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Efficacy of the Survivor Health and Resilience Education (SHARE) Program to Improve Bone Health Behaviors among Adolescent Survivors of Childhood Cancer

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Abstract

Purpose—To test the efficacy of the Survivor Health and Resilience Education (SHARE) Program intervention—a manualized, behavioral intervention focusing on bone health behaviors among adolescent survivors of childhood cancer.

Methods—Participants were 75 teens age 11 – 21 years, 1 or more years post-treatment, currently cancer-free. Teens were randomized to a group-based intervention focusing on bone health, or a wait-list control. Bone health behaviors were assessed at baseline and 1-month post-intervention.

Results—Controlling for baseline outcome measures and theoretical predictors, milk consumption frequency ($p = 0.03$), past month calcium supplementation ($p < 0.001$), days in the past month with calcium supplementation ($p < 0.001$), and dietary calcium intake ($p = 0.04$) were significantly greater at 1-month follow-up among intervention participants compared with control participants.

Conclusions—The intervention had a significant short-term impact on self-reported bone health behaviors among adolescent survivors of childhood cancer. Research examining long-term intervention effectiveness is warranted.

Keywords

cancer; pediatrics; survivors; bone health; behavioral intervention

Introduction

As a result of significant advances in the detection and treatment of pediatric cancer, the 5-year survival rate of pediatric cancer now exceeds 80% [1]. This represents an increase from the early 1970s when only 56% of children and adolescents were predicted to live 5 years or more after diagnosis [2]. While clinical advances have improved childhood cancer survival rates, many of these treatments lead to cancer late-effects among survivors, including risks of secondary cancers, cardiovascular disease, and musculoskeletal problems [3,4].

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Conflict of Interest Statement:

The authors have no conflicts of interest to disclose.

Survivors of childhood cancer have an increased risk for skeletal morbidity as a result of bone mineral density deficits that are caused by cancer therapies [5]. Research has consistently shown that survivors often have suboptimal bone density, and clinical signs of osteopenia and other bone health morbidities are common [5]. Bone mineral deficits are influenced by a number of factors, including cancer type and treatment received, and may predispose survivors of childhood cancer to early-onset osteoporosis and more severe complications from osteoporosis [5]. Bone mineral deficits have also been linked to stunted growth and other bone-related morbidities among survivors, such as an increased risk for fractures [6-8].

Radiation therapy is one of the leading causes of bone mineral deficits among young survivors of pediatric cancer due to radiation-related endocrine system disruption [5,9]. Additionally, chemotherapeutic agents, such as corticosteroids (e.g., prednisone) and methotrexate, have been associated with reduced bone mineral density through impairment of gonadal function and inhibition of new bone growth [5,10]. Bone mineral density deficits that result from cancer therapies may be further exacerbated by the fact that few survivors of childhood cancer meet recommended criteria for daily calcium consumption and other good bone health behaviors [5,11,12].

Increasing calcium and vitamin D intake through diet and dietary supplementation are effective methods of improving bone density among children [5,13-17]. Peak bone density is typically achieved at levels of calcium intake between 1200 – 1500 mg per day in children [18]; current recommendations suggest that children age 9 – 18 consume 1300 mg of calcium daily for optimal bone health [17]. Although cancer late-effects related to bone health often are not clinically manifest until later in life [5], encouraging bone health-promoting practices among young survivors may be an effective prevention strategy [3,5,12,19]. Prior evidence supports the effectiveness of health behavior interventions targeting survivors of childhood cancer, particularly those focusing on dietary behaviors [11].

To our knowledge, however, evidence-based behavioral interventions targeting bone health behaviors among adolescent survivors of pediatric cancer are lacking [20]. In order to fill this research gap, this small-scale, randomized controlled trial sought to examine the efficacy of the Survivor Health and Resilience Education (SHARE) Program intervention for immediately improving bone health behaviors among adolescent survivors of pediatric cancer. SHARE is a manualized, health education and multiple health behavior change intervention for adolescent survivors of childhood cancer focusing in part on improving their bone health behaviors, including milk consumption, calcium supplementation, and dietary calcium intake [21,22].

Materials and Methods

Setting and Study Participants

The Survivor Health and Resilience Education (SHARE) Program was designed as a randomized controlled trial testing the efficacy of a single, half-day, group-based health education and health behavior counseling intervention for risk-reducing, lifestyle-related outcomes among adolescent survivors of childhood cancer [22]. The methods for the trial have been described in detail previously [21-23] and are summarized briefly below.

Trial eligibility criteria included adolescents age 11 – 21 years who were treated for an oncologic malignancy, were 1 or more years post-cancer treatment, and 1 or more years cancer-free. Two pediatric cancer treatment and research centers served as the recruitment sites for the trial. The two sites are in close proximity to one another (< 5 miles), provide

inpatient and outpatient services to large and diverse patient populations, and have active pediatric hematology-oncology programs that include follow-up care and late-effects programs.

Recruitment

All study recruitment procedures were approved by an institutional review board. Tumor registries from the two sites were used to identify patients who were potentially trial-eligible. Parents of potentially-eligible patients were mailed a letter from the child's treating oncologist that introduced the trial and were asked to respond to the mailing by contacting a research staff member. If parents responded and expressed interest in their child participating, eligibility screening was conducted by the trial coordinator. If eligible, active informed consent and assent were obtained. The trial coordinator subsequently initiated telephone calls to non-responding parents to confirm their receipt of the mailing, learn if they were interested in the trial, and obtain informed consent and assent. Among eligible patients, the consent rate was 49% [22]. Commonly cited reasons for declining participation included time and interest. Detailed reporting of the recruitment and enrollment process is documented previously [22].

SHARE participants completed a comprehensive baseline assessment via two successive telephone calls lasting approximately 30 – 40 minutes each. During the first call, participants completed demographic and health behavior questions and were asked to maintain a written dietary record for three days and provided with instruction on how to do so. Participants returned the completed record by postal mail and were then re-contacted via telephone for the remainder of the baseline assessment, which included a 24-hour dietary recall interview. After completing a baseline assessment, participants were randomly allocated to either the intervention or control condition. Ongoing enrollment continued until a minimum number of participants (approximately 10) were reached and could then be scheduled for intervention. The median number of days from baseline to intervention was 52. Participants completed a follow-up assessment via telephone approximately 1-month after the end of the intervention (*Median* = 41 days). Control participants completed follow-up assessments at an equivalent time point. All telephone interviews were administered by a trained research assistant who was masked to trial condition.

Measures

Demographic and Clinical Characteristics—Demographic characteristics assessed included age, gender, race (white or non-white), household composition (two-parent household or other), and school performance. Clinical characteristics assessed included cancer type (Leukemia or other type), time since cancer diagnosis (in years), and time since ending treatment (in years).

Theoretical Predictors of Bone Health Behavior—Bone health knowledge was assessed at baseline and follow-up using six multiple choice items adapted from the U.S. Department of Health and Human Services (U.S. DHHS) National Bone Health Campaign for children [24] and prior research [25,26]. Each item posed a multiple-choice question regarding nutrition, calcium intake, or physical activity; participants selected a response from four possible options. Bone health knowledge was operationalized using a continuous variable reflecting the proportion of items each participant answered correctly (range 0 – 100%). Participants' baseline levels of bone health knowledge were similar to those observed among teens in prior research [26–29]. A continuous variable reflecting change in bone health knowledge from baseline to 1-month follow-up was created for multivariate analyses.

Calcium consumption self-efficacy was assessed using an 11-item scale adapted from earlier research [30]. Response options ranged from ‘not at all confident’ (1) to ‘extremely confident’ (5). Items were summed to create an overall self-efficacy score; higher values indicated greater self-efficacy (range 0 – 55; baseline $M=38.9$, $SD=7.9$ Cronbach’s $\alpha=0.86$; 1-month follow-up $M=40.7$, $SD=7.3$ Cronbach’s $\alpha=0.90$). A continuous variable representing change in self-efficacy from baseline to 1-month was created for multivariate analyses.

Bone Health Behaviors—Milk consumption frequency was assessed using a single item adapted from the U.S. DHHS National Bone Health Campaign [24]. The item asked participants “*How often would you say you drink milk?*” The response options to the original item were adapted to a 4-point Likert-type scale that ranged from (1) ‘never’ to (4) ‘always.’ Milk consumption frequency was operationalized as a continuous variable—higher values reflected more frequent milk consumption. At baseline, self-reported milk consumption frequency was significantly associated with dietary calcium consumption assessed via 24-hour recall interview ($r=0.31$, $p=0.007$).

Dietary calcium intake was estimated based on the U.S. Department of Agriculture (USDA) 5-Step Multiple Pass 24-hour recall method, which has been demonstrated to produce valid and reliable data when administered via telephone [31,32]. This method asks participants to list everything that he or she ate/drank for a preceding 24-hour period, and subsequently asks questions about when and where foods were eaten, details about each food, and then reviews information with participants. To facilitate accurate recall, participants were provided with a reference guide/tips sheet equating food portions to commonly encountered objects (e.g., a baseball) for use during the interview. The interview was administered by a trained research assistant.

Recalled dietary data were entered into Nutritionist Pro (Axxya Systems, Stafford, TX), which is third party software that converts reported food consumption data into average daily nutritional intake information [33]. Dietary calcium intake (in milligrams [mg]) was estimated based on dietary data and operationalized as a continuous variable for analyses. To verify accurate conversion of reported food consumption into nutritional data 16 participants’ recalled food data at baseline was entered into Nutritionist Pro by two independent dietitians and results were examined for consistency. With respect to calcium consumption, mean values were virtually identical ($p=0.93$), confirming consistency.

Calcium supplementation during the previous month was assessed using a single item asking “On how many of the past 30 days did you take a calcium supplement?” The item was preceded by a definition of a calcium supplement, including common brand-name examples (e.g., Caltrate®, Viactiv®). Two variables were created to operationalize calcium supplementation: a dichotomous variable indicating whether participants reported taking any calcium supplement (yes/no), and a continuous variable totaling the number of days within the past month that respondents reported taking a calcium supplement (range 0 – 30). Again, the number of days with calcium supplementation at baseline was significantly correlated with baseline dietary calcium consumption ($r=0.25$, $p=0.03$).

Intervention Condition

SHARE was developed based on a rigorous formative research process that involved target audience members as a core component of intervention development. Details of the intervention development have been described previously [22]. Briefly, the SHARE intervention was informed by Green and Kreuter’s PRECEDE-PROCEED model [34], a multi-organization partnership, capacity-building, formative research, and a pilot study of the intervention [22]. The resulting intervention was comprised of a half-day interactive

behavioral workshop that included messages and skill-building exercises addressing relevant risk-reducing and health-promoting behaviors for adolescent survivors of childhood cancer. Intervention content and outcome assessments were further informed by health behavior theory, the Health Belief Model, the Transtheoretical Model of behavior change, and Social Cognitive Theory [35]. Key intervention objectives included increasing participants' awareness of cancer late-effects, reducing barriers and increasing perceived benefits of health-promoting behaviors, and improving self-efficacy to lead a healthy lifestyle [22].

The intervention had a strong emphasis on nutrition and bone health behaviors, including calcium consumption, with the goal of promoting good bone health habits and preventing bone-related morbidity. Intervention content that focused on promoting bone health included didactic presentations of bone health, demonstrations of healthy and unhealthy bone, and a discussion of meeting USDA-recommended daily calcium consumption level of 1300 mg per day [17,22]. Nutritional aspects of the intervention related to bone health focused on reading and understanding food labels, taste-testing calcium-rich foods, and role-playing of making calcium-rich food choices [22]. Intervention participants received workshop gift packs, which included samples of Viactiv® soft calcium supplements, sunscreen, and educational pamphlets.

Intervention sessions were facilitated by a masters-level registered dietitian who was a member of the research team. The facilitator was trained to administer the intervention by a multi-disciplinary research team, which included experts in pediatric oncology, nutrition, and behavioral sciences. A detailed intervention manual was developed to guide implementation, including text, scripts, and intervention handouts, worksheets, and activities. The intervention format allowed the facilitator to follow the structured guide while providing flexibility to accommodate specific dynamics of each group based on participants' age and interests. To ensure intervention fidelity, 30% of sessions were videotaped and reviewed by study team members.

Control Condition

The control condition was a standard care wait-list condition [22]. Control participants were offered the intervention at the conclusion of the study.

Statistical Methods

Analyses were conducted using SAS 9.2 (SAS Institute, Cary, NC). Differences between the intervention and control participants based on demographic characteristics, medical information, theoretical predictors, and baseline bone health behaviors were assessed using appropriate bivariate statistics (i.e., χ^2 tests, *t*-tests). Three linear regression models were created to examine whether differences existed between the study groups in continuous bone health behaviors at 1-month post-intervention, including milk consumption frequency, number of days taking a calcium supplement in the past 30 days, and dietary calcium intake [36]. A logistic regression model was created to examine whether there was a significant difference between study groups in the odds of reporting any calcium supplementation in the past 30 days at follow-up.

A variable indicating study group was dummy-coded (1 = intervention, 0 = control) and was the focal independent variable in the models. Baseline measures of each bone health behavior were included as control variables in the respective regression models; variables indicating change in bone health knowledge and calcium self-efficacy from baseline to 1-month post-intervention were included to account for potential theoretical explanatory factors. To identify additional candidate control variables, we examined whether demographic or clinical characteristics measured at baseline were significantly associated

with bone health behavior. No significant relationships were noted and these characteristics were not included. Dietary calcium intake variables were divided by 100 to ease interpretation of model parameter estimates.

Results

Participant Baseline Characteristics

Participant characteristics by study condition are shown in Table 1. Participants allocated to the intervention and control conditions did not significantly differ based on demographics, clinical characteristics, theoretical predictors, or bone health behaviors assessed at baseline, indicating successful randomization.

Bone Health Behaviors

Milk Consumption Frequency—Average milk consumption frequency was significantly higher among intervention participants at 1-month post-intervention ($M = 3.36$, $SD = 0.72$) compared with control participants ($M = 2.93$, $SD = 0.88$; $t_{63} = 2.16$, $p = 0.03$). After adjusting for change in self-efficacy, change in bone health knowledge, and baseline milk consumption frequency (Table 2), intervention participants reported significantly more frequent milk consumption at 1-month follow-up compared with control participants ($B = 0.50$, 95% Confidence Interval (CI) = 0.08, 0.92, $p = 0.02$). Our model explained 32% of the variance in milk consumption frequency 1-month post-intervention.

Past Month Calcium Supplementation—At 1-month follow-up, a significantly greater proportion of intervention participants (82.9%) reported taking any calcium supplements in the past 30 days compared with control participants (24.1%; χ^2 1 df = 22.2, $p < 0.001$). After adjusting for changes in self-efficacy, bone health knowledge, and baseline calcium supplementation, the odds of reporting any calcium consumption in the past 30 days was significantly higher among intervention participants at 1-month follow-up (Odds Ratio = 24.49, 95% CI = 4.91, 143.05, $p < 0.001$). Our model explained 53% of the variance in current calcium supplementation (Table 2).

Similarly, the mean number of days with calcium supplementation in the past month was significantly higher among intervention participants ($M = 14.45$, $SD = 10.97$) compared with control participants ($M = 3.03$, $SD = 7.86$, $t_{62} = 4.74$, $p < 0.001$). Regression analysis demonstrated that at 1-month follow-up intervention participants reported taking calcium supplements on significantly more days within the past month than control participants ($B = 10.25$, 95% CI = 4.94, 15.55, $p < 0.001$), after adjusting for baseline calcium supplementation and theoretical predictors. Overall, the model explained 39% of the outcome variance (Table 2).

Dietary Calcium Intake—At the bivariate level, no significant difference existed between intervention ($M = 1263.7$ mg, $SD = 736.2$ mg) and control ($M = 1152.1$ mg, $SD = 891.6$ mg) participants in average dietary calcium intake at 1-month follow-up ($t_{64} = 0.56$, $p = 0.58$). However, regression analysis revealed that, after adjusting for baseline calcium intake, and changes in knowledge and self-efficacy, intervention participants evidenced significantly greater calcium consumption at 1-month follow-up ($B = 4.92$, 95% CI = 0.33, 9.52, $p = 0.04$) compared with control participants, explaining 15% of the variance (Table 2).

Discussion

Despite research suggesting cancer survivors often improve dietary behaviors following diagnosis, concern remains regarding the fact that survivors of childhood cancer are at an

increased risk for bone-related morbidity, and many do not meet behavioral recommendations for promoting healthy bone development [5,11]. Compounding this problem is that the evidence-base for behavioral interventions targeting bone health behaviors among adolescent survivors of childhood cancer remains scarce [20]. Our study examined the immediate efficacy of the Survivor Health and Resilience Education (SHARE) Program, a health-promoting multiple behavior change counseling intervention for adolescent survivors of childhood cancer, on improving their bone health behaviors. To our knowledge, this is among the first studies to do so in this special population. The findings indicate that the group-based intervention was efficacious in improving self-reported milk consumption frequency, calcium supplementation, and dietary calcium intake at 1-month follow-up. The results point to potentially fruitful areas of future research.

An interim evaluation of SHARE indicated intervention participants found the group-based format to be relevant, understandable, beneficial, and acceptable [22]. Our findings add to the evidence supporting the program's approach, suggesting it is not only well-received within the target population, but that it also represents an efficacious approach to bone health behavior improvement. Nevertheless, practical factors limited participation by some teens. Those who lived farther away from the intervention site were more difficult to engage, possibly due to travel and other logistical barriers [22]. Indeed, recent research suggests cancer survivors may readily accept distance-based approaches to behavioral intervention, further reducing barriers to in-person engagement [12,37].

In order to expand the reach and impact of such interventions within this population, additional work examining strategies to lower barriers among teens is warranted, especially those teens that were more difficult to reach in SHARE [12,22,37]. For instance, intervention approaches applying interactive communication technologies, such as the Internet and wireless mobile technology, could improve program reach and impact [22]. Additional intervention approaches that reduce barriers to participation, such as offering the intervention in multiple geographic locations within the community, may also improve program reach.

After accounting for change in theoretical predictors of bone health and baseline dietary calcium intake, dietary calcium intake was significantly greater 1-month post-intervention among intervention participants, compared with control participants. Though we did not use an objective measure of bone health (i.e., bone density scan) to examine bone health outcomes, it is unlikely that short-term changes in bone density would be observable. However, our findings do suggest the intervention appears promising in moving participants toward that direction. Peak bone density is typically achieved at levels of daily calcium intake between 1200 – 1500 mg in children [18]; participants in the intervention were, on average, within this critical range at 1-month post-intervention. In addition, dietary protein and calcium have been found to interact to affect bone density: when both protein and calcium are consumed at recommended levels, a positive net impact on bone density has been observed among young adult females [38]. Milk contains both protein and calcium, and the fact that the intervention improved calcium supplementation and increased milk consumption may lead to such effects if sustained over time [38].

While we are only able to draw conclusions regarding immediate post-intervention behavior change, prior work suggests long-term outcomes among cancer survivors are achievable [11,37]. Among young survivors, there is evidence suggesting health behavior interventions can produce sustained outcomes up to 12-months [39], and that young survivors are interested in improving their diets, physical activity levels, and lifestyle-related risk factors [12]. Whether or not a full complement of such changes is possible or durable in the long-term remains to be seen.

Ensuring that cancer survivors receive optimum risk-based medical care is critical to prevent cancer late-effect morbidities among survivors [3,5]. Optimum risk-based care entails systematic planning for lifelong screening, surveillance, and prevention of cancer late-effects among survivors of childhood cancer that considers risks based on previous cancer type, cancer therapy, genetic predispositions, lifestyle behaviors, and comorbid conditions [5]. Encouraging a healthy lifestyle among survivors of pediatric cancer is essential to optimum risk-based care and prevention [3,5]. Moreover, it is important that risk-based care addresses individual-level survivor-related factors, including knowledge, self-efficacy, and motivation necessary to engage in a healthy lifestyle and address behavioral factors contributing to cancer late-effects [3].

These issues are central to SHARE's intervention approach, which includes directed health behavior changes that could be integrated into optimum risk-based care for survivors of pediatric malignancies. The ideal time at which to deliver health behavior interventions among cancer survivors has not been firmly established [3,11,37]. However, age-appropriate recommendations and approaches should be integrated across the continuum of cancer care to encourage young survivors to take increasing responsibility for their health and healthcare. Future research is needed to examine how health behavior interventions such as the SHARE Program can be best integrated into long-term care to achieve this purpose.

Our findings should be interpreted in light of important study limitations, including the sample size and homogeneity, the immediate follow-up period, self-report methods of assessment, and limited reach. In particular, the fact that we relied on self-reported measures of bone health behavior, some of which were developed for this research and were not previously well-established psychometrically, is an important limitation. Future work can improve on this by including more diverse, randomly-selected samples to address generalizability of findings, and utilizing multi-dimensional, multi-modal assessments to strengthen study measures. In addition, research is needed to establish the reliability and validity of self-reported behavioral assessments for milk consumption frequency and calcium supplementation used in this study. Our cursory observation associating it with 24-hour recall calcium consumption data is encouraging, but limited. Research is also needed over longer follow-up periods to examine the durability of the intervention. Objective measures of bone density (i.e., bone density scans) may be important to pursue, along with more systematic comparisons among active treatment components (i.e., education, behavioral counseling, calcium supplementation) to discern those with maximal effect. Finally, research exploring alternative intervention modalities that address barriers to participation within this population appears warranted.

The limitations of this small-scale study notwithstanding, the findings suggest the multi-component, manualized SHARE Program intervention was efficacious in producing short-term improvements in milk consumption frequency, calcium supplementation, and dietary calcium intake at 1-month follow-up among pediatric cancer survivors. Health behavior and health education interventions appear useful in promoting good bone health habits among young cancer survivors, possibly preventing and controlling the onset of osteoporosis and related late-effects.

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Canada. (2004), the National Conference on Child Health Psychology, Charleston, SC (2004), and the Eastern Society for Pediatric Research, Philadelphia, PA (2009).

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Table 1

Baseline sample characteristics by study condition

	Intervention (n = 38)			Control (n = 37)			p-value
<u>Sociodemographics</u>							
Age	m	sd	n	m	sd	n	%
	14.2	2.0		14.2	2.8		
Race/Ethnicity							
White			31			25	67.6
Non-white			7			12	32.4
Gender							
Male			17			19	51.4
Female			21			18	48.6
Household Composition							
Two parent home			31			31	83.8
Other composition			7			6	16.2
School Achievement							
Mostly A's/B's			28			29	78.4
Other			10			8	21.6
<u>Clinical Characteristics</u>							
Primary Diagnosis							
Leukemia			21			18	48.9
Other			17			19	51.4
<u>Theoretical Predictors of Bone Health</u>							
Bone Health Knowledge	0.36	0.17		0.39	0.20		0.52
Calcium Consumption Self-Efficacy	37.8	8.5		39.9	7.1		0.26
<u>Baseline Bone Health Outcomes</u> *							
Milk Consumption Frequency	3.1	0.80		2.8	0.97		0.24
Any Current Calcium Supplementation			11			8	21.6
Days with Calcium Supplementation	5.1	9.7		2.5	6.4		0.18
Calcium Intake (mg/day)	955.4	461.3		1027.5	557.9		0.54

* Milk consumption frequency was based on a 4-point Likert-type scale ranging from (1) "Never" to (4) "Always"

Table 2

Analysis of 1-month follow-up data on bone health behavior outcomes

	1-Month Follow-up Bone Health Behavior Outcomes							
	Milk Consumption Frequency		Any Calcium Supplementation		Days with Calcium Supplementation		Dietary Calcium Intake ^a	
	B	95% CI	OR	95% CI	B	95% CI	B	95% CI
Intervention Condition	0.50 *	0.08, 0.92	24.49 ***	4.19, 143.05	10.25 ***	4.94, 15.55	4.92 *	0.33, 9.52
Bone Health Knowledge Δ	-0.61	-1.52, 0.30	0.64	0.18, 26.15	0.58	-11.05, 12.21	-9.66	-19.50, 0.29
Calcium Consumption Self-Efficacy Δ	0.002	-0.02, 0.03	1.04	0.95, 1.14	-0.02	-0.32, 0.28	-0.21	-0.46, 0.05
Baseline Bone Health Behavior	0.49 ***	0.29, 0.69	8.51 *	1.53, 47.54	0.52 *	0.26, 0.77	0.52 **	0.16, 0.88
Adjusted R ²	0.32		0.53		0.39		0.15	

OR = Odds Ratio; CI = Confidence Interval; Δ = Change

* $p < 0.05$ ** $p < 0.01$ *** $p < 0.001$ ^a Dietary calcium intake variables were rescaled (divided by 100) for regression analyses