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# BMJ Open

## 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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4 1 **Title:**

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6 2 **Effect of a financial incentive on increasing the number of daily walking**  
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9 3 **steps among community-dwelling adults in Japan: A randomized**  
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11  
12 4 **controlled trial**

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## 1 ABSTRACT

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

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

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

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

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

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

1 to the intervention (n = 36) and control groups (n = 36). During the  
2 intervention period, the increase in mean daily steps was significantly higher  
3 in the intervention than in the control group (1650 vs. 514, respectively; p <  
4 0.001). In addition, compared with the controls, a significantly higher  
5 proportion of participants in the intervention group showed an increase of  $\geq$   
6 1000 in mean daily steps (69.4% vs. 30.6%, respectively; odds ratio = 5.17,  
7 95% confidence interval = 1.89, 14.08).

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

10 **Trial Registration:** UMIN000033276

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12 **Keywords:** financial incentive, walking steps, randomized controlled trial,  
13 Japan

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4 **1 Strengths and limitations of this study**  
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- 6  
7 2 ➤ This study is the first to offer a noncash financial incentive  
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9 3 ➤ The present study would be first Asian trial.  
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12 4 ➤ The intervention involved only one type of financial incentive.  
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15 5 ➤ Only the effect of a short-term intervention (over 3 weeks) was  
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18 6 evaluated.  
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## 1 **Introduction**

2 Physical inactivity is a serious problem all around the world. According to  
3 the Global Action Plan on Physical Activity 2018–2030<sup>1</sup>, one in four adults  
4 (1.4 billion people worldwide) do not meet the World Health Organization  
5 (WHO) recommendations for physical activity levels. Therefore, physical  
6 inactivity imposes a substantial burden on health care costs. For example, in  
7 the US, failure to meet recommended physical activity levels has been  
8 associated with approximately 117 billion USD in annual health care costs  
9 and 10% of all premature mortality.<sup>2 3</sup> To help solve these problems, the  
10 WHO and national governments have developed various policies to promote  
11 higher levels of physical activity.<sup>1-5</sup>

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

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4 1 may have been the results of differences in methodologies, the ages of the  
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7 2 participants, the intervention periods, or the amount of incentives.  
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9 3 Therefore, the aim of the present study was to examine the effects of a  
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12 4 financial incentive on the number of daily walking steps among  
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15 5 community-dwelling adults in Japan.  
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4 1 ***Methods***

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7 2 *Study design*

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9 3 The protocol of the present study has been reported in detail elsewhere.<sup>9</sup>

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12 4 Briefly, this was a single-center, single-blind, parallel-group RCT in which  
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15 5 participants were randomly assigned to an intervention or a control group.

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18 6 The protocol was approved by the ethics committee of Tohoku University

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21 7 Graduate School of Medicine (No. 2018-1-171), and written informed

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24 8 consent was obtained from all participants. The present study was also

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27 9 registered in the University Hospital Medical Information Network (No.

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29 10 UMIN000033276).

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34 12 *Participants*

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37 13 In August 2018, leaflets were distributed to each house in the Nakayama area

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40 14 of Aoba-ku in Sendai city, Japan. Applicants who met the inclusion criteria

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43 15 could apply through an online application, fax, or telephone.

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48 17 *Inclusion and exclusion criteria*

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51 18 Individuals could apply for participation in the present study if they met all

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54 19 of the following inclusion criteria: 1) adult (aged  $\geq 20$  years) living in the

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57 20 Nakayama area; 2) possession of a community development integrated circuit

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60 21 (IC) card in the Nakayama area (*Nakayama Machi-dukuri IC Card*); and 3)

1 ability to walk unaided without using a cane, walker, or wheelchair.  
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4 1 ability to walk unaided without using a cane, walker, or wheelchair.  
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7 2 Individuals who met any of the following exclusion criteria could not  
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10 3 participate in the study: 1) physical activity restricted by a physician; 2)  
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12 4 history of heart attack or stroke within the last 6 months; 3) blood pressure  
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15 5 exceeding 180 mmHg systolic or 110 mmHg diastolic; or 4) already  
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18 6 habitually exercising (task of  $\geq 4$  metabolic equivalents) more than twice per  
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21 7 week.  
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### 9 *Power and sample size*

10 Based on a previous study carried out in 2013<sup>7</sup>, we assumed that an average  
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12 difference of 1302 steps would be achieved in the intervention period (4–6  
13  
14 weeks) by offering a financial incentive of 2000 JPY and setting the standard  
15  
16 deviation (SD) at 1711. When an  $\alpha$  error of 0.05 and a statistical power of  
17  
18 0.90 was applied, the minimum sample size was 74 persons (37 persons per  
19  
20 group). When an  $\alpha$  error of 0.05 and a statistical power of 0.80 were applied  
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22 with this sample size, a mean difference of  $\geq 1,130$  steps was considered  
23  
24 statistically significant.  
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### 19 *Study procedure*

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

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

### 7 8 *Randomization*

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

### 13 14 *Blinding*

15 The assignment data could only be accessed by the random assignment  
16 researchers; all other staffs were blinded to the random assignments.

17 In addition, all statistical analyses were blinded to the assignments. The  
18 random assignment researchers were not involved in the statistical analyses.

### 19 20 *Intervention*

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

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

3 1. If the mean number of daily walking steps in the intervention period was  $\geq$   
4 6000, shopping points worth 1000 JPY were awarded.

5 2. If the mean number of daily walking steps during the intervention period  
6 increased by  $\geq 1000$  from baseline, shopping points worth 1000 JPY were  
7 awarded.

8 Based on the exchange rate on August 31, 2018, 2000 JPY was equivalent to  
9 18 USD. During the intervention period (4–6 weeks), the intervention group  
10 could gain the financial incentive if they achieved their daily step goals.

11 After the end of the study (i.e., after 10–12 weeks), the wait-list control  
12 group could also gain the financial incentive.

### 13 14 *Measurements*

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

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7 2 *Outcome measurements*  
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10 3 Daily step evaluations were carried out and feedback was collected every 3  
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12 4 weeks. All participants were instructed to wear the pedometer while awake  
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15 5 every day during the study period (9 weeks).

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18 6 The primary outcome was the mean increase in the number of daily steps  
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21 7 compared with that at baseline.

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23 8 The secondary outcomes were: 1) an increase in the number of daily steps by  
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26 9  $\geq 1000$  at 4–6 or 7–9 weeks from baseline; 2) incident falls at 4–6 or 7–9  
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29 10 weeks; and 3) incident pain at 4–6 or 7–9 weeks.

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34 12 *Statistical analyses*

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37 13 In regard to the primary outcome, the *t*-test was applied to examine whether  
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40 14 the mean increases and rate of change in the number of daily steps at 4–6 and  
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43 15 7–9 weeks from baseline differed significantly between the intervention and  
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46 16 control groups.

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48 17 In regard to the secondary outcomes, logistic regression models were applied  
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51 18 to examine whether the proportions of participants with an increase of  $\geq$   
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54 19 1000 steps were significantly different, and to assess the probabilities of  
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57 20 incident falls and incident pain. Odds ratios (ORs) and 95% confidence  
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60 21 intervals (CIs) were also estimated.

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4 1 In addition, stratified analyses were conducted to check for any differences  
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7 2 in the number of daily steps in terms of sex, age, frailty, physical activity  
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10 3 level, transportation when going out, education level, work, subjective  
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13 4 economic status, time affluence, and obesity.

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15 5 All analyses were performed using IBM SPSS Statistics (version 25; IBM  
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18 6 SPSS, Chicago, IL, USA).

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23 8 *Patient and Public Involvement*

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26 9 Patients or the public were not involved in the design, or conduct, or  
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29 10 reporting, or dissemination plans of our trial.

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## 1 **Results**

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

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

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

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

5 Regarding the mean increase rate in the number of daily steps from baseline  
6 to the follow-up period, no significant difference was found between groups  
7 ( $p = 0.270$ ) (**Supplementary Table 2**).

8 A comparison of the proportion of participants who increased the mean  
9 number of daily steps by  $\geq 1000$  from baseline to the intervention period is  
10 shown in **Table 2**. The proportion in the intervention group was 69.4%  
11 ( $n=25$ ) and that in the control group was 30.6% ( $n=11$ ). The proportion was  
12 significantly higher in the intervention than in the control group ( $OR = 5.17$ ;  
13 95%  $CI = 1.89, 14.08$ ).

14 **Table 3** shows the results of analyses stratified by baseline status conducted  
15 to check for any differences in the mean increase in the number of daily  
16 steps from baseline to the intervention period. Even after stratifying by sex  
17 or age, the mean increase in the number of daily steps was significantly  
18 larger in the intervention than in the control group in all strata ( $p < 0.05$ ).

19 Among participants stratified by the number of daily steps at baseline ( $<$   
20 6000 and  $\geq 6000$ ), the mean increase in the number of daily steps was larger  
21 in the intervention than in the control group, but the only significant

1 difference was among those with < 6000 daily steps ( $p < 0.001$ ). In both  
2 physical activity groups (high and low), the mean increase in the number of  
3 daily steps was larger in the intervention than in the control group, but the  
4 only significant difference was among those with a low physical activity  
5 level ( $p = 0.001$ ). In both BMI groups ( $< 25$  and  $\geq 25$  kg/m<sup>2</sup>), the mean  
6 increase in the number of daily steps was larger in the intervention than in  
7 the control group, but the only significant difference was among those with a  
8 BMI  $< 25$  ( $p = 0.001$ ). In both time affluence groups (affluent and  
9 non-affluent), the mean increase in the number of daily steps was larger in  
10 the intervention than in the control group, but this difference was marginally  
11 non-significant among the non-affluent group ( $p = 0.054$ ). After stratifying  
12 by frailty, educational level, employment, and economic affluence, each  
13 mean increase in the number of daily steps was significantly larger in the  
14 intervention than in the control group ( $p < 0.05$  for all).

15 Incident falls were reported in two participants (5.7%) in the intervention  
16 group and one participant (2.9%) in the control group, and the incident rate  
17 was not significantly different ( $p = 0.555$ ). Incident pain was reported in four  
18 participants (14.3%) in the intervention group and one participant (4.2%) in  
19 the control group, and the incident rate was not significantly different ( $p =$   
20 0.217).

## 1 *Discussion*

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

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

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

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4 1 increase the number of daily walking steps among physically inactive adults  
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7 2 could be expected to reduce health disparities between groups of unequal  
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10 3 socioeconomic status.  
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12 4 Previous studies aiming to increase physical activity levels have used cash as  
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15 5 a financial incentive.<sup>7 8 23 24</sup> In the present study, we chose to use shopping  
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18 6 points that could only be redeemed at stores in the study area because we  
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21 7 believed that it would cause the participants to patronize local stores in the  
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24 8 community more frequently. Therefore, a unique aspect of the present study  
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27 9 is that it aimed to promote both health and economic activities in the local  
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30 10 community. In fact, local stores in the study area chose to resume the  
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33 11 financial incentive program after this RCT was completed.  
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36 12 This study had several notable strengths. First, all of the participants  
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39 13 completed each program during the trial period. Second, to our knowledge,  
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42 14 this study is the first to offer a noncash financial incentive. Third, the  
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45 15 present results are considered to be generalizable to the community-dwelling  
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48 16 adult population in Japan because the mean number of daily walking steps  
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51 17 among the study participants at baseline was similar to the nationwide  
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54 18 average.<sup>19</sup>

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### 20 *Limitations*

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

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

### 10 ***Conclusions***

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

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3  
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5 YT and IT were involved in the design. FT and IT prepared draft manuscript.  
6 SA, SM, YK, DN, KM, YLi, SZ, YLu, YS, SB, TY, TO, and TS revised the  
7 manuscript. SZ carried out the statistical analyses. All authors approved  
8 submission of this manuscript.

9  
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12  
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20  
21 **Data availability statement:** Data are available upon reasonable request.

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4 1 8. Patel MS, Asch DA, Rosin R, et al. Individual Versus Team-Based  
5  
6  
7 2 Financial Incentives to Increase Physical Activity: A Randomized,  
8  
9  
10 3 Controlled Trial. *J Gen Intern Med* 2016;31(7):746-54.  
11  
12 4 9. Tomata Y, Tanji F, Nurrika D, et al. Randomised controlled trial of a  
13  
14  
15 5 financial incentive for increasing the number of daily walking steps:  
16  
17  
18 6 study protocol. *BMJ Open* 2019;9(6):e026086.  
19  
20  
21 7 10. Arai H, Satake S: English translation of the Kihon Checklist. *Geriatr*  
22  
23 8 *Gerontol Int* 2015;15(4):518-9.  
24  
25  
26 9 11. Fukutomi E, Okumiya K, Wada T, et al. Relationships between each  
27  
28  
29 10 category of 25-item frailty risk assessment (Kihon Checklist) and newly  
30  
31  
32 11 certified older adults under Long-Term Care Insurance: A 24-month  
33  
34  
35 12 follow-up study in a rural community in Japan. *Geriatr Gerontol Int*  
36  
37 13 2015;15(7):864-71.  
38  
39  
40 14 12. Satake S, Senda K, Hong YJ, et al. Validity of the Kihon Checklist for  
41  
42  
43 15 assessing frailty status. *Geriatr Gerontol Int* 2016;16(6):709-15  
44  
45  
46 16 13. Sewo Sampaio PY, Sampaio RA, Yamada M, et al. Validation and  
47  
48  
49 17 translation of the Kihon Checklist (frailty index) into Brazilian  
50  
51  
52 18 Portuguese. *Geriatr Gerontol Int* 2014;14(3):561-9.  
53  
54  
55 19 14. Tomata Y, Hozawa A, Ohmori-Matsuda K, et al. Validation of the Kihon  
56  
57 20 Checklist for predicting the risk of 1-year incident long-term care  
58  
59 21 insurance certification: the Ohsaki Cohort 2006 Study [in Japanese].

- 1  
2  
3  
4 1 *Nihon Koshu Eisei Zasshi* 2011;58(1):3-13.  
5  
6  
7 2 15. Fujii H, Yamamoto S, Takeda-Imai F, et al. Validity and applicability of a  
8  
9 3 simple questionnaire for the estimation of total and domain-specific  
10  
11 4 physical activity. *Diabetology International* 2011;2(2):47-54.  
12  
13  
14  
15 5 16. Sasai H, Nakata Y, Murakami H, et al. Simultaneous Validation of Seven  
16  
17 6 Physical Activity Questionnaires Used in Japanese Cohorts for  
18  
19 7 Estimating Energy Expenditure: A Doubly Labeled Water Study. *J*  
20  
21 8 *Epidemiol* 2018;28(10):437-42.  
22  
23  
24  
25  
26 9 17. Ministry of Internal Affairs and Communications. Population Census.  
27  
28 10 1996 <http://www.stat.go.jp/english/data/kokusei/index.html>  
29  
30  
31 11 18. Tomata Y, Tanno K, Zhang S, et al. Subjective Household Economic Status  
32  
33 12 and Obesity in Toddlers: A Cross-Sectional Study of Daycare Centers in  
34  
35 13 Japan. *J Epidemiol.* 2019;29(1):33-37.  
36  
37  
38  
39  
40 14 19. The Ministry of Health, Labor and Welfare in Japan. National Health and  
41  
42 15 Nutrition Survey.  
43  
44 16 [https://www.mhlw.go.jp/bunya/kenkou/kenkou\\_eiyou\\_chousa.html](https://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyou_chousa.html) [in  
45  
46 17 Japanese]  
47  
48  
49  
50  
51 18 20 Mackenbach JP, Stirbu I, Roskam AJ, et al. Socioeconomic inequalities in  
52  
53 19 health in 22 European countries. *N Engl J Med* 2008;358(23): 2468-81.  
54  
55  
56  
57 20 21 Nurriika D, Zhang S, Tomata Y, et al. Education level and incident  
58  
59 21 functional disability in elderly Japanese: The Ohsaki Cohort 2006 study.  
60

- 1  
2  
3  
4 1 *PLoS One* 2019;14(3): e0213386.  
5  
6  
7 2 22 Hakim AA, Petrovitch H, Burchfiel CM, et al. Effects of walking on  
8  
9 mortality among nonsmoking retired men. *N Engl J Med* 1998;338(2):  
10 3  
11  
12 4 94-9.  
13  
14  
15 5 23 Finkelstein EA, Brown DS, Brown DR, Buchner DM. A randomized study  
16  
17 of financial incentives to increase physical activity among sedentary older  
18 6  
19 adults. *Prev Med* 2008;47(2): 182-7.  
20 7  
21  
22  
23 8 24 Patel MS, Asch DA, Rosin R, et al. Framing Financial Incentives to  
24  
25 Increase Physical Activity Among Overweight and Obese Adults: A  
26 9  
27 Randomized, Controlled Trial. *Ann Intern Med* 2016;164(6): 385-94.  
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4 1 **Fig. 1.** CONSORT flowchart of the study procedure.  
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9 3 **Fig. 2.** Changes in the number of daily walking steps during the intervention  
10 and follow-up periods (means and 95% confidential intervals).  
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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	
Non-affluent	19.4	13.9	0.527
Subjective time affluence			
Affluent	72.2	77.8	
Non-affluent	27.8	22.2	0.586
Pain			
Absent	22.2	44.4	
Present	5.6	2.8	0.011
Body mass index, kg/m <sup>2</sup> (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).

	n	Intervention period		
		Proportion <sup>a</sup>	OR <sup>b</sup>	(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.

<sup>a</sup> Proportions of participants who increased the number of daily steps by 1000 or more from baseline.

<sup>b</sup> Logistic regression analysis.

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

Subgroup		n	Intervention period			p-value <sup>a</sup>
			Mean	(95% CI)		
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.

<sup>a</sup> *t*-test.

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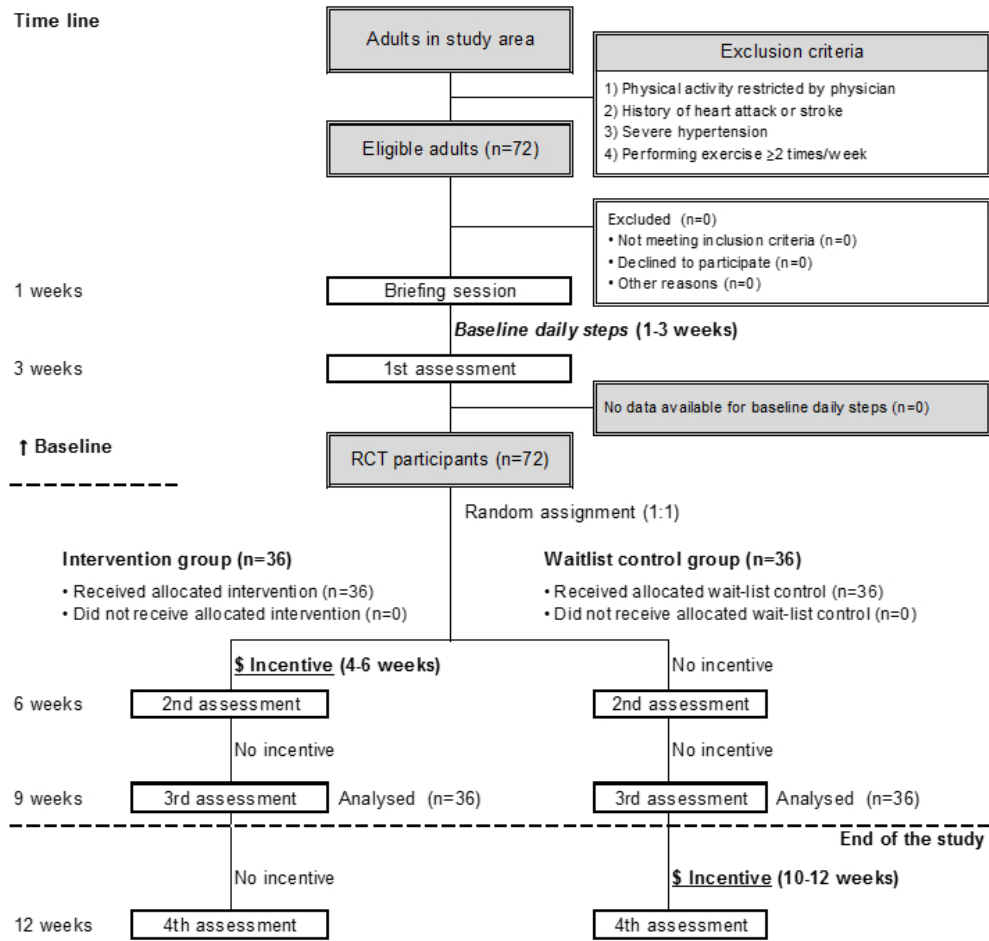


Fig.1. CONSORT flowchart of the study procedure.

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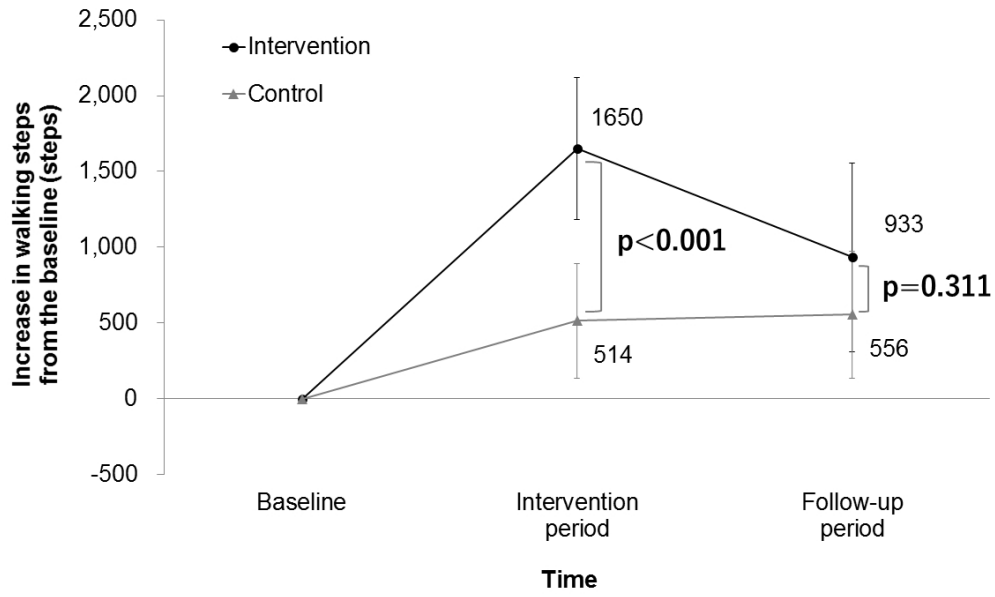


Fig. 2. Changes in the number of daily walking steps during the intervention and follow-up periods (means and 95% confidential intervals).

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

	n	Number of steps, mean (SD)		Increase in number of steps			Increase rate <sup>b</sup>		
		Baseline	Intervention period	Mean	(95% CI)	p-value <sup>a</sup>	Mean	(95% CI)	p-value <sup>a</sup>
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.

<sup>a</sup> *t*-test.

<sup>b</sup> Rate (%) of change in mean number of steps/day.

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

	n	Number of steps, mean (SD)		Increase in number of steps			Increase rate <sup>b</sup>		
		Baseline	Follow-up	Mean	(95% CI)	p-value <sup>a</sup>	Mean	(95% CI)	p-value <sup>a</sup>
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.

<sup>a</sup> t-test.

<sup>b</sup> Rate (%) of change in mean number of steps/day.

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

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	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
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	Page 6-7
	2b	Specific objectives or hypotheses	Page 6-7
<b>Methods</b>			
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
<b>Randomisation:</b>			
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:e0260 86. Page 4)

1	Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 10
2				
3	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 10
4				
5		11b	If relevant, description of the similarity of interventions	n/a
6				
7	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 12
8		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 12
9				
10	<b>Results</b>			
11	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
12		13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
13	Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 8, 9, 14
14		14b	Why the trial ended or was stopped	n/a
15				
16	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
17	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
18				
19	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
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Figure 1, Supplementary Table 1&2
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27	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page 15,16
28				
29	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 16
30				
31	<b>Discussion</b>			
32	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 18,19
33	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 17-19
34	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 17,18
35				
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37	<b>Other information</b>			
38	Registration	23	Registration number and name of trial registry	Page 8
39	Protocol	24	Where the full trial protocol can be accessed, if available	Page 8
40	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 21
41				
42				

1 \*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  
2 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.  
3 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).  
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# 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-037303.R1
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Date Submitted by the Author:	13-Jul-2020
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<b>Primary Subject Heading</b> :	Epidemiology
<b>Secondary Subject Heading</b> :	Public health, Sports and exercise medicine
<b>Keywords</b> :	EPIDEMIOLOGY, PUBLIC HEALTH, PREVENTIVE MEDICINE





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4 1 **Title:**

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6 2 **Effect of a financial incentive (shopping point) on increasing the number**  
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9 3 **of daily walking steps among community-dwelling adults in Japan: A**  
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12 4 **randomized controlled trial**

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## 1 ABSTRACT

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

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

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

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

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

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

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

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

10 **Trial Registration:** UMIN000033276

11  
12 **Keywords:** financial incentive, walking steps, randomized controlled trial,  
13 Japan

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4 **1 Strengths and limitations of this study**

- 5  
6  
7 2 ➤ This study offered ‘shopping points’ as an unique financial incentive.  
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9 3 ➤ The financial incentive was a fairly small amount.  
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12 4 ➤ The intervention involved only one type of financial incentive.  
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15 5 ➤ Only the effect of a short-term intervention (over 3 weeks) was  
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18 6 evaluated.

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For peer review only



## 1 **Introduction**

2 Physical inactivity is a serious problem all around the world. According to  
3 the Global Action Plan on Physical Activity 2018–2030<sup>1</sup>, one in four adults  
4 (1.4 billion people worldwide) do not meet the World Health Organization  
5 (WHO) recommendations for physical activity levels. According to reports  
6 from the USA,<sup>2,3</sup> a failure to meet recommended physical activity levels is  
7 associated with approximately 117 billion USD in annual health care costs  
8 and 10% of all premature deaths. Therefore, physical inactivity imposes a  
9 substantial burden on health care costs and longevity. To help solve these  
10 problems, the WHO and national governments have developed various  
11 policies to promote higher levels of physical activity.<sup>1-5</sup> Walking is a popular  
12 and major source of physical activity worldwide.<sup>1 2 6</sup>In the Japanese National  
13 Health Promotion Movement (“Health Japan 21”), a higher number of daily  
14 walking steps is a target for physical activity as follows: 9000 and 8500  
15 steps in men and women aged < 65 years, and 7000 and 6000 steps in men  
16 and women aged ≥ 65 years, respectively.<sup>7</sup>

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

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

9         Although walking is a major source of physical activity in daily life  
10 for Japanese people, the national average number of daily walking steps for  
11 Japanese adults (age  $\geq 20$  years) has been decreasing, from 7655 in 2000 to  
12 6322 in 2017.<sup>10</sup> Considering the rapid aging of the population and escalating  
13 health care costs, more effective measures aimed at promoting walking at the  
14 population level need to be established. Therefore, the aim of the present  
15 study was to examine the effects of a financial incentive on the number of  
16 daily walking steps among community-dwelling adults in Japan.

17

## 1 *Methods*

### 2 *Study design*

3 The protocol of the present study has been reported in detail elsewhere.<sup>11</sup>

4 Briefly, this was a single-center, single-blind, parallel-group RCT in which  
5 participants were randomly assigned to an intervention or a control group.

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

### 11 12 *Participants*

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

### 16 17 *Inclusion and exclusion criteria*

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

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

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

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

#### 14 *Power and sample size*

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

1 and another study reported that an increase of 1000 steps had some impact on  
2 health at the population level because it contributes to a 3.2% reduction in  
3 the average relative risk of noncommunicable diseases, dementia,  
4 joint-musculoskeletal impairment, and mortality.<sup>4</sup> When an  $\alpha$  error of 0.05  
5 and a statistical power of 0.90 was applied, the minimum sample size was 74  
6 persons (37 persons per group). When an  $\alpha$  error of 0.05 and a statistical  
7 power of 0.80 were applied with this sample size, a mean difference of  $\geq$   
8 1,130 steps was considered statistically significant.

#### 10 *Study procedure*

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

1 for all participants.

2

### 3 *Randomization*

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

8

### 9 *Blinding*

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

20

### 21 *Intervention*

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

- 4 1. If the mean number of daily walking steps in the intervention period was  $\geq$   
5 6000, shopping points worth 1000 JPY were awarded.
- 6 2. If the mean number of daily walking steps during the intervention period  
7 increased by  $\geq$  1000 from baseline, shopping points worth 1000 JPY were  
8 awarded.

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

#### 17 *Wait list control group*

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

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7 2 *Measurements*  
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10 3 The participants' baseline characteristics were assessed at the date of the  
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12 4 briefing session. Interviews with trained interviewers were conducted to  
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15 5 obtain information regarding medical history, frailty (the Kihon checklist)  
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18 6 <sup>13-17</sup>, physical activity level<sup>18 19</sup>, transportation when going out, education  
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20  
21 7 level<sup>20</sup>, work, subjective economic status, time affluence (having spare time)  
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23  
24 8 <sup>21</sup>, body height, weight, pain, and falling. Blood pressure was also measured  
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26  
27 9 using an automated sphygmomanometer (HEM-1040; Omron, Kyoto, Japan).

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29 10 Transportation when going out was assessed by asking the question  
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32 11 "What kinds of transportation have you used more than twice per week when  
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35 12 going out in the last month?", for which, the available responses were:  
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38 13 "walking", "bicycle", "motorbike", "car", "train", "bus", "taxi", or "other".  
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40 14 Economic affluence was assessed by asking the question "How do you  
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43 15 feel about your current household situation?" The participants were asked to  
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46 16 choose one of the following five answers: "most affluent", "more affluent",  
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49 17 "neither more nor less", "less affluent", and "non-affluent". We classified  
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52 18 the first three answers as "affluent" and the last two as "non-affluent".  
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54 19 Time affluence (having spare time) was assessed by asking the  
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57 20 question "Do you have enough time available to take rest or enjoy leisure in  
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60 21 daily life?" The participants were asked to choose one of the following four



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

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

### 9 10 *Outcome measurements*

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

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

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

1 4–6 or 7–9; and 3) incident pain at weeks 4–6 or 7–9.

2

3 *Statistical analyses*

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

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

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

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

19  
20 *Patient and Public Involvement*

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

1 reporting, or dissemination plans of our trial.

## 2 **Results**

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

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

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

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4 1 intervention period was significantly higher in the intervention than in the  
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7 2 control group (31.0% vs. 9.1%, respectively;  $p < 0.001$ ) (**Supplementary**  
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10 3 **Table 1**). The mean increase in the number of daily steps from baseline to  
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12 4 the follow-up period was larger in the intervention (933, 95% CI = 312,  
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15 5 1555) than in the control group (556, 95% CI = 136, 976) (**Fig. 2**); however,  
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18 6 no significant difference was observed between groups ( $p = 0.311$ ).  
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21 7 Regarding the mean increase rate in the number of daily steps from baseline  
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24 8 to the follow-up period, no significant difference was found between groups  
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27 9 ( $p = 0.270$ ) (**Supplementary Table 2**).

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29 10 A comparison of the proportion of participants who increased the  
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32 11 mean number of daily steps by  $\geq 1000$  from baseline to the intervention  
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35 12 period is shown in **Table 2**. The proportion in the intervention group was  
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38 13 69.4% ( $n=25$ ) and that in the control group was 30.6% ( $n=11$ ). The  
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41 14 proportion was significantly higher in the intervention than in the control  
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44 15 group (OR = 5.17; 95% CI = 1.89, 14.08).

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46 16 **Table 3** shows the results of the analyses stratified by baseline  
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49 17 characteristics. The subgroup analyses showed a significant increase in the  
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52 18 number of daily steps among participants with a lower ( $< 6000$ ) compared  
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55 19 with those with a higher ( $\geq 6000$ ) baseline step count ( $p$ -interaction = 0.012).  
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58 20 Although no significant interaction was found, significant differences were  
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60 21 observed for those with a low but not those with a high physical activity

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

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

12

## 1 *Discussion*

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

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

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

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

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

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

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4 1 Although most of study participants were classified as affluent in terms of  
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7 2 their economic status, the relatively small financial incentive was still  
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10 3 effective for increasing the number of daily walking steps. Fourth, the  
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12 4 present results are considered to be generalizable to the community-dwelling  
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15 5 adult population in Japan because the mean number of daily walking steps  
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18 6 among the study participants at baseline was similar to the nationwide  
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21 7 average.<sup>10</sup>  
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26 9 *Limitations*

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29 10 This study also had several limitations. First, the intervention involved only  
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32 11 one type of financial incentive; therefore, the effects of changes in the  
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35 12 corresponding financial incentive or its application (e.g., donations) are  
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38 13 unclear. Second, only the effect of a short-term intervention (over 3 weeks)  
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41 14 was evaluated; whether an intervention involving a financial incentive would  
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44 15 be effective for maintaining an increase in the number of daily walking steps  
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47 16 over the long term is unclear. Third, the study participants were all Japanese  
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50 17 adults; therefore, the present results may not generalizable to non-Japanese  
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53 18 populations. Fourth, the possibility of overestimation due to the small sample  
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56 19 size cannot be ruled out. However, the sample size set at the start of the  
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59 20 study was almost achieved.  
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4 1 ***Conclusions***  
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7 2 The results of the present study indicated that offering a financial incentive  
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9 3 was effective for increasing the number of daily walking steps among  
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12 4 Japanese community-dwelling adults, even though the intervention period  
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15 5 was as short as 3 weeks. The difference between the intervention and control  
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18 6 groups was not significant at follow-up after the incentives were removed.  
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21 7 Future research should explore whether the continuation of financial  
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24 8 incentives can maintain an increased number of daily steps over the long  
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7 2 The most important acknowledgment is to the participants.  
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15 5 YT and IT were involved in the design. FT and IT prepared draft manuscript.  
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18 6 SA, SM, YK, DN, KM, YLi, SZ, YLu, YS, SB, TY, TO, and TS revised the  
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21 7 manuscript. SZ carried out the statistical analyses. All authors approved  
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32 11 association with this study.  
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40 14 Ethics Committee of Tohoku University Graduate School of Medicine.  
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59 21 **Data availability statement:** Data are available upon reasonable request.  
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4 1 meta-analysis. *PLoS One* 2014;9(3):e90347.  
5  
6  
7 2 9. Mitchell MS, Orstad SL, Biswas A, et al. Financial incentives for physical  
8  
9 3 activity in adults: systematic review and meta-analysis. *Br J Sports Med*  
10  
11  
12 4 2019;bjsports-2019-100633. doi: 10.1136/bjsports-2019-100633. Online  
13  
14  
15 5 ahead of print.  
16  
17  
18 6 10. The Ministry of Health, Labor and Welfare in Japan. National Health and  
19  
20 7 Nutrition Survey.  
21  
22  
23 8 [https://www.mhlw.go.jp/bunya/kenkou/kenkou\\_eiyouchousa.html](https://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyouchousa.html) [in  
24  
25  
26 9 Japanese]  
27  
28  
29 10 11. Tomata Y, Tanji F, Nurrikan D, et al. Randomised controlled trial of a  
30  
31 11 financial incentive for increasing the number of daily walking steps:  
32  
33  
34 12 study protocol. *BMJ Open* 2019;9(6):e026086.  
35  
36  
37 13 12. Harkins KA, Kullgren JT, Bellamy SL, et al. A Trial of Financial and  
38  
39  
40 14 Social Incentives to Increase Older Adults' Walking. *Am J Prev Med*  
41  
42  
43 15 2017;52(5):e123-30.  
44  
45  
46 16 13. Arai H, Satake S: English translation of the Kihon Checklist. *Geriatr*  
47  
48 17 *Gerontol Int* 2015;15(4):518-9.  
49  
50  
51 18 14. Fukutomi E, Okumiya K, Wada T, et al. Relationships between each  
52  
53  
54 19 category of 25-item frailty risk assessment (Kihon Checklist) and newly  
55  
56  
57 20 certified older adults under Long-Term Care Insurance: A 24-month  
58  
59  
60 21 follow-up study in a rural community in Japan. *Geriatr Gerontol Int*

- 1  
2  
3  
4 1 2015;15(7):864-71.  
5  
6  
7 2 15. Satake S, Senda K, Hong YJ, et al. Validity of the Kihon Checklist for  
8  
9 3 assessing frailty status. *Geriatr Gerontol Int* 2016;16(6):709-15  
10  
11  
12 4 16. Sewo Sampaio PY, Sampaio RA, Yamada M, et al. Validation and  
13  
14 5 translation of the Kihon Checklist (frailty index) into Brazilian  
15  
16 6 Portuguese. *Geriatr Gerontol Int* 2014;14(3):561-9.  
17  
18  
19  
20 7 17. Tomata Y, Hozawa A, Ohmori-Matsuda K, et al. Validation of the Kihon  
21  
22 8 Checklist for predicting the risk of 1-year incident long-term care  
23  
24 9 insurance certification: the Ohsaki Cohort 2006 Study [in Japanese].  
25  
26  
27 10 *Nihon Koshu Eisei Zasshi* 2011;58(1):3-13.  
28  
29  
30  
31 11 18. Fujii H, Yamamoto S, Takeda-Imai F, et al. Validity and applicability of a  
32  
33 12 simple questionnaire for the estimation of total and domain-specific  
34  
35 13 physical activity. *Diabetology International* 2011;2(2):47-54.  
36  
37  
38  
39 14 19. Sasai H, Nakata Y, Murakami H, et al. Simultaneous Validation of Seven  
40  
41 15 Physical Activity Questionnaires Used in Japanese Cohorts for  
42  
43 16 Estimating Energy Expenditure: A Doubly Labeled Water Study. *J*  
44  
45 17 *Epidemiol* 2018;28(10):437-42.  
46  
47  
48  
49 18 20. Ministry of Internal Affairs and Communications. Population Census.  
50  
51 19 1996 <http://www.stat.go.jp/english/data/kokusei/index.html>  
52  
53  
54  
55 20 21. Tomata Y, Tanno K, Zhang S, et al. Subjective Household Economic Status  
56  
57 21 and Obesity in Toddlers: A Cross-Sectional Study of Daycare Centers in  
58  
59  
60

- 1  
2  
3  
4 1 Japan. *J Epidemiol.* 2019;29(1):33-37.  
5  
6  
7 2 22. Mackenbach JP, Stirbu I, Roskam AJ, et al. Socioeconomic inequalities in  
8  
9  
10 3 health in 22 European countries. *N Engl J Med* 2008;358(23): 2468-81.  
11  
12 4 23. Nurrika D, Zhang S, Tomata Y, et al. Education level and incident  
13  
14  
15 5 functional disability in elderly Japanese: The Ohsaki Cohort 2006 study.  
16  
17  
18 6 *PLoS One* 2019;14(3): e0213386.  
19  
20  
21 7 24. Hakim AA, Petrovitch H, Burchfiel CM, et al. Effects of walking on  
22  
23  
24 8 mortality among nonsmoking retired men. *N Engl J Med* 1998;338(2):  
25  
26  
27 9 94-9.  
28  
29 10 25. Finkelstein EA, Brown DS, Brown DR, Buchner DM. A randomized study  
30  
31  
32 11 of financial incentives to increase physical activity among sedentary older  
33  
34  
35 12 adults. *Prev Med* 2008;47(2): 182-7.  
36  
37  
38 13 26. Patel MS, Asch DA, Rosin R, et al. Framing Financial Incentives to  
39  
40  
41 14 Increase Physical Activity Among Overweight and Obese Adults: A  
42  
43  
44 15 Randomized, Controlled Trial. *Ann Intern Med* 2016;164(6): 385-94.  
45  
46  
47 16 27. Patel MS, Asch DA, Rosin R, et al. Individual Versus Team-Based  
48  
49  
50 17 Financial Incentives to Increase Physical Activity: A Randomized,  
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52  
53 18 Controlled Trial. *J Gen Intern Med* 2016;31(7):746-54.  
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1 **Fig. 1.** CONSORT flowchart of the study procedure.

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

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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 $\pm$ SD)	62.0 $\pm$ 16.5	60.4 $\pm$ 16.1	0.671
Blood pressure, mmHg (mean $\pm$ SD)			
Systolic blood pressure	130.7 $\pm$ 20.7	125.5 $\pm$ 18.5	0.264
Diastolic blood pressure	79.0 $\pm$ 11.4	76.7 $\pm$ 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 $\pm$ SD)	35.8 $\pm$ 8.5	36.1 $\pm$ 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, %			
$\geq$ 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	
Non-affluent	19.4	13.9	0.527
Subjective time affluence			
Affluent	72.2	77.8	
Non-affluent	27.8	22.2	0.586
Pain			
Absent	22.2	44.4	
Present	5.6	2.8	0.011
Body mass index, kg/m <sup>2</sup> (mean $\pm$ SD)	22.1 $\pm$ 3.0	23.2 $\pm$ 4.6	0.250
Baseline number of steps/day (mean $\pm$ SD)	6859 $\pm$ 3223	5869 $\pm$ 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).

	n	Intervention period (weeks 4-6)		
		Proportion <sup>a</sup>	OR <sup>b</sup>	(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.

<sup>a</sup> Proportions of participants who increased the number of daily steps by 1000 or more from baseline.

<sup>b</sup> Logistic regression analysis.

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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)			p-value <sup>a</sup>	p-interaction <sup>a</sup>
		Mean	(95% CI)			
<b>Sex</b>						
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 )		
<b>Age (years)</b>						
< 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 )		
<b>Baseline number of steps</b>						
< 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 )		
<b>Physical activity</b>						
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 )		
<b>Body mass index</b>						
≥ 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 )		
<b>Time affluence</b>						
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 )		
<b>Frailty</b>						
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 )		
<b>Educational level</b>						
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 )		
<b>Employment status</b>						
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 )		
<b>Economic affluence</b>						
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.

<sup>a</sup> *t*-test.

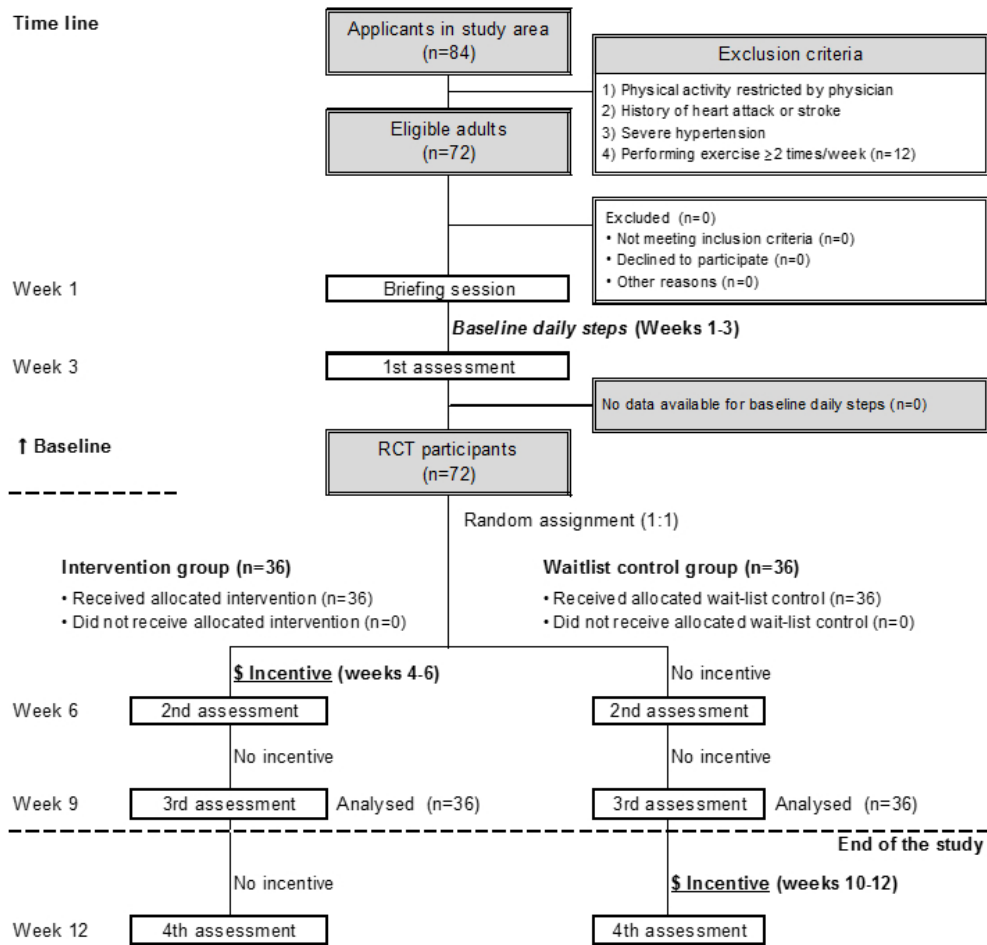


Fig. 1. CONSORT flowchart of the study procedure.

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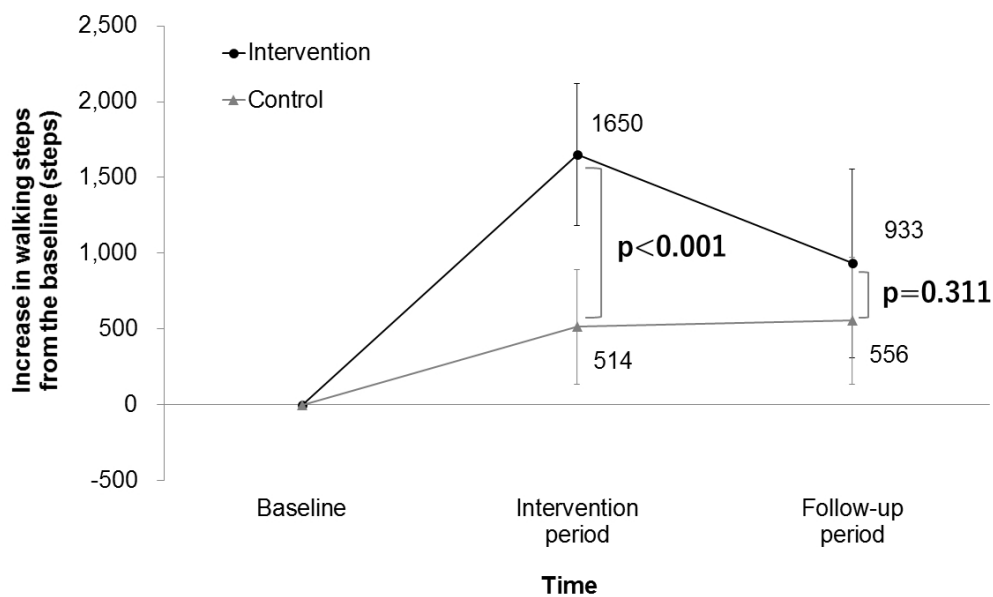


Fig. 2. Changes in the number of daily walking steps during the intervention and follow-up periods (means and 95% confidential intervals).

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

	n	Number of steps, mean (SD)		Increase in number of steps			Increase rate <sup>b</sup>		
		Baseline	Intervention period	Mean	(95% CI)	p-value <sup>a</sup>	Mean	(95% CI)	p-value <sup>a</sup>
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.

<sup>a</sup> *t*-test.

<sup>b</sup> Rate (%) of change in mean number of steps/day.

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

	n	Number of steps, mean (SD)		Increase in number of steps			Increase rate <sup>b</sup>		
		Baseline	Follow-up	Mean	(95% CI)	p-value <sup>a</sup>	Mean	(95% CI)	p-value <sup>a</sup>
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.

<sup>a</sup> t-test.

<sup>b</sup> 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
<b>Title and abstract</b>			
	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
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	Page 6-7
	2b	Specific objectives or hypotheses	Page 7
<b>Methods</b>			
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
<b>Randomisation:</b>			
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)



1	Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 11
2				
3	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 11
4				
5		11b	If relevant, description of the similarity of interventions	n/a
6				
7	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 15
8		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 15
9				
10	<b>Results</b>			
11	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
12		13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
13	Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 8, 16
14		14b	Why the trial ended or was stopped	n/a
15				
16	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
17	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
18				
19	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
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Fig. 2, Supplementary Table 1&2
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27	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page 17,18
28				
29	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 18
30				
31	<b>Discussion</b>			
32	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 21
33	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 19, 21
34	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 19, 20
35				
36	<b>Other information</b>			
37	Registration	23	Registration number and name of trial registry	Page 8
38	Protocol	24	Where the full trial protocol can be accessed, if available	Page 8
39	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 23
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\*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](http://www.consort-statement.org).

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# 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

Journal:	<i>BMJ Open</i>
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Keywords:	EPIDEMIOLOGY, PUBLIC HEALTH, PREVENTIVE MEDICINE





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4 1 **Title:**

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6 2 **Effect of a financial incentive (shopping point) on increasing the number**  
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9 3 **of daily walking steps among community-dwelling adults in Japan: A**  
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12 4 **randomized controlled trial**

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4 1 **ABSTRACT**

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7 2 **Objective:** The aim of the present study was to investigate the effect of a  
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10 3 financial incentive on the number of daily steps among community-dwelling  
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12 4 adults in Japan.

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15 5 **Study design:** Two-arm, parallel-group RCT.

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18 6 **Setting/participants:** We recruited physically inactive community-dwelling  
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21 7 adults in Sendai city, Japan. Eligible participants were randomly allocated to  
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24 8 an intervention or a wait-list control group. Pedometers were used to assess  
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27 9 the mean number of daily steps in three periods: baseline (weeks 1-3),  
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29 10 intervention (weeks 4-6), and follow-up (weeks 7-9).

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32 11 **Intervention:** The intervention group was offered a financial incentive  
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35 12 (shopping points) to meet the target number of increased daily steps in the  
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38 13 intervention period.

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40 14 **Main outcome measures:** The primary outcome was an increase in the mean  
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43 15 number of daily steps in the intervention and follow-up periods compared  
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46 16 with baseline.

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48 17 **Results:** Seventy-two participants (69.4% female; mean age,  $61.2 \pm 16.2$   
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51 18 years; mean number of daily steps at baseline,  $6364 \pm 2804$ ) were randomized  
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54 19 to the intervention ( $n = 36$ ) and control groups ( $n = 36$ ). During the  
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57 20 intervention period, the increase in mean daily steps was significantly higher  
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60 21 in the intervention ( $1650$ , 95% confidence interval [CI] =  $1182, 2119$ ) than in



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

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

10 **Trial Registration:** UMIN000033276

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12 **Keywords:** financial incentive, walking steps, randomized controlled trial,  
13 Japan

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4 1 **Strengths and limitations of this study**

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7 2 ➤ **This study is unique in offering financial incentives in the form of**  
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9 3 **local shopping points.**

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12 4 ➤ The financial incentive was a fairly small amount.

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15 5 ➤ The intervention involved only one type of financial incentive.

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18 6 ➤ Only the effect of a short-term intervention (over 3 weeks) was  
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21 7 evaluated.

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## 1 **Introduction**

2 Physical inactivity is a serious problem all around the world. According to  
3 the Global Action Plan on Physical Activity 2018–2030<sup>1</sup>, one in four adults  
4 (1.4 billion people worldwide) do not meet the World Health Organization  
5 (WHO) recommendations for physical activity levels. According to reports  
6 from the USA,<sup>2,3</sup> a failure to meet recommended physical activity levels is  
7 associated with approximately 117 billion USD in annual health care costs  
8 and 10% of all premature deaths. Therefore, physical inactivity imposes a  
9 substantial burden on health care costs and longevity. To help solve these  
10 problems, the WHO and national governments have developed various  
11 policies to promote higher levels of physical activity.<sup>1-5</sup> Walking is a popular  
12 and major source of physical activity worldwide.<sup>1 2 6</sup>In the Japanese National  
13 Health Promotion Movement (“Health Japan 21”), a higher number of daily  
14 walking steps is a target for physical activity as follows: 9000 and 8500  
15 steps in men and women aged < 65 years, and 7000 and 6000 steps in men  
16 and women aged ≥ 65 years, respectively.<sup>7</sup>

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

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

6         Although walking is a major source of physical activity in daily life  
7 for Japanese people, the national average number of daily walking steps for  
8 Japanese adults (age  $\geq 20$  years) has been decreasing, from 7655 in 2000 to  
9 6322 in 2017.<sup>10</sup> Considering the rapid aging of the population and escalating  
10 health care costs, more effective measures aimed at promoting walking at the  
11 population level need to be established. Therefore, the aim of the present  
12 study was to examine the effects of a financial incentive on the number of  
13 daily walking steps among community-dwelling adults in Japan.

14

## 1 *Methods*

### 2 *Study design*

3 The protocol of the present study has been reported in detail elsewhere.<sup>11</sup>

4 Briefly, this was a single-center, single-blind, parallel-group RCT in which  
5 participants were randomly assigned to an intervention or a control group.

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

### 11 *Participants*

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

### 15 *Inclusion and exclusion criteria*

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

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

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

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

#### 14 *Power and sample size*

15 Based on a previous study carried out in 2013<sup>12</sup>, we assumed that an average  
16 difference of 1302 steps would be achieved in the intervention period (weeks  
17 4-6) by offering a financial incentive of 2000 JPY ( $\approx 18$  USD at the time of  
18 the study in 2018) and setting the standard deviation (SD) at 1711.

19 Additionally, our previous study reported that an increase of 1000 steps was  
20 associated with reduced medical costs of 1300 JPY ( $\approx 12$  USD) per month<sup>13</sup>,

1 and another study reported that an increase of 1000 steps had some impact on  
2 health at the population level because it contributes to a 3.2% reduction in  
3 the average relative risk of noncommunicable diseases, dementia,  
4 joint-musculoskeletal impairment, and mortality.<sup>4</sup> When an  $\alpha$  error of 0.05  
5 and a statistical power of 0.90 was applied, the minimum sample size was 74  
6 persons (37 persons per group). When an  $\alpha$  error of 0.05 and a statistical  
7 power of 0.80 were applied with this sample size, a mean difference of  $\geq$   
8 1,130 steps was considered statistically significant.

#### 10 *Study procedure*

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

1 for all participants.

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### 3 *Randomization*

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

8

### 9 *Blinding*

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

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### 21 *Intervention*



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

- 4 1. If the mean number of daily walking steps in the intervention period was  $\geq$   
5 6000, shopping points worth 1000 JPY were awarded.
- 6 2. If the mean number of daily walking steps during the intervention period  
7 increased by  $\geq 1000$  from baseline, shopping points worth 1000 JPY were  
8 awarded.

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

#### 17 18 *Wait list control group*

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

1 All conditions except for the timing were the same as those for the  
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1 All conditions except for the timing were the same as those for the  
2 intervention group.  
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#### 4 *Measurements*

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

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

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

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

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

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

### 12 13 *Outcome measurements*

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

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

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4 1 baseline.

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7 2 The secondary outcomes were: 1) an increase in the number of daily  
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9 3 steps by  $\geq 1000$  at weeks 4–6 or 7–9 from baseline; 2) incident falls at weeks  
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12 4 4–6 or 7–9; and 3) incident pain at weeks 4–6 or 7–9.

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18 6 *Statistical analyses*

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21 7 In regard to the primary outcome, the *t*-test was applied to examine whether  
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24 8 the mean increases and rate of change in the number of daily steps at weeks  
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26 9 4–6 and 7–9 from baseline differed significantly between the intervention  
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29 10 and control groups.

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32 11 In regard to the secondary outcomes, logistic regression models were  
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35 12 applied to examine whether the proportions of participants with an increase  
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37 13 of  $\geq 1000$  steps were significantly different, and to assess the probabilities of  
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40 14 incident falls and incident pain. Odds ratios (ORs) and 95% confidence  
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43 15 intervals (CIs) were also estimated.

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46 16 In addition, stratified analyses were conducted to check for any  
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49 17 differences in the number of daily steps in terms of sex, age, frailty, physical  
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52 18 activity level, transportation when going out, education level, work,  
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54 19 subjective economic status, time affluence, and obesity.

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57 20 All analyses were performed using IBM SPSS Statistics (version 25; IBM  
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60 21 SPSS, Chicago, IL, USA).

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7 2 *Patient and Public Involvement*  
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10 3 Patients or the public were not involved in the design, or conduct, or  
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12 4 reporting, or dissemination plans of our trial.  
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For peer review only

## 1 **Results**

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

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

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

1 control group (31.0% vs. 9.1%, respectively;  $p < 0.001$ ) (**Supplementary**  
2 **Table 1**). The mean increase in the number of daily steps from baseline to  
3 the follow-up period was larger in the intervention (933, 95% CI = 312,  
4 1555) than in the control group (556, 95% CI = 136, 976) (**Fig. 2**); however,  
5 no significant difference was observed between groups ( $p = 0.311$ ).  
6 Regarding the mean increase rate in the number of daily steps from baseline  
7 to the follow-up period, no significant difference was found between groups  
8 ( $p = 0.270$ ) (**Supplementary Table 2**).

9 A comparison of the proportion of participants who increased the  
10 mean number of daily steps by  $\geq 1000$  from baseline to the intervention  
11 period is shown in **Table 2**. The proportion in the intervention group was  
12 69.4% ( $n=25$ ) and that in the control group was 30.6% ( $n=11$ ). The  
13 proportion was significantly higher in the intervention than in the control  
14 group (OR = 5.17; 95% CI = 1.89, 14.08).

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

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

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

4

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## 1 *Discussion*

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

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

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

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

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

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

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

### 9 *Limitations*

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

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4 1 ***Conclusions***  
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7 2 The results of the present study indicated that offering a financial incentive  
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9 3 was effective for increasing the number of daily walking steps among  
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12 4 Japanese community-dwelling adults, even though the intervention period  
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15 5 was as short as 3 weeks. The difference between the intervention and control  
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18 6 groups was not significant at follow-up after the incentives were removed.  
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21 7 Future research should explore whether the continuation of financial  
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24 8 incentives can maintain an increased number of daily steps over the long  
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3  
4 **Authors' contributions:** IT supervised this study and is the guarantor. FT,  
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6 SA, SM, YK, DN, KM, YLi, SZ, YLu, YS, SB, TY, TO, and TS revised the  
7 manuscript. SZ carried out the statistical analyses. All authors approved  
8 submission of this manuscript.

9  
10 **Competing interests:** The authors have no financial disclosures in  
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20  
21 **Data availability statement:** Data are available upon reasonable request.

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8 [group.bmj.com/ products/ journals/instructions-for-authors/licence-forms/](http://group.bmj.com/products/journals/instructions-for-authors/licence-forms/))

## 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](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

- 1  
2  
3  
4 1 meta-analysis. *PLoS One* 2014;9(3):e90347.  
5  
6  
7 2 9. Mitchell MS, Orstad SL, Biswas A, et al. Financial incentives for physical  
8  
9 3 activity in adults: systematic review and meta-analysis. *Br J Sports Med*  
10  
11 4 2019;bjsports-2019-100633. doi: 10.1136/bjsports-2019-100633. Online  
12  
13 5 ahead of print.  
14  
15  
16  
17 6 10. The Ministry of Health, Labor and Welfare in Japan. National Health and  
18  
19 7 Nutrition Survey.  
20  
21 8 [https://www.mhlw.go.jp/bunya/kenkou/kenkou\\_eiyou\\_chousa.html](https://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyou_chousa.html) [in  
22  
23 9 Japanese]  
24  
25  
26  
27 10 11. Tomata Y, Tanji F, Nurrika D, et al. Randomised controlled trial of a  
28  
29 11 financial incentive for increasing the number of daily walking steps:  
30  
31 12 study protocol. *BMJ Open* 2019;9(6):e026086.  
32  
33  
34  
35 13 12. Harkins KA, Kullgren JT, Bellamy SL, et al. A Trial of Financial and  
36  
37 14 Social Incentives to Increase Older Adults' Walking. *Am J Prev Med*  
38  
39 15 2017;52(5):e123-30.  
40  
41  
42  
43 16 13. Tsuji I, Takahashi K, Nishino Y, et al. Impact of walking upon medical  
44  
45 17 care expenditure in Japan: the Ohsaki Cohort Study. *Int J Epidemiol*  
46  
47 18 2003;32 (5):809-14.  
48  
49  
50  
51 19 14. Arai H, Satake S: English translation of the Kihon Checklist. *Geriatr*  
52  
53 20 *Gerontol Int* 2015;15(4):518-9.  
54  
55  
56  
57 21 15. Fukutomi E, Okumiya K, Wada T, et al. Relationships between each  
58  
59  
60



- 1  
2  
3  
4 1 category of 25-item frailty risk assessment (Kihon Checklist) and newly  
5  
6  
7 2 certified older adults under Long-Term Care Insurance: A 24-month  
8  
9  
10 3 follow-up study in a rural community in Japan. *Geriatr Gerontol Int*  
11  
12 4 2015;15(7):864-71.  
13  
14  
15 5 16. Satake S, Senda K, Hong YJ, et al. Validity of the Kihon Checklist for  
16  
17  
18 6 assessing frailty status. *Geriatr Gerontol Int* 2016;16(6):709-15  
19  
20  
21 7 17. Sewo Sampaio PY, Sampaio RA, Yamada M, et al. Validation and  
22  
23  
24 8 translation of the Kihon Checklist (frailty index) into Brazilian  
25  
26  
27 9 Portuguese. *Geriatr Gerontol Int* 2014;14(3):561-9.  
28  
29 10 18. Tomata Y, Hozawa A, Ohmori-Matsuda K, et al. Validation of the Kihon  
30  
31  
32 11 Checklist for predicting the risk of 1-year incident long-term care  
33  
34  
35 12 insurance certification: the Ohsaki Cohort 2006 Study [in Japanese].  
36  
37  
38 13 *Nihon Koshu Eisei Zasshi* 2011;58(1):3-13.  
39  
40 14 19. Fujii H, Yamamoto S, Takeda-Imai F, et al. Validity and applicability of a  
41  
42  
43 15 simple questionnaire for the estimation of total and domain-specific  
44  
45  
46 16 physical activity. *Diabetology International* 2011;2(2):47-54.  
47  
48  
49 17 20. Sasai H, Nakata Y, Murakami H, et al. Simultaneous Validation of Seven  
50  
51  
52 18 Physical Activity Questionnaires Used in Japanese Cohorts for  
53  
54  
55 19 Estimating Energy Expenditure: A Doubly Labeled Water Study. *J*  
56  
57  
58 20 *Epidemiol* 2018;28(10):437-42.  
59  
60 21 21. Ministry of Internal Affairs and Communications. Population Census.

- 1  
2  
3  
4 1 1996 <http://www.stat.go.jp/english/data/kokusei/index.html>  
5  
6  
7 2 22. Tomata Y, Tanno K, Zhang S, et al. Subjective Household Economic Status  
8  
9 3 and Obesity in Toddlers: A Cross-Sectional Study of Daycare Centers in  
10  
11  
12 4 Japan. *J Epidemiol.* 2019;29(1):33-37.  
13  
14  
15 5 23. Mackenbach JP, Stirbu I, Roskam AJ, et al. Socioeconomic inequalities in  
16  
17 6 health in 22 European countries. *N Engl J Med* 2008;358(23): 2468-81.  
18  
19  
20 7 24. Nurrika D, Zhang S, Tomata Y, et al. Education level and incident  
21  
22 8 functional disability in elderly Japanese: The Ohsaki Cohort 2006 study.  
23  
24 9 *PLoS One* 2019;14(3): e0213386.  
25  
26  
27  
28 10 25. Hakim AA, Petrovitch H, Burchfiel CM, et al. Effects of walking on  
29  
30 11 mortality among nonsmoking retired men. *N Engl J Med* 1998;338(2):  
31  
32 12 94-9.  
33  
34  
35  
36  
37 13 26. Finkelstein EA, Brown DS, Brown DR, Buchner DM. A randomized study  
38  
39 14 of financial incentives to increase physical activity among sedentary older  
40  
41 15 adults. *Prev Med* 2008;47(2): 182-7.  
42  
43  
44  
45 16 27. Patel MS, Asch DA, Rosin R, et al. Framing Financial Incentives to  
46  
47 17 Increase Physical Activity Among Overweight and Obese Adults: A  
48  
49 18 Randomized, Controlled Trial. *Ann Intern Med* 2016;164(6): 385-94.  
50  
51  
52  
53 19 28. Patel MS, Asch DA, Rosin R, et al. Individual Versus Team-Based  
54  
55 20 Financial Incentives to Increase Physical Activity: A Randomized,  
56  
57 21 Controlled Trial. *J Gen Intern Med* 2016;31(7):746-54.  
58  
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1 **Fig. 1.** CONSORT flowchart of the study procedure.

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

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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 $\pm$ SD)	62.0 $\pm$ 16.5	60.4 $\pm$ 16.1	0.671
Blood pressure, mmHg (mean $\pm$ SD)			
Systolic blood pressure	130.7 $\pm$ 20.7	125.5 $\pm$ 18.5	0.264
Diastolic blood pressure	79.0 $\pm$ 11.4	76.7 $\pm$ 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 $\pm$ SD)	35.8 $\pm$ 8.5	36.1 $\pm$ 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, %			
$\geq$ 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	
Non-affluent	19.4	13.9	0.527
Subjective time affluence			
Affluent	72.2	77.8	
Non-affluent	27.8	22.2	0.586
Pain			
Absent	22.2	44.4	
Present	5.6	2.8	0.011
Body mass index, kg/m <sup>2</sup> (mean $\pm$ SD)	22.1 $\pm$ 3.0	23.2 $\pm$ 4.6	0.250
Baseline number of steps/day (mean $\pm$ SD)	6859 $\pm$ 3223	5869 $\pm$ 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).

	n	Intervention period (weeks 4-6)		
		Proportion <sup>a</sup>	OR <sup>b</sup>	(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.

<sup>a</sup> Proportions of participants who increased the number of daily steps by 1000 or more from baseline.

<sup>b</sup> 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)			p-value <sup>a</sup>	p-interaction <sup>a</sup>
		Mean	(95% CI)			
<b>Sex</b>						
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 )		
<b>Age (years)</b>						
< 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 )		
<b>Baseline number of steps</b>						
< 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 )		
<b>Physical activity</b>						
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 )		
<b>Body mass index</b>						
≥ 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 )		
<b>Time affluence</b>						
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 )		
<b>Frailty</b>						
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 )		
<b>Educational level</b>						
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 )		
<b>Employment status</b>						
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 )		
<b>Economic affluence</b>						
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.

<sup>a</sup> *t*-test.

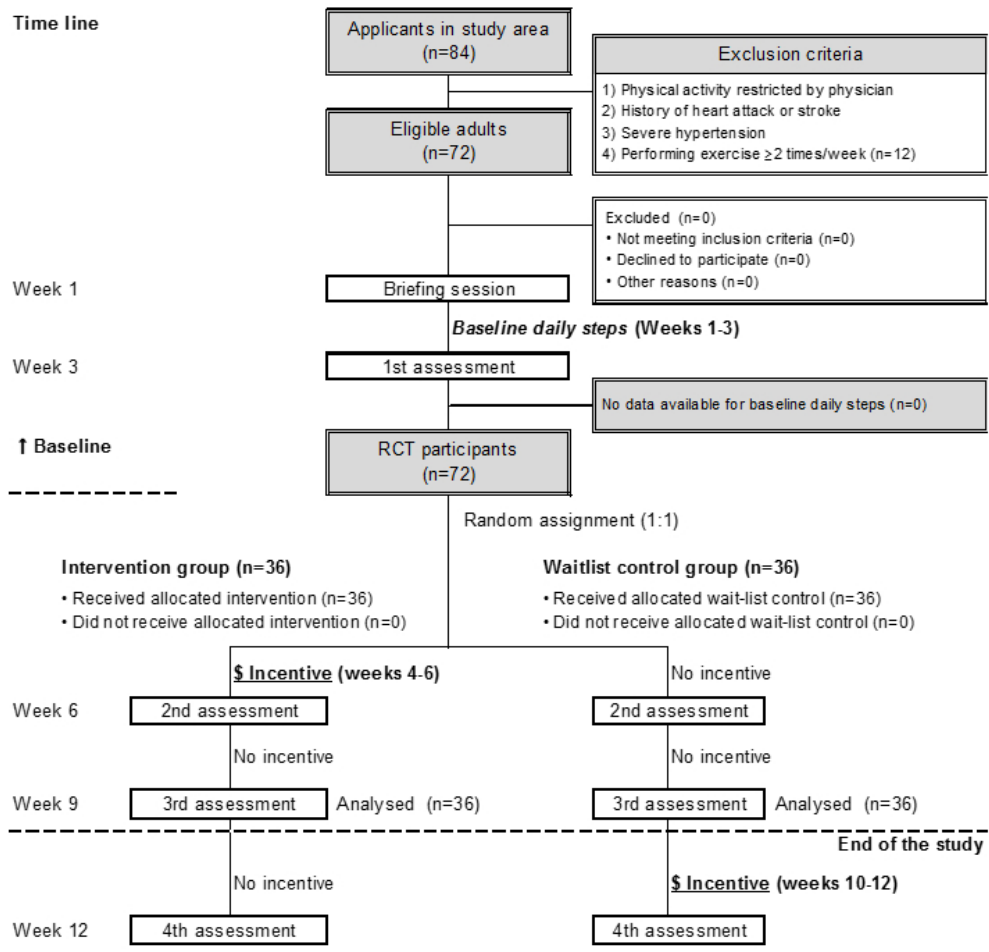


Fig. 1. CONSORT flowchart of the study procedure.

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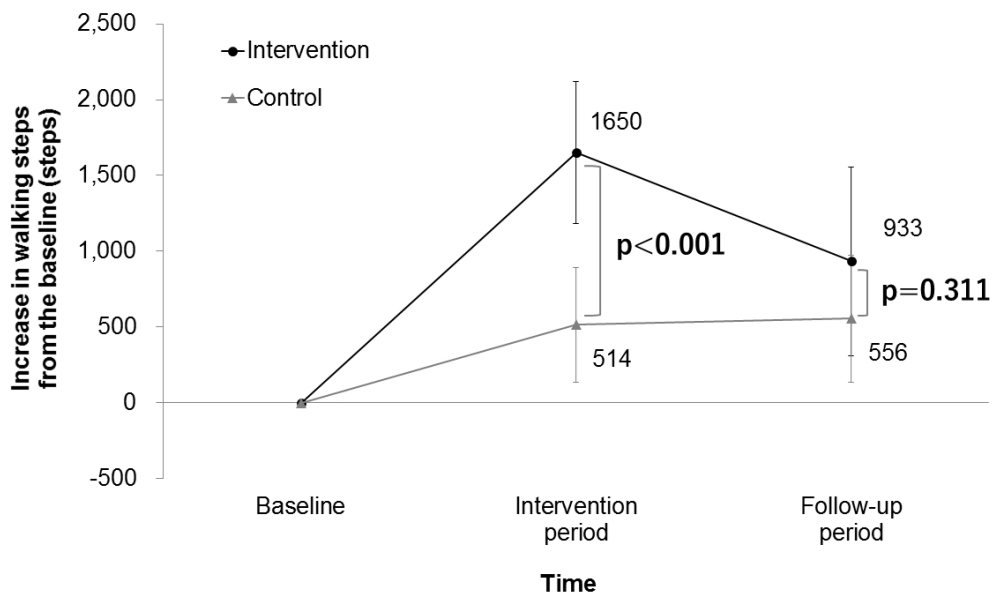


Fig. 2. Changes in the number of daily walking steps during the intervention and follow-up periods (means and 95% confidential intervals).

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

	n	Number of steps, mean (SD)		Increase in number of steps			Increase rate <sup>b</sup>		
		Baseline	Intervention period	Mean	(95% CI)	p-value <sup>a</sup>	Mean	(95% CI)	p-value <sup>a</sup>
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.

<sup>a</sup> *t*-test.

<sup>b</sup> Rate (%) of change in mean number of steps/day.

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

	n	Number of steps, mean (SD)		Increase in number of steps			Increase rate <sup>b</sup>		
		Baseline	Follow-up	Mean	(95% CI)	p-value <sup>a</sup>	Mean	(95% CI)	p-value <sup>a</sup>
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.

<sup>a</sup> t-test.

<sup>b</sup> 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
<b>Title and abstract</b>			
	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
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	Page 6-7
	2b	Specific objectives or hypotheses	Page 7
<b>Methods</b>			
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
<b>Randomisation:</b>			
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:e0260 86. Page 4)

1	Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 11
2				
3	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 11
4				
5		11b	If relevant, description of the similarity of interventions	n/a
6				
7	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 15
8		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 15
9				
10	<b>Results</b>			
11	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
12				
13		13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
14	Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 8
15				
16		14b	Why the trial ended or was stopped	n/a
17	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
18	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
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20				
21	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
22				
23		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Fig. 2, Supplementary Table 1&2
24				
25				
26				
27	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page 18
28				
29	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 18, 19
30				
31	<b>Discussion</b>			
32	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 22
33	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 20, 22
34	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 20, 21
35				
36				
37	<b>Other information</b>			
38	Registration	23	Registration number and name of trial registry	Page 8
39	Protocol	24	Where the full trial protocol can be accessed, if available	Page 8
40	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 24
41				
42				

1 \*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  
2 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.  
3 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).  
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