Dark chocolate for children's blood pressure: randomised trial

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Received 10 November 2011
Accepted 2 April 2012
Published Online First 9 June 2012

ABSTRACT

Background Higher adult blood pressure, even without hypertension, predicts cardiovascular outcomes, and is predicted by childhood blood pressure. Regular dark chocolate intake lowers blood pressure in adults, but effects in children are unknown.

Aim To examine the feasibility of school-based provision of dark chocolate and its short-term efficacy in reducing mean group blood pressure.

Methods 194 children (aged 10–12 years) were randomised by class to intervention (7 g dark chocolate daily for 7 weeks, n=124) or control (n=70) groups; 98% and 93% provided baseline and follow-up measurements, respectively.

Results Intervention and control students had similar systolic (mean difference 1.7 mm Hg, 95% CI −0.6 to 4.1) and diastolic (−1.2 mm Hg, 95% CI −3.6 to 1.3) blood pressure, anthropometry and well-being at outcome.

Conclusion Results show that providing dark chocolate is feasible and acceptable in the school setting. For a definitive trial, the authors recommend a larger sample, endovascular function measures, and consideration of higher antioxidant 'dose' by virtue of duration and/or content.

What is already known on this topic

- Higher blood pressure, even within the normal range, strongly predicts cardiovascular diseases and has its roots in early life.
- Successfully maintaining lower childhood blood pressure across the normal range, using acceptable non-pharmacological universal interventions, could reduce the population burden of disease in adulthood.
- Regular dark chocolate intake lowers blood pressure in adults, but its effects in children are unknown.

What this study adds

- Daily dark chocolate is feasible and acceptable as a school-based public health intervention.
- Future trials should consider measures of endovascular function and higher antioxidant exposure in the form of higher daily dose and/or longer duration.

INTRODUCTION

Ischaemic heart disease and stroke are the two leading causes of death in most developed countries, accounting for nearly 34 000 deaths in Australia alone in 2009. Not only frank hypertension (affecting over 25% of adults worldwide),[1] but also incrementally higher blood pressure throughout the normal range[2] strongly predict both diseases. Childhood blood pressure tracks strongly into adulthood.[3]

Even in childhood, molecular and microscopic blood vessel wall changes occur prior to persistently raised blood pressure,[4] while macroscopic changes, visible as narrower retinal vessel calibre, correlate with higher blood pressure across the range of normal in healthy children as young as 6 years of age.[5] Most children who will go on to die of cardiovascular diseases have blood pressure within the normal range in childhood, so pharmacological treatment is out of the question. Nonetheless, successfully maintaining a lower childhood blood pressure across the normal range, using acceptable non-pharmacological universal interventions, could reduce the population burden of disease in adulthood.[6]

Recent research in adults suggests that dark chocolate consumption predicts substantial reductions in cardiovascular disease and stroke.[7 8] Its health effects are attributed to cocoa antioxidants—the polyphenols epicatechin and catechin (flavanol monomers)[9 10]—that improve endovascular function[11] through increased bioactive nitric oxide.[12] The magnitude of blood pressure decrease is similar to that achievable through improved diet and physical activity.[13]

Few children are frankly hypertensive. As yet, no studies have examined whether dark chocolate consumption in children improves cardiovascular health at a population level. We report a small randomised trial that assessed:

- Feasibility and acceptability to children, parents and teachers of a school-based intervention providing daily dark chocolate for 7 weeks; and
- Preliminary evidence regarding possible (a) benefits to blood pressure and (b) harms to body mass index (BMI), body fat, health-related quality of life, body dissatisfaction and self-perception.

METHODS

We conducted a randomised controlled trial (ISCRTN60409644) in two independent (ie, private) Melbourne primary schools with approval by the Human Research Ethics Committee at the Royal Children's Hospital in Melbourne, Australia (HREC 30049). All 270 Grade 5 and 6 students in those schools were approached. Parents provided informed consent and children were excluded if they were receiving pharmacological treatment for hypertension; had nut or dairy anaphylaxis and carried epinephrine auto-injector(s); had a significant health condition limiting participation; or if their class had an overall consent rate below 65%. Study recruitment and retention are summarised in figure 1.

The study was designed to determine the feasibility of the intervention in a school setting and collect preliminary measurements of children's blood pressure (primary outcome), anthropometry and well-being. Randomisation by class was chosen to minimise the potential for contamination through children sharing chocolate with classmates. Using a cluster size of 20 and assuming an intra-class correlation of 0.01 (in the absence of data regarding the usual intra-class correlation of blood pressure measurements within school classes), we estimated that a sample size of 160 in each arm would have 80% power to detect a 3 mm Hg drop in blood pressure, while 60 in each arm would suffice for a 5 mm drop.

Baseline measurements were collected at the schools prior to randomisation by the research team. While students completed the baseline questionnaire, blood pressure measurements were taken using an automated sphygmomanometer on the student's non-dominant arm. During this period, height, weight, body fat and waist circumference were measured individually by researchers (see table 1 for details of measures). Students were given a record of their height, weight and blood pressure, and parents were informed if clinical hypertension was identified.

Classes were randomly allocated by an independent statistician using a computerised randomisation sequence, stratified by school and by year level with a ratio of two intervention classes to one control. All strata included at least one class in each group. Researchers involved in outcome measures remained blinded to intervention status allocation throughout.

Haigh's Chocolates[19] was chosen from two commercially-available brands of dark chocolate as having the higher epicatechin/catechin content via independent testing by the Centre for Phytochemistry and Pharmacology, Southern Cross University, South Australia (A Dowell, written communication, November 2010). Intervention children received 7 g (two pastilles) each school day before lunch from their classroom teacher for 7 weeks during October–November 2010. The 7 g contained 8.4 mg epicatechin and 2.8 mg catechin (similar to the dose in Taubert's efficacious adult intervention).[20] No intervention was administered to control children, mainly because the characteristic bitter taste and dark-coloured appearance associated with polyphenols in cacao-rich dark chocolate means there is no adequate placebo commercially available. In addition, the use of cacao-free 'chocolate' (eg, white chocolate) as placebo would prevent the determination of any detrimental effects of chocolate intake, such as weight gain or changes in body satisfaction. All children were asked not to change their regular diet and lifestyle.

Student measurements were repeated post-intervention, including additional questionnaire items evaluating the trial's acceptability. All teachers completed a brief feedback questionnaire regarding the trial's acceptability and feasibility. Outcome measures were analysed by the intention-to-treat principle, using linear regression analysis accounting for clustering by class and adjusting for age, gender and parent education as potential confounders and for corresponding baseline values.

RESULTS

Of the 194 recruited 10–12-year-olds (124 intervention, 70 control), 190 (98%) and 184 (93%) provided measurements at baseline and follow-up, respectively. In the intervention and control groups, 41.9% and 54.3% were boys, mean age was 11.5 (SD 0.7) and 11.6 (0.5) years, and 72% and 78% had tertiary-educated parents, respectively.

Students found the trial acceptable and were enthusiastic from beginning to end. Initial questions related to trial processes and the intervention (for example 'Can we choose whether we get chocolate or not?', 'What chocolate are we

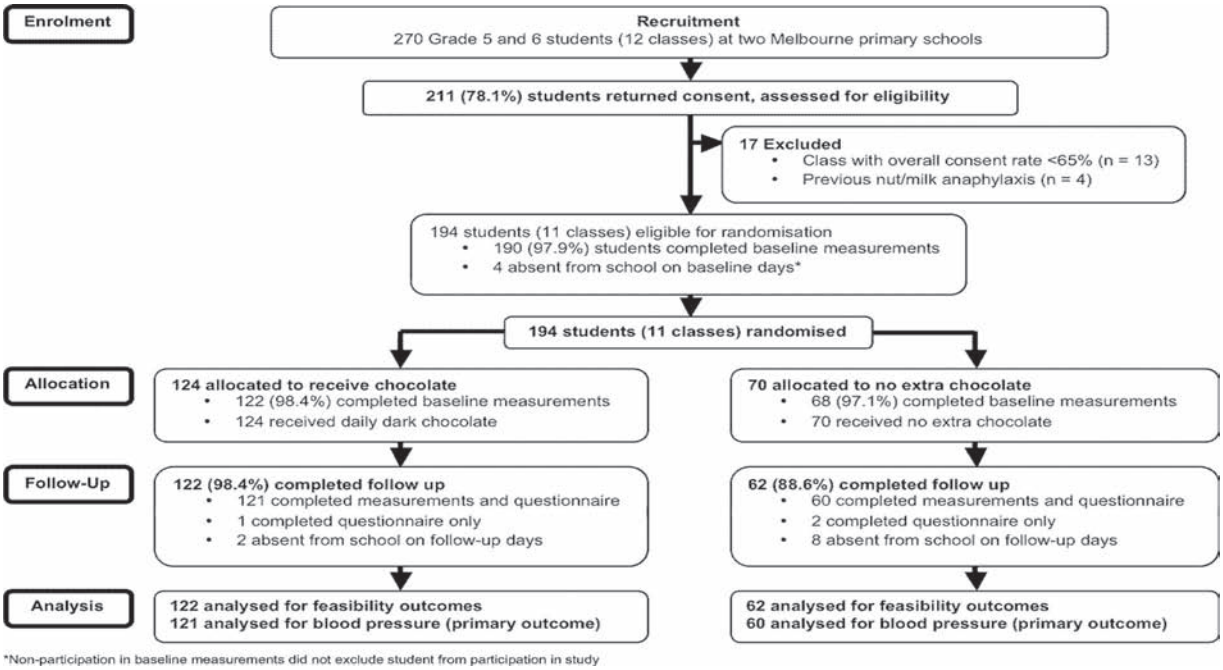

Figure 1 CONSORT flow diagram of enrolment and follow-up of students.

Table 1 Measures

Construct	Measure/instrument	Additional information	T1*	T2*
Primary outcomes				
Blood pressure (mm Hg)	Automated sphygmomanometer on non-dominant arm, A&D UA787	Mean of two measurements taken 5 min apart, with a third taken if the first two were greatly different. Where one of the first two measurements was unexpectedly extreme (systolic blood pressure <70 mm Hg or >140 mm Hg, diastolic blood pressure <30 mm Hg or >100 mm Hg), the third measurement was substituted where available. Each student's average blood pressure was compared against normative centiles for their age and height to determine stage 1 or stage 2 hypertension.[14]	•	•
Acceptability and feasibility of study	Student and teacher follow-up questionnaire	Questions evaluating acceptability of intervention programme and study components. Items include 4-point Likert-type rating scale, free answer and word associations.		•
Secondary outcomes				
Body mass index	Weight/height^2 (kg/m^2); Weight: scales, Tanita BC351;	Overweight and obesity classifications based on age[15]: Mean of two measurements;	•	•
	Height: portable rigid stadiometer, Invicta IP0955	Mean of two measurements; recorded to the nearest 0.1 cm. If the two measurements differed by half a centimetre or more, a third measurement was taken and the two closer measurements were used.		
Body fat (%)	Portable composition scale, Tanita BC351	Mean of two readings: assessed using a two-point body composition analyser, recorded to nearest 0.1%. Bioelectrical impedance analysis measures the impedance of a small electrical current through body tissues. Height^2/impedance is proportional to total body water, from which fat mass and percentage body fat can be estimated.	•	•
Waist circumference (cm)	Anthropometric steel tape, Lufkin W606PM	Mean of two measurements: recorded to the nearest 0.1 cm. If the two measures differed by 1 cm or more, a third measurement was taken and the two closer measurements were used.	•	•
Health-related quality of life	Paediatric Quality of Life Inventory 4.0[16]	A 23-item validated child self-report measure for children aged 8–12 years. It provided total, physical and psychosocial scores, each with a possible range of 0–100 (0=ill health, 100=ideal health).	•	•
Body dissatisfaction	Collins body figure perception questionnaire[17]	Student self-reported perceived ideal self image and perceived actual self image. Picture scale of 1–7 (1=underweight, 7=obese) from which child picked perceived and ideal selves. 'Perceived' minus 'ideal' self yielded a discrepancy index, with positive and negative scores representing desires to be thinner and fatter, respectively.	•	•
Self-perception profile	Modified Harter's Scale for Self-Perception[18]	Student self report. Six pairs of statements with binary response option; children chose the statement from each pair that was closest to their competence. Each of the six responses was then coded as being either 'positive/better perception' or 'negative/worse perception'. The six responses were summed and analysed as a single outcome.	•	•

*T1, baseline; T2, outcome (at 7 weeks).

eating?', 'What are the side effects?'). Researchers were readily able to assuage anthropometric concerns ('How do you measure blood pressure?', 'Will other people see my weight?'). Overall, students received their chocolate on 97% of school days during the intervention period (range 84–100% for individual classes). The two most common reasons for missing chocolate were student absence or whole-class excursions.

At outcome, 99% of intervention and 88% of control students reported that they would participate in the trial again, while 94% of intervention and 77% of control students would recommend taking part to a friend. The two groups reported a similar likelihood of eating daily dark chocolate in the future (5% intervention; 3% control). Of 11 teachers, nine reported enjoying the study and seven would recommend the study to other schools. Intervention teachers saw many positive effects, including student interest in research, the opportunity to discuss health issues with students and eating chocolate. Conversely, control teachers reported no benefits and perceived their students not receiving chocolate a negative. Nonetheless, one control teacher noted students still found the trial quite enjoyable.

The two groups were similar on all measures at outcome (table 2). The adjusted mean difference for systolic/diastolic blood pressure between intervention and control groups at outcome was 1.7 mm Hg/–1.2 mm Hg (95% CI: systolic −0.6 to 4.1; diastolic −3.6 to 1.3). There was little evidence of negative effects on any measure of anthropometry or well-being, although slightly higher scores for body dissatisfaction were reported by the intervention students (adjusted mean difference 0.4 points, 95% CI 0.01 to 0.7).

DISCUSSION

This small trial has demonstrated that daily dark chocolate is feasible and acceptable as a public health intervention in primary school. It did not show evidence that dark chocolate offers short-term benefit to blood pressure in healthy children, and the questions as to its impact on endovascular function remain unanswered.

Past cocoa research has been heterogeneous due to the diversity of available food matrices, varied description of antioxidant content, and unspecified methodology for the measurement of antioxidants.[21] We characterised antioxidant content clearly and used a single batch of dark chocolate throughout the trial. With nearly 200 participants, the sample size was considerably larger than efficacious, widely-reported adult studies. Our students were from a high socioeconomic background, and it is hard to predict how extension to less socially-advantaged groups might play out. Uptake might be lower, but need (and therefore endovascular response) could be greater, given that cardiovascular risk and poor nutrition cluster in the more disadvantaged, even during childhood.

A larger and longer trial would be essential to detect or rule out real effects, if they exist, since these are likely to be small in children—noting that small effects can have important population health implications. Such a trial could now be confidently planned, for which we would recommend: (1) a sample size

Table 2 Baseline characteristics and post-intervention outcomes

	Baseline, mean (SD)		Outcome, mean (SD)		Adjusted difference*		
Variable	**Intervention**	**Control**	**Intervention**	**Control**	**Mean**	**95% CI**	**p Value**
Blood pressure, mm Hg							
Systolic	107.5 (9.6)	106.8 (9.2)	106.0 (11.0)	104.6 (9.8)	1.7	(−0.6 to 4.1)	0.1
Diastolic	72.6 (10.2)	69.5 (9.4)	67.2 (7.3)	67.8 (8.1)	−1.2	(−3.6 to 1.3)	0.3
Body mass index, kg/m^2	18.5 (2.6)	18.2 (2.7)	18.6 (2.6)	18.4 (2.9)	−0.02	(−0.3 to 0.2)	0.9
Body fat, %	20.6 (6.6)	19.7 (6.1)	19.9 (6.8)	18.8 (6.7)	0.2	(−1.4 to 1.7)	0.8
Waist circumference, cm	64.4 (7.0)	63.8 (6.8)	65.1 (7.5)	64.7 (7.2)	0.3	(−0.5 to 1.1)	0.4
Health-related quality of life							
Total score	85.3 (9.0)	83.3 (10.1)	86.5 (9.9)	84.8 (9.6)	1.0	(−0.8 to 2.8)	0.3
Physical summary	87.8 (10.1)	88.0 (9.2)	89.3 (10.1)	89.2 (7.8)	0.9	(−1.2 to 2.9)	0.4
Psychosocial summary	83.9 (10.1)	80.7 (11.8)	85.0 (10.7)	82.4 (11.2)	1.1	(−1.0 to 3.3)	0.3
Body dissatisfaction	0.2 (1.0)	0.2 (0.9)	0.4 (1.1)	0.1 (1.3)	0.4	(0.01 to 0.7)	0.04
Self-perception profile	1.7 (0.4)	1.7 (0.4)	1.7 (0.4)	1.8 (0.3)	−0.03	(−0.09 to 0.03)	0.3

*Adjusted for age, gender, parent education and corresponding baseline measure; total n for each outcome analysis varies from 168 to 174.

sufficiently large to examine effectiveness for children with different starting levels of blood pressure and differing social circumstances; (2) the most precise portable sphygmomanometers and exploring new measures of endovascular function suitable for community use; (3) serial testing of the chocolate for integrity of antioxidant content throughout the trial; and (4) consideration of higher antioxidant 'dose' (which may be more efficacious),[11 12] longer duration (such as Taubert's intervention[20] in which blood pressure continued to fall throughout 18 weeks of the trial), and/or chocolate on weekends as well as weekdays.

In conclusion, we have demonstrated that daily dark chocolate can be feasibly delivered in schools in a dose previously found efficacious in prehypertensive adults.[20] We have successfully demonstrated a mechanism for rigorously testing this question in a definitive trial that might be of longer duration, greater power and/or higher cocoa content.

Acknowledgements The authors would like to acknowledge the teachers, families and students of the participating schools, Haigh's Chocolates, Southern Cross University, research assistant Elissa York, intern Lauren Anderson, administrative assistant Abigail Miller, and student Niels Kruyt, without whom the research could not have been conducted.

Contributors The project was conceived, initiated and supervised by MW. EC led the project and the paper, supervised by MW, with all authors providing critical contributions to reviewing, editing and approving its final version. JQ and EC led the fieldwork. FM conducted the analyses. MW is the guarantor and accepts full responsibility for the conduct of the study, had access to the data, and controlled the decision to publish.

Competing interests None.

Ethics approval Obtained from the Human Research Ethics Committee at the Royal Children's Hospital in Melbourne, Australia (HREC 30049).

Funding "ChocHealth for Kids!" was funded by The Centre for Community Child Health and the Murdoch Childrens Research Institute (MCRI). MCRI research is supported by the Victorian Government's Operational Infrastructure Program. Drs Mensah, Quach and Wake are all supported by the Australian National Health & Medical Research Council.

Provenance and peer review Not commissioned; externally peer reviewed.

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Arch Dis Child 2012 97: 637-640 originally published online June 9, 2012
doi: 10.1136/archdischild-2011-301305