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Efficacy of a school-based physical activity and nutrition intervention on child weight status: Findings from a cluster randomized controlled trial

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ABSTRACT

Despite the benefits of factorial designs in quantifying the relative benefits of different school-based approaches to prevent unhealthy weight gain among students, few have been undertaken. The aims of this 2 × 2 cluster randomized factorial trial was to evaluate the impact of a physical activity and nutrition intervention on child weight status and quality of life. Twelve primary schools in New South Wales, Australia randomly allocated to one of four groups: (i.) physical activity (150 min of planned in-school physical activity); (ii.) nutrition (a healthy school lunch-box); (iii.) combined physical activity and nutrition; or (iv.) control. Outcome data assessing child weight and quality of life were collected at baseline and 9-months post-baseline. Within Grades 4–6 in participating schools, 742 students participated in anthropometric measurements, including child body mass index (BMI) and waist circumference, at baseline and follow-up. Findings indicated that students that received the nutrition intervention had higher odds of being classified in the BMI category of underweight/healthy weight (OR 1.64 95%CI 1.07, 2.50; $p = 0.0220$), while those who received the physical activity intervention reported a lower waist circumference (mean difference − 1.86 95%CI -3.55, −0.18; $p = 0.030$). There were no significant effects of the nutrition or physical activity intervention on child BMI scores or child quality of life, and no significant synergistic effects of the two interventions combined. Future research assessing the longer-term impact of both intervention strategies, alone and combined, is warranted to better understand their potential impact on child health.

Trial registration: Australian Clinical Trials Registry ACTRN: ACTRN12616001228471.

1. Introduction

Globally, over 340 million children aged 5 to 19 years were overweight or obese in 2016 (World Health Organization, 2020a). As childhood overweight and obesity is likely to track into adulthood (Singh et al., 2008), excessive weight gain during childhood can substantially increase the risk of developing other non-communicable diseases in later years (World Health Organisation, 2017). Unhealthy lifestyle behaviors, including poor diet and inadequate physical activity, are the primary modifiable drivers of excessive weight gain (Swinburn et al., 2004). In response to this, national and international recommendations have been established to provide nutrition and physical activity guidance to populations (Government of Canada, 2016; United States Government, 2019; Public Health England, 2016; Australian Institute of Health and Welfare, 2020; Australian Department of Health, 2017). For example, recent guidelines from the World Health Organization recommend for children and adolescents to complete an average of 60 min of moderate- to vigorous-intensity physical activity daily (World Health Organization, 2020b). However, current child nutrition intake and physical activity levels remain inadequate. International

Abbreviations: Randomized controlled trial, (RCT); Moderate-vigorous physical activity, (MVPA); Body mass index, (BMI); New South Wales, (NSW); Physically active children in education, (PACE); Physical education, (PE); Socio-economic for areas, (SEIFA); Accessibility and remoteness index of Australia, (ARIA); Quality of life, (QoL); Odds ratio, (OR).

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research indicates children are consuming suboptimal serves of fruit and vegetables whilst overconsuming foods high in added sugar, saturated fat and sodium (Ruxton and Derbyshire, 2011; Brady et al., 2000; Department of Health, 2007; Black and Billette, 2013). Further, 60–78% of children fail to meet daily physical activity recommendations specified within national and international guidelines (Australian Institute of Health and Welfare, 2019; Centers for Disease Control and Prevention, 2020; Statistics Canada, 2019; National Health Service, 2016).

Schools are an important setting to influence children's nutrition and physical activity behaviors to reduce their risk of unhealthy weight gain (World Health Organization, 2012). As children attend school for prolonged periods, the setting provides continual access to children during a crucial period of development (World Health Organisation, 2017; World Health Organization, 2012). Children can consume at least one third of their daily nutrition intake and are recommended to accumulate half of their daily physical activity requirements during school-time (Regan et al., 2008). Interventions targeting the school setting, therefore, have the potential to improve child weight status. A large volume of research has been conducted within the school-setting, with a Cochrane systematic review identifying 153 randomized controlled trials testing the efficacy of interventions on preventing obesity in children and adolescents, 90 of which were school-based interventions (Brown et al., 2019). The review found considerable variability in the effects of school-based interventions on physical activity and/or nutrition, with meta-analyses providing low-certainty evidence of a modest effect on body mass index (Brown et al., 2019).

While systematic reviews examining the effectiveness of school-based interventions to improve child weight status exist, it remains unknown what combination of intervention components have the greatest impact on child weight status. Systematic reviews have identified components of school-based interventions that are associated with greater improvements in child health outcomes (Liu et al., 2019). Interventions that are multi-component (e.g. targeting physical activity and nutrition), employed strategies to involve parents and school staff, and were theoretically informed, have been found to have greater effects on child health outcomes, such as weight status (Liu et al., 2019). However, subgroup analyses in systematic reviews provide indirect, and likely confounded evidence of the relative benefit of different interventions on outcome measures. As randomized factorial designs provide one of the most robust means of assessing the relative contribution of intervention components, employing this study design within school-based interventions is a novel and potentially effective approach to addressing limitations of the current evidence base (Montgomery et al., 2003). Factorial designs enable the effects of two or more interventions, or combinations thereof, to be compared directly within the one trial. Despite the advantages of employing a factorial design in comparison to traditionally employed designs which do not enable direct comparison of interventions, relatively few school-based factorial trials have been undertaken. For example only two school-based trials within the Cochrane review (Brown et al., 2019) employed factorial designs (Crespo et al., 2012; Bonsergent et al., 2013). Both factorial trials tested combinations of school- and home-based intervention components, with mixed findings in child BMI z-scores the prevalence of overweight and obesity among students. (Crespo et al., 2012; Bonsergent et al., 2013) However, neither study enabled direct comparison of nutrition and physical activity intervention components (Crespo et al., 2012; Bonsergent et al., 2013). A difficulty with undertaking a factorial design with a purpose of assessing the combined and possible synergistic effects of two or more interventions is the large sample size required (Bahçecitapar et al., 2016).

The lack of factorial trials precludes a clear understanding of the relative benefits of components of school-based child obesity-prevention interventions, and hinders the development of more effective and efficient approaches to preventing obesity in the setting. As such, the primary aim of this study was to evaluate the impact of a randomized controlled trial employing a factorial design testing the potential efficacy of a physical activity and nutrition interventions separately on child weight status and quality of life. The secondary aim of the study was to explore the potential synergistic effects of the two intervention strategies (i.e. physical activity and nutrition) on these outcomes.

2. Methods

2.1. Ethics and registration

Ethics approval to conduct the trial was obtained by University of Newcastle (Reference: H-2008-0343), New England Human Research Ethics Committee (Reference: 06/07/26/4.04) and the Maitland-Newcastle Catholic Schools Office. The trial and outcomes reported upon within this paper were prospectively registered with Australian New Zealand Clinical Trials Register (ACTRN12616001228471) and aligns with the CONSORT reporting guidelines for randomized controlled trials (Appendix 1) (Eldridge et al., 2016).

2.2. Design and setting

A cluster randomized controlled trial (RCT) employing a 2 × 2 factorial design was conducted from January to September 2017. The trial sought to assess the impact of two programmes: (i) a physical activity intervention to support schools to increase time scheduled for student engagement in moderate-vigorous physical activity (MVPA) across the school week; and (ii) a nutrition intervention to improve the nutritional quality of foods packed within children's lunchboxes by parents. Employing a 2 × 2 factorial design enabled the potential efficacy of two programmes to be tested efficiently. Physical activity and nutrition outcomes from the trial have been published separately elsewhere (Sutherland et al., 2019; Nathan et al., 2020). The physical activity intervention resulted in significant overall improvements in child school-day MVPA (3.0 min, 95%CI 2.2, 3.8, $p < 0.001$) (Nathan et al., 2020), whilst findings of the nutrition intervention reported a reduction in total kilojoules packed within children's lunchboxes (−118.39 kJ, 95%CI -307.08, 70.30, $p = 0.22$) (Sutherland et al., 2019). The impact of the two interventions on anthropometric outcomes, including waist circumference and body mass index (BMI), are reported within this paper.

The trial was conducted within 12 Catholic primary schools, located within the Hunter region of New South Wales (NSW), Australia. Primary schools typically cater for children aged 5–12 years. There are approximately 201 primary schools in the Hunter Region, 37 of these were Catholic schools (NSW Government, 2021). Within these schools, parents are required to pack foods from home for children to consume during the day. However in some schools, children also have access to school canteens where they can purchase food and beverages. Schools were randomized to one of four treatment groups: (i.) physical activity support only; (ii.) nutrition support only; (iii.) physical activity and nutrition support; or (iv.) usual care (i.e. waitlist control).

2.3. Sample and participants

2.3.1. Schools

Primary schools located within the Hunter region were eligible for inclusion in the trial if they: (i.) were a Catholic school; (ii.) enrolled >120 students; (iii.) currently used a preferred school mobile communication app (used within the nutrition intervention); and (iv.) were not currently participating in other nutrition or physical activity trials. Schools were excluded from the study if they: (i.)solely catered for children with special needs; (ii.)) catered for children aged 13–18 years; or (iii.)() were currently participating in another physical activity or nutrition intervention. Recruitment packages, including a study information statement and consent form, were progressively distributed to the principals of potentially eligible schools in random order. Schools were asked to sign a written consent form to confirm participation in the study, with recruitment continuing until the required sample ($n = 12$) was reached.

2.3.2. Students

All students aged 5–12 years (Kindergarten to Grade 6) attending participating schools were invited to participate in the trial, with anthropometric outcomes solely assessed for children in Grades 4–6. A recruitment package consisting of a study information statement and consent form were distributed to parents by school staff on behalf of the research team. For children to participate, parents were required to return a signed consent form prior to data collection. Two weeks following the distribution of recruitment packages, parents who had not yet returned a consent form were telephoned by school staff to obtain consent for their child to participate. In addition to written parental consent, student assent was also required on the day of data collection.

2.4. Randomization and blinding

Following the completion of baseline data collection, schools were randomly allocated in a 1:1:1:1 ratio to one of the four trial arms by an independent statistician using a computerized random number function in Microsoft Excel. Data collection staff, including coordinators and assistants, were blinded to group allocation at baseline. At follow-up, data collection coordinators were aware of group allocation, whilst data collection assistants were not informed of group allocation in an effort to ensure blinding. Nonetheless it is possible that data collection assistants may have become aware of group allocation during data collection should school staff or students disclose such information. School staff were aware of group allocation.

2.5. Intervention

2.5.1. Physical activity (group one)

Schools allocated to the physical activity group received the 9-month Physically Active Children in Education (PACE) intervention. The aim of PACE was to support teachers to implement a physical activity policy, specifically the scheduling of 150 min of planned physical activity across the school week, as recommended by NSW Government guidelines (NSW Government, 2019). The PACE intervention components have been described elsewhere (Nathan et al., 2020), with greater detail provided in Appendix 2. Teachers and school champions were provided with training, educational materials and ongoing support by health promotion officers to facilitate the scheduling of the required duration of physical activity across the school week (Nathan et al., 2020). physical activity could be comprised of physical education (PE), sport, energisers (i.e. activities to break-up sitting time) and active lessons (i.e. integrating physical activity within other subjects) (Nathan et al., 2020).

2.5.2. Nutrition (group two)

Schools allocated to the nutrition group received the 5–6 month SWAP IT intervention. The aim of SWAP IT was to support parents to improve to the nutritional quality of children's lunchboxes, thus improving child dietary intake whilst at school. The intervention strategies within SWAP IT have been described elsewhere, (Sutherland et al., 2019) with greater detail provided in Appendix 2. Schools were supported to develop and implement school nutrition guidelines and lunchbox-related education within the curriculum, whilst weekly messages containing nutrition information and resources addressing barriers to packing healthy lunchboxes were disseminated to parents for 10 weeks via an existing school mobile communication app (Sutherland et al., 2019).

2.5.3. Physical activity and nutrition (group three)

Schools allocated to the combined physical activity and nutrition group received both the PACE and SWAP IT interventions described above. Schools received both interventions concurrently.

2.6. Control (group four)

Control schools did not receive the physical activity or nutrition interventions (i.e. waitlist control) and were asked to continue with usual practices. Schools within the control group were not offered nutrition or physical activity support during the intervention period, which was monitored by the research team. However, schools were still able to access general nutrition and physical activity support available via NSW Government health promotion programmes, which included educational materials (e.g. factsheets and learning resources). At the time of the trial, to promote physical activity this could have included in-class activities, ciricula and environmental changes, although such initiatives were not directed specifically at achieving the 150 min policy. For nutrition, such support may have included support to improve the provision of healthy foods at school canteens, ciricula changes and the provision of nutrition information to families, although there was no specific lunchbox-focussed programme.

2.7. Data collection and measures

Baseline data was collected from children between February–March 2017. Follow-up data collection was conducted between October–November 2017, approximately nine months post-baseline.

2.7.1. Student and teacher demographics

Parents were asked to report on the student consent form their child's age, sex, and postcode of residence. The 2016 Socio-Economic for Areas (SEIFA) Index was used to classify students as residing in an area of low or high social disadvantage using student postcodes. Those in the highest decile (>5) were categorized as residing in an area of low social disadvantage and those with a corresponding score in the lowest decile (≤5) were categorized as residing in an area of high social disadvantage (Australian Bureau of Statistics, 2018). The 2016 Accessibility and Remoteness Index of Australia (ARIA) was used to classify students as residing in an urban (i.e. major cities) or regional (i.e. inner or outer regional, remote) (Australian Bureau of Statistics, 2016). Teachers demographics, including gender and if they were a specialist Personal Development, Health and Physical Education (PDHPE) teacher were captured via paper-based survey.

2.7.2. Child BMI

Child height and weight were objectively measured by trained data collection assistants for consenting children in Grades 4–6 (typically aged 9 to 12 years) at baseline and follow-up. Trained assistants followed the International Society for Advanced Kinanthropometry procedures to measure weight and height using a calibrated digital scale (Model no.UC-321PC, A&D Company Ltd) and standing portable stadiometer (Model no.PE087, Mentone Educational Centre) on a flat, solid surface. Data collection instruments were calibrated by a certified weighing company prior to data collection. Prior to collecting the measurement, children were asked to remove thick outer-garments, belts, shoes and any heavy objects within their pockets. To address potential concerns from students regarding the measurements, students were instructed to step onto the scales facing backwards to avoid the measurements being visible, and were not told their weight by the trained assistants. Two height (cm) and weight measurements (in kilograms (kg)) were taken for each child, with the means of each used as the final measurement. Child BMI scores were calculated by dividing their weight by their height (in metres) squared (kg/m2). BMI categories were calculated using the World Health Organization classification, with BMI scores classified into age and gender standardized categories of underweight, healthy weight, overweight and obese (World Health Organization, 2021). BMI z-scores were calculated using the World Health Organization 2007 classification values (World Health Organization, 2021).

2.7.3. Waist circumference

Waist circumference was objectively measured for all consenting children in Grades 4–6 by trained data collection assistants at baseline and follow-up. Children were asked to remove thick outer-garments to ensure accurate recording. Similar to the above approach to address potential concerns, the measurements were not visible to the students or discussed by the trained assistants. Two measurements were taken for each child using a tape measure (Model no.PE079, Mentone Educational Centre), with the means of each used as the final measurement.

2.7.4. Quality of life (QoL)

Self-reported QoL for students in Grades 4–6 was assessed using the Paediatric Quality of Life Inventory (PedsQL) (Varni et al., 2001) at baseline and follow-up. The PedsQL is a validated and reliable 23-item scale incorporating four domains of health and wellbeing, including: social functioning (5 items), physical functioning (8 items), school functioning (5 items) and emotional functioning (5 items) (Varni et al., 2001). Students responded to each item on a four-point Likert scale (0 = never, 4 = almost always). Each item was reverse scored and transformed to a score ranging from 0 to 100, with higher values reflecting a better QoL.

2.8. Sample size

The study was powered to detect changes in the primary outcomes (reported elsewhere), including the mean kilojoule content of lunchboxes and counts per minute of physical activity (Sutherland et al., 2019; Nathan et al., 2020). While not undertaken a priori – based on the following sample parameters at baseline: an ICC of 0.017, mean of 19.54, SD of 3.83, a mean of 67 teachers per school and 6 schools per arm, with alpha of 0.05, and power 80%, the study could detected a difference in child BMI of 1.21 kg/m2.

2.9. Analysis

Statistical analyses were conducted using SAS v9.4. Descriptive statistics, including proportions, means and standard deviations, were used to describe the study sample. An intention to treat approach was used in the analyses of all trial outcomes, with all schools included in the analysis and all participants with baseline data included in the analysis. For the primary analyses, to assess the effects of the nutrition and physical activity interventions separately, mixed effects regression models were used to assess between group differences in strategies (physical activity vs no physical activity intervention; and nutrition vs no nutrition intervention) in student outcomes at follow-up. For continuous outcomes (i.e. BMI, waist circumference and QoL), a linear mixed model was used. For the dichotomized variable BMI classification, a generalized linear mixed model with a binomial distribution and logit link function was used. Each model included a fixed effect for each intervention group. A fixed effect for remoteness classification and socio-economic location were also included in the models due to an imbalance between student baseline values in these variables. Random level intercepts for school and class nested within school were also included to account for the clustered data. An additional fixed effect for the baseline value of the outcome was also included in all linear mixed models.

Due to the small number of clusters, the Kenward Roger degrees of freedom were used. A sub-group analysis assessing the differential effects of the BMI and waist circumference outcomes by gender was undertaken as a secondary analysis, by including a gender interaction term in the models. If the interaction term between each intervention and gender had a p-value <0.2, the differential effects were assessed further. To ensure all analyses followed the ITT principles analyses, missing follow-up data was imputed in 50 datasets using the fully conditional method and estimates were combined using Rubin's rule. Analyses of the outcomes employed a two-tailed test with an alpha level of 5%.

For the secondary outcome analyses, the synergistic effects between the two intervention strategies were explored by including a physical activity by nutrition group interaction term in all models. We examined the potential interaction between intervention strategies by graphically displaying outcome measures by group given the small sample size and the limited power to detect an interaction effect.

3. Results

3.1. Sample

Twenty-six of the 37 Catholic primary schools within the study sampling frame were assessed (in random order) for eligibility. Six schools were deemed ineligible. Of the 20 eligible schools eight declined and 12 provided consent to participate (Fig. 1). All students within Grades 4–6 in participating schools (n = 1586) were invited to participate in the study, with 916 students providing consent to participate in anthropometric and QoL measurements (overall consent rate of 57.8%). Anthropometric measurements were collected from 89% (n = 815) of consenting students at baseline (ranging from 83.1% in the control group to 92.6% in the nutrition group). Of these students, 742 provided baseline and follow-up data. The proportion of students providing follow-up data was similar between groups ranging from 86% in the control group to 91.4% in the physical activity group.

Student demographics were similar across experimental groups at baseline, except for remoteness classification and measures of socio-economic disadvantage (Table 1). A higher percentage of students (99.6%) within the physical activity only group resided in a major city compared to those in other experimental groups. Comparatively, a higher percentage of students (66%) within the nutrition group only resided in a regional or remote location compared to those in other experimental groups. A higher percentage of students (49%) within the physical activity group only resided in the least disadvantaged areas of NSW compared to other experimental groups; while a higher percentage of students (82%) within the control group resided in the most disadvantaged areas of NSW compared to other experimental groups.

3.2. Primary analyses

3.2.1. Child BMI

There were no significant differences in child BMI scores or child BMI z-scores at follow-up between students who received the physical activity intervention compared to those who did not receive the physical activity intervention (child BMI score: adjusted mean difference − 0.10 95%CI -0.31, 0.11; p = 0.3606) (Table 2). Similarly, there were no group (physical activity vs no physical activity intervention) by gender interactions for either of these outcomes (p-value >0.2).

There were no significant differences in child BMI scores or child BMI z-scores between students at follow-up who received the nutrition intervention compared to those who did not (child BMI score: adjusted mean difference 0.13 95%CI -0.06, 0.31; p = 0.1744). However, there was a significant interaction for the nutrition intervention by gender, with males reporting a larger decrease than females for both BMI scores (p = 0.0055) and BMI z-scores (p = 0.0055). By subgroup, girls who received the nutrition intervention recorded significantly higher BMI scores (adjusted mean difference 0.30; 95%CI 0.09, 0.52; p = 0.0047) and BMI z-scores (adjusted mean difference 0.13; 95%CI 0.02, 0.23; p = 0.0149) compared to girls who did not. There was no significant difference in BMI scores (adjusted mean difference − 0.07 95%CI -0.29, 0.16; p = 0.5620) or BMI z-scores (adjusted mean difference − 0.02 95% CI -0.12, 0.08; p = 0.7119) among boys.

At follow-up, students allocated to schools receiving the nutrition intervention had 1.64 times the odds of being classified as underweight/healthy weight (OR 1.64 95%CI 1.07, 2.50; p = 0.0220) relative to students attending schools that did not receive the nutrition intervention. There was no significant differences in BMI categories for students

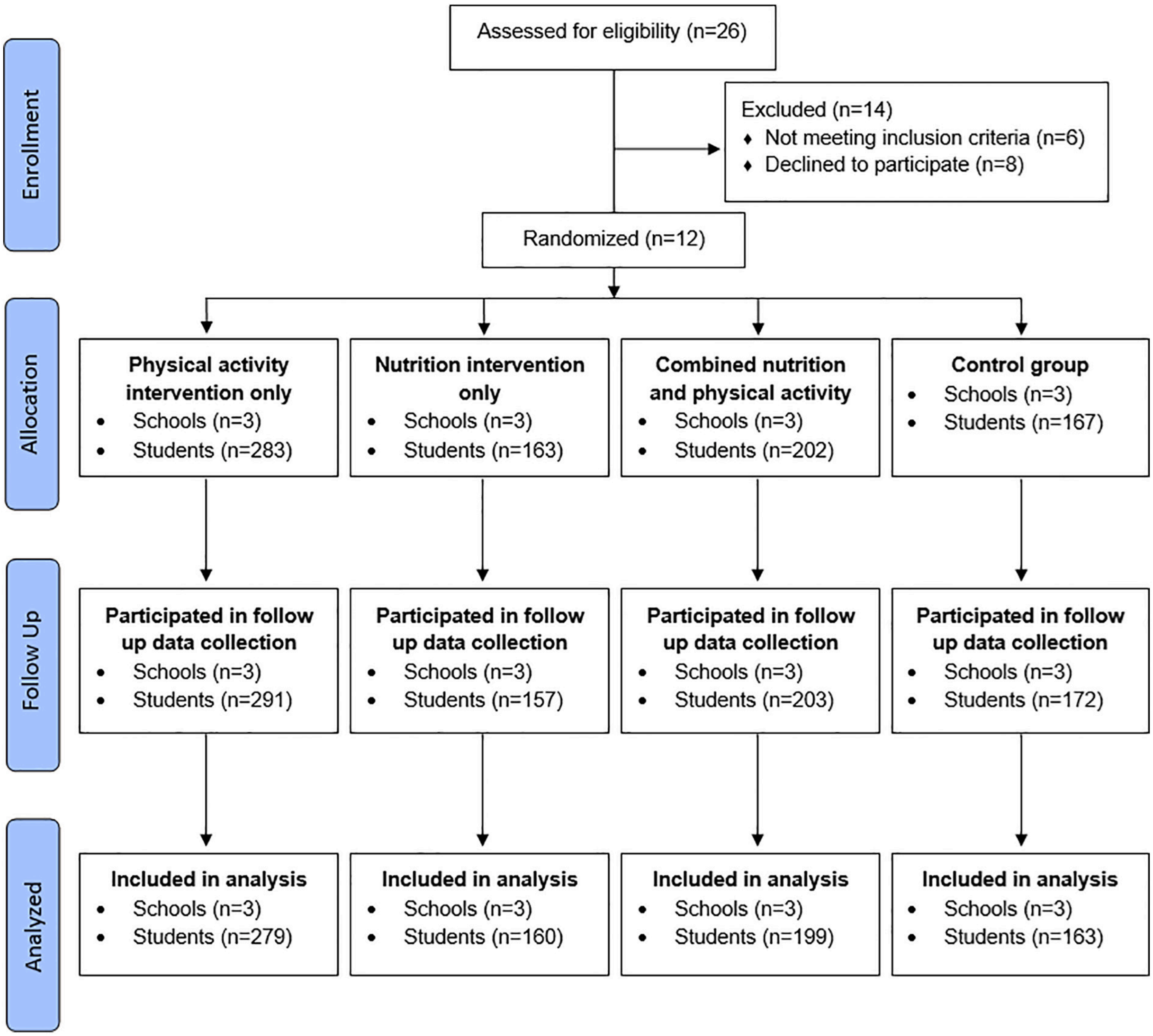

Fig. 1. Consort flow diagram.

at schools which did and did not receive physical activity intervention (OR 0.89 95%CI 0.55, 1.44; $p = 0.6377$). Furthermore there were no significant interactions for intervention (nutrition or physical activity) and gender ($p > 0.05$). The proportion of students within the underweight, healthy weight, overweight and obese BMI categories at follow-up has been reported in Table 5.

3.2.2. *Waist circumference*

There was a significant effect of the physical activity intervention for waist circumference when assessed overall between experimental groups (adjusted mean difference − 1.86 95%CI -3.55, −0.18; $p = 0.0304$) (Table 2). No differential effects of the physical activity intervention by gender on waist circumference were identified.

There were no significant differences in waist circumference between students attending schools that received the nutrition intervention compared to those who did not (adjusted mean difference − 0.38; 95%CI -1.92, 1.15; $p = 0.6240$). The (nutrition vs no nutrition intervention) by gender interactions was above the pre-specified threshold of $p < 0.2$ ($p = 0.0510$), with males (adjusted mean difference − 0.97 95% CI -2.65, 0.70; $p = 0.2548$) reporting a slightly larger decrease then females (adjusted mean difference 0.19 95%CI -1.48, 1.86; $p = 0.8260$). There were no statistically significant within subgroup differences.

3.2.3. *QoL*

There were no significant differences between students attending schools that received the physical activity intervention compared to those that did not in self-reported QoL total scores (adjusted mean difference − 0.20; 95%CI -2.87, 2.47; $p = 0.8836$) or individual domains (i.e. physical functioning, emotional functioning, social functioning, school functioning) (Table 3). Similarly for those that received the nutrition intervention compared to those that did not, there was no significant difference in self-reported QoL total scores (adjusted mean difference − 0.16; 95%CI -2.49, 2.18; $p = 0.8958$) or individual domains.

3.3. *Secondary analyses*

3.3.1. *Synergistic effect between physical activity and nutrition intervention strategies*

At follow-up, there was little difference in mean child BMI scores, child BMI z-scores, waist circumference or QoL total scores across the four experimental groups (Table 4). The mean child BMI scores ranged from 18.67 to 19.54 kg/m^2 at follow-up, whilst the mean waist circumference ranged from 67.60 to 71.17 cm, and the mean QoL score ranged from 77.86 to 81.14. Additionally, there were no significant physical activity by nutrition group synergistic effect for child BMI

Table 1
School and student baseline characteristics by experimental group.

	Control n (%)	Nutrition n (%)	Physical activity n (%)	Combined n (%)
School characteristics				
Total schools	$n = 3$	n = 3	n = 3	n = 3
Remoteness classification				
Urban (major cities)	2 (67%)	1 (33%)	3 (100%)	3 (100%)
Regional (inner/outer regional/remote)	1 (33%)	2 (67%)	0	0
SEIFA disadvantage classification				
Most disadvantaged	2 (67%)	2 (67%)	2 (67%)	2 (67%)
Least disadvantaged	1 (33%)	1 (33%)	1 (33%)	1 (33%)
Teacher characteristics				
Total teachers	$n = 19$	$n = 29$	$n = 34$	$n = 24$
Gender				
Male	4 (21%)	4 (14%)	6 (18%)	4 (17%)
Female	15 (79%)	25 (86%	28 (82%)	20 (83%)
Specialist personal development, health and physical education teachers	1 (5%)	1 (3.4%)	1 (2.9%)	1 (4.3%)
Student characteristics				
Total students	$n = 167$	$n = 163$	$n = 283$	$n = 202$
Gender				
Male	76 (46%)	83 (51%)	145 (51%)	89 (44%)
Female	91 (54%)	80 (49%)	138 (49%)	113 (56%)
School grade				
Grade 4	52 (31%)	63 (39%)	104 (37%)	70 (35%)
Grade 5	56 (34%)	44 (27%)	113 (40%)	78 (39%)
Grade 6	59 (35%)	56 (34%)	66 (23%)	54 (27%)
Remoteness classification				
Urban (major cities)	127 (76%)	56 (34%)	282 (99.6%)	186 (92%)
Regional (inner/outer regional/remote)	40 (24%)	107 (66%)	1 (0.4%)	16 (7.9%)
SEIFA disadvantage classification				
Most disadvantaged	137 (82%)	125 (77%)	143 (51%)	158 (78%)
Least disadvantaged	30 (18%)	38 (23%)	140 (49%)	44 (22%)
Child BMI categories				
Underweight	8 (4.8%)	4 (2.5%)	16 (5.7%)	6 (3.0%)
Healthy weight	108 (65%)	117 (72%)	180 (64%)	145 (72%)
Overweight	34 (20%)	33 (20%)	62 (22%)	39 (19%)
Obese	17 (10%)	9 (5.5%)	24 (8.5%)	11 (5.5%)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Child BMI score	19.23 (3.81)	18.69 (3.21)	18.71 (3.61)	18.43 (3.27)
Child BMI z-score	0.72 (1.25)	0.59 (1.09)	0.57 (1.26)	0.48 (1.14)
Waist circumference (cm)	68.42 (10.48)	66.86 (9.36)	67.4 (10.01)	67.59 (9.43)
Quality of life: Total scale score	77.99 (13.55)	81.14 (13.19)	77.37 (13.42)	79.57 (13.35)

SEIFA = Socio-Economic for Areas (SEIFA) Index; SD = standard deviation; BMI = body mass index; cm = centimetre.

scores (coefficient − 0.03; SE 0.19; $p = 0.8792$), waist circumference (coefficient 1.59; SE 1.54; $p = 0.3012$) or QOL total scores ($p = 0.7760$).

4. Discussion

This study is one of few to employ a randomized factorial design to test the potential efficacy of a physical activity and nutrition intervention, alone and to explore in combination on measures of child adiposity and self-reported child quality of life. The trial found significant main effects for the nutrition intervention on child BMI category ($p = 0.0220$), as well as the physical activity intervention on waist circumference ($p = 0.0304$). Such findings suggest that both interventions hold promise as strategies to reduce the population adiposity that warrant further investigation. However, no significant effects on child quality of life was reported in either intervention strategies.

Although the lack of effect on child BMI scores following the physical activity and nutrition interventions is discouraging, it is largely consistent to findings of a Cochrane review, which suggest that school-based nutrition interventions broadly are typically ineffective in improving student weight status (Brown et al., 2019). However, the significant effect of the nutrition intervention on BMI category (OR 1.64; 95%CI 1.07, 2.50; $p = 0.0220$) is encouraging, and is consistent with interventions specifically targeting the packing of healthy school lunchboxes that have reported reductions in energy intake following the intervention (Nathan et al., 2019). The findings are also consistent with a quasi-experimental study by Swinburne et al. that reported students had 37% lower odds of being overweight or obese at follow-up following a lunchbox nutrition intervention consisting of resource intensive face-to-face training and workshops (OR 0.63, $p < 0.001$) (Swinburn et al., 2014). The parental focus of lunchbox-targeted interventions may, in part, explain their effects on this measure of weight status. Systematic reviews have suggested parental involvement is key to the success of previous school-based child obesity prevention interventions (Verjans-Janssen et al., 2018). This may be due to the effects of school-based interventions that build the nutrition knowledge, skills and capacity of parents also yielding improvements to the home food environments (Golan, 2006; Katz et al., 2008; Langford et al., 2014). Given the primary component for the lunchbox nutrition intervention tested within this trial was technology-based, provided direct access to parents, and has the capacity to be delivered at scale (via existing school communication infrastructure), such positive effects of this intervention have particular appeal as a strategy to improve public health nutrition and prevent unhealthy weight gain.

The significant improvement in waist circumference within children receiving the physical activity intervention (mean difference − 1.86 cm; 95%CI -3.55,-0.18; $p = 0.0304$) is also promising. Such findings are consistent with a recent systematic review by Yuksel et al., which evaluated the effect of school-based physical activity interventions on preventing obesity in students (Yuksel et al., 2020). The review found that four of the eight studies evaluating the impact of interventions on student waist circumference reported significant improvements, whilst an additional three studies reported non-significant improvements (Yuksel et al., 2020). The components of those interventions that were effective were similar to those tested in this trial, namely the scheduling and provision of physical activity during class time through strategies such as the provision of equipment and lesson plans (Bhave et al., 2016; Grydeland et al., 2014; Kipping et al., 2014). Given the improvements in child physical activity following school-based interventions have been typically modest (Hartwig et al., 2021), it is encouraging to note that such interventions may result in important improvements in children's waist circumference. For example, reductions in abdominal adiposity achieved in this trial, approximately 2 cm, have been found to be significant reductions in the risk of developing metabolic syndrome and hypertension if sustained (Dyrstad et al., 2019).

The lack of improvement in student QoL total scores in those receiving either the physical activity (adjusted mean difference −0.20;

Table 2
Difference in anthropometric outcomes following the physical activity and nutrition interventions.

Intervention type	Outcome	Received intervention - mean (SD)	Did not receive intervention - mean (SD)	n*	Effect size (95% CI)	p-value
Physical activity	Child BMI[a] score	18.72 (3.42)	19.28 (3.51)	798	MD -0.10 (−0.31, 0.11)	0.3606
	Child BMI z-score	0.74 (1.17)	0.93 (1.12)	798	MD -0.01 (−0.11, 0.09)	0.8549
	Waist circumference (cm)[b]	68.12 (9.41)	70.08 (10.27)	778	MD -1.86 (−3.55, −0.18)	0.0304
	BMI category: Underweight/healthy weight	334/447	210/295	798	OR 0.89 (0.55, 1.44)	0.6377
Nutrition	Child BMI[c] score	18.83 (3.30)	19.04 (3.59)	798	MD 0.13 (−0.06, 0.31)	0.1744
	Child BMI z-score	0.80 (1.07)	0.83 (1.21)	798	MD 0.05 (−0.04, 0.14)	0.2388
	Waist circumference (cm)[d]	68.22 (9.51)	69.44 (10.00)	778	MD -0.38 (−1.92, 1.15)	0.6240
	BMI category: Underweight/healthy weight	250/328	294/414	798	OR 1.64 (1.07, 2.50)	0.0220

MD = Adjusted Mean Difference; OR = Odds Ratio; *n may not equal total sample due to missing baseline values and 15 participants missing a value for class.

Table 3
Quality of life total and domain scores following the physical activity and nutrition interventions.

Intervention type	Outcome	Received intervention - mean (SD)	Did not receive intervention - mean (SD)	n*	Effect size (95% CI)	p-value
Physical activity	QoL: Total scale score	78.52 (13.34)	80.25 (13.14)	794	MD -0.20 (−2.87, 2.47)	0.8836
	QoL: Physical functioning domain score	84.16 (13.72)	85.99 (11.87)	794	MD -1.12 (−4.64, 2.41)	0.5337
	QoL: Emotional functioning domain score	69.56 (19.15)	72.13 (19.98)	792	MD -0.78 (−4.68, 3.11)	0.6935
	QoL: Social functioning domain score	82.57 (17.13)	83.41 (17.94)	794	MD 1.31 (−3.24, 5.87)	0.5714
	QoL: School functioning domain score	74.54 (17.02)	75.96 (16.63)	792	MD 0.62 (−3.30, 4.55)	0.7552
Nutrition	QoL: Total scale score	80.22 (13.25)	78.39 (13.27)	794	MD -0.16 (−2.49, 2.18)	0.8958
	QoL: Physical functioning domain score	85.77 (12.74)	84.17 (13.26)	794	MD 0.96 (−2.24, 4.17)	0.5564
	QoL: Emotional functioning domain score	72.36 (18.94)	69.15 (19.86)	792	MD 0.59 (−2.83, 4.01)	0.7346
	QoL: Social functioning domain score	82.94 (17.00)	82.87 (17.83)	794	MD -1.22 (−5.32, 2.89)	0.5613
	QoL: School functioning domain score	76.35 (16.24)	74.09 (17.30)	792	MD 0.90 (−2.56, 4.35)	0.6105

MD = Adjusted Mean Difference; *n may not equal total sample due to missing baseline values and 15 participants missing a value for class.

Table 4
Mean and standard deviation for the experimental groups at follow-up, with the *p*-value from interaction terms between the four groups.

Outcome	Control - mean (SD)	Nutrition - mean (SD)	Physical activity - mean (SD)	Combined - mean (SD)	Coefficient (SE)	p-value from interaction term
Waist circumference (cm)	71.17 (10.91)	68.99 (9.50)	68.48 (9.34)	67.60 (9.51)	1.59 (1.54)	0.3012
Child BMI score	19.54 (3.83)	19.02 (3.14)	18.76 (3.42)	18.67 (3.42)	−0.03 (0.19)	0.8792
Child BMI z-score	1.00 (1.20)	0.87 (1.05)	0.73 (1.22)	0.74 (1.09)	−0.04 (0.10)	0.6420
BMI category: Underweight/healthy weight	100 (68%)	110 (75%)	194 (73%)	140 (77%)	0.02 (0.45)	0.9585
QoL: Total scale score	79.36 (13.41)	81.14 (12.86)	77.86 (13.18)	79.48 (13.55)	−0.71 (2.48)	0.7760
QoL: Physical functioning domain score	85.04 (12.17)	86.92 (11.54)	83.69 (13.82)	84.85 (13.58)	−0.60 (3.43)	0.8603
QoL: Emotional functioning domain score	69.83 (21.43)	74.40 (18.24)	68.79 (18.99)	70.70 (19.39)	−0.43 (3.57)	0.9033
QoL: Social functioning domain score	83.85 (19.12)	82.98 (16.77)	82.34 (17.10)	82.90 (17.22)	−0.12 (4.39)	0.9776
QoL: School functioning domain score	75.09 (17.79)	76.81 (15.42)	73.56 (17.05)	75.98 (16.92)	−1.19 (3.65)	0.7441

SD = Standard deviation; SE = Standard error.

95%CI -2.87, 2.47; $p = 0.8836$) or nutrition interventions (adjusted mean difference −0.16; 95%CI -2.49, 2.18; $p = 0.8958$) is consistent with previous school-based trials conducted internationally (Hartmann et al., 2010). A cluster-RCT testing the impact of a physical activity program on the QoL of 540 students in Switzerland determined the intervention had little effect on QOL in elementary students (Hartmann et al., 2010). Similarly, an experimental study aimed at improving student QoL through a nutrition program in Brazil reported no significant

Table 5
Child BMI categories at follow-up BMI category.

	Control n (%)	Nutrition n (%)	Physical activity n (%)	Combined n (%)
Underweight	7 (4.7%)	5 (3.4%)	15 (5.6%)	7 (3.9%)
Healthy weight	93 (63%)	105 (71%)	179 (67%)	133 (73%)
Overweight	34 (23%)	30 (20%)	54 (20%)	36 (20%)
Obese	14 (9.5%)	7 (4.8%)	18 (6.8%)	5 (2.8%)

improvements in student QoL following the intervention (Poll et al., 2019). Given the studies had a relatively short duration (≤1 year), it is possible that improvements in student QoL outcomes take longer to accrue, and as such, may display changes in longer term follow-ups.

When analysed to explore potential synergistic effects between the two intervention strategies, the trial found no significant interaction for child BMI scores, waist circumference, QoL or BMI category. The lack of an interaction is likely due to the limited power to detect an interaction effect, a circumstance acknowledged in the sample size calculations a-priori (Sutherland et al., 2019; Nathan et al., 2020). Nonetheless, whilst non-significant, the pattern of effects were consistent with what was broadly hypothesized with measures of waist circumferences and child BMI scores highest in the control group (waist circumference 71.17 cm; BMI 19.54 kg/m^2) and lowest in the combined group (waist circumference 67.60 cm; BMI 18.67 kg/m^2). The findings indicate the combination of both interventions may have the greatest impact on adiposity. However, such assertions are speculative and a larger trial with longer-term follow up is required to robustly substantiate this hypothesis.

5. Limitations

As the trial was powered to detect a difference in the nutrition and physical activity primary outcomes, it was not powered to detect clinically meaningful effects on anthropometric outcomes or to detect potential synergistic effect between the two intervention strategies. Therefore, a larger more robust trial would be required in order to establish the true effects of the two interventions on child weight status and to examine the synergetic effect between the two. Nonetheless, significant improvements in waist circumference within the physical activity group and BMI category in the nutrition group are promising. The relatively short intervention periods of 12 weeks to nine months may not have been of sufficient duration to have an impact on student BMI, waist circumference and quality of life, and as such, undermined the potential effect of the interventions. While all students from participating schools were invited to participate (and those in grades 4–6 in anthropometric assessments), participation rates were lower than 80%, thus increasing the risk of bias. Nonetheless baseline characteristics, participation rates and rates of attrition were similar between study arms, suggesting confounding was unlikely. The external validity of the study should also be considered when interpreting the trial findings. The study only included Catholic schools from one region in NSW, Australia. Whether the effects of the intervention would generalise to other school systems, elsewhere in Australia, or internationally, is unclear.

6. Conclusion

This trial provided a novel approach to evaluating the impact of school-based physical activity and nutrition interventions on child weight status and quality of life simultaneously via employing a factorial trial design. Despite promising results from the physical activity intervention in reducing child waist circumference and improvements in BMI categories as a result of the nutrition intervention, neither intervention strategy resulted in improvements in child BMI scores or quality of life. As such, a fully powered trial assessing the longer-term impact of both intervention strategies, alone and in combination, is warranted to better understand their potential impact on child health outcomes.

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Contributions

CB and LW led the drafting of the manuscript. LW, RS and NN conceived the study. LW, RS, NN, MP and NM designed the interventions. RS, NN, MP, AB and NM contributed to the acquisition of data. AH led statistical analysis. The authors would like to acknowledge the contributions of Lisa Jannsen, Benjamin Elton, Christophe Lecathelinais and Kathryn Reilly in the design, conduct and evaluation of the study. All authors contributed to the drafting of the manuscript, accept full responsibility for, and have read and approved the final manuscript.

Data availability statement

The data presented in this study are available on request from the corresponding author.

Informed consent statement

Informed consent was obtained from all subjects involved in the study.

Declaration of competing interest

The authors declare that they have no conflicts of interest.

Appendix 1. CONSORT 2010 checklist

Section/topic	Item no	Checklist item	Reported on page no
Title and abstract			
	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3–4

(*continued on next page*)

(*continued*)

Section/topic	Item no	Checklist item	Reported on page no
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4–5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5–6
	4b	Settings and locations where the data were collected	4–5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6–7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7–9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	N/A
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9–10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9–10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig. 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Fig. 1, Tables 2–4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Tables 2–4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	15
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	18–20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	18–20
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	18–20
Other information			
Registration	23	Registration number and name of trial registry	Page 2
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	21

Appendix 2. Strategies employed within the physical activity and nutrition interventions

Intervention	Intervention strategy	Description
Physical activity	Mandate change	Health promotion officers met with the school executive, including the principal, to discuss the importance and benefits of scheduled physical activity. The school executive were asked to show support for implementing the policy (i.e. the scheduling of 150 min of planned physical activity across the school week) through development of a local school physical activity policy and discussing expectations of the policy to staff.
	Identify and prepare champions	At least two existing teachers at each school were nominated as school champions, who under the guidance of the principal and assisted by the health promotion officers, were responsible for driving the implementation of the physical activity policy at their school.
	Distribute educational materials	An intervention manual was provided to each school champion and classroom teachers received varies educational materials to assist their scheduling and implementation of physical activity across the school week. Example lesson and classroom plans were provided by teachers to demonstrate how to implement the 150 min of scheduled physical activity across the school week.
	Educational outreach visits	All teachers from each school met face-to-face with health promotion officers once for 1–2 h at the commencement of the intervention to introduce the school champion and discus their role in driving implementation of the intervention; provide guidance on the development of how to implement the policy; and to discuss any barriers or facilitators to implementation.
	Provide ongoing consultation	

(*continued on next page*)

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Intervention	Intervention strategy	Description
		School champions received support remotely by health promotion officers via email or telephone twice per term during the intervention period. The aim of these contacts were to support the implementation of the intervention, identify barriers to implementation and brainstorm strategies to address such barriers.
	Centralised technical support	Health promotion officers provided technical assistance to schools throughout the intervention period to support the implementation of the 150 min of scheduled physical activity across the school week.
Nutrition	Nutrition guidelines for schools	Support was provided to schools to develop a nutrition guideline detailing 'recommended' foods from the core food groups to be packed in lunchboxes every day in replace of 'discretionary foods', as per the Australian guide to healthy eating (AGHE). Schools were encouraged to involve parents in the development of guideline, which was then communicated to parents via the school newsletter, school website and mobile communication app.
	Lunchbox flipchart lessons	A flipchart for each classroom was provided to schools at the start of the intervention. The flipchart included ideas to help teachers facilitate discussion on healthy lunchboxes and lunchbox samples for each of the 10 weeks of the intervention.
	Static content and push notifications delivered via school communication app	A school mobile communication app was used to communicate messages to parents addressing barriers to packing a healthy lunchbox. To increase the reach of intervention materials, parents were given instructions on how to download the app at the beginning of the intervention period if they were not active members. Eight static lunchbox themed pages were uploaded to the app in addition to weekly messages distributed to parents once per week via push notifications through the app. The static content and push notifications encouraged simple lunchbox swaps from 'discretionary' foods commonly found within lunchboxes to 'recommended' foods consistent with the AGHE. Push notifications addressed barriers to packing healthy lunchboxes and included a headline, example lunchbox pictures and swaps, a short message, links to videos and/or health organization websites which contained additional content and an email address to request further information. Once a message had been pushed via the app, it appeared as static content on the app for parents to access at a later time.
	Resources	Students received an information package containing tools and resources, including a lunchbox ideas booklet consisting of seasonal, low-cost and easy lunchbox examples, ice-brick and 'water only' drink bottle.

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