# ChocHealth for Kids! A pilot randomised controlled trial of dark chocolate health effects in healthy children

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# Introduction

- Risk of cardiovascular mortality and morbidity rises across the entire range of blood pressure (BP) in adults, starting from normal values above 115/75mmHg.<sup>1</sup>
- Childhood BP has strong predictive associations with adult hypertension.<sup>2</sup>
- Strategies that could sustain a lower childhood BP could have important benefits at a population level, even if the absolute reduction is small.
- Regular dark chocolate intake lowers BP in hypertensive and normotensive adults,<sup>3,4</sup> but its effects have not been studied in children.
- Feasibility and acceptability data are needed before launching a fully powered randomised trial.

# Aims

- To conduct a pilot randomised trial to determine:
- Feasibility and acceptability to children, parents and teachers, of

  daily dark chocolate, compared to no extra chocolate, in a school setting,
  recruitment, baseline and outcome measurement methods.

  Pilot data on the intervention's possible benefits and/or harms.

# Procedures

### Figure 1: CONSORT flow diagram



# Methods

## Design

Pilot randomised controlled trial (ISRCTN60409644).

### **Participants**

Convenience sample of all Grades 5 and 6 students at two primary schools in Melbourne.

### Exclusion criteria

- Previous anaphylaxis to nuts or dairy.
- Pharmacological treatment for hypertension.
- Significant health condition limiting participation in study.
- Member of class with class consent rate below 65%.

### Randomisation

- Cluster unit of randomisation = the class.
- Classes stratified by school and year level.
- Classes in each stratum randomised at a maximum ratio of two intervention classes to one control class.
- Randomisation followed baseline measurements, conducted by an independent statistician.

### Intervention

- Commercially available dark chocolates were analysed at an independent laboratory for antioxidants (catechin and epicatechin) by sequential extraction and high-performance liquid chromatography.
- The chocolate with the highest antioxidant content was chosen for use as intervention.

\*Non-participation in baseline measurements did not exclude student from participation in study

# Statistical analysis

- Acceptability and feasibility described by:
- Study participation rates
- Feedback response (follow-up questionnaire).
- Pilot data analysed on intention-to-treat principle.
- Unadjusted and adjusted linear regression analysis of BP and all secondary outcomes.
- Analyses adjusted for confounders chosen a priori (age, gender, parent education) and for corresponding baseline value.

# Discussion

- This is the first trial examining the effects of daily dark chocolate on children's health.
- Uptake and retention were excellent, and the intervention was well received.
- A definitive trial would need to consider:
- Longer duration of chocolate
- Higher antioxidant (but more bitter) chocolate
- Weekend and holiday administration

- Students in intervention classes received 7g of dark chocolate (2.8mg catechin and 8.4mg epicatechin) every school day over seven weeks.
- Students in control classes received no extra chocolate.

# Sample characteristics

 Table 1: Demographic and household characteristics of sample

	Intervention (%)	Control (%)
Child		
Male sex	41.9	54.3
Age (years), mean (SD)	11.5 (0.7)	11.6 (0.5)
Socioeconomic background and lifestyle		
Living with both parents	92.7	94.1
Main language English	90.8	95.5
One or both parents has tertiary degree education	72.1	77.9
One or both parents employed full time	98.4	97.1
Screen time more than 2 hours a day		
On school days	45.5	42.0
On non-school days	86.2	85.5
One or more smokers at home	4.0	4.3

### Table 2: Students' baseline physical and well-being characteristics

	Intervention Mean (SD)	Control Mean (SD)
Blood pressure (BP)		
Systolic BP (mmHg)	107.5 (9.6)	106.8 (9.2)
Diastolic BP (mmHg)	72.6 (10.2)	69.5 (9.4)
Body mass index (kg/m²)	18.5 (2.6)	18.2 (2.7)
Overweight/obese	14.2%	13.4%
Body fat (%)	20.6 (6.6)	19.7 (6.1)
Waist circumference (cm)	64.4 (7.0)	63.8 (6.8)
Health-related quality of life		
Total health summary	85.3 (9.0)	83.3 (10.1)
Physical health summary	87.8 (10.1)	88.0 (9.2)
Psychosocial health summary	83.9 (10.1)	80.7 (11.8)
Body dissatisfaction	0.21 (1.0)	0.23 (0.9)
Self-perception profile	1.7 (0.4)	1.7 (0.4)

# Results

- Students generally enjoyed participating in the study (Table 3).
- Dark chocolate was very acceptable to students (Table 3).
- The future frequency of eating dark chocolate was similar in the two groups.
- 64% of teachers (n=11) would recommend the study to others.
- Teachers found measurements at baseline (45%) and at follow up (36%) fairly disruptive.
- BP and anthropometric measures were similar in the two groups at 7 weeks (Table 4).

### Table 3: Student feedback

	Intervention (%)	Control (%)	p value*
Would participate again	99	88	0.001
Would recommend to friend	94	77	0.001
Perceives dark chocolate as			
Yummy	71	65	0.3
Healthy	44	36	0.3
Bad for you	3	2	0.5
Bitter	28	34	0.4
Sweet	27	32	0.5
Yukky	7	8	0.9

\*p values derived from Pearson chi-squared test

### Table 4: Physical and anthropometric outcomes

	Intervention	Control	Adjusted*	
	Mean (SD)	Mean (SD)	Mean difference (95%CI)	p value
Blood pressure (BP)				
Systolic BP (mmHg)	106.0 (11.0)	104.6 (9.8)	1.7 (-0.6 to 4.1)	0.1
Diastolic BP (mmHg)	67.2 (7.3)	67.8 (8.1)	-1.1 (-3.6 to 1.3)	0.3
BMI (kg/m2)	18.6 (2.6)	18.4 (2.9)	-0.02 (-0.3 to 0.2)	0.9
Overweight/obese	15.1%	13.6%		
Body fat (%)	19.9 (6.8)	18.8 (6.7)	0.2 (-1.4 to 1.7)	0.8
Waist circumference (cm)	65.1 (7.5)	64.7 (7.2)	0.3 (-0.5 to 1.1)	0.4
Health-related quality of life				
Total health summary	86.5 (9.9)	84.8 (9.6)	1.0 (-0.8 to 2.8)	0.3
Physical summary	89.3 (10.1)	89.2 (7.8)	0.9 (-1.2 to 2.9)	0.4
Psychosocial summary	85.0 (10.7)	82.4 (11.2)	1.1 (-1.0 to 3.3)	0.3
Body dissatisfaction	0.4 (1.1)	0.1 (1.3)	0.4 (0.01 to 0.7)	0.04
Self-perception profile	1.7 (0.4)	1.8 (0.3)	-0.03 (-0.09 to 0.03)	0.3

There was no evidence of harm to intervention students.

# Conclusion

A larger definitive trial appears acceptable and feasible in the school setting. Further research is required to determine if daily dark chocolate affects children's blood pressure.

Body mass index = weight/height<sup>2</sup>

# Primary outcomes

- Study participation rates
- Feedback response (students and teachers)
- Blood pressure (mmHg) measured by automated sphygmomanometer

# Secondary outcomes

- Measured body mass index (kg/m<sup>2</sup>)
- Body fat (%) by two-limb bioelectrical impedance analysis
- Waist circumference (cm)
- Self-reported health-related quality of life Pediatric Quality of Life Inventory<sup>5</sup>
- Body dissatisfaction Collins Body Figure Rating Scale<sup>6</sup>
- Self-perception profile modified Harter Scale<sup>7</sup>

Body mass index = weight/height<sup>2</sup>

\* Adjusted for age, gender, parent education and corresponding baseline value

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