BMJ Open

Effects of a home-based Radio-Taiso exercise programme on health-related quality of life in older adults with frailty: protocol for an assessor-blind randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-063201
Article Type:	Protocol
Date Submitted by the Author:	24-Mar-2022
Complete List of Authors:	Osuka, Yosuke; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Kojima, Narumi; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Sugie, Masamitsu; Tokyo Metropolitan Geriatric Hospital and Institute of Gerontology, Department of Cardiology Omura, Takuya; Tokyo Metropolitan Institute of Gerontology, Department of Geriatric Medicine Motokawa, Keiko; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Ueda, Takuya; Tokyo Metropolitan Institute of Gerontology, The Tokyo Metropolitan Support Center for Preventative Long-term and Frail Elderly Care Maruo, Kazushi; University of Tsukuba, Department of Biostatistics, Faculty of Medicine Ono, Risa; Japan Radio-Taiso Federation Aoyama, Toshihiko; Japan Radio-Taiso Federation Inoue, Shigeru; Tokyo Medical University, Department of Preventive Medicine and Public Health Kim, Hunkyung; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Sasai, Hiroyuki; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health
Keywords:	GERIATRIC MEDICINE, MENTAL HEALTH, PUBLIC HEALTH, SPORTS MEDICINE

Effects of a home-based Radio-Taiso exercise programme on health-related quality of life in older adults with frailty: protocol for an assessor-blind randomized controlled trial

Yosuke Osuka[1], PhD; Narumi Kojima, MS[1]; Masamitsu Sugie[2], MD, PhD; Takuya Omura[3], MD, PhD; Keiko Motokawa[1], PhD; Takuya Ueda[4], PhD; Kazushi Maruo[5], PhD; Risa Ono[6], MS; Toshihiko Aoyama[6]; Shigeru Inoue[7], MD, PhD; Hunkyung Kim[1], PhD; and Hiroyuki Sasai[1], PhD

[1]Research Team for Promoting Independence and Mental Health, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan
[2]Department of Cardiology, Tokyo Metropolitan Geriatric Hospital and Institute of Gerontology, Tokyo, Japan
[3]Department of Geriatric Medicine, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan
[4]The Tokyo Metropolitan Support Center for Preventative Long-term and Frail Elderly Care, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan
[5]Department of Biostatistics, Faculty of Medicine, University of Tsukuba, Tsukuba, Japan
[6]Japan Radio-Taiso Federation, Tokyo, Japan
[7]Department of Preventive Medicine and Public Health, Tokyo Medical University, Tokyo, Japan

Corresponding author
Yosuke Osuka, PhD
Research Team for Promoting Independence and Mental Health,
Tokyo Metropolitan Institute of Gerontology
35-2 Sakae-cho, Itabashi-ku, Tokyo 173-0015, Japan.
Phone: +81-3-3964-3241; Email: osuka@tmig.or.jp

Word count
5295/4000 words

Abstract

Introduction

Few clinical trials have examined the effects of home-based exercise programmes on health-related quality of life (HR-QoL) in older adults with frailty. Radio-Taiso is the most famous exercise programme in Japan, and a home-based Radio-Taiso exercise programme can serve as an accessible, scalable, and sustainable care intervention for this population. The primary aims of this trial is to test whether older adults with frailty who attend our home-based Radio-Taiso exercise programme will receive greater benefits to HR-QoL than those who do not. Potential mechanisms explaining the effectiveness of the programme will be identified, as well as the effects of its use on daily lifestyle.

Methods and analysis

This is an assessor blind randomised controlled trial that will be conducted at the Tokyo Metropolitan Institute of Gerontology (TMIG) in Itabashi-ku, Tokyo, Japan. From April to May 2022, 226 older adults with pre-frailty or frailty by the revised Japanese version of the Cardiovascular Health Study criteria will be included from a large database of the TMIG. After the baseline assessment in June 2022, participants will be randomly assigned to the intervention (home-based Radio-Taiso exercise and nutrition programme) or control groups (nutrition programme) in a 1:1 ratio. After intervention completion, a follow-up assessment will be conducted in September 2022. The primary outcome is the change in the mental domain of HR-QoL. Secondary outcomes include physical and role/social domains and subscales of HR-QoL, frailty phenotype, physical fitness, posture, cognition, exercise self-efficacy, depressive symptoms, brain-derived neurotrophic factor, social network, habitual energy intake, physical activity, and sleep conditions.

Ethics and dissemination

The research protocol has been approved by the Research Ethics Committee of TMIG. This trial will be conducted in accordance with the principles of the Declaration of Helsinki. The findings will be presented at an international academic conference and published in peer-reviewed international journals.

Trial registration

Registry name: UMIN-CTR

URL: https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000053863

Protocol version

Date: 18 March 2022

Version identifer:4.2

Strengths and Limitations

- The feasibility of this Phase III trial has been enhanced based on the processes, resources, management, and scientific data of the pilot trial.
- The trial will include older adults with frailty defined by a validated assessment tool.
- Random allocation, the blinding of assessors and analysts, interpretation of results based on the intention-to-treat principle, and disclosure of protocol papers reduce the risk of selection, measurement, reduction, and reporting bias.
- The non-blinding of allocation information to participants and care providers increases the risk of performance bias.
- It is unclear to what extent the findings from this study can be generalised to non-Japanese populations.

INTRODUCTION

Frailty is defined as when homeostatic responses to stressors becomes vulnerable owing to a cumulative age-related decline of physiological systems.[1] A research showed that 7% and 47% of older adults had frailty and pre-frailty, respectively, and their risk of falls, disabilities, nursing home admission, and death was significantly higher than those of robust older adults.[2] Interventions to reduce frailty prevalence/severity can benefit older adults with care needs, the caregivers, and the public social insurance system. However, clinical trials involving older adults with frailty defined by validated assessment tools are required for confirming the effectiveness of such interventions.[1]

Interventions such as exercise and nutritional programmes are useful in reducing the prevalence of frailty, but stakeholders have shown concerns that research on such interventions has focused exclusively on improving physical outcomes.[3] Studies focused on patient-reported outcomes (e.g. health-related quality of life [HR-QoL]) may be able to address such gap between scientific evidence and clinical practice.[4] Exercise interventions are reportedly the most effective in improving HR-QoL among older adults with frailty.[5] To enhance this argument's reliability/validity, robust clinical trials should be conducted on the effects of such interventions.[5] However, evidence on the effects of home-based exercise interventions on HR-QoL remains uncertain.[6] As older adults with frailty have declined mobility, [7] readily available home-based exercise programmes may be feasible and rational interventions.

Radio-Taiso is the most famous Japanese exercise programme, with around 96.9% of the national population reportedly knowing about the program.[8] In 1928, the Postal Life Insurance Bureau of the Ministry of Communications (successor agency: Japan Post Insurance Co., Ltd.) developed Radio-Taiso as a "National Health Exercise" to improve the Japanese people's health.[9] Since then, Radio-Taiso has been customarily practiced in numerous Japanese homes/schools/workplaces/communities and is currently firmly established in the Japanese culture (Figure 1).[10] It is broadcasted daily by the Japan Broadcasting Corporation via public radio and television, making it easy for Japanese older adults with frailty to access it at home.

We recently conducted a pilot randomised controlled trial to examine the feasibility and potential effectiveness of a home-based Radio-Taiso exercise programme in community-dwelling older adults with pre-frailty and frailty. It showed high adherence and that the programme can lead to clinically important improvements in the mental domain of HR-QoL (submitted to a journal). However, the programme's effectiveness remains to be validated by robust clinical trials.

This trial primarily aims at testing whether older adults with pre-frailty and frailty

who receive the programme obtain greater benefits on the mental domain of HR-QoL than those who do not receive it. It also aims at identifying the potential mechanisms explaining the effectiveness of the programme, and the impacts on the participants' lifestyles (Figure 2).

METHODS AND ANALYSIS

Study design, setting, procedure, and ethics

This is a randomised, assessor-blind, parallel-design, two-arm, phase III trial. The protocol was designed in accordance with the SPIRIT statement (Supplementary Material 1) and with some aspects of the SPIRIT-PRO Extension.

All outcomes will be assessed at the Tokyo Metropolitan Institute of Gerontology (TMIG) in Itabashi-ku, Tokyo, Japan; participants will practice the programme at their homes. Six face-to-face group sessions will be conducted at the TMIG or a nearby community facilities (Figure 3). Recruitment will be conducted in April 2022, and informed consents will be obtained in the subsequent month (May 2022). The baseline and follow-up assessments will be conducted in June and September 2022, respectively. After baseline assessment, participants who meet eligibility criteria will be included in the trial and randomly assigned to the intervention (home-based Radio-Taiso exercise programme + nutrition programme) or control (nutrition programme) groups. The intervention will begin in June and end in September 2022.

The Research Ethics Committee of TMIG approved the protocol on 16 December 2021. The study protocol was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) on 20 March 2022 (trial registration no. UMIN000047229). All amendments to the study protocol will be disclosed to UMIN-CTR.

Participants

Inclusion criteria are: 1) aged 65 years or older; and 2) frailty or pre-frailty as defined by the revised Japanese version of the Cardiovascular Health Study (J-CHS) criteria (see below).

Exclusion criteria are: 1) inability to participate in both baseline and follow-up assessments; 2) diagnosed with dementia or prescribed anti-dementia drugs; 3) impaired in basic activities of daily living; 4) not allowed to exercise (except for light-intensity exercise) by the family physician; 5) unstable/severe medical conditions that prevent trial physicians from allowing study participation; 6) history of angina pectoris, myocardial infarction, or cardiac surgery for the past 3 months, having a terminal illness, or receiving palliative care; 7) practising the exercises in Radio-Taiso ≥1 day/week for the past month;

8) participating in a specific rehabilitation programme; 9) unable to walk ≥10 m independently; 10) participating or will participate in other clinical trials; 11) not having a television at home; 12) difficulty in communicating in Japanese; 13) judged by the principal investigator/trial physicians to be ineligible; and 14) cannot give their consent to participate.

Potential participants will be recruited from a large database of trial-ready cohorts managed by the TMIG. In our pilot trial in 2020, 902 individuals were newly enrolled or had their information updated. Of these, 186 (20.6%) met all eligibility criteria and were willing to participate. Thus, at least 1,097 new registrations or updates are required to ensure that the current randomized controlled trial reaches the target number of 226 participants (rationale below).

Invitation letters will be sent to individuals diagnosed with frailty or pre-frailty between October 2021 and March 2022. The eligibility criteria checklist will be enclosed with the invitation letter. Participants who meet all eligibility criteria and wish to participate will be given a detailed verbal explanation of the study (i.e. aims, procedures, confidentiality, possible benefits/disadvantages, anticipated risks, and how the risks will be addressed). Only those who provide written informed consent will partake in the study. If there are more people willing to participate than the target sample size, participants will be randomly selected using a computer-generated random sequence. During baseline assessment, trial physicians will check compliance with exclusion criteria 2, 5, and 6.

Allocation and blinding

After baseline assessment, participants will be randomly allocated to the intervention and control groups in a 1:1 ratio. The sequence for generating the allocation code will be stratified by sex (male, female), age (<75 or ≥75 years), and frailty severity (pre-frail or frailty), and blocking will be applied.

The principal investigator (YO) at the TMIG will send eligible participants' identification codes to an allocator (KM) who has no contact with any participant. KM will combine the codes with a prescribed randomisation code, which will be generated prior to baseline assessment. An independent research staff member will inform participants of their group based on the allocation code sent by KM. Group labels will not be disclosed to the assessor and statistical analyst until the primary analysis is complete.

Intervention

During the 12-week intervention period, participants will be asked not to start new exercise or nutrition programmes. To address the ethical disadvantages of the control group, a nutrition programme will be provided to both groups.

Home-based Radio-Taiso exercise programme

Radio-Taiso includes three exercise patterns: Radio-Taiso No. 1 and 2 and Minna no Taiso. These patterns comprise 8–13 rhythmic whole-body movements with music. Each pattern starts with a low-intensity movement, gradually increases intensity, and ends with another low-intensity movement, allowing anyone to practise it safely. The smooth execution of movements requires fitness in various physical domains (strength, flexibility, endurance, and balance), making Radio-Taiso a multi-component exercise programme (details in Supplementary Material 2).

The home-based programme comprises six 60-min face-to-face group sessions with a certified instructor from the Japan Radio-Taiso Federation and daily practise in participants' homes. Before the programme, the intervention group will receive a face-to-face group session on how to correctly perform the three exercise patterns. In the first four weeks of the intervention, they will receive a face-to-face group session on how to effectively perform these exercise programmes. In week 8, a face-to-face group session will be provided to review the key points of each exercise programme.

Participants will be asked to complete a three-pattern exercise programme once daily at home by themselves via a broadcast by the Japan Broadcasting Corporation or a DVD. If the participants feel unwell while doing any exercise or feel that the exercise intensity is too high, they will be instructed to stop or reduce the number of sessions. Participants will be asked to record the following information in an exercise diary: 1) whether they perform the exercise programme; and 2) whether they comply with the key points for the effective implementation of the programme. On the day of the face-to-face group session, the research staff will check the exercise diary, adverse events, and participation in the new rehabilitation programme. In weeks when this session is not provided, these details will be checked by telephone every fortnight.

The pilot trial confirmed good adherence to the home-based Radio-Taiso exercise programme (retention rate: 100%; median [interquartile range] of practice rate: 97.6 [88.1–98.8] %). However, no trend towards improvement in physical outcomes was observed. To provide participants with a programme that yields better physical outcomes, the number of face-to-face sessions will increase from three to six and will include processes that help familiarise participants with the key points of the programme. An item will be also added to the exercise diary to check compliance with these points.

Nutrition programme

The nutrition programme comprises: 1) distribution of a nutrition leaflet; 2) recording of a dietary variety score; and 3) telephone nutrition counselling. One week before intervention onset, participants will receive a face-to-face briefing from a dietitian

on how the programme will work. A nutrition leaflet will be distributed once per week during the first four weeks of the intervention, detailing the nutritional role and recommended intake amounts of protein, calcium, vitamins/minerals, and carbohydrates/fats, as well as specific recipes for the efficient intake of these nutrients. Participants will be asked to record daily in a nutrition diary whether they have consumed 10 food groups (meat, seafood, eggs, soya and soya products, milk, green and yellow vegetables, seaweed, potatoes, fruit, and oil) using a dietary variety score; specifically, they will be requested to provide a score on the intake of these food groups on a 10-point scale.[11] A high dietary variety score has been reported to be associated with lower frailty severity.[12] Participants will be allowed to call the dietitian one day per week to discuss how to proceed with this nutrition programme or if they have any questions.

Outcome measures

The primary outcome is change in the mental component summary (MCS) score of HR-QoL. Secondary outcomes are the physical component summary (PCS) score, role/social component summary (RCS) score, and eight subscales of HR-QoL, as well as frailty phenotype, physical fitness, posture, cognition, exercise self-efficacy, depressive symptoms, brain-derived neurotrophic factor (BDNF), social network, habitual energy intake, physical activity, and sleep conditions.

Baseline information

Baseline information includes age, sex, disease history (hypertension, heart disease, diabetes, hyperlipidemia, osteoporosis, and respiratory disease), and low-back and knee pain. This information will be obtained by face-to-face interview.

Assessments

Some objective outcomes will be assessed by research staff that will be blinded to allocation information.

HR-QoL

The HR-QoL will be assessed using the Japanese version of the SF-36, which is widely used, reliable, and validated worldwide.[13 14] It measures eight health concepts: physical function, physical role, body pain, general health, vitality, social function, emotional role, and mental health. These concepts are aggregated and scored into the MCS, PCS, and RCS (Figure 2).[15] These scores are then standardised as T-scores using the 2017 Japanese national norm.[16] A change of three or more points in the MCS or two or more points in the PCS is a minimal clinically important difference, allowing for

the clinical interpretation of the change in scores.[17]

Frailty phenotype

Frailty phenotype will be assessed using Fried's frailty criteria, characterised by five limitations: slowness, weakness, exhaustion, low activity, and weight loss. The trial will use the revised J-CHS criteria to define frailty (three or more limitations) and pre-frailty (one or two limitations).[18]

Slowness

Slowness is assessed based on usual gait speed. An 11 m walking path is used with a 3 m acceleration/deceleration path at each end. The assessor measures the time taken between the 3 and 8 m markers.[19] The measurement will be performed once, and slowness is defined as a gait speed of less than 1.0 m/sec.

Weakness

Weakness is assessed by grip strength using a handheld Smedley-type dynamometer; participants are instructed to grip the device as strong as possible with their dominant hand in a standing position.[19] The measurement will be performed once, and weakness is defined as less than 28 kg for men and less than 18 kg for women.

Exhaustion

Exhaustion is assessed using question 25 of the Kihon checklist developed by the Ministry of Health, Labour and Welfare:[20] "In the last 2 weeks, have you felt tired for no reason?" Exhaustion is defined by a "yes" response.

Low activity

Low activity is assessed using two simple questions about participation in exercise or physical activity: 1) "How often do you engage in light intensity exercise or calisthenics?" And 2) "How often do you engage in exercise or sports activities"? Low activity is defined by a "less than once a week" response to both questions.

Weight loss

Weight loss is assessed using question 11 of the Kihon checklist developed by the Ministry of Health, Labour and Welfare:[20] "Have you lost 2 kg or more in the past six months?" Having weight loss is defined by a "yes" response.

Physical fitness

Six physical fitness domains (agility/dynamic balance, lower body strength, upper body strength, lower body flexibility, upper body flexibility, and aerobic endurance) will be assessed using Senior Fitness Tests.[21]

Agility and dynamic balance

Agility and dynamic balance are assessed using the 8-foot up-and-go test.

Participants will be instructed to stand up at the start signal, walk around a cone 8 ft away, turn around, and sit down again; this sequence should be performed as quickly as possible. After one practise session, two trials are performed, and the values for the minimum time required will be used in the analysis.

Lower body strength

Lower body strength is assessed using the chair stand test. At test onset, participants are instructed to stand up and sit down again while having their arms crossed in front of the chest. After 2–3 practice sequences of this exercise, a single trial will be performed, in which this sequence is repeated as quickly as possible for 30 s. The values of the number of sequences achieved will be used in the analysis.

Upper body strength

Upper body strength is assessed using the arm curl test. Participants will be requested to flex and extend the elbow of the dominant arm while holding a dumbbell (3 kg for men and 2 kg for women) at the start signal, with both upper arms in a natural down position. After 2–3 practice sequences, a single trial will be performed, in which the sequence will be repeated as quickly as possible for 30 s.

Lower body flexibility

Lower body flexibility is assessed using the chair sit-and-reach test. Participants are requested to sit shallowly in a chair and extend their dominant leg. Then, they are instructed to place the fingertips of both hands together, slowly flex the upper body towards the toes of the dominant leg until reaching their limit, and remaining still for 2 seconds. The assessor measures the distance between the participant's toes of the dominant leg and the fingertips of both hands using a ruler. A plastic block is placed on the sole of the foot to hold the ankle joint at 90°. After two practice sessions, the measurements will be performed twice, and the best values will be used in analysis.

Upper body flexibility

Upper body flexibility is assessed using the back scratch test. In an upright position, the participant is instructed to rotate the dominant hand backwards obliquely upward and the non-dominant hand backwards obliquely downward to the posterior region. The assessor measures the shortest distance between the middle fingers of both hands using measuring tape. The measurement will be performed twice and the best values will be used in analysis.

Aerobic endurance

Aerobic endurance is assessed using a 2-minute step-in-place test. The assessor marks a wall with masking tape midway between the participant's patella and iliac crest. The participant stands up right next to the wall and is asked to march in place for 2 min.

Participants who have difficulty marching for the two minutes are allowed to take a break and hold the wall or a stable chair. The assessor records the number of times the right knee reaches the marker within 2 minutes. The trial will be conducted once.

Anthropometric indices

Body height, weight, and body mass index

Height will be measured using a digital height meter (DSN-70; MURATEC-KDS Corporation). Body weight is measured using a body composition analyser (InBody770, InBody Co. Ltd., Seoul, Korea). Body mass index is calculated by dividing the weight (kg) by the square of the height (m).

Posture

Posture will be assessed by the degree of kyphosis and the range of motion of the spine. The degree of kyphosis is assessed by the kyphosis angle (KA),[22] thoracic KA, and lumbar lordosis angle.[23 24]

The KA is measured using a small gyro-embedded device (Horizon; Yuki Trading Corporation, Japan). The participant is first instructed to stand in a normal posture, and then the evaluator checks the seventh cervical vertebra (C7), posterior superior iliac spine (PSIS), and kyphosis vertex using palpation and visual examination. The arm of the device is aligned with the C7 and kyphosis vertices and the angle is measured. Subsequently, the arm of the device is aligned with the kyphosis vertex and the midpoint of the PSIS, and the angle is measured. The trial is conducted once. KA is calculated from the following formula: KA (°) = 180° (straight line angle between C7 and kyphosis vertex + straight line angle between the kyphosis vertex and the midpoint of the PSIS). The smaller the angle, the severer the kyphosis.[22]

Thoracic KA and lumbar lordosis angles are measured using the Idiag M360 (Idiag AG, Switzerland). The participant is first instructed to stand in a normal position, and then the assessor moves the Idiag M360 along the spinous processes from the vertebra prominens (C7) to the third cervical vertebra (C3). The trial is conducted once, and the smaller the angle of the thoracic KA, the severer the kyphosis, whereas the larger the lumbar lordosis angle, the severer the kyphosis.[23 24]

The range of motion of the spine is measured using the Idiag M360 (Idiag AG, Switzerland).[23 24] The assessor moves the Idiag M360 over the spinous processes from C7 to C3 in the maximum forward flexion and extension positions. Range of motion is assessed as the difference between the thoracic KA and lumbar lordosis angle at maximum forward flexion and maximum extension, based on the angles measured for the thoracic KA and lumbar lordosis angle.

Cognition

Attention and executive function will be assessed using Parts A and B of the trail making test (TMT).[25] In Part A, participants must connect the numbers in ascending order, and the time taken for finalizing the task is measured (i.e. 1-2-3-4...). In Part B, the task is to connect the numbers and kana characters in an alternating order (i.e. 1-A-2-I...), and the time taken for finalizing the task is measured.

Home-based exercise self-efficacy

The participants' home-based exercise self-efficacy will be assessed using the Home-Exercise Barrier Self-Efficacy Scale.[26] Participants are asked to respond to six exercise situations at home (1: when I am tired, 2: when I am in pain, 3: when I do not feel very good, 4: when I do not have time, 5: when I do not have the equipment or environment to exercise, 6: when I am alone) on a 5-point Likert scale ranging from 1 (*not at all confident*) to 5 (*absolutely confident*). Details on items and scoring are described in prior research.[26] Total scores range from 5–30, with higher scores indicating greater self-efficacy in home-based exercise.

Depressive symptoms

Depressive symptoms will be assessed using the short version of the Geriatric Depression Scale.[27] Participants are asked to answer to 15 yes-or-no questions about their daily mood. Details on items and scoring are described in prior research.[27] Total scores range from 0–15, with higher scores indicating a more depressed mood.

BDNF

BDNF is the most widely expressed neurotrophic in the mammalian brain and an important regulator of the development and function of neural circuits in the brain.[28] Exercise-induced BDNF mediates neuronal differentiation and growth, synapse formation and plasticity, and may explain how exercise training improves mental health and cognitive function.[29]

Participants will fast for at least two hours and a blood sample will be collected from the anterior elbow vein. To exclude the potential effects of acute exercise, participants will be asked to refrain from engaging in vigorous intensity exercise for 36 hours before the blood sample is collected. To control for diurnal variation, participants will have their blood drawn at the same time of day in both the baseline and follow-up assessments. Blood samples will be processed according to the manufacturer's specifications: plasma

is obtained by centrifugation at 2,000 g for 15 min at 24°C, aliquoted, and stored at -80°C until measurement. Plasma samples will be assessed for BDNF concentrations using a commercially available two-site sandwich enzyme-linked immunosorbent assay kit (R&D Systems, Minneapolis, MN, USA). The analysis is conducted centrally in an independent laboratory.

Social network

Social network will be assessed using the Japanese version of the Lubben Social Network Scale-6 (LSNS-6).[30] Participants answer to six questions on support the number of family members and friends who can provide them with five options of emotional and instrumental support. Details on items/scoring are described in prior research.[30] Total scores range from 0–30, with higher scores indicating a larger social network.

Habitual energy intake

Habitual energy intake will be assessed using a reliable and valid brief self-administered diet history questionnaire developed to provide a simple estimate of energy intake over the past month.[31 32] Participants are asked to recall their average dietary habits over the past month and indicate the frequency of consumption of each food item. Habitual energy intake will be calculated using a special software provided by Gender Medical Research Co. Japan.

Habitual physical activity

Habitual physical activity levels will be assessed based on the average number of steps taken per day. The number of steps will be measured using validated tri-axis accelerometers and algorithms (Active style Pro HJA-750C; Omron Healthcare, Tokyo, Japan).[33 34] The participants are instructed to wear the device around the waist for 7 days during all activities of daily living from waking to bedtime, except for underwater activities (e.g. bathing and swimming). A record is valid if the device is worn for at least 10 h/day.[35] If valid records are collected for more than three days, the number of steps per day is calculated.

Habitual sleep conditions

Sleep condition will be subjectively assessed using the Japanese version of the Pittsburgh Sleep Quality Index,[36 37] comprising 7 components: sleep quality, time to fall asleep, time to stay asleep, sleep efficiency, difficulty sleeping, use of sleeping pills,

and difficulty waking up during the day in the past month. Details on items and scoring are described in prior research.[36 37] Total scores range from 0–21, with higher scores indicating a worse subjective sleep condition.

Sleep condition will also be objectively assessed using validated tri-axis accelerometers and algorithms (ActiGraph GT3X + ActiGraph, FL, USA). Participants will be asked to wear the device on the wrist of their non-dominant arm for 7 days. Sleep parameters will include sleep duration (time spent in bed during which the person is judged to be asleep), sleep efficiency (percentage of time spent in bed that is actually spent asleep), sleep latency (time between getting into bed and during which the person is judged to be asleep), awake after sleep onset (time spent awake after being judged to be asleep), and the number of awakenings (the number of awakenings after being judged to be asleep). These parameters are calculated using the algorithm (Cole-Kripke method) installed in the dedicated analysis software (ActiLife ver. 6.13.4).[38]

Adverse events

Adverse events are defined in this study as any undesirable/unintended sign, symptom, or disease occurring during the intervention, regardless of causality. The number of adverse events that occur during the intervention period will be assessed. Trial physicians will determine adverse event severity and potential relevance to the intervention. Any adverse events (e.g. subjective symptoms, falls, and other surgical or medical findings) suspected to relate to the intervention will be recorded. Research staff will ask participants if they have experienced an adverse event by telephone or in person every fortnight.

Adherence

Adherence will be assessed by the retention rate during the intervention period and the rate of practice of the Radio-Taiso exercise programme. Retention rate is calculated as the percentage of participants who complete the follow-up assessment. The rate of practice of the programme is calculated by dividing the number of practice days (days when the exercises are practiced at least once a day) by 84 days. The total number of practice sessions of the programme will also be assessed.

Sample size

Based on the pilot trial, the effect size (Cohen's d) of the programme on MCS score was 0.395. Using G*Power version 3.1.9.2 for Windows (Heinrich-Heine-Universität Düsseldorf),[39] with the alpha error set at 5%, a power of 80%, and this

effect size, the sample required was 204. Considering a 10% drop-out rate, the target sample is 226.

Data management

Data quality control comprises 1) measurements based on established standard operating procedures, 2) manual checks (visual checks) of questionnaires and case reports, and 3) data entry using the double-entry method. Manual checks include confirmation of compliance with eligibility criteria, missing measurements, and value ranges. After all the data are entered, the person responsible for the analysis will perform logical check (programming check) and data coding to ensure and fix any issues pertaining to data quality. These checks include examining for outliers.

Statistical analysis

As "tests of baseline homogeneity" in randomized controlled trials do not have any practical value,[40] comparison of baseline characteristics will not be performed in this study. At baseline, continuous variables are presented as mean (standard deviation) or median (interquartile range) and categorical variables as n (%).

Main analysis

To test programme effectiveness, changes in the primary outcome will be compared between both groups using an ANCOVA model adjusted for allocation stratification factors and baseline values. Changes in secondary outcomes will be compared using the same model. Differences between groups in change for each outcome will be expressed as differences in adjusted means (95% confidence intervals). Statistical significance will be set at a $P < 0.05$.

The results of the main analyses will be interpreted based on the intention-to-treat principle. All enrolled participants will be analysed, irrespective of whether they comply with the study protocol. It is permissible as a conservative analysis strategy to exclude participants: 1) who are subsequently found not to meet the eligibility criteria; 2) never participated in the intervention programme; or 3) for whom no post-randomisation data are available.[41] The full analysis set will exclude these participants and be applied as the primary analysis population.

Additional analysis

Additional analyses using a per-protocol set will be conducted to assess the extent to which adherence affects the results. The per-protocol set will include participants who have practiced at least 75% of the home-based Radio-Taiso exercises stipulated.[42]

A sensitivity analysis will be performed to assess heterogeneity owing to missing

follow-up data (missing bias). Missing data will be processed through multiple imputation by applying the chained equation method to generate 20 imputed datasets based on the outcome, allocation, and group variables at baseline.

To assess study generalizability, subgroup analyses will be conducted based on participants' background data (male vs. female, <75 vs. ≥75 years, and frailty vs. pre-frailty).

Retention rates and the incidence of adverse events (one or more for those who report them) will be compared between groups using Fisher's exact test or the χ-square test. All analyses will be carried out using R, version 4.1.2 or higher (The R Foundation for Statistical Computing Platform).

Patient and public involvement

This study will be conducted without participant involvement. Participants will not be invited to comment on study design, define relevant outcomes or interpret the results, nor contribute to the writing or editing of this paper for readability or accuracy.

ETHICS AND DISSEMINATION

The research protocol has been approved by the Research Ethics Committee of the TMIG and will be conducted in accordance with the Declaration of Helsinki. Study results will be presented at an international scientific conference and reported in a peer-reviewed international journal. After publication, a summary of the results will be published on the TMIG and Japan Post Insurance Co., Ltd., websites.

DISCUSSION

Few trials have examined the effect of exercise interventions on HR-QoL in older adults with frailty diagnosed by validated assessment tools.[3 5 6] Thus, this robustly designed trial will strengthen the evidence needed to support the effectiveness of home-based exercise programmes on HR-QoL. International health policy bodies, regulators and patients are increasingly recognizing the importance of patient-reported outcomes, including HR-QoL, for health.[43] The results of this study will provide valuable insights that may serve to address the evidence and clinical practice gaps associated with care programmes for older adults with frailty. This study will also contribute to a better understanding of the potential mechanisms by which home-based exercise programmes can improve HR-QoL by analysing various secondary outcomes.

Researchers systematically compared HR-QoL between frailty and non-frailty groups, showing a moderate or greater standardised mean difference between the groups

and that the frailty group had a worse HR-QoL.[44] The measures to curb the COVID-19 pandemic also limit the life-space mobility of older adults with frailty and have a significant impact on QoL.[45] Patient-reported outcomes from clinical trials using scientifically robust methodologies are reflected in clinical decision-making and influence health and social care policy.[43] Thus, if this study helps to clarify the effectiveness of the proposed programme on HR-QoL, this may enable for invested stakeholders to develop a policy framework for care programmes from the perspective of older adults with frailty.

For a care programme targeting people with frailty to be implemented in public health policy, it must have good accessibility (i.e. low cost and high acceptability/availability) and be delivered equitably and continuously.[4] A care programme that draws on existing cultural and social resources may be able to meet these requirements. In Japan, the Radio-Taiso exercise programme has a long history of being customarily watched in different settings and is familiar to many older adults, thus being a cultural exercise programme in the country.[10] In fact, our pilot trial confirmed that adherence to the programme is very good and that it is highly compatible with daily life. Radio-Taiso is also available with low-cost to everyone via television/radio on a daily basis. To date, more than 24,600 certified Radio-Taiso instructors have been trained, and there are more than 2,000 regional bases where the programme is practised nationwide.[46] Rich in cultural and social resources, the Radio-Taiso exercise programme may serve as a socially implementable public health strategy.

This study has several limitations. First, although the study addresses measurement, attrition, and reporting bias, participants and treatment providers will not be blinded to allocation information; this increases the risk of performance bias and reduce effect estimation accuracy. Second, calisthenic programmes like Radio-Taiso are popular in some countries, such as China, Korea, and Scandinavia, but it remains unclear to what extent the usefulness of the Radio-Taiso exercise programmes is generalisable to non-Japanese older adults with frailty.

Acknowledgments

We are grateful to the participants and the staff members of the TMIG.

Author contributions

Yosuke Osuka: study concept and design, data collection and interpretation, manuscript preparation. Narumi Kojima: study concept and design, data collection and interpretation, manuscript preparation. Masamitsu Sugie: study concept and design,

safety assessment, manuscript preparation. Takuya Omura: study concept and design, safety assessment, manuscript preparation. Keiko Motokawa: study concept and design, data collection and interpretation, manuscript preparation. Takuya Ueda: study concept and design, data collection and interpretation, manuscript preparation. Kazushi Maruo: study concept and design, statistical advice, randomazation, data interpretation, manuscript preparation. Risa Ono: study concept and design, intervention, data interpretation, manuscript preparation. Toshihiko Aoyama: study concept and design, data interpretation, manuscript preparation. Shigeru Inoue: study concept and design, data interpretation, manuscript preparation. Hunkyung Kim: study concept and design, data interpretation, manuscript preparation. Hiroyuki Sasai: study concept and design, analysis, data interpretation, manuscript preparation.

Funding

This study will be conducted under a collaborative agreement between four institutions (TMIG, Tokyo Medical University, Japan Post Insurance Co., Ltd., and the Japan Radio-Taiso Federation). Japan Post Insurance Co., Ltd. will financially support the study and will provide the Radio-Taiso DVD free of charge, but will not be involved in the design of the study, selection of methods, recruitment of participants, data collection, analysis and interpretation, or writing of the manuscript.

The Japan Radio-Taiso Federation will provide certified Radio-Taiso instructors free of charge and will be involved in the design of the study, intervention, data interpretation, and writing of the manuscript.

Competing interests

Yosuke Osuka is the principal investigator of a joint research agreement between the four organisations; Risa Ono and Toshihiko Aoyama are accredited instructors for the Japan Radio-Taiso Federation. The Japan Post Insurance Co., Ltd. and the Japan Radio-Taiso Federation are committed to the promotion and dissemination of Radio-Taiso. The other authors have no conflicts of interest to declare.

Patient consent

Not applicable

Ethics approval

Approved by Research Ethics Committee of TMIG on 16 December 2021.

Data availability statement

Data are available upon reasonable request.

REFERENCES

1. Clegg A, Young J, Iliffe S, et al. Frailty in elderly people. *Lancet* 2013;381(9868):752-62.
2. Fried LP, Tangen CM, Walston J, et al. Frailty in older adults: evidence for a phenotype. *J Gerontol A Biol Sci Med Sci* 2001;56(3):M146-56.
3. Puts MTE, Toubasi S, Andrew MK, et al. Interventions to prevent or reduce the level of frailty in community-dwelling older adults: a scoping review of the literature and international policies. *Age Ageing* 2017;46(3):383-92.
4. Dent E, Martin FC, Bergman H, et al. Management of frailty: opportunities, challenges, and future directions. *Lancet* 2019;394(10206):1376-86.
5. Negm AM, Kennedy CC, Thabane L, et al. Management of frailty: a systematic review and network meta-analysis of randomized controlled trials. *J Am Med Dir Assoc* 2019;20(10):1190-98.
6. Clegg AP, Barber SE, Young JB, et al. Do home-based exercise interventions improve outcomes for frail older people? Findings from a systematic review. *Rev Clin Gerontol* 2012;22(1):68-78.
7. Navarrete-Villanueva D, Gómez-Cabello A, Marín-Puyalto J, et al. Frailty and physical fitness in elderly people: a systematic review and meta-analysis. *Sports Med* 2021;51(1):143-60.
8. Japan Post Insurance Co., Ltd. Recognition and participation rates for "Radio-Taiso". 2021 [Available from: https://www.jp-life.japanpost.jp/information/assets/pdf/211011pr-6-2.pdf accessed March 10 2022.
9. Public Relations Office, Government of Japan. Higlighting Japan 2019 [14-15]. Available from: https://dwl.gov-online.go.jp/video/cao/dl/public_html/gov/book/hlj/20191001/html5.html#page=15137.
10. British Broadcasting Corporation. The lifelong exercise that keeps Japan moving. 2020 [Available from: https://www.bbc.com/worklife/article/20200609-the-life-long-exercise-that-keeps-japan-moving accessed March 10 2022.
11. Kumagai S, Watanabe S, Shibata H, et al. [Effects of dietary variety on declines in high-level functional capacity in elderly people living in a community]. *Nihon Koshu Eisei Zasshi* 2003;50(12):1117-24.
12. Motokawa K, Watanabe Y, Edahiro A, et al. Frailty Severity and Dietary Variety in Japanese Older Persons: A Cross-Sectional Study. *J Nutr Health Aging* 2018;22(3):451-56.

13. Fukuhara S, Bito S, Green J, et al. Translation, adaptation, and validation of the SF-36 Health Survey for use in Japan. *J Clin Epidemiol* 1998;51(11):1037-44.
14. Fukuhara S, Ware JE, Jr., Kosinski M, et al. Psychometric and clinical tests of validity of the Japanese SF-36 Health Survey. *J Clin Epidemiol* 1998;51(11):1045-53.
15. Suzukamo Y, Fukuhara S, Green J, et al. Validation testing of a three-component model of Short Form-36 scores. *J Clin Epidemiol* 2011;64(3):301-8.
16. Fukuhara S, Suzukamo Y. Manual of SF-36v2 Japanese version. Kyoto: iHope International Inc 2004, 2019.
17. Maruish ME. User's Manual for the SF-36v2 Health Survey: Quality Metric Incorporated 2011.
18. Satake S, Arai H. The revised Japanese version of the Cardiovascular Health Study criteria (revised J-CHS criteria). *Geriatr Gerontol Int* 2020;20(10):992-93.
19. Shinkai S, Watanabe S, Kumagai S, et al. Walking speed as a good predictor for the onset of functional dependence in a Japanese rural community population. *Age Ageing* 2000;29(5):441-6.
20. Sewo Sampaio PY, Sampaio RA, Yamada M, et al. Systematic review of the Kihon Checklist: Is it a reliable assessment of frailty? *Geriatr Gerontol Int* 2016;16(8):893-902.
21. Rikli RE, Jones CJ. Development and validation of a functional fitness test for community-residing older adults. *J Aging Phys Act* 1999;7(2):129-61.
22. Ueda T, Shiba Y, Watanabe S, et al. A New Device for Measuring Spinal Kyphosis: Validity and Reproducibility of Measurements Obtained Using a Small Gyro-embedded Device. *Journal of the Japanese Physical Therapy Association* 2015;18(1):41-41.
23. Mannion AF, Knecht K, Balaban G, et al. A new skin-surface device for measuring the curvature and global and segmental ranges of motion of the spine: reliability of measurements and comparison with data reviewed from the literature. *Eur Spine J* 2004;13(2):122-36.
24. Post RB, Leferink VJ. Spinal mobility: sagittal range of motion measured with the SpinalMouse, a new non-invasive device. *Arch Orthop Trauma Surg* 2004;124(3):187-92.
25. Army Individual Test Battery. Washington, DC: War Department: Adjutant General's Office 1944.
26. Arita N, Takenaka K, Shimazaki T. Development of a home-exercise barrier self-efficacy scale for elderly people requiring support and care. *Physical Therapy Japan* 2014;41(6):338-46.

27. Yatomi N. The factor structure and item characteristic of the GDS (Geratric Depression Scale) short version in a Japanese elderly sample. *Japanese Journal of Gerontology* 1994;16(1):29-36.
28. Park H, Poo MM. Neurotrophin regulation of neural circuit development and function. *Nat Rev Neurosci* 2013;14(1):7-23.
29. Knaepen K, Goekint M, Heyman EM, et al. Neuroplasticity - exercise-induced response of peripheral brain-derived neurotrophic factor: a systematic review of experimental studies in human subjects. *Sports Med* 2010;40(9):765-801.
30. Kurimoto A, Awata S, Ohkubo T, et al. [Reliability and validity of the Japanese version of the abbreviated Lubben Social Network Scale]. *Nihon Ronen Igakkai Zasshi* 2011;48(2):149-57.
31. Kobayashi S, Murakami K, Sasaki S, et al. Comparison of relative validity of food group intakes estimated by comprehensive and brief-type self-administered diet history questionnaires against 16 d dietary records in Japanese adults. *Public Health Nutr* 2011;14(7):1200-11.
32. Kobayashi S, Honda S, Murakami K, et al. Both comprehensive and brief self-administered diet history questionnaires satisfactorily rank nutrient intakes in Japanese adults. *J Epidemiol* 2012;22(2):151-9.
33. Oshima Y, Kawaguchi K, Tanaka S, et al. Classifying household and locomotive activities using a triaxial accelerometer. *Gait Posture* 2010;31(3):370-4.
34. Ohkawara K, Oshima Y, Hikihara Y, et al. Real-time estimation of daily physical activity intensity by a triaxial accelerometer and a gravity-removal classification algorithm. *Br J Nutr* 2011;105(11):1681-91.
35. Troiano RP, Berrigan D, Dodd KW, et al. Physical activity in the United States measured by accelerometer. *Med Sci Sports Exerc* 2008;40(1):181-8.
36. Doi Y, Minowa M, Uchiyama M, et al. Psychometric assessment of subjective sleep quality using the Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J) in psychiatric disordered and control subjects. *Psychiatry Res* 2000;97(2-3):165-72.
37. Doi Y, Minowa M, Okawa M, et al. Development of the Japanese version of the Pittsburgh Sleep Quality Index. *Japanese Journal of Psychiatry Treatment* 1998;13(6):755-63 (in Japanese).
38. Cole RJ, Kripke DF, Gruen W, et al. Automatic sleep/wake identification from wrist activity. *Sleep* 1992;15(5):461-9.
39. Faul F, Erdfelder E, Lang AG, et al. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods*

2007;39(2):175-91.
40. Senn S. Testing for baseline balance in clinical trials. *Stat Med* 1994;13(17):1715-26.
41. The International Council for Harmonisation. E9 Statistical Principles for Clinical Trials: The International Council for Harmonisation; 1998 [Available from: https://database.ich.org/sites/default/files/E9_Guideline.pdf accessed October 16 2021.
42. Hawley-Hague H, Horne M, Skelton DA, et al. Review of how we should define (and measure) adherence in studies examining older adults' participation in exercise classes. *BMJ Open* 2016;6(6):e011560.
43. Calvert M, Kyte D, Mercieca-Bebber R, et al. Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols: The SPIRIT-PRO Extension. *JAMA* 2018;319(5):483-94.
44. Crocker TF, Brown L, Clegg A, et al. Quality of life is substantially worse for community-dwelling older people living with frailty: systematic review and meta-analysis. *Qual Life Res* 2019;28(8):2041-56.
45. Saraiva MD, Apolinario D, Avelino-Silva TJ, et al. The Impact of Frailty on the Relationship between Life-Space Mobility and Quality of Life in Older Adults during the COVID-19 Pandemic. *J Nutr Health Aging* 2021;25(4):440-47.
46. The Japan Radio-Taiso Federation. Information of certified instructors and regional bases. 2022 [Available from: https://www.radio-exercises.org/ accessed March 10 2022.

FIGURE LEGENDS

Figure 1. Pictures of the Radio-Taiso as a firmly established, traditional Japanese exercise programme.

A: Community-dwelling children get together to practice Radio-Taiso. B: Physical education classes. C: Practice in the workplace. D: Gathering and practising during community events. All pictures are provided by courtesy of the Japan Post Insurance Co., Ltd.

Figure 2. A conceptual model to explain the mechanisms of the effect of the home-based Radio-Taiso exercise programme.

HR-QoL: health-related quality of life, PCS: physical component summary, MCS: mental component summary, and RCS: role/social component summary

Figure 3. Study flow diagram.

IC: informed consent, RT: Radio-Taiso

Figure 1. Pictures of the Radio-Taiso as a firmly established, traditional Japanese exercise programme. A: Community-dwelling children get together to practice Radio-Taiso. B: Physical education classes. C: Practice in the workplace. D: Gathering and practising during community events. All pictures are provided by courtesy of the Japan Post Insurance Co., Ltd.

169x166mm (300 x 300 DPI)

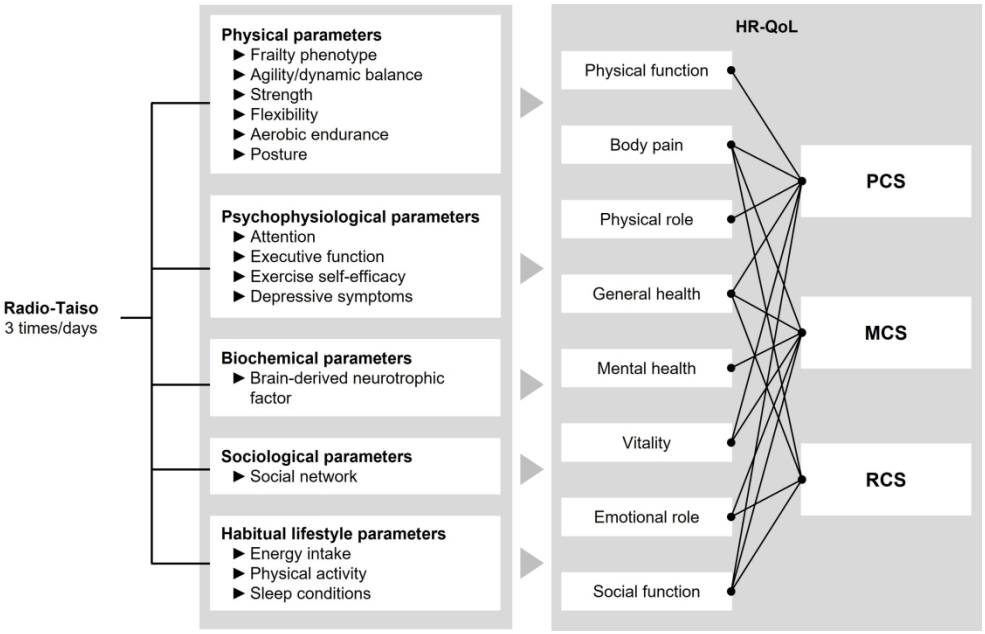

Figure 2. A conceptual model to explain the mechanisms of the effect of the home-based Radio-Taiso exercise programme. HR-QoL: health-related quality of life, PCS: physical component summary, MCS: mental component summary, and RCS: role/social component summary

255x160mm (300 x 300 DPI)

Figure **3.** Study timeline of enrolment, interventions, and assessments.

Study events	Enrolment	IC	Baseline assessment	Instruction	Intervention (84 days)							Follow-up assessment
Days	**-90**	**-60**	**0**	**7**	**14**	**21**	**28**	**35**	**49**	**63**	**91**	**98**
Allowance	±30	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3
ENROLMENT:												
Eligibility assessment	X	X	X									
IC		X										
Allocation			X									
INTERVENTIONS:												
RT exercise program				X	X	X	X	X		X		
Nutrition program				X	X	X	X	X				
ASSESSMENTS:												
Baseline variables			X									
Outcome variables			X									X
Adverse events						X		X	X	X	X	

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

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 2
	2b	All items from the World Health Organization Trial Registration Data Set	Not applicable
Protocol version	3	Date and version identifier	Page 2
Funding	4	Sources and types of financial, material, and other support	Page 18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Pages 17–18
	5b	Name and contact information for the trial sponsor	Page 18
	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	Page 18
	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)	Not applicable

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 4
	6b	Explanation for choice of comparators	Page 4
Objectives	7	Specific objectives or hypotheses	Pages 4–5
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 5
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 5
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)	Pages 5–6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Pages 6–8
	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)	Page 7
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Pages 7–8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 6
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	Pages 8–14
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)	Figure 3

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	Pages 14–15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6
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 6
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 6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Not applicable
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	Pages 8–14 Page 15
	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	Pages 7–8

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 15
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 15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Pages 15–16
	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)	Pages 15–16
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. Alternatively, an explanation of why a DMC is not needed	Not applicable
	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	Not applicable
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 14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not applicable
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 5
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 5

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
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 6
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 18
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 18
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	Page 6
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 16
	31b	Authorship eligibility guidelines and any intended use of professional writers	Not applicable
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Not applicable
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not applicable
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	Not applicable

*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.

Supplementary Table 1. Radio-Taiso part 1 (3 min 10 sec)

	Movement	Purpose
1	Stretch entire body	Raising the arms and stretching the entire body helps to achieve better posture
2	Swing the arms and bend the legs	Swinging the arms to the sides while bending and stretching the legs helps to stimulate blood circulation throughout the body
3	Arm rotations	Rotating the arms in large circles helps to keep the shoulder joint flexible.
4	Chest stretches	Opening up the chest helps to correct posture and promote respiratory function.
5	Bends to each side	Bending the upper body to the side helps to maintain the flexibility of the spine to make lateral movements.
6	Backward and forward bends	Stretching the back and abdomen helps to maintain the flexibility of the spine to make forward and backward movements.
7	Body twists	Twisting the body helps to stretch the muscles around the hips and maintain the flexibility of the spine to make rotational movements.
8	Stretch the arms up and down	Stretching the arms up and down quickly and powerfully helps to develop strength and instantaneous power.
9	Bend the body downwards at an angle and chest stretches	Bending the body downwards helps to develop muscle flexibility from the back to the back of the legs. By opening the chest, posture is corrected and respiratory function is improved.
10	Whole-body rotation	Rotating the upper body in a large circle helps to increase the flexibility of the entire spine, especially its lower back portion.
11	Jumps	Making rhythmic jumps helps to promote blood circulation throughout the body and increase leg strength.
12	Swing the arms and bend the legs	Swinging the arms to the side and bending and stretching the legs together while being aware of

		breathing helps the person take time to organise their body, mind and breath.
13	Deep breath	Breathing deeply while moving the arms widely helps bring the body back to a normal state.

URL: https://www.youtube.com/watch?v=_YZZfaMGEOU

Supplementary Table 2. Radio-Taiso part 2 (3 min 5 sec)

	Movement	Purpose
1	Shake the whole body	Making light jumps helps to shake and relax the whole body and prepare it for the exercises.
2	Bend and stretch the arms and legs	Vigorously bending and stretching the arms and legs helps to promote blood circulation throughout the body.
3	Open arms from the front and rotate	Opening and rotating of the arms helps to relax the muscles around the shoulder and increase the range of motion of the shoulder joint.
4	Chest stretches	Opening up the chest helps to correct posture and promote respiratory function.
5	Bends to each side	Bending the upper body to the side helps to maintain the flexibility of the spine to make lateral movements.
6	Backward and forward bends	Stretching the back and abdomen helps to maintain the flexibility of the spine to make forward and backward movements.
7	Body twists	Twisting the body helps to stretch the muscles around the hips and maintain the flexibility of the spine to make rotational movements.
8	One-legged jump and step exercise	Making jumps and steps with just one leg helps to increase muscle strength, instantaneous power in the legs, and blood circulation throughout the body.
9	Bend backwards with twist and bend downwards at angle	Twisting and bending the whole body helps to stretch the muscles of the torso and chest and increase flexibility.
10	Tilt the body forward	Moving the upper body up and down while leaning forward helps to strengthen the muscles of the back and achieve better posture.
11	Jumps	Making rhythmic jumps helps to promote blood circulation throughout the body and increase leg

		strength.
12	Swing the arms and bend the legs	Swinging the arms and bending the legs together while being aware of breathing helps the person to take some time to organise the body, mind, and breath.
13	Deep breath	Breathing deeply while moving your arms widely helps to bring the body back to a normal state.

URL: https://www.youtube.com/watch?v=yi1TbzML2cU

Supplementary Table 3. Minna no Taiso (4 min 30 sec)

	Movement	Purpose
1	Hands and arms exercises	Moving the hands and arms well promotes peripheral blood circulation and the development of a sense of movement.
2	Chest exercise	Making chest movements helps to correct posture and improve respiratory function.
3	Upper body bounce	Bouncing the entire body while bending the upper body helps to relax the whole body, promote blood circulation, and maintain chest flexibility.
4	Neck exercises	Moving and stretching the neck helps to stretch the muscles from the neck to the shoulders and stimulate blood circulation in these areas.
5	Moving quickly	Quickly extending the arm while shifting the body weight helps to increase the instantaneous power of the whole body.
6	Leg and hip exercises	Moving the legs and hip helps to strengthen the muscles of these parts, increase hip flexibility, and a sense of balance.
7	Arm and leg exercises	Making movements with the arms and legs that lead the person to try to make the arm movements match the movements of the whole body helps to develop coordination of movement.
8	Deep breath	Breathing deeply while moving your arms widely helps to bring the body back to a normal state.

URL: https://www.youtube.com/watch?v=1MGsuinRElk

BMJ Open

Effects of a home-based Radio-Taiso exercise programme on health-related quality of life in older adults with frailty: protocol for an assessor-blind randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-063201.R1
Article Type:	Protocol
Date Submitted by the Author:	23-Aug-2022
Complete List of Authors:	Osuka, Yosuke; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Kojima, Narumi; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Sugie, Masamitsu; Tokyo Metropolitan Geriatric Hospital and Institute of Gerontology, Department of Cardiology Omura, Takuya; Tokyo Metropolitan Institute of Gerontology, Department of Geriatric Medicine Motokawa, Keiko; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Ueda, Takuya; Tokyo Metropolitan Institute of Gerontology, The Tokyo Metropolitan Support Center for Preventative Long-term and Frail Elderly Care Maruo, Kazushi; University of Tsukuba, Department of Biostatistics, Faculty of Medicine Ono, Risa; Japan Radio-Taiso Federation Aoyama, Toshihiko; Japan Radio-Taiso Federation Inoue, Shigeru; Tokyo Medical University, Department of Preventive Medicine and Public Health Kim, Hunkyung; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Sasai, Hiroyuki; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health
Primary Subject Heading:	Public health
Secondary Subject Heading:	Geriatric medicine, Mental health, Sports and exercise medicine
Keywords:	GERIATRIC MEDICINE, MENTAL HEALTH, PUBLIC HEALTH, SPORTS MEDICINE

Effects of a home-based Radio-Taiso exercise programme on health-related quality of life in older adults with frailty: protocol for an assessor-blind randomised controlled trial

Yosuke Osuka[1], PhD; Narumi Kojima, MS[1]; Masamitsu Sugie[2], MD, PhD; Takuya Omura[3], MD, PhD; Keiko Motokawa[1], PhD; Takuya Ueda[4], PhD; Kazushi Maruo[5], PhD; Risa Ono[6], MS; Toshihiko Aoyama[6]; Shigeru Inoue[7], MD, PhD; Hunkyung Kim[1], PhD; and Hiroyuki Sasai[1], PhD

[1]Research Team for Promoting Independence and Mental Health, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan
[2]Department of Cardiology, Tokyo Metropolitan Geriatric Hospital and Institute of Gerontology, Tokyo, Japan
[3]Department of Geriatric Medicine, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan
[4]The Tokyo Metropolitan Support Center for Preventative Long-term and Frail Elderly Care, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan
[5]Department of Biostatistics, Faculty of Medicine, University of Tsukuba, Tsukuba, Japan
[6]Japan Radio-Taiso Federation, Tokyo, Japan
[7]Department of Preventive Medicine and Public Health, Tokyo Medical University, Tokyo, Japan

Corresponding author
Yosuke Osuka, PhD
Research Team for Promoting Independence and Mental Health,
Tokyo Metropolitan Institute of Gerontology
35-2 Sakae-cho, Itabashi-ku, Tokyo 173-0015, Japan.
Phone: +81-3-3964-3241; Email: osuka@tmig.or.jp

Word count
5111/4000 words

ABSTRACT

Introduction

Few clinical trials have examined the effects of home-based exercise programmes on health-related quality of life (HR-QoL) in older adults with frailty. Radio-Taiso is the most famous exercise programme in Japan. A home-based Radio-Taiso exercise programme may serve as an accessible, scalable, and sustainable care intervention for older adults with frailty. The primary aims of this trial is to test whether older adults with frailty who are prescribed our home-based Radio-Taiso exercise programme will receive greater benefits for HR-QoL compared to those who are not prescribed the exercise programme. Potential mechanisms underlying the effectiveness of the programme and the effects of the programme on daily lifestyle will be also investigated.

Methods and analysis

This assessor-blind randomised controlled trial will be conducted at the Tokyo Metropolitan Institute of Gerontology (TMIG) in Itabashi-ku, Tokyo, Japan. From April to May 2022, 226 older adults with pre-frailty or frailty according to the revised Japanese version of the Cardiovascular Health Study criteria will be included from a large database. After a baseline assessment in June 2022, participants will be randomly assigned to the intervention (home-based Radio-Taiso exercise and nutrition programme) or control groups (nutrition programme) at a 1:1 ratio. After intervention completion, a follow-up assessment will be conducted in September 2022. The primary outcome is the change in the mental domain of HR-QoL assessed using SF-36®. Secondary outcomes include physical and role/social domains and subscales of HR-QoL, frailty phenotype, physical fitness, posture, cognition, exercise self-efficacy, depressive symptoms, brain-derived neurotrophic factor, social network, habitual energy intake, physical activity, and sleep conditions.

Ethics and dissemination

The Research Ethics Committee of TMIG has approved the research protocol. This trial will be conducted in accordance with the principles of the Declaration of Helsinki. The findings will be presented at international academic conferences and published in peer-reviewed international journals.

Trial registration

Registry name: UMIN-CTR

URL: https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000053863

Protocol version

Date: 9 May 2022

Version identifier: 4.4

Strengths and Limitations

- The feasibility of this Phase III trial has been enhanced based on the processes, resources, management, and scientific data of a pilot trial.
- The trial will include older adults with frailty defined using a validated assessment tool.
- Random allocation, blinding of assessors and analysts, interpretation of results based on the intention-to-treat principle, and disclosure of protocol papers will reduce the risk of selection, measurement, reduction, and reporting bias.
- The non-blinding of allocation information to participants and care providers may increase the risk of performance bias.
- The generalisability of the study findings to non-Japanese populations is unclear.

INTRODUCTION

Frailty is defined as vulnerability of homeostatic responses to stressors due to cumulative age-related decline of physiological systems.[1] Research suggests that 7% and 47% of older adults have frailty and pre-frailty, respectively, and their risk of falls, disabilities, nursing home admission, and death is significantly higher than that of robust older adults.[2] Interventions to reduce frailty prevalence and severity may benefit older adults with care needs, their caregivers, and the public social insurance system. However, clinical trials involving older adults with frailty defined using validated assessment tools are required to confirm the effectiveness of these interventions.[1]

Interventions such as exercise and nutritional programmes are useful for reducing the prevalence of frailty, but stakeholders have raised concerns that research on these interventions has focused predominantly on improving physical outcomes.[3] Studies focusing on patient-reported outcomes (e.g. health-related quality of life [HR-QoL]) may address the gaps between scientific evidence and clinical practice.[4] Exercise interventions are reportedly the most effective for improving HR-QoL among older adults with frailty, but this warrants validation in robust clinical trials.[5] Nevertheless, evidence for the effects of home-based exercise interventions on HR-QoL remains scarce.[6] As older adults with frailty exhibit decreased mobility,[7] readily available home-based exercise programmes are feasible and rational interventions.

Radio-Taiso is the most famous Japanese exercise programme, with reports suggesting that approximately 96.9% of the national population are aware of the programme.[8] In 1928, the Postal Life Insurance Bureau of the Ministry of Communications (successor agency: Japan Post Insurance Co., Ltd.) developed Radio-Taiso as a "National Health Exercise" to improve health among Japanese people.[9] Radio-Taiso is customarily practiced in numerous settings and is firmly established in Japanese culture (Figure 1).[10] It is broadcasted daily by the Japan Broadcasting Corporation via public radio and television, thus facilitating home access by Japanese older adults with frailty.

Our recent pilot randomised controlled trial examined the feasibility and potential effectiveness of a home-based Radio-Taiso exercise programme in community-dwelling older adults with pre-frailty and frailty. Participants demonstrated high adherence and the results suggested that the programme may lead to clinically important improvements in the mental domain of HR-QoL (under review). However, the effectiveness of the programme remains to be validated by robust clinical trials.

This trial aims to test whether older adults with pre-frailty and frailty who undergo the programme will experience greater benefits in the mental domain of HR-QoL

compared to those who do not undergo the programme. Further, the trial aims to identify the mechanisms underlying programme effectiveness and the impact of the programme on participants' lifestyles (Figure 2).

METHODS AND ANALYSIS

Study design, setting, and procedures

This is a 12-week randomised, assessor-blind, parallel-design, two-arm, phase III trial. The protocol was designed in accordance with the SPIRIT statement (Supplementary Material 1) and several aspects of the SPIRIT-PRO Extension.

All outcomes will be assessed at the Tokyo Metropolitan Institute of Gerontology (TMIG) in Itabashi-ku, Tokyo, Japan. Participants will practice the programme at home. Six face-to-face group sessions will be conducted at the TMIG or nearby community facilities (Figure 3). Recruitment will be conducted in April 2022. Informed consent will be obtained in the subsequent month (May 2022). Baseline and follow-up assessments will be conducted in June and September 2022, respectively. After baseline assessments, participants who meet the eligibility criteria will be included in the trial and randomly assigned to the intervention (home-based Radio-Taiso exercise programme + nutrition programme) or control (nutrition programme) groups. The intervention will begin and end in June and September 2022, respectively.

Participants

Inclusion criteria are: 1) aged 65 years or older; and 2) frailty or pre-frailty as defined by the revised Japanese version of the Cardiovascular Health Study (J-CHS) criteria (see below).

Exclusion criteria are: 1) inability to participate in both baseline and follow-up assessments; 2) diagnosed with dementia or prescribed anti-dementia drugs; 3) self-reports of being unable to eat, excrete, dress, move, or bathe independently; 4) not allowed to exercise (except for light-intensity exercise) by the family physician; 5) unstable/severe medical conditions that prevent trial physicians from permitting study participation; 6) history of angina pectoris, myocardial infarction, or cardiac surgery in the past 3 months, having a terminal illness, or receiving palliative care; 7) practising Radio-Taiso exercises for ≥1 day/week for the past month; 8) participating in a specific rehabilitation programme; 9) unable to walk ≥10 m independently; 10) participating or will participate in other clinical trials; 11) lacking a television at home; 12) difficulty communicating in Japanese; 13) evaluated by the principal investigator and/or trial physicians to be ineligible; and 14) unable to provide consent to participate.

Potential participants will be recruited from a large database of trial-ready cohorts managed by the TMIG. In our pilot trial in 2020, 902 individuals were newly enrolled or had their information updated. Of these, 514 (60%) met the pre-frailty or frailty criteria and 186 (recruitment rate: 20.6%) met all eligibility criteria and were willing to participate. Thus, at least 1,097 new registrations or updates are required to ensure that the target number of 226 participants is reached (described in more detail in the sample size section).

Invitation letters and eligibility criteria checklist will be sent to individuals diagnosed with frailty or pre-frailty between October 2021 and March 2022. Participants who meet all eligibility criteria and intend to participate will be provided a detailed verbal explanation of the study (i.e. aims, procedures, confidentiality, possible benefits and disadvantages, anticipated risks, and methods to address risks). Only individuals who provide written informed consent will participate. If there are more individuals willing to participate than the target sample size, participants will be randomly selected using a computer-generated random sequence. During baseline assessments, trial physicians will assess compliance with exclusion criteria numbered 2, 5, and 6.

Allocation and blinding

After baseline assessments, participants will be randomly allocated to the intervention and control groups at a 1:1 ratio. The sequence for generating the allocation code will be stratified by sex (male or female), age (<75 or ≥75 years), and frailty severity (pre-frail or frailty). Blocking will be applied.

The principal investigator (YO) at the TMIG will send identification codes of eligible participants to an allocator (KM) who has no contact with participants. KM will combine the codes with a prescribed randomisation code, which will be generated prior to baseline assessments. An independent research staff member will inform participants of their group based on the allocation code sent by KM. Group labels will not be disclosed to the assessor and statistical analyst until completion of the primary analysis.

Intervention

During the 12-week intervention period, participants will be instructed to avoid starting new exercise or nutrition programmes. To address the ethical disadvantages of the control group, a nutrition programme will be provided to both groups.

Home-based Radio-Taiso exercise programme

Radio-Taiso includes three exercise patterns: Radio-Taiso No. 1 and 2 and Minna

no Taiso. These patterns comprise 8–13 rhythmic whole-body movements with music. Each pattern starts with a low-intensity movement, gradually increases in intensity, and ends with another low-intensity movement, allowing safe practice. The smooth execution of movements requires fitness in various physical domains (strength, flexibility, endurance, and balance), making Radio-Taiso a multi-component exercise programme (details in Supplementary Tables 1–3).

The home-based programme comprises six 60-min face-to-face group sessions with a certified instructor from the Japan Radio-Taiso Federation and daily practice in participants' homes. Before the programme, the intervention group will receive a face-to-face group session on correctly performing the three exercise patterns. In the first 4 weeks of the intervention, participants will receive face-to-face group sessions on effectively performing the exercise programmes. In week 8, a face-to-face group session will be provided to review the key points of each exercise programme.

Participants will be instructed to complete a three-pattern exercise programme once daily at home by themselves via a broadcast by the Japan Broadcasting Corporation or DVD. If the participants feel unwell while performing any exercise or feel that the exercise intensity is too high, they will be instructed to stop or reduce the number of sessions. Participants will be required to record whether (1) they performed the exercise programme and (2) compliance with key points for effective programme implementation in an exercise diary. On the day of face-to-face group sessions, research staff will check the exercise diary, adverse events, and participation in the new rehabilitation programme. In weeks when sessions are not provided, these details will be checked by telephone every fortnight.

The pilot trial confirmed good adherence to the home-based Radio-Taiso exercise programme (retention rate: 100%; median [interquartile range] practice rate: 97.6 [88.1–98.8] %). However, no trend towards improvements in physical outcomes was observed. Radio-Taiso may not include properties that significantly improve physical outcomes because it predominately consists of flexibility exercises. However, thoroughly completing the purpose of each movement in Radio-Taiso necessitates quicker and larger movements, which require muscle endurance and whole-body endurance. In this regard, several participants who received face-to-face instructions in the pilot study reported that it is important to understand the purpose of each movement of the Radio-Taiso via face-to-face instructions to improve the quality of practice at home. Thus, to provide participants with a programme that yields better physical outcomes, the number of face-to-face sessions will be increased from three to six and include processes that help participants familiarise with the key points of the programme. An item will be added to

the exercise diary to check compliance with these points.

Nutrition programme

The nutrition programme comprises: 1) distribution of a nutrition leaflet; 2) recording of a dietary variety score; and 3) telephone nutrition counselling. One week before intervention onset, participants will receive a face-to-face briefing from a dietitian on programme implementation. A nutrition leaflet will be distributed once weekly during the first 4 weeks of the intervention, detailing the nutritional role and recommended intake amounts of protein, calcium, vitamins/minerals, and carbohydrates/fats, alongside specific recipes for the efficient intake of these nutrients. Participants will be instructed to record daily in a nutrition diary the consumption of 10 food groups (meat, seafood, eggs, soya and soya products, milk, green and yellow vegetables, seaweed, potatoes, fruit, and oil) using a dietary variety score. Participants will be requested to provide scores on intake of these food groups on a 10-point scale.[11] A high dietary variety score has been associated with lower frailty severity.[12] Participants will be allowed to call the dietitian 1 day per week to discuss how to proceed with the nutrition programme or if they have any questions.

Outcome measures

The primary outcome is changes in the mental component summary (MCS) score of HR-QoL. Secondary outcomes are the physical component summary (PCS) score, role/social component summary (RCS) score, and eight subscales of HR-QoL as well as frailty phenotype, physical fitness, posture, cognition, exercise self-efficacy, depressive symptoms, brain-derived neurotrophic factor (BDNF), social network, habitual energy intake, physical activity, and sleep conditions. All outcomes excluding habitual physical activity will be assessed at a baseline survey within 2 weeks prior to the start of the intervention and at a follow-up survey within 1 week after the end of the intervention (Figure 3).

Baseline information

Baseline information including age, sex, disease history (hypertension, heart disease, diabetes, hyperlipidaemia, osteoporosis, and respiratory disease), and low-back and knee pain will be obtained by face-to-face interview.

Assessments

Objective outcomes including physical fitness, posture, cognition, BDNF, and

physical activity will be assessed by research staff blinded to allocation information.

HR-QoL

HR-QoL will be assessed using the Japanese version of the SF-36, which is a widely used, reliable, and validated tool.[13 14] The SF-36 measures eight health domains: physical function, physical role, body pain, general health, vitality, social function, emotional role, and mental health. These domains are aggregated and scored into the MCS, PCS, and RCS (Figure 2).[15] These scores are standardised as T-scores using the 2017 Japanese national norm.[16] A change of three or more points in the MCS or two or more points in the PCS constitutes a minimal clinically important difference, enabling clinical interpretation of changes in scores.[17]

Frailty phenotype

Frailty phenotype will be assessed using Fried's frailty criteria, characterised by five limitations: slowness, weakness, exhaustion, low activity, and weight loss.[2] The trial will use the revised J-CHS criteria to define frailty (three or more limitations) and pre-frailty (one or two limitations).[18]

Slowness

Slowness will be assessed based on usual gait speed. An 11 m walking path will be used, with a 3 m acceleration/deceleration path at each end. The assessor will measure the time taken between the 3 and 8 m markers.[19] The measurement will be performed once. Slowness will be defined as a gait speed of less than 1.0 m/sec.

Weakness

Weakness will be assessed based on grip strength using a handheld Smedley-type dynamometer. Participants will be instructed to grip the device as strongly as possible with their dominant hand in a standing position.[19] The measurement will be performed once. Weakness will be defined as less than 28 and 18 kg for men and women, respectively.

Exhaustion

Exhaustion will be assessed using question 25 of the Kihon checklist developed by the Ministry of Health, Labour and Welfare, as follows:[20] "In the last 2 weeks, have you felt tired for no reason?" Exhaustion will be defined by a "yes" response.

Low activity

Low activity will be assessed using two simple questions regarding participation in exercise or physical activity, as follows: 1) "How often do you engage in light intensity exercise or calisthenics?" and 2) "How often do you engage in exercise or sports activities"? Low activity will be defined by a response of "less than once a week" to both questions.

Weight loss

Weight loss will be assessed using question 11 of the Kihon checklist developed by the Ministry of Health, Labour and Welfare, as follows:[20] "Have you lost 2 kg or more in the past 6 months?" Weight loss will be defined by a "yes" response.

Physical fitness

Six physical fitness domains (agility/dynamic balance, lower body strength, upper body strength, lower body flexibility, upper body flexibility, and aerobic endurance) will be assessed using Senior Fitness Tests.[21]

Agility and dynamic balance

Agility and dynamic balance will be assessed using the 8-foot up-and-go test. Participants will be instructed to stand up at the start signal, walk around a cone 8 ft away, turn around, and sit down again. This sequence must be performed as quickly as possible. After one practice session, two trials will be performed. The values for the minimum time required will be used in the analysis.

Lower body strength

Lower body strength will be assessed using the chair stand test. At test onset, participants will be instructed to stand up and sit down again with their arms crossed in front of the chest. After 2–3 practice sequences of this exercise, a single trial will be performed, in which the sequence is repeated as quickly as possible for 30 s. The values of the number of sequences achieved will be used in the analysis.

Upper body strength

Upper body strength will be assessed using the arm curl test. Participants will be requested to flex and extend the elbow of the dominant arm while holding a dumbbell (8 lb for men and 5 lb for women) at the start signal, with both upper arms in a natural down position. After 2–3 practice sequences, a single trial will be performed, in which the

sequence will be repeated as quickly as possible for 30 s.

Lower body flexibility

Lower body flexibility will be assessed using the chair sit-and-reach test. Participants will be requested to sit in a shallow position on a chair and extend their favourite leg. Participants will then be instructed to place the fingertips of both hands together, slowly flex the upper body towards the toes of the favourite leg until reaching their limit, and remaining still for 2 s. Participants will be instructed to hold the ankle joint at 90°. The assessor will measure the distance between the toes of the favourite leg and fingertips of both hands using a ruler. After two practice sessions, the measurements will be performed twice. The best values will be used in the analysis.

Upper body flexibility

Upper body flexibility will be assessed using the back scratch test. In an upright position, the participant will be instructed to rotate the favourite hand backwards obliquely upward and the other hand backwards obliquely downward to the posterior region. The assessor will measure the shortest distance between the middle fingers of both hands using a ruler. The measurement will be performed twice. The best values will be used in the analysis.

Aerobic endurance

Aerobic endurance will be assessed using a 2-min step-in-place test. The assessor will mark a wall with masking tape midway between the participant's patella and iliac crest. The participant will be instructed to stand next to the wall and march in place for 2 min. Participants who face difficulties marching for the 2 min will be allowed to take a break and hold the wall or a stable chair. The assessor will record the number of times the right knee reaches the marker within 2 minutes. The trial will be conducted once.

Anthropometric indices

Body height, weight, and body mass index

Height will be measured using a digital height meter (DSN-70; MURATEC-KDS Corporation). Body weight is measured using a body composition analyser (InBody770, InBody Co. Ltd., Seoul, Korea). Body mass index is calculated by dividing the weight (kg) by the square of the height (m).

Posture

Posture will be assessed by the degree of kyphosis and the range of motion of the

spine. The degree of kyphosis is assessed by the thoracic kyphosis angle (KA) and lumbar lordosis angle.[22 23]

Thoracic KA and lumbar lordosis angles are measured using the Idiag M360 (Idiag AG, Switzerland). The participant is first instructed to stand in a normal position, and then the assessor moves the Idiag M360 along the spinous processes from the vertebra prominens (C7) to the third cervical vertebra (C3). The trial is conducted once, and the smaller the angle of the thoracic KA, the severer the kyphosis, whereas the larger the lumbar lordosis angle, the severer the kyphosis.[22 23]

The range of motion of the spine is measured using the Idiag M360 (Idiag AG, Switzerland).[22 23] The assessor moves the Idiag M360 over the spinous processes from C7 to C3 in the maximum forward flexion and extension positions. Range of motion is assessed as the difference between the thoracic KA and lumbar lordosis angle at maximum forward flexion and maximum extension, based on the angles measured for the thoracic KA and lumbar lordosis angle.

Cognition

Attention and executive function will be assessed using Parts A and B of the trail making test (TMT).[24] In Part A, participants must connect the numbers in ascending order, and the time taken for finalising the task is measured (i.e. 1-2-3-4...). In Part B, the task is to connect the numbers and kana characters in an alternating order (i.e. 1-A-2-I...), and the time taken for finalising the task is measured.

Home-based exercise self-efficacy

The participants' home-based exercise self-efficacy will be assessed using the Home-Exercise Barrier Self-Efficacy Scale.[25] Participants will be asked to respond to six exercise situations at home (1: when I am tired, 2: when I am in pain, 3: when I do not feel very good, 4: when I do not have time, 5: when I do not have the equipment or environment to exercise, 6: when I am alone) on a 5-point Likert scale ranging from 1 (*not at all confident*) to 5 (*absolutely confident*). Details on items and scoring are described in prior research.[25] Total scores range from 5–30, with higher scores indicating greater self-efficacy in home-based exercise.

Depressive symptoms

Depressive symptoms will be assessed using the short version of the Geriatric Depression Scale.[26] Participants will be asked to answer to 15 yes-or-no questions about their daily mood. Details on items and scoring are described in prior research.[26]

Total scores range from 0–15, with higher scores indicating a more depressed mood.

BDNF

BDNF is the most widely expressed neurotrophic in the mammalian brain and an important regulator of the development and function of neural circuits in the brain.[27] Exercise-induced BDNF mediates neuronal differentiation and growth, synapse formation and plasticity, and may explain how exercise training improves mental health and cognitive function.[28]

Participants will fast for at least two hours and a blood sample will be collected from the anterior elbow vein. To exclude the potential effects of acute exercise, participants will be asked to refrain from engaging in vigorous intensity exercise for 36 hours before the blood sample collection. To control for diurnal variation, participants will have their blood drawn at the same time of day in both the baseline and follow-up assessments. Blood samples will be processed according to the manufacturer's specifications: plasma is obtained by centrifugation at 3,000 g for 10 min at 22°C, aliquoted, and stored at -80°C until measurement. Plasma samples will be assessed for BDNF concentrations using a commercially available two-site sandwich enzyme-linked immunosorbent assay kit (R&D Systems, Minneapolis, MN, USA). The analysis will be conducted centrally in an independent laboratory.

Social network

Social network will be assessed using the Japanese version of the Lubben Social Network Scale-6 (LSNS-6).[29] Participants will answer six questions regarding support, indicating the number of family members and friends who can provide them with emotional and instrumental support from the five given options. Details on items/scoring are described in prior research.[29] Total scores range from 0–30, with higher scores indicating a larger social network.

Habitual energy intake

Habitual energy intake will be assessed using a reliable and valid brief self-administered diet history questionnaire developed to provide a simple estimate of energy intake over the past month.[30 31] Participants will be asked to recall their average dietary habits over the past month and indicate the frequency of consumption of each food item. Habitual energy intake will be calculated using a special software provided by Gender Medical Research Co. Japan.

Habitual physical activity

Habitual physical activity levels will be assessed based on the average number of steps taken daily. The number of steps will be measured using validated tri-axis accelerometers and algorithms (Active style Pro HJA-750C; Omron Healthcare, Tokyo, Japan).[32 33] Participants will be instructed to wear the device around the waist for 7 days from baseline and follow-up assessments during all activities of daily living from waking to bedtime, except for underwater activities (e.g. bathing and swimming). A record is valid if the device is worn for at least 10 h/day.[34] If valid records are collected for more than three days, the number of steps daily is calculated.

Habitual sleep conditions

Sleep condition will be subjectively assessed using the Japanese version of the Pittsburgh Sleep Quality Index,[35 36] comprising 7 components: sleep quality, time to fall asleep, time to stay asleep, sleep efficiency, difficulty sleeping, use of sleeping pills, and difficulty waking up during the day in the past month. Details on items and scoring are described in prior research.[35 36] Total scores range from 0–21, with higher scores indicating a worse subjective sleep condition.

Adverse events

Adverse events are defined in this study as any undesirable/unintended sign, symptom, or disease occurring during the intervention, regardless of causality. The number of adverse events that occur during the intervention period will be assessed. Trial physicians will determine adverse event severity and potential relevance to the intervention. Any adverse events (e.g. subjective symptoms, falls, and other surgical or medical findings) suspected to relate to the intervention will be recorded. Research staff will ask participants if they have experienced an adverse event by telephone or in person every fortnight.

Adherence

Adherence will be assessed by the retention rate during the intervention period and the rate of practice of the Radio-Taiso exercise programme. Retention rate is calculated as the percentage of participants who complete the follow-up assessment. The rate of practice of the programme is calculated by dividing the number of practice days (days when the exercises are practiced at least once a day) by 84 days. The total number of practice sessions of the programme will also be assessed.

Sample size

Based on the pilot trial, the effect size (Cohen's d) of the programme on MCS score was 0.395. Using G*Power version 3.1.9.2 for Windows (Heinrich-Heine-Universität Düsseldorf),[37] with the alpha error set at 5%, a power of 80%, and this effect size, the sample required was 204. Considering a 10% drop-out rate, the target sample is 226.

Data management

Data quality control comprises 1) measurements based on established standard operating procedures, 2) manual checks (visual checks) of questionnaires and case reports, and 3) data entry using the double-entry method. Manual checks include confirmation of compliance with eligibility criteria, missing measurements, and value ranges. After entering all the data, the person responsible for the analysis will perform logical check (programming check) and data coding to ensure and fix any issues pertaining to data quality. These checks include examining for outliers.

Statistical analysis

As "tests of baseline homogeneity" in randomised controlled trials do not have any practical value,[38] comparison of baseline characteristics will not be performed in this study. At baseline, continuous variables are presented as mean (standard deviation) or median (interquartile range) and categorical variables as n (%).

Main analysis

To test programme effectiveness, changes in the primary outcome will be compared between both groups using an ANCOVA model adjusted for allocation stratification factors and baseline values. Changes in secondary outcomes will be compared using the same model. Differences between groups in change for each outcome will be expressed as differences in adjusted means (95% confidence intervals). Statistical significance will be set at a $P < 0.05$.

The results of the main analyses will be interpreted based on the intention-to-treat principle. The full analysis set will exclude participants 1) who are subsequently found not to meet the eligibility criteria; 2) never participated in the intervention programme; or 3) for whom no post-randomisation data are available,[39] and be applied as the main analysis population. The International Council for Harmonisation guideline recommends applying a full analysis set that excludes these participants from the main analyses as a conservative strategy.[39]

Additional analysis

Additional analyses using a per-protocol set will be conducted to assess the extent to which adherence affects the results. The per-protocol set will include participants who have practiced at least 75% of the home-based Radio-Taiso exercises stipulated.[40]

A sensitivity analysis will be performed to assess heterogeneity owing to missing follow-up data (missing bias). Missing data will be processed through multiple imputation by applying the chained equation method to generate 20 imputed datasets based on the outcome, allocation, and group variables at baseline.

To assess study generalisability, subgroup analyses will be conducted based on participants' background data (male vs. female, <75 vs. ≥75 years, and frailty vs. pre-frailty).

Retention rates and the incidence of adverse events (one or more for those who report them) will be compared between groups using Fisher's exact test or the χ-square test. All analyses will be carried out using R, version 4.1.2 or higher (The R Foundation for Statistical Computing Platform).

Patient and public involvement

This study will be conducted without participant involvement. Participants will not be invited to comment on study design, define relevant outcomes or interpret the results, nor contribute to the writing or editing of this paper for readability or accuracy.

ETHICS AND DISSEMINATION

The research protocol will be conducted in accordance with the Declaration of Helsinki. The Research Ethics Committee of TMIG approved the protocol on 16 December 2021. The study protocol was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) on 20 March 2022 (trial registration no. UMIN000047229). All amendments to the study protocol will be disclosed to UMIN-CTR.

Study results will be presented at an international scientific conference and reported in a peer-reviewed international journal. After publication, a summary of the results will be published on the TMIG and Japan Post Insurance Co., Ltd., websites.

DISCUSSION

Few trials have examined the effect of exercise interventions on HR-QoL in older adults with frailty diagnosed by validated assessment tools.[3 5 6] Thus, this robustly designed trial will strengthen the evidence needed to support the effectiveness of home-

based exercise programmes on HR-QoL. International health policy bodies, regulators and patients are increasingly recognising the importance of patient-reported outcomes, including HR-QoL, for health.[41] The results of this study will provide valuable insights that may serve to address the evidence and clinical practice gaps associated with care programmes for older adults with frailty. This study will also contribute to a better understanding of the potential mechanisms by which home-based exercise programmes can improve HR-QoL by analysing various secondary outcomes.

Researchers systematically compared HR-QoL between frailty and non-frailty groups, showing a moderate or greater standardised mean difference between the groups and that the frailty group had a worse HR-QoL.[42] The measures to curb the COVID-19 pandemic also limit the life-space mobility of older adults with frailty and have a significant impact on QoL.[43] Patient-reported outcomes from clinical trials using scientifically robust methodologies are reflected in clinical decision-making and influence health and social care policy.[41] Thus, if this study helps to clarify the effectiveness of the proposed programme on HR-QoL, this may enable for invested stakeholders to develop a policy framework for care programmes from the perspective of older adults with frailty.

For a care programme targeting people with frailty to be implemented in public health policy, it must have good accessibility (i.e. low cost and high acceptability/availability) and be delivered equitably and continuously.[4] A care programme that draws on existing cultural and social resources may be able to meet these requirements. In Japan, the Radio-Taiso exercise programme has a long history of being customarily watched in different settings and is familiar to many older adults, thus being a cultural exercise programme in the country.[10] In fact, our pilot trial confirmed that adherence to the programme is very good and that it is highly compatible with daily life. Radio-Taiso is also available with low-cost to everyone via television/radio on a daily basis. To date, more than 24,600 certified Radio-Taiso instructors have been trained, and there are more than 2,000 regional bases where the programme is practised nationwide.[44] Rich in cultural and social resources, the Radio-Taiso exercise programme may serve as a socially implementable public health strategy.

This study has several limitations. First, although the study addresses measurement, attrition, and reporting bias, participants and treatment providers will not be blinded to allocation information; this increases the risk of performance bias and reduce effect estimation accuracy. Second, calisthenic programmes like Radio-Taiso are popular in some countries, such as China, Korea, and Scandinavia, but it remains unclear to what extent the usefulness of the Radio-Taiso exercise programmes is generalisable to

non-Japanese older adults with frailty.

Acknowledgments

We are grateful to the participants and the staff members of the TMIG.

Author contributions

Yosuke Osuka: study concept and design, data collection and interpretation, manuscript preparation. Narumi Kojima: study concept and design, data collection and interpretation, manuscript preparation. Masamitsu Sugie: study concept and design, safety assessment, manuscript preparation. Takuya Omura: study concept and design, safety assessment, manuscript preparation. Keiko Motokawa: study concept and design, data collection and interpretation, manuscript preparation. Takuya Ueda: study concept and design, data collection and interpretation, manuscript preparation. Kazushi Maruo: study concept and design, statistical advice, randomisation, data interpretation, manuscript preparation. Risa Ono: study concept and design, intervention, data interpretation, manuscript preparation. Toshihiko Aoyama: study concept and design, data interpretation, manuscript preparation. Shigeru Inoue: study concept and design, data interpretation, manuscript preparation. Hunkyung Kim: study concept and design, data interpretation, manuscript preparation. Hiroyuki Sasai: study concept and design, analysis, data interpretation, manuscript preparation.

Funding

This study will be conducted under a collaborative agreement between four institutions (TMIG, Tokyo Medical University, Japan Post Insurance Co., Ltd., and the Japan Radio-Taiso Federation). Japan Post Insurance Co., Ltd. will financially support the study and will provide the Radio-Taiso DVD free of charge, but will not be involved in the design of the study, selection of methods, recruitment of participants, data collection, analysis and interpretation, or writing of the manuscript.

The Japan Radio-Taiso Federation will provide certified Radio-Taiso instructors free of charge and will be involved in the design of the study, intervention, data interpretation, and writing of the manuscript.

Competing interests

Yosuke Osuka is the principal investigator of a joint research agreement between the four organisations; Risa Ono and Toshihiko Aoyama are accredited instructors for the Japan Radio-Taiso Federation. The Japan Post Insurance Co., Ltd. and the Japan Radio-Taiso

Federation are committed to the promotion and dissemination of Radio-Taiso. The other authors have no conflicts of interest to declare.

Patient consent

Patient consent form are attached in Supplementary Material 2

Ethics approval

Approved by Research Ethics Committee of TMIG on 16 December 2021.

Data availability statement

Data are available upon reasonable request.

REFERENCES

1. Clegg A, Young J, Iliffe S, et al. Frailty in elderly people. *Lancet* 2013;381(9868):752-62.
2. Fried LP, Tangen CM, Walston J, et al. Frailty in older adults: evidence for a phenotype. *The Journals of Gerontology Series A, Biological Sciences and Medical Sciences* 2001;56(3):M146-56.
3. Puts MTE, Toubasi S, Andrew MK, et al. Interventions to prevent or reduce the level of frailty in community-dwelling older adults: a scoping review of the literature and international policies. *Age and Ageing* 2017;46(3):383-92.
4. Dent E, Martin FC, Bergman H, et al. Management of frailty: opportunities, challenges, and future directions. *Lancet* 2019;394(10206):1376-86.
5. Negm AM, Kennedy CC, Thabane L, et al. Management of frailty: a systematic review and network meta-analysis of randomized controlled trials. *J Am Med Dir Assoc* 2019;20(10):1190-98.
6. Clegg AP, Barber SE, Young JB, et al. Do home-based exercise interventions improve outcomes for frail older people? Findings from a systematic review. *Reviews in Clinical Gerontology* 2012;22(1):68-78.
7. Navarrete-Villanueva D, Gómez-Cabello A, Marín-Puyalto J, et al. Frailty and physical fitness in elderly people: a systematic review and meta-analysis. *Sports Med* 2021;51(1):143-60.
8. Japan Post Insurance Co., Ltd. Recognition and participation rates for "Radio-Taiso". 2021 [Available from: https://www.jp-life.japanpost.jp/information/assets/pdf/211011pr-6-2.pdf accessed March 10 2022.
9. Public Relations Office, Government of Japan. Higlighting Japan 2019 [14-15]. Available from: https://dwl.gov-online.go.jp/video/cao/dl/public_html/gov/book/hlj/20191001/html5.html#page=

15137.
10. British Broadcasting Corporation. The lifelong exercise that keeps Japan moving. 2020 [Available from: https://www.bbc.com/worklife/article/20200609-the-life-long-exercise-that-keeps-japan-moving accessed March 10 2022.
11. Kumagai S, Watanabe S, Shibata H, et al. [Effects of dietary variety on declines in high-level functional capacity in elderly people living in a community]. *Nihon Koshu Eisei Zasshi* 2003;50(12):1117-24.
12. Motokawa K, Watanabe Y, Edahiro A, et al. Frailty Severity and Dietary Variety in Japanese Older Persons: A Cross-Sectional Study. *J Nutr Health Aging* 2018;22(3):451-56.
13. Fukuhara S, Bito S, Green J, et al. Translation, adaptation, and validation of the SF-36 Health Survey for use in Japan. *Journal of Clinical Epidemiology* 1998;51(11):1037-44.
14. Fukuhara S, Ware JE, Jr., Kosinski M, et al. Psychometric and clinical tests of validity of the Japanese SF-36 Health Survey. *Journal of Clinical Epidemiology* 1998;51(11):1045-53.
15. Suzukamo Y, Fukuhara S, Green J, et al. Validation testing of a three-component model of Short Form-36 scores. *Journal of Clinical Epidemiology* 2011;64(3):301-8.
16. Fukuhara S, Suzukamo Y. Manual of SF-36v2 Japanese version. Kyoto: iHope International Inc 2004, 2019.
17. Maruish ME. User's Manual for the SF-36v2 Health Survey: Quality Metric Incorporated 2011.
18. Satake S, Arai H. The revised Japanese version of the Cardiovascular Health Study criteria (revised J-CHS criteria). *Geriatr Gerontol Int* 2020;20(10):992-93.
19. Shinkai S, Watanabe S, Kumagai S, et al. Walking speed as a good predictor for the onset of functional dependence in a Japanese rural community population. *Age Ageing* 2000;29(5):441-6.
20. Sewo Sampaio PY, Sampaio RA, Yamada M, et al. Systematic review of the Kihon Checklist: Is it a reliable assessment of frailty? *Geriatrics & Gerontology International* 2016;16(8):893-902.
21. Rikli RE, Jones CJ. Development and validation of a functional fitness test for community-residing older adults. *J Aging Phys Act* 1999;7(2):129-61.
22. Mannion AF, Knecht K, Balaban G, et al. A new skin-surface device for measuring the curvature and global and segmental ranges of motion of the spine: reliability of measurements and comparison with data reviewed from the literature. *Eur*

Spine J 2004;13(2):122-36.
23. Post RB, Leferink VJ. Spinal mobility: sagittal range of motion measured with the SpinalMouse, a new non-invasive device. *Arch Orthop Trauma Surg* 2004;124(3):187-92.
24. Army Individual Test Battery. Washington, DC: War Department: Adjutant General's Office 1944.
25. Arita N, Takenaka K, Shimazaki T. Development of a home-exercise barrier self-efficacy scale for elderly people requiring support and care. *Journal of the Japanese Physical Therapy Association* 2014;41(6):338-46.
26. Yatomi N. The factor structure and item characteristic of the GDS (Geratric Depression Scale) short version in a Japanese elderly sample. *Japanese Journal of Gerontology* 1994;16(1):29-36.
27. Park H, Poo MM. Neurotrophin regulation of neural circuit development and function. *Nat Rev Neurosci* 2013;14(1):7-23.
28. Knaepen K, Goekint M, Heyman EM, et al. Neuroplasticity - exercise-induced response of peripheral brain-derived neurotrophic factor: a systematic review of experimental studies in human subjects. *Sports Med* 2010;40(9):765-801.
29. Kurimoto A, Awata S, Ohkubo T, et al. [Reliability and validity of the Japanese version of the abbreviated Lubben Social Network Scale]. *Nihon Ronen Igakkai Zasshi* 2011;48(2):149-57.
30. Kobayashi S, Murakami K, Sasaki S, et al. Comparison of relative validity of food group intakes estimated by comprehensive and brief-type self-administered diet history questionnaires against 16 d dietary records in Japanese adults. *Public Health Nutrition* 2011;14(7):1200-11.
31. Kobayashi S, Honda S, Murakami K, et al. Both comprehensive and brief self-administered diet history questionnaires satisfactorily rank nutrient intakes in Japanese adults. *Journal of Epidemiology* 2012;22(2):151-9.
32. Oshima Y, Kawaguchi K, Tanaka S, et al. Classifying household and locomotive activities using a triaxial accelerometer. *Gait Posture* 2010;31(3):370-4.
33. Ohkawara K, Oshima Y, Hikihara Y, et al. Real-time estimation of daily physical activity intensity by a triaxial accelerometer and a gravity-removal classification algorithm. *Br J Nutr* 2011;105(11):1681-91.
34. Troiano RP, Berrigan D, Dodd KW, et al. Physical activity in the United States measured by accelerometer. *Medicine and Science in Sports and Exercise* 2008;40(1):181-8.
35. Doi Y, Minowa M, Uchiyama M, et al. Psychometric assessment of subjective sleep

quality using the Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J) in psychiatric disordered and control subjects. *Psychiatry Research* 2000;97(2-3):165-72.
36. Doi Y, Minowa M, Okawa M, et al. Development of the Japanese version of the Pittsburgh Sleep Quality Index. *Japan Journal of Psychiatry Treatment* 1998;13(6):755-63 (in Japanese).
37. Faul F, Erdfelder E, Lang AG, et al. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;39(2):175-91.
38. Senn S. Testing for baseline balance in clinical trials. *Stat Med* 1994;13(17):1715-26.
39. The International Council for Harmonisation. E9 Statistical Principles for Clinical Trials: The International Council for Harmonisation; 1998 [Available from: https://database.ich.org/sites/default/files/E9_Guideline.pdf accessed October 16 2021.
40. Hawley-Hague H, Horne M, Skelton DA, et al. Review of how we should define (and measure) adherence in studies examining older adults' participation in exercise classes. *BMJ Open* 2016;6(6):e011560.
41. Calvert M, Kyte D, Mercieca-Bebber R, et al. Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols: The SPIRIT-PRO Extension. *JAMA* 2018;319(5):483-94.
42. Crocker TF, Brown L, Clegg A, et al. Quality of life is substantially worse for community-dwelling older people living with frailty: systematic review and meta-analysis. *Qual Life Res* 2019;28(8):2041-56.
43. Saraiva MD, Apolinario D, Avelino-Silva TJ, et al. The Impact of Frailty on the Relationship between Life-Space Mobility and Quality of Life in Older Adults during the COVID-19 Pandemic. *J Nutr Health Aging* 2021;25(4):440-47.
44. The Japan Radio-Taiso Federation. Information of certified instructors and regional bases. 2022 [Available from: https://www.radio-exercises.org/ accessed March 10 2022.

FIGURE LEGENDS

Figure 1. Pictures of the Radio-Taiso as a firmly established, traditional Japanese exercise programme.

A: Community-dwelling children get together to practice Radio-Taiso. B: Physical education classes. C: Practice in the workplace. D: Gathering and practising during community events. All pictures are provided by courtesy of the Japan Post Insurance Co.,

Ltd.

Figure 2. A conceptual model for explaining the mechanisms of the effect of the home-based Radio-Taiso exercise programme.

HR-QoL: health-related quality of life, PCS: physical component summary, MCS: mental component summary, and RCS: role/social component summary

Figure 3. Study flow diagram.

IC: informed consent, RT: Radio-Taiso

Figure 1. Pictures of the Radio-Taiso as a firmly established, traditional Japanese exercise programme. A: Community-dwelling children get together to practice Radio-Taiso. B: Physical education classes. C: Practice in the workplace. D: Gathering and practising during community events. All pictures are provided by courtesy of the Japan Post Insurance Co., Ltd.

169x166mm (330 x 330 DPI)

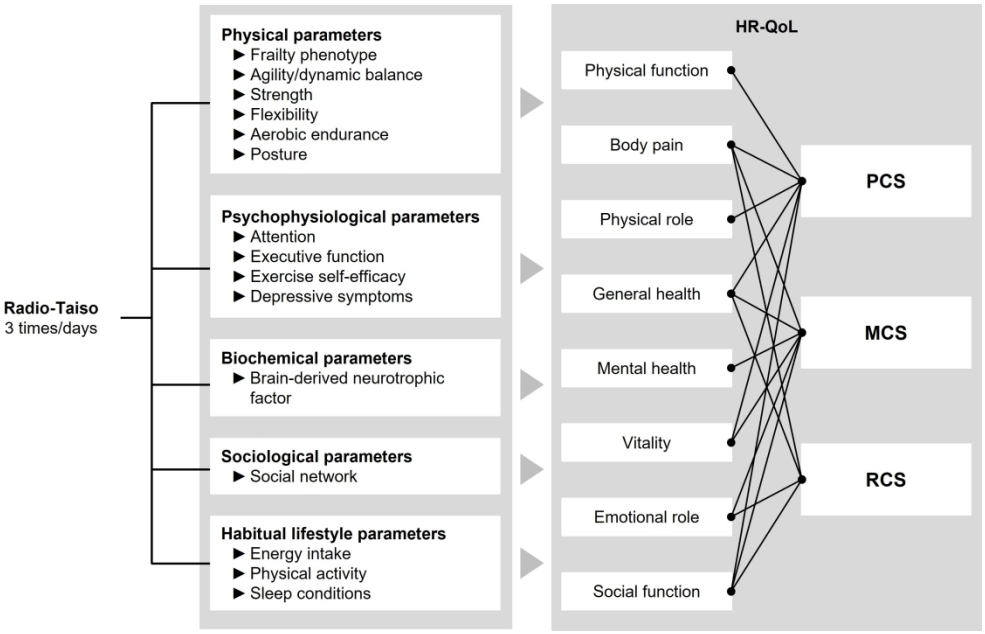

Figure 2. A conceptual model to explain the mechanisms of the effect of the home-based Radio-Taiso exercise programme. HR-QoL: health-related quality of life, PCS: physical component summary, MCS: mental component summary, and RCS: role/social component summary

255x160mm (330 x 330 DPI)

Figure **3.** Study timeline of enrolment, interventions, and assessments.

Study events	Enrolment	IC	Baseline assessment	Instruction	Intervention (84 days)							Follow-up assessment
Days	**-90**	**-60**	**0**	**7**	**14**	**21**	**28**	**35**	**49**	**63**	**91**	**98**
Allowance	±30	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3
ENROLMENT:												
Eligibility assessment	X	X	X									
IC		X										
Allocation			X									
INTERVENTIONS:												
RT exercise program				X	X	X	X	X		X		
Nutrition program				X	X	X	X	X				
ASSESSMENTS:												
Baseline variables			X									
Outcome variables			X									X
Adverse events						X		X	X	X	X	

Supplementary Table 1. Radio-Taiso part 1 (3 min 10 sec)

	Movement	Purpose
1	Stretch entire body	Raising the arms and stretching the entire body helps to achieve better posture
2	Swing the arms and bend the legs	Swinging the arms to the sides while bending and stretching the legs helps to stimulate blood circulation throughout the body
3	Arm rotations	Rotating the arms in large circles helps to keep the shoulder joint flexible.
4	Chest stretches	Opening up the chest helps to correct posture and promote respiratory function.
5	Bends to each side	Bending the upper body to the side helps to maintain the flexibility of the spine to make lateral movements.
6	Backward and forward bends	Stretching the back and abdomen helps to maintain the flexibility of the spine to make forward and backward movements.
7	Body twists	Twisting the body helps to stretch the muscles around the hips and maintain the flexibility of the spine to make rotational movements.
8	Stretch the arms up and down	Stretching the arms up and down quickly and powerfully helps to develop strength and instantaneous power.
9	Bend the body downwards at an angle and chest stretches	Bending the body downwards helps to develop muscle flexibility from the back to the back of the legs. By opening the chest, posture is corrected and respiratory function is improved.
10	Whole-body rotation	Rotating the upper body in a large circle helps to increase the flexibility of the entire spine, especially its lower back portion.
11	Jumps	Making rhythmic jumps helps to promote blood circulation throughout the body and increase leg strength.
12	Swing the arms and bend the legs	Swinging the arms to the side and bending and stretching the legs together while being aware of

		breathing helps the person take time to organise their body, mind, and breath.
13	Deep breath	Breathing deeply while moving the arms widely helps bring the body back to a normal state.

URL: https://www.youtube.com/watch?v=_YZZfaMGEOU

Supplementary Table 2. Radio-Taiso part 2 (3 min 5 sec)

	Movement	Purpose
1	Shake the whole body	Making light jumps helps to shake and relax the whole body and prepare it for the exercises.
2	Bend and stretch the arms and legs	Vigorously bending and stretching the arms and legs helps to promote blood circulation throughout the body.
3	Open arms from the front and rotate	Opening and rotating of the arms helps to relax the muscles around the shoulder and increase the range of motion of the shoulder joint.
4	Chest stretches	Opening up the chest helps to correct posture and promote respiratory function.
5	Bends to each side	Bending the upper body to the side helps to maintain the flexibility of the spine to make lateral movements.
6	Backward and forward bends	Stretching the back and abdomen helps to maintain the flexibility of the spine to make forward and backward movements.
7	Body twists	Twisting the body helps to stretch the muscles around the hips and maintain the flexibility of the spine to make rotational movements.
8	One-legged jump and step exercise	Making jumps and steps with just one leg helps to increase muscle strength, instantaneous power in the legs, and blood circulation throughout the body.
9	Bend backwards with twist and bend downwards at angle	Twisting and bending the whole body helps to stretch the muscles of the torso and chest and increase flexibility.
10	Tilt the body forward	Moving the upper body up and down while leaning forward helps to strengthen the muscles of the back and achieve better posture.
11	Jumps	Making rhythmic jumps helps to promote blood circulation throughout the body and increase leg

		strength.
12	Swing the arms and bend the legs	Swinging the arms and bending the legs together while being aware of breathing helps the person to take some time to organise the body, mind, and breath.
13	Deep breath	Breathing deeply while moving your arms widely helps to bring the body back to a normal state.

URL: https://www.youtube.com/watch?v=yi1TbzML2cU

Supplementary Table 3. Minna no Taiso (4 min 30 sec)

	Movement	Purpose
1	Hands and arms exercises	Moving the hands and arms well promotes peripheral blood circulation and the development of a sense of movement.
2	Chest exercise	Making chest movements helps to correct posture and improve respiratory function.
3	Upper body bounce	Bouncing the entire body while bending the upper body helps to relax the whole body, promote blood circulation, and maintain chest flexibility.
4	Neck exercises	Moving and stretching the neck helps to stretch the muscles from the neck to the shoulders and stimulate blood circulation in these areas.
5	Moving quickly	Quickly extending the arm while shifting the body weight helps to increase the instantaneous power of the whole body.
6	Leg and hip exercises	Moving the legs and hip helps to strengthen the muscles of these parts, increase hip flexibility, and a sense of balance.
7	Arm and leg exercises	Making movements with the arms and legs that lead the person to try to make the arm movements match the movements of the whole body helps to develop coordination of movement.
8	Deep breath	Breathing deeply while moving your arms widely helps to bring the body back to a normal state.

URL: https://www.youtube.com/watch?v=1MGsuinRElk

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

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 2
	2b	All items from the World Health Organization Trial Registration Data Set	Not applicable
Protocol version	3	Date and version identifier	Page 2
Funding	4	Sources and types of financial, material, and other support	Page 18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Pages 18
	5b	Name and contact information for the trial sponsor	Page 17–18
	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	Page 17–18
	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)	Not applicable

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 4
	6b	Explanation for choice of comparators	Page 4
Objectives	7	Specific objectives or hypotheses	Pages 4–5
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 5
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 5
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)	Pages 5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Pages 6–8
	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)	Page 7
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Pages 7–8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 6
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	Pages 8–14
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)	Figure 3

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	Pages 15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6
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 6
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 6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Not applicable
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	Pages 8–14 Page 15
	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	Pages 7–8

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 15
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 15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Pages 16
	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)	Pages 16
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. Alternatively, an explanation of why a DMC is not needed	Not applicable
	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	Not applicable
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 14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not applicable
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 16
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 16

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
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 6
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 18–19
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 19
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	Page 6
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 16
	31b	Authorship eligibility guidelines and any intended use of professional writers	Not applicable
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Not applicable
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary Material 2
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	Not applicable

*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.

2022年5月9日｜第14.0版

同意書

東京都健康長寿医療センター

センター長　殿

私は、「フレイル高齢者に対するラジオ体操の有効性を検討するランダム化並行群間比較試験」（研究代表者：大須賀洋祐）の概要についての詳細な説明を受け、自らの意思で研究に参加します。また、検査および調査結果の学術的な目的での利用に同意します。

説明を受け、理解した項目に☑してください。

- ☐ 1. 研究タイトル
- ☐ 2. 研究の背景
- ☐ 3. 研究の目的と意義
- ☐ 4. 研究の具体的な内容
- ☐ 5. 調査内容
- ☐ 6. 研究に参加することにより期待される利益と不利益
- ☐ 7. 予測される有害事象と健康被害への補償
- ☐ 8. 研究結果の取り扱い
- ☐ 9. 個人情報の保護および資料等の保管・廃棄の方法
- ☐ 10. 同意の自由と同意撤回
- ☐ 11. 費用の負担
- ☐ 12. 研究資金源および本研究に関わる利益相反
- ☐ 13. 研究計画の情報公開の方法
- ☐ 14. お問合せ先

参加者

署名日　令和4年　　月　　日

ご氏名：＿＿＿＿＿＿＿＿＿＿＿＿

説明者

署名日　令和4年　　月　　日

氏名：＿＿＿＿＿＿＿＿＿＿＿＿

Note from the Editors: Instructions for reviewers of study protocols

Since launching in 2011, BMJ Open has published study protocols for planned or ongoing research studies. If data collection is complete, we will not consider the manuscript.

Publishing study protocols enables researchers and funding bodies to stay up to date in their fields by providing exposure to research activity that may not otherwise be widely publicised. This can help prevent unnecessary duplication of work and will hopefully enable collaboration. Publishing protocols in full also makes available more information than is currently required by trial registries and increases transparency, making it easier for others (editors, reviewers and readers) to see and understand any deviations from the protocol that occur during the conduct of the study.

The scientific integrity and the credibility of the study data depend substantially on the study design and methodology, which is why the study protocol requires a thorough peer-review.

BMJ Open will consider for publication protocols for any study design, including observational studies and systematic reviews.

Some things to keep in mind when reviewing the study protocol:

- Protocol papers should report planned or ongoing studies. The dates of the study should be included in the manuscript.
- Unfortunately we are unable to customize the reviewer report form for study protocols. As such, some of the items (i.e., those pertaining to results) on the form should be scores as Not Applicable (N/A).
- While some baseline data can be presented, there should be no results or conclusions present in the study protocol.
- For studies that are ongoing, it is generally the case that very few changes can be made to the methodology. As such, requests for revisions are generally clarifications for the rationale or details relating to the methods. If there is a major flaw in the study that would prevent a sound interpretation of the data, we would expect the study protocol to be rejected.

BMJ Open

Effects of a home-based Radio-Taiso exercise programme on health-related quality of life in older adults with frailty: protocol for an assessor-blind randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-063201.R2
Article Type:	Protocol
Date Submitted by the Author:	27-Aug-2022
Complete List of Authors:	Osuka, Yosuke; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Kojima, Narumi; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Sugie, Masamitsu; Tokyo Metropolitan Geriatric Hospital and Institute of Gerontology, Department of Cardiology Omura, Takuya; Tokyo Metropolitan Institute of Gerontology, Department of Geriatric Medicine Motokawa, Keiko; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Ueda, Takuya; Tokyo Metropolitan Institute of Gerontology, The Tokyo Metropolitan Support Center for Preventative Long-term and Frail Elderly Care Maruo, Kazushi; University of Tsukuba, Department of Biostatistics, Faculty of Medicine Ono, Risa; Japan Radio-Taiso Federation Aoyama, Toshihiko; Japan Radio-Taiso Federation Inoue, Shigeru; Tokyo Medical University, Department of Preventive Medicine and Public Health Kim, Hunkyung; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health Sasai, Hiroyuki; Tokyo Metropolitan Institute of Gerontology, Research Team for Promoting Independence and Mental Health
Primary Subject Heading:	Public health
Secondary Subject Heading:	Geriatric medicine, Mental health, Sports and exercise medicine
Keywords:	GERIATRIC MEDICINE, MENTAL HEALTH, PUBLIC HEALTH, SPORTS MEDICINE

Effects of a home-based Radio-Taiso exercise programme on health-related quality of life in older adults with frailty: protocol for an assessor-blind randomised controlled trial

Yosuke Osuka[1], PhD; Narumi Kojima[1], MS; Masamitsu Sugie[2], MD, PhD; Takuya Omura[3], MD, PhD; Keiko Motokawa[1], PhD; Takuya Ueda[4], PhD; Kazushi Maruo[5], PhD; Risa Ono[6], MS; Toshihiko Aoyama[6]; Shigeru Inoue[7], MD, PhD; Hunkyung Kim[1], PhD; and Hiroyuki Sasai[1], PhD

[1]Research Team for Promoting Independence and Mental Health, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan
[2]Department of Cardiology, Tokyo Metropolitan Geriatric Hospital and Institute of Gerontology, Tokyo, Japan
[3]Department of Geriatric Medicine, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan
[4]The Tokyo Metropolitan Support Center for Preventative Long-term and Frail Elderly Care, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan
[5]Department of Biostatistics, Faculty of Medicine, University of Tsukuba, Tsukuba, Japan
[6]Japan Radio-Taiso Federation, Tokyo, Japan
[7]Department of Preventive Medicine and Public Health, Tokyo Medical University, Tokyo, Japan

Corresponding author
Yosuke Osuka, PhD
Research Team for Promoting Independence and Mental Health,
Tokyo Metropolitan Institute of Gerontology
35-2 Sakae-cho, Itabashi-ku, Tokyo 173-0015, Japan.
Phone: +81-3-3964-3241; Email: osuka@tmig.or.jp

Word count
5124/4000 words

ABSTRACT

Introduction

Few clinical trials have examined the effects of home-based exercise programmes on health-related quality of life (HR-QoL) in older adults with frailty. Radio-Taiso is the most famous exercise programme in Japan. A home-based Radio-Taiso exercise programme may serve as an accessible, scalable, and sustainable care intervention for older adults with frailty. The primary aim of this trial is to test whether older adults with frailty who are prescribed our home-based Radio-Taiso exercise programme will receive greater benefits for HR-QoL compared to those who are not prescribed the exercise programme. Potential mechanisms underlying the effectiveness of the programme and the effects of the programme on daily lifestyle will also be investigated.

Methods and analysis

This assessor-blind randomised controlled trial will be conducted at the Tokyo Metropolitan Institute of Gerontology (TMIG) in Itabashi-ku, Tokyo, Japan. From April to May 2022, 226 older adults with pre-frailty or frailty according to the revised Japanese version of the Cardiovascular Health Study criteria will be included from a large database. After a baseline assessment in June 2022, participants will be randomly assigned to the intervention (home-based Radio-Taiso exercise and nutrition programme) or control groups (nutrition programme) at a 1:1 ratio. After intervention completion, a follow-up assessment will be conducted in September 2022. The primary outcome is the change in the mental domain of HR-QoL assessed using SF-36®. Secondary outcomes include physical and role/social domains and subscales of HR-QoL, frailty phenotype, physical fitness, posture, cognition, exercise self-efficacy, depressive symptoms, brain-derived neurotrophic factor, social network, habitual energy intake, physical activity, and sleep conditions.

Ethics and dissemination

The Research Ethics Committee of TMIG has approved the research protocol. This trial will be conducted in accordance with the principles of the Declaration of Helsinki. The findings will be presented at international academic conferences and published in peer-reviewed international journals.

Trial registration

Registry name: UMIN-CTR

URL: https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000053863

Protocol version

Date: 9 May 2022

Version identifier: 4.4

Strengths and Limitations

- The feasibility of this Phase III trial has been enhanced based on the processes, resources, management, and scientific data of a pilot trial.
- The trial will include older adults with frailty defined using a validated assessment tool.
- Random allocation, blinding of assessors and analysts, interpretation of results based on the intention-to-treat principle, and disclosure of protocol papers will reduce the risk of selection, measurement, reduction, and reporting bias.
- The non-blinding of allocation information to participants and care providers may increase the risk of performance bias.
- The generalisability of the study findings to non-Japanese populations is unclear.

INTRODUCTION

Frailty is defined as vulnerability of homeostatic responses to stressors due to cumulative age-related decline of physiological systems.[1] Research suggests that 7% and 47% of older adults have frailty and pre-frailty, respectively, and their risk of falls, disabilities, nursing home admission, and death is significantly higher than that of robust older adults.[2] Interventions to reduce frailty prevalence and severity may benefit older adults with care needs, their caregivers, and the public social insurance system. However, clinical trials involving older adults with frailty defined using validated assessment tools are required to confirm the effectiveness of these interventions.[1]

Interventions such as exercise and nutritional programmes are useful for reducing the prevalence of frailty, but stakeholders have raised concerns that research on these interventions has focused predominantly on improving physical outcomes.[3] Studies focusing on patient-reported outcomes (e.g. health-related quality of life [HR-QoL]) may address the gaps between scientific evidence and clinical practice.[4] Exercise interventions are reportedly the most effective for improving HR-QoL among older adults with frailty, but this warrants validation in robust clinical trials.[5] Nevertheless, evidence for the effects of home-based exercise interventions on HR-QoL remains scarce.[6] As older adults with frailty exhibit decreased mobility,[7] readily available home-based exercise programmes are feasible and rational interventions.

Radio-Taiso is the most famous Japanese exercise programme, with reports suggesting that approximately 96.9% of the national population are aware it.[8] In 1928, the Postal Life Insurance Bureau of the Ministry of Communications (successor agency: Japan Post Insurance Co., Ltd.) developed Radio-Taiso as a “National Health Exercise” to improve health among Japanese people.[9] Radio-Taiso is customarily practiced in numerous settings and is firmly established in Japanese culture (Figure 1).[10] It is broadcasted daily by the Japan Broadcasting Corporation via public radio and television, thus facilitating home access by Japanese older adults with frailty.

Our recent pilot randomised controlled trial examined the feasibility and potential effectiveness of a home-based Radio-Taiso exercise programme in community-dwelling older adults with pre-frailty and frailty. Participants demonstrated high adherence and the results suggested that the programme may lead to clinically important improvements in the mental domain of HR-QoL (under review). However, the effectiveness of the programme remains to be validated by robust clinical trials.

This trial aims to test whether older adults with pre-frailty and frailty who undergo the programme will experience greater benefits in the mental domain of HR-QoL compared to those who do not undergo the programme. Further, the trial aims to identify

the mechanisms underlying programme effectiveness and the impact of the programme on participants' lifestyles (Figure 2).

METHODS AND ANALYSIS

Study design, setting, and procedures

This is a 12-week randomised, assessor-blind, parallel-design, two-arm, phase III trial. The protocol was designed in accordance with the SPIRIT statement (Supplementary Material 1) and several aspects of the SPIRIT-PRO Extension.

All outcomes will be assessed at the Tokyo Metropolitan Institute of Gerontology (TMIG) in Itabashi-ku, Tokyo, Japan. Participants will practice the programme at home. Six face-to-face group sessions will be conducted at the TMIG or nearby community facilities (Figure 3). Recruitment will be conducted in April 2022. Informed consent will be obtained in the subsequent month (May 2022). Baseline and follow-up assessments will be conducted in June and September 2022, respectively. After baseline assessments, participants who meet the eligibility criteria will be included in the trial and randomly assigned to the intervention (home-based Radio-Taiso exercise programme + nutrition programme) or control (nutrition programme) groups. The intervention will begin and end in June and September 2022, respectively.

Participants

Inclusion criteria are: 1) aged 65 years or older; and 2) frailty or pre-frailty, as defined by the revised Japanese version of the Cardiovascular Health Study (J-CHS) criteria (see below).

Exclusion criteria are: 1) inability to participate in both baseline and follow-up assessments; 2) diagnosed with dementia or prescribed anti-dementia drugs; 3) self-reports of being unable to eat, excrete, dress, move, or bathe independently; 4) not allowed to exercise (except for light-intensity exercise) by the family physician; 5) unstable/severe medical conditions that prevent trial physicians from permitting study participation; 6) angina pectoris, myocardial infarction, or cardiac surgery in the past 3 months, having a terminal illness, or receiving palliative care; 7) practising Radio-Taiso exercises for ≥1 day/week for the past month; 8) participating in a specific rehabilitation programme; 9) unable to walk ≥10 m independently; 10) participating or will participate in other clinical trials; 11) lacking a television at home; 12) difficulty communicating in Japanese; 13) deemed by the principal investigator and/or trial physicians to be ineligible; and 14) unable to provide consent to participate.

Potential participants will be recruited from a large database of trial-ready cohorts

managed by the TMIG. In our pilot trial in 2020, 902 individuals were newly enrolled or had their information updated. Of these, 514 (60%) met the pre-frailty or frailty criteria and 186 (recruitment rate: 20.6%) met all eligibility criteria and were willing to participate. Thus, at least 1,097 new registrations or updates are required to ensure that the target number of 226 participants is reached (described in more detail in the sample size section).

Invitation letters and eligibility criteria checklists will be sent to individuals diagnosed with frailty or pre-frailty between October 2021 and March 2022. Participants who meet all eligibility criteria and intend to participate will be provided a detailed verbal explanation of the study (i.e. aims, procedures, confidentiality, possible benefits and disadvantages, anticipated risks, and methods to address risks). Only individuals who provide written informed consent will participate. If more individuals are willing to participate than the target sample size, participants will be randomly selected using a computer-generated random sequence. During baseline assessments, trial physicians will assess compliance with exclusion criteria numbered 2, 5, and 6.

Allocation and blinding

After baseline assessments, participants will be randomly allocated to the intervention and control groups at a 1:1 ratio. The sequence for generating the allocation code will be stratified by sex (male or female), age (<75 or ≥75 years), and frailty severity (pre-frail or frailty). Block randomisation will be applied.

The principal investigator (YO) at the TMIG will send identification codes of eligible participants to an allocator (KM) who has no contact with participants. KM will combine the codes with a prescribed randomisation code, which will be generated prior to baseline assessments. An independent research staff member will inform participants of their group based on the allocation code sent by KM. Group labels will not be disclosed to the assessor and statistical analyst until completion of the primary analysis.

Intervention

During the 12-week intervention period, participants will be instructed to avoid starting new exercise or nutrition programmes. To address the ethical disadvantages of the control group, a nutrition programme will be provided to both groups.

Home-based Radio-Taiso exercise programme

Radio-Taiso includes three exercise patterns: Radio-Taiso No. 1 and 2 and Minna no Taiso. These patterns comprise 8–13 rhythmic whole-body movements with music.

Each pattern starts with a low-intensity movement, gradually increases in intensity, and ends with another low-intensity movement, allowing safe practice. The smooth execution of movements requires fitness in various physical domains (strength, flexibility, endurance, and balance), making Radio-Taiso a multi-component exercise programme (details in Supplementary Tables 1–3).

The home-based programme comprises six 60-min face-to-face group sessions with a certified instructor from the Japan Radio-Taiso Federation and daily practice in participants' homes. Before the programme, the intervention group will receive a face-to-face group session on correctly performing the three exercise patterns. In the first 4 weeks of the intervention, participants will receive face-to-face group sessions on effectively performing the exercise programmes. In week 8, a face-to-face group session will be provided to review the key points of each exercise programme.

Participants will be instructed to complete a three-pattern exercise programme once daily at home by themselves via a broadcast by the Japan Broadcasting Corporation or on DVD. If the participants feel unwell while performing any exercise or feel that the exercise intensity is too high, they will be instructed to stop or reduce the number of sessions. Participants will be required to record (1) whether they performed the exercise programme and (2) compliance with key points for effective programme implementation in an exercise diary. On the day of face-to-face group sessions, research staff will check the exercise diary, adverse events, and participation in the new rehabilitation programme. In weeks when sessions are not provided, these details will be checked by telephone every fortnight.

The pilot trial confirmed good adherence to the home-based Radio-Taiso exercise programme (retention rate: 100%; median [interquartile range] practice rate: 97.6% [88.1%–98.8%]). However, no trend towards improvements in physical outcomes was observed. Radio-Taiso may not include properties that significantly improve physical outcomes because it predominately consists of flexibility exercises. However, thoroughly completing the purpose of each movement in Radio-Taiso necessitates quicker and larger movements, which require muscle endurance and whole-body endurance. In this regard, several participants who received face-to-face instructions in the pilot study reported that it is important to understand the purpose of each movement of the Radio-Taiso via face-to-face instructions to improve the quality of practice at home. Thus, to provide participants with a programme that yields better physical outcomes, the number of face-to-face sessions will be increased from three to six and include processes that help participants familiarise with the key points of the programme. An item will be added to the exercise diary to check compliance with these points.

Nutrition programme

The nutrition programme comprises: 1) distribution of a nutrition leaflet; 2) recording of a dietary variety score; and 3) telephonic nutrition counselling. One week before intervention onset, participants will receive a face-to-face briefing from a dietitian on programme implementation. A nutrition leaflet will be distributed once weekly during the first 4 weeks of the intervention, detailing the nutritional role and recommended intake amounts of protein, calcium, vitamins/minerals, and carbohydrates/fats, alongside specific recipes for the efficient intake of these nutrients. Participants will be instructed to record daily in a nutrition diary the consumption of 10 food groups (meat, seafood, eggs, soya and soya products, milk, green and yellow vegetables, seaweed, potatoes, fruit, and oil) using a dietary variety score. Participants will be requested to provide scores on intake of these food groups on a 10-point scale.[11] A high dietary variety score has been associated with lower frailty severity.[12] Participants will be allowed to call the dietitian 1 day per week to discuss how to proceed with the nutrition programme or to ask any questions.

Outcome measures

The primary outcome is changes in the mental component summary (MCS) score of HR-QoL. Secondary outcomes are the physical component summary (PCS) score, role/social component summary (RCS) score, and eight subscales of HR-QoL as well as frailty phenotype, agility/dynamic balance, strength, flexibility, aerobic endurance, posture, attention, executive function, exercise self-efficacy, depressive symptoms, brain-derived neurotrophic factor (BDNF), social network, habitual energy intake, physical activity, sleep conditions, safety, and adherence. All outcomes excluding habitual physical activity will be assessed at a baseline survey within 2 weeks prior to the start of the intervention and at a follow-up survey within 1 week after the end of the intervention (Figure 3).

Baseline information

Baseline information including age, sex, disease history (hypertension, heart disease, diabetes, hyperlipidaemia, osteoporosis, and respiratory disease), and low-back and knee pain will be obtained by face-to-face interview.

Assessments

Objective outcomes including physical fitness, posture, cognition, BDNF, and

physical activity will be assessed by research staff blinded to allocation information.

HR-QoL

HR-QoL will be assessed using the Japanese version of the SF-36, which is a widely used, reliable, and validated tool.[13 14] The SF-36 measures eight health domains: physical function, physical role, body pain, general health, vitality, social function, emotional role, and mental health. These domains are aggregated and scored into the MCS, PCS, and RCS (Figure 2).[15] These scores are standardised as T-scores using the 2017 Japanese national norm.[16] A change of three or more points in the MCS or two or more points in the PCS constitutes a minimal clinically important difference, enabling clinical interpretation of changes in scores.[17]

Frailty phenotype

Frailty phenotype will be assessed using Fried's frailty criteria, characterised by five limitations: slowness, weakness, exhaustion, low activity, and weight loss.[2] The trial will use the revised J-CHS criteria to define frailty (three or more limitations) and pre-frailty (one or two limitations).[18]

Slowness

Slowness will be assessed based on usual gait speed. An 11 m walking path will be used, with a 3 m acceleration/deceleration path at each end. The assessor will measure the time taken between the 3- and 8-m markers.[19] The measurement will be performed once. Slowness will be defined as a gait speed of less than 1.0 m/sec.

Weakness

Weakness will be assessed based on grip strength using a handheld Smedley-type dynamometer. Participants will be instructed to grip the device as strongly as possible with their dominant hand in a standing position.[19] The measurement will be performed once. Weakness will be defined as less than 28 and 18 kg for men and women, respectively.

Exhaustion

Exhaustion will be assessed using question 25 of the Kihon checklist developed by the Ministry of Health, Labour and Welfare, as follows:[20] "In the last 2 weeks, have you felt tired for no reason?" Exhaustion will be defined as a "yes" response.

Low activity

Low activity will be assessed using two simple questions regarding participation in exercise or physical activity, as follows: 1) "How often do you engage in light intensity exercise or calisthenics?" and 2) "How often do you engage in exercise or sports activities"? Low activity will be defined by a response of "less than once a week" to both questions.

Weight loss

Weight loss will be assessed using question 11 of the Kihon checklist developed by the Ministry of Health, Labour and Welfare, as follows:[20] "Have you lost 2 kg or more in the past 6 months?" Weight loss will be defined as a "yes" response.

Physical fitness

Six physical fitness domains (agility/dynamic balance, lower body strength, upper body strength, lower body flexibility, upper body flexibility, and aerobic endurance) will be assessed using Senior Fitness Tests.[21]

Agility and dynamic balance

Agility and dynamic balance will be assessed using the 8-foot up-and-go test. Participants will be instructed to stand up at the start signal, walk around a cone 8 ft away, turn around, and sit down again. This sequence must be performed as quickly as possible. After one practice session, two trials will be performed. The values for the minimum time required will be used in the analysis.

Lower body strength

Lower body strength will be assessed using the chair stand test. At test onset, participants will be instructed to stand up and sit down again with their arms crossed in front of the chest. After 2–3 practice sequences of this exercise, a single trial will be performed, in which the sequence is repeated as quickly as possible for 30 s. The number of sequences achieved will be used in the analysis.

Upper body strength

Upper body strength will be assessed using the arm curl test. Participants will be requested to flex and extend the elbow of the dominant arm while holding a dumbbell (8 lb for men and 5 lb for women) at the start signal, with both upper arms in a natural down position. After 2–3 practice sequences, a single trial will be performed, in which the

sequence will be repeated as quickly as possible for 30 s.

Lower body flexibility

Lower body flexibility will be assessed using the chair sit-and-reach test. Participants will be requested to sit in a shallow position on a chair and extend their favourite leg. Participants will then be instructed to place the fingertips of both hands together, slowly flex the upper body towards the toes of the favourite leg until reaching their limit, and remain still for 2 s. Participants will be instructed to hold the ankle joint at 90°. The assessor will measure the distance between the toes of the favourite leg and fingertips of both hands using a ruler. After two practice sessions, the measurements will be performed twice. The best values will be used in the analysis.

Upper body flexibility

Upper body flexibility will be assessed using the back scratch test. In an upright position, the participant will be instructed to rotate the favourite hand backwards obliquely upward and the other hand backwards obliquely downward to the posterior region. The assessor will measure the shortest distance between the middle fingers of both hands using a ruler. The measurement will be performed twice. The best values will be used in the analysis.

Aerobic endurance

Aerobic endurance will be assessed using a 2-min step-in-place test. The assessor will mark a wall with masking tape midway between the participant's patella and iliac crest. The participant will be instructed to stand next to the wall and march in place for 2 min. Participants who face difficulties marching for the 2 min will be allowed to take a break and hold the wall or a stable chair. The assessor will record the number of times the right knee reaches the marker within 2 minutes. The trial will be conducted once.

Anthropometric indices

Height, body weight, and body mass index

Height will be measured using a digital height meter (DSN-70; MURATEC-KDS Corporation, Kyoto, Japan). Body weight is measured using a body composition analyser (InBody770, InBody Co. Ltd., Seoul, Korea). Body mass index is calculated by dividing the weight (kg) by the square of the height (m).

Posture

Posture will be assessed by the degree of kyphosis and the range of motion of the

spine. The degree of kyphosis is assessed by the thoracic kyphosis angle (KA) and lumbar lordosis angle.[22 23]

Thoracic KA and lumbar lordosis angles are measured using the Idiag M360 (Idiag AG, Switzerland). The participant is first instructed to stand in a normal position, and then the assessor moves the Idiag M360 along the spinous processes from the vertebra prominens (C7) to the third cervical vertebra (C3). The trial is conducted once, and the smaller the angle of the thoracic KA, the severer the kyphosis, whereas the larger the lumbar lordosis angle, the severer the kyphosis.[22 23]

The range of motion of the spine is measured using the Idiag M360 (Idiag AG, Switzerland).[22 23] The assessor moves the Idiag M360 over the spinous processes from C7 to C3 in the maximum forward flexion and extension positions. Range of motion is assessed as the difference between the thoracic KA and lumbar lordosis angle at maximum forward flexion and maximum extension, based on the angles measured for the thoracic KA and lumbar lordosis angle.

Cognition

Attention and executive function will be assessed using Parts A and B of the trail making test (TMT).[24] In Part A, participants must connect the numbers in ascending order, and the time taken for finalising the task is measured (i.e. 1-2-3-4...). In Part B, the task is to connect the numbers and kana characters in an alternating order (i.e. 1-A-2-I...), and the time taken to finalise the task is measured.

Home-based exercise self-efficacy

The participants' home-based exercise self-efficacy will be assessed using the Home-Exercise Barrier Self-Efficacy Scale.[25] Participants will be asked to respond to six exercise situations at home (1: when I am tired, 2: when I am in pain, 3: when I do not feel very good, 4: when I do not have time, 5: when I do not have the equipment or environment to exercise, 6: when I am alone) on a 5-point Likert scale ranging from 1 (*not at all confident*) to 5 (*absolutely confident*). Details on items and scoring are described in prior research.[25] Total scores range from 6–30, with higher scores indicating greater self-efficacy in home-based exercise.

Depressive symptoms

Depressive symptoms will be assessed using the short version of the Geriatric Depression Scale.[26] Participants will be asked to answer to 15 yes-or-no questions about their daily mood. Details on items and scoring are described in prior research.[26]

Total scores range from 0–15, with higher scores indicating a more depressed mood.

BDNF

BDNF is the most widely expressed neurotrophin in the mammalian brain and an important regulator of the development and function of neural circuits in the brain.[27] Exercise-induced BDNF mediates neuronal differentiation and growth, synapse formation and plasticity, and may explain how exercise training improves mental health and cognitive function.[28]

Participants will fast for at least two hours and a blood sample will be collected from the anterior elbow vein. To exclude the potential effects of acute exercise, participants will be asked to refrain from engaging in vigorous intensity exercise for 36 hours before the blood sample collection. To control for diurnal variation, participants will have their blood drawn at the same time of day in both the baseline and follow-up assessments. Blood samples will be processed according to the manufacturer's specifications: plasma is obtained by centrifugation at 3,000 g for 10 min at 22°C, aliquoted, and stored at -80°C until measurement. Plasma samples will be assessed for BDNF concentrations using a commercially available two-site sandwich enzyme-linked immunosorbent assay kit (R&D Systems, Minneapolis, MN, USA). The analysis will be conducted centrally in an independent laboratory.

Social network

Social network will be assessed using the Japanese version of the Lubben Social Network Scale-6 (LSNS-6).[29] Participants will answer six questions regarding support, indicating the number of family members and friends who can provide them with emotional and instrumental support from the five given options. Details on items/scoring are described in prior research.[29] Total scores range from 0–30, with higher scores indicating a larger social network.

Habitual energy intake

Habitual energy intake will be assessed using a reliable and valid, brief, self-administered diet history questionnaire developed to provide a simple estimate of energy intake over the past month.[30 31] Participants will be asked to recall their average dietary habits over the past month and indicate the frequency of consumption of each food item. Habitual energy intake will be calculated using special software provided by Gender Medical Research Co. Japan.

Habitual physical activity

Habitual physical activity levels will be assessed based on the average number of daily steps taken. The number of steps will be measured using validated tri-axis accelerometers and algorithms (Active style Pro HJA-750C; Omron Healthcare, Tokyo, Japan).[32 33] Participants will be instructed to wear the device around the waist for 7 days from baseline to follow-up assessments during all activities of daily living, from waking to bedtime, except for underwater activities (e.g. bathing and swimming). A record is valid if the device is worn for at least 10 h/day.[34] If valid records are collected for more than three days, the number of daily steps is calculated.

Habitual sleep conditions

Sleep conditions will be subjectively assessed using the Japanese version of the Pittsburgh Sleep Quality Index,[35 36] comprising seven components: sleep quality, time to fall asleep, time stayed asleep, sleep efficiency, difficulty sleeping, use of sleeping pills, and difficulty waking up during the day in the past month. Details on items and scoring are described in prior research.[35 36] Total scores range from 0–21, with higher scores indicating a worse subjective sleep condition.

Adverse events

Adverse events are defined in this study as any undesirable/unintended sign, symptom, or disease occurring during the intervention, regardless of causality. The number of adverse events that occur during the intervention period will be assessed. Trial physicians will determine adverse event severity and potential relevance to the intervention. Any adverse events (e.g. subjective symptoms, falls, and other surgical or medical findings) suspected to be related to the intervention will be recorded. Every fortnight, research staff will ask participants, telephonically or in person, whether they have experienced an adverse event.

Adherence

Adherence will be assessed via the retention rate during the intervention period and the rate of practice of the Radio-Taiso exercise programme. The retention rate will be calculated as the percentage of participants who complete the follow-up assessment. The rate of practice of the programme will be calculated by dividing the number of practice days (days when the exercises are practiced at least once a day) by 84 days. The total number of practice sessions of the programme will also be assessed.

Sample size

Based on the pilot trial, the effect size (Cohen's d) of the programme on the MCS score is 0.395. Using G*Power version 3.1.9.2 for Windows (Heinrich-Heine-Universität Düsseldorf, Germany),[37] with the alpha error set at 5%, a power of 80%, and this effect size, the sample required is 204. Considering a 10% drop-out rate, the target sample is 226.

Data management

Data quality control comprises 1) measurements based on established standard operating procedures, 2) manual checks (visual checks) of questionnaires and case reports, and 3) data entry using the double-entry method. Manual checks include confirmation of compliance with eligibility criteria, missing measurements, and value ranges. After entering all the data, the person responsible for the analysis will perform logical checks (programming checks) and data coding to ensure and fix any issues pertaining to data quality. These checks include examining for outliers.

Statistical analysis

As "tests of baseline homogeneity" in randomised controlled trials do not have any practical value,[38] comparison of baseline characteristics will not be performed in this study. At baseline, continuous variables are presented as means (standard deviations) or medians (interquartile ranges), and categorical variables as n (%).

Main analysis

To test programme effectiveness, changes in the primary outcome will be compared between the groups using an ANCOVA model adjusted for allocation stratification factors and baseline values. Changes in secondary outcomes will be compared using the same model. Differences between groups in the change of each outcome will be expressed as differences in adjusted means (95% confidence intervals). Statistical significance will be set at a $P < 0.05$.

The results of the main analyses will be interpreted based on the intention-to-treat principle. The full analysis set will exclude participants 1) who are subsequently found not to meet the eligibility criteria; 2) who never participated in the intervention programme; or 3) for whom no post-randomisation data are available;[39] the resulting sample will be applied as the main analysis population. The International Council for Harmonisation guideline recommends applying a full analysis set that excludes these participants from the main analyses as a conservative strategy.[39]

Additional analyses

Additional analyses using a per-protocol set will be conducted to assess the extent to which adherence affects the results. The per-protocol set will include participants who have practiced at least 75% of the stipulated home-based Radio-Taiso exercises.[40]

A sensitivity analysis will be performed to assess heterogeneity owing to missing follow-up data (missing data bias). Missing data will be processed through multiple imputation by applying the chained equation method to generate 20 imputed datasets based on the outcome, allocation, and group variables at baseline.

To assess study generalisability, subgroup analyses will be conducted based on participants' background data (male vs female, <75 vs ≥75 years of age, and frailty vs pre-frailty).

Retention rates and the incidence of adverse events (one or more for those who report them) will be compared between groups using Fisher's exact test or the χ-square test. All analyses will be carried out using R version 4.1.2 or higher (The R Foundation for Statistical Computing, Vienna, Austria).

Patient and public involvement

This study will be conducted without participant involvement. Participants will not be invited to comment on study design, define relevant outcomes, or interpret the results, nor contribute to the writing or editing of this paper for readability or accuracy.

ETHICS AND DISSEMINATION

The research protocol will be conducted in accordance with the Declaration of Helsinki. The Research Ethics Committee of TMIG approved the protocol on 16 December 2021. The study protocol was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) on 20 March 2022 (trial registration no. UMIN000047229). All amendments to the study protocol will be disclosed to UMIN-CTR.

Study results will be presented at an international scientific conference and reported in a peer-reviewed international journal. After publication, a summary of the results will be published on the TMIG and Japan Post Insurance Co., Ltd. websites.

DISCUSSION

Few trials have examined the effect of exercise interventions on HR-QoL in older adults with frailty, diagnosed with validated assessment tools.[3 5 6] Thus, this robustly

designed trial will strengthen the evidence needed for or against the effectiveness of home-based exercise programmes on HR-QoL. International health policy bodies, regulators, and patients are increasingly recognising the importance of patient-reported outcomes, including HR-QoL, for health.[41] The results of this study will provide valuable insights that may serve to address the evidence and clinical practice gaps associated with care programmes for older adults with frailty. This study will also contribute to a better understanding of the potential mechanisms by which home-based exercise programmes can improve HR-QoL, by analysing various secondary outcomes.

Researchers have systematically compared HR-QoL between frailty and non-frailty groups, showing a moderate or greater standardised mean difference between the groups and that the frailty group had a worse HR-QoL.[42] The measures to curb the COVID-19 pandemic also limit the life-space mobility of older adults with frailty and have a significant impact on QoL.[43] Patient-reported outcomes from clinical trials using scientifically robust methodologies are reflected in clinical decision-making and influence health and social care policy.[41] Thus, if this study helps to clarify the effectiveness of the proposed programme on HR-QoL, this may enable invested stakeholders to develop a policy framework for care programmes of older adults with frailty.

For a care programme targeting people with frailty to be implemented in public health policy, it must be accessible (i.e. low cost and high acceptability/availability) and be delivered equitably and continuously.[4] A care programme that draws on existing cultural and social resources may be able to meet these requirements. In Japan, the Radio-Taiso exercise programme has a long history of being customarily watched in different settings and is familiar to many older adults; thus, it is a cultural exercise programme in the country.[10] In fact, our pilot trial confirmed that adherence to the programme is very high and that it is highly compatible with daily life. Radio-Taiso is also available at low cost to everyone via television/radio on a daily basis. To date, more than 24,600 certified Radio-Taiso instructors have been trained, and the programme is practised nationwide at more than 2,000 regional bases.[44] Rich in cultural and social resources, the Radio-Taiso exercise programme may serve as a socially implementable public health strategy.

This study has several limitations. First, although the study addresses measurement, attrition, and reporting bias, participants and treatment providers will not be blinded to allocation information; this increases the risk of performance bias and reduces effect estimation accuracy. Second, calisthenic programmes such as Radio-Taiso are popular in some countries, such as China, Korea, and Scandinavian countries, but it remains unclear to what extent the usefulness of the Radio-Taiso exercise programmes is

generalisable to non-Japanese older adults with frailty.

Acknowledgments

We are grateful to the participants and the staff members of the TMIG.

Author contributions

Yosuke Osuka: study concept and design, data collection and interpretation, manuscript preparation. Narumi Kojima: study concept and design, data collection and interpretation, manuscript preparation. Masamitsu Sugie: study concept and design, safety assessment, manuscript preparation. Takuya Omura: study concept and design, safety assessment, manuscript preparation. Keiko Motokawa: study concept and design, data collection and interpretation, manuscript preparation. Takuya Ueda: study concept and design, data collection and interpretation, manuscript preparation. Kazushi Maruo: study concept and design, statistical advice, randomisation, data interpretation, manuscript preparation. Risa Ono: study concept and design, intervention, data interpretation, manuscript preparation. Toshihiko Aoyama: study concept and design, data interpretation, manuscript preparation. Shigeru Inoue: study concept and design, data interpretation, manuscript preparation. Hunkyung Kim: study concept and design, data interpretation, manuscript preparation. Hiroyuki Sasai: study concept and design, analysis, data interpretation, manuscript preparation.

Funding

This study will be conducted under a collaborative agreement between four institutions (TMIG, Tokyo Medical University, Japan Post Insurance Co., Ltd., and the Japan Radio-Taiso Federation). Japan Post Insurance Co., Ltd. will financially support the study and will provide the Radio-Taiso DVD free of charge but will not be involved in the design of the study, selection of methods, recruitment of participants, data collection, analysis and interpretation, or writing of the manuscript.

The Japan Radio-Taiso Federation will provide certified Radio-Taiso instructors free of charge and will be involved in the design of the study, intervention, data interpretation, and writing of the manuscript.

Competing interests

Yosuke Osuka is the principal investigator of a joint research agreement between the four organisations; Risa Ono and Toshihiko Aoyama are accredited instructors for the Japan Radio-Taiso Federation. Japan Post Insurance Co., Ltd. and the Japan Radio-Taiso

Federation are committed to the promotion and dissemination of Radio-Taiso. The other authors have no conflicts of interest to declare.

Patient consent

Patient consent forms are attached in Supplementary Material 2

Ethics approval

Approved by the Research Ethics Committee of TMIG on 16 December 2021.

Data availability statement

Data are available upon reasonable request.

REFERENCES

1. Clegg A, Young J, Iliffe S, et al. Frailty in elderly people. *Lancet* 2013;381(9868):752-62.
2. Fried LP, Tangen CM, Walston J, et al. Frailty in older adults: evidence for a phenotype. *The Journals of Gerontology Series A, Biological Sciences and Medical Sciences* 2001;56(3):M146-56.
3. Puts MTE, Toubasi S, Andrew MK, et al. Interventions to prevent or reduce the level of frailty in community-dwelling older adults: a scoping review of the literature and international policies. *Age and Ageing* 2017;46(3):383-92.
4. Dent E, Martin FC, Bergman H, et al. Management of frailty: opportunities, challenges, and future directions. *Lancet* 2019;394(10206):1376-86.
5. Negm AM, Kennedy CC, Thabane L, et al. Management of frailty: a systematic review and network meta-analysis of randomized controlled trials. *J Am Med Dir Assoc* 2019;20(10):1190-98.
6. Clegg AP, Barber SE, Young JB, et al. Do home-based exercise interventions improve outcomes for frail older people? Findings from a systematic review. *Reviews in Clinical Gerontology* 2012;22(1):68-78.
7. Navarrete-Villanueva D, Gómez-Cabello A, Marín-Puyalto J, et al. Frailty and physical fitness in elderly people: a systematic review and meta-analysis. *Sports Med* 2021;51(1):143-60.
8. Japan Post Insurance Co., Ltd. Recognition and participation rates for "Radio-Taiso". 2021 [Available from: https://www.jp-life.japanpost.jp/information/assets/pdf/211011pr-6-2.pdf accessed March 10 2022.

9. Public Relations Office, Government of Japan. Higlighting Japan 2019 [14-15]. Available from: https://dwl.gov-online.go.jp/video/cao/dl/public_html/gov/book/hlj/20191001/html5.html#page=15137.
10. British Broadcasting Corporation. The lifelong exercise that keeps Japan moving. 2020 [Available from: https://www.bbc.com/worklife/article/20200609-the-life-long-exercise-that-keeps-japan-moving accessed March 10 2022.
11. Kumagai S, Watanabe S, Shibata H, et al. [Effects of dietary variety on declines in high-level functional capacity in elderly people living in a community]. *Nihon Koshu Eisei Zasshi* 2003;50(12):1117-24.
12. Motokawa K, Watanabe Y, Edahiro A, et al. Frailty Severity and Dietary Variety in Japanese Older Persons: A Cross-Sectional Study. *J Nutr Health Aging* 2018;22(3):451-56.
13. Fukuhara S, Bito S, Green J, et al. Translation, adaptation, and validation of the SF-36 Health Survey for use in Japan. *Journal of Clinical Epidemiology* 1998;51(11):1037-44.
14. Fukuhara S, Ware JE, Jr., Kosinski M, et al. Psychometric and clinical tests of validity of the Japanese SF-36 Health Survey. *Journal of Clinical Epidemiology* 1998;51(11):1045-53.
15. Suzukamo Y, Fukuhara S, Green J, et al. Validation testing of a three-component model of Short Form-36 scores. *Journal of Clinical Epidemiology* 2011;64(3):301-8.
16. Fukuhara S, Suzukamo Y. Manual of SF-36v2 Japanese version. Kyoto: iHope International Inc 2004, 2019.
17. Maruish ME. User's Manual for the SF-36v2 Health Survey: Quality Metric Incorporated 2011.
18. Satake S, Arai H. The revised Japanese version of the Cardiovascular Health Study criteria (revised J-CHS criteria). *Geriatr Gerontol Int* 2020;20(10):992-93.
19. Shinkai S, Watanabe S, Kumagai S, et al. Walking speed as a good predictor for the onset of functional dependence in a Japanese rural community population. *Age Ageing* 2000;29(5):441-6.
20. Sewo Sampaio PY, Sampaio RA, Yamada M, et al. Systematic review of the Kihon Checklist: Is it a reliable assessment of frailty? *Geriatrics & Gerontology International* 2016;16(8):893-902.
21. Rikli RE, Jones CJ. Development and validation of a functional fitness test for community-residing older adults. *J Aging Phys Act* 1999;7(2):129-61.

22. Mannion AF, Knecht K, Balaban G, et al. A new skin-surface device for measuring the curvature and global and segmental ranges of motion of the spine: reliability of measurements and comparison with data reviewed from the literature. *Eur Spine J* 2004;13(2):122-36.
23. Post RB, Leferink VJ. Spinal mobility: sagittal range of motion measured with the SpinalMouse, a new non-invasive device. *Arch Orthop Trauma Surg* 2004;124(3):187-92.
24. Army Individual Test Battery. Washington, DC: War Department: Adjutant General's Office 1944.
25. Arita N, Takenaka K, Shimazaki T. Development of a home-exercise barrier self-efficacy scale for elderly people requiring support and care. *Journal of the Japanese Physical Therapy Association* 2014;41(6):338-46.
26. Yatomi N. The factor structure and item characteristic of the GDS (Geratric Depression Scale) short version in a Japanese elderly sample. *Japanese Journal of Gerontology* 1994;16(1):29-36.
27. Park H, Poo MM. Neurotrophin regulation of neural circuit development and function. *Nat Rev Neurosci* 2013;14(1):7-23.
28. Knaepen K, Goekint M, Heyman EM, et al. Neuroplasticity - exercise-induced response of peripheral brain-derived neurotrophic factor: a systematic review of experimental studies in human subjects. *Sports Med* 2010;40(9):765-801.
29. Kurimoto A, Awata S, Ohkubo T, et al. [Reliability and validity of the Japanese version of the abbreviated Lubben Social Network Scale]. *Nihon Ronen Igakkai Zasshi* 2011;48(2):149-57.
30. Kobayashi S, Murakami K, Sasaki S, et al. Comparison of relative validity of food group intakes estimated by comprehensive and brief-type self-administered diet history questionnaires against 16 d dietary records in Japanese adults. *Public Health Nutrition* 2011;14(7):1200-11.
31. Kobayashi S, Honda S, Murakami K, et al. Both comprehensive and brief self-administered diet history questionnaires satisfactorily rank nutrient intakes in Japanese adults. *Journal of Epidemiology* 2012;22(2):151-9.
32. Oshima Y, Kawaguchi K, Tanaka S, et al. Classifying household and locomotive activities using a triaxial accelerometer. *Gait Posture* 2010;31(3):370-4.
33. Ohkawara K, Oshima Y, Hikihara Y, et al. Real-time estimation of daily physical activity intensity by a triaxial accelerometer and a gravity-removal classification algorithm. *Br J Nutr* 2011;105(11):1681-91.
34. Troiano RP, Berrigan D, Dodd KW, et al. Physical activity in the United States

measured by accelerometer. *Medicine and Science in Sports and Exercise* 2008;40(1):181-8.
35. Doi Y, Minowa M, Uchiyama M, et al. Psychometric assessment of subjective sleep quality using the Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J) in psychiatric disordered and control subjects. *Psychiatry Research* 2000;97(2-3):165-72.
36. Doi Y, Minowa M, Okawa M, et al. Development of the Japanese version of the Pittsburgh Sleep Quality Index. *Japan Journal of Psychiatry Treatment* 1998;13(6):755-63 (in Japanese).
37. Faul F, Erdfelder E, Lang AG, et al. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;39(2):175-91.
38. Senn S. Testing for baseline balance in clinical trials. *Stat Med* 1994;13(17):1715-26.
39. The International Council for Harmonisation. E9 Statistical Principles for Clinical Trials: The International Council for Harmonisation; 1998 [Available from: https://database.ich.org/sites/default/files/E9_Guideline.pdf accessed October 16 2021.
40. Hawley-Hague H, Horne M, Skelton DA, et al. Review of how we should define (and measure) adherence in studies examining older adults' participation in exercise classes. *BMJ Open* 2016;6(6):e011560.
41. Calvert M, Kyte D, Mercieca-Bebber R, et al. Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols: The SPIRIT-PRO Extension. *JAMA* 2018;319(5):483-94.
42. Crocker TF, Brown L, Clegg A, et al. Quality of life is substantially worse for community-dwelling older people living with frailty: systematic review and meta-analysis. *Qual Life Res* 2019;28(8):2041-56.
43. Saraiva MD, Apolinario D, Avelino-Silva TJ, et al. The Impact of Frailty on the Relationship between Life-Space Mobility and Quality of Life in Older Adults during the COVID-19 Pandemic. *J Nutr Health Aging* 2021;25(4):440-47.
44. The Japan Radio-Taiso Federation. Information of certified instructors and regional bases. 2022 [Available from: https://www.radio-exercises.org/ accessed March 10 2022.

FIGURE LEGENDS

Figure 1. Pictures of Radio-Taiso as a firmly established, traditional Japanese exercise programme.

A: Community-dwelling children get together to practice Radio-Taiso. B: Physical education classes. C: Practice in the workplace. D: Gathering and practising during community events. All pictures were provided by courtesy of Japan Post Insurance Co., Ltd.

Figure 2. A conceptual model for explaining the mechanisms of the effect of the home-based Radio-Taiso exercise programme.

HR-QoL: health-related quality of life, PCS: physical component summary, MCS: mental component summary, and RCS: role/social component summary

Figure 3. Study flow diagram.

IC: informed consent, RT: Radio-Taiso

Figure 1. Pictures of the Radio-Taiso as a firmly established, traditional Japanese exercise programme. A: Community-dwelling children get together to practice Radio-Taiso. B: Physical education classes. C: Practice in the workplace. D: Gathering and practising during community events. All pictures are provided by courtesy of the Japan Post Insurance Co., Ltd.

169x166mm (330 x 330 DPI)

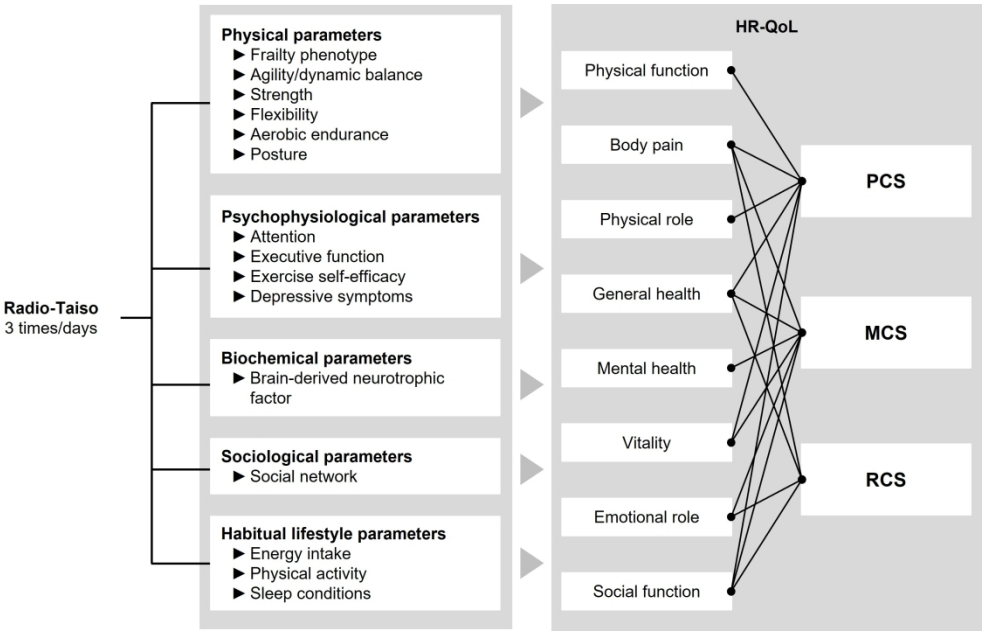

Figure 2. A conceptual model to explain the mechanisms of the effect of the home-based Radio-Taiso exercise programme. HR-QoL: health-related quality of life, PCS: physical component summary, MCS: mental component summary, and RCS: role/social component summary

255x160mm (330 x 330 DPI)

Figure **3.** Study timeline of enrolment, interventions, and assessments.

Study events	Enrolment	IC	Baseline assessment	Instruction	Intervention (84 days)							Follow-up assessment
Days	**-90**	**-60**	**0**	**7**	**14**	**21**	**28**	**35**	**49**	**63**	**91**	**98**
Allowance	±30	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3
ENROLMENT:												
Eligibility assessment	X	X	X									
IC		X										
Allocation			X									
INTERVENTIONS:												
RT exercise program				X	X	X	X	X		X		
Nutrition program				X	X	X	X	X				
ASSESSMENTS:												
Baseline variables			X									
Outcome variables			X									X
Adverse events						X		X	X	X	X	

Supplementary Table 1. Radio-Taiso part 1 (3 min 10 sec)

	Movement	Purpose
1	Stretch entire body	Raising the arms and stretching the entire body helps to achieve better posture
2	Swing the arms and bend the legs	Swinging the arms to the sides while bending and stretching the legs helps to stimulate blood circulation throughout the body
3	Arm rotations	Rotating the arms in large circles helps to keep the shoulder joint flexible.
4	Chest stretches	Opening up the chest helps to correct posture and promote respiratory function.
5	Bends to each side	Bending the upper body to the side helps to maintain the flexibility of the spine to make lateral movements.
6	Backward and forward bends	Stretching the back and abdomen helps to maintain the flexibility of the spine to make forward and backward movements.
7	Body twists	Twisting the body helps to stretch the muscles around the hips and maintain the flexibility of the spine to make rotational movements.
8	Stretch the arms up and down	Stretching the arms up and down quickly and powerfully helps to develop strength and instantaneous power.
9	Bend the body downwards at an angle and chest stretches	Bending the body downwards helps to develop muscle flexibility from the back to the back of the legs. By opening the chest, posture is corrected and respiratory function is improved.
10	Whole-body rotation	Rotating the upper body in a large circle helps to increase the flexibility of the entire spine, especially its lower back portion.
11	Jumps	Making rhythmic jumps helps to promote blood circulation throughout the body and increase leg strength.
12	Swing the arms and bend the legs	Swinging the arms to the side and bending and stretching the legs together while being aware of

		breathing helps the person take time to organise their body, mind and breath.
13	Deep breath	Breathing deeply while moving the arms widely helps bring the body back to a normal state.

URL: https://www.youtube.com/watch?v=_YZZfaMGEOU

Supplementary Table 2. Radio-Taiso part 2 (3 min 5 sec)

	Movement	Purpose
1	Shake the whole body	Making light jumps helps to shake and relax the whole body and prepare it for the exercises.
2	Bend and stretch the arms and legs	Vigorously bending and stretching the arms and legs helps to promote blood circulation throughout the body.
3	Open arms from the front and rotate	Opening and rotating of the arms helps to relax the muscles around the shoulder and increase the range of motion of the shoulder joint.
4	Chest stretches	Opening up the chest helps to correct posture and promote respiratory function.
5	Bends to each side	Bending the upper body to the side helps to maintain the flexibility of the spine to make lateral movements.
6	Backward and forward bends	Stretching the back and abdomen helps to maintain the flexibility of the spine to make forward and backward movements.
7	Body twists	Twisting the body helps to stretch the muscles around the hips and maintain the flexibility of the spine to make rotational movements.
8	One-legged jump and step exercise	Making jumps and steps with just one leg helps to increase muscle strength, instantaneous power in the legs, and blood circulation throughout the body.
9	Bend backwards with twist and bend downwards at angle	Twisting and bending the whole body helps to stretch the muscles of the torso and chest and increase flexibility.
10	Tilt the body forward	Moving the upper body up and down while leaning forward helps to strengthen the muscles of the back and achieve better posture.
11	Jumps	Making rhythmic jumps helps to promote blood circulation throughout the body and increase leg

		strength.
12	Swing the arms and bend the legs	Swinging the arms and bending the legs together while being aware of breathing helps the person to take some time to organise the body, mind, and breath.
13	Deep breath	Breathing deeply while moving your arms widely helps to bring the body back to a normal state.

URL: https://www.youtube.com/watch?v=yi1TbzML2cU

Supplementary Table 3. Minna no Taiso (4 min 30 sec)

	Movement	Purpose
1	Hands and arms exercises	Moving the hands and arms well promotes peripheral blood circulation and the development of a sense of movement.
2	Chest exercise	Making chest movements helps to correct posture and improve respiratory function.
3	Upper body bounce	Bouncing the entire body while bending the upper body helps to relax the whole body, promote blood circulation, and maintain chest flexibility.
4	Neck exercises	Moving and stretching the neck helps to stretch the muscles from the neck to the shoulders and stimulate blood circulation in these areas.
5	Moving quickly	Quickly extending the arm while shifting the body weight helps to increase the instantaneous power of the whole body.
6	Leg and hip exercises	Moving the legs and hip helps to strengthen the muscles of these parts, increase hip flexibility, and a sense of balance.
7	Arm and leg exercises	Making movements with the arms and legs that lead the person to try to make the arm movements match the movements of the whole body helps to develop coordination of movement.
8	Deep breath	Breathing deeply while moving your arms widely helps to bring the body back to a normal state.

URL: https://www.youtube.com/watch?v=1MGsuinRElk

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

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 2
	2b	All items from the World Health Organization Trial Registration Data Set	Not applicable
Protocol version	3	Date and version identifier	Page 2
Funding	4	Sources and types of financial, material, and other support	Page 18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Pages 18
	5b	Name and contact information for the trial sponsor	Page 17–18
	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	Page 17–18
	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)	Not applicable

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 4
	6b	Explanation for choice of comparators	Page 4
Objectives	7	Specific objectives or hypotheses	Pages 4–5
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 5
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 5
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)	Pages 5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Pages 6–8
	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)	Page 7
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Pages 7–8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 6
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	Pages 8–14
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)	Figure 3

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	Pages 15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6
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 6
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 6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Not applicable
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	Pages 8–14 Page 15
	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	Pages 7–8

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 15
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 15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Pages 16
	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)	Pages 16
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. Alternatively, an explanation of why a DMC is not needed	Not applicable
	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	Not applicable
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 14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not applicable
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 16
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 16

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
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 6
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 18–19
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 19
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	Page 6
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 16
	31b	Authorship eligibility guidelines and any intended use of professional writers	Not applicable
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Not applicable
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary Material 2
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	Not applicable

*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.

2022年5月9日｜第14.0版

同意書

東京都健康長寿医療センター

センター長　殿

私は、「フレイル高齢者に対するラジオ体操の有効性を検討するランダム化並行群間比較試験」（研究代表者：大須賀洋祐）の概要についての詳細な説明を受け、自らの意思で研究に参加します。また、検査および調査結果の学術的な目的での利用に同意します。

説明を受け、理解した項目に☑してください。

- ☐ 1. 研究タイトル
- ☐ 2. 研究の背景
- ☐ 3. 研究の目的と意義
- ☐ 4. 研究の具体的な内容
- ☐ 5. 調査内容
- ☐ 6. 研究に参加することにより期待される利益と不利益
- ☐ 7. 予測される有害事象と健康被害への補償
- ☐ 8. 研究結果の取り扱い
- ☐ 9. 個人情報の保護および資料等の保管・廃棄の方法
- ☐ 10. 同意の自由と同意撤回
- ☐ 11. 費用の負担
- ☐ 12. 研究資金源および本研究に関わる利益相反
- ☐ 13. 研究計画の情報公開の方法
- ☐ 14. お問合せ先

参加者

署名日　令和4年　　月　　日

ご氏名：＿＿＿＿＿＿＿＿＿＿＿＿＿＿

説明者

署名日　令和4年　　月　　日

氏名：＿＿＿＿＿＿＿＿＿＿＿＿＿＿