Introduction

- Risk of cardiovascular mortality and morbidity rises across the entire range of blood pressure (BP) in adults, starting from normal values above 115/75 mmHg.
- Childhood BP has strong predictive associations with adult hypertension.
- 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, 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.

Methods

Design
Pilot randomised controlled trial (CRICHTN040164).

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 consent rate below 65%.

Randomisation
- Cluster unit of randomisation - the class.
- Classes stratified by school and year level.
- 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.
- Students in intervention classes received 3g of dark chocolate (2.8mg catechin and 6.4mg 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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (%)</th>
<th>Control (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>49.1</td>
<td>54.3</td>
</tr>
<tr>
<td>Age (years)</td>
<td>11.0 (0.7)</td>
<td>11.0 (0.6)</td>
</tr>
<tr>
<td>Income background and lifestyle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living with both parents</td>
<td>92.7</td>
<td>94.1</td>
</tr>
<tr>
<td>Parent's education</td>
<td>80.9</td>
<td>85.5</td>
</tr>
<tr>
<td>One or both parents have tertiary education</td>
<td>72.1</td>
<td>77.9</td>
</tr>
<tr>
<td>One or both parents employed full time</td>
<td>98.4</td>
<td>97.1</td>
</tr>
<tr>
<td>Screen time &gt;2 hours a day</td>
<td>45.5</td>
<td>42.0</td>
</tr>
<tr>
<td>On school days</td>
<td>66.2</td>
<td>66.5</td>
</tr>
<tr>
<td>One or more smokers at home</td>
<td>4.1</td>
<td>4.3</td>
</tr>
</tbody>
</table>

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

Primary outcomes

- BP and anthropometric measures were similar in the two groups – Study participation rates.
- Feedback response (follow-up questionnaire).
- Pilot data on intention-to-treat principle.
- Unadjusted and adjusted linear regression analysis of BP and all secondary outcomes.
- Analyses adjusted for confounders shown a priori (age, gender, parent education) and for corresponding baseline value.

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.
- 44% of teachers (n=7) would recommend the study to others.
- Teachers found measurements at baseline (45%) and at follow up (38%) fairly disruptive.
- BP and anthropometric measures were similar in the two groups at 7 weeks (Table 4).

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
- 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 chocolate affects children’s blood pressure.