Osteoporos Int (2008) 19:1445–1456
DOI 10.1007/s00198-008-0589-z

ORIGINAL ARTICLE

Does a novel school-based physical activity model benefit femoral neck bone strength in pre- and early pubertal children?

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Received: 19 November 2007 / Accepted: 30 January 2008 / Published online: 21 March 2008

Abstract
Summary The effects of physical activity on bone strength acquisition during growth are not well understood. In our cluster randomized trial, we found that participation in a novel school-based physical activity program enhanced bone strength acquisition and bone mass accrual by 2–5% at the femoral neck in girls; however, these benefits depended on teacher compliance with intervention delivery. Our intervention also enhanced bone mass accrual by 2–4% at the lumbar spine and total body in boys.
Introduction We investigated the effects of a novel school-based physical activity program on femoral neck (FN) bone strength and mass in children aged 9–11 yrs.
Methods We used hip structure analysis to compare 16-month changes in FN bone strength, geometry and bone mineral content (BMC) between 293 children who participated in Action Schools! BC (AS! BC) and 117 controls. We assessed proximal femur (PF), lumbar spine (LS) and total body (TB) BMC using DXA. We compared change in bone outcomes between groups using linear regression accounting for the random school effect and select covariates.
Results Change in FN strength (section modulus, Z), cross-sectional area (CSA), subperiosteal width and BMC was similar between control and intervention boys, but intervention boys had greater gains in BMC at the LS (+2.7%, p=0.05) and TB (+1.7%, p=0.03) than controls. For girls, change in FN-Z tended to be greater (+3.5%, p=0.1) for intervention girls than controls. The difference in change increased to 5.4% (p=0.05) in a per-protocol analysis that included girls whose teachers reported 80% compliance.
Conclusion AS! BC benefits bone strength and mass in school-aged children; however, our findings highlight the importance of accounting for teacher compliance in classroom-based physical activity interventions.

Keywords Bone mass · Bone strength · Children · DXA · Hip structure analysis · Physical activity

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Introduction

Intervention studies have demonstrated that exercise programs can increase bone mass in the growing skeleton [1–6]. Bone *mass* (mineral content) is closely associated with bone failure, [7] but it is ultimately whole bone *structure* that determines bone's mechanical competence (strength) [8]. To date, only one school-based exercise intervention evaluated changes in *both* bone mass and structure at the clinically relevant proximal femur in boys [9, 10] and girls [11–13]. The Healthy Bones Study II

(HBS II) intervention, implemented within the school physical education (PE) curriculum, was a circuit program that required 10–12 minutes of moderate- to high-impact activity 3 times a week [13]. Given competing curricular demands and limited access to gymnasium space and equipment in elementary schools, a PE-based model may not be feasible on a large scale. To be sustainable, a school-based physical activity program may need to be simple for teachers to administer in the classroom setting, of short duration, and require little equipment. The Action Schools! BC (AS! BC) program meets these criteria [14].

Recently, we reported that the AS! BC intervention increased estimated bone strength at the distal tibia as measured by peripheral quantitative computed tomography (pQCT) in prepubertal boys [15]. The main bone-loading component of AS! BC was Bounce at the Bell [16], which provided children with short, frequent bouts of weight-bearing activity three times during the school day. This program incorporated principles of bone adaptation to loading defined in animal studies [17–19]. In our non-randomized pilot study, boys and girls who participated in Bounce at the Bell for an 8-month school year experienced significantly greater gains in proximal femur bone mass compared with children in control schools. Bone structural responses at the proximal femur as estimated with hip structure analysis (HSA) were in favour of the intervention children, but were not statistically significant [16]. That study was not powered to demonstrate a sex difference in response to the intervention and may also have been underpowered to demonstrate a bone strength response.

Therefore, the primary objective of the present study was to evaluate the effectiveness of AS! BC, which included Bounce at the Bell, for enhancing femoral neck bone strength (section modulus, Z) as estimated with HSA in boys and girls. To assess the changes in femoral neck bone mass and geometry that underpinned changes in bone strength, we also examined HSA-derived cross-sectional area (CSA) and subperiosteal width (SPW) and DXA measures of bone mineral content (BMC). The secondary objective of this study was to determine the effectiveness of AS! BC for enhancing DXA-derived BMC at the total proximal femur (PF), lumbar spine (LS) and total body (TB).

Materials and methods

Study design

Our methods are detailed in previous reports [14, 15] and are summarized briefly here. We conducted a cluster randomized, controlled, school-based intervention trial. Ten schools from the Vancouver and Richmond School Districts in British Columbia, Canada were randomly assigned to control (CON, three schools), Level 1 intervention (four schools) or Level 2 intervention (three schools). The intervention arms differed in the amount of facilitation provided to teachers and not in the activity delivered to students [14]. Thus, the two intervention arms were collapsed (INT, 7 schools) for the present analysis. Recruitment began in January 2003. Phase I of the intervention was 3 months in duration (April – June 2003) and this was followed by a 2-month summer holiday. Phase II of the intervention was 8 months in duration (September 2003 – May 2004). Thus, this was a 16-month study period with 11 months of intervention.

Participants

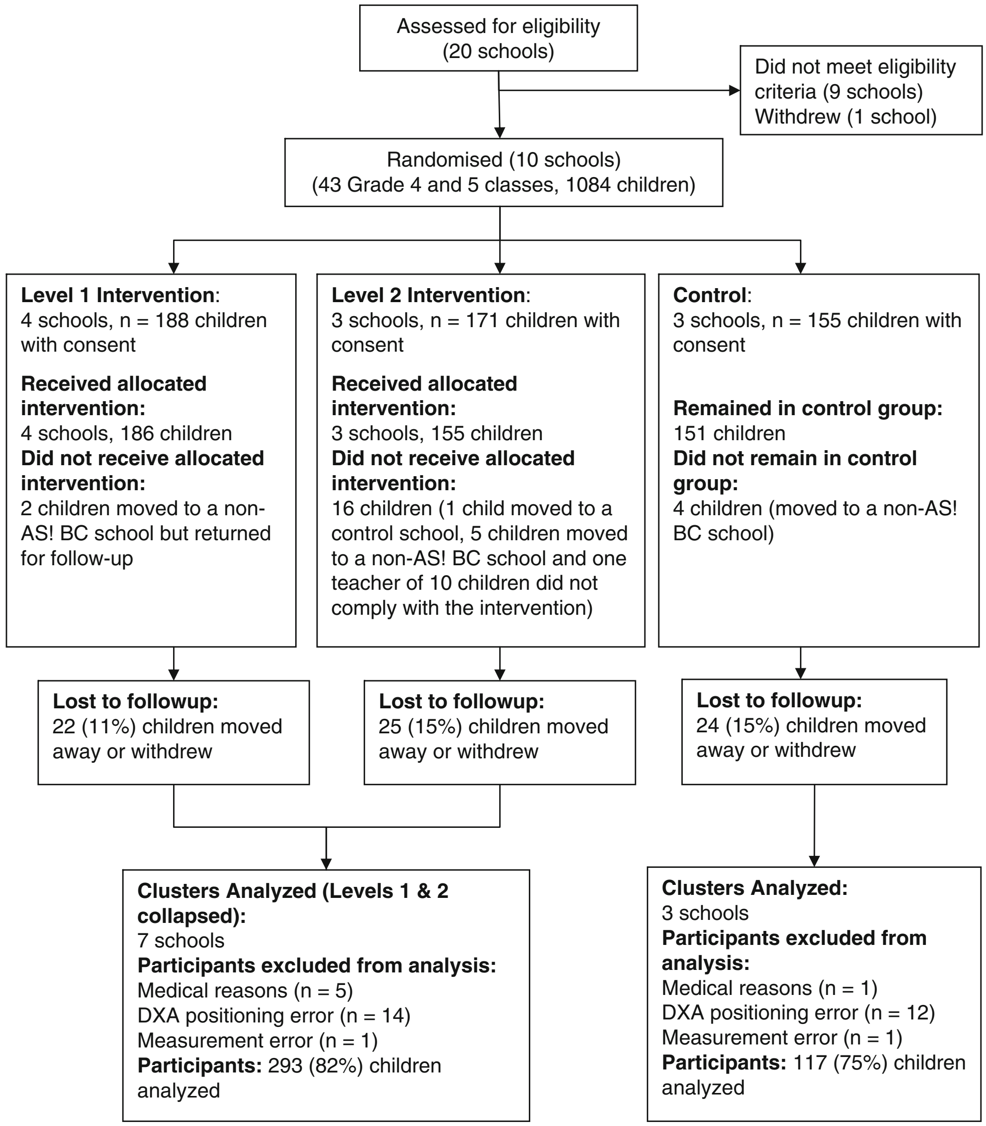
We recruited schools to participate through presentations to school administrators at meetings in the Vancouver and Richmond School Districts. Of 103 potential elementary schools, the first 20 (19%) schools that volunteered to participate were evaluated against our inclusion criterion which was based on student and parent satisfaction with the current level of physical activity provided at school [20]. One school withdrew prior to randomization; thus, 10 schools were randomly assigned to Level 1 Intervention, Level 2 Intervention or Control (Fig. 1).

All children in grades 4 and 5 attending intervention schools took part in the AS! BC intervention. Of these, 514 (47%) boys and girls (257 boys, 257 girls) aged 9–11 years received parental consent to participate in the evaluation. From a health history questionnaire completed by parents at baseline, five children (1 CON, 4 INT) were identified as having medical conditions that prevented participation in regular physical education or were reported to be taking medications known to affect bone metabolism. These children were excluded from the present analysis. As in previous studies by our group [9, 11], ethnicity classification was based on parents' or grandparents' place of birth as reported by parents in the health history questionnaire. The majority of the children were Asian (53%) with either both parents or all four grandparents born in Hong Kong or China, India, Philippines, Vietnam, Korea or Taiwan. The remainder of the sample were Caucasian (35%) with parents born in North America or Europe and children of mixed ethnicity or other ethnic origins (12%).

Action Schools! BC

The AS! BC model is detailed elsewhere [14, 21]. Briefly, AS! BC is an 'active school' model that aimed to increase physical activity opportunities for children throughout the school day. In addition to their regular program of physical education (2, 40 minute classes per week), INT teachers

Fig. 1 Flow of schools and participants through the trial



provided their students with an additional 15 minutes of physical activity, 5 days a week (Classroom Action). Teachers chose from a number of different activities including skipping, dancing, playground circuits and simple resistance exercises with exercise bands. All activities required minimal equipment and could be performed in the classroom, hallway or in the school playground. Teachers were given a Classroom Action Bin that contained equipment and resources to facilitate these activities.

Within Classroom Action, INT teachers implemented Bounce at the Bell [16]. Briefly, Bounce at the Bell required children to perform short bouts of high-impact jumping 3 times a day (at the morning, noon and end of day school bell), 4 days a week. During Phase I of the intervention students performed five two-foot landing jumps (or 10 one-foot landing jumps) at each session. During Phase II teachers were instructed to increase the number of jumps (starting from five per session) over each month of the school year until a maximum of 36 jumps per day was achieved.

The AS! BC Support Team conducted in-school training of INT teachers (N=48 across Phases I and II) at the beginning of Phases I and II. To monitor compliance and program delivery, INT teachers completed weekly activity logs. Teachers recorded the type, frequency and duration of each activity undertaken with their class each day [14]. Intervention teachers also recorded the number of sessions of Bounce at the Bell and the number of jumps per session that their students performed each day. We were unable to assess individual student compliance with Bounce at the Bell. However, INT teachers delivered Bounce at the Bell and other Classroom Action activities to all students in their classroom, regardless of whether students had volunteered to be evaluated. We determined student attendance from school records. Children at CON schools participated in their regular program of physical education, which typically involved two 40-minute classes per week. Teachers at CON schools completed a modified version of the activity log.

Measurements

We collected anthropometry, questionnaire and bone data at baseline (February - March 2003) and follow-up (May - June 2004) at the University of British Columbia Bone Health Research Laboratory.

Descriptive outcomes

We measured standing and sitting height to the nearest 0.1 cm, and body weight to the nearest 0.1 kg as previously reported [15]. For each variable we report the mean of two measures. We obtained measures of total body bone mineral free lean mass (kg) and fat mass (kg) from total body DXA scans. We used mean standing height, sitting height and body weight and chronological age at follow-up to estimate years from peak height velocity (maturity offset) according to the sex-specific equations developed by Mirwald and colleagues [22]. We also assessed maturity status at baseline and follow-up using self-rated Tanner staging [15, 23] and determined girls' menarcheal status by self-report questionnaire.

To estimate lower limb power, we measured maximal height (cm) for vertical jump and maximal distance (cm) for standing long jump as previously reported [15]. We used a modified version of the Physical Activity Questionnaire for Children (PAQ-C) to assess leisure-time physical activity [24, 25]. We calculated a general physical activity score (*PA Score*) as an average of 9 PAQ-C items in a continuous range between 1 (low activity) and 5 (high activity). We modified Item 1 to provide an estimate of time (hrs/wk) spent in common sports and activities designated as loaded (impact > walking, *load time*) [11, 26]. We used a validated food frequency questionnaire (FFQ) [27] to assess dietary calcium intake (mg/day). We administered the PAQ-C and FFQ at baseline and follow-up plus three additional times during the study period (June 2003, September 2003 and January 2004). Similar to our previous report [15] we report the average across the five reports for PA Score, load time and dietary calcium.

Primary and secondary outcomes

Bone mineral content

We used a Hologic QDR 4500 W bone densitometer (DXA, Hologic Inc., Waltham, MA, USA) to assess bone mineral content (BMC, g) of the total body, total proximal femur and femoral neck sub-region and lumbar spine. Three trained technicians acquired all scans in array mode and one of these technicians analyzed all scans. Scan acquisition and analysis were performed according to standardized procedures [28] and quality assurance (QA) scans were performed daily at baseline and follow-up. Coefficients of variation for repeated BMC measurements for the TB, FN and LS in our laboratory ranged from 0.6% to 2.2% in 15 healthy adult volunteers. Due to a technical error in scan acquisition, baseline lumbar spine data were not available for one girl (CON) and baseline proximal femur data were not available for one boy (INT) at baseline.

Femoral neck bone structure and strength

To address our primary objective, we applied the HSA program (Version 3.0) [29] to proximal femur DXA scans to estimate the *primary outcome*, section modulus (Z, cm^3) at the femoral neck across its narrowest point (narrow-neck). This region is located proximal to the femoral neck sub-region measured with DXA. Briefly, the HSA program generates a projection of the bone cross-section (bone mass profile) from a line of pixel values traversing the bone width. At the narrow neck region, bone geometric properties are averaged over five contiguous bone mass profiles, spaced 1 mm apart. Thus, the total cross-section is approximately 5 mm thick [30]. Section modulus, a determinant of bone bending strength, is calculated as $Z = CSMI/d_{max}$ where the cross-sectional moment of inertia (CSMI) equals the integral of the bone mass profile weighted by the square of the distance from the centre of mass and d_{max} equals the maximum distance from the centre of mass to the outer cortical margin. The integral of the bone mass profile and the (blur corrected) width of the profile provide the *secondary HSA outcomes* of bone cross-sectional area (CSA, cm^2) and subperiosteal (SPW, cm), respectively. Bone CSA, an indicator of axial stress, is analogous to conventional BMC in that it measures the amount of bone within the cross-section. Although estimates of average cortical thickness and endocortical width can also be obtained with HSA, these outcomes rely on assumptions regarding bone shape and mass distribution [30]. Thus, we chose to focus on Z, CSA and SPW only. One investigator (HMac) analyzed all scans under the supervision of Dr. Tom Beck and Lisa Semanick at Johns Hopkins University. To assess intraoperator precision for scan analysis, the same individual (HMac) analyzed 20 randomly selected scans two times. Coefficients of variation for analysis ranged from less than 0.1% to 0.6%. We checked the proximal femur scans closely for positioning errors (i.e., insufficient length of the femoral shaft, lack of internal rotation). As a result of such errors, we excluded scans of 14 INT (7 boys, 7 girls) and 12 CON (3 boys, 9 girls) participants from the present analysis.

Statistical analysis

We performed all analyses using STATA, Version 9.2 (StataCorp, College Station, TX). We determined sample size for the present study according to results from our pilot study that demonstrated a 4% greater improvement in narrow neck Z for intervention girls compared with control girls following a 7-month jumping intervention [12]. Based on a 2:1 randomization (Level 1 and 2 intervention schools collapsed), 80% power, a Type I error rate of 5% (two-sided) and a standard deviation of 5%, a total of 60 children (30 per group) were required. To allow for within-sex and between-maturity group comparisons and a 10% attrition rate we required 264 children (across the 10 schools). However, we invited all children in grades 4 and 5 in each of the ten schools to participate and the consent rate (47%) was greater than expected. Thus, we randomized a larger number of children (n=514) to control and intervention groups. This calculation does not account for the clustered study design; however, we did account for clustering within our statistical analysis.

Due to the relatively small number of schools (or clusters, n=10) and the large range of participants in each school (range: 6–40) we took the following steps for the present analysis using an intent-to-treat approach. First, we fit multivariable linear regression models with change in each bone outcome as the dependent variable. We created separate models for boys and girls due to the known difference in the tempo and timing of growth, maturation and bone mineral accrual between sexes [23, 31]. We chose covariates based on known biological and biomechanical relationships with the primary and secondary bone outcomes and relationships established in univariate analyses (data not shown). For boys, we included the following covariates in each model: baseline weight (to adjust for the baseline imbalance in body weight between groups), height change (to adjust for differences in linear growth) and TB lean mass change (to adjust for change in estimated muscle force). Covariates were similar for girls with one exception; we included maturity offset at follow-up as it was significantly associated with the dependent variables in univariate analyses. We used residual plots to check the assumptions of normality, linearity and homoscedascity.

Second, to account for the clustered design, we multiplied the standard error of the estimated intervention effect (adjusted difference in change between groups) by the square root of the design effect (D) (or variance inflation factor) [32, 33]. We calculated the design effect as $D=1+(m-1)*ICC$ where m = median number of boys or girls per cluster (m=20 in the present study) and ICC = intracluster correlation coefficient. There are no published reports of the ICC for HSA outcomes in school-based intervention trials. Therefore, we estimated the ICC for DXA and HSA outcomes at baseline using the standard one-way analysis of variance (ANOVA) method [34] as implemented in STATA (*oneway*). The ICC at baseline ranged from 0 to 0.05, and we used 0.05 as a conservative estimate for the present analysis. As we were unable to fit mixed linear models in this analysis, we could not determine the ICC for change in primary and secondary bone outcomes.

We also conducted a per-protocol analysis to determine the efficacy of the AS! BC intervention and the effect of teacher compliance on child-level change in primary and secondary bone outcomes. This analysis included only those children whose teacher provided at least 80% of the required Bounce at the Bell sessions during Phase II. This criterion also excluded those children who did not receive any intervention during Phase II (i.e., those children who moved away but returned for follow-up measurement).

Results

Participants and compliance

We provide the flow of schools and participants through the trial in Fig. 1. With exclusions from the HSA analysis accounted for, the present analysis includes 410 children (293 INT, 117 CON).

As Bounce at the Bell was only progressive during Phase II of the intervention, we consider teacher compliance during this period only. Teachers at INT schools delivered approximately 60 minutes more physical activity per week than teachers at CON schools (+58.9 min/wk; 95% CI, 25.4, 92.4) [14]. Median compliance with Bounce at the Bell was 74% (IQR: 50 – 89%) across teachers at INT schools. Fifteen teachers (44%) reported completing at least 80% of the required Bounce at the Bell sessions. Student attendance averaged 96% across all schools over the course of the study.

Descriptives

Baseline and change in descriptive characteristics of boys and girls are presented (Table 1). At baseline, CON boys tended to be heavier (+2.7 kg) and have a greater fat mass (+1.8 kg) than INT boys. Control and INT boys had similar changes in body size and body composition; however, INT boys tended to have a greater improvement in long jump (7.9% vs. 5.2%) and vertical jump (16.6% vs. 9.9%) performance. The majority of CON and INT boys were prepubertal (71% and 61%, respectively) at baseline and average maturity offset values at follow-up indicated that boys were approximately 2 years away from peak height velocity.

Table 1 Baseline and change (where appropriate) in descriptive outcomes for control and Intervention boys and girls

	BOYS				*GIRLS*			
	Control (n=62)		Intervention (n=151)		Control (n=55)		Intervention (n=142)	
	Baseline	Change (95% CI)	Baseline	Change (95% CI)	Baseline	Change (95% CI)	Baseline	Change (95% CI)
Age at baseline (yrs)	10.3 (0.7)	–	10.2 (0.5)	–	10.2 (0.5)	–	10.2 (0.6)	–
Age at follow-up (yrs)	11.4 (0.6)	–	11.4 (0.6)	–	11.4 (0.5)	–	11.4 (0.6)	–
No. Asian/Caucasian/ other	32/19/11	–	85/52/14	–	30/19/6	–	78/45/19	–
Maturity offset at follow-up	-1.9 (1.2)	–	-2.2 (1.5)	–	-0.54 (0.64)	–	-0.50 (0.68)	–
Height (cm)	141.7 (6.9)	6.7 (6.3, 7.1)	141.5 (7.4)	6.9 (6.5, 7.2)	139.7 (6.7)	8.2 (7.7, 8.7)	141.0 (7.5)	7.5 (7.2, 7.8)
Sitting height (cm)	75.0 (3.5)	2.9 (2.5, 3.3)	74.2 (3.6)	2.9 (2.6, 3.2)	73.5 (3.4)	4.2 (3.8, 4.5)	74.4 (3.8)	3.5 (3.3, 3.8)
Weight (kg)	40.7 (10.2)	6.3 (5.5, 7.1)	37.4 (9.7)	5.6 (5.2, 6.0)	33.8 (6.5)	6.4 (5.6, 7.1)	36.1 (8.4)	6.0 (5.6, 6.5)
TB lean mass (kg)	26.8 (4.6)	4.3 (3.9, 4.8)	25.8 (3.8)	4.1 (3.8, 4.4)	23.2 (3.9)	4.8 (4.3, 5.2)	24.2 (4.1)	4.3 (4.0, 4.6)
TB fat mass (kg)	11.8 (6.2)	1.6 (1.1, 2.2)	9.6 (6.0)	1.1 (0.7, 1.4)	8.8 (3.8)	1.1 (0.7, 1.6)	10.0 (4.9)	1.1 (0.8, 1.4)
Long jump (cm)	132.6 (19.4)	6.4 (2.6, 10.2)	133.5 (17.2)	10.2 (7.8, 12.6)	121.1 (15.1)	3.7 (0.4, 7.0)	121.0 (14.0)	9.9 (7.3, 12.4)
Vertical jump (cm)	28.2 (5.2)	2.4 (1.2, 3.7)	27.8 (5.7)	4.2 (3.3, 5.2)	25.3 (5.3)	3.3 (2.0, 4.6)	25.2 (4.6)	3.4 (2.5, 4.2)
Average PA score (/5)*	2.7 (0.4)	–	2.8 (0.4)	–	2.6 (0.3)	–	2.5 (0.5)	–
Average load time (hrs/week)*	6.6 (3.9)	–	6.9 (4.2)	–	4.1 (3.2)	–	4.2 (3.2)	–
Average dietary calcium (mg/day)*	930 (460)	–	937 (432)	–	797 (363)	–	894 (467)	–

SD = standard deviation; CI = confidence interval; PA = physical activity. Means, SD, CI were determined without accounting for clustering
* Physical activity and dietary calcium variables are the average of 5 reports
Values are mean (SD) for baseline and mean (95% CI) for change (unless otherwise indicated)

For girls at baseline, body size (height, sitting height, weight) and lean and fat mass tended to be slightly greater in the INT group than CON group. Over 16-months, CON girls tended to have a greater increase in standing height (5.9% vs. 5.4%), sitting height (5.7% vs. 4.8%), weight (19.0% vs. 16.9%) and lean mass (20.7% vs. 17.8%) than INT girls, whereas INT girls tended to have a greater improvement in long jump performance than CON girls (8.6% vs. 3.4%). At baseline, the majority of CON and INT girls were early pubertal (56% and 61%, respectively) and maturity offset values at follow-up indicated that, on average, CON and INT girls were less than one year away from reaching peak height velocity. The proportion of girls who were post-menarcheal at follow-up was slightly higher in the INT group (20%) than the CON group (15%) as was the proportion who were estimated to be post-peak height velocity at follow-up (23% and 20% for INT and CON, respectively).

Primary objective – intent-to-treat

Baseline and follow-up values for FN bone mass, size and strength for CON and INT boys and girls and adjusted mean difference in change in bone outcomes between groups are presented in Table 2 (boys) and Table 3 (girls).

For boys, there was no significant difference in change between groups for estimated FN bone strength (Z) or any other bone outcomes at the FN. For girls, change in estimated FN bone strength tended to be greater for INT (+0.107 mm^3; 95% CI: 0.096, 0.118) compared with CON (+0.091 mm^3; 95% CI: 0.074, 0.108) (Fig. 2). The slightly greater gain (3.5%) in bone strength for INT girls was explained by a trend for an approximately 2% greater gain in CSA (+0.23 cm^2; 95% CI: 0.21, 0.25) compared with CON girls (+0.20 cm^2; 95% CI: 0.17, 0.23). Similarly, change in FN BMC was approximately 2% greater for INT girls (+0.37 g; 95% CI: 0.33, 0.40) than CON girls (+0.31 g; 95% CI: 0.26, 0.37), although this difference was not statistically significant. There was no significant difference in change between CON and INT girls for femoral neck SPW.

Secondary objective – intent-to-treat

Change in proximal femur BMC and BA was similar between CON and INT boys. At the lumbar spine, INT boys tended to have a greater gain (2.7%) in BMC (+4.3 g; 95% CI: 3.9, 4.7) compared with CON boys (+3.5 g; 95% CI: 2.9, 4.2). Boys in the INT group also had a significantly greater increase (1.7%) in TB BMC (+184.1 g; 95% CI:

Table 2 Baseline, follow-up and adjusted difference in change between intervention (INT) and control (CON) boys for primary and secondary bone outcomes

Outcome	Group	Baseline mean (SD)	Follow-up mean (SD)	*Intent-to-treat* (n=62 CON, 151 INT)		*Per-protocol* (n=58 CON, 66 INT)	
				Difference in change (95% CI)[a]	*P*	Difference in change (95% CI)[a]	*p*
HSA							
NN Z (cm^3)	CON	0.64 (0.13)	0.74 (0.15)	0.005 (-0.015, 0.025)	0.62	0.006 (-0.019, 0.031)	0.61
	INT	0.63 (0.13)	0.74 (0.16)				
NN CSA (cm^2)	CON	1.70 (0.24)	1.88 (0.28)	0.019 (-0.014, 0.052)	0.26	0.019 (-0.027, 0.065)	0.41
	INT	1.69 (0.26)	1.88 (0.29)				
NN SPW (cm)	CON	2.68 (0.20)	2.82 (0.20)	-0.010 (-0.043, 0.023)	0.55	-0.008 (-0.044, 0.028)	0.66
	INT	2.64 (0.21)	2.78 (0.22)				
DXA							
FN BMC (g)	CON	2.83 (0.41)	3.10 (0.48)	0.010 (-0.061, 0.081)	0.78	0.018 (-0.064, 0.100)	0.67
	INT	2.79 (0.43)	3.08 (0.48)				
PF BMC (g)	CON	16.0 (3.0)	19.6 (3.9)	0.05 (-0.43, 0.53)	0.84	0.18 (-0.56, 0.76)	0.56
	INT	16.1 (3.4)	19.6 (4.5)				
LS BMC (g)	CON	23.6 (4.3)	27.2 (5.1)	0.77 (-0.001, 1.55)	0.05	0.96 (-0.003, 1.93)	0.05
	INT	23.1 (4.9)	27.3 (6.4)				
TB BMC (g)	CON	1098.1 (178.1)	1259.9 (206.6)	24.8 (5.6, 43.8)	0.03	30.8 (7.2, 54.4)	0.01
	INT	1078.6 (193.1)	1260.3 (237.6)				

SD = standard deviation; CI = confidence interval; HSA = hip structure analysis; NN = narrow neck; Z = section modulus; CSA = cross-sectional area; SPW = subperiosteal width; DXA = dual energy X-ray absorptiometry; FN = femoral neck; BMC = bone mineral content; PF = proximal femur; LS = lumbar spine; TB = total body

[a] Adjusted for baseline weight, change in height and change in total body lean mass

Results are presented for the intent-to-treat and per-protocol analyses

Table 3 Baseline, follow-up and adjusted difference in change between intervention (INT) and control (CON) girls for primary and secondary bone outcomes

Outcome	Group	Baseline mean (SD)	Follow-up mean (SD)	*Intent-to-treat* (n=55 CON, 142 INT)		*Per-protocol* (n=55 CON, 43 INT)	
				Difference in change (95% CI)[a]	*p*	Difference in change (95% CI)[a]	*p*
HSA							
NN Z (cm^3)	CON	0.54 (0.11)	0.64 (0.14)	0.017 (-0.003, 0.037)	0.10	0.029 (0.003, 0.057)	0.05
	INT	0.56 (0.12)	0.66 (0.15)				
NN CSA (cm^2)	CON	1.50 (0.23)	1.71 (0.29)	0.030 (-0.008, 0.068)	0.13	0.057 (0.002, 0.112)	0.04
	INT	1.55 (0.26)	1.78 (0.32)				
NN SPW (cm)	CON	2.57 (0.16)	2.68 (0.17)	0.018 (-0.015, 0.051)	0.30	0.013 (-0.029, 0.055)	0.54
	INT	2.56 (0.19)	2.67 (0.18)				
DXA							
FN BMC (g)	CON	2.47 (0.38)	2.80 (0.50)	0.050 (-0.002, 0.13)	0.16	0.09 (0.005, 0.172)	0.04
	INT	2.53 (0.42)	2.89 (0.52)				
PF BMC (g)	CON	14.4 (2.9)	18.4 (4.0)	-0.023 (0.525, 0.479)	0.93	-0.008 (-0.636, 0.634)	0.98
	INT	15.2 (3.5)	19.0 (4.5)				
LS BMC (g)	CON	23.2 (4.9)	29.6 (7.0)	0.58 (-0.53, 1.69)	0.30	0.92 (-0.55, 2.39)	0.22
	INT	24.0 (6.1)	30.8 (8.4)				
TB BMC (g)	CON	1003.5 (159.1)	1216.3 (213.8)	6.9 (-15.8, 29.7)	0.60	20.1 (-9.6, 49.8)	0.18
	INT	1040.3 (213.2)	1253.2 (263.6)				

SD = standard deviation; CI = confidence interval; NN = narrow neck; HSA = hip structure analysis; Z = section modulus; CSA = cross-sectional area; SPW = subperiosteal width; DXA = dual energy X-ray absorptiometry; FN = femoral neck; BMC = bone mineral content; PF = proximal femur; LS = lumbar spine; TB = total body

[a] Adjusted for baseline weight, change in height, change in total body lean mass and maturity offset at follow-up

Results are presented for the intent-to-treat and per-protocol analyses

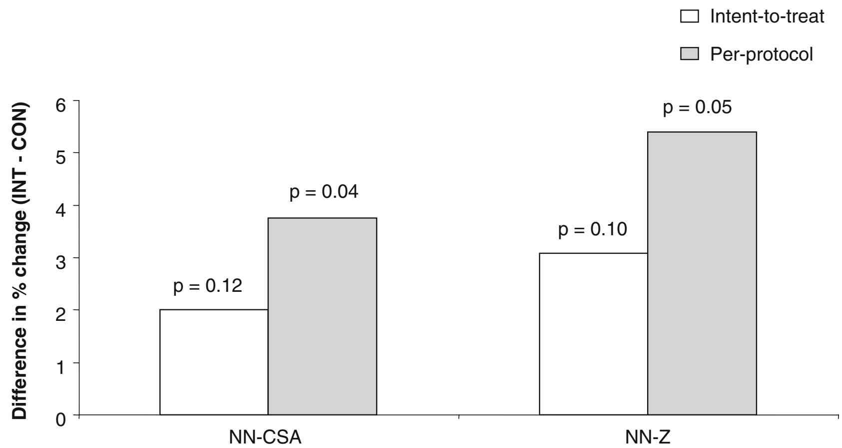


Fig. 2 Difference in percent (%) change between Intervention (INT) and Control (CON) girls for femoral neck cross-sectional area (CSA) and section modulus (Z). Results are presented for both the intent-to-treat (white) and per-protocol (grey) analyses

174.0, 194.3) compared with CON boys (+159.5 g; 95% CI: 143.3, 175.3). For girls, change in PF, LS and TB BMC were not significantly different between CON and INT groups.

Primary objective – per protocol

For boys, the per-protocol analysis included 58 CON boys and 66 INT boys (Table 2). Results from the per-protocol analysis were similar to those obtained from the intent-to-treat analysis — change in femoral neck Z, CSA, SPW and BMC was similar between CON and INT boys.

For girls, the per-protocol analysis included 55 CON and 43 INT. Change in estimated FN bone strength tended ($p=0.05$) to be greater for INT (+0.118 cm^3; 95% CI: 0.097, 0.139) than CON girls (+0.089 cm^3; 95% CI: 0.070, 0.108) (Fig. 2). This was equivalent to a 5.4% greater gain in FN bone strength in INT girls than CON girls. Similarly, change in neck CSA was 3.7% greater for INT (+0.256 cm^2; 95% CI: 0.215, 0.297) than CON girls (+0.199 cm^2; 95% CI: 0.163, 0.235) and change in FN BMC was 3.7% greater for INT (+0.40 g; 95% CI: 0.34, 0.46) than CON girls (+0.31 g; 95% CI: 0.26, 0.36). Change in SPW was similar between CON and INT girls.

Secondary objective – per protocol

For boys, when non-compliant INT classes were excluded, change in LS and TB BMC was slightly greater between INT and CON boys (4.1% and 2.7%, respectively) than that observed for the intent-to-treat analysis (Table 2). Change in PF BMC was not significantly different between CON and INT boys in the per-protocol analysis.

For girls in the per-protocol analysis, change in LS BMC tended to be greater (4.1%) for INT girls (+7.3 g; 95% CI: 6.2, 8.4) than CON girls (+6.4 g; 95% CI: 5.4, 7.4) (Table 3). Similarly, change in TB BMC tended to be greater (1.6%) for INT girls (+228.9 g; 95% CI: 207.2, 250.6) than CON girls (+208.8 g; 95% CI: 189.1, 228.5). There was no significant difference between CON and INT girls for change in PF BMC.

Discussion

The Action Schools! BC model includes a novel bone-loading program – Bounce at the Bell – that requires only a few minutes of classroom time each day. As per our previous trials [9, 11], intervention boys' bone mineral accrual was enhanced at both the TB and LS whereas FN bone mass and strength were augmented only in girls whose teachers were compliant with the intervention. Of note, the magnitude of the response we observed following this simple intervention was similar to previous studies that involved more intensive bone-loading programs [2, 4–6, 9, 11].

Schools-based effectiveness trials

Children spend more than 50% of their waking hours in school and schools support a diverse population of children from across ethnicities and socioeconomic groups [35]. Thus, schools may represent the most effective pathway for interventions to deliver health benefits to children on a national or global scale. To determine the effectiveness of a school-based intervention, randomization at the level of the school rather than the individual is necessary to avoid contamination within schools or classrooms. Therefore, such trials must account for a clustered hierarchy (schools, classrooms and children). In the present study change in the individual child is the unit of analysis; therefore, both within- and between-school variance must be accounted for within the statistical analysis so as not to inflate the Type I error [34].

In our previous trial we demonstrated as much variability within as between schools for FN and LS BMC in girls

[13, 36] - suggesting a negligible school effect (ICC= 0.002). Despite this, and as there are no published estimates of the ICC for HSA outcomes, we accounted for the clustered design within our analysis by applying a variance inflation factor (D=1.4) to our linear regression model. This conservative approach provides important context for the interpretation of our findings. Despite a magnitude of change in the intervention children at par with other studies, the effect of the intervention was not significant in the intent-to-treat analysis. If one disregards school clusters, the difference in change between groups for boys' LS and TB BMC and girls' FN BMC, CSA and Z is significant ($p < 0.01$ for boys and $p < 0.05$ for girls, data not shown) although the magnitude of the difference is similar to results for the clustered intent-to-treat analysis. In order for future studies to have adequate power to show an intervention effect in an intent-to-treat analysis, an accurate a priori ICC value (for primary outcomes) is required to determine the appropriate sample size. As discussed, we estimated the ICC using baseline data. With this estimate, the design effect we calculated suggests that a cluster randomized trial investigating change in DXA and HSA outcomes would require 1.4 times as many participants as a study where children were randomized individually. Although we had the appropriate number of participants, the small number of schools and the wide range of participants in each of the ten schools reduced our power to detect an intervention effect in the intent-to-treat analysis.

Skeletal adaptations to increased physical activity in boys

As in previous trials we observed a site- and sex-specific response to the intervention. For boys, the mean 1.7% greater intervention response for total body BMC was similar to the significant change we reported for same-age, prepubertal boys following a more intense 7-month intervention (2% change) [9]. Also, the 3% change we observed in lumbar spine BMC approximated the size of change found after a 20-month intervention in early pubertal boys (3.7%) [10]. However, as in other published studies of prepubertal boys that assessed the femoral neck [2, 9], we did not observe a bone mass or strength accrual advantage in the exercise group. This may be due to at least two possibilities. First, the intervention period (11 months) in the current study may have been too short. Second, the boys may not have been mature enough for AS! BC to have a positive effect at the femoral neck. Findings from the UBC Healthy Bones Study [10–12] suggested that, in girls and boys, early puberty may represent a maturational time point when exercise benefits at the femoral neck are enhanced. Some might argue that our intervention was not intense enough, diverse enough or progressive enough to augment femoral neck strength in these boys who were already performing 6 hours of physical activity per week at baseline, on average. We note, however, that the maximum ground reaction forces (GRF) from the two-foot counter-movement jumps used in Bounce at the Bell (5×body weight) [37]) were substantially greater than GRFs associated with running and skipping (1–3×BW) [38, 39]. In addition, strain gauge data from an adult study suggest that multi-directional activities similar to the Bounce at the Bell jumps are associated with a more varied strain distribution than pattern activities such as walking and running [40].

It is becoming increasingly clear that the pattern of adaptation of the skeleton to physical activity is complex and may vary by maturity and sex at different skeletal sites. The results of the present study together with our recent findings of greater gain in pQCT-derived bone strength at the distal tibia and tibial midshaft in intervention boys [15] support this notion. Adaptation may be further complicated due to the known differences in the timing and velocity of growth between the axial and appendicular skeleton in boys (and girls) [41, 42]. Growth of the appendicular skeleton accelerates in early puberty while "take-off" for accelerated growth of the axial skeleton occurs later, on average, is of lesser magnitude and traverses a longer period of growth. It is not entirely clear how the pattern of differential growth is influenced by physical activity interventions although studies that address this would be of some interest.

Skeletal adaptations to increased physical activity in girls

The 3.5% difference for change in our primary outcome (femoral neck bending strength) between intervention and control girls approached values (4%) reported by Petit et al. [12] following a more intense intervention over a shorter time frame (7 months). In the present analysis we were unable to determine whether the bone response to the intervention differed between maturity groups. However, given that the majority of the girls in our cohort were early pubertal (~60%) at baseline and were, on average, one year away from reaching peak growth in height at follow-up, our results support the findings of Petit et al. [12] in early pubertal girls.

Our per-protocol analysis demonstrated a change almost twice as large as that of the intent-to-treat analysis (5.4%). Similarly, the bone mass accrual response was almost two times greater at the femoral neck and lumbar spine, and total body BMC change more than doubled in the per-protocol analysis. Clearly, teacher compliance is an important determinant of success in school-based physical activity interventions. Although teachers delivered 80% of the required amount of classroom physical activity, compliance with Bounce at the Bell was slightly lower (74% (IQR: 50 – 89%)). In a separate study, we conducted a process evaluation to determine the barriers to undertaking a school-based model of physical activity and the most often cited limitations were competing curricular demands, lack of preparation time and needing a supportive school environment [14]. It is important to note that although we were unable to assess each child's individual participation in the study – teachers' reported providing physical activity opportunities to all students.

We also investigated the change in bone geometry underpinning the change in bone strength. Section modulus, an indicator of bone bending strength, is correlated with the amount of bone material in the cross-section (represented by both CSA and BMC) as well as the distribution of the bone material from the centre of mass (represented by SPW) [43]. Change in femoral neck CSA tended to be greater in intervention girls (~2% in the intent-to-treat analysis and 3.7% in the per-protocol analysis). For SPW, the difference in change between groups was smaller (~1% in favour of intervention girls). However, since bone bending strength varies as the square of the distance of bone material from the centre of mass [43] even the slightly greater increase in SPW in intervention girls, in combination with the change in CSA, may have contributed to the trend for greater gains in Z. Similar findings were reported by Forwood and colleagues [44] using 7 years of longitudinal data from the Saskatchewan Paediatric Bone and Mineral Accrual Study. Among girls, physical activity was a significant independent predictor of change in both Z and CSA, but not SPW. The authors suggested that for a change in Z of about 4%, only a 0.5% increase in SPW would be required. Detection of such a small increase in SPW is below the detection limit of current DXA technology.

Despite enhanced bone mineral accrual at the femoral neck, our intervention did not benefit tibial bone strength in girls [15]. This apparent site-specificity is similar to the results of Heinonen et al. [4] who reported a significant intervention effect at the femoral neck and lumbar spine but no significant intervention effect at the tibial midshaft in premenarcheal girls following 9-months of a high-impact jumping program. As discussed for boys, the relationship between maturational stage and sex- and site-specific skeletal responses to physical activity intervention requires further investigation.

Limitations of the study

We acknowledge several limitations. First, HSA is a valuable tool for estimating bone structural parameters, but there are limitations to assessing a three-dimensional structure using two-dimensional imaging techniques. Second, section modulus is estimated for bending in the scan plane only. This limitation is important as errors in positioning (i.e., femoral anteversion) may alter the location and orientation of the image plane at the narrow neck region and result in uncertainty in structural outcomes [30, 43]. This is of particular concern when a study relies on serial measurements. In the present study, we minimized this source of error by having trained operators acquire all scans and by standardizing positioning techniques between operators. In addition, scans were checked for positioning errors prior to HSA analysis and those with inadequate rotation were excluded. We note that as section modulus is estimated for bending in the scan plane only, structural changes that influence the distribution of bone mass in other planes (i.e., orthogonal to the scan plane) cannot be assessed [43].

A final limitation of HSA technology for pediatric studies is the assumption that bone mass in the region of interest is fully mineralized. Since average tissue mineralization is clearly lower in children than adults, geometric properties are underestimated by about 20% [10]. That said, we observed no difference in bone geometry at baseline between children in intervention and control groups and thus, the underestimation of geometric properties would likely be consistent across groups.

Implications of the findings

Our intervention provided generalist teachers the opportunity to engage children in classroom based physical activity that required only a few minutes each day. The AS! BC intervention required minimal training of classroom teachers, no equipment, no additional gymnasium time and no modifications to existing PE curricula. Further, despite the low compliance in some schools, AS! BC was well-accepted by teachers and students [14]. The demanding, overcrowded curriculum means that teachers generally eschew time-intensive physical activity programs within schools. Despite the very modest time commitment of AS! BC, we observed gains in bone mass and strength accrual at the femoral neck in girls at par with previous studies that demanded more time either within physical education [5, 6, 11] or outside of school [4].

Summary

In summary, a simple model of physical activity in elementary schools – Action Schools! BC - enhanced bone mass at the lumbar spine and total body in boys and both bone mass and strength at the femoral neck in girls whose teachers were at least 80% compliant with the intervention. The magnitude of the bone response equalled or exceeded the change reported for our previous 7- and 20-month interventions. Results from this study highlight the importance of teacher compliance with intervention delivery. Large, innovative trials are needed to account for the clustered nature of school-based designs a priori, and to determine how best to enhance teacher compliance with school-based intervention models.

Acknowledgements We thank the principals, teachers, parents and children from the Vancouver and Richmond School Districts for their support and participation in this research. We thank Leslie Bryant MacLean for her technical assistance with the DXA scanning and analysis, Lisa Semanick for training on the HSA program and Dr. Penny Brasher for statistical guidance. We are grateful to the BC Ministry of Health, 2010 Legacies Now, BC Ministry of Education and the Canadian Institutes of Health Research for funding support. Dr. McKay is a Michael Smith Foundation for Health Research (MSFHR) Senior Scholar.

Conflicts of interest None.

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