

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

Submission date 24/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/09/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/09/2010	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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