TABLE 2. Basic Characteristics of Subjects in the Current Study, 1993–2007

	Participants in BOOCS Program	Comparative Obese Controls*	Reference Subjects†	*P*
Male				
No. of subjects	1,565	1,230	11,012	
Mean age ± SD‡	41.6 ± 8.5	44.4 ± 9.4	41.2 ± 9.3	<0.0001
Occupation, %				
Clerk	1,137 (72.7)	852 (69.3)	7,614 (69.1)	<0.0001
Firefighter	168 (10.7)	132 (10.7)	1,562 (14.2)	
Technician	75 (4.8)	91 (7.4)	575 (5.2)	
Health care	23 (1.5)	25 (2.0)	341 (3.1)	
Others	162 (10.4)	130 (10.6)	920 (8.4)	
Female				
No. of subjects	742	605	6,426	
Mean age ± SD†	45.5 ± 7.7	42.9 ± 9.9	41.0 ± 9.6	<0.0001
Occupation, %				
Clerk	363 (48.9)	226 (37.4)	2,532 (39.4)	<0.0001
Food supply	131 (17.7)	112 (18.5)	1.011 (15.7)	
Kindergarten teacher/nurse	143 (19.3)	141 (23.3)	1,442 (22.4)	
Health care	50 (6.7)	69 (11.4)	1,048 (16.3)	
Others	55 (7.4)	57 (9.4)	393 (6.1)	

Abbreviation: BOOCS, Brain-Oriented Obesity Control System.
*Those who had obesity with body mass index ≥25 or obesity-related health problems, and who did not participate in BOOCS program.
†Those who were the rest of nonparticipants after excluding the comparative obese controls.
‡As of March 31, 1993.

TABLE 3. Results of Follow-Up for Subjects in the Current Study, 1993–2007

	Participants in BOOCS Program	Comparative Obese Controls*	Reference Subjects†
Male			
Observed person-years	15,896.0	13,301.3	137,131.4
Status at the end of follow-up, %			
Active employee at the end of study	940 (60.1)	550 (44.7)	6,611 (60.0)
Retired or left before the end of study	603 (38.5)	645 (52.4)	4,195 (38.1)
Deceased	22 (1.4)	35 (2.9)	206 (1.9)
Female			
Observed person-years	6,076.6	6,511.4	73,591.7
Status at the end of follow-up, %			
Active employee at the end of study	246 (33.2)	243 (40.2)	3,039 (47.3)
Retired or left before the end of study	494 (66.6)	357 (59.0)	3,334 (51.9)
Deceased	2 (0.3)	5 (0.8)	53 (0.8)

Abbreviation: BOOCS, Brain-Oriented Obesity Control System.
*Those who had obesity with body mass index ≥25 or obesity-related health problems, and who did not participate in BOOCS program.
†Those who were the rest of nonparticipants after excluding the comparative obese controls.

DISCUSSION

In this study, protective effect for mortality by BOOCS program was indicated by significantly decreased HR for all causes of deaths to 0.54 (95% CI: 0.31 to 0.94) and its persistence in males until the end of follow-up ($P = 0.014$ by log-rank test). One of the reasons for such preventive effects of BOOCS program may be related to improvement of obesity during follow-up. Using the same data set of male workers in this study, we obtained the results that changes of BMI during the first 5 years were more remarkable, that is, higher by 1% to 5%, in participants than those in both comparative obese controls and reference subjects.[17] These data coincide with the previous reports[18-22] that both all-cause and cancer mortality were associated with obesity. So-called "legacy effect" may exist in this study because only participant group showed mortality benefit after better BMI control disappeared.[23] These effects brought by BOOCS program may result in the protective effect for mortality in this study.

As mentioned earlier, BOOCS program is a unique method with a way of psychosomatic approach prioritizing mental and physical recovery from fatigue. Although relevant lectures regarding nutrition, physical exercise, and risk factors of lifestyle-related diseases

TABLE 4. Mortality From Selected Causes of Death, 1993 to 2007

	Participants in BOOCS Program			Comparative Obese Controls*			Reference Subjects†		
Cause of Death (*ICD-10*)	Obs‡	Exp§	SMR (95% CI)	Obs‡	Exp§	SMR (95% CI)	Obs‡	Exp§	SMR (95% CI)
Male									
All causes	22	61.8	0.36 (0.22–0.52)	35	40.3	0.87 (0.69–1.29)	206	464.2	0.44 (0.38–0.51)
Malignant neoplasms (C00-C95)	10	20.8	0.48 (0.23–0.82)	16	17.7	0.90 (0.52–1.39)	90	156.8	0.57 (0.46–0.70)
Cardiovascular disease (I00-I99)	5	8.0	0.62 (0.20–1.28)	6	6.8	0.88 (0.32–1.72)	50	61.7	0.81 (0.60–1.05)
Suicide (X60-X84)	5	7.7	0.65 (0.21–1.33)	9	5.9	1.53 (0.70–2.67)	38	59.2	0.64 (0.45–0.86)
Female									
All causes	2	13.9	0.14 (0.01–0.41)	5	11.1	0.45 (0.14–0.93)	53	117.7	0.45 (0.33–0.58)
Malignant neoplasms (C00-C95)	2	7.0	0.28 (0.02–0.81)	2	5.6	0.35 (0.03–1.01)	36	59.7	0.60 (0.42–0.82)

Abbreviations: BOOCS, Brain-Oriented Obesity Control System; *ICD-10, International Classification of Diseases, Tenth Revision*; SMR, standardized mortality ratio.
*Those who had obesity with body mass index ≥25 or obesity-related health problems, and who did not participate in BOOCS program.
†Those who were the rest of nonparticipants after excluding the comparative obese controls
‡Observed number of death.
§Expected number of death.

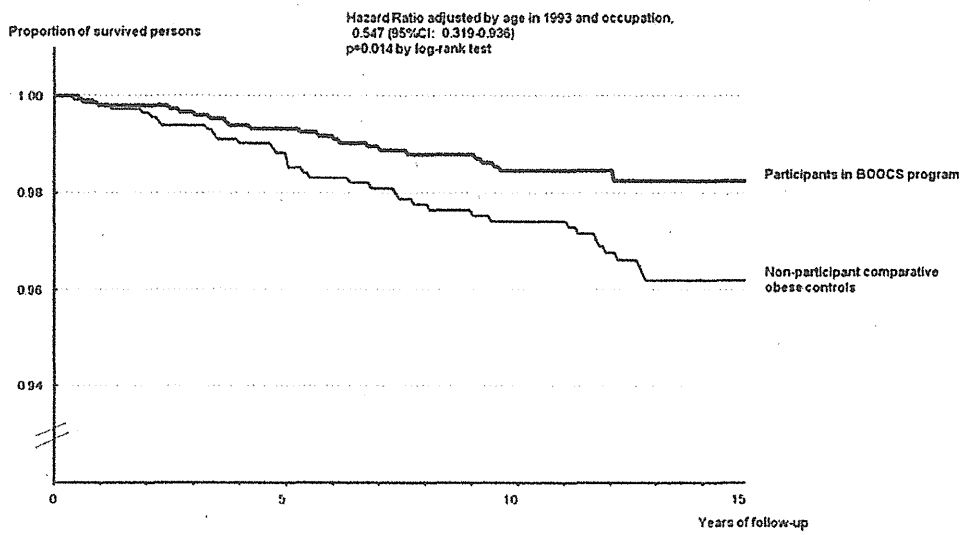

FIGURE 2. Survival curves of subjects according to BOOCS participation, 1993 to 2007 (all deaths, male). BOOCS indicates Brain-Oriented Obesity Control System.

are sufficiently provided in BOOCS program, it should be noted that harmful factors for health, for example, smoking and drinking, are not initially inhibited. According to Fujino,[14] the founder of the program, this approach is quite useful for making the participants fully aware of the fundamentals of health promotion and disease prevention, which leads them to modify their health behavior. He also insists that prohibitive and compulsive instructions are ineffective for behavior modification, and, in particular, those people who understand significance of health would result in failure through such methods and fall into vicious circle such as rebounding body weight. This approach may be consisted of the concept of behavior science and several reputed methods.[14,24-30] Nevertheless, the mechanism why BOOCS program is effective for behavior modification has not been clarified yet; therefore, further studies are strongly needed in the future.

The reason why such effect was not seen in females may be a small number of deceased workers and the low statistical power of our analysis. In addition, some sociological factors might be related to the results in female workers. In Japan, the traditional gender roles still remain, which argues that women should do housework.[31] The actual situations, where the promotion in the workplace is provided more for males than for females, and many Japanese women have retired after marriage or childbearing until recently, are seen. As shown in Table 3, more retired or left subjects were found among female workers than among male workers during the follow-up period. Some studies pointed out that working women may have more physical and mental health problems than housewives.[31,32] Although only a few female workers died in this study, we should pay attention to health status among them.

Advantages of this study are as follows: it is based on a large-scale working-population, long-term follow-up, and almost no dropouts from follow-up. All of those points may be fundamental and important in epidemiological studies, and make our results valid and reliable. On the contrary, limitations of this study are as follows: no randomization was considered when dividing the subjects into participants and nonparticipants, and no information was collected on lifestyle such as smoking and drinking. Therefore, attention should be paid in interpreting the results because they may include potential confounders that could influence on the mortality risks calculated in the study.

In occupational epidemiology, the healthy-worker effect (HWE) is usually seen as the workers show significantly lower mortality risks than the general population.[33] Indeed, decreased SMRs were found in both participants and nonparticipants in this study, which could conceal the real mortality effect in the population. This potential problem can be controlled by the risk indicators, such as HRs, which is calculated for the internal reference group. Therefore, we believe this approach minimized potential bias by HWE.

In conclusion, in quasi-experimentally 15-year follow-up study of health effect of participation in BOOCS program with 13,835 male and 7791 female Japanese workers, the numbers of deceased workers were 22, 35, and 206 males and 2, 5, and 53 females among participants, comparative obese controls, and reference subjects, respectively. The SMRs for all causes and all neoplasms in comparison with the general population were statistically lower among participants and reference subjects, which may be due to the HWE. Mortality risk from all causes in comparison with comparative obese controls was statistically lower in participants with HR = 0.54 (95% CI: 0.31 to 0.94) accompanied by significantly different survival curves ($P = 0.014$ by log-rank test) in males. Such protective effect on mortality in males may be related to improvement of obesity by participation in the program. The results indicate a mortality benefit by participation in BOOCS program. For prevention of metabolic syndrome, effective measures are strongly needed in the future, and it is suggested that BOOCS program will contribute to them as a new approach for health promotion.

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RESEARCH ARTICLE Open Access

Association between difficulty initiating sleep in older adults and the combination of leisure-time physical activity and consumption of milk and milk products: a cross-sectional study

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Abstract

Background: Research has shown that engaging in leisure-time physical activity (LTPA) and consuming dairy foods can lead to better sleep. Combining these two non-invasive prescriptions may be more effective for helping people fall asleep. This study investigates whether participating in LTPA in conjunction with consuming milk and milk products has a beneficial association with difficulty initiating sleep (DIS) among older adults.

Methods: The present study looked at 421 community-dwelling older people aged 65 years and older living in Ibaraki prefecture, Japan (mean age 74.9 ± 5.5 years, male 43.7%). We measured LTPA and sleep latency with the Physical Activity Scale for the Elderly and the Pittsburgh Sleep Quality Index, respectively. Participants who needed 30 minutes or more to fall asleep were defined as having DIS. We assessed dairy consumption as participants' habitual intake of milk, yogurt and cheese.

Results: After adjusting for covariates, participants who engaged in sufficient levels of LTPA as well as consumed milk (OR = 0.27, 95% CI = 0.10-0.73) or cheese (OR = 0.34, 95% CI = 0.14-0.85) were less likely to complain of DIS compared with people who neither engaged in LTPA nor ingested milk or cheese.

Conclusions: Our findings suggest that the combination of engaging in LTPA and consuming milk or cheese is necessary as a prescription to improve falling asleep for older adults suffering from DIS. Additionally, engaging in LTPA along with dairy consumption may effectively improve a problem with falling asleep.

Keywords: Exercise, Dairy, Insomnia, Elderly

Background

As people age, the quality and quantity of their sleep often deteriorate, and sleep complaints are extremely common in older adults. In a previous study approximately one out of three Japanese older adults reported insomnia symptoms [1]. Difficulty initiating sleep (DIS), difficulty remaining asleep, waking up early in the morning and lack of satisfying sleep are known as insomnia symptoms [2], with DIS being one of the most common symptoms in older people. Chronic DIS leads to high risks of mortality [3], diabetes [4], depression [5], poor physical function [6] and cognitive impairment [7]. Finding ways for older adults to improve their ability to fall asleep is essential to their well-being.

It has been established that regular leisure-time physical activity (LTPA), including exercise, has a beneficial effect on a person's physical and psychological health [8,9]. Recently, habitual LTPA is being recognized as a potentially effective factor for treating or preventing sleep problems; it is considered a non-pharmacological intervention to improve sleep. Previous randomized control trials (RCTs) [10,11] have revealed that participating

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in LTPA decreases sleep latency (the time required to fall asleep). Furthermore, an epidemiological study [12] showed a relationship between engaging in exercise and a lower prevalence of DIS in older adults.

Primarily in western countries, people have consumed milk and milk products before bedtime as an effective means of improving their sleep. In fact, dairy products contain nutrients, particularly, tryptophan, a precursor to serotonin and melatonin, which play an important role in promoting sleep, including falling asleep [13]. Therefore, ingesting milk and milk products has been considered helpful in improving sleep, and a previous RCT reported that sleep efficiency is increased by melatonin-rich nighttime milk consumption in older people [14]. Since engaging in LTPA and consuming milk and dairy products are beneficial agents for sleep promotion, combining these two non-invasive prescriptions may more effectively help older adults suffering from DIS. However, there is limited literature on the relationship between sleep in older adults and the combination of these two daily activities. This study has two objectives: confirm independent associations between DIS and engaging in LTPA or consuming milk and milk products, and to examine whether combining these two habits is more strongly associated with a lower prevalence of DIS.

Methods

Data collection

A total of 437 community-dwelling, older Japanese individuals participated in the survey. The participants, aged 65 years and older, were recruited in Tsuchiura and Kasama Cities in Ibaraki prefecture, Japan in 2013. The Tsuchiura City participants consisted of 160 community dwellers (mean age 75.6 ± 6.2 years, male 34.0%) recruited through local advertisements and flyers or invited by municipal employees from June to November 2013. For Kasama City, we used data from 277 randomly selected individuals (mean age 74.5 ± 5.0 years, male 49.6%) who participated in the "Kasama study" [15] from July to August 2013. We started with 437 participants, but we rejected 16 individuals due to incomplete data. There were 421 final participants (mean age 74.9 ± 5.5 years, male 43.7%) in the data analysis. All participants provided a signed informed consent. The Ethics committee of the University of Tsukuba approved this study.

Leisure-time physical activity

To assess the amount of LTPA, we used the Japanese version of the Physical Activity Scale for the Elderly (PASE) [16]. A previous study deemed the PASE to be reliable and valid [16]. LTPA contains five activities: walking (for both recreation and transportation); light-, moderate-, and vigorous-intensity recreational activities; and muscle strength training. We measured a participant's frequency (day/week) and duration (minute/day) of each activity during the previous 7 days and calculated a total LTPA score using frequency, duration and weight for each activity used in the analysis.

Milk/milk products consumption

We assessed the consumption of milk, yogurt and cheese during the previous couple months using a self-reported questionnaire and the following questions: "How many days a week do you drink milk (or eat yogurt/cheese) [day (s)/week]?" and "How much milk (or yogurt/cheese) do you usually consume each day [milliliters or grams/day]?" Additionally, we supplied examples of portion size (e.g. a glass of milk = 200 ml) to help participants answer the questions. Using these two questions, we calculated consumption of each food item, and the sum of the three items equaled a participant's total dairy consumption used in the analysis. To estimate total dairy consumption, units of milk intake were converted from milliliters to grams using the following equivalency: 100 ml = 103.2 gm" [17]. No participants had a milk allergy. Previous studies have used self-reported questionnaires to evaluate the frequency and the portion size of daily milk and milk product consumption; those authors confirmed a moderate correlation (r = 0.4–0.6) with the weighed dietary recording considered the gold standard for assessing dietary methods [18,19].

Sleep

We gathered information on total sleep time and sleep latency during the previous month and evaluated these data by referencing the Pittsburgh Sleep Quality Index (PSQI) [20]. PSQI is used to identify sleep disorders in both clinical and research fields throughout the world, and validity and reliability have been confirmed [20].

Potential confounders

We referenced previous studies to determine minimum required potential confounders for our study: age, gender, body mass index (BMI), hypnotic use for sleep [21], engaging in LTPA [22] and dairy consumption [23,24]. We obtained age, gender and hypnotic use with a self-report questionnaire. We measured height and weight with a stadiometer or a digital weight scale and calculated BMI calculated as weight in kg divided by height in meters squared.

Statistical analysis

LTPA participation was divided into 3 groups based on median level of engagement or no engagement at all: 1) nothing, 2) low level and 3) high level. Total dairy consumption was divided into 3 groups using tertiles: 1) low level, 2) moderate level and 3) high level. A variable composed of the following 4 groups combining

LTPA and intake of dairy products was created: 1) LTPA with large dairy intake, 2) LTPA with small dairy intake, 3) no LTPA with large dairy intake and 4) no LTPA with small dairy intake. By referencing previous studies [25], people who took more than 30 min to fall asleep were defined as having DIS.

We analyzed group differences (non-DIS vs. DIS), using independent *t*-test and chi-square test. We used logistic regression analysis to examine the association between participation in LTPA, consumption of dairy products or a combination of those two variables (dependent variables) with DIS (independent variable) adjusting for age, gender, hypnotic use, BMI and those LTPAs or dairy products which were not used as dependent variables. In addition to the odds ratios, we also calculated *P* for trend. Statistical analysis was performed by IBM SPSS Statistics version 19.0 with the level of significance set at $P < 0.05$.

Results

Description of the study participants

The characteristics of study participants are shown in Table 1. The mean age was 74.9 ± 5.5 years, and the subjects' usual sleep time was 405.9 ± 73.4 min/night. Out of 421 participants, 135 individuals met the definition of DIS (32.1%) and 80 people (19.0%) habitually used sleeping pills. Compared with participants who did not have DIS, individuals defined as having DIS were more likely to be women, experienced shorter total sleep duration and long sleep latency, engaged less in LTPA and were more likely to use hypnotics ($P < 0.05$).

LTPA and DIS

An association between LTPA and DIS is presented in Table 2. After adjusting for age, gender, hypnotic use, BMI and consumption of milk and milk products, a high

Table 1 Characteristics of study participants

	All (n = 421)	Non-DIS (n = 286)	DIS (n = 135)
	Mean ± SD	Mean ± SD	Mean ± SD
Age, years	74.9 ± 5.5	74.7 ± 5.5	75.3 ± 5.6
Women, n (%)	237 (56.3)	149 (52.1)	88 (65.2)*
Height, cm	155.2 ± 9.0	156.0 ± 8.6	153.6 ± 9.5*
Weight, kg	56.1 ± 9.6	56.9 ± 9.7	54.4 ± 9.3*
Body mass index, kg/m^2	23.2 ± 2.9	23.3 ± 2.9	23.0 ± 2.8
Total sleep time, min	405.9 ± 73.4	411.6 ± 70.8	393.7 ± 77.3*
Sleep latency, min	21.1 ± 21.5	10.7 ± 5.5	43.2 ± 25.8*
Hypnotic use, n (%)	80 (19.0)	34 (11.9)	46*
Leisure-time physical activity, points	21.7 ± 25.1	23.7 ± 26.9	17.6 ± 20.5*
Milk consumption			
Frequency, days/week	3.6 ± 2.9	3.8 ± 3.0	3.2 ± 2.9
Volume, ml/day	155.9 ± 127.1	162.9 ± 129.4	141.0 ± 121.1
Total consumption, ml/week	784.3 ± 813.4	819.0 ± 833.1	710.9 ± 767.7
Yogurt consumption			
Frequency, days/week	4.0 ± 2.8	3.9 ± 2.9	4.1 ± 2.8
Volume, g/day	104.6 ± 79.0	100.6 ± 72.2	113.4 ± 91.9
Total consumption, g/week	506.6 ± 491.4	469.9 ± 418.7	587.1 ± 616.0*
Cheese consumption			
Frequency, days/week	1.3 ± 1.8	1.3 ± 1.8	1.3 ± 2.0
Volume, g/day	14.3 ± 16.6	15.6 ± 17.3	11.5 ± 14.8*
Total consumption, g/week	35.6 ± 55.3	37.4 ± 56.6	31.9 ± 52.6
Total dairy consumption			
Frequency, days/week	5.4 ± 2.4	5.4 ± 2.4	5.3 ± 2.3
Volume, g/day	193.9 ± 149.4	194.2 ± 145.0	193.5 ± 159.0
Total consumption, g/week	1357.5 ± 1045.9	1359.1 ± 1015.0	1354.3 ± 1112.9

*$P < 0.05$ (Non-DIS vs. DIS).
DIS: difficulty initiating sleep (30 min ≤ sleep latency).
SD: standard deviation.

Table 2 Association between LTPA and DIS

	DIS		
	n(%)	Odds ratio	95% CI
Leisure-time physical activity		Trend *P* value = 0.076	
Not engaging	57 (14.4)	1.00	
Low level (0.1–16.9 points)	168 (42.3)	0.72	0.38–1.37
High level (≥17.0 points)	172 (43.3)	**0.48**	**0.25–0.93**

Bold numbers indicate $P < 0.05$.
DIS: difficulty initiating sleep (30 min ≥ sleep latency); LTPA: leisure-time physical activity; 95% CI: 95% confidence interval.
Odds ratios and 95% confidence intervals were adjusted for age, gender, hypnotic use, body mass index and consumption of milk and milk products.

level of LTPA was associated with decreased prevalence of DIS compared to no engagement in LTPA (OR = 0.48, 95% CI = 0.25-0.93).

Milk/milk products and DIS

As shown in Table 3, participants were less likely to perceive DIS when they consumed a high level of milk (OR = 0.47, 95% CI = 0.26-0.84) even after adjusting for age, gender, hypnotic use, BMI, LTPA engagement and yogurt and cheese intake. Moreover, a significant dose–response relationship was observed between milk intake and prevalence of DIS (Trend $P < 0.05$). There were no significant associations between consumption of yogurt, cheese or total dairy and DIS.

LTPA with milk/milk products and DIS

As Table 4 indicates, after controlling for age, gender, hypnotic use, BMI and yogurt and cheese consumption, participants who engaged in LTPA as well as consumed milk were less likely to complain of DIS compared with those who neither engaged in LTPA nor consumed milk (OR = 0.27, 95% CI = 0.10-0.73). Similarly, after adjusting for multiple confounding variables, we found that the combination of LTPA engagement and cheese consumption was associated with decreased prevalence of DIS (OR = 0.34, 95% CI = 0.14-0.85). We did not find a significant association between DIS and the combination of LTPA and yogurt or total dairy consumption.

Discussion

We found that higher levels of LTPA and greater milk consumption were each associated with lower prevalence of DIS in older adults. Furthermore, we found that combining LTPA participation and milk and/or cheese consumption was more favorably linked with lower prevalence of DIS.

Description of the study participants

In the present study, complaints of DIS were reported by 37.1% of women and by 25.5% of men, which is similar to other Japanese studies [1]. Furthermore, since a large body of evidence also indicates there is a higher prevalence of insomnia in older women than in older men

Table 3 Association between milk and milk products consumption and DIS

	DIS			
	n(%)	Odds ratio	95% CI	
Milk consumption		**Trend *P* value = 0.041**		
Not consuming	105 (26.4)	1.00		
Low level (0–1049 ml/w)	149 (37.5)	0.66	0.37–1.18	
High level (≥1050 ml/w)	143 (36.0)	**0.47**	**0.26–0.84**	
Yogurt consumption		Trend *P* value = 0.554		
Not consuming	72 (18.1)	1.00		
Low level (0–599 g/w)	164 (41.3)	0.98	0.51–1.87	
High level (≥600 g/w)	161 (40.6)	1.27	0.66–2.45	
Cheese consumption		Trend *P* value = 0.089		
Not consuming	179 (45.1)	1.00		
Low level (0–49 g/w)	115 (29.0)	0.58	0.33–1.01	
High level (≥50 g/w)	103 (25.9)	0.61	0.34–1.08	
Total dairy consumption		Trend *P* value = 0.242		
Low level (0–805 g/w)	133 (33.5)	1.00		
Moderate level (806–1605 g/w)	132 (33.2)	1.22	0.71	2.10
High level (≥1606 g/w)	132 (33.2)	1.22	0.43	1.34

Bold numbers indicate $P < 0.05$.
DIS: difficulty initiating sleep (30 min ≥ sleep latency); 95% CI: 95% confidence interval.
Odds ratios and 95% confidence intervals were adjusted for age, gender, hypnotic use, body mass index, leisure-time physical activity and consumption of milk and milk products that were not used as independent variables.

Table 4 Associations between DIS and LTPA along with milk and milk products consumption

			DIS		
			n(%)	Odds ratio	95% CI
LTPA		*Milk*			
Not engaging	×	Not consuming	19 (4.8)	1.00	
Not engaging	×	Consuming	38 (9.6)	0.42	0.13–1.37
Engaging	×	Not consuming	86 (21.7)	0.45	0.16–1.30
Engaging	×	Consuming	254 (64.0)	**0.27**	**0.10–0.73**
LTPA		*Yogurt*			
Not engaging	×	Not consuming	14 (3.5)	1.00	
Not engaging	×	Consuming	43 (10.8)	1.08	0.30–3.96
Engaging	×	Not consuming	58 (14.6)	0.57	0.16–2.06
Engaging	×	Consuming	282 (71.0)	0.64	0.20–2.03
LTPA		*Cheese*			
Not engaging	×	Not consuming	26 (6.5)	1.00	
Not engaging	×	Consuming	31 (7.8)	0.66	0.21–2.09
Engaging	×	Not consuming	153 (38.5)	0.59	0.24–1.45
Engaging	×	Consuming	187 (47.1)	**0.34**	**0.14–0.85**
LTPA		*Total dairy*			
Not engaging	×	Low level (0–12933 g/w)	32 (8.1)	1.00	
Not engaging	×	High level (≥12934 g/w)	25 (6.3)	1.90	0.62–5.82
Engaging	×	Low level (0–12933 g/w)	167 (42.1)	0.83	0.36–1.91
Engaging	×	High level (≥12934 g/w)	173 (43.6)	0.77	0.33–1.76

Bold numbers indicate $P < 0.05$.
DIS: difficulty initiating sleep (30 min ≥ sleep latency); LTPA: leisure-time physical activity.
Odds ratios and 95% confidence intervals were adjusted for age, gender, hypnotic use, body mass index and consumption of milk and milk products that were not used as independent variables.

[26], the rates of insomnia in the study participants do not appear to be specific to our study population.

LTPA and DIS

In this study, sufficient LTPA was associated with a lower prevalence of DIS, which is in accord with a large amount of research showing that exercise improves sleep latency [10,11,27] and physically fit individuals have shorter sleep latency [28]. Although the mechanisms are not clear, earlier studies have suggested that physical activity may improve sleep due to 1) body temperature increases, 2) energy expenditure, 3) antianxiety and antidepressant effects and 4) entrainment of circadian rhythm [22,29]. The improvement we saw in DIS in our study may be a consequence of these physiological and psychological effects of LTPA.

Milk/milk products and DIS

We found a positive link between decreased prevalence of DIS and the intake of milk, but not yogurt, cheese or total dairy consumption. At present, there are divergent opinions as to the effects of milk on sleep; some researchers found that consuming milk improves sleep quality [30,31], whereas, others reported no significant effects of milk intake [14,32]. Yamamura et al. demonstrated a significant improvement in sleep efficiency after ingesting melatonin-rich milk before bedtime [14]. From results of our study, we suggest that daily intake of ordinary commercial milk may also facilitate falling asleep. Our findings confirmed the beneficial effect that commercial milk consumption can have on the prevalence of DIS, which is useful information for the older adult population.

We also found a significant linear trend between drinking milk and a lower prevalence of DIS, that is, DIS became less frequent as the amount of milk consumed increased. To our knowledge, literature concerning the association between sleep and milk/milk products intake in older people is limited. In particular, the dose–response relationship between these factors is still unclear. Hence, our findings contribute to this developing area of research.

LTPA with milk/milk products and DIS

To our knowledge, although some studies have investigated the relationship between sleep and either LTPA or milk/milk products, no prior study has evaluated the association between DIS and LTPA in conjunction with dairy intake. Our research produced interesting and novel

findings as it shows that older adults who engaged in LTPA and consumed milk or cheese reported DIS less frequently than people who neither engaged in LTPA nor consumed milk or cheese. Additionally, individuals who only engaged in LTPA or only consumed milk or cheese had higher odds ratios than people with both habits. The combination of LTPA and milk or cheese consumption may be an effective tool to help people fall asleep.

In modern society, older adults frequently complain of insomnia symptoms including difficulty falling asleep [1]. They may turn to medication to attain sleep, although medications have a greater risk of side effects e.g. falling [33] and even death [34]. Attele et al. showed that older people are often reluctant to take sleeping pills because of the negative impacts on their health [35], hence, non-pharmacological therapy with less adverse effects is needed. Along with the beneficial effects on sleep, LTPA provides other health benefits such as maintaining physical function [36] and decreased risks of mortality [37] and dementia [38]. Milk and milk products also contribute significant amounts of calcium, which plays an important role in reducing risks of osteoporosis [39] and hypertension [40]. Due to these benefits, participating in LTPA and consuming milk or dairy foods are recommended for well-being in later life. Furthermore, taking into account our findings on sleep improvement, we suggest that habitual LTPA along with milk or cheese consumption are helpful not only for maintaining general health, but also as a non-drug intervention for DIS in older adults.

Limitations

There are some limitations in our study. First, the generalization of the study's results is uncertain. Almost all study participants entered the study after receiving an invitation letter or seeing a local advertisement. Thus, the study may underestimate the proportion of older adults with poor living habits (e.g. inactive, low consumption of dairy products or insomnia) or those in poor health. Additionally, sample size was small, specifically with regards to people who did not participate in LTPA and/or consume dairy products; this limits confidence in the results. To verify our results, future investigations with larger sample sizes in unhealthy, older adults are needed. Second, we did not assess depressive symptoms, cognitive function/dementia, chronic illness (e.g. heart disease or lung disease) [41,42] or a number of medications [43] which could be potential confounders for our results. Third, since LTPA, dairy consumption and sleep were assessed via self-reported questionnaires, there may be recalling/reporting bias in our data. In particular, Silva et al. suggested that sleep latency might be overestimated by a self-reported measure [44], thus, future studies should include objective measures of sleep, such as the use of actigraphy. Fourth, because of the present study's cross-sectional design, we could not prove a causal relationship. There may be a bidirectional relationship between physical activity and sleep [45,46]. To reveal a causal relationship, a prospective cohort study and an intervention study are needed. Finally, unfortunately, we did not assess the times of day that participants' practiced LTPA and consumed milk/dairy products. The effect that exercise has on initiating sleep differs depending on when it was performed [22]. Similarly, ingesting milk and other milk products, which contain several nutrients with potential sleep-promoting properties, may be effective for falling asleep when these food items are consumed before bedtime.

Because earlier studies have revealed that LTPA and dairy intake separately have positive effects on DIS, it is reasonable to conclude from our findings that LTPA in combination with milk or cheese intake may help decrease DIS, even with the above study limitations.

Conclusions

We studied the association between LTPA in conjunction with milk or other dairy products intake and DIS in older adults. Our data revealed that higher levels of LTPA related to a lower prevalence of DIS and decreased complaints of difficulty falling asleep, in a dose–response relationship, with consumption of milk. Moreover, it is worth mentioning that people who engage in LTPA and drink milk or eat cheese may be falling asleep easily in contrast to those who do not engage in either of those activities. This information could be useful in the development of a non-pharmacological intervention for insomnia and to help promote sleep quality in older people.

Abbreviations

DIS: Difficulty Initiating Sleep; LTPA: Leisure-time Physical Activity; BMI: Body Mass Index; PSQI: Pittsburgh Sleep Quality Index.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KN. planned and designed the study, performed the statistical analysis and drafted the manuscript. KN, TK, TT, OY. and JT. collected and interpreted the data. TK and OT. supervised and coordinated the study. TK, TT, OY, JT, TK and OT. developed the manuscript. All authors read and approved the final manuscript.

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Original Article

Weight Loss Maintenance for 2 Years after a 6-Month Randomised Controlled Trial Comparing Education-Only and Group-Based Support in Japanese Adults

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Key Words
Behavioural interventions · Dietary treatment · Metabolic syndrome · Obesity management · Physical activity

Abstract
Objective: Our previous study, a 6-month randomised controlled trial, demonstrated that a group-based support promoted weight loss as compared to an education-only intervention. The purpose of this study was to examine weight loss maintenance for 2 years. ***Methods:*** Originally, 188 overweight Japanese adults, aged 40–65 years, were randomly assigned to 3 groups: control, education-only or group-based support. After the 6-month intervention, 125 participants in the education-only and the group-based support groups were followed up for 2 years. The primary outcome was the amount of weight lost. The participants were retrospectively grouped into quartiles of percent weight loss for secondary analyses. ***Results:*** At the end of follow-up, the amount of weight lost in the education-only and the group-based support groups was the same (3.3 kg). Secondary analyses using data of those who completed the study (n = 100) revealed that the participants in the highest quartile of percent weight loss significantly increased their step counts and moderate-to-vigorous physical activity compared with the lowest quartile. No significant differences were observed in the energy intake among the four groups. ***Conclusion:*** The effects of group-based support disappear within 2 years. Increasing physical activity may be a crucial factor for successful maintenance of weight loss.

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Introduction

Excess body weight is a major public health concern. Globally, the mean BMI has increased since 1980 [1]. Between 1980 and 2008, individuals in Japan had a lower BMI than individuals in other high-income countries; the mean BMI of men increased from 22.1 to 23.5 kg/m^2 and that of women from 21.3 to 23.3 kg/m^2 [1]. Obesity is associated with high mortality [2] and high incidence of cancer [3], cardiovascular disease [4], coronary heart disease [5, 6] and diabetes [6]. Since April 2008, a nationwide health screening and intervention programme specifically targeting metabolic syndrome [7] is routinely conducted in Japan; however, the obesity statistics have not improved [8].

Treatment of obesity and maintenance of weight loss are challenging. Previous studies have examined the short- and long-term effects of various behavioural weight loss interventions. Although both diet [9] and exercise interventions [10] are important for more effective weight loss, diet intervention is prioritized over exercise intervention because of its larger effect on short-term weight loss [11]. A meta-analysis of changes in BMI after weight loss phases suggested that approximately 0.02–0.03 kg/m^2 of the weight lost per month is regained [9]. To attain successful weight loss maintenance, a few weight maintenance programmes have been developed [12, 13].

In a previous 6-month randomised controlled trial (RCT), we focused on providing educational materials (e.g., textbooks, notebooks and a pedometer) and implementing group-based support as effective individual components of a weight loss programme [14]. The weight lost in 6 months in the education-only group was 4.7 kg (95% confidence interval (CI) 3.7–5.7 kg) and was significantly larger than that in the control group (2.9 kg; 95% CI 1.9–3.9 kg), which was provided only a single motivational lecture. Weight loss in the group-based support group was 7.7 kg (95% CI 6.7–8.8 kg) and was significantly larger than that in the control and the education-only groups. The RCT provided evidence that both educational materials and group-based support were effective components of a weight loss programme. However, no weight loss maintenance was observed after the intervention period.

Thus, in the present study, we conducted a 2-year, non-interventional, observational follow-up and annual follow-up measurements for participants in the education-only and the group-based support groups. Due to ethical concerns, we provided group-based support to the control group after the 6-month intervention period and did not include them in the follow-up measurements. A certain amount of weight regain might be inevitable because of the absence of weight maintenance programmes. However, a recent study demonstrated the effectiveness of motivational interviewing intervention at 12 months post intervention [15]. If the superiority of group-based support is conserved during the maintenance phase, it could be an essential approach on both short-term and long-term bases. However, if such superiority is not observed, a weight maintenance programme might be essential to maintain the effect of group-based support; thus, the factors responsible for successful weight loss maintenance could be explored. Therefore, in this study, we conducted a 2-year follow-up study, after completion of the 6-month intervention period, to examine and compare the effects of group-based support and education-only on weight loss maintenance.

Material and Methods

Study Design and Participants

The randomised trial method has been previously described [14, 16], and the protocol was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN000001259). In brief, we conducted a 30-month RCT comprising a 6-month intervention between April and October 2009 and a 2-year, follow-up non-intervention that continued until October 2011; the study was conducted at the

Mito Kyodo General Hospital in Ibaraki, Japan. During the intervention phase, the participants were randomly assigned to one of the following 3 groups: control, education-only or group-based support. Considering an intervention-related group difference of 2.5 ± 4.0 kg in the amount of weight lost at the end of 6 months, a two-sided alpha value of 0.0167 (with a Bonferroni's adjustment for post hoc tests), a power of 80% and an average attrition rate of 10%, the required sample size was estimated to be more than 60 participants in each group (180 participants in total). Accordingly, 188 adults (145 women and 43 men) participated in the present study.

After the intervention phase had ended, the participants in the education-only and the group-based support groups underwent annual follow-up measurements during a 2-year follow-up period. Owing to ethical concerns, we provided group-based support to participants in the control group after the 6-month intervention period and did not include them in the follow-up measurements. Finally, 125 overweight adults (92 women and 33 men) from the education-only and the group-based support groups (62 and 63 adults, respectively) underwent follow-up. Assuming a two-sided alpha value of 0.05, the number of participants in this study yielded 93% power to detect a group difference of 2.5 ± 4.0 kg in the amount of weight lost at the end of 2-year follow-up. The participants received no financial compensation or gifts. The protocol was approved by the ethical committee of Mito Kyodo General Hospital and by the Institutional Review Board of the University of Tsukuba.

Participants were recruited through newspaper advertisements. The eligibility criteria for the participants included an age of 40–65 years, a BMI of 25–40 kg/m^2 and the presence of at least one of the following components involved in the diagnosis of metabolic syndrome, according to the Japanese criteria [17]: i) waist circumference ≥ 85 cm in men or ≥ 90 cm in women, ii) systolic blood pressure ≥ 130 mm Hg, iii) diastolic blood pressure ≥ 85 mm Hg, iv) triglyceride level ≥ 150 mg/dl (1.70 mmol/l), v) high-density lipoprotein cholesterol level < 40 mg/dl (1.04 mmol/l) and vi) fasting plasma glucose level ≥ 110 mg/dl (6.11 mmol/l). The age and BMI ranges were based on the target for active support in the Japanese national intervention programme specifically targeted at metabolic syndrome [7]. The criteria for ineligibility included current or planned pregnancy, past history of coronary disease or stroke, and drug treatment for diabetes to avoid a potential influence on weight change [9]. To avoid a ripple effect on weight loss [18], participants whose cohabiting family member(s) participated in this study were also considered ineligible.

Interventions

After taking the baseline measurements in which the participants were assessed for eligibility, all participants attended a 2-hour, group-based, single motivational lecture conducted by an investigator (YN). The lecture consisted of the introduction of the Japanese national health screening and intervention programme conducted since April 2008 that specifically target at metabolic syndrome [7], combined cardiovascular risk factors and the outcome [19], and the target value for improving metabolic syndrome [20]. The participants also received typical weight control instructions on diet, exercise and behavioural changes. The recommendations included a calorie-restricted diet of 1,200 and 1,600 kcal/day for women and men, respectively [20–22] and a minimum of 1,000 kcal/week of increased physical activity [23]. All participants were encouraged to self-monitor their body weight every day.

After the motivational lecture, the participants were randomly assigned to one of the 3 groups using simple randomisation procedures involving computerised random numbers. The allocation data were generated by an investigator (MO) who had no contact with the participants or other staff members, and the data were maintained at a central secure location until completion of the motivational lecture.

At week 1, the participants in the education-only and the group-based support groups attended a group-based, 2-hour session in which they were provided with educational materials such as textbooks and notebooks containing information on daily diet and other lifestyle-related issues. The content of the textbooks and notebooks was based on the prior work of the investigators [20, 24]. The dietary programme was based on the Four-Food-Group Point Method [14, 25]. Participants in the education-only and the group-based support groups were encouraged to modify their diet according to the information in the provided textbooks and were instructed to record their body weight, the content of meals and the daily step counts in the provided notebook. A pedometer (FB-720; Tanita, Tokyo, Japan) was also provided to motivate the participants to increase their physical activity [26].

The participants in the group-based support group attended a group-based, 2-hour session at weeks 2, 4, 6, 10, 14, 18 and 22. The frequency of support meeting was suggested to be one of the independent predictors of weight change [9]. In the present study, in the initial part of the intervention period, we reduced the frequency of the support meetings from every 2 weeks to every 4 weeks in order to provide the partici-

Obes Facts 2014;7:376–387
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pants information on the basics of changing behaviours. Each group-based support meeting was conducted by 3 staff members who were trained by the investigators (YN and KT). One staff member conducted lectures to explain the content of the textbooks, and 2 other staff members reviewed the participants' notebooks and advised them on their diet and other lifestyle factors at each session.

Outcome Measures

Data were collected at baseline and at months 3, 6, 18 and 30 in the hospital by trained hospital staff members who were blinded to the treatment assignment process.

The primary outcome measure was the amount of weight lost from baseline to 30 months. Wing and Hill [27] defined successful long-term weight loss maintenance as intentionally losing at least 10% of initial body weight and keeping it off for at least 1 year. According to the definition, the authors pre-determined the primary outcome as the 30-month changes from baseline. Weight was measured to the nearest 0.05 kg using a calibrated digital scale (WB-150; Tanita). The participants wore light clothes and no shoes for the weight measurement. Height was measured to the nearest 0.1 cm on a wall-mounted stadiometer at baseline to estimate the BMI.

The secondary outcome measures were waist circumference, systolic and diastolic blood pressures, triglyceride level, high-density lipoprotein cholesterol level and fasting plasma glucose level. The waist circumference was measured to the nearest 0.1 cm at the umbilicus level using a flexible plastic tape, with the participants in the standing position. Blood pressure was measured using a manual sphygmomanometer, with the participants maintained in the seated position after a 20-min rest period. Two readings of systolic and diastolic blood pressures were recorded, and the average value was used for data analysis [28]. Approximately 10 ml of blood was drawn from each participant (between 10:30 and 11:30 am) after a fasting period of more than 12 h. Fresh samples were used for enzymatic analysis of triglycerides, and fasting plasma glucose level was assayed using glucose oxidase. The serum high-density lipoprotein cholesterol level was measured using heparin-manganese precipitation. Venous blood was analysed by an independent laboratory (Kotobiken Medical Laboratories, Ibaraki, Japan).

We measured the energy intake by using 3-day food records and physical activity using an Active style Pro three-axis accelerometer (HJA-350IT; Omron Healthcare, Kyoto, Japan). The participants were asked to record everything they consumed for 3 days, i.e., 2 weekdays and 1 weekend day. Foods were measured using standard measuring cups, spoons and digital scales. To ensure overall comparability, a skilled nutritionist who was blinded to the treatment assignment process analysed all of the food records. Furthermore, the participants were asked to wear the accelerometer on their waists throughout the day for 14 days. The accelerometer counted daily steps and estimated the intensity of physical activity, expressed as metabolic equivalents [29, 30]. The devices were not worn when sleeping, while engaged in a water-based activity (e.g., bathing or swimming) or while participating in activities such as contact sports for safety reasons. Records obtained were defined as valid when a device was worn for at least 10 h/day [31]. If no acceleration signal was obtained over a 10-second time interval for 20 consecutive min or more, the period was defined as 'non-wear' [32]. When valid records were collected for more than 2 weekdays and 1 weekend day, we calculated the mean of the daily step counts and the total daily minutes of moderate-to-vigorous (≥3 metabolic equivalents) physical activity (MVPA).

Statistical Analysis

The purpose of the initial part (6 months) of the present RCT was to examine the effectiveness of education-only and groups-based support using controls. Our previous study [14] used an intention-to-treat analysis, with the missing data replaced by the last observation carried forward. In the present follow-up study, we aimed at comparing the amount of weight lost from baseline to the end of follow-up in the education-only and the group-based support groups. Thus, an intention-to-treat analysis, with the missing data replaced by baseline observation carried forward, was applied to the measures of body weight and related outcome variables. An unpaired t test was used to examine the statistical significance of between-group differences, and a χ^2 test was used to compare proportions. The participants were retrospectively grouped into quartiles of percent changes of initial body weight from baseline to the end of follow-up for secondary analyses, in order to explore the success factors for weight loss maintenance. Differences among the quartiles were examined using one-way analysis of variance for continuous variables and χ^2 test for categorical variables. Data were analysed using IBM SPSS Statistics 20 (SPSS Inc., Chicago, IL, USA), with the level of statistical significance set at 5%.

Obes Facts 2014;7:376–387
DOI: 10.1159/000369913

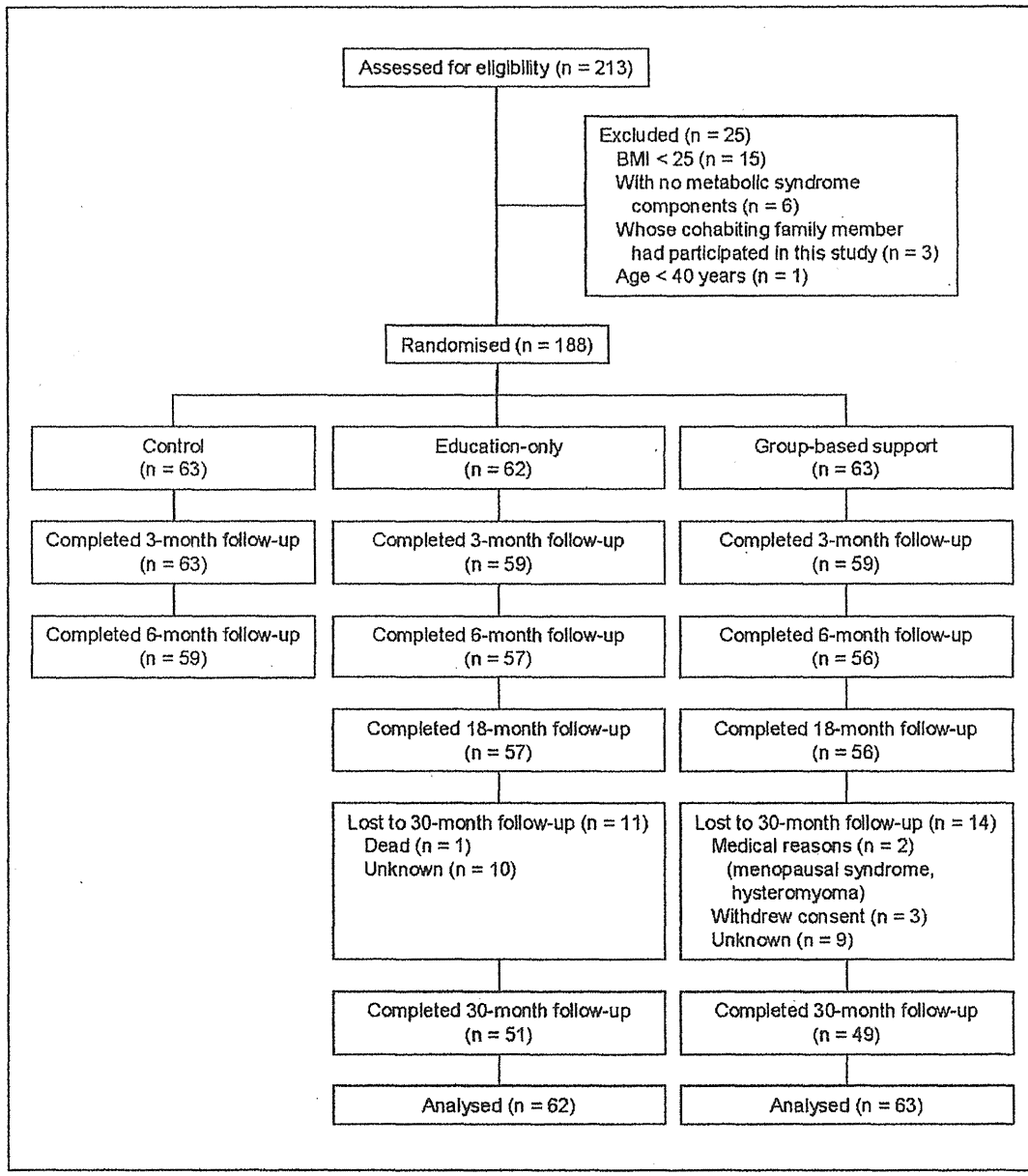

Fig. 1. Flow diagram of the participant progress through the 30-month randomised trial.

Results

Participants

Figure 1 shows the number of participants through the course of the study. We recruited 222 participants between November 2008 and March 2009 and assessed 213 participants for eligibility (9 did not attend). After excluding 25 ineligible participants, 188 adults (145 women and 43 men) were enrolled in the intervention phase. After the intervention phase, participants in the education-only and the group-based support groups were followed up for 2 years. Table 1 provides the baseline characteristics of the followed-up participants. Signif-

Obes Facts 2014;7:376–387
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Table 1. Baseline characteristics of followed-up participants by treatment assignment[a]

	Education-only (n = 62)	Group-based support (n = 63)	p-value[b]
Age, years	51.7 (6.8)	50.7 (6.7)	0.414
Women, no. (%)	41 (66)	51 (81)	0.059
Current smoker, no. (%)	3 (5)	3 (5)	0.984
Lipid-lowering therapy, no. (%)	10 (16)	3 (5)	0.033
Antihypertensive therapy, no. (%)	16 (26)	15 (24)	0.796
Height, cm	160.0 (9.0)	159.1 (7.2)	0.577
Weight, kg	74.9 (12.1)	73.5 (9.9)	0.476
BMI, kg/m^2	29.2 (3.8)	29.0 (3.0)	0.670
Waist circumference, cm	100.7 (7.9)	99.2 (7.3)	0.269
Systolic blood pressure, mm Hg	131.2 (14.5)	131.9 (16.4)	0.793
Diastolic blood pressure, mm Hg	80.2 (7.4)	79.9 (10.2)	0.849
Triglycerides, mmol/l	1.57 (0.71)	1.26 (0.59)	0.009
HDL cholesterol, mmol/l	1.39 (0.34)	1.49 (0.31)	0.093
Fasting plasma glucose, mmol/l	5.50 (0.96)	5.25 (0.59)	0.079
Energy intake, kcal/day	2,181 (417)	2,169 (414)	0.880
Step counts, step/day[c]	6,198 (2,740)	6,435 (3,016)	0.650
MVPA, min/day[c]	86 (30)	93 (35)	0.191

HDL = High-density lipoprotein; MVPA = moderate-to-vigorous physical activity.
[a]Data are presented as mean (standard deviation) unless otherwise specified.
[b]p value of unpaired *t*-test or χ^2 test at baseline between groups.
[c]Data from 123 eligible participants were available (61 and 62 in the education-only and the group-based support groups, respectively).

icant group differences were observed in the number of participants who were receiving lipid-lowering therapy and in the triglyceride levels. The attrition rates were 9.6% (12/125) and 20.0% (25/125) at months 18 and 30, respectively (fig. 1). The numbers of individuals lost to follow-up at 30 months were similar in both groups (p = 0.531). The medical reasons for attrition during 30 months included menopausal syndrome and hysteromyoma that developed during the intervention phase. One participant died during the follow-up period, but the cause was not confirmed. No clinically significant adverse events related to participation in the trial occurred, as judged by the investigators.

Intention-to-Treat Analyses

The pattern of weight change is shown in figure 2. The mean weight loss during the 6-month intervention phase in the education-only and the group-based support groups was 4.7 kg (95% CI 3.7–5.7 kg) and 7.7 kg (95% CI 6.7–8.8 kg) respectively. The weight difference between the 2 groups reduced by half at 1 year (3.0 kg at 6 months to 1.5 kg at the 1 year) and disappeared at 2 years (0.0 kg; 95% CI –1.7 to 1.8 kg). Table 2 shows changes in the secondary outcome measures, energy intake and physical activity. Most values (weight, BMI, waist circumference, systolic and diastolic blood pressures, high-density lipoprotein cholesterol level and energy intake) improved at 30 months as compared to the baseline values in each group, whereas no significant differences were observed between the 2 groups with respect to all variables. The stratified analysis by gender showed consistent results (data not shown).

Secondary Analyses

100 participants who completed the 30-month assessment were retrospectively grouped into quartiles of percent weight loss from baseline to the end of follow-up for secondary

Obes Facts 2014;7:376–387
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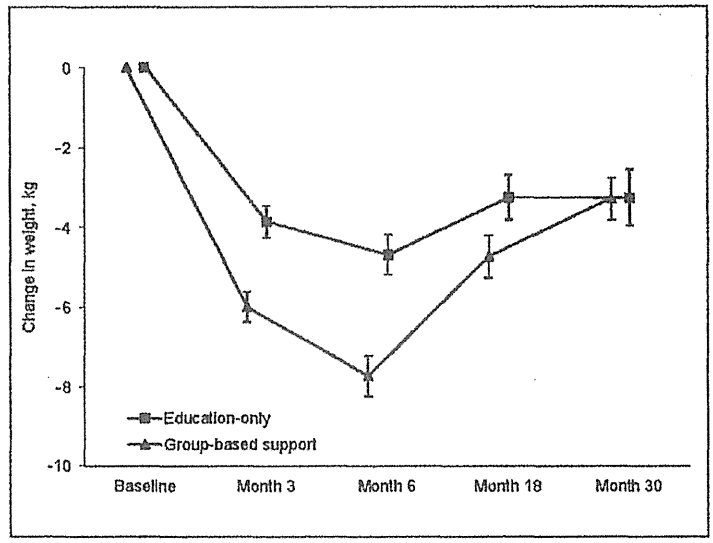

Fig. 2. Pattern of change in body weight by treatment assignment. Each data point represents the mean value for all randomised participants, with missing data replaced by the last observation carried forward at months 3 and 6 and by the baseline observation carried forward at months 18 and 30. Error bars indicate standard errors. Points and error bars are jittered horizontally to improve visibility.

analyses (table 3). Baseline characteristics were not significantly different among the groups. Significant differences were observed in 30-month changes in waist circumference, systolic blood pressure, triglyceride level and high-density lipoprotein cholesterol level. The participants in the 4th quartile group who accomplished the most successful weight loss maintenance increased their step counts by 2,607 steps, which was higher than that observed in the other groups ($p < 0.05$ by Bonferroni's post hoc test). They also increased their MVPA by 21 min/day, which was higher than that in the 1st and 3rd quartile groups ($p < 0.05$ by Bonferroni's post hoc test). In contrast to physical activity, 30-month changes in energy intake were not significantly different among the groups ($p = 0.602$).

Discussion

The initial part of the present RCT (6-month intervention period) revealed that group-based support is an effective method for promoting weight loss on a short-term basis. However, the present follow-up study revealed that the short-term effects disappeared after a 2-year non-intervention period.

A meta-analysis of changes in BMI after the weight loss phase suggests a regain of approximately 0.02–0.03 kg/m^2 per month during the maintenance phase [9]. The present study involved a 2-year (24-month) follow-up period. Accordingly, a regain of 0.48–0.72 kg/m^2 was estimated. In fact, the BMI of participants in the education-only group increased by 0.5 kg/m^2 during the maintenance phase, which approximately equalled the estimated value. On the other hand, the BMI of the group-based support group increased by 1.7 kg/m^2 during the maintenance phase. The regain in the group-based support group was approximately 3 times greater than that in the education-only group.

From the abovementioned data, it is evident that the group-based support was not effective after the 2-year follow-up period. This could be because group-based support appears to allow participants to interact with each other and provides short-term benefits in terms of achieving weight loss [33]. Further, the staff members motivated the participants. Although this is a strength of group-based support, it turns into a weakness if the programme is not continued. The intensive support might increase dependence on the staff members, and

Obesity Facts
The European Journal of Obesity
Obes Facts 2014;7:376–387
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Table 2. Changes in primary and secondary outcome measures, energy intake, and physical activity by intention-to-treat analysis[a]

	Education-only (n = 62)				Group-based support (n = 63)				p-value[b]
	baseline	month 6	month 30	30-month change	baseline	month 6	month 30	30-month change	
Weight, kg	74.9 (12.1)	70.2 (12.6)	71.6 (12.5)	−3.3 (−4.7 to −1.9)	73.5 (9.9)	65.7 (9.5)	70.2 (10.6)	−3.3 (−4.4 to −2.2)	0.967
BMI, kg/m^2	29.2 (3.8)	27.4 (4.0)	28.0 (4.0)	−1.3 (−1.8 to −0.7)	29.0 (3.0)	25.9 (3.0)	27.7 (3.5)	−1.3 (−1.7 to −0.9)	0.945
WC, cm	100.7 (7.9)	96.0 (9.1)	96.1 (9.1)	−4.6 (−6.1 to −3.0)	99.2 (7.3)	91.1 (8.4)	94.3 (8.5)	−4.9 (−6.3 to −3.4)	0.773
SBP, mm Hg	131.2 (14.5)	120.5 (13.3)	124.3 (13.3)	−6.9 (−10.1 to −3.7)	131.9 (16.4)	119.6 (18.1)	126.4 (17.5)	−5.5 (−8.6 to −2.3)	0.530
DBP, mm Hg	80.2 (7.4)	73.2 (9.1)	74.9 (8.1)	−5.3 (−7.3 to −3.3)	79.9 (10.2)	71.3 (9.7)	76.0 (10.3)	−3.9 (−5.9 to −1.8)	0.322
TG, mmol/l	1.57 (0.71)	1.23 (0.68)	1.36 (0.70)	−0.21 (−0.35 to −0.07)	1.26 (0.59)	0.95 (0.43)	1.20 (0.65)	−0.06 (−0.18 to 0.06)	0.113
HDL-C, mmol/l	1.39 (0.34)	1.44 (0.35)	1.49 (0.39)	0.10 (0.04 to 0.17)	1.49 (0.31)	1.56 (0.35)	1.55 (0.38)	0.06 (0.00 to 0.13)	0.378
FPG, mmol/l	5.50 (0.96)	5.16 (0.82)	5.36 (0.90)	−0.14 (−0.29 to −0.01)	5.25 (0.59)	4.91 (0.38)	5.23 (0.56)	−0.01 (−0.08 to 0.06)	0.084
Energy intake, kcal/day	2,181 (417)	1,799 (440)	1,983 (416)	−197 (−285 to −110)	2,169 (414)	1,524 (354)	1,918 (396)	−251 (−339 to −163)	0.384
Step counts, step/day[c]	6,198 (2,740)	7,468 (3,676)	6,890 (3,455)	692 (215 to 1,170)	6,435 (3,016)	7,525 (3,326)	6,916 (4310)	481 (−367 to 1,330)	0.667
MVPA, min/day[c]	86 (30)	96 (37)	90 (38)	5 (−1 to 11)	93 (35)	99 (37)	95 (45)	2 (−6 to 10)	0.565

DBP = Diastolic blood pressure; FPG = fasting plasma glucose; HDL-C = high-density lipoprotein cholesterol; MVPA = moderate-to-vigorous physical activity; SBP = systolic blood pressure; TG = triglycerides; WC = waist circumference.

[a]Data at baseline and months 6 and 30 are presented as mean (standard deviation). Changes from baseline to month 30 are presented as mean (95% confidence interval).

[b]p value of unpaired *t*-test for 30-month change between groups.

[c]Data from 123 eligible participants were available (61 and 62 in the education-only and the group-based support groups, respectively).

Obes Facts 2014;7:376–387
DOI: 10.1159/000369913

Table 3. Baseline characteristics and changes in outcome measures based on quartiles of percent weight loss[a]

	Percent weight loss at 30 months				p-value[b]
	1st quartile (n = 25)	2nd quartile (n = 25)	3rd quartile (n = 25)	4th quartile (n = 25)	
Age, years	50.6 (6.6)	51.3 (7.0)	52.4 (7.9)	51.0 (6.2)	0.813
Women, no. (%)	16 (64)	21 (84)	20 (80)	16 (64)	0.230
Group-based support, no. (%)	10 (40)	14 (56)	12 (48)	13 (52)	0.704
Current smoker, no. (%)	1 (4)	1 (4)	2 (8)	0 (0)	0.414
Lipid-lowering therapy, no. (%)	2 (8)	3 (12)	4 (16)	2 (8)	0.778
Antihypertensive therapy, no. (%)	5 (20)	8 (32)	6 (24)	4 (16)	0.582
Height, cm	162.1 (9.7)	157.5 (5.8)	157.5 (6.6)	161.4 (8.2)	0.074
Weight, kg					
Baseline	75.0 (12.8)	73.0 (8.2)	74.1 (12.0)	74.3 (10.6)	0.931
Changes	+1.4 (1.6)	−1.8 (0.7)	−5.0 (1.8)	−10.9 (4.2)	<0.001
BMI, kg/m^2					
Baseline	28.4 (2.9)	29.4 (3.7)	29.8 (3.9)	28.4 (2.3)	0.312
Changes	+0.5 (0.6)	−0.7 (0.2)	−2.0 (0.6)	−4.2 (1.5)	<0.001
WC, cm					
Baseline	99.4 (7.0)	100.2 (8.8)	101.8 (7.8)	98.8 (5.3)	0.500
Changes	−0.4 (4.4)	−3.6 (3.1)	−7.4 (3.3)	−12.1 (5.2)	<0.001
SBP, mm Hg					
Baseline	128.5 (16.6)	132.6 (12.7)	136.3 (16.5)	129.3 (13.3)	0.242
Changes	−4.7 (9.9)	−3.2 (14.9)	−11.0 (14.4)	−12.0 (13.0)	0.045
DBP, mm Hg					
Baseline	78.2 (8.2)	80.9 (7.6)	79.8 (7.7)	80.2 (9.2)	0.686
Changes	−4.2 (7.9)	−5.7 (9.6)	−4.4 (7.3)	−8.7 (8.9)	0.222
TG, mmol/l					
Baseline	1.57 (0.80)	1.29 (0.51)	1.34 (0.50)	1.45 (0.63)	0.397
Changes	−0.08 (0.52)	+0.00 (0.51)	−0.07 (0.58)	−0.52 (0.58)	0.004
HDL-C, mmol/l					
Baseline	1.41 (0.32)	1.49 (0.28)	1.48 (0.28)	1.41 (0.40)	0.738
Changes	+0.02 (0.21)	+0.00 (0.18)	+0.04 (0.24)	+0.36 (0.30)	<0.001
FPG, mmol/l					
Baseline	5.28 (0.90)	5.34 (0.58)	5.62 (1.13)	5.31 (0.65)	0.460
Changes	+0.03 (0.30)	−0.09 (0.37)	−0.07 (0.56)	−0.27 (0.63)	0.191
Energy intake, kcal/day					
Baseline	2,189 (467)	2,082 (321)	2,118 (318)	2,223 (488)	0.602
Changes	−226 (443)	−219 (274)	−331 (386)	−345 (352)	0.492
Step counts, step/day[c]					
Baseline	6,210 (2,748)	6,784 (2,727)	6,167 (3,076)	6,925 (3,516)	0.752
Changes	−33 (1,142)	+379 (2,924)	+65 (2,705)	+2,607 (4,000)	0.005
MVPA, min/day[c]					
Baseline	87 (33)	93 (28)	91 (36)	94 (35)	0.883
Changes	−4 (18)	+5 (28)	−3 (30)	+21 (41)	0.018

DBP = Diastolic blood pressure; FPG = fasting plasma glucose; HDL-C = high-density lipoprotein cholesterol; MVPA = moderate-to-vigorous physical activity; SBP = systolic blood pressure; TG = triglycerides; WC = waist circumference.

[a]Data are presented as mean (standard deviation) unless otherwise specified.

[b]p value of one-way analysis of variance or χ^2 test among groups.

[c]Data from 97 eligible participants were available (25, 25, 23 and 24 in the 1st, 2nd, 3rd, and 4th quartile groups, respectively).

Obes Facts 2014;7:376–387
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the participants become prone to regaining weight. Therefore, the implementation of weight maintenance programmes after a group-based weight loss intervention might be essential to achieve successful weight loss maintenance.

The secondary analyses in the present study revealed that the participants who successfully maintained their weight loss over 30 months (highest quartile of percent weight loss) increased their step counts (2,607 steps/day) significantly more than those in the other groups (1st to 3rd quartiles). Furthermore, participants in the highest quartile group spent much more time in MVPA (21 min/day) than those in the 1st and 3rd quartile groups. Conversely, no significant difference was observed in the change in energy intake among the groups. These results suggest that increasing physical activity may be a crucial factor for successfully maintaining weight loss.

The American College of Sports Medicine Position Stand [34] recommended 250 min/week of physical activity for weight loss maintenance. However, the position stand also stated that no evidence from well-designed RCTs exists to judge the effectiveness of physical activity for prevention of weight regain after weight loss. A few previous studies facilitating maintenance of weight loss by focusing on increasing physical activity [35, 36] concluded that the prescribed physical activity intervention did not influence the weight loss outcomes, but post hoc analysis showed that individuals sustaining successful weight loss performed more physical activity. Although improving adherence to the prescribed physical activity interventions is difficult, the effectiveness of increasing physical activity during the weight maintenance phase should be closely examined in future studies.

The major strength of this study is that it was a carefully designed long-term RCT with a relatively good retention rate. This study also had a few limitations. First, the study population included only Japanese participants, aged 40–65 years, who were willing and motivated, which limits the generalisation of the results. Additionally, most participants were women. Second, we could not follow up the control group of the initial part of the present RCT due to ethical concerns. Moreover, the attrition rate was 20.0% at 30 months. Although this figure is modest, an intention-to-treat analysis would have produced overly conservative results in hypothesis testing. Finally, secondary analyses suggest that increasing physical activity may be effective in successfully maintaining weight loss; however, RCTs are needed to demonstrate the effectiveness of the concept.

In conclusion, group-based support is an effective method for promoting weight loss on a short-term basis, but the effect disappears in the absence of weight maintenance programmes. For successful weight loss maintenance, additional approaches during the weight maintenance phase are necessary. Increasing physical activity may be crucial for successfully maintaining weight loss. Further RCTs are required to show that increasing physical activity can contribute to weight loss maintenance.

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