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Title:

Effect of a financial incentive on increasing the number of daily walking steps among community-dwelling adults in Japan: A randomized controlled trial

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ABSTRACT

Objective: To our knowledge, only two randomized controlled trials (RCTs) have examined the effects of financial incentives on the mean number of daily walking steps among community-dwelling adults, and the results were inconsistent. The aim of the present study was to investigate the effect of a financial incentive on the number of daily steps among community-dwelling adults in Japan.

Study design: Two-arm, parallel-group RCT.

Setting/participants: We recruited physically inactive community-dwelling adults in Sendai city, Japan. Eligible participants were randomly allocated to an intervention or a wait-list control group. Pedometers were used to assess the mean number of daily steps in three periods: baseline (1–3 weeks), intervention (4–6 weeks), and follow-up (7–9 weeks).

Intervention: The intervention group was offered a financial incentive (shopping points) to meet the target number of increased daily steps in the intervention period.

Main outcome measures: The primary outcome was an increase in the mean number of daily steps in the intervention and follow-up periods compared with baseline.

Results: Seventy-two participants (69.4% female; mean age, 61.2 ± 16.2 years; mean number of daily steps at baseline, 6364 ± 2804) were randomized

to the intervention (n = 36) and control groups (n = 36). During the intervention period, the increase in mean daily steps was significantly higher in the intervention than in the control group (1650 vs. 514, respectively; $p < 0.001$). In addition, compared with the controls, a significantly higher proportion of participants in the intervention group showed an increase of ≥ 1000 in mean daily steps (69.4% vs. 30.6%, respectively; odds ratio = 5.17, 95% confidence interval = 1.89, 14.08).

Conclusions: Present results suggest that financial incentives are effective for promoting short-term increases in physical activity.

Trial Registration: UMIN000033276

Keywords: financial incentive, walking steps, randomized controlled trial, Japan

Strengths and limitations of this study

- This study is the first to offer a noncash financial incentive
- The present study would be first Asian trial.
- The intervention involved only one type of financial incentive.
- Only the effect of a short-term intervention (over 3 weeks) was evaluated.

Introduction

Physical inactivity is a serious problem all around the world. According to the Global Action Plan on Physical Activity 2018–2030[1], one in four adults (1.4 billion people worldwide) do not meet the World Health Organization (WHO) recommendations for physical activity levels. Therefore, physical inactivity imposes a substantial burden on health care costs. For example, in the US, failure to meet recommended physical activity levels has been associated with approximately 117 billion USD in annual health care costs and 10% of all premature mortality.[2 3] To help solve these problems, the WHO and national governments have developed various policies to promote higher levels of physical activity.[1-5]

A systematic review (meta-analysis) has suggested that financial incentives are effective for promoting health behaviors such as smoking cessation, vaccinations, and participation in cancer screening.[6] To our knowledge, only two randomized controlled trials (RCTs) have been conducted to examine the effects of financial incentives on the number of daily walking steps, and the results were not consistent.[7 8] One study reported that the use of individual financial incentives could increase the number of daily walking steps among community-dwelling older adults aged ≥ 65 years[7], and the other that individual financial incentives were not effective for increasing the number of daily walking steps among employees aged ≥ 18 years.[8] This inconsistency

may have been the results of differences in methodologies, the ages of the participants, the intervention periods, or the amount of incentives. Therefore, the aim of the present study was to examine the effects of a financial incentive on the number of daily walking steps among community-dwelling adults in Japan.

Methods

Study design

The protocol of the present study has been reported in detail elsewhere.[9] Briefly, this was a single-center, single-blind, parallel-group RCT in which participants were randomly assigned to an intervention or a control group. The protocol was approved by the ethics committee of Tohoku University Graduate School of Medicine (No. 2018-1-171), and written informed consent was obtained from all participants. The present study was also registered in the University Hospital Medical Information Network (No. UMIN000033276).

Participants

In August 2018, leaflets were distributed to each house in the Nakayama area of Aoba-ku in Sendai city, Japan. Applicants who met the inclusion criteria could apply through an online application, fax, or telephone.

Inclusion and exclusion criteria

Individuals could apply for participation in the present study if they met all of the following inclusion criteria: 1) adult (aged ≥ 20 years) living in the Nakayama area; 2) possession of a community development integrated circuit (IC) card in the Nakayama area (*Nakayama Machi-dukuri IC Card*); and 3)

ability to walk unaided without using a cane, walker, or wheelchair. Individuals who met any of the following exclusion criteria could not participate in the study: 1) physical activity restricted by a physician; 2) history of heart attack or stroke within the last 6 months; 3) blood pressure exceeding 180 mmHg systolic or 110 mmHg diastolic; or 4) already habitually exercising (task of ≥ 4 metabolic equivalents) more than twice per week.

Power and sample size

Based on a previous study carried out in 2013[7], we assumed that an average difference of 1302 steps would be achieved in the intervention period (4–6 weeks) by offering a financial incentive of 2000 JPY and setting the standard deviation (SD) at 1711. When an α error of 0.05 and a statistical power of 0.90 was applied, the minimum sample size was 74 persons (37 persons per group). When an α error of 0.05 and a statistical power of 0.80 were applied with this sample size, a mean difference of ≥ 1,130 steps was considered statistically significant.

Study procedure

The flow of the study procedure is shown in **Fig. 1**. In a briefing session held in September 2018, the researchers rechecked the inclusion and exclusion

criteria for each applicant. All participants selected provided informed consent to participate in the study. At the briefing session, each participant was provided with a pedometer (FS-800; ESTERA Corp., Saitama, Japan) containing a three-axis acceleration sensor. The number of daily walking steps at baseline was measured in the first 3 weeks of the study period (1–3 weeks) for all participants.

Randomization

After confirming eligibility, the enrolled participants were assigned to one of the two groups (1:1 allocation) based on the permuted block method by computer-generated randomization. The allocation sequence was managed by two experienced random assignment researchers.

Blinding

The assignment data could only be accessed by the random assignment researchers; all other staffs were blinded to the random assignments. In addition, all statistical analyses were blinded to the assignments. The random assignment researchers were not involved in the statistical analyses.

Intervention

The intervention was a financial incentive in the form of shopping points that

could be redeemed at 14 stores in the study area. The following two kinds of financial incentives were offered:

1. If the mean number of daily walking steps in the intervention period was ≥ 6000, shopping points worth 1000 JPY were awarded.
2. If the mean number of daily walking steps during the intervention period increased by ≥ 1000 from baseline, shopping points worth 1000 JPY were awarded.

Based on the exchange rate on August 31, 2018, 2000 JPY was equivalent to 18 USD. During the intervention period (4–6 weeks), the intervention group could gain the financial incentive if they achieved their daily step goals. After the end of the study (i.e., after 10–12 weeks), the wait-list control group could also gain the financial incentive.

Measurements

The participants' baseline characteristics were assessed at the date of the briefing session. Interviews with trained interviewers were conducted to obtain information regarding medical history, frailty (the Kihon checklist) [10-14], physical activity level[15 16], transportation when going out, education level[17], work, subjective economic status, time affluence (having spare time) [18], body height, weight, pain, and falling. Blood pressure was also measured using an automated sphygmomanometer (HEM-1040; Omron, Kyoto, Japan).

Outcome measurements

Daily step evaluations were carried out and feedback was collected every 3 weeks. All participants were instructed to wear the pedometer while awake every day during the study period (9 weeks).

The primary outcome was the mean increase in the number of daily steps compared with that at baseline.

The secondary outcomes were: 1) an increase in the number of daily steps by ≥ 1000 at 4–6 or 7–9 weeks from baseline; 2) incident falls at 4–6 or 7–9 weeks; and 3) incident pain at 4–6 or 7–9 weeks.

Statistical analyses

In regard to the primary outcome, the *t*-test was applied to examine whether the mean increases and rate of change in the number of daily steps at 4–6 and 7–9 weeks from baseline differed significantly between the intervention and control groups.

In regard to the secondary outcomes, logistic regression models were applied to examine whether the proportions of participants with an increase of ≥ 1000 steps were significantly different, and to assess the probabilities of incident falls and incident pain. Odds ratios (ORs) and 95% confidence intervals (CIs) were also estimated.

In addition, stratified analyses were conducted to check for any differences in the number of daily steps in terms of sex, age, frailty, physical activity level, transportation when going out, education level, work, subjective economic status, time affluence, and obesity.

All analyses were performed using IBM SPSS Statistics (version 25; IBM SPSS, Chicago, IL, USA).

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our trial.

Results

The mean age (SD) of the participants (69.4% female) was 61.2 (16.2) years, and 30.6% had an undergraduate or graduate degree.

At baseline, the mean numbers of daily steps (SD) in the intervention and control groups were 6859 (3,223) and 5869 (2249), respectively; this difference was not significant (p = 0.135) (**Table 1**). Participants in the intervention group were significantly more likely to have pain than those in the control group (p = 0.011). No significant differences in age, sex, blood pressure, history of disease, frailty, physical activity level, transportation, educational level, employment, subjective household economic status, subjective time affluence, or body mass index (BMI) were found between the two groups.

All 72 participants completed the intervention (4–6 weeks) and follow-up periods (7–9 weeks). Comparisons of steps between the baseline and intervention or follow-up periods in the intervention and control groups are shown in **Fig. 2**. The mean increases in the numbers of daily steps from baseline to the intervention period in the intervention and control groups were 1650 and 514, respectively, indicating a significant difference between groups (p < 0.001). The mean increase rate in the number of daily steps from baseline to the intervention period was significantly higher in the intervention than in the control group (31.0% vs. 9.1%, respectively; p <

0.001) (**Supplementary Table 1**). The mean increase in the number of daily steps from baseline to the follow-up period was larger in the intervention than in the control group (933 vs. 556 steps, respectively) (**Fig. 2**); however, no significant difference was observed between groups (p = 0.311). Regarding the mean increase rate in the number of daily steps from baseline to the follow-up period, no significant difference was found between groups (p = 0.270) (**Supplementary Table 2**).

A comparison of the proportion of participants who increased the mean number of daily steps by ≥ 1000 from baseline to the intervention period is shown in **Table 2**. The proportion in the intervention group was 69.4% (n=25) and that in the control group was 30.6% (n=11). The proportion was significantly higher in the intervention than in the control group (OR = 5.17; 95% CI = 1.89, 14.08).

Table 3 shows the results of analyses stratified by baseline status conducted to check for any differences in the mean increase in the number of daily steps from baseline to the intervention period. Even after stratifying by sex or age, the mean increase in the number of daily steps was significantly larger in the intervention than in the control group in all strata (p < 0.05). Among participants stratified by the number of daily steps at baseline (< 6000 and ≥ 6000), the mean increase in the number of daily steps was larger in the intervention than in the control group, but the only significant

difference was among those with < 6000 daily steps ($p < 0.001$). In both physical activity groups (high and low), the mean increase in the number of daily steps was larger in the intervention than in the control group, but the only significant difference was among those with a low physical activity level ($p = 0.001$). In both BMI groups (< 25 and ≥ 25 kg/m^2), the mean increase in the number of daily steps was larger in the intervention than in the control group, but the only significant difference was among those with a BMI < 25 ($p = 0.001$). In both time affluence groups (affluent and non-affluent), the mean increase in the number of daily steps was larger in the intervention than in the control group, but this difference was marginally non-significant among the non-affluent group ($p = 0.054$). After stratifying by frailty, educational level, employment, and economic affluence, each mean increase in the number of daily steps was significantly larger in the intervention than in the control group ($p < 0.05$ for all).

Incident falls were reported in two participants (5.7%) in the intervention group and one participant (2.9%) in the control group, and the incident rate was not significantly different ($p = 0.555$). Incident pain was reported in four participants (14.3%) in the intervention group and one participant (4.2%) in the control group, and the incident rate was not significantly different ($p = 0.217$).

Discussion

The present RCT examined the effects of a financial incentive (shopping points) on the number of daily walking steps among community-dwelling Japanese adults. The increase in the number of daily steps was significantly larger in the intervention than in the control group, with a particularly substantial increase in those with low physical activity levels at baseline; however, the increased number of daily steps was not maintained after receiving the incentive.

Although most of the study participants might have been considered more health-conscious than average because they volunteered to participate in this RCT, the present results are considered to be generalizable to the community-dwelling adult population in Japan because the mean number of daily steps among the study participants at baseline was similar to the nationwide average (6364 vs. 6322, respectively).[19]

Previous studies have reported that socioeconomic status, which includes occupation and education and income levels, is associated with health inequality.[20 21] However, the results of the present study demonstrated that offering a financial incentive to increase the number of daily walking steps was not affected by economic affluence or education level. Walking has considerable health benefits[22] and does not require any special training or substantial additional costs. Therefore, offering a financial incentive to

increase the number of daily walking steps among physically inactive adults could be expected to reduce health disparities between groups of unequal socioeconomic status.

Previous studies aiming to increase physical activity levels have used cash as a financial incentive.[7 8 23 24] In the present study, we chose to use shopping points that could only be redeemed at stores in the study area because we believed that it would cause the participants to patronize local stores in the community more frequently. Therefore, a unique aspect of the present study is that it aimed to promote both health and economic activities in the local community. In fact, local stores in the study area chose to resume the financial incentive program after this RCT was completed.

This study had several notable strengths. First, all of the participants completed each program during the trial period. Second, to our knowledge, this study is the first to offer a noncash financial incentive. Third, the present results are considered to be generalizable to the community-dwelling adult population in Japan because the mean number of daily walking steps among the study participants at baseline was similar to the nationwide average.[19]

Limitations

This study also had several limitations. First, the intervention involved only

one type of financial incentive; therefore, the effects of changes in the corresponding financial incentive or its application (e.g., donations) are unclear. Second, only the effect of a short-term intervention (over 3 weeks) was evaluated; whether an intervention involving a financial incentive would be effective for maintaining an increase in the number of daily walking steps over the long term is unclear. Third, the study participants were all Japanese adults; therefore, the present results may not generalizable to non-Japanese populations.

Conclusions

The results of the present study indicated that offering a financial incentive was effective for increasing the number of daily walking steps among Japanese community-dwelling adults. Future research should explore whether the continuation of financial incentives can maintain an increased number of daily steps over the long term.

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Authors' contributions: IT supervised this study and is the guarantor. FT, YT and IT were involved in the design. FT and IT prepared draft manuscript. SA, SM, YK, DN, KM, YLi, SZ, YLu, YS, SB, TY, TO, and TS revised the manuscript. SZ carried out the statistical analyses. All authors approved submission of this manuscript.

Competing interests: The authors have no financial disclosures in association with this study.

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References

1. World Health Organization. Global action plan on physical activity 2018-2030. More active people for a healthier world. Geneva: World Health Organization; 2018.
2. Piercy KL, Troiano RP, Ballard RM, et al. The Physical Activity Guidelines for Americans. *JAMA* 2018;320(19):2020-8.
3. US Department of Health and Human Services: Physical Activity Guidelines for Americans. 2nd ed. Washington, DC: U.S. Department of Health and Human Services; 2018.
4. Miyachi M, Tripette J, Kawakami R, Murakami H. "+10 min of Physical Activity per Day": Japan Is Looking for Efficient but Feasible Recommendations for Its Population. *Journal of nutritional science and vitaminology* 2015;61:S7-9.
5. Nishi N. Monitoring Obesity Trends in Health Japan 21. *Journal of nutritional science and vitaminology* 2015;61:S17-9.
6. Giles EL, Robalino S, McColl E, et al. The effectiveness of financial incentives for health behaviour change: systematic review and meta-analysis. *PLoS One* 2014;9(3):e90347.
7. Harkins KA, Kullgren JT, Bellamy SL, et al. A Trial of Financial and Social Incentives to Increase Older Adults' Walking. *Am J Prev Med* 2017;52(5):e123-30.

8. Patel MS, Asch DA, Rosin R, et al. Individual Versus Team-Based Financial Incentives to Increase Physical Activity: A Randomized, Controlled Trial. *J Gen Intern Med* 2016;31(7):746-54.

9. Tomata Y, Tanji F, Nurrika D, et al. Randomised controlled trial of a financial incentive for increasing the number of daily walking steps: study protocol. *BMJ Open* 2019;9(6):e026086.

10. Arai H, Satake S: English translation of the Kihon Checklist. *Geriatr Gerontol Int* 2015;15(4):518-9.

11. Fukutomi E, Okumiya K, Wada T, et al. Relationships between each category of 25-item frailty risk assessment (Kihon Checklist) and newly certified older adults under Long-Term Care Insurance: A 24-month follow-up study in a rural community in Japan. *Geriatr Gerontol Int* 2015;15(7):864-71.

12. Satake S, Senda K, Hong YJ, et al. Validity of the Kihon Checklist for assessing frailty status. *Geriatr Gerontol Int* 2016;16(6):709-15

13. Sewo Sampaio PY, Sampaio RA, Yamada M, et al. Validation and translation of the Kihon Checklist (frailty index) into Brazilian Portuguese. *Geriatr Gerontol Int* 2014;14(3):561-9.

14. Tomata Y, Hozawa A, Ohmori-Matsuda K, et al. Validation of the Kihon Checklist for predicting the risk of 1-year incident long-term care insurance certification: the Ohsaki Cohort 2006 Study [in Japanese].

Nihon Koshu Eisei Zasshi 2011;58(1):3-13.

15. Fujii H, Yamamoto S, Takeda-Imai F, et al. Validity and applicability of a simple questionnaire for the estimation of total and domain-specific physical activity. *Diabetology International* 2011;2(2):47-54.

16. Sasai H, Nakata Y, Murakami H, et al. Simultaneous Validation of Seven Physical Activity Questionnaires Used in Japanese Cohorts for Estimating Energy Expenditure: A Doubly Labeled Water Study. *J Epidemiol* 2018;28(10):437-42.

17. Ministry of Internal Affairs and Communications. Population Census. 1996 http://www.stat.go.jp/english/data/kokusei/index.html

18. Tomata Y, Tanno K, Zhang S, et al. Subjective Household Economic Status and Obesity in Toddlers: A Cross-Sectional Study of Daycare Centers in Japan. *J Epidemiol*. 2019;29(1):33-37.

19. The Ministry of Health, Labor and Welfare in Japan. National Health and Nutrition Survey. https://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyou_chousa.html [in Japanese]

20 Mackenbach JP, Stirbu I, Roskam AJ, et al. Socioeconomic inequalities in health in 22 European countries. *N Engl J Med* 2008;358(23): 2468-81.

21 Nurrika D, Zhang S, Tomata Y, et al. Education level and incident functional disability in elderly Japanese: The Ohsaki Cohort 2006 study.

PLoS One 2019;14(3): e0213386.

22 Hakim AA, Petrovitch H, Burchfiel CM, et al. Effects of walking on mortality among nonsmoking retired men. *N Engl J Med* 1998;338(2): 94-9.

23 Finkelstein EA, Brown DS, Brown DR, Buchner DM. A randomized study of financial incentives to increase physical activity among sedentary older adults. *Prev Med* 2008;47(2): 182-7.

24 Patel MS, Asch DA, Rosin R, et al. Framing Financial Incentives to Increase Physical Activity Among Overweight and Obese Adults: A Randomized, Controlled Trial. *Ann Intern Med* 2016;164(6): 385-94.

Fig. 1. CONSORT flowchart of the study procedure.

Fig. 2. Changes in the number of daily walking steps during the intervention and follow-up periods (means and 95% confidential intervals).

Table 1. Baseline characteristics of the study participants (n = 72).

Characteristics	Intervention (n = 36)	Control (n = 36)	p-value
Female, %	69.4	69.4	1.000
Age, years (mean ± SD)	62.0 ± 16.5	60.4 ± 16.1	0.671
Blood pressure, mmHg (mean ± SD)			
Systolic blood pressure	130.7 ± 20.7	125.5 ± 18.5	0.264
Diastolic blood pressure	79.0 ± 11.4	76.7 ± 10.8	0.378
History of disease, %			
Stroke	2.8	0.0	0.314
Hypertension	25.0	30.6	0.599
Myocardial infarction	0.0	5.6	0.151
Diabetes	8.3	8.3	1.000
Arthritis	2.8	5.6	0.555
Osteoporosis	5.6	0.0	0.151
Cancer	16.7	8.3	0.285
Frailty, %	5.6	19.4	0.075
Physical activity, MET (mean ± SD)	35.8 ± 8.5	36.1 ± 5.3	0.822
Transportation, %			
Motorbike or car	61.1	80.6	0.070
Educational attainment, %			
High school or less	52.8	47.2	
College/university	16.7	22.2	0.820
Undergraduate or graduate degree	30.6	30.6	
Employment, %			
≥ 4 days/week	27.8	36.1	
< 4 days/week	19.4	11.1	0.546
Not working	52.8	52.8	
Subjective household economic status			
Affluent	80.6	86.1	0.527
Non-affluent	19.4	13.9	
Subjective time affluence			
Affluent	72.2	77.8	0.586
Non-affluent	27.8	22.2	
Pain			
Absent	22.2	44.4	0.011
Present	5.6	2.8	
Body mass index, kg/m^2 (mean ± SD)	22.1 ± 3.0	23.2 ± 4.6	0.250
Baseline number of steps/day (mean ± SD)	6859 ± 3223	5869 ± 2249	0.135

MET, metabolic equivalent; SD, standard deviation.

Table 2. Comparison of proportions of participants who increased the number of daily steps by 1000 or more from baseline (n = 72).

		Intervention period		
	n	Proportion[a]	OR[b]	(95% CI)
Intervention	36	69.4	5.17	(1.89 , 14.08)
Control	36	30.6	1.00	(Reference)

CI, confidence interval; OR, odds ratio.

[a] Proportions of participants who increased the number of daily steps by 1000 or more from baseline.

[b] Logistic regression analysis.

Table 3. Subgroup analysis: Comparison of increases in the number of steps (n = 72).

Subgroup		n	Intervention period Mean	(95% CI)	p-value[a]
Sex					
Male	Intervention	11	2199	(783 , 3615)	0.021
	Control	11	401	(–331 , 1134)	
Female	Intervention	25	1409	(1054 , 1765)	0.005
	Control	25	563	(91 , 1036)	
Age (years)					
< 65	Intervention	17	1650	(780 , 2519)	0.006
	Control	17	148	(–475 , 771)	
≥ 65	Intervention	19	1651	(1127 , 2175)	0.019
	Control	19	841	(390 , 1292)	
Baseline number of steps					
< 6000	Intervention	16	2193	(1331 , 3056)	< 0.001
	Control	18	264	(–183 , 712)	
≥ 6000	Intervention	20	1216	(745 , 1687)	0.229
	Control	18	763	(130 , 1397)	
Physical activity					
Low	Intervention	19	1796	(1060 , 2531)	0.001
	Control	17	181	(–286 , 648)	
High	Intervention	17	1488	(856 , 2121)	0.107
	Control	19	812	(223 , 1400)	
Body mass index					
≥ 25	Intervention	4	1433	(–1262 , 4127)	0.333
	Control	8	577	(–435 , 1590)	
< 25	Intervention	32	1678	(1184 , 2172)	0.001
	Control	28	496	(65 , 926)	
Time affluence					
Non-affluent	Intervention	10	998	(338 , 1658)	0.054
	Control	8	–236	(–1550 , 1077)	
Affluent	Intervention	26	1901	(1311 , 2492)	0.001
	Control	28	728	(390 , 1066)	
Frailty					
Yes	Intervention	2	1692	(–10558 , 13941)	0.043
	Control	7	–599	(–1637 , 438)	
No	Intervention	34	1648	(1158 , 2138)	0.007
	Control	29	783	(421 , 1144)	
Educational level					
High	Intervention	17	1697	(869 , 2525)	0.022
	Control	19	569	(–5 , 1142)	
Low	Intervention	19	1609	(1035 , 2182)	0.004
	Control	17	453	(–92 , 997)	
Employment status					
Working	Intervention	17	1286	(770 , 1802)	0.015
	Control	17	285	(–363 , 932)	
Not working	Intervention	19	1977	(1201 , 2752)	0.006
	Control	19	719	(257 , 1180)	
Economic affluence					
Affluent	Intervention	29	1670	(1112 , 2228)	0.002
	Control	31	572	(156 , 988)	

Non-affluent	Intervention	7	1569	(	591	,	2547	)	0.043
	Control	5	154	(	−1118	,	1425	)	

CI, confidence interval.

[a] *t*-test.

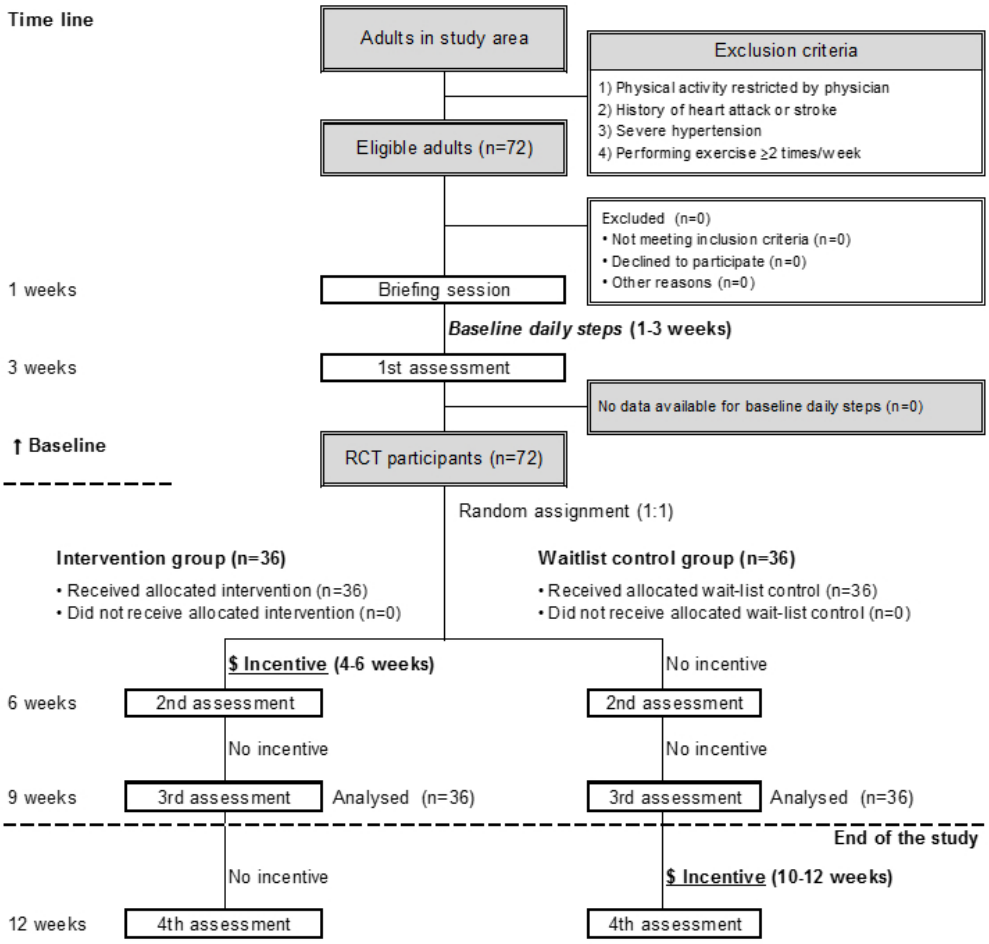

Fig.1. CONSORT flowchart of the study procedure.

190x189mm (96 x 96 DPI)

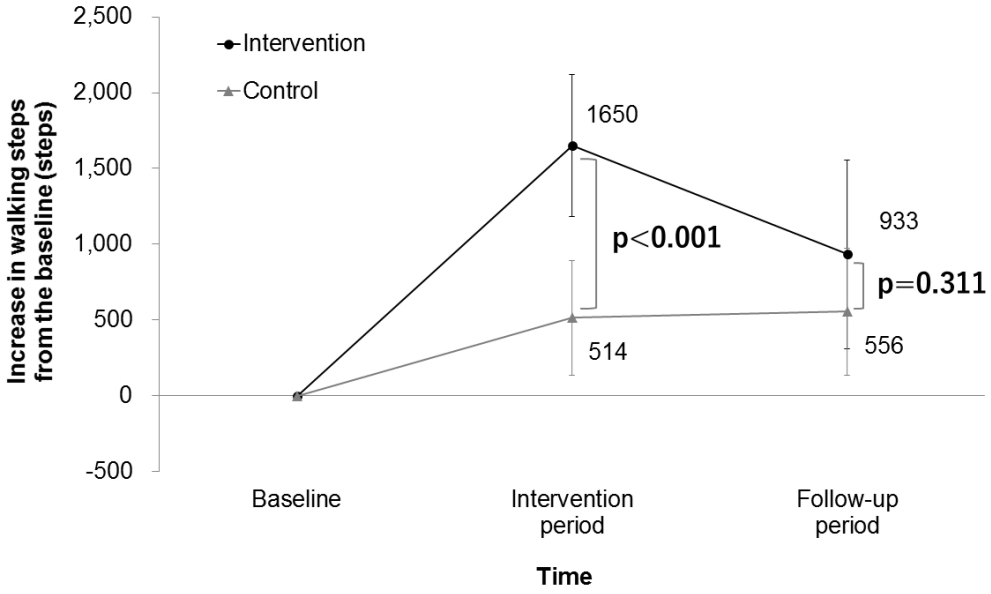

Fig. 2. Changes in the number of daily walking steps during the intervention and follow-up periods (means and 95% confidential intervals).

300x190mm (96 x 96 DPI)

Supplementary Table 1. Comparison of steps between baseline and the intervention period (n = 72).

		Number of steps, mean (SD)		Increase in number of steps			Increase rate[b]		
	n	Baseline	Intervention period	Mean	(95% CI)	p-value[a]	Mean	(95% CI)	p-value[a]
Intervention	36	6859 (3223)	8510 (3155)	1650	(1182 , 2119)	< 0.001	31.0	(20.9 , 41.2)	< 0.001
Control	36	5869 (2249)	6383 (2737)	514	(136 , 891)		9.1	(2.5 , 15.7)	

CI, confidence interval.

[a] *t*-test.

[b] Rate (%) of change in mean number of steps/day.

Supplementary Table 2. Comparison of steps between baseline and the follow-up period.

		Number of steps, mean (SD)		Increase in number of steps			Increase rate[b]		
	n	Baseline	Follow-up	Mean	(95% CI)	p-value[a]	Mean	(95% CI)	p-value[a]
Intervention	36	6859 (3223)	7793 (3166)	933	(312 , 1555)	0.311	20.3	(7.6 , 33.1)	0.270
Control	36	5869 (2249)	6425 (2504)	556	(136 , 976)		12.1	(4.2 , 20.0)	

CI, confidence interval.

[a] t-test.

[b] Rate (%) of change in mean number of steps/day.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 4-5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 6-7
	2b	Specific objectives or hypotheses	Page 6-7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	Page 8-9
	4b	Settings and locations where the data were collected	Page 8-10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 10-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	Page 9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Protocol paper (Tomata Y, et al. BMJ Open 2019;9:e026086. Page 4)

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 10
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 12
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Page 14
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 8, 9, 14
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Page 14-16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Figure 1, Supplementary Table 1&2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page 15,16
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 16
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 18,19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 17-19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 17,18
Other information			
Registration	23	Registration number and name of trial registry	Page 8
Protocol	24	Where the full trial protocol can be accessed, if available	Page 8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 21

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Effect of a financial incentive (shopping point) on increasing the number of daily walking steps among community-dwelling adults in Japan: A randomized controlled trial

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Primary Subject Heading:	Epidemiology
Secondary Subject Heading:	Public health, Sports and exercise medicine
Keywords:	EPIDEMIOLOGY, PUBLIC HEALTH, PREVENTIVE MEDICINE

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Title:

Effect of a financial incentive (shopping point) on increasing the number of daily walking steps among community-dwelling adults in Japan: A randomized controlled trial

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ABSTRACT

Objective: The aim of the present study was to investigate the effect of a financial incentive on the number of daily steps among community-dwelling adults in Japan.

Study design: Two-arm, parallel-group RCT.

Setting/participants: We recruited physically inactive community-dwelling adults in Sendai city, Japan. Eligible participants were randomly allocated to an intervention or a wait-list control group. Pedometers were used to assess the mean number of daily steps in three periods: baseline (weeks 1-3), intervention (weeks 4–6), and follow-up (weeks 7–9).

Intervention: The intervention group was offered a financial incentive (shopping points) to meet the target number of increased daily steps in the intervention period.

Main outcome measures: The primary outcome was an increase in the mean number of daily steps in the intervention and follow-up periods compared with baseline.

Results: Seventy-two participants (69.4% female; mean age, 61.2 ± 16.2 years; mean number of daily steps at baseline, 6364 ± 2804) were randomized to the intervention (n = 36) and control groups (n = 36). During the intervention period, the increase in mean daily steps was significantly higher in the intervention (1650, 95% confidence interval [CI] = 1182, 2119) than in

the control group (514, 95% CI = 136, 891; p < 0.001). However, the difference between groups was not significant at follow-up after the incentives were removed (p = 0.311). In addition, compared with the controls, a significantly higher proportion of participants in the intervention group showed an increase of ≥ 1000 in mean daily steps (69.4% vs. 30.6%, respectively; odds ratio = 5.17, 95% CI = 1.89, 14.08). There were no adverse effects from the intervention.

Conclusions: Present results suggest that financial incentives are effective for promoting short-term increases in physical activity.

Trial Registration: UMIN000033276

Keywords: financial incentive, walking steps, randomized controlled trial, Japan

Strengths and limitations of this study

- This study offered 'shopping points' as an unique financial incentive.
- The financial incentive was a fairly small amount.
- The intervention involved only one type of financial incentive.
- Only the effect of a short-term intervention (over 3 weeks) was evaluated.

Introduction

Physical inactivity is a serious problem all around the world. According to the Global Action Plan on Physical Activity 2018–2030[1], one in four adults (1.4 billion people worldwide) do not meet the World Health Organization (WHO) recommendations for physical activity levels. According to reports from the USA,[2,3] a failure to meet recommended physical activity levels is associated with approximately 117 billion USD in annual health care costs and 10% of all premature deaths. Therefore, physical inactivity imposes a substantial burden on health care costs and longevity. To help solve these problems, the WHO and national governments have developed various policies to promote higher levels of physical activity.[1-5] Walking is a popular and major source of physical activity worldwide.[1 2 6]In the Japanese National Health Promotion Movement ("Health Japan 21"), a higher number of daily walking steps is a target for physical activity as follows: 9000 and 8500 steps in men and women aged < 65 years, and 7000 and 6000 steps in men and women aged ≥ 65 years, respectively.[7]

A systematic review (meta-analysis) has suggested that financial incentives are effective for promoting health behaviors such as smoking cessation, vaccinations, and participation in cancer screening.[8] Mitchell et al.[9] conducted a systematic review of randomized controlled trials (RCTs) on the effects of financial incentives on physical activity and reported the

results of a meta-analysis of studies promoting changes in daily walking steps. The findings of that study indicated that financial incentives were effective for increasing the number of daily walking steps during the intervention and post-intervention periods. However, these studies did have methodological differences in terms of incentives (e.g., cash, charity, lottery, team incentives) and target populations (e.g., overweight and obese adults). Most RCTs have been conducted in the USA, whereas only one has been conducted in Asia (Singapore).

Although walking is a major source of physical activity in daily life for Japanese people, the national average number of daily walking steps for Japanese adults (age ≥ 20 years) has been decreasing, from 7655 in 2000 to 6322 in 2017.[10] Considering the rapid aging of the population and escalating health care costs, more effective measures aimed at promoting walking at the population level need to be established. Therefore, the aim of the present study was to examine the effects of a financial incentive on the number of daily walking steps among community-dwelling adults in Japan.

Methods

Study design

The protocol of the present study has been reported in detail elsewhere.[11] Briefly, this was a single-center, single-blind, parallel-group RCT in which participants were randomly assigned to an intervention or a control group.

The protocol was approved by the ethics committee of Tohoku University Graduate School of Medicine (No. 2018-1-171), and written informed consent was obtained from all participants. The present study was also registered in the University Hospital Medical Information Network (No. UMIN000033276).

Participants

In August 2018, leaflets were distributed to each house in the Nakayama area of Aoba-ku in Sendai city, Japan. Applicants who met the inclusion criteria could apply through an online application, fax, or telephone.

Inclusion and exclusion criteria

Individuals could apply for participation in the present study if they met all of the following inclusion criteria: 1) adult (aged ≥ 20 years) living in the Nakayama area; 2) possession of a community development integrated circuit (IC) card in the Nakayama area (*Nakayama Machi-dukuri IC Card*); and 3)

ability to walk unaided without using a cane, walker, or wheelchair.

Individuals who met any of the following exclusion criteria could not participate in the study: 1) physical activity restricted by a physician; 2) history of heart attack or stroke within the last 6 months; 3) blood pressure exceeding 180 mmHg systolic or 110 mmHg diastolic; or 4) already habitually exercising (task of ≥ 4 metabolic equivalents) more than twice per week.

Shopping points are added to an IC card when the customer purchases goods or participates in community activities in the Nakayama area. Customers can redeem their points during payment transactions while shopping. IC cards are also intended to enhance social interaction among locals.

Power and sample size

Based on a previous study carried out in 2013[12], we assumed that an average difference of 1302 steps would be achieved in the intervention period (4–6 weeks) by offering a financial incentive of 2000 JPY (≈18 USD at the time of the study in 2018) and setting the standard deviation (SD) at 1711. The difference of 1302 steps was the effect size reported in a previous study. Additionally, our previous study reported that an increase of 1000 steps was associated with reduced medical costs of 1300 JPY (≈12 USD) per month,

and another study reported that an increase of 1000 steps had some impact on health at the population level because it contributes to a 3.2% reduction in the average relative risk of noncommunicable diseases, dementia, joint-musculoskeletal impairment, and mortality.[4] When an α error of 0.05 and a statistical power of 0.90 was applied, the minimum sample size was 74 persons (37 persons per group). When an α error of 0.05 and a statistical power of 0.80 were applied with this sample size, a mean difference of ≥ 1,130 steps was considered statistically significant.

Study procedure

The flow of the study procedure is shown in **Fig. 1**. In a briefing session held in September 2018, the researchers rechecked the inclusion and exclusion criteria for each applicant. All participants selected provided informed consent to participate in the study. At the briefing session, each participant was provided with a pedometer (FS-800; ESTERA Corp., Saitama, Japan) containing a three-axis acceleration sensor. To maintain the accuracy of the pedometer, all participants received an explanation that they should wear the pedometer close to their waist because steps will not be counted correctly when worn on a different location, placed in a handbag, or set in any other position results in irregular movements. The number of daily walking steps at baseline was measured in the first 3 weeks of the study period (weeks 1–3)

for all participants.

Randomization

After confirming eligibility, the enrolled participants were assigned to one of the two groups (1:1 allocation) based on the permuted block method by computer-generated randomization. The allocation sequence was managed by two experienced random assignment researchers.

Blinding

The assignment data could only be accessed by the random assignment researchers; all other staffs were blinded to the random assignments. The assignment information was kept in a password-protected storage device. The researchers involved exclusively in the random assignment notified the participants about their own assignment in a closed room separated from the other examination locations. During the notification process, these random assignment researchers warned the participants not to talk about their assignment with anyone else. In addition, all statistical analyses were blinded to the assignments. The random assignment researchers were not involved in the statistical analyses.

Intervention

The intervention was a financial incentive in the form of shopping points that could be redeemed at 14 stores in the study area. The following two kinds of financial incentives were offered:

1. If the mean number of daily walking steps in the intervention period was ≥ 6000, shopping points worth 1000 JPY were awarded.
2. If the mean number of daily walking steps during the intervention period increased by ≥ 1000 from baseline, shopping points worth 1000 JPY were awarded.

Based on the exchange rate on August 31, 2018, 2000 JPY was equivalent to 18 USD. All participants in the intervention and control groups who achieved their daily step goals were rewarded with shopping points worth 1000 or 2000 JPY on their IC card at that time (after the end of the trial, i.e., week 12). However, we did not specify how the shopping points could be used, so it is possible that they might have used the points for unhealthy purchases (e.g., cigarettes).

Wait list control group

The wait list control group was also asked to increase their daily steps in the last 3 weeks (weeks 10–12). They could gain a financial incentive only if they achieved the goals. All conditions except for the timing were the same as those for the intervention group.

Measurements

The participants' baseline characteristics were assessed at the date of the briefing session. Interviews with trained interviewers were conducted to obtain information regarding medical history, frailty (the Kihon checklist) [13-17], physical activity level[18 19], transportation when going out, education level[20], work, subjective economic status, time affluence (having spare time) [21], body height, weight, pain, and falling. Blood pressure was also measured using an automated sphygmomanometer (HEM-1040; Omron, Kyoto, Japan).

Transportation when going out was assessed by asking the question "What kinds of transportation have you used more than twice per week when going out in the last month?", for which, the available responses were: "walking", "bicycle", "motorbike", "car", "train", "bus", "taxi", or "other".

Economic affluence was assessed by asking the question "How do you feel about your current household situation?" The participants were asked to choose one of the following five answers: "most affluent", "more affluent", "neither more nor less", "less affluent", and "non-affluent". We classified the first three answers as "affluent" and the last two as "non-affluent".

Time affluence (having spare time) was assessed by asking the question "Do you have enough time available to take rest or enjoy leisure in daily life?" The participants were asked to choose one of the following four

answers: “more affluent”, “little affluent”, “less affluent”, and “non-affluent”. We classified the first two answers as “affluent” and the last two as “non-affluent”.

Incident falls were assessed based on the question “Have you fallen in the past 3 weeks?” The participants were asked to answer either “yes” or “no”. Incident pain was assessed based on the question “How much pain have you experienced during the past 3 weeks?”, with the participants asked to choose one of the following six answers: “none”, “very mild”, “mild”, “moderate”, “severe”, or “very severe”.

Outcome measurements

The participants were asked to visit the study center every 3 weeks, and evaluations of individual daily steps were carried out during each visit. For each visit, we transferred data on the number of daily steps to a computer and asked the participants whether they had experienced any pain or falls in the 3-week period. All participants were instructed to wear the pedometer while awake every day during the study period (weeks 9).

The primary outcome was the mean increase in the number of daily steps during the intervention period (weeks 4–6) compared with that at baseline.

The secondary outcomes were: 1) an increase in the number of daily steps by ≥ 1000 at weeks 4–6 or 7–9 from baseline; 2) incident falls at weeks

4–6 or 7–9; and 3) incident pain at weeks 4–6 or 7–9.

Statistical analyses

In regard to the primary outcome, the *t*-test was applied to examine whether the mean increases and rate of change in the number of daily steps at weeks 4–6 and 7–9 from baseline differed significantly between the intervention and control groups.

In regard to the secondary outcomes, logistic regression models were applied to examine whether the proportions of participants with an increase of ≥ 1000 steps were significantly different, and to assess the probabilities of incident falls and incident pain. Odds ratios (ORs) and 95% confidence intervals (CIs) were also estimated.

In addition, stratified analyses were conducted to check for any differences in the number of daily steps in terms of sex, age, frailty, physical activity level, transportation when going out, education level, work, subjective economic status, time affluence, and obesity.

All analyses were performed using IBM SPSS Statistics (version 25; IBM SPSS, Chicago, IL, USA).

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or

reporting, or dissemination plans of our trial.

Results

The mean age (SD) of the participants (69.4% female) was 61.2 (16.2) years, and 30.6% had an undergraduate or graduate degree.

At baseline, the mean numbers of daily steps (SD) in the intervention and control groups were 6859 (3,223) and 5869 (2249), respectively; this difference was not significant (p = 0.135) (**Table 1**). Participants in the intervention group were significantly more likely to have pain than those in the control group (p = 0.011). No significant differences in age, sex, blood pressure, history of disease, frailty, physical activity level, transportation, educational level, employment, subjective household economic status, subjective time affluence, or body mass index (BMI) were found between the two groups.

All 72 participants completed the intervention (weeks 4–6) and follow-up periods (weeks 7–9). Comparisons of steps between the baseline and intervention or follow-up periods in the intervention and control groups are shown in **Fig. 2**. The mean increases in the numbers of daily steps from baseline to the intervention period in the intervention and control groups were 1650 (95% CI = 1182, 2119) and 514 (95% CI = 136, 891), respectively, indicating a significant difference between groups (p < 0.001). The mean increase rate in the number of daily steps from baseline to the

intervention period was significantly higher in the intervention than in the control group (31.0% vs. 9.1%, respectively; $p < 0.001$) (**Supplementary Table 1**). The mean increase in the number of daily steps from baseline to the follow-up period was larger in the intervention (933, 95% CI = 312, 1555) than in the control group (556, 95% CI = 136, 976) (**Fig. 2**); however, no significant difference was observed between groups ($p = 0.311$). Regarding the mean increase rate in the number of daily steps from baseline to the follow-up period, no significant difference was found between groups ($p = 0.270$) (**Supplementary Table 2**).

A comparison of the proportion of participants who increased the mean number of daily steps by ≥ 1000 from baseline to the intervention period is shown in **Table 2**. The proportion in the intervention group was 69.4% (n=25) and that in the control group was 30.6% (n=11). The proportion was significantly higher in the intervention than in the control group (OR = 5.17; 95% CI = 1.89, 14.08).

Table 3 shows the results of the analyses stratified by baseline characteristics. The subgroup analyses showed a significant increase in the number of daily steps among participants with a lower (< 6000) compared with those with a higher (≥ 6000) baseline step count (p-interaction = 0.012). Although no significant interaction was found, significant differences were observed for those with a low but not those with a high physical activity

level, those with a BMI < 25 but not those with a BMI ≥ 25, and those with time affluence; only a marginally nonsignificant difference was observed for the non-affluent group. Otherwise, significant increases in the number of daily steps were observed for both strata of sex, age group, frailty, education level, employment status, and economic affluence.

Incident falls were reported in two participants (5.7%) in the intervention group and one participant (2.9%) in the control group, and the incident rate was not significantly different (p = 0.555). Incident pain was reported in four participants (14.3%) in the intervention group and one participant (4.2%) in the control group, and the incident rate was not significantly different (p = 0.217).

Discussion

The present RCT examined the effects of a financial incentive (shopping points) on the number of daily walking steps among community-dwelling Japanese adults. The increase in the number of daily steps was significantly larger in the intervention than in the control group, with a particularly substantial increase in those with low physical activity levels at baseline. However, caution is required when interpreting the present findings because the intervention period was as short as 3 weeks and the increased number of daily steps was not maintained after receiving the incentive. Whether the incentive needs to be continued so that the participants maintain their increased number of daily steps remains unclear.

Although most of the study participants might be considered more health-conscious than average because they volunteered to participate in this RCT and were classified as economically affluent, the present results are considered to be generalizable to the community-dwelling adult population in Japan because the mean number of daily steps among the study participants at baseline was similar to the nationwide average (6364 vs. 6322, respectively).[10] The study area was safe for walking and has sidewalks that are favorable for pedestrians, which is typical in local communities in Japan.

Previous studies have reported that socioeconomic status, which includes occupation and education and income levels, is associated with

health inequality.[22 23] However, the results of the present study demonstrated that offering a financial incentive to increase the number of daily walking steps was not affected by economic affluence or education level. Walking has considerable health benefits[24] and does not require any special training or substantial additional costs. This could be the reason why the financial incentive resulted in an increase in the number of daily walking steps, regardless of socioeconomic status.

Previous studies aiming to increase physical activity levels have used cash as a financial incentive.[12 25-27] In this study, we chose to use shopping points (a non-cash incentive) that could only be redeemed at stores in the study area because we believed that it would cause the participants to patronize local stores in the community more frequently. Therefore, a unique aspect of the present study is that it aimed to promote both health and economic activities in the local community. In fact, local stores in the study area chose to resume the financial incentive program after this RCT was completed.

This study had several notable strengths. First, all of the participants completed each program during the trial period. Second, to our knowledge, this study offered 'shopping points' as an unique financial incentive. Third, the financial incentive offered in this study was a fairly low amount compared with other financial incentive studies involving physical activity.

Although most of study participants were classified as affluent in terms of their economic status, the relatively small financial incentive was still effective for increasing the number of daily walking steps. Fourth, the present results are considered to be generalizable to the community-dwelling adult population in Japan because the mean number of daily walking steps among the study participants at baseline was similar to the nationwide average.[10]

Limitations

This study also had several limitations. First, the intervention involved only one type of financial incentive; therefore, the effects of changes in the corresponding financial incentive or its application (e.g., donations) are unclear. Second, only the effect of a short-term intervention (over 3 weeks) was evaluated; whether an intervention involving a financial incentive would be effective for maintaining an increase in the number of daily walking steps over the long term is unclear. Third, the study participants were all Japanese adults; therefore, the present results may not generalizable to non-Japanese populations. Fourth, the possibility of overestimation due to the small sample size cannot be ruled out. However, the sample size set at the start of the study was almost achieved.

Conclusions

The results of the present study indicated that offering a financial incentive was effective for increasing the number of daily walking steps among Japanese community-dwelling adults, even though the intervention period was as short as 3 weeks. The difference between the intervention and control groups was not significant at follow-up after the incentives were removed. Future research should explore whether the continuation of financial incentives can maintain an increased number of daily steps over the long term.

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References

1. World Health Organization. Global action plan on physical activity 2018-2030. More active people for a healthier world. Geneva: World Health Organization; 2018.
2. Piercy KL, Troiano RP, Ballard RM, et al. The Physical Activity Guidelines for Americans. *JAMA* 2018;320(19):2020-8.
3. US Department of Health and Human Services: Physical Activity Guidelines for Americans. 2nd ed. Washington, DC: U.S. Department of Health and Human Services; 2018.
4. Miyachi M, Tripette J, Kawakami R, Murakami H. "+10 min of Physical Activity per Day": Japan Is Looking for Efficient but Feasible Recommendations for Its Population. *Journal of nutritional science and vitaminology* 2015;61:S7-9.
5. Nishi N. Monitoring Obesity Trends in Health Japan 21. *Journal of nutritional science and vitaminology* 2015;61:S17-9.
6. Althoff, T, Sosič, R, Hicks, J. L, et al. Large-scale physical activity data reveal worldwide activity inequality. Nature. 2017;547(7663):336-339.
7. Ministry of Health, Labour and Welfare. Health Japan 21. 2012. https://www.mhlw.go.jp/bunya/kenkou/dl/kenkounippon21_01.pdf .
8. Giles EL, Robalino S, McColl E, et al. The effectiveness of financial incentives for health behaviour change: systematic review and

meta-analysis. *PLoS One* 2014;9(3):e90347.

9. Mitchell MS, Orstad SL, Biswas A, et al. Financial incentives for physical activity in adults: systematic review and meta-analysis. Br J Sports Med 2019;bjsports-2019-100633. doi: 10.1136/bjsports-2019-100633. Online ahead of print.

10. The Ministry of Health, Labor and Welfare in Japan. National Health and Nutrition Survey. https://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyou_chousa.html [in Japanese]

11. Tomata Y, Tanji F, Nurrika D, et al. Randomised controlled trial of a financial incentive for increasing the number of daily walking steps: study protocol. *BMJ Open* 2019;9(6):e026086.

12. Harkins KA, Kullgren JT, Bellamy SL, et al. A Trial of Financial and Social Incentives to Increase Older Adults' Walking. *Am J Prev Med* 2017;52(5):e123-30.

13. Arai H, Satake S: English translation of the Kihon Checklist. *Geriatr Gerontol Int* 2015;15(4):518-9.

14. Fukutomi E, Okumiya K, Wada T, et al. Relationships between each category of 25-item frailty risk assessment (Kihon Checklist) and newly certified older adults under Long-Term Care Insurance: A 24-month follow-up study in a rural community in Japan. *Geriatr Gerontol Int*

2015;15(7):864-71.

15. Satake S, Senda K, Hong YJ, et al. Validity of the Kihon Checklist for assessing frailty status. *Geriatr Gerontol Int* 2016;16(6):709-15

16. Sewo Sampaio PY, Sampaio RA, Yamada M, et al. Validation and translation of the Kihon Checklist (frailty index) into Brazilian Portuguese. *Geriatr Gerontol Int* 2014;14(3):561-9.

17. Tomata Y, Hozawa A, Ohmori-Matsuda K, et al. Validation of the Kihon Checklist for predicting the risk of 1-year incident long-term care insurance certification: the Ohsaki Cohort 2006 Study [in Japanese]. *Nihon Koshu Eisei Zasshi* 2011;58(1):3-13.

18. Fujii H, Yamamoto S, Takeda-Imai F, et al. Validity and applicability of a simple questionnaire for the estimation of total and domain-specific physical activity. *Diabetology International* 2011;2(2):47-54.

19. Sasai H, Nakata Y, Murakami H, et al. Simultaneous Validation of Seven Physical Activity Questionnaires Used in Japanese Cohorts for Estimating Energy Expenditure: A Doubly Labeled Water Study. *J Epidemiol* 2018;28(10):437-42.

20. Ministry of Internal Affairs and Communications. Population Census. 1996 http://www.stat.go.jp/english/data/kokusei/index.html

21. Tomata Y, Tanno K, Zhang S, et al. Subjective Household Economic Status and Obesity in Toddlers: A Cross-Sectional Study of Daycare Centers in

Japan. *J Epidemiol*. 2019;29(1):33-37.

22. Mackenbach JP, Stirbu I, Roskam AJ, et al. Socioeconomic inequalities in health in 22 European countries. *N Engl J Med* 2008;358(23): 2468-81.

23. Nurrika D, Zhang S, Tomata Y, et al. Education level and incident functional disability in elderly Japanese: The Ohsaki Cohort 2006 study. *PLoS One* 2019;14(3): e0213386.

24. Hakim AA, Petrovitch H, Burchfiel CM, et al. Effects of walking on mortality among nonsmoking retired men. *N Engl J Med* 1998;338(2): 94-9.

25. Finkelstein EA, Brown DS, Brown DR, Buchner DM. A randomized study of financial incentives to increase physical activity among sedentary older adults. *Prev Med* 2008;47(2): 182-7.

26. Patel MS, Asch DA, Rosin R, et al. Framing Financial Incentives to Increase Physical Activity Among Overweight and Obese Adults: A Randomized, Controlled Trial. *Ann Intern Med* 2016;164(6): 385-94.

27. Patel MS, Asch DA, Rosin R, et al. Individual Versus Team-Based Financial Incentives to Increase Physical Activity: A Randomized, Controlled Trial. *J Gen Intern Med* 2016;31(7):746-54.

Fig. 1. CONSORT flowchart of the study procedure.

Fig. 2. Changes in the number of daily walking steps during the intervention and follow-up periods (means and 95% confidential intervals).

Table 1. Baseline characteristics of the study participants (n = 72).

Characteristics	Intervention (n = 36)	Control (n = 36)	p-value
Female, %	69.4	69.4	1.000
Age, years (mean ± SD)	62.0 ± 16.5	60.4 ± 16.1	0.671
Blood pressure, mmHg (mean ± SD)			
Systolic blood pressure	130.7 ± 20.7	125.5 ± 18.5	0.264
Diastolic blood pressure	79.0 ± 11.4	76.7 ± 10.8	0.378
History of disease, %			
Stroke	2.8	0.0	0.314
Hypertension	25.0	30.6	0.599
Myocardial infarction	0.0	5.6	0.151
Diabetes	8.3	8.3	1.000
Arthritis	2.8	5.6	0.555
Osteoporosis	5.6	0.0	0.151
Cancer	16.7	8.3	0.285
Frailty, %	5.6	19.4	0.075
Physical activity, MET (mean ± SD)	35.8 ± 8.5	36.1 ± 5.3	0.822
Transportation, %			
Motorbike or car	61.1	80.6	0.070
Educational attainment, %			
High school or less	52.8	47.2	
College/university	16.7	22.2	0.820
Undergraduate or graduate degree	30.6	30.6	
Employment, %			
≥ 4 days/week	27.8	36.1	
< 4 days/week	19.4	11.1	0.546
Not working	52.8	52.8	
Subjective household economic status			
Affluent	80.6	86.1	0.527
Non-affluent	19.4	13.9	
Subjective time affluence			
Affluent	72.2	77.8	0.586
Non-affluent	27.8	22.2	
Pain			
Absent	22.2	44.4	0.011
Present	5.6	2.8	
Body mass index, kg/m^2 (mean ± SD)	22.1 ± 3.0	23.2 ± 4.6	0.250
Baseline number of steps/day (mean ± SD)	6859 ± 3223	5869 ± 2249	0.135

MET, metabolic equivalent; SD, standard deviation.

1

2

Table 2. Comparison of the proportions of participants with an increase in the number of daily steps of 1000 or more from baseline to the intervention period (weeks 4–6) (n = 72).

		Intervention period (weeks 4-6)		
	n	Proportion[a]	OR[b]	(95% CI)
Intervention	36	69.4	5.17	(1.89 , 14.08)
Control	36	30.6	1.00	(Reference)

CI, confidence interval; OR, odds ratio.

[a] Proportions of participants who increased the number of daily steps by 1000 or more from baseline.

[b] Logistic regression analysis.

Table 3. Subgroup analysis: Comparison of increases in the number of steps from baseline to the intervention period (weeks 4–6) (n = 72).

Subgroup		n	Intervention period (weeks 4-6) Mean	(95% CI)	p-value[a]	p-interaction[a]
Sex						
Male	Intervention	11	2199	(783 , 3615)	0.021	0.140
	Control	11	401	(−331 , 1134)		
Female	Intervention	25	1409	(1054 , 1765)	0.005	
	Control	25	563	(91 , 1036)		
Age (years)						
< 65	Intervention	17	1650	(780 , 2519)	0.006	0.245
	Control	17	148	(−475 , 771)		
≥ 65	Intervention	19	1651	(1127 , 2175)	0.019	
	Control	19	841	(390 , 1292)		
Baseline number of steps						
< 6000	Intervention	16	2193	(1331 , 3056)	< 0.001	0.012
	Control	18	264	(−183 , 712)		
≥ 6000	Intervention	20	1216	(745 , 1687)	0.229	
	Control	18	763	(130 , 1397)		
Physical activity						
Low	Intervention	19	1796	(1060 , 2531)	0.001	0.116
	Control	17	181	(−286 , 648)		
High	Intervention	17	1488	(856 , 2121)	0.107	
	Control	19	812	(223 , 1400)		
Body mass index						
≥ 25	Intervention	4	1433	(−1262 , 4127)	0.333	0.701
	Control	8	577	(−435 , 1590)		
< 25	Intervention	32	1678	(1184 , 2172)	0.001	
	Control	28	496	(65 , 926)		
Time affluence						
Non-affluent	Intervention	10	998	(338 , 1658)	0.054	0.926
	Control	8	−236	(−1550 , 1077)		
Affluent	Intervention	26	1901	(1311 , 2492)	0.001	
	Control	28	728	(390 , 1066)		
Frailty						
Yes	Intervention	2	1692	(−10558 , 13941)	0.043	0.166
	Control	7	−599	(−1637 , 438)		
No	Intervention	34	1648	(1158 , 2138)	0.007	
	Control	29	783	(421 , 1144)		
Educational level						
High	Intervention	17	1697	(869 , 2525)	0.022	0.964
	Control	19	569	(−5 , 1142)		
Low	Intervention	19	1609	(1035 , 2182)	0.004	
	Control	17	453	(−92 , 997)		
Employment status						
Working	Intervention	17	1286	(770 , 1802)	0.015	0.661
	Control	17	285	(−363 , 932)		
Not working	Intervention	19	1977	(1201 , 2752)	0.006	
	Control	19	719	(257 , 1180)		
Economic affluence						
Affluent	Intervention	29	1670	(1112 , 2228)	0.002	0.698
	Control	31	572	(156 , 988)		
Non-affluent	Intervention	7	1569	(591 , 2547)	0.043	
	Control	5	154	(−1118 , 1425)		

CI, confidence interval.
[a] *t*-test.

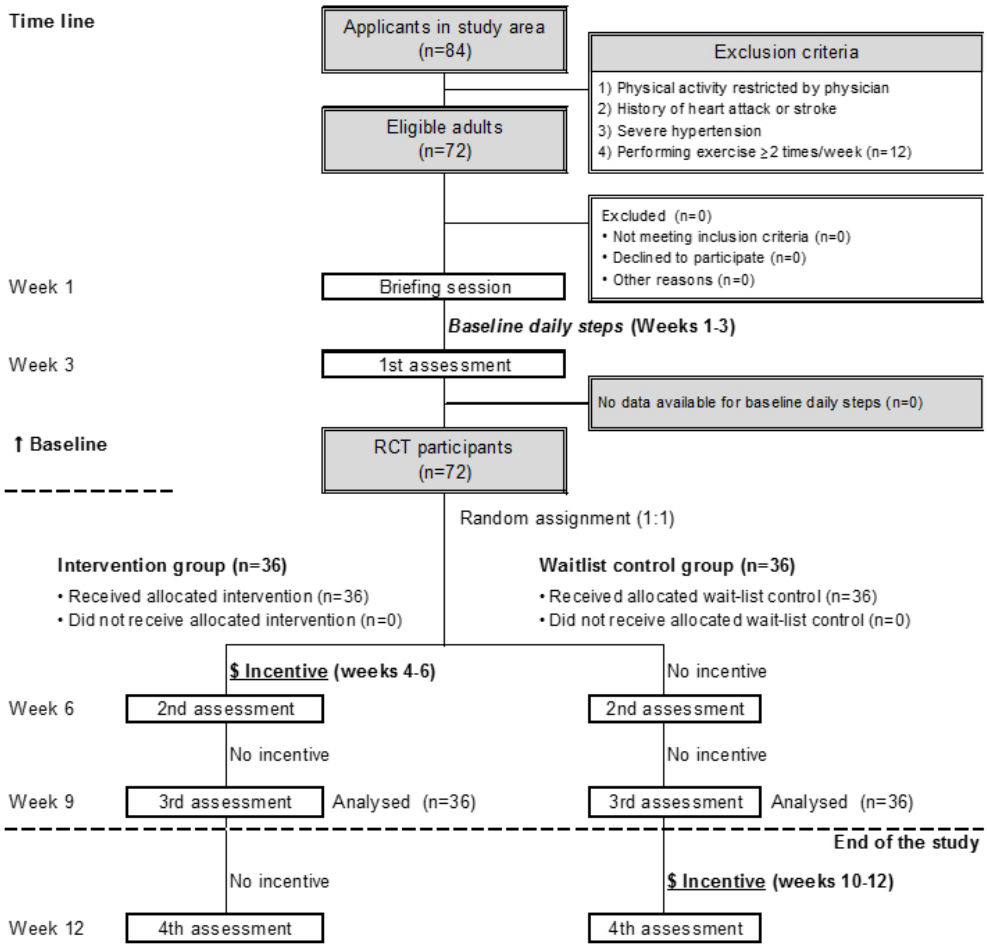

Fig. 1. CONSORT flowchart of the study procedure.

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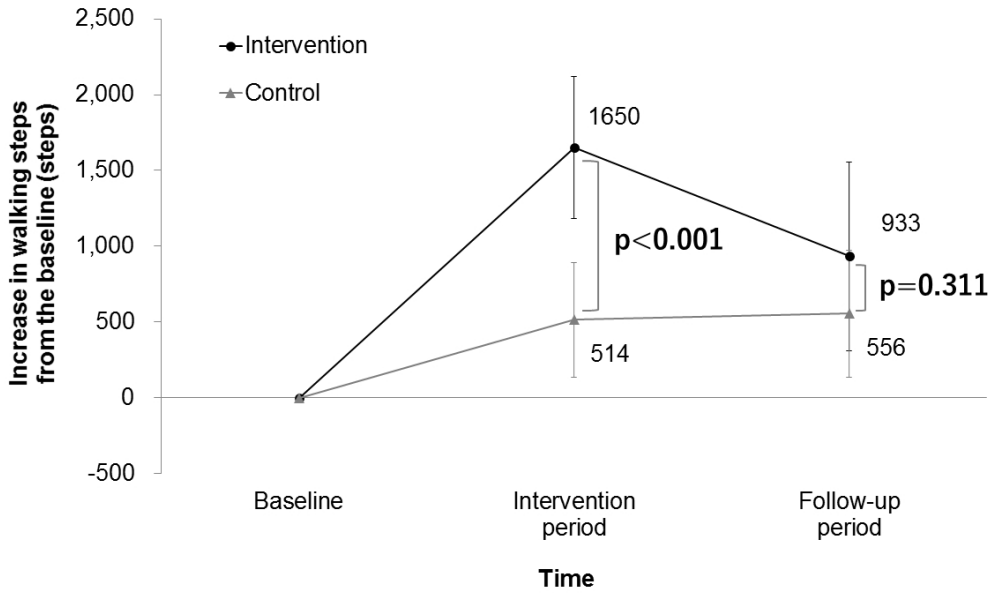

Fig. 2. Changes in the number of daily walking steps during the intervention and follow-up periods (means and 95% confidential intervals).

300x190mm (96 x 96 DPI)

Supplementary Table 1. Comparison of steps between baseline and the intervention period (weeks 4-6) (n = 72).

		Number of steps, mean (SD)		Increase in number of steps			Increase rate[b]		
	n	Baseline	Intervention period	Mean	(95% CI)	p-value[a]	Mean	(95% CI)	p-value[a]
Intervention	36	6859 (3223)	8510 (3155)	1650	(1182 , 2119)	< 0.001	31.0	(20.9 , 41.2)	< 0.001
Control	36	5869 (2249)	6383 (2737)	514	(136 , 891)		9.1	(2.5 , 15.7)	

CI, confidence interval.

[a] *t*-test.

[b] Rate (%) of change in mean number of steps/day.

Supplementary Table 2. Comparison of steps between baseline and the follow-up period (weeks 7-9) (n = 72).

		Number of steps, mean (SD)		Increase in number of steps			Increase rate[b]		
	n	Baseline	Follow-up	Mean	(95% CI)	p-value[a]	Mean	(95% CI)	p-value[a]
Intervention	36	6859 (3223)	7793 (3166)	933	(312 , 1555)	0.311	20.3	(7.6 , 33.1)	0.270
Control	36	5869 (2249)	6425 (2504)	556	(136 , 976)		12.1	(4.2 , 20.0)	

CI, confidence interval.

[a] t-test.

[b] Rate (%) of change in mean number of steps/day.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 6-7
	2b	Specific objectives or hypotheses	Page 7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	Page 8-9
	4b	Settings and locations where the data were collected	Page 8-10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 11-12
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 14
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	Page 9-10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 11
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 11
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Protocol paper (Tomata Y, et al. BMJ Open 2019;9:e026086. Page 4)

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 11
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 11
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Page 16
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 8, 16
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Page 16-18
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Fig. 2, Supplementary Table 1&2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page 17,18
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 18
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 21
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 19, 21
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 19, 20
Other information			
Registration	23	Registration number and name of trial registry	Page 8
Protocol	24	Where the full trial protocol can be accessed, if available	Page 8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 23

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Effect of a financial incentive (shopping point) on increasing the number of daily walking steps among community-dwelling adults in Japan: A randomized controlled trial

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Title:

Effect of a financial incentive (shopping point) on increasing the number of daily walking steps among community-dwelling adults in Japan: A randomized controlled trial

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ABSTRACT

Objective: The aim of the present study was to investigate the effect of a financial incentive on the number of daily steps among community-dwelling adults in Japan.

Study design: Two-arm, parallel-group RCT.

Setting/participants: We recruited physically inactive community-dwelling adults in Sendai city, Japan. Eligible participants were randomly allocated to an intervention or a wait-list control group. Pedometers were used to assess the mean number of daily steps in three periods: baseline (weeks 1-3), intervention (weeks 4–6), and follow-up (weeks 7–9).

Intervention: The intervention group was offered a financial incentive (shopping points) to meet the target number of increased daily steps in the intervention period.

Main outcome measures: The primary outcome was an increase in the mean number of daily steps in the intervention and follow-up periods compared with baseline.

Results: Seventy-two participants (69.4% female; mean age, 61.2 ± 16.2 years; mean number of daily steps at baseline, 6364 ± 2804) were randomized to the intervention (n = 36) and control groups (n = 36). During the intervention period, the increase in mean daily steps was significantly higher in the intervention (1650, 95% confidence interval [CI] = 1182, 2119) than in

the control group (514, 95% CI = 136, 891; $p < 0.001$). However, the difference between groups was not significant at follow-up after the incentives were removed ($p = 0.311$). In addition, compared with the controls, a significantly higher proportion of participants in the intervention group showed an increase of ≥ 1000 in mean daily steps (69.4% vs. 30.6%, respectively; odds ratio = 5.17, 95% CI = 1.89, 14.08). There were no adverse effects from the intervention.

Conclusions: Present results suggest that financial incentives are effective for promoting short-term increases in physical activity.

Trial Registration: UMIN000033276

Keywords: financial incentive, walking steps, randomized controlled trial, Japan

Strengths and limitations of this study

- **This study is unique in offering financial incentives in the form of local shopping points.**
- The financial incentive was a fairly small amount.
- The intervention involved only one type of financial incentive.
- Only the effect of a short-term intervention (over 3 weeks) was evaluated.

Introduction

Physical inactivity is a serious problem all around the world. According to the Global Action Plan on Physical Activity 2018–2030[1], one in four adults (1.4 billion people worldwide) do not meet the World Health Organization (WHO) recommendations for physical activity levels. According to reports from the USA,[2,3] a failure to meet recommended physical activity levels is associated with approximately 117 billion USD in annual health care costs and 10% of all premature deaths. Therefore, physical inactivity imposes a substantial burden on health care costs and longevity. To help solve these problems, the WHO and national governments have developed various policies to promote higher levels of physical activity.[1-5] Walking is a popular and major source of physical activity worldwide.[1 2 6]In the Japanese National Health Promotion Movement ("Health Japan 21"), a higher number of daily walking steps is a target for physical activity as follows: 9000 and 8500 steps in men and women aged < 65 years, and 7000 and 6000 steps in men and women aged ≥ 65 years, respectively.[7]

A systematic review (meta-analysis) has suggested that financial incentives are effective for promoting health behaviors such as smoking cessation, vaccinations, and participation in cancer screening.[8] Mitchell et al.[9] conducted a systematic review of randomized controlled trials (RCTs) on the effects of financial incentives on physical activity and reported the

results of a meta-analysis of studies promoting changes in daily walking steps. However, these studies did have methodological differences in terms of incentives (e.g., cash, charity, lottery, or team incentives) and target populations (e.g., overweight and obese adults) And only one study from Asia (Singapore) was included in this meta-analysis.

Although walking is a major source of physical activity in daily life for Japanese people, the national average number of daily walking steps for Japanese adults (age ≥ 20 years) has been decreasing, from 7655 in 2000 to 6322 in 2017.[10] Considering the rapid aging of the population and escalating health care costs, more effective measures aimed at promoting walking at the population level need to be established. Therefore, the aim of the present study was to examine the effects of a financial incentive on the number of daily walking steps among community-dwelling adults in Japan.

Methods

Study design

The protocol of the present study has been reported in detail elsewhere.[11] Briefly, this was a single-center, single-blind, parallel-group RCT in which participants were randomly assigned to an intervention or a control group.

The protocol was approved by the ethics committee of Tohoku University Graduate School of Medicine (No. 2018-1-171), and written informed consent was obtained from all participants. The present study was also registered in the University Hospital Medical Information Network (No. UMIN000033276).

Participants

In August 2018, leaflets were distributed to each house in the Nakayama area of Aoba-ku in Sendai city, Japan. Applicants who met the inclusion criteria could apply through an online application, fax, or telephone.

Inclusion and exclusion criteria

Individuals could apply for participation in the present study if they met all of the following inclusion criteria: 1) adult (aged ≥ 20 years) living in the Nakayama area; 2) possession of a community development integrated circuit (IC) card in the Nakayama area (*Nakayama Machi-dukuri IC Card*); and 3)

ability to walk unaided without using a cane, walker, or wheelchair.

Individuals who met any of the following exclusion criteria could not participate in the study: 1) physical activity restricted by a physician; 2) history of heart attack or stroke within the last 6 months; 3) blood pressure exceeding 180 mmHg systolic or 110 mmHg diastolic; or 4) already habitually exercising (task of ≥ 4 metabolic equivalents) more than twice per week.

Shopping points are added to an IC card when the customer purchases goods or participates in community activities in the Nakayama area. Customers can redeem their points during payment transactions while shopping. For example, customers can get 1 point when they purchase goods worth 200JPY (≈2 USD). IC cards are also intended to enhance social interaction among locals.

Power and sample size

Based on a previous study carried out in 2013[12], we assumed that an average difference of 1302 steps would be achieved in the intervention period (weeks 4-6) by offering a financial incentive of 2000 JPY (≈18 USD at the time of the study in 2018) and setting the standard deviation (SD) at 1711. Additionally, our previous study reported that an increase of 1000 steps was associated with reduced medical costs of 1300 JPY (≈12 USD) per month[13],

and another study reported that an increase of 1000 steps had some impact on health at the population level because it contributes to a 3.2% reduction in the average relative risk of noncommunicable diseases, dementia, joint-musculoskeletal impairment, and mortality.[4] When an α error of 0.05 and a statistical power of 0.90 was applied, the minimum sample size was 74 persons (37 persons per group). When an α error of 0.05 and a statistical power of 0.80 were applied with this sample size, a mean difference of ≥ 1,130 steps was considered statistically significant.

Study procedure

The flow of the study procedure is shown in **Fig. 1**. In a briefing session held in September 2018, the researchers rechecked the inclusion and exclusion criteria for each applicant. All participants selected provided informed consent to participate in the study. At the briefing session, each participant was provided with a pedometer (FS-800; ESTERA Corp., Saitama, Japan) containing a three-axis acceleration sensor. To maintain the accuracy of the pedometer, all participants received an explanation that they should wear the pedometer close to their waist because steps will not be counted correctly when worn on a different location, placed in a handbag, or set in any other position results in irregular movements. The number of daily walking steps at baseline was measured in the first 3 weeks of the study period (weeks 1–3)

for all participants.

Randomization

After completing the 3 weeks baseline period, participants were randomized to one of the two groups (1:1 allocation) based on the permuted block method by computer-generated randomization. The allocation sequence was managed by two experienced random assignment researchers.

Blinding

The assignment data could only be accessed by the random assignment researchers; all other staffs were blinded to the random assignments. The assignment information was kept in a password-protected storage device. The researchers involved exclusively in the random assignment notified the participants about their own assignment in a closed room separated from the other examination locations. During the notification process, these random assignment researchers warned the participants not to talk about their assignment with anyone else. In addition, data analyst was blinded to the assignments. The random assignment researchers were not involved in the statistical analyses.

Intervention

The intervention was a financial incentive in the form of shopping points that could be redeemed at 14 stores in the study area. The following two kinds of financial incentives were offered:

1. If the mean number of daily walking steps in the intervention period was ≥ 6000, shopping points worth 1000 JPY were awarded.
2. If the mean number of daily walking steps during the intervention period increased by ≥ 1000 from baseline, shopping points worth 1000 JPY were awarded.

Based on the exchange rate on August 31, 2018, 2000 JPY was equivalent to 18 USD. Participants in the intervention group who achieved their daily step goals during the intervention period (weeks 4-6) were rewarded with shopping points worth 1000 or 2000 JPY on their IC card at that time (after the end of the trial, i.e., week 12). And then, their incentive removed for the follow-up period (weeks 7-9). We did not specify how the shopping points could be used, so it is possible that they might have used the points for unhealthy purchases (e.g., cigarettes).

Wait list control group

The wait list control group had no incentives all the way through the end of the follow-up period. It was only after the study was complete that they were offered the same incentives as the intervention group during weeks 10-12.

All conditions except for the timing were the same as those for the intervention group.

Measurements

The participants' baseline characteristics were assessed at the date of the briefing session. Interviews with trained interviewers were conducted to obtain information regarding medical history, frailty (the Kihon checklist) [14-18], physical activity level[19 20], transportation when going out, education level[21], work, subjective economic status, time affluence (having spare time) [22], body height, weight, pain, and falling. Blood pressure was also measured using an automated sphygmomanometer (HEM-1040; Omron, Kyoto, Japan).

Transportation when going out was assessed by asking the question "What kinds of transportation have you used more than twice per week when going out in the last month?", for which, the available responses were: "walking", "bicycle", "motorbike", "car", "train", "bus", "taxi", or "other".

Economic affluence was assessed by asking the question "How do you feel about your current household situation?" The participants were asked to choose one of the following five answers: "most affluent", "more affluent", "neither more nor less", "less affluent", and "non-affluent". We classified the first three answers as "affluent" and the last two as "non-affluent".

Time affluence (having spare time) was assessed by asking the

question “Do you have enough time available to take rest or enjoy leisure in daily life?” The participants were asked to choose one of the following four answers: “more affluent”, “little affluent”, “less affluent”, and “non-affluent”. We classified the first two answers as “affluent” and the last two as “non-affluent”.

Incident falls were assessed based on the question “Have you fallen in the past 3 weeks?” The participants were asked to answer either “yes” or “no”. Incident pain was assessed based on the question “How much pain have you experienced during the past 3 weeks?”, with the participants asked to choose one of the following six answers: “none”, “very mild”, “mild”, “moderate”, “severe”, or “very severe”.

Outcome measurements

The participants were asked to visit the study center every 3 weeks, and evaluations of individual daily steps were carried out during each visit. For each visit, we transferred data on the number of daily steps to a computer and asked the participants whether they had experienced any pain or falls in the 3-week period. All participants were instructed to wear the pedometer while awake every day during the study period (weeks 9).

The primary outcome was the mean increase in the number of daily steps during the intervention period (weeks 4–6) compared with that at

baseline.

The secondary outcomes were: 1) an increase in the number of daily steps by ≥ 1000 at weeks 4–6 or 7–9 from baseline; 2) incident falls at weeks 4–6 or 7–9; and 3) incident pain at weeks 4–6 or 7–9.

Statistical analyses

In regard to the primary outcome, the *t*-test was applied to examine whether the mean increases and rate of change in the number of daily steps at weeks 4–6 and 7–9 from baseline differed significantly between the intervention and control groups.

In regard to the secondary outcomes, logistic regression models were applied to examine whether the proportions of participants with an increase of ≥ 1000 steps were significantly different, and to assess the probabilities of incident falls and incident pain. Odds ratios (ORs) and 95% confidence intervals (CIs) were also estimated.

In addition, stratified analyses were conducted to check for any differences in the number of daily steps in terms of sex, age, frailty, physical activity level, transportation when going out, education level, work, subjective economic status, time affluence, and obesity.

All analyses were performed using IBM SPSS Statistics (version 25; IBM SPSS, Chicago, IL, USA).

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our trial.

Results

The mean age (SD) of the participants (69.4% female) was 61.2 (16.2) years, and 30.6% had an undergraduate or graduate degree.

At baseline, the mean numbers of daily steps (SD) in the intervention and control groups were 6859 (3,223) and 5869 (2249), respectively; this difference was not significant (p = 0.135) (**Table 1**). Participants in the intervention group were significantly more likely to have pain than those in the control group (p = 0.011). No significant differences in age, sex, blood pressure, history of disease, frailty, physical activity level, transportation, educational level, employment, subjective household economic status, subjective time affluence, or body mass index (BMI) were found between the two groups.

All 72 participants completed the intervention (weeks 4–6) and follow-up periods (weeks 7–9). Comparisons of steps between the baseline and intervention or follow-up periods in the intervention and control groups are shown in **Fig. 2**. The mean increases in the numbers of daily steps from baseline to the intervention period in the intervention and control groups were 1650 (95% CI = 1182, 2119) and 514 (95% CI = 136, 891), respectively, indicating a significant difference between groups (p < 0.001). The mean increase rate in the number of daily steps from baseline to the intervention period was significantly higher in the intervention than in the

control group (31.0% vs. 9.1%, respectively; p < 0.001) (**Supplementary Table 1**). The mean increase in the number of daily steps from baseline to the follow-up period was larger in the intervention (933, 95% CI = 312, 1555) than in the control group (556, 95% CI = 136, 976) (**Fig. 2**); however, no significant difference was observed between groups (p = 0.311). Regarding the mean increase rate in the number of daily steps from baseline to the follow-up period, no significant difference was found between groups (p = 0.270) (**Supplementary Table 2**).

A comparison of the proportion of participants who increased the mean number of daily steps by ≥ 1000 from baseline to the intervention period is shown in **Table 2**. The proportion in the intervention group was 69.4% (n=25) and that in the control group was 30.6% (n=11). The proportion was significantly higher in the intervention than in the control group (OR = 5.17; 95% CI = 1.89, 14.08).

Table 3 shows the results of the analyses stratified by baseline characteristics. The subgroup analyses showed a significant increase in the number of daily steps among participants with a lower (< 6000) compared with those with a higher (≥ 6000) baseline step count (p-interaction = 0.012).

Incident falls were reported in two participants (5.7%) in the intervention group and one participant (2.9%) in the control group, and the incident rate was not significantly different (p = 0.555). Incident pain was

reported in four participants (14.3%) in the intervention group and one participant (4.2%) in the control group, and the incident rate was not significantly different ($p = 0.217$).

Discussion

The present RCT examined the effects of a financial incentive (shopping points) on the number of daily walking steps among community-dwelling Japanese adults. The increase in the number of daily steps was significantly larger in the intervention than in the control group, with a particularly substantial increase in those with low physical activity levels at baseline. However, caution is required when interpreting the present findings because the intervention period was as short as 3 weeks and the increased number of daily steps was not maintained after receiving the incentive. Whether the incentive needs to be continued so that the participants maintain their increased number of daily steps remains unclear.

Although most of the study participants might be considered more health-conscious than average because they volunteered to participate in this RCT and were classified as economically affluent, the present results are considered to be generalizable to the community-dwelling adult population in Japan because the mean number of daily steps among the study participants at baseline was similar to the nationwide average (6364 vs. 6322, respectively).[10] The study area was safe for walking and has sidewalks that are favorable for pedestrians, which is typical in local communities in Japan.

Previous studies have reported that socioeconomic status, which includes occupation and education and income levels, is associated with

health inequality.[23 24] However, the results of the present study demonstrated that offering a financial incentive to increase the number of daily walking steps was not affected by economic affluence or education level. Walking has considerable health benefits[25] and does not require any special training or substantial additional costs. This could be the reason why the financial incentive resulted in an increase in the number of daily walking steps, regardless of socioeconomic status.

Previous studies aiming to increase physical activity levels have used cash as a financial incentive.[12 26-28] In this study, we chose to use shopping points (a non-cash incentive) that could only be redeemed at stores in the study area because we believed that it would cause the participants to patronize local stores in the community more frequently. Therefore, a unique aspect of the present study is that it aimed to promote both health and economic activities in the local community. In fact, local stores in the study area chose to resume the financial incentive program after this RCT was completed.

This study had several notable strengths. First, all of the participants completed each program during the trial period. Second, to our knowledge, this study is unique in offering financial incentives in the form of local shopping points. Third, the financial incentive offered in this study was a fairly low amount compared with other financial incentive studies involving

physical activity. Although most of study participants were classified as affluent in terms of their economic status, the relatively small financial incentive was still effective for increasing the number of daily walking steps. Fourth, the present results are considered to be generalizable to the community-dwelling adult population in Japan because the mean number of daily walking steps among the study participants at baseline was similar to the nationwide average.[10]

Limitations

This study also had several limitations. First, the intervention involved only one type of financial incentive; therefore, the effects of changes in the corresponding financial incentive or its application (e.g., donations) are unclear. Second, only the effect of a short-term intervention (over 3 weeks) was evaluated; whether an intervention involving a financial incentive would be effective for maintaining an increase in the number of daily walking steps over the long term is unclear. Third, the study participants were all Japanese adults; therefore, the present results may not generalizable to non-Japanese populations. Fourth, the possibility of overestimation due to the small sample size cannot be ruled out. However, the sample size set at the start of the study was almost achieved.

Conclusions

The results of the present study indicated that offering a financial incentive was effective for increasing the number of daily walking steps among Japanese community-dwelling adults, even though the intervention period was as short as 3 weeks. The difference between the intervention and control groups was not significant at follow-up after the incentives were removed. Future research should explore whether the continuation of financial incentives can maintain an increased number of daily steps over the long term.

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Authors' contributions: IT supervised this study and is the guarantor. FT, YT and IT were involved in the design. FT and IT prepared draft manuscript. SA, SM, YK, DN, KM, YLi, SZ, YLu, YS, SB, TY, TO, and TS revised the manuscript. SZ carried out the statistical analyses. All authors approved submission of this manuscript.

Competing interests: The authors have no financial disclosures in association with this study.

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References

1. World Health Organization. Global action plan on physical activity 2018-2030. More active people for a healthier world. Geneva: World Health Organization; 2018.

2. Piercy KL, Troiano RP, Ballard RM, et al. The Physical Activity Guidelines for Americans. *JAMA* 2018;320(19):2020-8.

3. US Department of Health and Human Services: Physical Activity Guidelines for Americans. 2nd ed. Washington, DC: U.S. Department of Health and Human Services; 2018.

4. Miyachi M, Tripette J, Kawakami R, Murakami H. "+10 min of Physical Activity per Day": Japan Is Looking for Efficient but Feasible Recommendations for Its Population. *Journal of nutritional science and vitaminology* 2015;61:S7-9.

5. Nishi N. Monitoring Obesity Trends in Health Japan 21. *Journal of nutritional science and vitaminology* 2015;61:S17-9.

6. Althoff, T, Sosič, R, Hicks, J. L, et al. Large-scale physical activity data reveal worldwide activity inequality. Nature. 2017;547(7663):336-339.

7. Ministry of Health, Labour and Welfare. Health Japan 21. 2012. https://www.mhlw.go.jp/bunya/kenkou/dl/kenkounippon21_01.pdf .

8. Giles EL, Robalino S, McColl E, et al. The effectiveness of financial incentives for health behaviour change: systematic review and

meta-analysis. *PLoS One* 2014;9(3):e90347.

9. Mitchell MS, Orstad SL, Biswas A, et al. Financial incentives for physical activity in adults: systematic review and meta-analysis. Br J Sports Med 2019;bjsports-2019-100633. doi: 10.1136/bjsports-2019-100633. Online ahead of print.

10. The Ministry of Health, Labor and Welfare in Japan. National Health and Nutrition Survey. https://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyou_chousa.html [in Japanese]

11. Tomata Y, Tanji F, Nurrika D, et al. Randomised controlled trial of a financial incentive for increasing the number of daily walking steps: study protocol. *BMJ Open* 2019;9(6):e026086.

12. Harkins KA, Kullgren JT, Bellamy SL, et al. A Trial of Financial and Social Incentives to Increase Older Adults' Walking. *Am J Prev Med* 2017;52(5):e123-30.

13. Tsuji I, Takahashi K, Nishino Y, et al. Impact of walking upon medical care expenditure in Japan: the Ohsaki Cohort Study. *Int J Epidemiol* 2003;32 (5):809-14.

14. Arai H, Satake S: English translation of the Kihon Checklist. *Geriatr Gerontol Int* 2015;15(4):518-9.

15. Fukutomi E, Okumiya K, Wada T, et al. Relationships between each

category of 25-item frailty risk assessment (Kihon Checklist) and newly certified older adults under Long-Term Care Insurance: A 24-month follow-up study in a rural community in Japan. *Geriatr Gerontol Int* 2015;15(7):864-71.

16. Satake S, Senda K, Hong YJ, et al. Validity of the Kihon Checklist for assessing frailty status. *Geriatr Gerontol Int* 2016;16(6):709-15

17. Sewo Sampaio PY, Sampaio RA, Yamada M, et al. Validation and translation of the Kihon Checklist (frailty index) into Brazilian Portuguese. *Geriatr Gerontol Int* 2014;14(3):561-9.

18. Tomata Y, Hozawa A, Ohmori-Matsuda K, et al. Validation of the Kihon Checklist for predicting the risk of 1-year incident long-term care insurance certification: the Ohsaki Cohort 2006 Study [in Japanese]. *Nihon Koshu Eisei Zasshi* 2011;58(1):3-13.

19. Fujii H, Yamamoto S, Takeda-Imai F, et al. Validity and applicability of a simple questionnaire for the estimation of total and domain-specific physical activity. *Diabetology International* 2011;2(2):47-54.

20. Sasai H, Nakata Y, Murakami H, et al. Simultaneous Validation of Seven Physical Activity Questionnaires Used in Japanese Cohorts for Estimating Energy Expenditure: A Doubly Labeled Water Study. *J Epidemiol* 2018;28(10):437-42.

21. Ministry of Internal Affairs and Communications. Population Census.

1 1996 http://www.stat.go.jp/english/data/kokusei/index.html

22. Tomata Y, Tanno K, Zhang S, et al. Subjective Household Economic Status and Obesity in Toddlers: A Cross-Sectional Study of Daycare Centers in Japan. *J Epidemiol*. 2019;29(1):33-37.

23. Mackenbach JP, Stirbu I, Roskam AJ, et al. Socioeconomic inequalities in health in 22 European countries. *N Engl J Med* 2008;358(23): 2468-81.

24. Nurrika D, Zhang S, Tomata Y, et al. Education level and incident functional disability in elderly Japanese: The Ohsaki Cohort 2006 study. *PLoS One* 2019;14(3): e0213386.

25. Hakim AA, Petrovitch H, Burchfiel CM, et al. Effects of walking on mortality among nonsmoking retired men. *N Engl J Med* 1998;338(2): 94-9.

26. Finkelstein EA, Brown DS, Brown DR, Buchner DM. A randomized study of financial incentives to increase physical activity among sedentary older adults. *Prev Med* 2008;47(2): 182-7.

27. Patel MS, Asch DA, Rosin R, et al. Framing Financial Incentives to Increase Physical Activity Among Overweight and Obese Adults: A Randomized, Controlled Trial. *Ann Intern Med* 2016;164(6): 385-94.

28. Patel MS, Asch DA, Rosin R, et al. Individual Versus Team-Based Financial Incentives to Increase Physical Activity: A Randomized, Controlled Trial. *J Gen Intern Med* 2016;31(7):746-54.

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Fig. 1. CONSORT flowchart of the study procedure.

Fig. 2. Changes in the number of daily walking steps during the intervention and follow-up periods (means and 95% confidential intervals).

Table 1. Baseline characteristics of the study participants (n = 72).

Characteristics	Intervention (n = 36)	Control (n = 36)	p-value
Female, %	69.4	69.4	1.000
Age, years (mean ± SD)	62.0 ± 16.5	60.4 ± 16.1	0.671
Blood pressure, mmHg (mean ± SD)			
Systolic blood pressure	130.7 ± 20.7	125.5 ± 18.5	0.264
Diastolic blood pressure	79.0 ± 11.4	76.7 ± 10.8	0.378
History of disease, %			
Stroke	2.8	0.0	0.314
Hypertension	25.0	30.6	0.599
Myocardial infarction	0.0	5.6	0.151
Diabetes	8.3	8.3	1.000
Arthritis	2.8	5.6	0.555
Osteoporosis	5.6	0.0	0.151
Cancer	16.7	8.3	0.285
Frailty, %	5.6	19.4	0.075
Physical activity, MET (mean ± SD)	35.8 ± 8.5	36.1 ± 5.3	0.822
Transportation, %			
Motorbike or car	61.1	80.6	0.070
Educational attainment, %			
High school or less	52.8	47.2	
College/university	16.7	22.2	0.820
Undergraduate or graduate degree	30.6	30.6	
Employment, %			
≥ 4 days/week	27.8	36.1	
< 4 days/week	19.4	11.1	0.546
Not working	52.8	52.8	
Subjective household economic status			
Affluent	80.6	86.1	0.527
Non-affluent	19.4	13.9	
Subjective time affluence			
Affluent	72.2	77.8	0.586
Non-affluent	27.8	22.2	
Pain			
Absent	22.2	44.4	0.011
Present	5.6	2.8	
Body mass index, kg/m^2 (mean ± SD)	22.1 ± 3.0	23.2 ± 4.6	0.250
Baseline number of steps/day (mean ± SD)	6859 ± 3223	5869 ± 2249	0.135

MET, metabolic equivalent; SD, standard deviation.

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Table 2. Comparison of the proportions of participants with an increase in the number of daily steps of 1000 or more from baseline to the intervention period (weeks 4–6) (n = 72).

		Intervention period (weeks 4-6)		
	n	Proportion[a]	OR[b]	(95% CI)
Intervention	36	69.4	5.17	(1.89 , 14.08)
Control	36	30.6	1.00	(Reference)

CI, confidence interval; OR, odds ratio.

[a] Proportions of participants who increased the number of daily steps by 1000 or more from baseline.

[b] Logistic regression analysis.

Table 3. Subgroup analysis: Comparison of increases in the number of steps from baseline to the intervention period (weeks 4–6) (n = 72).

Subgroup		n	Intervention period (weeks 4-6) Mean	(95% CI)	p-value[a]	p-interaction[a]
Sex						
Male	Intervention	11	2199	(783 , 3615)	0.021	0.140
	Control	11	401	(−331 , 1134)		
Female	Intervention	25	1409	(1054 , 1765)	0.005	
	Control	25	563	(91 , 1036)		
Age (years)						
< 65	Intervention	17	1650	(780 , 2519)	0.006	0.245
	Control	17	148	(−475 , 771)		
≥ 65	Intervention	19	1651	(1127 , 2175)	0.019	
	Control	19	841	(390 , 1292)		
Baseline number of steps						
< 6000	Intervention	16	2193	(1331 , 3056)	< 0.001	0.012
	Control	18	264	(−183 , 712)		
≥ 6000	Intervention	20	1216	(745 , 1687)	0.229	
	Control	18	763	(130 , 1397)		
Physical activity						
Low	Intervention	19	1796	(1060 , 2531)	0.001	0.116
	Control	17	181	(−286 , 648)		
High	Intervention	17	1488	(856 , 2121)	0.107	
	Control	19	812	(223 , 1400)		
Body mass index						
≥ 25	Intervention	4	1433	(−1262 , 4127)	0.333	0.701
	Control	8	577	(−435 , 1590)		
< 25	Intervention	32	1678	(1184 , 2172)	0.001	
	Control	28	496	(65 , 926)		
Time affluence						
Non-affluent	Intervention	10	998	(338 , 1658)	0.054	0.926
	Control	8	−236	(−1550 , 1077)		
Affluent	Intervention	26	1901	(1311 , 2492)	0.001	
	Control	28	728	(390 , 1066)		
Frailty						
Yes	Intervention	2	1692	(−10558 , 13941)	0.043	0.166
	Control	7	−599	(−1637 , 438)		
No	Intervention	34	1648	(1158 , 2138)	0.007	
	Control	29	783	(421 , 1144)		
Educational level						
High	Intervention	17	1697	(869 , 2525)	0.022	0.964
	Control	19	569	(−5 , 1142)		
Low	Intervention	19	1609	(1035 , 2182)	0.004	
	Control	17	453	(−92 , 997)		
Employment status						
Working	Intervention	17	1286	(770 , 1802)	0.015	0.661
	Control	17	285	(−363 , 932)		
Not working	Intervention	19	1977	(1201 , 2752)	0.006	
	Control	19	719	(257 , 1180)		
Economic affluence						
Affluent	Intervention	29	1670	(1112 , 2228)	0.002	0.698
	Control	31	572	(156 , 988)		
Non-affluent	Intervention	7	1569	(591 , 2547)	0.043	
	Control	5	154	(−1118 , 1425)		

CI, confidence interval.
[a] *t*-test.

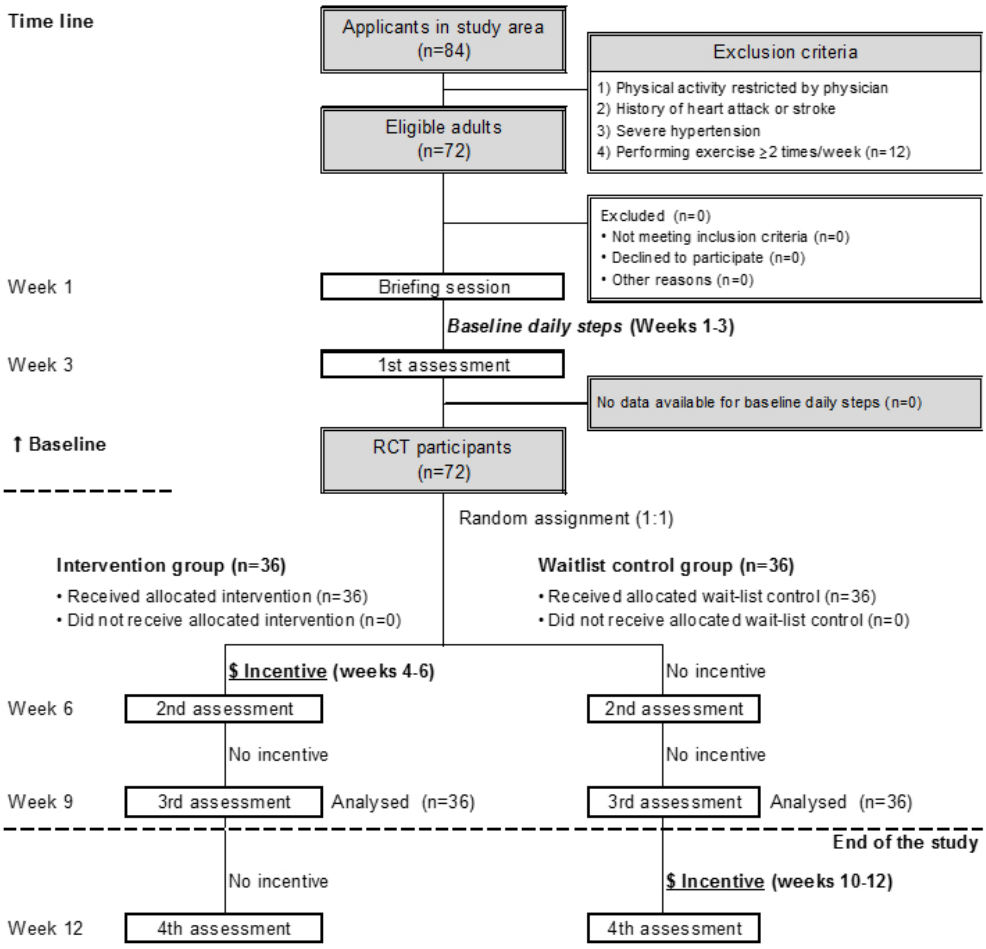

Fig. 1. CONSORT flowchart of the study procedure.

190x189mm (96 x 96 DPI)

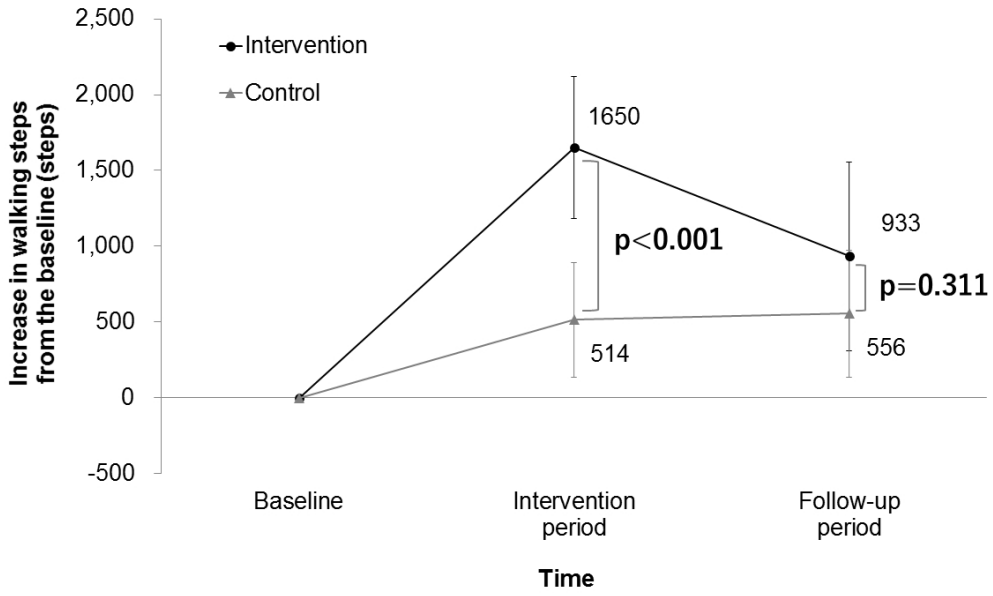

Fig. 2. Changes in the number of daily walking steps during the intervention and follow-up periods (means and 95% confidential intervals).

300x190mm (96 x 96 DPI)

Supplementary Table 1. Comparison of steps between baseline and the intervention period (weeks 4-6) (n = 72).

		Number of steps, mean (SD)		Increase in number of steps			Increase rate[b]		
	n	Baseline	Intervention period	Mean	(95% CI)	p-value[a]	Mean	(95% CI)	p-value[a]
Intervention	36	6859 (3223)	8510 (3155)	1650	(1182 , 2119)	< 0.001	31.0	(20.9 , 41.2)	< 0.001
Control	36	5869 (2249)	6383 (2737)	514	(136 , 891)		9.1	(2.5 , 15.7)	

CI, confidence interval.

[a] *t*-test.

[b] Rate (%) of change in mean number of steps/day.

Supplementary Table 2. Comparison of steps between baseline and the follow-up period (weeks 7-9) (n = 72).

		Number of steps, mean (SD)		Increase in number of steps			Increase rate[b]		
	n	Baseline	Follow-up	Mean	(95% CI)	p-value[a]	Mean	(95% CI)	p-value[a]
Intervention	36	6859 (3223)	7793 (3166)	933	(312 , 1555)	0.311	20.3	(7.6 , 33.1)	0.270
Control	36	5869 (2249)	6425 (2504)	556	(136 , 976)		12.1	(4.2 , 20.0)	

CI, confidence interval.

[a] t-test.

[b] Rate (%) of change in mean number of steps/day.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 6-7
	2b	Specific objectives or hypotheses	Page 7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	Page 8-9
	4b	Settings and locations where the data were collected	Page 8-10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 11-12
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 14
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	Page 9-10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 11
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 11
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Protocol paper (Tomata Y, et al. BMJ Open 2019;9:e026086. Page 4)

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 11
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 11
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Page 17
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 8
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Page 17-18
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Fig. 2, Supplementary Table 1&2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page 18
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 18, 19
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 22
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 20, 22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 20, 21
Other information			
Registration	23	Registration number and name of trial registry	Page 8
Protocol	24	Where the full trial protocol can be accessed, if available	Page 8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 24

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.