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ChocHealth for Kids! The effects of dark chocolate on childrens blood pressure

Submission date	Recruitment status	[ ] Prospectively registered
24/07/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/09/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/09/2010	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of dark chocolate on children's blood pressure: a pilot randomised controlled trial

Acronym
ChocHealth for Kids!

Study objectives
The aims of this pilot randomised controlled trial are to:
1. Determine whether a school-based program promoting daily low dose consumption of dark chocolate by healthy Grade 5 and 6 children on school days over 8 weeks could be an acceptable and feasible intervention in Melbourne metropolitan primary schools for reducing blood pressure
2. Identify and fine-tune the easiest and most acceptable methods of delivery
3. Document any barriers in the implementation and uptake of such a program
4. Establish the feasibility of measuring endovascular function by pulse wave analysis using SphygmoCor in schools
5. Estimate variability in blood pressure and conduct preliminary comparisons between the intervention and control groups on key outcomes, both of which will inform sample size estimates for a larger trial should it proceed

We hypothesise that:
1. The intervention will be feasible and acceptable for 10 - 12 year old children, their parents, and their schools
2. At 2 months post-randomisation the intervention group, when compared with the non-intervention group, will show:
2.1. Trends towards a lower mean systolic and diastolic blood pressure, and
2.2. No difference in the mean body weight, body mass index, body percentage fat or reported health-related quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research and Ethics Committee of the Royal Children's Hospital Melbourne approved on the 26th July 2010 (ref: 30049)

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Hypertension

Interventions
6 - 7 g of dark chocolate rich in antioxidants will be delivered by teachers to each participant in intervention arm classes on school days over School Term 4, in 2010 (about 8 weeks), and none will be given to participants in control arm classes. Outcome assessments will be performed before and after intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measured at baseline and 8 weeks:
1. Acceptability and feasibility of the study as assessed by recruitment rate and participant (students and teachers) feedback
2. Blood pressure outcomes between intervention and control groups

Secondary outcome measures
Measured at baseline and 8 weeks:
1. Anthropometry - weight, height, BMI and waist girth
2. Percentage body fat, as measured by multiple frequency bioelectrical impedance analysis (BIA)
3. Health-related quality of life and body image - assessed through the 23-item PEDS QL 4.0 Child Self-Report, a validated measure of child quality of life, and a pictorial body perception and preference scale used in many of our previous studies

Overall study start date
02/08/2010

Completion date
31/12/2011

Eligibility

Key inclusion criteria
All Grade 5 and 6 children (aged between 10 - 13 years old, either sex) in participating classes whose parents consent

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
Around 200 students (intervention: 120; control: 80)

Key exclusion criteria
1. Hypertension under pharmacological treatment
2. Major medical or developmental condition(s) limiting participation in the study (at the discretion of the research team and child's family)
3. Anaphylaxis to nuts (hazelnut or almond) or dairy in children who carry Epipen(s). Dark chocolate does not contain milk, and we will use varieties that do not contain nuts. However, chocolate manufacturers usually state that their chocolate is manufactured on equipment that is also used for foods that contain nuts and/or milk. Therefore, we think it prudent to exclude children with serious nut or milk allergy.

Date of first enrolment
02/08/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Australia

Study participating centre
The Royal Children's Hospital Melbourne
Parkville
Australia
3052

Sponsor information

Organisation

Murdoch Childrens Research Institute (MCRI) (Australia)

Sponsor details
Royal Children's Hospital Melbourne
Flemington Road
Parkville
Australia
3052

Sponsor type
Research organisation

Website
http://www.mcri.edu.au

ROR
https://ror.org/048fyec77

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Children's Hospital Melbourne (Australia) - Centre for Community Child Health

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration