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Randomized controlled trial of a financial incentive for increasing the number of daily walking steps: Study protocol

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Title:

Randomized controlled trial of a financial incentive for increasing the number of daily walking steps: Study protocol

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ABSTRACT

Introduction: Physical activity is one of the major modifiable factors for promotion of public health. Although it has been reported that financial incentives would be effective for promoting health behaviors such as smoking cessation or attendance for cancer screening, few randomized controlled trials (RCTs) have examined the effect of financial incentives for increasing the number of daily steps among individuals in a community setting. The aim of this study is to investigate the effects of financial incentives for increasing the number of daily steps among community-dwelling adults in Japan.

Methods and analysis: This study will be a two-arm, parallel-group RCT. We will recruit community-dwelling adults who have no exercise habits in a suburban area (Nakayama) of Sendai city, Japan, using leaflets and posters. Participants that meet the inclusion criteria will be randomly allocated to an intervention group or a waitlist control group. The intervention group will be offered a financial incentive (a chance to get shopping points) if participants increase their daily steps from their baseline. The primary outcome will be the average increase in the number of daily steps (at 3-6 weeks and 6-9 weeks) relative to the average number of daily steps at the baseline (0-3 weeks).

Ethics and dissemination: This study has been ethically approved by the research ethics committee of Tohoku University Graduate School of Medicine, Japan (No. 2018-1-171). The results will be submitted and published in a

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- 1 peer-reviewed scientific journal.
- 2 **Registration:** UMIN000033276; Pre-results.

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

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6 2 ➤ This trial will examine the effectiveness of a financial incentive for
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9 3 increasing the number of daily walking steps.
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11 4 ➤ The present study would be first Asian trial.
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14 5 ➤ Limitations include the fact that the intervention will be only one type of
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16 6 financial incentive.
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19 7 ➤ Only short-term effects during 9 weeks will be evaluated.
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1 INTRODUCTION

2 Physical activity is a major modifiable factor that has benefits in terms of
3 physical and mental health¹. Therefore public health strategies to increase
4 physical activity are implemented worldwide². In the Japanese National
5 Health Promotion Movement ("Health Japan 21"), a higher number of daily
6 walking steps is a target for physical activity^{3 4}.

7 Recently, to encourage individuals who are not lifestyle-conscious to
8 increase the number of steps they walk daily, it has been suggested that
9 offering them financial incentives might be an effective approach. The
10 Ministry of Health, Labor and Welfare in Japan has provided a guideline for
11 promotion of public health using financial incentives⁵. One such incentive is
12 the introduction of a "health point system" in which local governments
13 provide "shopping points" that can be redeemed in local stores when an
14 individual achieves a healthy lifestyle goal such as an increase in the number
15 of daily walking steps.

16 A systematic review (meta-analysis) has suggested that financial
17 incentives would be effective for promotion of health behaviors such as
18 smoking cessation, or attendance for vaccination or cancer screening⁶.

19 Although a few randomized controlled trials (financial incentives vs. no
20 intervention) have examined the effect of financial incentives for increasing
21 the amount of daily steps by individuals in a community setting, the results

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1 were not consistent^{7 8}.

2 The aim of the present study will be to examine the effect of offering a
3 financial incentive for increasing the number of daily walking steps in a
4 community setting.

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1 **METHODS**

2 ***Study design***

3 The design is a randomized controlled trial (single-center, single-blind,
4 parallel-group study) in which subjects are randomly assigned to one of two
5 groups: an intervention group or a waitlist control group.

7 ***Recruitment***

8 In August 2018, two types of leaflets (preliminary notice, and information
9 about recruitment) related to the study will be distributed to individual
10 households in the Nakayama area, Aoba-ku, Sendai city, Japan. Posters giving
11 details about recruitment will also be displayed in the Nakayama area.
12 Inclusion criteria and exclusion criteria will be stated on the entry form.
13 Applicants who meet the inclusion criteria and not the exclusion criteria will
14 be able to apply by Web application, FAX, or telephone. We will accept 80
15 applicants.

17 ***Inclusion criteria***

18 Individuals will be able to apply for participation in this study if they meet all
19 of the following criteria: 1) Men and women (aged 20 years or more) living in
20 the Nakayama area, 2) Possession of an IC Card for Community Development
21 in the Nakayama area (*Nakayama Machi-dukuri IC Card*), 3) Ability to walk

1 unaided without using a cane, Zimmer frame, or wheelchair.

2 According to the 2015 Population Census, the number of adults (aged
3 20 years or more) living in Nakayama area was 13,734 persons.

4 5 ***Exclusion criteria***

6 Individuals who meet any of the following criteria will not be able to
7 participate in the study: 1) Individuals whose physical activity is restricted by
8 a physician, 2) History of heart attack or stroke within the last 6 months, 3)
9 Blood pressure exceeding 180 mmHg systolic or 110 mmHg diastolic, 4)
10 Already habitually exercising (task of ≥ 4 metabolic equivalents) more than
11 twice per week.

12 13 ***Study procedure***

14 **Figure 1** illustrates the flow of the study procedure.

15 In the briefing session on September 2018, chosen subjects will provide
16 informed consent to participate in the study. Blood pressure measurement, an
17 interview using a questionnaire, and explanation about use of a pedometer
18 will then be performed. At the briefing session, all participants will be
19 provided with a pedometer.

20 The day after the briefing session will be the start date of steps
21 evaluation. We will perform evaluation and feedback about daily steps every 3

1 weeks. All participants must wear the pedometer every day during the study period (12 weeks).

For all participants, the number of daily steps at the baseline will be measured in first 3 weeks of the study period (**Table 1**). Then, participants who provide their data of daily steps will be randomly assigned to the intervention group or the control group. At this stage, we assume that approximately 74 persons (i.e. the target sample size) would be included in the random assignment.

During the next 3 weeks (intervention period), the participants in the intervention group will be given a financial incentive if they achieve their daily steps goals.

On the other hand, the control group will be given a chance to gain a financial incentive (mentioned above) in the last three weeks, and thereby all participants will have a fair opportunity to gain such an incentive.

Intervention

The intervention is a financial incentive in the form of shopping points, which can be redeemed at stores in the study area (Nakayama area). Two kinds of financial incentive will be offered:

1. If the average number of daily steps in the intervention period is $\geq 6,000$, shopping points worth 1,000 Japanese yen will be awarded.

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4 1 2. If the average number of daily steps during the intervention period
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6 2 increases by $\geq 1,000$ from the baseline level, shopping points worth 1,000
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8 3 Japanese yen will be awarded.

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11 4 For example, if a person keeps walking 6,500 steps during both the baseline
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13 5 and intervention periods, only financial incentive “1” (1,000 Japanese yen
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15 6 worth of points) will be awarded. If a person walks 3,000 steps in the baseline
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17 7 period and 4,000 steps in the intervention period, only financial incentive “2”
18
19 8 (1,000 Japanese yen worth of points) will be awarded. If a person walks 5,000
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21 9 steps in the baseline period and 7,000 steps in the intervention period, both
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23 10 financial incentives “1” and “2” (2,000 Japanese yen worth of points) will be
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25 11 awarded.
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34 13 *Waitlist control group*

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37 14 The waitlist control group is also given a financial incentive in the last three
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39 15 weeks (**Figure 1**).
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45 17 *Randomization*

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47 18 After confirming their eligibility, enrolled participants will be assigned to one
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49 19 of the two groups (1:1 allocation) based on the permuted block method (block
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51 20 size=2) by computer-generated randomization. The allocation sequence will
52
53 21 be managed by a researcher in the data management section.
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1 **Blinding**

2 A blinded endpoint evaluation design will be applied.

3 In addition, statistical analyses will be blinded to the assignment. The
4 researcher in the data management section with knowledge of the assignment
5 detail will not conduct the statistical analysis.

6 Only the researcher in the data management section can access the
7 original data.

9 **Baseline characteristics**

10 Baseline characteristics will be assessed on the date of the briefing session.

11 We will conduct an interview to obtain information about medical
12 history, frailty (the Kihon checklist), physical activity, transportation when
13 going out, education level, work, subjective economic status, time affluence
14 (having spare time), pain, and falling. We will also measure the blood
15 pressure of each participant.

16 History of diseases will include stroke, hypertension, myocardial
17 infarction, renal disease, hepatic disease, diabetes mellitus, arthritis,
18 osteoporosis, cancer, and dyslipidemia.

19 Frailty will be assessed by the Kihon checklist (devised by the
20 Japanese Ministry of Health, Labor and Welfare), which is a 25-item
21 self-administered questionnaire designed to identify frail elderly individuals⁹.

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4 1 Previous studies have reported the validity of the Kihon checklist¹⁰⁻¹³.

5
6 2 Physical activity will be assessed by the Japan Public Health Centre
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8 3 Physical Activity Questionnaire (JPHC PAQ)^{14 15}. This questionnaire includes
9
10 4 information about the average daily amount of time and frequency spent in
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12 5 work-related (including commuting and housework) physical activity,
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14 6 leisure-time physical activity, and sleep¹⁴. The total physical activity level is
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16 7 calculated as metabolic equivalents of task-hours per day. The correlation
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18 8 between metabolic equivalents estimated by this questionnaire and daily
19
20 9 activities reported in 24-hour records was 0.69¹⁴.

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26 10 Transportation when going out will be assessed by asking the question
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28 11 “What kinds of transportation did you use more than twice per week when you
29
30 12 went out in the last 1 month?”, for which available responses were: “walking”,
31
32 13 “bicycle”, “motorbike”, “car”, “train”, “bus”, “taxi”, or “other”.

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37 14 Education level will be assessed by asking the question applied in the
38
39 15 2010 Population Census (Japan) “Please indicate the last school you graduated
40
41 16 from.”, for which available responses were: “primary school or junior high
42
43 17 school”, “senior high school or middle school (under the old system of
44
45 18 education)”, “junior college or higher professional school”, “college,
46
47 19 university or graduate school”¹⁶.

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52 20 Work will be assessed by asking the question “Do you do any paid work
53
54 21 now?”, for which available responses were: “≥4 times/week”, “2-3

1 times/week”, “1 time/week”, “1-3 times/month”, “few times/year”, or “none”.

2 Subjective household economic status will be assessed by asking the
3 question “How do you feel about your current household economic situation?”,
4 for which available responses will be: “most affluent”, “more affluent”,
5 “neither more nor less”, “less affluent”, or “non-affluent”.

6 Time affluence (having spare time) will be assessed by asking the
7 question “Do you have time affluence for rest or leisure in daily life?
8 Alternatively, do not you have time affluence for work, housework, or
9 studies?”, for which available responses will be: “more affluent”, “little
10 affluent”, “less affluent”, or “non-affluent”¹⁷.

11 Falling will be assessed based on question no. 9 of the Kihon checklist
12 “Have you experienced a fall in the last year?”⁹.

13 Pain will be assessed based on the question “How much pain have you
14 experienced during the last 1 month?”, for which available responses will be:
15 “none,” “very mild,” “mild,” “moderate,” “severe,” or “very severe”¹⁸.

16 Location of the pain will be also ascertained, for which available responses
17 will be: “shoulder”, “lower back” or “knee”.

18 Blood pressure in a seated position after 3 min of rest will be assessed
19 using an automated sphygmomanometer HEM-1040 (Omron, Kyoto, Japan).
20 Two measurements taken 3 min apart will be averaged for analysis.

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4 1 ***Outcome measurements***
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6 2 Daily steps will be counted by a pedometer FS-800 (ESTERA Corporation.
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8 3 Saitama, Japan) containing a 3-axis acceleration sensor. Data on daily steps
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10 4 will be automatically recorded in the pedometer for 90 days, and the data will
11
12 5 be transferred from the pedometer to a personal computer via the Near Field
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14 6 Communication function.
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19 7 Incident falls will be assessed based on question no. 9 of the Kihon
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21 8 checklist. Because the assessment will be conducted every three weeks for
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23 9 follow-up, we will modify the timing of this question to “Have you fallen in
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25 10 the past three weeks?”. Incident falls are defined as new episodes of falling
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27 11 after the baseline.
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32 12 Incident pain will be assessed based on the question “How much pain
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34 13 have you experienced during the past three weeks?”, and expressed as a
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36 14 six-point verbal rating scale: “none,” “very mild,” “mild,” “moderate,”
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38 15 “severe,” and “very severe”. Incident pain is defined as worsening of pain
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40 16 severity after the baseline.
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47 18 ***Primary outcome***
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50 19 The primary outcome is the average increase in the number of daily steps
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52 20 compared with the average number during the baseline period (**Table 1, Table**
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54 21 **2**).
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1 *Secondary outcome*

2 The secondary outcomes will be 1) the proportion of participants who increase
3 their number of daily steps by 1,000 or more in 3-6 weeks or 6-9 weeks from
4 the baseline level (average); 2) incident falls in 3-6 weeks or 6-9 weeks; and
5 3) incident pain in 3-6 weeks or 6-9 weeks (**Table 2**).

7 *Power and sample size*

8 The sample size was estimated using the average increase in the number of
9 daily steps in a previous study conducted in 2013⁷. The average difference in
10 the number of daily steps between the intervention group and the control
11 group was 1,302 (an increase of 2,348 steps in the intervention group vs. an
12 increase of 1,046 steps in the control group) when the intervention group was
13 given an incentive of \$20 (approximately ¥2,000 at the time of the study in
14 2013). In this previous study, the standard deviation in the control group was
15 1,711 steps.

16 Therefore, we assumed that same result (an average difference of 1,302
17 steps) would be achieved by offering a financial incentive of ¥2,000, and
18 setting the standard deviation at 1,711. When an α error of 0.05 and a
19 statistical power of 0.90 was applied, the minimum sample size was 74
20 persons (37 persons per group). Therefore, a total number of 74 participants
21 (37 participants in each group) was set as the target sample size for analysis.

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4 1 ***Statistical analyses***
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6 2 To compare the primary outcome (average difference) between the
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8 3 intervention group and the waitlist control group, t-test or a linear mixed
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11 4 model will be applied.
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14 5 For comparison of secondary outcomes between the intervention group
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16 6 and the waitlist control group, chi-squared test or a logistic regression model
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19 7 will be applied.
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21 8 In addition, stratified analyses will be conducted to check for any
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24 9 differences in the number of steps in terms of sex, age, frailty, physical
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27 10 activity level, transportation when going out, education level, work,
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29 11 subjective economic status, time affluence (having spare time), pain, and
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32 12 obesity.
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34 13 To apply the intention-to-treat principle, multiple imputations will be
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37 14 conducted to consider the effects of missing values on outcome variables.
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39 15 All of the above analyses will be performed using SAS version 9.4 (SAS
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42 16 Institute Inc. North Carolina, USA).
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1 **ETHICS AND DISSEMINATION**

2 *Ethical considerations*

3 The ethics committee of Tohoku University Graduate School of Medicine
4 (Sendai, Japan) has reviewed and approved the study protocol (No.
5 2018-1-171).

6 The investigator will explain the research proposal along with the
7 documents, and provide enough time for individuals to consider their
8 participation. Handwritten signatures will be required on the consent
9 document. The consent form will guarantee protection of personal information,
10 and use of the dataset only for academic purposes. Consent documents will be
11 kept by the principal investigator, and copies will be given to the participants.

12 All data on participants will be managed by use of an ID number.
13 Personal information will be strictly managed at Tohoku University Graduate
14 School of Medicine. Personal information will be deleted from the dataset for
15 statistical analysis. After the research period, participant's information data
16 will be disposed of in a prescribed way.

17 Because this trial is a noninvasive intervention, no Data Monitoring
18 Committee will be organized.

19 If the research protocol needs to change, the principal investigator
20 must obtain approval from the chief of the research institution through the
21 ethical review committee.

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1 ***Dissemination of research findings***

2 Results and findings will be submitted and published in a peer-reviewed
3 scientific journal according to the guidelines of CONSORT for RCTs.

4 Conflicts of interest among researchers is managing by the Conflict of Interest
5 Management Committee at Tohoku University.

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1 DISCUSSION

2 This protocol outlines the objectives of the study and explains the study
3 design.

4 If this study is conducted in accordance with the present plan, the
5 present study would be first RCT for examining the effect of financial
6 incentives for increasing the number of daily steps in Asian population.

7 This study has several limitations. First, the intervention involves only
8 one type of financial incentive. Thus, the effect of a change in the
9 corresponding financial incentive or its application (e.g. donation) would be
10 unclear. Second, only short-term effects during 9 weeks will be evaluated.
11 Thus, the long-term effect (maintaining a higher number of daily walking
12 steps) of the financial incentive would be unclear.

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4 1 **Authors' contributions:** Ichiro Tsuji supervised this study and is the
5
6 2 guarantor. Yasutake Tomata, Fumiya Tanji and Ichiro Tsuji have made were
7
8 3 involved in the design. Yasutake Tomata, Dieta Nurrika, Yingxu Liu and Shu
9
10 4 Zhang prepared draft manuscript. Saho Abe, Kouichi Matsumoto, Shu Zhang,
11
12 5 Yumika Kotaki, Sanae Matsuyama, Yukai Lu, Yumi Sugawara, Shino Bando,
13
14 6 Teiichiro Yamazaki, Tatsui Otsuka, and Toshimasa Sone revised the
15
16 7 manuscript. Yasutake Tomata carried out the statistical calculation. All
17
18 8 authors approved submission of this manuscript.

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24 9 **Competing interests:** The authors have no financial disclosures in association
25
26 10 with this study.

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29 11 **Ethical approval:** The study protocol was reviewed and approved by the
30
31 12 Ethics Committee of Tohoku University Graduate School of Medicine.

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1 **Figure 1:** Flow chart of the study procedure.

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(Study protocol ver. 1)
page. 28

1 **Table 1:** Time line for the evaluation.

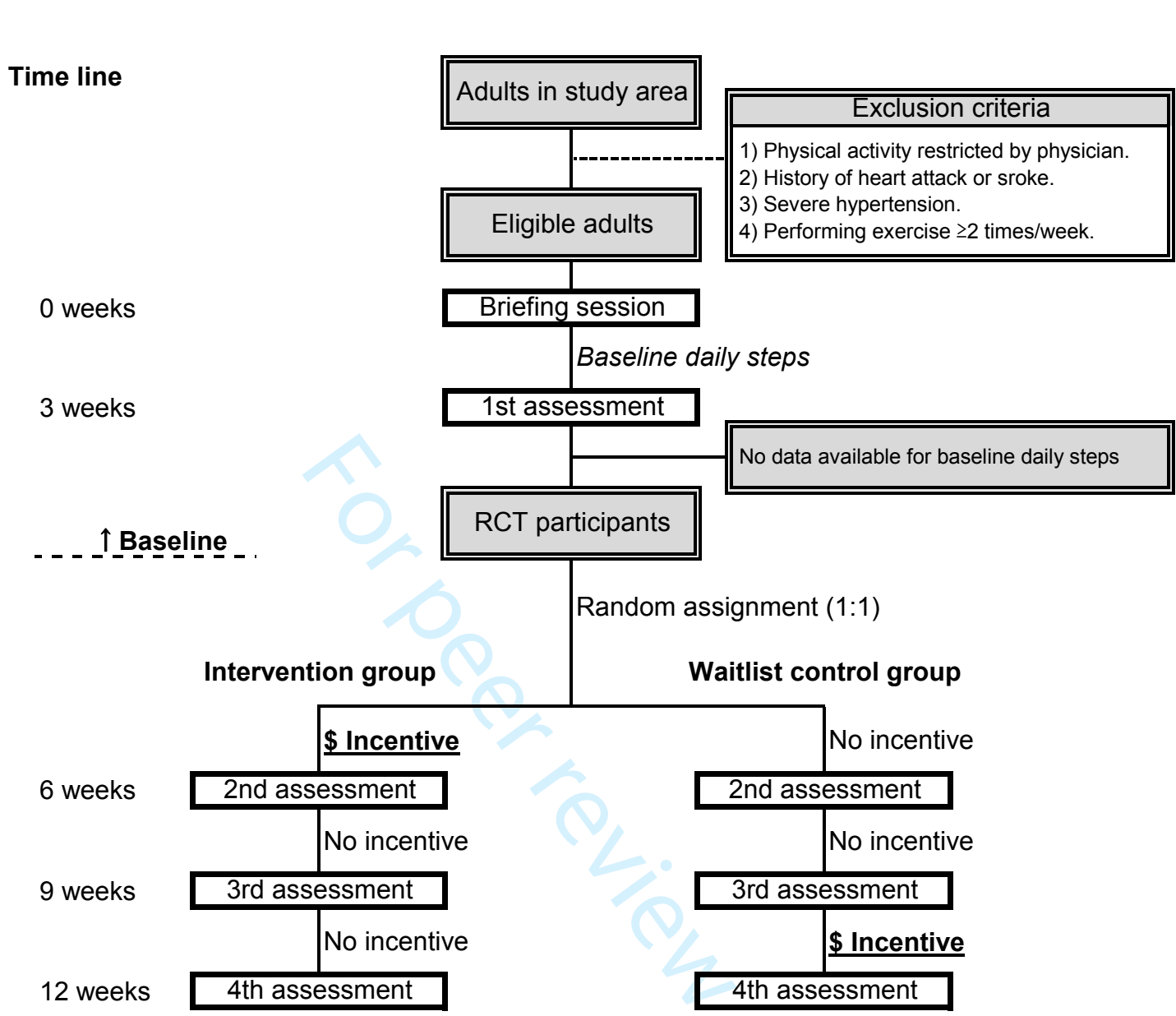
Time line	Purpose of evaluation	Hypothesis
0-3 weeks	Baseline number of steps	
3-6 weeks	Effect of incentive	Number of steps in the intervention group will be higher?
6-9 weeks	Sustained effect of incentive	Number of steps in the intervention group will remain higher?
9-12 weeks	Chance for waitlist control ^a	

a. Period for providing a chance of financial incentive for the waitlist control group. Thus, this period will not be included in the statistical analysis of this trial.

1 **Table 2:** Study outcomes.

Measurement	Definition
Primary outcome	
– Increase in number of steps	Mean increase in the average number of steps (in 3-6 weeks or 6-9 weeks) compared with the baseline number.
Secondary outcome	
– Proportion of participants who increase their steps	Proportion of participants who increase their average number of steps by 1,000 from the baseline.
– Incident falls	Incident rate of falls in 3-6 weeks or 6-9 weeks.
– Incident pain	Incident rate of pain in 3-6 weeks or 6-9 weeks.

2



1 SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

2 [Randomized controlled trial of a financial incentive for increasing the number of daily walking steps: Study protocol](#)

Section/item	Item No	Description	Page, line
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1, line 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 4, line 2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Page 1
Funding	4	Sources and types of financial, material, and other support	Page 21, line 14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 21, line 1
	5b	Name and contact information for the trial sponsor	Page 21, line 14
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 6, line 7
	6b	Explanation for choice of comparators	Page 6, line 19
Objectives	7	Specific objectives or hypotheses	Page 7, line 2
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 8, line 3
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 8, line 10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 8, line 17
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 9, line 14
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 15, line 19
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 9, line 14
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 16, line 8
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 8, line 8

Methods: Assignment of interventions (for controlled trials)**Allocation:**

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 11, line 18
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 11, line 18
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 11, line 20
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 12, line 2
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 12, line 10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 12, line 2
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 17, line 2
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 17, line 8
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 17, line 13

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol.	Page 18, line 17
		Alternatively, an explanation of why a DMC is not needed	Page 18, line 17
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 18, line 17
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A

Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 18, line 3
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 18, line 19
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 18, line 6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 18, line 12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 21, line 9
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 12, line 2
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 19, line 2
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 21, line 1
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Randomized controlled trial of a financial incentive for increasing the number of daily walking steps: Study protocol

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Article Type:	Protocol
Date Submitted by the Author:	06-Mar-2019
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Manuscripts

(Study protocol R1)

page. 1

Title:

Randomized controlled trial of a financial incentive for increasing the number of daily walking steps: Study protocol

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- 2 # Word count for abstract: words: 238
- 3 # Word count for text: words: 2,704
- 4 # Number of references: 18
- 5 # Number of tables: 2
- 6 # Number of figure: 1
- 7 # Number of supplementary tables: 0

For peer review only

1 ABSTRACT

2 **Introduction:** Physical activity is one of the major modifiable factors for
3 promotion of public health. Although it has been reported that financial
4 incentives would be effective for promoting health behaviors such as
5 smoking cessation or attendance for cancer screening, few randomized
6 controlled trials (RCTs) have examined the effect of financial incentives for
7 increasing the number of daily steps among individuals in a community
8 setting. The aim of this study is to investigate the effects of financial
9 incentives for increasing the number of daily steps among
10 community-dwelling adults in Japan.

11 **Methods and analysis:** This study will be a two-arm, parallel-group RCT. We
12 will recruit community-dwelling adults who are physically inactive in a
13 suburban area (Nakayama) of Sendai city, Japan, using leaflets and posters.
14 Participants that meet the inclusion criteria will be randomly allocated to an
15 intervention group or a waitlist control group. The intervention group will be
16 offered a financial incentive (a chance to get shopping points) if participants
17 increase their daily steps from their baseline. The primary outcome will be
18 the average increase in the number of daily steps (at 4-6 weeks and 7-9
19 weeks) relative to the average number of daily steps at the baseline (1-3
20 weeks). For the sample size calculation, we assumed that an average
21 difference of 1,302 steps would be achieved.

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4 1 **Ethics and dissemination:** This study has been ethically approved by the
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7 2 research ethics committee of Tohoku University Graduate School of
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9
10 3 Medicine, Japan (No. 2018-1-171). The results will be submitted and
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12 4 published in a peer-reviewed scientific journal.
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15 5 **Registration:** UMIN000033276; Pre-results.
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1 **Strengths and limitations of this study**

- 2 ➤ This trial will examine the effectiveness of a financial incentive for
3 increasing the number of daily walking steps.
- 4 ➤ The present study would be first Asian randomized controlled trials of
5 financial incentives intervention.
- 6 ➤ Limitations include the fact that the intervention will be only one type of
7 financial incentive.
- 8 ➤ Only short-term effects during 9 weeks will be evaluated.

1 INTRODUCTION

2 Physical activity is a major modifiable factor that has benefits in terms of
3 physical and mental health¹. Therefore public health strategies to increase
4 physical activity are implemented worldwide². In the Japanese National
5 Health Promotion Movement ("Health Japan 21"), a higher number of daily
6 walking steps is a target for physical activity^{3 4}.

7 Recently, to encourage individuals who are not concerned about
8 health-related behavior to increase the number of steps they walk daily, it
9 has been suggested that offering them financial incentives might be an
10 effective approach. The Ministry of Health, Labor and Welfare in Japan has
11 provided a guideline for promotion of public health using financial
12 incentives⁵. One such incentive is the introduction of a "health point system"
13 in which local governments provide "shopping points" that can be redeemed
14 in local stores when an individual achieves a health-related behavior goal
15 such as an increase in the number of daily walking steps.

16 A systematic review (meta-analysis) has suggested that financial
17 incentives would be effective for promotion of health behaviors such as
18 smoking cessation, or attendance for vaccination or cancer screening⁶.

19 Although a few randomized controlled trials (financial incentives vs. no
20 intervention) have examined the effect of financial incentives for increasing
21 the amount of daily steps by individuals in a community setting, the results

(Study protocol R1)

page. 7

1 were not consistent^{7 8}; One previous study reported that the target proportion
2 of steps in the financial intervention group was significantly higher than that
3 in the control group (relative risk =3.71) during the intervention period⁷,
4 whereas another study reported that the mean proportion of days on which a
5 7,000-steps goal was achieved as a result of individual incentive was not
6 significantly higher than in the control group (0.25 vs 0.18)⁸.

7 The aim of the present study will be to examine the effect of offering
8 a financial incentive for increasing the number of daily walking steps among
9 physically inactive adults in a community setting.

1 2 3 4 1 **METHODS**

5 6 2 *Study design*

7
8
9 3 The design is a randomized controlled trial (single-center, single-blind,
10 4 parallel-group study) in which subjects are randomly assigned to one of two
11
12 5 groups: an intervention group or a waitlist control group.
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16

17 6 18 19 20 7 *Recruitment*

21
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23 8 In August 2018, two types of leaflets (preliminary notice, and information
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25 9 about recruitment) related to the study will be distributed to each house in
26
27 10 the Nakayama area, Aoba-ku, Sendai city, Japan. Posters giving details about
28
29 11 recruitment will also be displayed in the Nakayama area. Inclusion criteria
30
31 12 and exclusion criteria will be stated on the entry form. Applicants who meet
32
33 13 the inclusion criteria and not the exclusion criteria will be able to apply by
34
35 14 Web application, FAX, or telephone. Considering an estimated attrition of
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37 15 about 10 individuals, we will accept 85 applicants.
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45 16 46 47 17 *Inclusion criteria*

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50 18 Individuals will be able to apply for participation in this study if they meet
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52 19 all of the following criteria: 1) Men and women (aged 20 years or more)
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54 20 living in the Nakayama area, 2) Possession of an IC Card for Community
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56 21 Development in the Nakayama area (*Nakayama Machi-dukuri IC Card*), 3)
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1 Ability to walk unaided without using a cane, Zimmer frame, or wheelchair.

2 All the above inclusion criteria will be judged on the basis of self-reports
3 from the participants.

4 Possession of the IC Card was considered to be an inclusion criterion
5 because it was a means of providing the intervention (financial incentive).

6 The IC Card was developed as a financial incentive to promote physical
7 activity. Persons possessing the IC Card are given shopping points when they
8 go shopping and participate in community activities in the Nakayama area.

9 The IC Card is also intended to enhance social interaction with locals. The
10 intervention in the present study is the first community activity project.

11 According to the 2015 Population Census, the number of adults (aged
12 20 years or more) living in Nakayama area was 13,734 persons.

13

14 ***Exclusion criteria***

15 Individuals who meet any of the following criteria will not be able to
16 participate in the study: 1) Individuals whose physical activity is restricted
17 by a physician, 2) History of heart attack or stroke within the last 6 months,
18 3) Blood pressure exceeding 180 mmHg systolic or 110 mmHg diastolic, 4)
19 Already habitually exercising (task of ≥ 4 metabolic equivalents) more than
20 twice per week. All exclusion criteria except for blood pressure will be
21 judged on the basis of self-reports from participants.

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4 1 ***Study procedure***

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6
7 2 **Figure 1** illustrates the flow of the study procedure.

8
9 3 In the briefing session in September 2018, the inclusion and exclusion
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11
12 4 criteria for each applicant will be rechecked by researchers in the study site
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14
15 5 (the Nakayama Tobinoko House). Chosen subjects will provide informed
16
17
18 6 consent to participate in the study. On the same day, blood pressure
19
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21 7 measurement, an interview using a questionnaire, and explanation about use
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23
24 8 of a pedometer will then be performed. At the briefing session, each
25
26
27 9 participant will be provided with a pedometer.

28
29 10 The day after the briefing session will be the start date of steps
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32 11 evaluation. We will perform evaluation and feedback about daily steps every
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34
35 12 3 weeks in the study site (the Nakayama Tobinoko House). All participants
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38 13 must wear the pedometer every day during the study period (12 weeks).

39
40 14 For all participants, the number of daily steps at the baseline will be
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43 15 measured in first 3 weeks of the study period (**Table 1**). Then, participants
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46 16 who provide their data of daily steps will be randomly assigned to the
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49 17 intervention group or the control group (participants who provide any data
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52 18 [≥ 1 days] at the baseline will be included). At this stage, we assume that
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55 19 approximately 74 persons (i.e. the target sample size) would be included in
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58 20 the random assignment.

59 21 During the next 3 weeks (intervention period), the participants in the
60

1 intervention group will be given a financial incentive if they achieve their
2 daily steps goals (for definition of goals, see the next section).

3 On the other hand, the control group will be given a chance to gain a
4 financial incentive (mentioned above) in the last three weeks (9-12 weeks),
5 and thereby all participants will have a fair opportunity to gain such an
6 incentive. The data obtained at 10-12 weeks will not be used for analysis to
7 evaluate the effect.

9 ***Intervention***

10 The intervention is a financial incentive in the form of shopping points,
11 which can be redeemed at facilities in the study area (14 facilities of
12 Nakayama area). Two kinds of financial incentive will be offered:

- 13 1. If the average number of daily steps in the intervention period is $\geq 6,000$,
14 shopping points worth 1,000 Japanese yen will be awarded.
- 15 2. If the average number of daily steps during the intervention period
16 increases by $\geq 1,000$ from the baseline level, shopping points worth 1,000
17 Japanese yen will be awarded.

18 These daily step targets have already been applied in Japanese national
19 health actions^{3 4}. National Health Action of Japan has emphasized that an
20 increase of 1,000 steps has some impact on population health, because it
21 contributes to a 3.2% reduction in the average relative risk of

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4 1 non-communicable diseases, dementia, joint-musculoskeletal impairment,
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7 2 and mortality³. For example, if a person keeps walking 6,500 steps during
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10 3 both the baseline and intervention periods, only financial incentive “1”
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12 4 (1,000 Japanese yen worth of points) will be awarded. If a person walks
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15 5 3,000 steps in the baseline period and 4,000 steps in the intervention period,
16
17
18 6 only financial incentive “2” (1,000 Japanese yen worth of points) will be
19
20
21 7 awarded. If a person walks 5,000 steps in the baseline period and 7,000 steps
22
23
24 8 in the intervention period, both financial incentives “1” and “2” (2,000
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27 9 Japanese yen worth of points) will be awarded. Based on the exchange rate
28
29 10 on 31st August 2018, 2,000 Japanese yen was equivalent to 14.0 British
30
31 11 Pounds.

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33
34 12 All participants will be provided shopping points at the same time
35
36
37 13 (after the end of the trial, i.e. the 12th week) regardless of the intervention
38
39
40 14 period.

41 42 15 43 44 45 16 ***Waitlist control group***

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48 17 The waitlist control group is also given a financial incentive in the last three
49
50
51 18 weeks (**Figure 1**). All conditions except for timing will be the same as for
52
53
54 19 the intervention group.

55 56 20 57 58 59 21 ***Power and sample size***

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4 1 The sample size was estimated by reference to the average increase in the
5
6
7 2 number of daily steps in a previous study conducted in 2013⁷. The average
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10 3 difference in the number of daily steps between the intervention group
11
12 4 (n=24) and the control group (n=16) was 1,302 (an increase of 2,348 steps in
13
14
15 5 the intervention group vs. an increase of 1,046 steps in the control group)
16
17
18 6 when the intervention group was given an incentive of \$20 (approximately
19
20 7 ¥2,000 at the time of the study in 2013). In this previous study, the standard
21
22
23 8 deviation in the control group of the increase was 1,711 steps.

24
25
26 9 Therefore, we assumed the result that an average difference of 1,302
27
28
29 10 steps would be achieved by offering a financial incentive of ¥2,000, and
30
31
32 11 setting the standard deviation at 1,711. When an α error of 0.05 and a
33
34 12 statistical power of 0.90 was applied, the minimum sample size was 74
35
36
37 13 persons (37 persons per group). Therefore, a total number of 74 participants
38
39
40 14 (37 participants in each group) was set as the target sample size for analysis.

41 42 43 44 45 16 ***Randomization***

46
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48 17 After confirming their eligibility, enrolled participants will be assigned to
49
50
51 18 one of the two groups (1:1 allocation) based on the permuted block method
52
53
54 19 by computer-generated randomization. The allocation sequence will be
55
56 20 managed by two exclusive researchers of the random assignment.
57
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1 **Blinding**

2 A blinded endpoint evaluation design will be applied. Only researchers of the
3 random assignment can access the assignment data, and other staffs were
4 blinded to the random assignment. The assignment information was managed
5 in password-locked dedicated storage media. Notification of the assignment
6 by the exclusive researchers of the random assignment will be conducted in a
7 closed room where is separated from the other examination places. In this
8 notification process, the exclusive researchers of the random assignment will
9 warn all participants not to talk about their assignment.

10 In addition, statistical analyses will be blinded to the assignment. The
11 exclusive researchers of the random assignment will not be involved with the
12 statistical analysis.

13

14 **Baseline characteristics**

15 Baseline characteristics will be assessed on the date of the briefing session.

16 Trained interviewers will conduct an interview to obtain information
17 about medical history, frailty (the Kihon checklist), physical activity,
18 transportation when going out, education level, work, subjective economic
19 status, time affluence (having spare time), pain, and falling. We will also
20 measure the blood pressure of each participant.

21 History of diseases will include stroke, hypertension, myocardial

1 infarction, renal disease, hepatic disease, diabetes mellitus, arthritis,
2 osteoporosis, cancer, and dyslipidemia.

3 Frailty will be assessed by the Kihon checklist (devised by the
4 Japanese Ministry of Health, Labor and Welfare), which is a 25-item
5 self-administered questionnaire designed to identify frail elderly
6 individuals⁹. Previous studies have reported the validity of the Kihon
7 checklist¹⁰⁻¹³.

8 Physical activity will be assessed by the Japan Public Health Centre
9 Physical Activity Questionnaire (JPHC PAQ)^{14 15}. This questionnaire
10 includes information about the average daily amount of time and frequency
11 spent in work-related (including commuting and housework) physical
12 activity, leisure-time physical activity, and sleep¹⁴. The total physical
13 activity level is calculated as metabolic equivalents of task-hours per day.
14 The correlation between metabolic equivalents estimated by this
15 questionnaire and daily activities reported in 24-hour records was 0.69¹⁴.

16 Transportation when going out will be assessed by asking the question
17 “What kinds of transportation did you use more than twice per week when
18 you went out in the last 1 month?”, for which available responses were:
19 “walking”, “bicycle”, “motorbike”, “car”, “train”, “bus”, “taxi”, or “other”.

20 Education level will be assessed by asking the question applied in the
21 2010 Population Census (Japan) “Please indicate the last school you

1 graduated from.”, for which available responses were: “primary school or
2 junior high school”, “senior high school or middle school (under the old
3 system of education)”, “junior college or higher professional school”,
4 “college, university or graduate school”¹⁶.

5 Work will be assessed by asking the question “Do you do any paid
6 work now?”, for which available responses were: “≥4 times/week”, “2-3
7 times/week”, “1 time/week”, “1-3 times/month”, “few times/year”, or
8 “none”.

9 Subjective household economic status will be assessed by asking the
10 question “How do you feel about your current household economic
11 situation?”, for which available responses will be: “most affluent”, “more
12 affluent”, “neither more nor less”, “less affluent”, or “non-affluent”
13 (selection from these 5 choices)¹⁷.

14 Time affluence (having spare time) will be assessed by asking the
15 question “Do you have time affluence for rest or leisure in daily life?
16 Alternatively, do not you have time affluence for work, housework, or
17 studies?”, for which available responses will be: “more affluent”, “little
18 affluent”, “less affluent”, or “non-affluent” (selection from these 5
19 choices)¹⁸.

20 Falling will be assessed based on question no. 9 of the Kihon
21 checklist “Have you experienced a fall in the last year?”⁹.

1 Pain will be assessed based on the question “How much pain have you
2 experienced during the last 1 month?”, for which available responses will be:
3 “none,” “very mild,” “mild,” “moderate,” “severe,” or “very severe”¹⁹.
4 Location of the pain will be also ascertained, for which available responses
5 will be: “shoulder”, “lower back” or “knee”.

6 Blood pressure in a seated position after 3 min of rest will be assessed
7 using an automated sphygmomanometer HEM-1040 (Omron, Kyoto, Japan).
8 Two measurements taken 3 min apart will be averaged for analysis.

10 *Outcome measurements*

11 Daily steps will be counted by a pedometer FS-800 (ESTERA Corporation,
12 Saitama, Japan) containing a 3-axis acceleration sensor. Data on daily steps
13 will be automatically recorded in the pedometer for 90 days. Every 3 weeks,
14 trained staffs will transfer data on the number of steps walked daily by
15 participants recorded by the pedometer to a computer as a Comma-Separated
16 Values file via the Near Field Communication function (not via internet). We
17 will provide a clip-on holder for wearing the pedometer on the waist, and we
18 explain to each participant how to use it. Because the pedometer will record
19 0 steps if a participant forgets to wear it, we will instruct the participants to
20 wear the pedometer at all times except when sleeping or taking a bath.

21 Because both effect and adverse effect resulting from falls and pain

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4 1 may be expected as a result of the intervention, we will check any tendencies
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7 2 for incident falls and pain.
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10 3 Incident falls will be assessed based on question no. 9 of the Kihon
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12 4 checklist. Because the assessment will be conducted every three weeks for
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15 5 follow-up, we will modify the timing of this question to “Have you fallen in
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17
18 6 the past three weeks?”. Incident falls are defined as new episodes of falling
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20
21 7 after the baseline.
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23 8 Incident pain will be assessed based on the question “How much pain
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26 9 have you experienced during the past three weeks?”, and expressed as a
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29 10 six-point verbal rating scale: “none,” “very mild,” “mild,” “moderate,”
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32 11 “severe,” and “very severe”. Incident pain is defined as worsening of pain
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35 12 severity after the baseline.
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37 13

39 14 ***Primary outcome***

41
42 15 The primary outcome is the average increase in the number of daily steps
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45 16 compared with the average number during the baseline period (**Table 1,**
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48 17 **Table 2**). We will thereby examine whether an increase of more than 1,302
49
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51 18 steps (mean value for sample size) can be expected, and the increase in the
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53
54 19 daily number of steps resulting from the financial incentive.
55

56 20

58 21 ***Secondary outcome***

1 The secondary outcomes will be 1) increase in the number of daily steps by
2 1,000 or more in 4-6 weeks or 7-9 weeks from the baseline level (1-3 weeks);
3 2) incident falls in 4-6 weeks or 7-9 weeks; and 3) incident pain in 4-6 weeks
4 or 7-9 weeks (**Table 2**).

6 ***Statistical analyses***

7 To compare the primary outcome (average difference), t-test will be applied
8 to examine whether the average daily increases in the number of steps 4-6
9 weeks and 7-9 weeks from the baseline differ significantly between the
10 intervention group and the control group.

11 For comparison of secondary outcomes between the intervention group
12 and the waitlist control group at 4-6 weeks and 7-9 weeks, logistic regression
13 models will be applied to examine whether the proportions of participants
14 with an increase of 1000 steps or more are significantly different, and
15 applied to assess the probabilities of incident falls and incident pain,
16 respectively.

17 In addition, stratified analyses will be conducted to check for any
18 differences in the number of steps in terms of sex, age, frailty, physical
19 activity level, transportation when going out, education level, work,
20 subjective economic status, time affluence (having spare time), pain, and
21 obesity.

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4 1 To apply the intention-to-treat principle, multiple imputations will be
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6
7 2 conducted to consider the effects of missing values on outcome variables.
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10 3 All of the above analyses will be performed using SAS version 9.4
11
12 4 (SAS Institute Inc. North Carolina, USA).
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1 ETHICS AND DISSEMINATION

2 *Ethical considerations*

3 The ethics committee of Tohoku University Graduate School of Medicine
4 (Sendai, Japan) has reviewed and approved the study protocol (No.
5 2018-1-171).

6 The investigator will explain the research proposal along with the
7 documents, and provide enough time for individuals to consider their
8 participation. Handwritten signatures will be required on the consent
9 document. The consent form will guarantee protection of personal
10 information, and use of the dataset only for academic purposes. Consent
11 documents will be kept by the principal investigator, and copies will be
12 given to the participants.

13 All data on participants will be managed by use of an ID number.
14 Personal information will be strictly managed at Tohoku University Graduate
15 School of Medicine. Personal information will be deleted from the dataset for
16 statistical analysis. After the research period, participant's information data
17 will be disposed of in a prescribed way.

18 Because this trial is a noninvasive intervention, no Data Monitoring
19 Committee will be organized.

20 If the research protocol needs to change, the principal investigator
21 must obtain approval from the chief of the research institution through the

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1 ethical review committee.

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4 1 ***Dissemination of research findings***
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7 2 Results and findings will be submitted and published in a peer-reviewed
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9 3 scientific journal according to the guidelines of CONSORT for RCTs.
10

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12 4 Conflicts of interest among researchers is managed by the Conflict of
13
14 5 Interest Management Committee at Tohoku University.
16

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20 7 **Patient and public involvement**
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22
23 8 To improve feasibility about the protocol of this trial in Nakayama area, we
24
25 9 discussed with members of Nakayama Community Development Center
26
27 10 (nonprofit organization corporation) and members of Nakayama Shopping
28
29 11 Street Promotion Association. Additionally, members of Nakayama
30
31 12 Neighborhood Association are involved to announce about the recruitment.
32
33 13 After the end of the trial, as a collaborative program with Nakayama
34
35 14 Community Development Center and Nakayama Shopping Street Promotion
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37 15 Association, we will hold the debrief session for study report to share results
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39 16 of the trail.
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4 1 **DISCUSSION**
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6 2 This protocol outlines the objectives of the study and explains the study
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9 3 design.
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12 4 If this study is conducted in accordance with the present plan, the
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15 5 present study would be first RCT for examining the effect of financial
16
17 6 incentives for increasing the number of daily steps in Asian population.
18

19
20 7 This study has several limitations. First, the intervention involves
21
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23 8 only one type of financial incentive. Thus, the effect of a change in the
24
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26 9 corresponding financial incentive or its application (e.g. donation) would be
27
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29 10 unclear. Second, only short-term effects during 9 weeks will be evaluated.
30
31 11 Thus, the long-term effect (maintaining a higher number of daily walking
32
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34 12 steps) of the financial incentive would be unclear. Third, a volunteer bias
35
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37 13 may exist in the present study. Participants may be more highly motivated to
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40 14 achieve the financial incentive goals in comparison with the total population
41
42 15 in the study area. Therefore, the external validity toward non-participants
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45 16 (involuntary participants) will be unclear.
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1 **Authors' contributions:** Ichiro Tsuji supervised this study and is the
2 guarantor. Yasutake Tomata, Fumiya Tanji and Ichiro Tsuji have made were
3 involved in the design. Yasutake Tomata, Dieta Nurrika, Yingxu Liu and Shu
4 Zhang prepared draft manuscript. Saho Abe, Kouichi Matsumoto, Shu Zhang,
5 Yumika Kotaki, Sanae Matsuyama, Yukai Lu, Yumi Sugawara, Shino Bando,
6 Teiichiro Yamazaki, Tatsui Otsuka, and Toshimasa Sone revised the
7 manuscript. Yasutake Tomata carried out the statistical calculation. All
8 authors approved submission of this manuscript.

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

11 **Ethical approval:** The study protocol was reviewed and approved by the
12 Ethics Committee of Tohoku University Graduate School of Medicine.

13 **Provenance and peer review:** Not commissioned; externally peer reviewed.

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(Study protocol R1)
page. 29

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1 **Figure 1:** Flow chart of the study procedure.

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1 **Table 1:** Time line for the evaluation.

Time line	Purpose of evaluation	Hypothesis
1-3 weeks	Baseline number of steps	
4-6 weeks	Effect of incentive	Is the number of steps in the intervention group higher than that in the control group?
7-9 weeks	Sustained effect of incentive	Does the number of steps in the intervention group remain higher than that in the control group even after the incentive period?
10-12 weeks	Chance for waitlist control ^a	

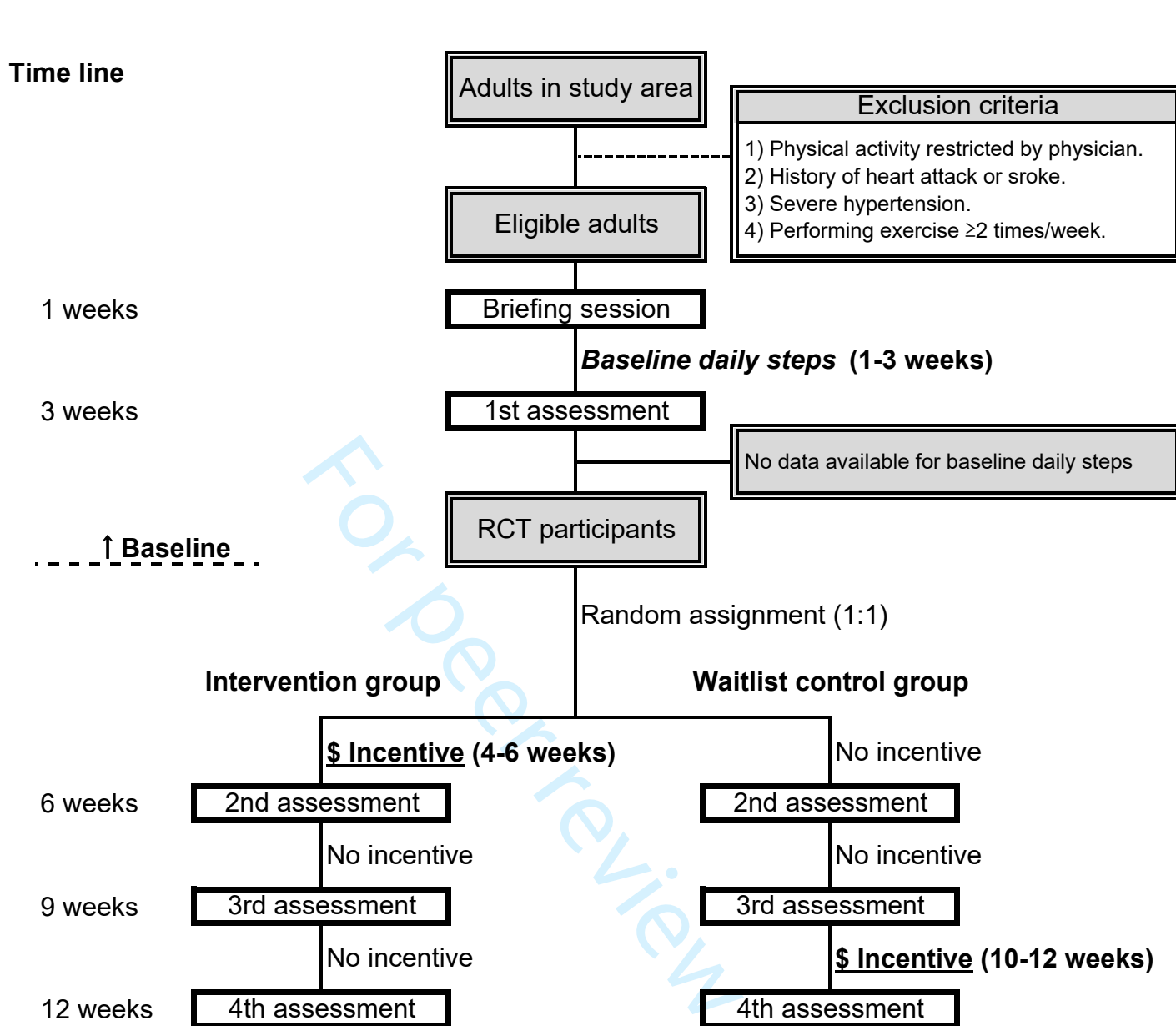
a. Period for providing a chance of financial incentive for the waitlist control group. Thus, this period will not be included in the statistical analysis of this trial.

2

1 **Table 2:** Study outcomes.

Measurement	Definition
Primary outcome	
– Increase in number of steps	Mean increase in the average number of steps (in 4-6 weeks or 7-9 weeks) compared with the baseline number.
Secondary outcome	
– Proportion of participants who increase their steps	Proportion of participants who increase their average number of steps by 1,000 from the baseline.
– Incident falls	Incident rate of falls in 4-6 weeks or 7-9 weeks.
– Incident pain	Incident rate of pain in 4-6 weeks or 7-9 weeks.

2



1 SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

2 [Randomized controlled trial of a financial incentive for increasing the number of daily walking steps: Study protocol](#)

Section/item	Item No	Description	Page, line
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1, line 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 4
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Page 1
Funding	4	Sources and types of financial, material, and other support	Page 23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 23
	5b	Name and contact information for the trial sponsor	Page 23
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 6
	6b	Explanation for choice of comparators	Page 6
Objectives	7	Specific objectives or hypotheses	Page 7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 18
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 10
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 8

Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 19
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 19
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol.	Page 20
		Alternatively, an explanation of why a DMC is not needed	Page 20
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 20
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A

Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 20
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 20
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 20
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 23
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 21
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 23
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Randomized controlled trial of a financial incentive for increasing the number of daily walking steps: Study protocol

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Manuscripts

(Study protocol R2)
page. 1

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4 1 **Title:**

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6 2 **Randomized controlled trial of a financial incentive for increasing the**
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8 3 **number of daily walking steps: Study protocol**
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ABSTRACT

Introduction: Physical activity is one of the major modifiable factors for promotion of public health. Although it has been reported that financial incentives would be effective for promoting health behaviors such as smoking cessation or attendance for cancer screening, few randomized controlled trials (RCTs) have examined the effect of financial incentives for increasing the number of daily steps among individuals in a community setting. The aim of this study is to investigate the effects of financial incentives for increasing the number of daily steps among community-dwelling adults in Japan.

Methods and analysis: This study will be a two-arm, parallel-group RCT. We will recruit community-dwelling adults who are physically inactive in a suburban area (Nakayama) of Sendai city, Japan, using leaflets and posters. Participants that meet the inclusion criteria will be randomly allocated to an intervention group or a waitlist control group. The intervention group will be offered a financial incentive (a chance to get shopping points) if participants increase their daily steps from their baseline. The primary outcome will be the average increase in the number of daily steps (at 4-6 weeks and 7-9 weeks) relative to the average number of daily steps at the baseline (1-3 weeks). For the sample size calculation, we assumed that the difference of primary outcome would be 1,302 steps.

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4 1 **Ethics and dissemination:** This study has been ethically approved by the
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7 2 research ethics committee of Tohoku University Graduate School of
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10 3 Medicine, Japan (No. 2018-1-171). The results will be submitted and
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12 4 published in a peer-reviewed scientific journal.
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1 **Strengths and limitations of this study**

- 2 ➤ This trial will examine the effectiveness of a financial incentive for
3 increasing the number of daily walking steps.
- 4 ➤ The present study would be first Asian randomized controlled trials of
5 financial incentives intervention.
- 6 ➤ Limitations include the fact that the intervention will be only one type of
7 financial incentive.
- 8 ➤ Only short-term effects during 9 weeks will be evaluated.

1 INTRODUCTION

2 Physical activity is a major modifiable factor that has benefits in terms of
3 physical and mental health¹. Therefore public health strategies to increase
4 physical activity are implemented worldwide². In the Japanese National
5 Health Promotion Movement ("Health Japan 21"), a higher number of daily
6 walking steps is a target for physical activity^{3 4}.

7 Recently, to encourage individuals who are not concerned about
8 health-related behavior to increase the number of steps they walk daily, it
9 has been suggested that offering them financial incentives might be an
10 effective approach. The Ministry of Health, Labor and Welfare in Japan has
11 provided a guideline for promotion of public health using financial
12 incentives⁵. One such incentive is the introduction of a "health point system"
13 in which local governments provide "shopping points" that can be redeemed
14 in local stores when an individual achieves a health-related behavior goal
15 such as an increase in the number of daily walking steps.

16 A systematic review (meta-analysis) has suggested that financial
17 incentives would be effective for promotion of health behaviors such as
18 smoking cessation, or attendance for vaccination or cancer screening⁶.

19 Although a few randomized controlled trials (financial incentives vs. no
20 intervention) have examined the effect of financial incentives for increasing
21 the amount of daily steps by individuals in a community setting, the results

(Study protocol R2)

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1 were not consistent^{7 8}; One previous study reported that the target proportion
2 of steps in the financial intervention group was significantly higher than that
3 in the control group (relative risk =3.71) during the intervention period⁷,
4 whereas another study reported that the mean proportion of days on which a
5 7,000-steps goal was achieved as a result of individual incentive was not
6 significantly higher than in the control group (0.25 vs 0.18)⁸.

7 The aim of the present study will be to examine the effect of offering
8 a financial incentive for increasing the number of daily walking steps among
9 physically inactive adults in a community setting.

1 Ability to walk unaided without using a cane, Zimmer frame, or wheelchair.

2 All the above inclusion criteria will be judged on the basis of self-reports
3 from the participants.

4 Possession of the IC Card was considered to be an inclusion criterion
5 because it was a means of providing the intervention (financial incentive).
6 The IC Card was developed as a financial incentive to promote physical
7 activity. Persons possessing the IC Card are given shopping points when they
8 go shopping and participate in community activities in the Nakayama area.
9 The IC Card is also intended to enhance social interaction with locals. The
10 intervention in the present study is the first community activity project.

11 According to the 2015 Population Census, the number of adults (aged
12 20 years or more) living in Nakayama area was 13,734 persons.

13

14 ***Exclusion criteria***

15 Individuals who meet any of the following criteria will not be able to
16 participate in the study: 1) Individuals whose physical activity is restricted
17 by a physician, 2) History of heart attack or stroke within the last 6 months,
18 3) Blood pressure exceeding 180 mmHg systolic or 110 mmHg diastolic, 4)
19 Already habitually exercising (task of ≥ 4 metabolic equivalents) more than
20 twice per week. All exclusion criteria except for blood pressure will be
21 judged on the basis of self-reports from participants.

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4 1 ***Study procedure***

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7 2 **Figure 1** illustrates the flow of the study procedure.

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10 3 In the briefing session in September 2018, the inclusion and exclusion
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12 4 criteria for each applicant will be rechecked by researchers in the study site
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14
15 5 (the Nakayama Tobinoko House). Chosen subjects will provide informed
16
17 6 consent to participate in the study. On the same day, blood pressure
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20 7 measurement, an interview using a questionnaire, and explanation about use
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23 8 of a pedometer will then be performed. At the briefing session, each
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26 9 participant will be provided with a pedometer.

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29 10 The day after the briefing session will be the start date of steps
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31 11 evaluation. We will perform evaluation and feedback about daily steps every
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34 12 3 weeks in the study site (the Nakayama Tobinoko House). All participants
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37 13 must wear the pedometer every day during the study period (12 weeks).

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40 14 For all participants, the number of daily steps at the baseline will be
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42 15 measured in first 3 weeks of the study period (**Table 1**). Then, participants
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44
45 16 who provide their data of daily steps will be randomly assigned to the
46
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48 17 intervention group or the control group (participants who provide any data
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50 18 [≥ 1 days] at the baseline will be included). At this stage, we assume that
51
52
53 19 approximately 74 persons (i.e. the target sample size) would be included in
54
55
56 20 the random assignment.

57
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59 21 During the next 3 weeks (intervention period), the participants in the
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1 intervention group will be given a chance to gain a financial incentive if they
2 achieve their daily steps goals (for definition of goals, see the next section).

3 During 7-9 weeks, a chance to gain a financial incentive will not be
4 provided in both the intervention group and the control group. This period
5 (7-9 weeks) is to examine whether the number of steps in the intervention
6 group remain higher than that in the control group even after the incentive
7 period (**Table 1**).

8 On the other hand, the control group will be given a chance to gain a
9 financial incentive (mentioned above) in the last three weeks (9-12 weeks),
10 and thereby all participants will have a fair opportunity to gain such an
11 incentive. The data obtained at 10-12 weeks will not be used for analysis to
12 evaluate the effect.

13

14 ***Intervention***

15 The intervention is a financial incentive in the form of shopping points,
16 which can be redeemed at facilities in the study area (14 facilities of
17 Nakayama area). Two kinds of financial incentive will be offered:

- 18 1. If the average number of daily steps in the intervention period is $\geq 6,000$,
19 shopping points worth 1,000 Japanese yen will be awarded.
- 20 2. If the average number of daily steps during the intervention period
21 increases by $\geq 1,000$ from the baseline level, shopping points worth 1,000

1 Japanese yen will be awarded.

2 These daily step targets have already been applied in Japanese national
3 health actions^{3 4}. National Health Action of Japan has emphasized that an
4 increase of 1,000 steps has some impact on population health, because it
5 contributes to a 3.2% reduction in the average relative risk of
6 non-communicable diseases, dementia, joint-musculoskeletal impairment,
7 and mortality³. For example, if a person keeps walking 6,500 steps during
8 both the baseline and intervention periods, only financial incentive “1”
9 (1,000 Japanese yen worth of points) will be awarded. If a person walks
10 3,000 steps in the baseline period and 4,000 steps in the intervention period,
11 only financial incentive “2” (1,000 Japanese yen worth of points) will be
12 awarded. If a person walks 5,000 steps in the baseline period and 7,000 steps
13 in the intervention period, both financial incentives “1” and “2” (2,000
14 Japanese yen worth of points) will be awarded. Based on the exchange rate
15 on 31st August 2018, 2,000 Japanese yen was equivalent to 14.0 British
16 Pounds.

17 All participants will be provided shopping points at the same time
18 (after the end of the trial, i.e. the 12th week) regardless of the intervention
19 period.

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21 ***Waitlist control group***

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4 1 The waitlist control group is also given a financial incentive in the last three
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6 2 weeks (**Figure 1**). All conditions except for timing will be the same as for
7
8 the intervention group.
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10 11 12 4 13 14 15 5 *Power and sample size*

16
17 6 The sample size was estimated by reference to the average increase in the
18
19 7 number of daily steps in a previous study conducted in 2013⁷. The average
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21 8 difference in the number of daily steps between the intervention group
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23 9 (n=24) and the control group (n=16) was 1,302 (an increase of 2,348 steps in
24
25 10 the intervention group vs. an increase of 1,046 steps in the control group)
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27 11 when the intervention group was given an incentive of \$20 (approximately
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29 12 ¥2,000 at the time of the study in 2013). In this previous study, the standard
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31 13 deviation in the control group of the increase was 1,711 steps.
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39 14 Therefore, we assumed the result that an average difference of 1,302
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41 15 steps would be achieved in the intervention period (4-6 weeks) by offering a
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43 16 financial incentive of ¥2,000, and setting the standard deviation at 1,711.
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45 17 When an α error of 0.05 and a statistical power of 0.90 was applied, the
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47 18 minimum sample size was 74 persons (37 persons per group). Therefore, a
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49 19 total number of 74 participants (37 participants in each group) was set as the
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51 20 target sample size for analysis. When an α error of 0.05 and statistical power
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53 21 of 0.80 was applied with this sample size (37 participants in each group), an
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4 1 average difference of $\geq 1,130$ steps was detectable as statistically significant.
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6 2 ***Randomization***

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9 3 After confirming their eligibility, enrolled participants will be assigned to
10 4 one of the two groups (1:1 allocation) based on the permuted block method
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15 5 by computer-generated randomization. The allocation sequence will be
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17 6 managed by two exclusive researchers of the random assignment.
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20 7 21 22 23 8 ***Blinding***

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26 9 A blinded endpoint evaluation design will be applied. Only researchers of the
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28 10 random assignment can access the assignment data, and other staffs were
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31 11 blinded to the random assignment. The assignment information was managed
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34 12 in password-locked dedicated storage media. Notification of the assignment
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37 13 by the exclusive researchers of the random assignment will be conducted in a
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39 14 closed room where is separated from the other examination places. In this
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42 15 notification process, the exclusive researchers of the random assignment will
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45 16 warn all participants not to talk about their assignment.
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48 17 In addition, statistical analyses will be blinded to the assignment. The
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50 18 exclusive researchers of the random assignment will not be involved with the
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53 19 statistical analysis.
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56 20 57 58 21 ***Baseline characteristics***

1 Baseline characteristics will be assessed on the date of the briefing session.

2 Trained interviewers will conduct an interview to obtain information
3 about medical history, frailty (the Kihon checklist), physical activity,
4 transportation when going out, education level, work, subjective economic
5 status, time affluence (having spare time), pain, and falling. We will also
6 measure the blood pressure of each participant.

7 History of diseases will include stroke, hypertension, myocardial
8 infarction, renal disease, hepatic disease, diabetes mellitus, arthritis,
9 osteoporosis, cancer, and dyslipidemia.

10 Frailty will be assessed by the Kihon checklist (devised by the
11 Japanese Ministry of Health, Labor and Welfare), which is a 25-item
12 self-administered questionnaire designed to identify frail elderly
13 individuals⁹. Previous studies have reported the validity of the Kihon
14 checklist¹⁰⁻¹³.

15 Physical activity will be assessed by the Japan Public Health Centre
16 Physical Activity Questionnaire (JPHC PAQ)^{14 15}. This questionnaire
17 includes information about the average daily amount of time and frequency
18 spent in work-related (including commuting and housework) physical
19 activity, leisure-time physical activity, and sleep¹⁴. The total physical
20 activity level is calculated as metabolic equivalents of task-hours per day.
21 The correlation between metabolic equivalents estimated by this

1 questionnaire and daily activities reported in 24-hour records was 0.69¹⁴.

2 Transportation when going out will be assessed by asking the question
3 “What kinds of transportation did you use more than twice per week when
4 you went out in the last 1 month?”, for which available responses were:
5 “walking”, “bicycle”, “motorbike”, “car”, “train”, “bus”, “taxi”, or “other”.

6 Education level will be assessed by asking the question applied in the
7 2010 Population Census (Japan) “Please indicate the last school you
8 graduated from.”, for which available responses were: “primary school or
9 junior high school”, “senior high school or middle school (under the old
10 system of education)”, “junior college or higher professional school”,
11 “college, university or graduate school”¹⁶.

12 Work will be assessed by asking the question “Do you do any paid
13 work now?”, for which available responses were: “≥4 times/week”, “2-3
14 times/week”, “1 time/week”, “1-3 times/month”, “few times/year”, or
15 “none”.

16 Subjective household economic status will be assessed by asking the
17 question “How do you feel about your current household economic
18 situation?”, for which available responses will be: “most affluent”, “more
19 affluent”, “neither more nor less”, “less affluent”, or “non-affluent”
20 (selection from these 5 choices)¹⁷.

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

1 question “Do you have time affluence for rest or leisure in daily life?
2 Alternatively, do not you have time affluence for work, housework, or
3 studies?”, for which available responses will be: “more affluent”, “little
4 affluent”, “less affluent”, or “non-affluent” (selection from these 5
5 choices)¹⁸.

6 Falling will be assessed based on question no. 9 of the Kihon
7 checklist “Have you experienced a fall in the last year?”⁹.

8 Pain will be assessed based on the question “How much pain have you
9 experienced during the last 1 month?”, for which available responses will be:
10 “none,” “very mild,” “mild,” “moderate,” “severe,” or “very severe”¹⁹.
11 Location of the pain will be also ascertained, for which available responses
12 will be: “shoulder”, “lower back” or “knee”.

13 Blood pressure in a seated position after 3 min of rest will be assessed
14 using an automated sphygmomanometer HEM-1040 (Omron, Kyoto, Japan).
15 Two measurements taken 3 min apart will be averaged for analysis.

17 ***Outcome measurements***

18 Daily steps will be counted by a pedometer FS-800 (ESTERA Corporation,
19 Saitama, Japan) containing a 3-axis acceleration sensor. Data on daily steps
20 will be automatically recorded in the pedometer for 90 days. On the display
21 of the pedometer, only daily steps in each of the last 14 days (not average

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4 1 steps for the selected period) can be checked. Every 3 weeks, trained staffs
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7 2 will transfer data on the number of steps walked daily recorded by the
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10 3 pedometer to a computer as a Comma-Separated Values file via the Near
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12 4 Field Communication function (not via internet). We will provide a clip-on
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15 5 holder for wearing the pedometer on the waist, and we explain to each
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18 6 participant how to use it. Because the pedometer will record 0 steps if a
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21 7 participant forgets to wear it, we will instruct the participants to wear the
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23 8 pedometer at all times except when sleeping or taking a bath.

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26 9 Because both effect and adverse effect resulting from falls and pain
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29 10 may be expected as a result of the intervention, we will check any tendencies
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32 11 for incident falls and pain.

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34 12 Incident falls will be assessed based on question no. 9 of the Kihon
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37 13 checklist. Because the assessment will be conducted every three weeks for
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40 14 follow-up, we will modify the timing of this question to “Have you fallen in
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43 15 the past three weeks?”. Incident falls are defined as new episodes of falling
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45 16 after the baseline.

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48 17 Incident pain will be assessed based on the question “How much pain
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51 18 have you experienced during the past three weeks?”, and expressed as a
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54 19 six-point verbal rating scale: “none,” “very mild,” “mild,” “moderate,”
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57 20 “severe,” and “very severe”. Incident pain is defined as worsening of pain
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59 21 severity after the baseline.
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7 2 **Primary outcome**
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9 3 The primary outcome is the average increase in the number of daily steps
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12 4 compared with the average number during the baseline period (**Table 1**,
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15 5 **Table 2**). We will thereby examine whether an increase of more than 1,302
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18 6 steps in 4-6 weeks from the baseline level (mean value for sample size) can
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21 7 be expected, and the increase in the daily number of steps resulting from the
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24 8 financial incentive.
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29 10 **Secondary outcome**

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31 11 The secondary outcomes will be 1) increase in the number of daily steps by
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34 12 1,000 or more in 4-6 weeks or 7-9 weeks from the baseline level (1-3 weeks);
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37 13 2) incident falls in 4-6 weeks or 7-9 weeks; and 3) incident pain in 4-6 weeks
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40 14 or 7-9 weeks (**Table 2**).
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45 16 **Statistical analyses**

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48 17 To compare the primary outcome (average difference), t-test will be applied
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50
51 18 to examine whether the average daily increases in the number of steps 4-6
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54 19 weeks and 7-9 weeks from the baseline differ significantly between the
55
56 20 intervention group and the control group.

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59 21 For comparison of secondary outcomes between the intervention group
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4 1 and the waitlist control group at 4-6 weeks and 7-9 weeks, logistic regression
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6
7 2 models will be applied to examine whether the proportions of participants
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10 3 with an increase of 1000 steps or more are significantly different, and
11
12 4 applied to assess the probabilities of incident falls and incident pain,
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15 5 respectively.

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17 6 In addition, stratified analyses will be conducted to check for any
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20 7 differences in the number of steps in terms of sex, age, frailty, physical
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23 8 activity level, transportation when going out, education level, work,
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26 9 subjective economic status, time affluence (having spare time), pain, and
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29 10 obesity.

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31 11 To apply the intention-to-treat principle, multiple imputations will be
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34 12 conducted to consider the effects of missing values on outcome variables.

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37 13 All of the above analyses will be performed using SAS version 9.4
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39
40 14 (SAS Institute Inc. North Carolina, USA).

1 ETHICS AND DISSEMINATION

2 *Ethical considerations*

3 The ethics committee of Tohoku University Graduate School of Medicine
4 (Sendai, Japan) has reviewed and approved the study protocol (No.
5 2018-1-171).

6 The investigator will explain the research proposal along with the
7 documents, and provide enough time for individuals to consider their
8 participation. Handwritten signatures will be required on the consent
9 document. The consent form will guarantee protection of personal
10 information, and use of the dataset only for academic purposes. Consent
11 documents will be kept by the principal investigator, and copies will be
12 given to the participants.

13 All data on participants will be managed by use of an ID number.
14 Personal information will be strictly managed at Tohoku University Graduate
15 School of Medicine. Personal information will be deleted from the dataset for
16 statistical analysis. After the research period, participant's information data
17 will be disposed of in a prescribed way.

18 Because this trial is a noninvasive intervention, no Data Monitoring
19 Committee will be organized.

20 If the research protocol needs to change, the principal investigator
21 must obtain approval from the chief of the research institution through the

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1 ethical review committee.

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4 1 ***Dissemination of research findings***
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7 2 Results and findings will be submitted and published in a peer-reviewed
8
9 3 scientific journal according to the guidelines of CONSORT for RCTs.

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12 4 Conflicts of interest among researchers is managed by the Conflict of
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14 5 Interest Management Committee at Tohoku University.
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20 7 **Patient and public involvement**
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23 8 To improve feasibility about the protocol of this trial in Nakayama area, we
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25 9 discussed with members of Nakayama Community Development Center
26
27 10 (nonprofit organization corporation) and members of Nakayama Shopping
28
29 11 Street Promotion Association. Additionally, members of Nakayama
30
31 12 Neighborhood Association are involved to announce about the recruitment.
32
33 13 After the end of the trial, as a collaborative program with Nakayama
34
35 14 Community Development Center and Nakayama Shopping Street Promotion
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37 15 Association, we will hold the debrief session for study report to share results
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39 16 of the trail.
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4 1 **DISCUSSION**
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6 2 This protocol outlines the objectives of the study and explains the study
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9 3 design.
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12 4 If this study is conducted in accordance with the present plan, the
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14
15 5 present study would be first RCT for examining the effect of financial
16
17 6 incentives for increasing the number of daily steps in Asian population.
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19
20 7 This study has several limitations. First, the intervention involves
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23 8 only one type of financial incentive. Thus, the effect of a change in the
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26 9 corresponding financial incentive or its application (e.g. donation) would be
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28
29 10 unclear. Second, only short-term effects during 9 weeks will be evaluated.
30
31
32 11 Thus, the long-term effect (maintaining a higher number of daily walking
33
34 12 steps) of the financial incentive would be unclear. Third, a volunteer bias
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37 13 may exist in the present study. Participants may be more highly motivated to
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40 14 achieve the financial incentive goals in comparison with the total population
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42 15 in the study area. Therefore, the external validity toward non-participants
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45 16 (involuntary participants) will be unclear.
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1 **Authors' contributions:** Ichiro Tsuji supervised this study and is the
2 guarantor. Yasutake Tomata, Fumiya Tanji and Ichiro Tsuji have made were
3 involved in the design. Yasutake Tomata, Dieta Nurrika, Yingxu Liu and Shu
4 Zhang prepared draft manuscript. Saho Abe, Kouichi Matsumoto, Shu Zhang,
5 Yumika Kotaki, Sanae Matsuyama, Yukai Lu, Yumi Sugawara, Shino Bando,
6 Teiichiro Yamazaki, Tatsui Otsuka, and Toshimasa Sone revised the
7 manuscript. Yasutake Tomata carried out the statistical calculation. All
8 authors approved submission of this manuscript.

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

11 **Ethical approval:** The study protocol was reviewed and approved by the
12 Ethics Committee of Tohoku University Graduate School of Medicine.

13 **Provenance and peer review:** Not commissioned; externally peer reviewed.

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(Study protocol R2)
page. 29

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1 **Figure 1:** Flow chart of the study procedure.

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1 **Table 1:** Time line for the evaluation.

Time line	Purpose of evaluation	Hypothesis
1-3 weeks	Baseline number of steps	
4-6 weeks	Effect of incentive	Is the number of steps in the intervention group higher than that in the control group?
7-9 weeks	Sustained effect of incentive	Does the number of steps in the intervention group remain higher than that in the control group even after the incentive period?
10-12 weeks	Chance for waitlist control ^a	

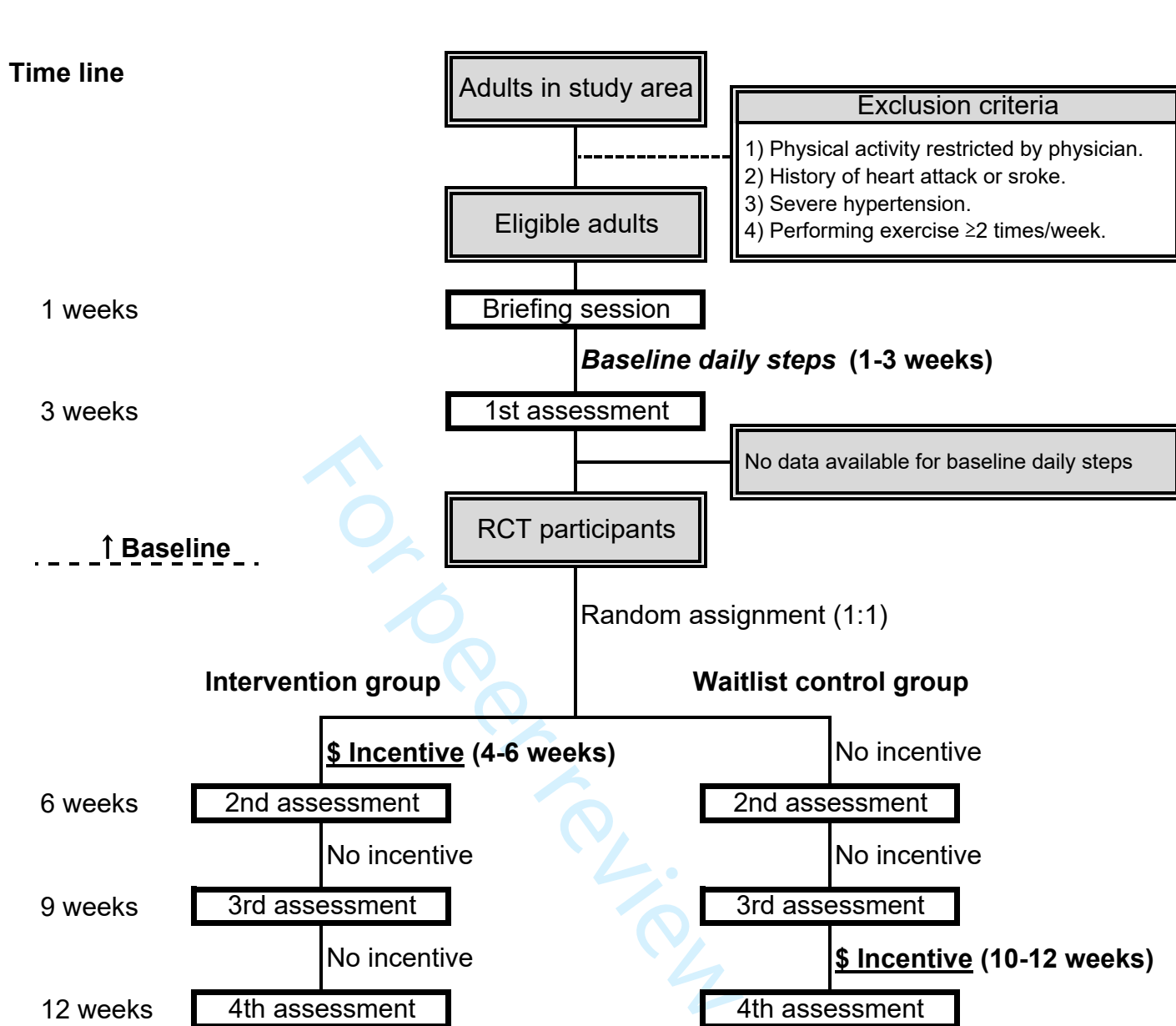
a. Period for providing a chance of financial incentive for the waitlist control group. Thus, this period will not be included in the statistical analysis of this trial.

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1 **Table 2:** Study outcomes.
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Measurement	Definition
Primary outcome	
– Increase in number of steps	Mean increase in the average number of steps (in 4-6 weeks or 7-9 weeks) compared with the baseline number.
Secondary outcome	
– Proportion of participants who increase their steps	Proportion of participants who increase their average number of steps by 1,000 from the baseline.
– Incident falls	Incident rate of falls in 4-6 weeks or 7-9 weeks.
– Incident pain	Incident rate of pain in 4-6 weeks or 7-9 weeks.

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1 SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

2 [Randomized controlled trial of a financial incentive for increasing the number of daily walking steps: Study protocol](#)

Section/item	Item No	Description	Page, line
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1, line 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 4
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Page 1
Funding	4	Sources and types of financial, material, and other support	Page 23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 23
	5b	Name and contact information for the trial sponsor	Page 23
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 6
	6b	Explanation for choice of comparators	Page 6
Objectives	7	Specific objectives or hypotheses	Page 7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 18
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 10
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 8

Methods: Assignment of interventions (for controlled trials)**Allocation:**

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 19
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 19

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol.	Page 20
		Alternatively, an explanation of why a DMC is not needed	Page 20
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 20
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A

Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 20
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 20
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 20
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 23
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 21
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 23
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.