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地域在住高齢者における教室終了後の郵送プログラムが長期的な運動継続に与える効果：ランダム化比較試験のデザイン

大久保善郎[1,2,3]，鄭　　松伊[4]，大須賀洋祐[2]，重松　良祐[5]，清野　　諭[6]，
小林　裕幸[1,7]，宮地　元彦[8]，竹中　晃二[9]，田中喜代次[4]

Effect of post-exercise class mailing program on long-term exercise adherence among community-dwelling older adults: A study design for a randomized controlled trial

Yoshiro OKUBO[1,2,3], Songee JUNG[4], Yosuke OSUKA[2,4,6],
Ryosuke SHIGEMATSU[5], Satoshi SEINO[6], Hiroyuki KOBAYASHI[4,7],
Motohiko MIYACHI[8], Koji TAKENAKA[9], Kiyoji TANAKA[4]

抄録

背景：高齢者における運動教室終了後の運動継続率は依然低い．本稿では，高齢者の長期的な運動継続のための運動教室と郵送支援の有効性を検証するランダム化比較試験の研究デザインを報告する．

方法：本研究では，地域在住高齢者230名を，ランダム化された２群（郵送支援の有無）と補足的な非ランダム化（無介入）対照群に割付ける．全27ヵ月間の本研究には，３ヵ月間の運動教室，12ヵ月間の郵送支援，12ヵ月間の追跡が含まれる．運動教室では，３軸加速度計，目標設定とセルフモニタリングのための運動日誌を利用し，速歩，筋力運動，柔軟性運動の実践を学ぶ．教室修了後に，参加者を郵送支援（MP）群または非郵送支援（NMP）群にランダムに割付け，MP群は運動日誌と運動新聞の郵送を受ける．運動新聞は，運動の知識と社会的支援の提供，友人の運動実践による動機づけを狙いとしている．MP群は切手付き封筒を用いて月末に運動日誌を指導者に郵送する．15ヵ月および27ヵ月時の追跡時に，運動実践率に加え，身体機能，社会・心理・生理的評価項目を測定する．

考察：郵送支援による長期的な運動継続が実現すれば，習慣的な運動実践による高齢者の持続的な健康増進に繋がると考えられる．

臨床試験登録：UMIN Clinical Trials Registry（UMIN000015099）

[1] 筑波大学大学院人間総合科学研究科　Graduate School of Comprehensive Human Sciences, University of Tsukuba
[2] 日本学術振興会　The Japan Society for the Promotion of Science
[3] 神経科学研究オーストラリア 転倒バランス研究班　Falls and Balance Research Group, Neuroscience Research Australia
[4] 筑波大学体育系　Faculty of Health and Sport Sciences, University of Tsukuba
Kiyoji Tanaka　Faculty of Health and Sport Sciences, University of Tsukuba, Tsukuba, JAPAN
Phone: 029-853-2655 Fax: 029-853-2986　E-mail: tanaka@taiiku.tsukuba.ac.jp
[5] 三重大学教育学部　Faculty of Education, Mie University
[6] 東京都健康長寿医療センター研究所　Tokyo Metropolitan Institute of Gerontology
[7] 筑波大学附属病院 水戸地域医療教育センター　Mito Medical Center, Tsukuba University Hospital
[8] 国立研究開発法人医薬基盤・健康・栄養研究所　健康増進研究部　National Institutes of Biomedical Innovation, Health and Nutrition, Department of Health Promotion and Exercise
[9] 早稲田大学人間科学学術院　Faculty of Human Sciences, Waseda University

Background

Various health benefits of regular exercise among the older population, including reductions in mortality, cardiovascular disease, and physical frailty, have been demonstrated over the past several decades [1]. However, approximately 48% of older adults cease exercising within six months after the initiation of an exercise program [2], leading to a loss of training effects [3]. To overcome the increasing health issues affecting aging populations around the globe [4], effective ways for maintaining long-term exercise adherence are warranted.

The strategies utilized to promote exercise adherence involve the use of telephone [5], mass media [6], community-wide campaigns [7], home visits [8], the internet (using electronic devices) [9], and mailings [10]. The advantages of internet- and mail-based approaches include the ability to distribute information to a wide or specific target population. In contrast, an in-person approach, such as a traditional exercise class, is useful for the initial adoption of an exercise routine, which often requires not only cognitive awareness – which the internet and mailings can provide – but also physical assistance and hands-on training [11]. However, short-term exercise classes often lack structured long-term support to generalize the exercise behaviors learned in the supervised environments to non-supervised contexts. After individuals successfully incorporate an exercise routine into their daily lives, less intensive support and information delivered through mailings are useful for maintaining the exercise routine [12]. In terms of an immediate application for the current older population who may have difficulty using technology [13], a mail-based approach may be advantageous compared to an internet-based approach using electronic devices.

We developed a structured, exercise-promoting mailing program following initial exercise classes. The classes specifically focus on guiding older participants to acquire "habitual exercise" by developing self-regulatory skills, including goal setting, exercising in their daily lives, and self-monitoring. The acquired habitual exercise routine will then be supported indirectly through the mailing program, which includes exercise newsletters and diaries. Although such coordinated approaches involving the use of a mailing program have the potential to promote maintenance of long-term exercise adherence among the older population, they have not been adequately examined. Therefore, this study will assess the effect of a mailing program on long-term exercise adherence among community-dwelling older adults.

Methods

Study design

The study design is a two-arm, parallel, randomized controlled trial with a supplemental, non-randomized control arm. The 27-month long study consists of a three-month exercise class, 12-month mailing program, and 12-month follow-up period without any support.

Ethical considerations

The study protocol was developed in accordance with the guidelines proposed in the Declaration of Helsinki and was approved by the Research Ethics Committee of the Faculty of Health and Sport Sciences of the University of Tsukuba, Japan (TAI26-38, 7-Aug-2014). The protocol was registered with the UMIN Clinical Trials Registry (UMIN000015099). The trial began in December 2014 and will continue until March 2017. We held a meeting for all potential participants to explain the study purpose, measurements that would be used and 27-month study design and to obtain written informed consent.

Participants

A flow diagram of the study participants is presented in Figure 1. The study participants were recruited through advertisements in a community newspaper. The eligibility criteria were as follows: aged 65 years or older; not care-dependent or support-dependent on the Japanese long-term care insurance system; not restricted from exercising by a doctor; able to walk without a walking aid; and no regular exercise habits. The exclusion criteria were as follows: participation in moderate-intensity (≥ 3.5 metabolic equivalents (METs)) exercise ≥ 150 min/week or strength exercise ≥ 2 days/week [1, 14] or participation in another clinical trial.

Physical activity is known to positively influence health and well being [1]. Thus, it was considered unethical to randomize inactive older adults who were willing to participate in a physical activity program into a control group and then ask them to continue their sedentary lifestyle. Therefore, we asked applicants who would be excluded due to a high frequency of regular exercise

and who agreed not to change their current exercise routine during the intervention period (3 months) to be included in the active control (AC) group. The AC group participated in all study assessments but not the intervention programs.

Randomization

After the post-intervention assessment, the participants were allocated into either the MP or non-mailing program (NMP) group using the permuted block method, with stratification by exercise adherence during the intervention (high/low), age (< 75 years/≥ 75 years) and gender at an allocation ratio of 1:1 (Figure 1). A researcher (who is not a co-author) performed the random group allocations using computer-generated random numbers and sent the assignments to a researcher via email. Then, this researcher notified the participants by mail. Each participant was instructed not to disclose their allocation or contents of the letter to the other participants.

Exercise class to initiate habitual exercise

The participants participated in an exercise class focused on introducing a new exercise habit into their daily lives. This class consisted of twelve 90 min sessions held at a university once per week for 12 weeks. Each session consisted of a warm-up (10-20 min), brisk walking (30-50 min), muscle strengthening (20-30 min) and a cool-down (10 min). The exercise program, which is focused on improving endurance, gait, and muscle strength [15], was designed to be simple, to not require the use of equipment, and to be feasible at any location, so that long-term exercise adherence would be possible for all participants.

Brisk walking on a safe pedestrian road was performed by groups of people with similar fitness levels and trained exercise instructors who ensured for their safety and proper walking forms. Brisk walking was defined as an exercise intensity of approximately 3.6 METs [16] or higher, as determined using a tri-axial accelerometer (Estyle-2, Suzuken Inc., Aichi, Japan) worn according to the manufacturer's instructions (placed in a pant or chest pocket). The duration of walking was extended from 30 min (approximately 3 km) during the 1st week to 50 min (approximately 5 km) by the 12th week. When walking outside was not feasible due to the weather conditions, a walking-related exercise [17] or cycling using stationary bikes were performed to ensure that a similar amount of aerobic exercise was performed. Brisk walking for 30 to 50 min for 3 to 5 days was also be recommended as home-based exercise [1]. Each participant received a tri-axial accelerometer to wear every day until the 27-month follow-up assessment. The participants were asked to manually record their brisk walking durations (min/day) in their exercise diaries for self-monitoring.

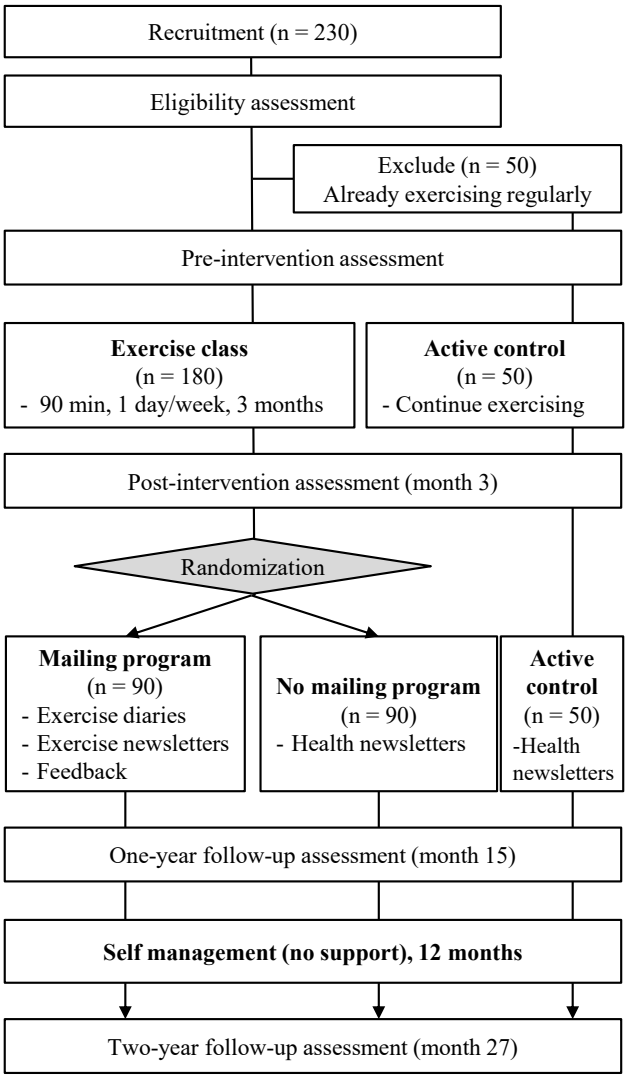

Figure 1. Flow chart of the study participants.

Muscle strengthening of the lower extremities and trunk using body weight was also be performed. Muscle strengthening consisted of ankle dorsiflexions and plantar flexions, hip abductions, squats, and sit-ups, with 10 to 20 repetitions using slow, consistent movements to ensure for sufficient tension in the target

muscle groups [18]. Stretching of the shoulder, back, hip, calf, hamstrings, thighs, and ankles were performed as warm-up and cool-down exercises. Muscle strengthening and stretching for three to five days were also recommended as home exercises, and the participants were asked to record their training in their exercise diaries.

The exercise diaries were used to create exercise habits based on planning, recording, monitoring, and self-evaluation (Figure 2). Each exercise diary included sections for goal setting, recording of daily exercises, reflection on exercises performed over the month, and feedback from an instructor. The participants were instructed to set their monthly exercise goals considering the generally recommended standard (brisk walking, 150 min/week; and muscle strengthening and stretching, 2 sets/week), their health conditions, daily and occasional schedules, and recent exercise histories (an increase in 10% from the last month was recommended). Brisk walking (minutes), muscle strengthening (sets), stretching (sets), and other exercises or physical activities (blank space) were recorded as daily exercises. The participants were asked to calculate the weekly and monthly exercise amounts, determine whether they have achieved their monthly goals, evaluate themselves (0 to 100 points), reflect on their exercise habits over the month (achievements, positive efforts, problems, and possible solutions) (no more than 140 Japanese characters or approximately 70 English words), and submit the completed records. Then, the instructors reviewed the exercise diaries and wrote brief feedback comments (no more than 70 Japanese characters or approximately 35 English words). The feedback comments focused on ensuring for effective self-monitoring and building exercise habits into the participants' daily lives. These comments included praise, suggestions, answers, recognition, sympathy, and encouragement.

During the last month of the 3-month exercise class, the participants were encouraged to lead muscle strengthening exercises for each other or to assist other participants to ensure that they have acquired the proper skills and knowledge to continue their exercise habits after completion of the class. At the end of the 3-month exercise class, a lecture was conducted by a university professor to encourage exercise maintenance. The exercise diaries were provided to the participants for one year to continue recording their exercises completed; however, they were told that they could stop recording and/or exercising any time that they wish. In addition to the brisk walking, muscle strengthening, and stretching exercises, the participants were permitted to start other types of exercises but were asked not to participate in other research projects related to exercise or physical interventions.

Mailing support program

Participants allocated to the MP group received the 12-month mailing support program, including the exercise diaries and newsletters (Figures 2 and 3). The participants were asked to send their exercise diaries to the instructors at the end of each month using a stamped envelope. The instructors reviewed the diaries and provide brief feedback as previously described and then returned them to the participants along with an exercise newsletter within two weeks.

The exercise newsletter consisted of sections containing a greeting from an exercise instructor, scientific information regarding exercise, a list of the participants' names who achieved their exercise goals, comments from participants, and announcements. These newsletters were designed to promote long-term exercise adherence by older people by expanding their knowledge about exercise [19], providing social support from the exercise instructors [20], and strengthening their self-efficacy by demonstrating that their friends are also exercising. The scientific topics covered included the proper walking form, ideal frequency, timing, duration, intensity, and health benefits of exercise, goal setting, managing joint pain, and preventing falls and heat syndromes. Several comments from the participants (from their exercise diaries) expressing positive efforts, successes, the overcoming of physical or environmental issues, and learning experiences/findings related to exercise habits were selected by the exercise instructors. Groups of participants who exercise together were able to post short announcements regarding their activities.

The NMP and AC groups received health newsletters with a similar format. They included a greeting from an exercise instructor and scientific information about health (i.e., information about diet, managing knee pain, prevention of falls and heat syndrome) but did not include exercise information and were mailed four times during the one-year follow-up period.

The mailing support program continued from the post-intervention assessment (month 3) to the one-year follow-up assessment (month 15). To determine whether this program leads to long-term exercise habits via goal setting, self-monitoring, and problem solving, no support will be provided between the one- and two-year follow-up assessments. The participants used the same exercise diaries and tri-axial accelerometer for 12 months, and were encouraged to maintain their exercise habits.

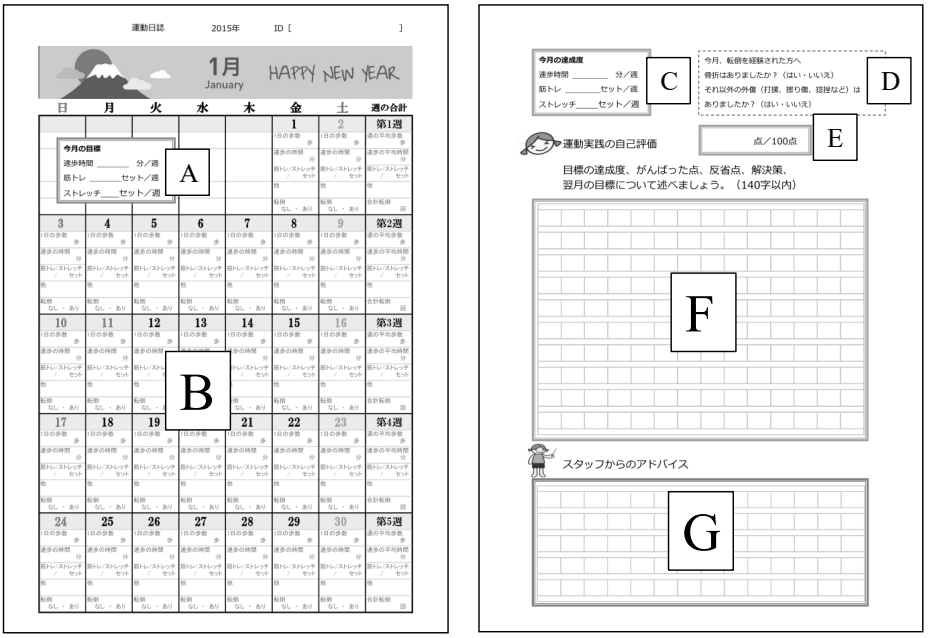

Figure 2. An example of an exercise diary. Each exercise diary included sections for goal setting [A], recording of daily exercises (steps, brisk walking time, strength and flexibility exercises, other exercises, and falls) [B], exercise completed over the month [C], injuries from falls [D], self-evaluation [E], reflection on exercises performed over the month [F], and feedback from an instructor [G].

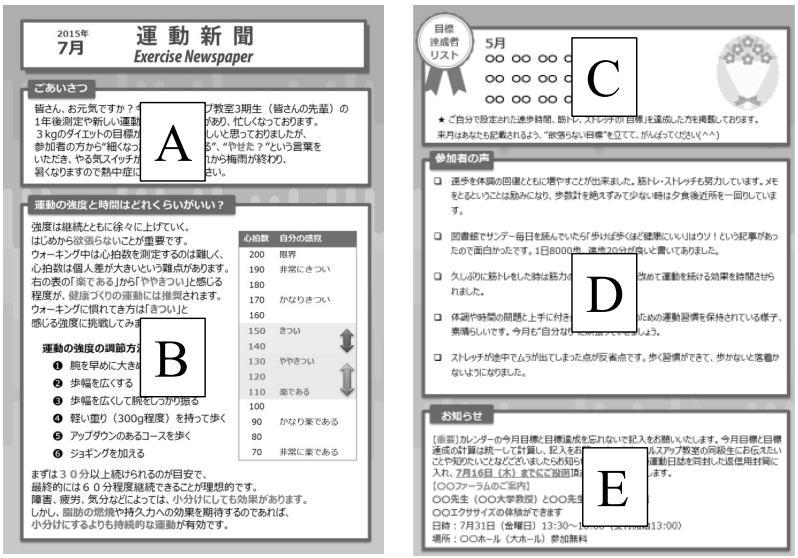

Figure 3. An example of an exercise newsletter. Each exercise newsletter consisted of sections containing a greeting by an exercise instructor [A], scientific information regarding exercise [B], a list of participant's names who achieved their exercise goals [C], comments from participants [D], and announcements [E]. These newsletters were designed to promote long-term exercise adherence by older people by expanding their knowledge about exercise, provide social support from the exercise instructors, and strengthening their self-efficacy by demonstrating that their friends are also exercising.

Data collection

Assessments will be conducted at baseline and at the 3-, 9-, 15-, and 27-month follow-ups (Table 1) by trained assessors who are blinded to the group allocations. To maintain blinding, the participants will be instructed not to reveal their group allocations or programs to the assessors.

Primary outcome

The primary outcome measure is exercise adherence at the 27-month follow-up. Exercise adherence will be assessed in terms of brisk walking, muscle strengthening, and stretching. The amount of actual exercise relative to the amount of total recommended exercise during the follow-up period will be used to assess the outcome measure. Participants who do not provide an exercise diary will be followed up by telephone.

Secondary outcomes

Functional fitness will be evaluated using the Senior Fitness Test battery [21], which consists of six items designed and validated to assess the physiological parameters that support physical mobility in older adults. Rikli *et al.*[21] reported a high validity coefficient (c) for older adults on all tests ($c \geq 0.75$). The physical fitness parameters selected are lower and upper body strength, lower and upper body flexibility, agility/dynamic balance and aerobic endurance. The items will be evaluated, respectively, using the following tests: 30-s chair stand (repetitions), arm curl (repetitions), chair sit-and-reach (cm), back scratch (cm), 8-ft up-and-go (s), and 6-min walk (m). In addition, hand grip strength will be assessed using a hand-held dynamometer (GRIP-D, T.K.K. 5401; Takei Scientific Instruments, Tokyo, Japan).

Social and psychological factors that potentially mediate the effects of a mailing support program on exercise adherence will be assessed. These factors include the stages of readiness to exercise [22], exercise self-efficacy [23], exercise-related social support [24], and a physical activity enjoyment [25, 26].

Economic evaluation

The cost of the initial exercise classes and mailing support program will be recorded.

Adverse events

Adverse events, which may be related to the mailing support program, will be assessed via questionnaires administered at the end of the program.

Other health-related factors

Body weight and fat and muscle volumes will be measured by multi-frequency bioelectrical impedance analysis (MC-980A, TANITA Inc., Tokyo, Japan). Body height, spinal curvature, and lower limb length will also be measured.

Disease diagnosis and prescribed medications will be assessed using participant medicine notebooks. Smoking, drinking, and living statuses, outing frequency, unintentional weight loss, the number of falls in the last year, fall-related injuries, fear of falling, urinary incontinence, the Tokyo Metropolitan Institute of Gerontology Index of Competence [27], and mobility limitation [28] will be assessed via questionnaires. Falls and fall-related injuries will be monitored via exercise diaries that the participants will be asked to complete each day.

Pre-planned sub-studies

Qualitative study: Focus-group interviews of participants (with low, medium, and high adherence) will be conducted to identify the effective components of the mailing support program. To ensure for objectivity, the interview will be conducted by a co-author who is an expert in qualitative analyses and has no other contact with the participants during the study. The interviews will be conducted three times. The groups will consist of several participants with low, medium, or high adherence during the post-intervention period.

Study of muscle quality: The changes in muscle quality over the study period will be assessed via muscle strength per muscle cross-sectional area [29, 30]. Electromyography recordings of the rectus femoris, vastus lateralis and vastus medialis, obtained using a multi-telemeter system (WEB-5000; Nihon Kohden Corp., Tokyo, Japan), and the thigh intermediate cross-sectional area, measured by magnetic resonance imaging (AIRIS Light (0.25-T); Hitachi Medical Corp., Tokyo, Japan), will be assessed. The maximum isometric knee extension strength will be determined using a wire strain gauge dynamometer (μ Tas MF-01; Anima Corp., Hamamatsu, Japan).

Table 1. List of measurements collected at baseline, 3-, 9-, 15-, and 27-month assessments

Category	Measurements	BL	M3	M9	M15	M27
Exercise adherence						
	Monthly exercise diary (brisk walking (≥3 METs using a tri-axial accelerometer), strength training, and stretching)		✔		✔	✓[P]
	Exercise history (type, frequency, time, subjective intensity, and continuity)	✔	✔		✔	✔
Functional fitness						
	Senior fitness tests (30s-chair stand, arm curl, chair sit-and-reach, back scratch, 8-ft up-and-go, and 6-min walk), hand grip strength	✔	✔		✔	✓[S]
Psychosocial factors						
	Physical activity enjoyment scale, social support, exercise self-efficacy, stages of exercise behavior change, exhaustion on CES-D, general health perceptions/physical role functioning on SF-36, Geriatric Depression Scale-revised	✔	✔		✔	✓[S]
Economic evaluation			✔		✔	
Adverse events					✔	
Health-related factors						
	Multi-frequency bioelectrical impedance analysis (body fat and muscle volumes), body weight and height, spinal curvature, lower limb length	✔	✔		✔	✔
	Disease diagnosis, prescribed medications, blood pressure, smoking, drinking, and living statuses, outing frequency, unintentional weight loss, falls, fall-related injuries, fear of falling, urinary incontinence, mobility limitation, Tokyo Metropolitan Institute of Gerontology Index of Competence	✔	✔		✔	✔
Qualitative study						
	Focus group interview [a]			✔		✔
	Comment descriptions (health issues, questions, achievements, commitment, excuses, etc.) in monthly exercise diaries		✔		✔	✔
Study of muscle quality						
	Electromyography (rectus femoris and vastus lateralis/medialis), magnetic resonance imaging (thigh intermediate cross-sectional area) [b], maximum isometric knee extension [b]	✔	✔		✔	✔

ADL: activity of daily living, BL: baseline, CES-D: Center for Epidemiologic Studies Depression Scale, M: month, METs: metabolic equivalents, SF-36: 36-Item Short Form Survey

[a] Assessed in a subsample (n = 18)

Sample size

To detect differences in exercise adherence between the intervention (75%) and control groups (50%) with 80% power and 5% alpha error, 164 participants are needed for final analysis. Considering a 10% refusal and 20% dropout rate, a total of 230 participants were recruited.

Statistical analyses

A co-author who is blinded to the group allocations will conduct pre-planned statistical analyses of the primary and secondary outcomes with an intention-to-treat basis. To maintain blinding, he will have no contact with the participants and will use random numbers to identify the group allocations. Missing data, including those from dropouts, will be imputed using the multiple imputation method, [31] with the exception of exercise adherence data, for which missing data indicates termination of exercise.

Linear mixed-effects models will be used to assess the effects of group, time and the group × time interaction on all primary and secondary outcomes. If a substantial difference in a variable is observed at baseline, then it will be adjusted using analysis of covariance.

Bonferroni adjustment will be applied for post-hoc multiple comparisons. The chi-square test will be used for categorical variables.

The data will be analyzed using IBM SPSS Statistics software, version 21 (SPSS Inc., IL, USA), and Stata 14.0 (StataCorp, TX, USA), and the level of significance will be set at 5%.

Discussion

This study will be the first RCT to examine the effect of a post-exercise class mailing program on long-term exercise adherence among community-dwelling older adults. The mailing program coordinated with an exercise class cultivates self-regulatory skills, such as goal setting and self-monitoring. We hypothesize that the participants in the MP group will maintain significantly higher exercise adherence at the 15- and 27-month follow-ups compared to those in the NMP and AC groups. Their increased exercise adherence at the 15-month follow-up will support the effectiveness of the mailing support program, which will be indirectly supervised by exercise instructors. Higher exercise adherence at the 27-month follow-up will indicate retention of self-regulatory skills and incorporation of exercise into their daily lives. According to the trans-theoretical model of exercise behavior change [22], an exercise class can shift people from the preparation and contemplation stages into the action stage. The mailing program is expected to guide the participants into the maintenance stage, which is essential for acquiring the enduring health benefits of regular exercise (Figure 4).

In an RCT performed by Kriska *et al.* [32], long-term exercise adherence was encouraged among middle-aged women using a monthly log, social gatherings, birthday, sympathy and get-well cards, phone calls and home visits, newsletters, and awards. Although the trial demonstrated success, with increasing walking activities of the women over two years, the effect of long-term exercise adherence on physical function was not evaluated [32]. Although walking is a widely accepted form of exercise [33, 34], the intensity of walking at home may not always be sufficient to improve the physical fitness of older adults [35]. In our current trial, brisk walking (≥ 3.6 METs) was performed, and its duration was used for self-monitoring. Brisk walking, which is equivalent to moderate- to vigorous-intensity physical activity, is significantly associated with lower-extremity performance [36, 37]. Further study is necessary to determine effective methods for promoting adherence to muscle strengthening and flexibility exercises among older adults, as these exercises are essential for maintaining their functional fitness levels[38, 39].

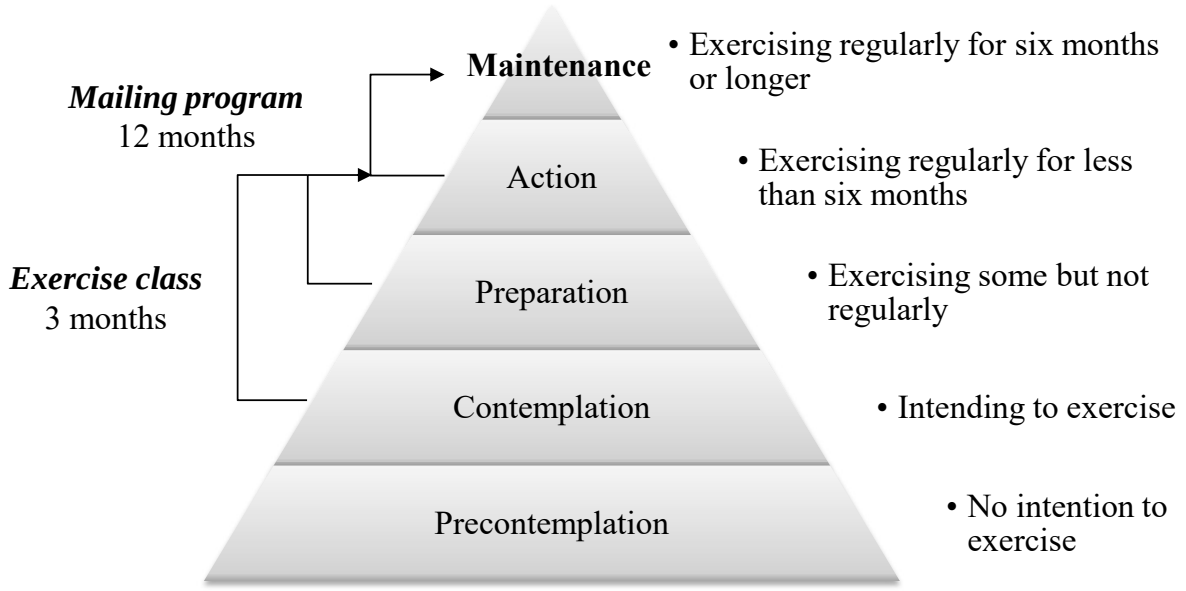

Figure 4. Hypothesized role of the mailing program in the stages of exercise behavior change. The mailing program is expected to bring participants from the action stage into the maintenance stage, which is most important for achieving the enduring health benefits of regular exercise.

Long-term exercise adherence in all of our study groups will likely be slightly higher than usual because the participants will be aware that they are being observed[40]. However, this study can accurately examine whether long-term exercise adherence is higher in the MP group than in the NMP group. Although the mailing program is expected to play an important role in maintaining long-term exercise adherence, the effect of the initial exercise class is not negligible. The brisk walking, muscle strengthening and flexibility exercises were selected for their high feasibilities at home. Exercises requiring machines or an instructor would be difficult to continue beyond the exercise class. The use of an exercise diary during the exercise class is also important because it requires assistance by an exercise instructor. It is expected that the participants will experience some reversion to an inactive lifestyle when they encounter various challenging situations, such as undesirable weather conditions, an inconvenient time of day, being alone, negative emotions, and fatigue [41]. The mailing program was designed to encourage the participants to self-monitor and reflect on issues and to create their own coping strategies.

In addition to quantitative assessments of social and psychological mediating factors, qualitative assessments involving a focus group interview and analysis of the participants' comments will clarify how the mailing support program affects the coping issues and maintenance of habitual exercise in their daily lives of the participants. If the mailing program successfully promotes long-term exercise adherence and maintenance of functional fitness, it will enable older adults to obtain the enduring health benefits of regular exercise. The results will expand our knowledge regarding mechanisms and methods for supporting exercise behavior changes among older adults.

Acknowledgement

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