An assessment of the construct validity	26/08/2021	12/09/2023	Yes	No
Other publications	Cost effectiveness	25/08/2021	12/09/2023	Yes	No