

Otherwise, calorie and fat intake was calculated based on the information on the questionnaire according to the Standard Tables of Food Composition in Japan 2010.

Results

There was a statistically significant difference between the groups in calorie intake from snacks 3 months after intervention, which was the primary endpoint of this study. The reduction in mean calorie intake from snacks in the study group was greater than that in the control group. The difference was, however, not statistically significant immediately after and 6 months after intervention.

One of the secondary endpoints of fat intake from snacks showed a difference between the groups in means immediately after intervention. The reduction of fat intake from snacks in the study group was greater than that in the control group. However, the difference was not statistically significant 3 and 6 months after intervention.

The nutritional education consisted of a lecture to the children that snack foods contain a lot of calories and fat. McNemar test was performed to determine the significant difference in the number of children who stopped eating snack foods and those who started eating snack foods after intervention. The results showed that there was no statistically significant difference in the number of children who stopped eating snack foods and those who started eating snack foods in the control group, while in the study group statistically significantly more children stopped eating snack foods up to 3 months after intervention.

Conclusion

The study confirmed that even a 45-minute class could produce educational effects that persist for 3 months. While it is difficult to allocate a lot of time to nutritional education within the curriculum of an elementary school, the study demonstrated that some positive effects could be achieved by even brief nutritional education.

Introduction

Background and Objective

As one of the countermeasures against lifestyle-related diseases in juveniles, controlling snacking habits is among the most important aspects of obesity prevention efforts in parallel with exercise. Some forward-looking municipalities, where countermeasures have been taken against lifestyle-related diseases in elementary and junior high school students, frequently deliver education on between-meal eating habits as part of health education.

However, few randomized controlled studies have assessed the effects of education on between-meal eating habits. Some studies in juveniles in which calorie and fat intake from snacks were used as a primary endpoint were identified from a systematic review published by Eto (2011)ⁱ. Devault et al. (2009)ⁱⁱ delivered 6 sessions of 30-minute nutritional education to 140 fourth graders and found an improvement in total fat intake and knowledge about fat. Matvienko (2007)ⁱⁱⁱ delivered a 20-minute lecture to 70 first graders at elementary school and sent newsletters to their parents and found that they came to choose healthier snacks. Friel et al. (1999)^{iv} provided 20 sessions of 30-minute intervention to 368 third and fourth graders at elementary school and reported a decrease in consumption of salty snacks. Lubans et al. (2009)^v provided information and lectures on exercise and diet to 124 junior high school students and observed a decrease in the frequency of eating high-calorie and low-nutrition snack foods in boys. Similar studies have been published by Lo et al. (2008)^{vi}, Fahlman et al. (2008)^{vii}, and other researchers. These studies included education on reading nutritional facts labels as intervention. Frenn et al. (2005)^{viii}

and French et al. (2004)^x delivered intervention on fat intake to junior high school students and showed that the intervention influenced the fat to energy ratio and purchase behavior for low fat products.

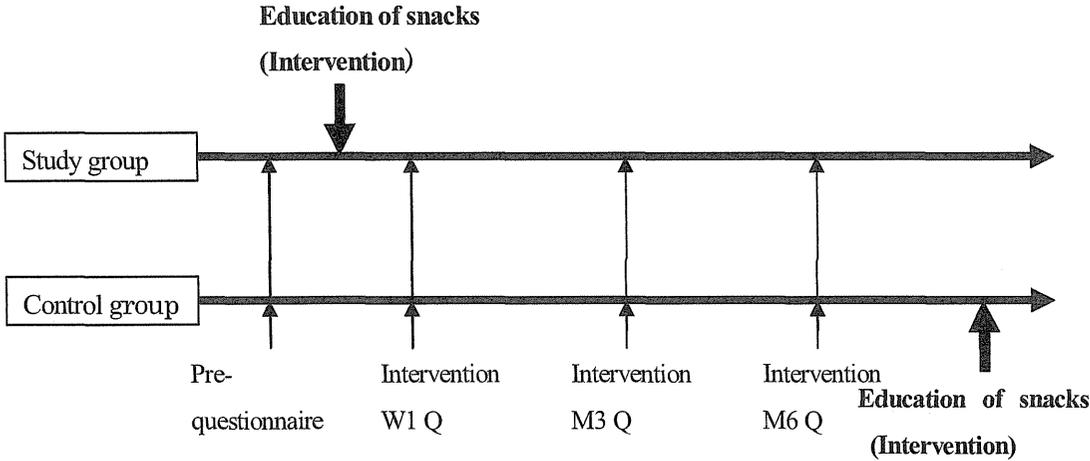
After the systematic review of Eto (2011) was published, some similar studies were identified by searching for articles using a similar method to that described by Eto (2011). Lippevelde (2012)^x investigated how much fat intake from snacks changed in 11- to 15-year-old students after education with their parents. The author reported that there was a statistically significant difference in fat intake between the students receiving education by themselves and those receiving education with their parents.

While there have been some reports on nutritional education about between-meal eating habits delivered by nutrition educators/school nutritionists in other countries, no randomized controlled studies have been published in Japan. It is of great significance to investigate to what extent these types of nutritional education are effective when such education is offered in line with the educational system of Japan.

In this study, we evaluated how such nutritional education influences the snacking behavior in school children and how long the influence may last.

Methods
Study design

Figure 1 Study flow



In this study, the study group attended a 45-minute educational class on calories in snacks that are frequently consumed on a daily basis and recommended calorie intake from snacks, and completed questionnaires that asked students about the types of snacks, the time of snacking, and their health status before and 1 week, 3 and 6 months after the session. The control group completed the same questionnaires at the same time points as the study group. The control group attended an identical educational class after completing the Month 6 questionnaire.

The elementary school curriculum allows one 45-minute educational class on between-meal eating habits by nutrition educators/school nutritionists. The duration of intervention was 45 minutes to assess the effectiveness of the education.

Blinding was impossible because it is obvious whether the subjects actually attended a class to both subjects and

instructors (nutrition educators/school nutritionists). Accordingly, this study was designed as an open-label, multicenter, randomized, controlled study. In this study, there were no significant methodological changes after the start of the study.

Participants

The intervention used in this study was delivered by nutrition educators/school nutritionists as a class session, and the subjects were all fourth and fifth graders of A and B Elementary Schools in Tokyo who received nutritional education on between-meal eating habits.

No exclusion criteria were planned in principle because the intervention was delivered as a class session and the intervention did not involve physical intervention. However, if a subject or his/her parent refused to complete the questionnaire, his/her intention was respected.

Intervention

In this study, the study group attended a 45-minute educational class on between-meal eating habits. The class was held in June 2011. The class focused on the time of snacking and the amount and type of snacks.

The children were taught not to eat snacks before going to bed. The recommended amount of snacks was set at nearly 200 kcal/day. The children were also taught about reading nutritional facts labels so that they could obtain the information on calories in commercial foods. The instructor gave some examples of foods, such as snack foods, that contain high amounts of calories and fat for a small serving. Examples of ideal snacks that contain high nutrition were also given.

Through this education session, the children were given an opportunity to review their previous between-meal eating habits, understand the significance of snacks as part of daily diet, and become aware of healthy dietary life.

Outcomes

The primary endpoint of this study was the difference between X and Y:

X: The difference in calorie intake from snacks between before intervention and 3 months after intervention in the study group

Y: The difference in calorie intake from snacks between before intervention and 3 months after intervention in the control group.

The intervention (education) used in this study was to determine the recommended calorie intake from snacks, and calories have been frequently used as a primary endpoint in previous studies; we therefore used the primary endpoint of the difference in the reduction of calorie intake from snacks 3 months after intervention between two groups (the difference between X and Y).

The children recorded the type and amount of snacks they consumed. When commercial snacks were consumed, the children were asked to attach the nutritional facts to a questionnaire for submission, if available. Otherwise, calorie and fat intake were calculated based on the information on the questionnaire according to the Standard Tables of Food Composition in Japan Fifth Revised and Enlarged Edition 2005.

Secondary endpoints included the difference in the reduction of fat intake from snacks 1 week and 3 and 6 months after intervention between the groups, knowledge about calories in snacks, knowledge about fat in snacks, and the type of snacks.

The same outcome as the primary endpoint (calorie intake from snacks) was evaluated 1 week and 6 months after intervention to assess the persistence of educational effects. Topics about fat in snacks and the importance of improving lifestyle were also regarded as outcomes because these were covered in the nutritional education in this study.

Other observations included the time snacks were consumed, physical conditions (10 items including headache and loss of appetite), wake-up and bedtime, frequency of missing breakfast, frequency of tooth brushing, and body height and weight.

In this study, there were no changes in outcomes after study initiation.

Sample size

A total of 100 subjects were to be enrolled in the study and control groups, each consisting of 50 subjects.

The rationale for the sample size is as follows:

A pretest conducted in nearly 40 subjects indicated that mean reduction from baseline in calorie intake from snacks 1 week after intervention was 121.2 kcal (standard deviation [SD] = 298.0), and the corresponding value 6 months after intervention was 64 kcal (SD = 290.9). Given that the reduction in calories at the time of evaluation for this study (3 months after intervention) was intermediate in value between these two extremes, the reduction in calories was estimated to be 90 kcal (SD = 294) in the study group. The reduction in calories in the control group was assumed as 0, with a similar SD.

In this case, the planned sample size n will be given by the following equation:

$$n = 2 (Z_{\alpha/2} + Z_{\beta})^2 \times (\sigma/\delta)^2$$

(α = significance level, β = power + 1, Z_{α} , Z_{β} = respective Z value, σ = SD, δ = difference in means between study and control groups)

When pretest values are substituted in this equation, the required sample size is 51 subjects, with a power of 80% and significance level of 5%. However, enrolling any children who do not belong to either study or control group would take away opportunities for education from the children. Accordingly, if 51 subjects each were left after allocation to the study and control groups at the participating elementary schools, the 51 subjects were to be additionally allocated to each of the two groups.

Randomization

As it was difficult to create a study group and control group within a class, an entire class was assigned to either the study or control group. The allocation was made by lot. Although allocation concealment should have been used to be exact, blinding was impossible because it was obvious in this study to subjects whether the subjects underwent nutritional education earlier or later; and therefore the lot allocation was made for expedient purposes.

Although efforts were made to approximate a randomization ratio to one-to-one, the actual ratio was 100 to 122 (4 classes to 5 classes) because the number of classes and the number of children in each class differed.

Both A and B Elementary Schools are in suburban Tokyo and there was no marked difference in the type of snacks that could be chosen between the schools. Sex and the level of understanding of the subjects were balanced between classes and the subjects could not choose which group to join, which resulted in a minimum level of blinding.

Statistical methods

X: The difference in calorie intake from snacks between before intervention and 3 months after intervention in the study group

Y: The difference in calorie intake from snacks between before intervention and 3 months after intervention in the control group.

A *t*-test was used to determine the effects of education with the null hypothesis that there is no difference between X and Y. The significance level was two-sided and set at 0.05.

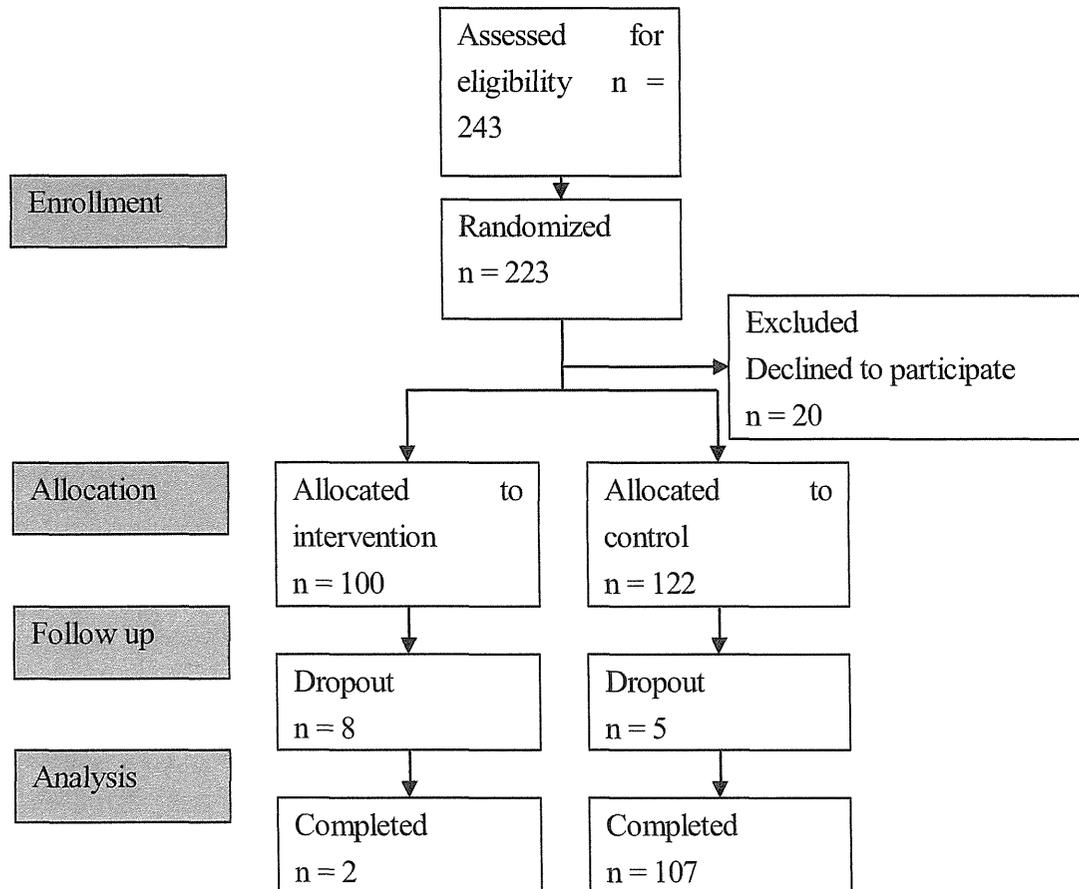
Similar to the primary endpoint, a *t*-test was performed to determine the effects of education for the outcomes that can be regarded as similar to the primary endpoint (e.g. the difference between X and Y 1 week and 6 months after intervention), with the null hypothesis that there is no difference between X and Y.

A McNemar test was performed to compare the number of incorrect answers that had been changed to correct answers and the number of correct answers that had been changed to incorrect answers to questions to test the knowledge of the subjects about fat in snacks for each of the study and control groups.

Results

Participant flow

Figure 2 Subject flow diagram



As described above, no subjects were excluded in principle because the intervention was delivered as a class session. No children refused to complete the questionnaire after the class. The dropouts were therefore the subjects who did not attend the class or submit the questionnaire.

Recruitment

A pre-intervention questionnaire was administered in June 2011, followed by the intervention 1 week after the questionnaire. The post-intervention questionnaire was administered 3 and 6 months after the intervention.

Baseline characteristics

Table 1 Number of subjects by sex and age

	Study group	Control group
Sex		
Boys	40	40
Girls	52	67
School year		
Fourth graders	45	61
Fifth graders	47	46
Total	92	107

Table 1 shows the number and sex of the subjects. Although slightly more fourth graders were allocated to the control group, a test based on the binominal distribution showed no statistically significant difference in the number of subjects. Similarly, there was no statistical imbalance between the groups in sex ratio.

Number analyzed

Statistical analysis was performed based on the randomized groups. The analysis included 92/100 subjects (4 classes) in the study group and 107/122 subjects (5 classes).

Outcomes and estimation

Table 2 Calorie intake from snacks (kcal)

kcal	Study group			Control group		
	n	Mean	S.E	n	Mean	S.E
Before intervention	100	215.26	18.37	122	195.00	18.26
1 week after intervention	83	156.03	12.85	104	173.61	17.36
3 months after intervention	97	117.29	14.50	112	148.27	14.83
6 months after intervention	96	151.76	15.00	115	138.08	16.04

Table 3 Fat intake from snacks (g)

g	Study group			Control group		
	n	Mean	S.E	n	Mean	S.E
Before intervention	100	8.58	0.87	122	7.94	0.94
1 week after intervention	83	4.89	0.59	104	6.92	0.82
3 months after intervention	97	4.83	0.72	112	5.46	0.64
6 months after intervention	96	6.35	0.81	115	5.01	0.70

There was no statistically significant difference in calorie and fat intake from snacks before intervention (Tables 2 and 3). Generally, calorie intake from snacks should be approximately 10% of total calories consumed daily. Based on the age of the subjects, calorie intake from snacks should be less than 200 kcal. Both in the study and control groups, approximately 40% of subjects consumed more than 200 kcal from snacks. Before intervention, the children frequently consumed ice creams, snack foods, and juice (including carbonated beverage).

Table 4 Changes in calorie intake from snacks (kcal)

(kcal)	Study group			Control group		
	n	Mean	S.E	n	Mean	S.E
After 1 week	80	-65.3	19.2	97	-28.5	21.1
After 3 months**	92	-101.9	23.0	107	-38.3	19.1
After 6 months	92	-74.4	21.8	109	-51.8	23.8

** $P < 0.05$ There is a statistically significant difference in the reduction of calorie intake between the study and control groups.

Table 5 Changes in fat intake from snacks (g)

(g)	Study group			Control group		
	n	Mean	S.E	n	Mean	S.E
After 1 week**	80	-4.2	0.8	97	-1.0	1.1
After 3 months	92	-3.8	1.1	107	-1.9	1.0
After 6 months	92	-2.8	1.1	108	-2.5	1.2

** $P < 0.05$ There is a statistically significant difference in the reduction of fat intake between the study and control groups.

Tables 4 and 5 show the results of the intervention. Although ITT analysis was planned originally, PPS analysis was used due to a higher withdrawal rate in the control group than in the study group.

There was a statistically significant difference between the groups in calorie intake from snacks 3 months after intervention, which was the primary endpoint of this study. The reduction in calorie intake from snacks in the study group was greater compared with that in the control group. The difference was, however, not statistically significant immediately after and 6 months after intervention (Tables 2 and 4).

One of the secondary endpoints of fat intake from snacks showed a difference between the groups in means immediately after intervention. The reduction of fat intake from snacks in the study group was greater than that in the control group. However, the difference was not statistically significant 3 and 6 months after intervention (Tables 3 and 5).

The nutritional education consisted of a lecture to the children that snack foods contain a lot of calories and fat. McNemar test was performed to determine the significant difference in the number of children who stopped eating snack foods and those who started eating snack foods after intervention. The results showed that there was no

statistically significant difference in the number of children who stopped eating snack foods and those who started eating snack foods in the control group, while in the study group statistically significantly more children stopped eating snack foods up to 3 months after intervention (Table 6).

Table 6 Changes in the snacking behavior after intervention (number of subjects)

n	Study group		Control group	
	Stopped eating snack foods	Started eating snack foods	Stopped eating snack foods	Started eating snack foods
After 1 week	28 **		7	21
After 3 months	24 **		9	18
After 6 months	22		10	21

* $P < 0.05$, McNemar test

Similarly, the McNemar test was used to test for a statistically significant difference in the number of incorrect answers that had been changed to correct answers and the number of correct answers that had been changed to incorrect answers to questions to determine whether the subjects knew that snack foods are high in calories and fat, and no statistically significant difference was observed.

Ancillary analysis

There was no statistically significant difference in the reduction of calorie and fat intake from snacks after intervention between the study and control groups in the fourth and fifth graders. The reduction in calorie intake did not differ between the study and control groups in age subgroups. In the study group, the reduction in calorie intake was much larger in the fifth graders than in the fourth graders, but no statistically significant difference was observed.

Next, we performed a similar analysis in sex subgroups and found no statistically significant difference in the reduction of calorie and fat intake from snacks after intervention in girls, but did find a statistically significant difference in the reduction of fat intake 1 week after intervention and calorie intake 3 weeks after intervention in boys. In the study group, there was no statistically significant difference in the reduction of calorie intake between boys and girls.

In the control group, calorie and fat intake from snacks decreased each time the questionnaire was administered.

Discussion

Limitations

In this study, an entire class in a school was assigned to either the study or control group. As the study group was not instructed to conceal the content of the education they received, the control group might have found out about the educational content from the study group. Furthermore, calorie and fat intake from snacks decreased each time the questionnaire was administered in the control group. These factors may have contributed to underestimation of the educational effects.

Generalizability

The intervention was delivered by two school nutritionists. This number is not representative of general nutrition

educators/school nutritionists, and generalizability is therefore limited. However, some positive effects can be expected, although the educational effects may vary among individuals.

Interpretation

The reduction in calorie and fat intake from snacks may be attributed to the reduction in the volume of snacks and the change in the type of snacks, particularly to the decreased frequency of eating snack foods.

The educational effects were more prominent in boys, which may be attributed to girls aged fourth to fifth grades generally wanting to be slim and already being more aware of calorie intake than boys.

The reason for no difference in the reduction 1 week and 6 months after intervention between the groups may be partly because the same educational effects as those for the study group may have affected the control group each time the questionnaire was given. The questionnaire was designed to ask what the subjects think about eating snacks, which makes the subjects aware of the content of snacks if not directly, leading to a reduction in calorie intake from snacks in the control group. In fact, there was a statistically significant difference in calorie intake from snacks between before intervention and 1 week after intervention and between before intervention and 3 months after intervention in the control group. Recording what snacks the subjects consumed and repeatedly answering the questionnaire may have induced the subjects think about what snacks to eat.

The study confirmed that even a shorter, 45-minute class, relative to other interventional studies, can produce educational effects that persist for 3 months. While it is difficult to allocate a lot of time to nutritional education in the elementary school curriculum, the study demonstrated some positive effects can be achieved by even brief education by carefully selecting the educational content and developing an educational plan.

Other information

Registration

The conduct of this study was approved by the Institutional Review Board at Komazawa Women's University under Approval No. 2013-021.

Funding

This study was conducted as a research project of the Ministry of Health, Labor and Welfare of Japan, but did not receive a research grant because the study was basically conducted as part of school education.

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研究成果の刊行に関する一覧表

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Toshiyo Tamura, Yutaka Kimura, Kotaro Minato	Assessment of participant compliance with a Web-based home healthcare system for promoting specific health checkups	Biocybernetics and Biomedical Engineering		in press	2014
久保田眞由美, 木村穰, 大谷肇, 岩坂壽二	心臓リハビリテーションによる性格特性の変化の検討	心臓リハビリテーション	33	236-240	2013
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多様なニーズに対応するための新たな保健指導方法の開発に関する研究
(H23-循環器等(生習)-一般-007)

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