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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

peer-reviewed scientific journal.

Registration: UMIN000033276; Pre-results.

Strengths and limitations of this study

- This trial will examine the effectiveness of a financial incentive for increasing the number of daily walking steps.
- The present study would be first Asian trial.
- Limitations include the fact that the intervention will be only one type of financial incentive.
- Only short-term effects during 9 weeks will be evaluated.

INTRODUCTION

Physical activity is a major modifiable factor that has benefits in terms of physical and mental health[1]. Therefore public health strategies to increase physical activity are implemented worldwide[2]. In the Japanese National Health Promotion Movement ("Health Japan 21"), a higher number of daily walking steps is a target for physical activity[3 4].

Recently, to encourage individuals who are not lifestyle-conscious to increase the number of steps they walk daily, it has been suggested that offering them financial incentives might be an effective approach. The Ministry of Health, Labor and Welfare in Japan has provided a guideline for promotion of public health using financial incentives[5]. One such incentive is the introduction of a "health point system" in which local governments provide “shopping points” that can be redeemed in local stores when an individual achieves a healthy lifestyle goal such as an increase in the number of daily walking steps.

A systematic review (meta-analysis) has suggested that financial incentives would be effective for promotion of health behaviors such as smoking cessation, or attendance for vaccination or cancer screening[6]. Although a few randomized controlled trials (financial incentives vs. no intervention) have examined the effect of financial incentives for increasing the amount of daily steps by individuals in a community setting, the results

were not consistent[7 8].

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

METHODS

Study design

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

Recruitment

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

Inclusion criteria

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

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

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

Exclusion criteria

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

Study procedure

Figure 1 illustrates the flow of the study procedure.

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

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

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 ≥6,000, shopping points worth 1,000 Japanese yen will be awarded.

2. If the average number of daily steps during the intervention period increases by ≥1,000 from the baseline level, shopping points worth 1,000 Japanese yen will be awarded.

For example, if a person keeps walking 6,500 steps during both the baseline and intervention periods, only financial incentive "1" (1,000 Japanese yen worth of points) will be awarded. If a person walks 3,000 steps in the baseline period and 4,000 steps in the intervention period, only financial incentive "2" (1,000 Japanese yen worth of points) will be awarded. If a person walks 5,000 steps in the baseline period and 7,000 steps in the intervention period, both financial incentives "1" and "2" (2,000 Japanese yen worth of points) will be awarded.

Waitlist control group

The waitlist control group is also given a financial incentive in the last three weeks (**Figure 1**).

Randomization

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

Blinding

A blinded endpoint evaluation design will be applied.

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

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

Baseline characteristics

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

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

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

Frailty will be assessed by the Kihon checklist (devised by the Japanese Ministry of Health, Labor and Welfare), which is a 25-item self-administered questionnaire designed to identify frail elderly individuals[9].

Previous studies have reported the validity of the Kihon checklist[10-13].

Physical activity will be assessed by the Japan Public Health Centre Physical Activity Questionnaire (JPHC PAQ)[14 15]. This questionnaire includes information about the average daily amount of time and frequency spent in work-related (including commuting and housework) physical activity, leisure-time physical activity, and sleep[14]. The total physical activity level is calculated as metabolic equivalents of task-hours per day. The correlation between metabolic equivalents estimated by this questionnaire and daily activities reported in 24-hour records was 0.69[14].

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

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

Work will be assessed by asking the question "Do you do any paid work now?", for which available responses were: "≥4 times/week", "2-3

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

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

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

Falling will be assessed based on question no. 9 of the Kihon checklist "Have you experienced a fall in the last year?"[9].

Pain will be assessed based on the question "How much pain have you experienced during the last 1 month?", for which available responses will be: "none," "very mild," "mild," "moderate," "severe," or "very severe"[18]. Location of the pain will be also ascertained, for which available responses will be: "shoulder", "lower back" or "knee".

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

Outcome measurements

Daily steps will be counted by a pedometer FS-800 (ESTERA Corporation. Saitama, Japan) containing a 3-axis acceleration sensor. Data on daily steps will be automatically recorded in the pedometer for 90 days, and the data will be transferred from the pedometer to a personal computer via the Near Field Communication function.

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

Incident pain will be assessed based on the question “How much pain have you experienced during the past three weeks?”, and expressed as a six-point verbal rating scale: “none,” “very mild,” “mild,” “moderate,” “severe,” and “very severe”. Incident pain is defined as worsening of pain severity after the baseline.

Primary outcome

The primary outcome is the average increase in the number of daily steps compared with the average number during the baseline period (**Table 1**, **Table 2**).

Secondary outcome

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

Power and sample size

The sample size was estimated using the average increase in the number of daily steps in a previous study conducted in 2013[7]. The average difference in the number of daily steps between the intervention group and the control group was 1,302 (an increase of 2,348 steps in the intervention group vs. an increase of 1,046 steps in the control group) when the intervention group was given an incentive of $20 (approximately ¥2,000 at the time of the study in 2013). In this previous study, the standard deviation in the control group was 1,711 steps.

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

Statistical analyses

To compare the primary outcome (average difference) between the intervention group and the waitlist control group, t-test or a linear mixed model will be applied.

For comparison of secondary outcomes between the intervention group and the waitlist control group, chi-squared test or a logistic regression model will be applied.

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

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

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

ETHICS AND DISSEMINATION

Ethical considerations

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

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

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

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

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

Dissemination of research findings

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

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

DISCUSSION

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

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

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

Authors' contributions: Ichiro Tsuji supervised this study and is the guarantor. Yasutake Tomata, Fumiya Tanji and Ichiro Tsuji have made were involved in the design. Yasutake Tomata, Dieta Nurrika, Yingxu Liu and Shu Zhang prepared draft manuscript. Saho Abe, Kouichi Matsumoto, Shu Zhang, Yumika Kotaki, Sanae Matsuyama, Yukai Lu, Yumi Sugawara, Shino Bando, Teiichiro Yamazaki, Tatsui Otsuka, and Toshimasa Sone revised the manuscript. Yasutake Tomata carried out the statistical calculation. All authors approved submission of this manuscript.

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

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

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

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Figure 1: Flow chart of the study procedure.

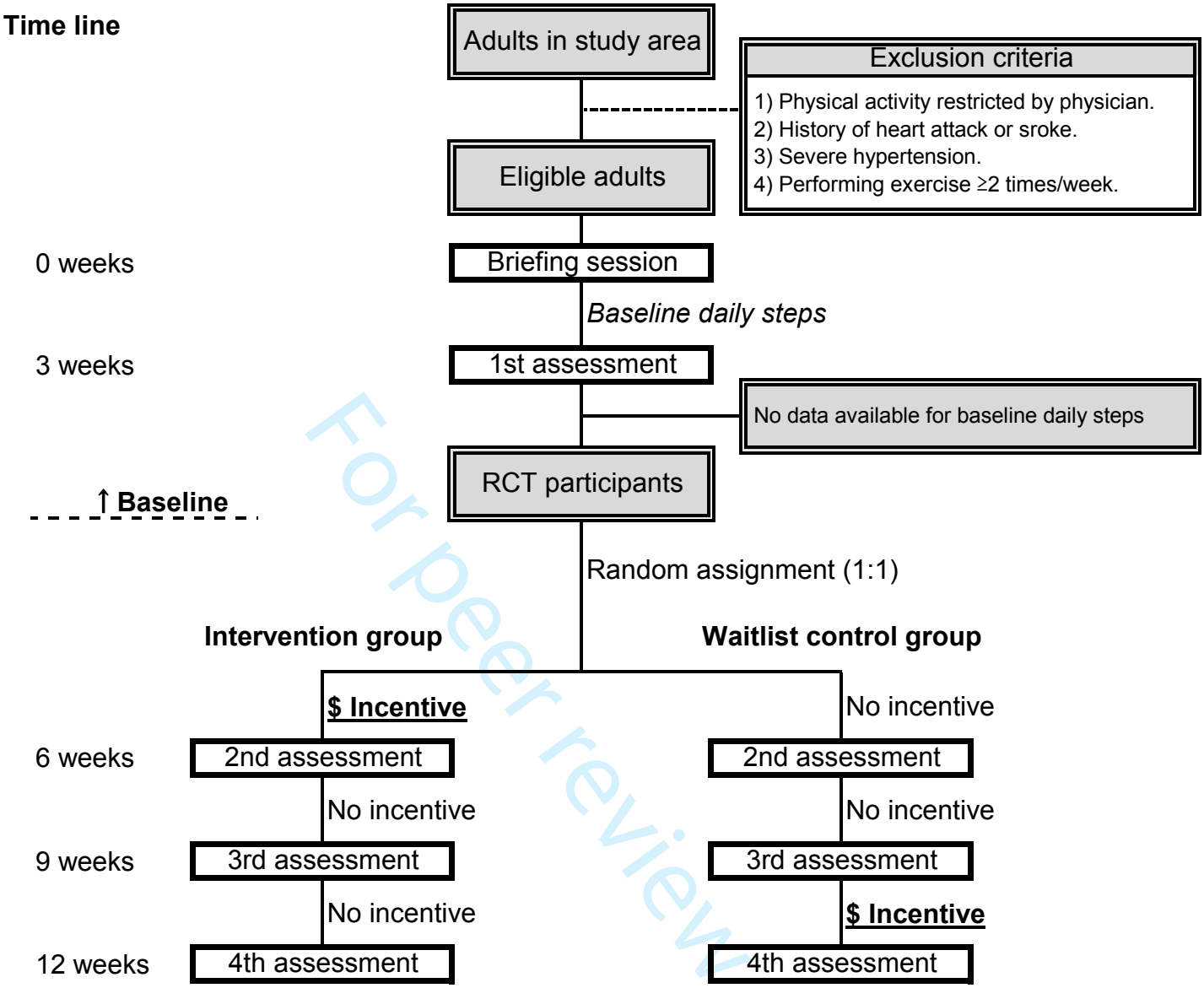
Table 1: Time line for the evaluation.

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.

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.



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

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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 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 an average difference of 1,302 steps would be achieved.

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 peer-reviewed scientific journal.

Registration: UMIN000033276; Pre-results.

Strengths and limitations of this study

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

INTRODUCTION

Physical activity is a major modifiable factor that has benefits in terms of physical and mental health[1]. Therefore public health strategies to increase physical activity are implemented worldwide[2]. In the Japanese National Health Promotion Movement ("Health Japan 21"), a higher number of daily walking steps is a target for physical activity[3 4].

Recently, to encourage individuals who are not concerned about health-related behavior to increase the number of steps they walk daily, it has been suggested that offering them financial incentives might be an effective approach. The Ministry of Health, Labor and Welfare in Japan has provided a guideline for promotion of public health using financial incentives[5]. One such incentive is the introduction of a "health point system" in which local governments provide “shopping points” that can be redeemed in local stores when an individual achieves a health-related behavior goal such as an increase in the number of daily walking steps.

A systematic review (meta-analysis) has suggested that financial incentives would be effective for promotion of health behaviors such as smoking cessation, or attendance for vaccination or cancer screening[6]. Although a few randomized controlled trials (financial incentives vs. no intervention) have examined the effect of financial incentives for increasing the amount of daily steps by individuals in a community setting, the results

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

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

METHODS

Study design

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

Recruitment

In August 2018, two types of leaflets (preliminary notice, and information about recruitment) related to the study will be distributed to each house in the Nakayama area, Aoba-ku, Sendai city, Japan. Posters giving details about recruitment will also be displayed in the Nakayama area. Inclusion criteria and exclusion criteria will be stated on the entry form. Applicants who meet the inclusion criteria and not the exclusion criteria will be able to apply by Web application, FAX, or telephone. Considering an estimated attrition of about 10 individuals, we will accept 85 applicants.

Inclusion criteria

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

Ability to walk unaided without using a cane, Zimmer frame, or wheelchair. All the above inclusion criteria will be judged on the basis of self-reports from the participants.

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

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

Exclusion criteria

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

Study procedure

Figure 1 illustrates the flow of the study procedure.

In the briefing session in September 2018, the inclusion and exclusion criteria for each applicant will be rechecked by researchers in the study site (the Nakayama Tobinoko House). Chosen subjects will provide informed consent to participate in the study. On the same day, blood pressure measurement, an interview using a questionnaire, and explanation about use of a pedometer will then be performed. At the briefing session, each participant will be provided with a pedometer.

The day after the briefing session will be the start date of steps evaluation. We will perform evaluation and feedback about daily steps every 3 weeks in the study site (the Nakayama Tobinoko House). 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 (participants who provide any data [≥1 days] at the baseline will be included). 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 (for definition of goals, see the next section).

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

Intervention

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

1. If the average number of daily steps in the intervention period is ≥6,000, shopping points worth 1,000 Japanese yen will be awarded.
2. If the average number of daily steps during the intervention period increases by ≥1,000 from the baseline level, shopping points worth 1,000 Japanese yen will be awarded.

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

non-communicable diseases, dementia, joint-musculoskeletal impairment, and mortality[3]. For example, if a person keeps walking 6,500 steps during both the baseline and intervention periods, only financial incentive "1" (1,000 Japanese yen worth of points) will be awarded. If a person walks 3,000 steps in the baseline period and 4,000 steps in the intervention period, only financial incentive "2" (1,000 Japanese yen worth of points) will be awarded. If a person walks 5,000 steps in the baseline period and 7,000 steps in the intervention period, both financial incentives "1" and "2" (2,000 Japanese yen worth of points) will be awarded. Based on the exchange rate on 31st August 2018, 2,000 Japanese yen was equivalent to 14.0 British Pounds.

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

Waitlist control group

The waitlist control group is also given a financial incentive in the last three weeks (**Figure 1**). All conditions except for timing will be the same as for the intervention group.

Power and sample size

The sample size was estimated by reference to the average increase in the number of daily steps in a previous study conducted in 2013[7]. The average difference in the number of daily steps between the intervention group (n=24) and the control group (n=16) was 1,302 (an increase of 2,348 steps in the intervention group vs. an increase of 1,046 steps in the control group) when the intervention group was given an incentive of $20 (approximately ¥2,000 at the time of the study in 2013). In this previous study, the standard deviation in the control group of the increase was 1,711 steps.

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

Randomization

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

Blinding

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

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

Baseline characteristics

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

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

History of diseases will include stroke, hypertension, myocardial

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

Frailty will be assessed by the Kihon checklist (devised by the Japanese Ministry of Health, Labor and Welfare), which is a 25-item self-administered questionnaire designed to identify frail elderly individuals[9]. Previous studies have reported the validity of the Kihon checklist[10-13].

Physical activity will be assessed by the Japan Public Health Centre Physical Activity Questionnaire (JPHC PAQ)[14 15]. This questionnaire includes information about the average daily amount of time and frequency spent in work-related (including commuting and housework) physical activity, leisure-time physical activity, and sleep[14]. The total physical activity level is calculated as metabolic equivalents of task-hours per day. The correlation between metabolic equivalents estimated by this questionnaire and daily activities reported in 24-hour records was 0.69[14].

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

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

graduated from.", for which available responses were: "primary school or junior high school", "senior high school or middle school (under the old system of education)", "junior college or higher professional school", "college, university or graduate school"[16].

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

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

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

Falling will be assessed based on question no. 9 of the Kihon checklist "Have you experienced a fall in the last year?"[9].

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

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

Outcome measurements

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

Because both effect and adverse effect resulting from falls and pain

may be expected as a result of the intervention, we will check any tendencies for incident falls and pain.

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

Incident pain will be assessed based on the question “How much pain have you experienced during the past three weeks?”, and expressed as a six-point verbal rating scale: “none,” “very mild,” “mild,” “moderate,” “severe,” and “very severe”. Incident pain is defined as worsening of pain severity after the baseline.

Primary outcome

The primary outcome is the average increase in the number of daily steps compared with the average number during the baseline period (**Table 1**, **Table 2**). We will thereby examine whether an increase of more than 1,302 steps (mean value for sample size) can be expected, and the increase in the daily number of steps resulting from the financial incentive.

Secondary outcome

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

Statistical analyses

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

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

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

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

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

ETHICS AND DISSEMINATION

Ethical considerations

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

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

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

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

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

ethical review committee.

Dissemination of research findings

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

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

Patient and public involvement

To improve feasibility about the protocol of this trial in Nakayama area, we discussed with members of Nakayama Community Development Center (nonprofit organization corporation) and members of Nakayama Shopping Street Promotion Association. Additionally, members of Nakayama Neighborhood Association are involved to announce about the recruitment. After the end of the trial, as a collaborative program with Nakayama Community Development Center and Nakayama Shopping Street Promotion Association, we will hold the debrief session for study report to share results of the trail.

DISCUSSION

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

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

This study has several limitations. First, the intervention involves only one type of financial incentive. Thus, the effect of a change in the corresponding financial incentive or its application (e.g. donation) would be unclear. Second, only short-term effects during 9 weeks will be evaluated. Thus, the long-term effect (maintaining a higher number of daily walking steps) of the financial incentive would be unclear. Third, a volunteer bias may exist in the present study. Participants may be more highly motivated to achieve the financial incentive goals in comparison with the total population in the study area. Therefore, the external validity toward non-participants (involuntary participants) will be unclear.

Authors' contributions: Ichiro Tsuji supervised this study and is the guarantor. Yasutake Tomata, Fumiya Tanji and Ichiro Tsuji have made were involved in the design. Yasutake Tomata, Dieta Nurrika, Yingxu Liu and Shu Zhang prepared draft manuscript. Saho Abe, Kouichi Matsumoto, Shu Zhang, Yumika Kotaki, Sanae Matsuyama, Yukai Lu, Yumi Sugawara, Shino Bando, Teiichiro Yamazaki, Tatsui Otsuka, and Toshimasa Sone revised the manuscript. Yasutake Tomata carried out the statistical calculation. All authors approved submission of this manuscript.

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

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

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Figure 1: Flow chart of the study procedure.

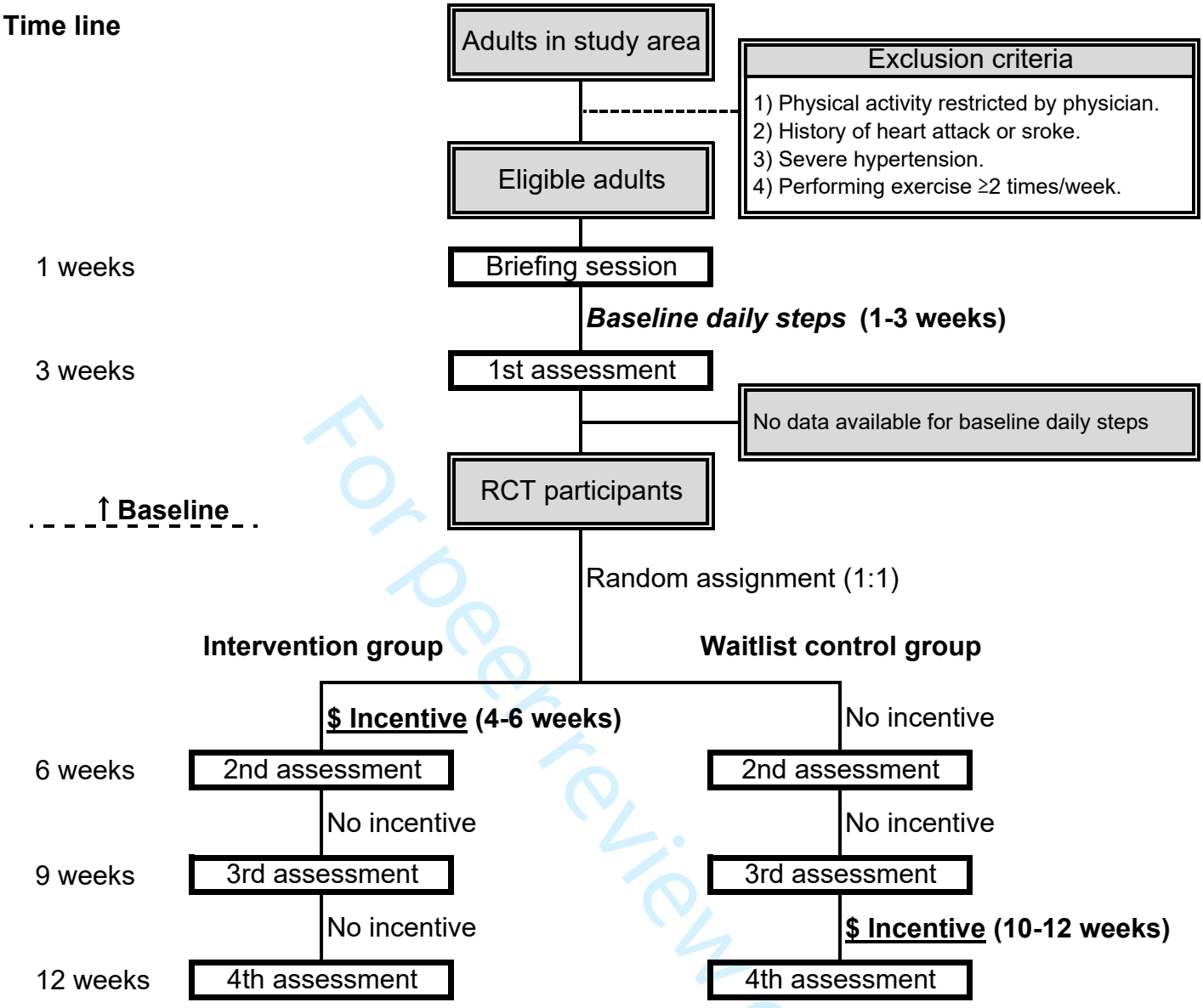
Table 1: Time line for the evaluation.

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.

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.



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

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

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 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.

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 peer-reviewed scientific journal.

Registration: UMIN000033276; Pre-results.

Strengths and limitations of this study

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

INTRODUCTION

Physical activity is a major modifiable factor that has benefits in terms of physical and mental health[1]. Therefore public health strategies to increase physical activity are implemented worldwide[2]. In the Japanese National Health Promotion Movement ("Health Japan 21"), a higher number of daily walking steps is a target for physical activity[3 4].

Recently, to encourage individuals who are not concerned about health-related behavior to increase the number of steps they walk daily, it has been suggested that offering them financial incentives might be an effective approach. The Ministry of Health, Labor and Welfare in Japan has provided a guideline for promotion of public health using financial incentives[5]. One such incentive is the introduction of a "health point system" in which local governments provide “shopping points” that can be redeemed in local stores when an individual achieves a health-related behavior goal such as an increase in the number of daily walking steps.

A systematic review (meta-analysis) has suggested that financial incentives would be effective for promotion of health behaviors such as smoking cessation, or attendance for vaccination or cancer screening[6]. Although a few randomized controlled trials (financial incentives vs. no intervention) have examined the effect of financial incentives for increasing the amount of daily steps by individuals in a community setting, the results

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

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

METHODS

Study design

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

Recruitment

In August 2018, two types of leaflets (preliminary notice, and information about recruitment) related to the study will be distributed to each house in the Nakayama area, Aoba-ku, Sendai city, Japan. Posters giving details about recruitment will also be displayed in the Nakayama area. Inclusion criteria and exclusion criteria will be stated on the entry form. Applicants who meet the inclusion criteria and not the exclusion criteria will be able to apply by Web application, FAX, or telephone. Considering an estimated attrition of about 10 individuals, we will accept 85 applicants.

Inclusion criteria

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

Ability to walk unaided without using a cane, Zimmer frame, or wheelchair. All the above inclusion criteria will be judged on the basis of self-reports from the participants.

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

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

Exclusion criteria

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

Study procedure

Figure 1 illustrates the flow of the study procedure.

In the briefing session in September 2018, the inclusion and exclusion criteria for each applicant will be rechecked by researchers in the study site (the Nakayama Tobinoko House). Chosen subjects will provide informed consent to participate in the study. On the same day, blood pressure measurement, an interview using a questionnaire, and explanation about use of a pedometer will then be performed. At the briefing session, each participant will be provided with a pedometer.

The day after the briefing session will be the start date of steps evaluation. We will perform evaluation and feedback about daily steps every 3 weeks in the study site (the Nakayama Tobinoko House). 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 (participants who provide any data [≥1 days] at the baseline will be included). 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 chance to gain a financial incentive if they achieve their daily steps goals (for definition of goals, see the next section).

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

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

Intervention

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

1. If the average number of daily steps in the intervention period is ≥6,000, shopping points worth 1,000 Japanese yen will be awarded.
2. If the average number of daily steps during the intervention period increases by ≥1,000 from the baseline level, shopping points worth 1,000

Japanese yen will be awarded.

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

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

Waitlist control group

The waitlist control group is also given a financial incentive in the last three weeks (**Figure 1**). All conditions except for timing will be the same as for the intervention group.

Power and sample size

The sample size was estimated by reference to the average increase in the number of daily steps in a previous study conducted in 2013[7]. The average difference in the number of daily steps between the intervention group (n=24) and the control group (n=16) was 1,302 (an increase of 2,348 steps in the intervention group vs. an increase of 1,046 steps in the control group) when the intervention group was given an incentive of $20 (approximately ¥2,000 at the time of the study in 2013). In this previous study, the standard deviation in the control group of the increase was 1,711 steps.

Therefore, we assumed the result that an average difference of 1,302 steps would be achieved in the intervention period (4-6 weeks) by offering a financial incentive of ¥2,000, and setting the standard deviation at 1,711. When an α error of 0.05 and a statistical power of 0.90 was applied, the minimum sample size was 74 persons (37 persons per group). Therefore, a total number of 74 participants (37 participants in each group) was set as the target sample size for analysis. When an α error of 0.05 and statistical power of 0.80 was applied with this sample size (37 participants in each group), an

average difference of ≥1,130 steps was detectable as statistically significant.

Randomization

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

Blinding

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

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

Baseline characteristics

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

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

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

Frailty will be assessed by the Kihon checklist (devised by the Japanese Ministry of Health, Labor and Welfare), which is a 25-item self-administered questionnaire designed to identify frail elderly individuals[9]. Previous studies have reported the validity of the Kihon checklist[10-13].

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

questionnaire and daily activities reported in 24-hour records was 0.69[14].

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

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

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

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

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

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

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

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

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

Outcome measurements

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

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

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

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

Incident pain will be assessed based on the question “How much pain have you experienced during the past three weeks?”, and expressed as a six-point verbal rating scale: “none,” “very mild,” “mild,” “moderate,” “severe,” and “very severe”. Incident pain is defined as worsening of pain severity after the baseline.

Primary outcome

The primary outcome is the average increase in the number of daily steps compared with the average number during the baseline period (**Table 1**, **Table 2**). We will thereby examine whether an increase of more than 1,302 steps in 4-6 weeks from the baseline level (mean value for sample size) can be expected, and the increase in the daily number of steps resulting from the financial incentive.

Secondary outcome

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

Statistical analyses

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

For comparison of secondary outcomes between the intervention group

and the waitlist control group at 4-6 weeks and 7-9 weeks, logistic regression models will be applied to examine whether the proportions of participants with an increase of 1000 steps or more are significantly different, and applied to assess the probabilities of incident falls and incident pain, respectively.

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

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

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

ETHICS AND DISSEMINATION

Ethical considerations

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

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

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

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

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

ethical review committee.

Dissemination of research findings

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

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

Patient and public involvement

To improve feasibility about the protocol of this trial in Nakayama area, we discussed with members of Nakayama Community Development Center (nonprofit organization corporation) and members of Nakayama Shopping Street Promotion Association. Additionally, members of Nakayama Neighborhood Association are involved to announce about the recruitment. After the end of the trial, as a collaborative program with Nakayama Community Development Center and Nakayama Shopping Street Promotion Association, we will hold the debrief session for study report to share results of the trail.

DISCUSSION

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

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

This study has several limitations. First, the intervention involves only one type of financial incentive. Thus, the effect of a change in the corresponding financial incentive or its application (e.g. donation) would be unclear. Second, only short-term effects during 9 weeks will be evaluated. Thus, the long-term effect (maintaining a higher number of daily walking steps) of the financial incentive would be unclear. Third, a volunteer bias may exist in the present study. Participants may be more highly motivated to achieve the financial incentive goals in comparison with the total population in the study area. Therefore, the external validity toward non-participants (involuntary participants) will be unclear.

Authors' contributions: Ichiro Tsuji supervised this study and is the guarantor. Yasutake Tomata, Fumiya Tanji and Ichiro Tsuji have made were involved in the design. Yasutake Tomata, Dieta Nurrika, Yingxu Liu and Shu Zhang prepared draft manuscript. Saho Abe, Kouichi Matsumoto, Shu Zhang, Yumika Kotaki, Sanae Matsuyama, Yukai Lu, Yumi Sugawara, Shino Bando, Teiichiro Yamazaki, Tatsui Otsuka, and Toshimasa Sone revised the manuscript. Yasutake Tomata carried out the statistical calculation. All authors approved submission of this manuscript.

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

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

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

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Figure 1: Flow chart of the study procedure.

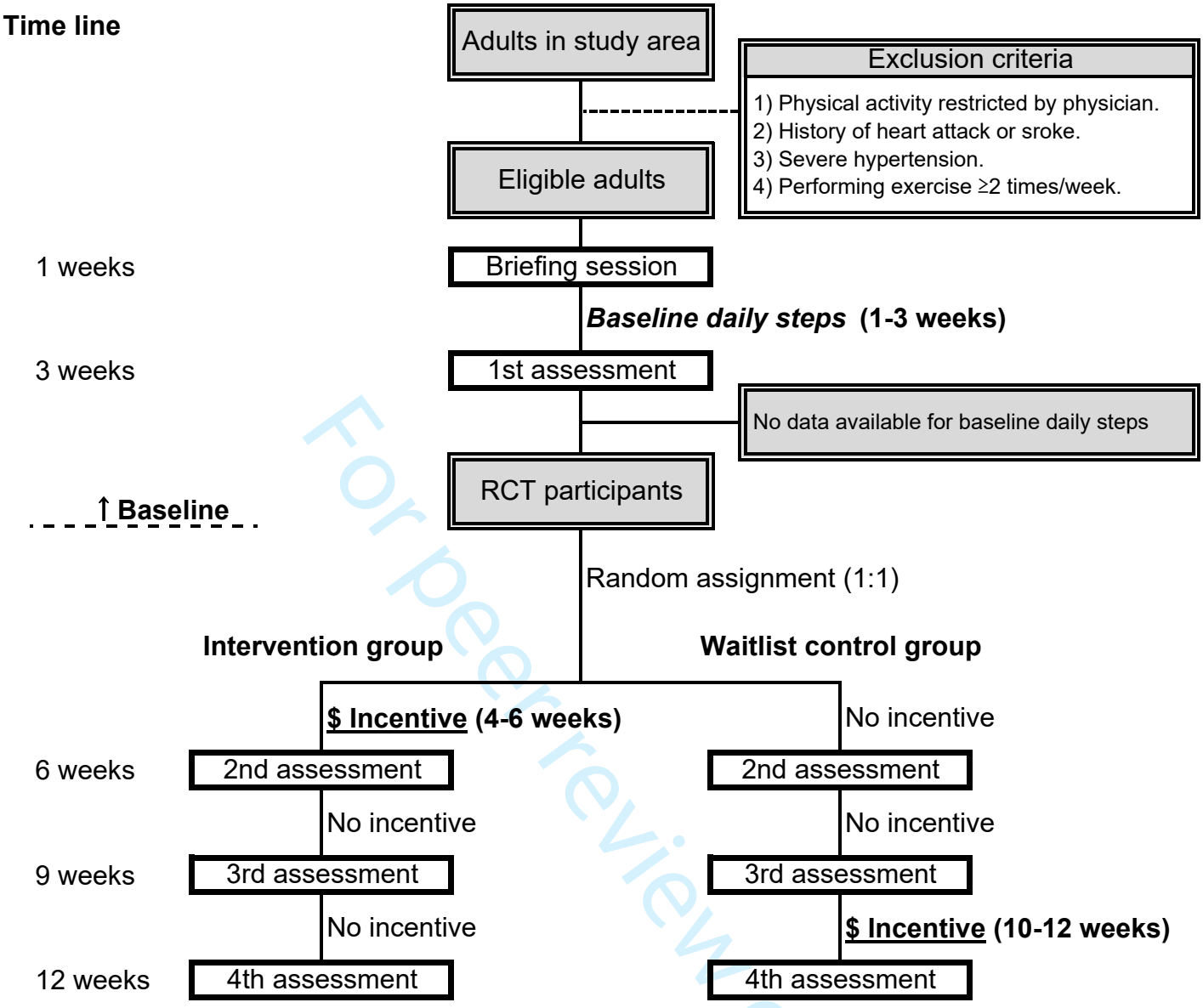
Table 1: Time line for the evaluation.

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.

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.



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