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ORIGINAL RESEARCH

Intervention for Social Frailty Focusing on Physical Activity and Reducing Loneliness: A Randomized Controlled Trial

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Purpose: During the COVID-19 pandemic, older adults living in the community experienced reduced physical activity (PA) and heightened loneliness, particularly those with less frequent outings—a key factor of social frailty. Promoting PA may foster social participation, increase outings, and reduce loneliness. This study investigates the effects of a multi-component intervention on PA and loneliness in socially frail older adults.

Materials and Methods: This single-blind, randomized controlled trial included 64 participants aged ≥ 60 years with social frailty and pre-frailty defined according to Makizako's Social Frailty Index. Participants were randomly assigned to either the intervention (n = 34) or the control (n = 30) group. Over eight weeks, the intervention group attended a weekly 60-min multi-component program that included health education, exercise, and self-monitoring. A simple exercise booklet was distributed to the control group at baseline. For both groups, outcome measures were assessed at baseline and after eight weeks. PA was assessed using a triaxial accelerometer. Loneliness was measured using the three-item version of the UCLA Loneliness Scale. We used repeated-measures analysis of variance with group-by-time interactions to estimate the intervention effects following the intention-to-treat approach.

Results: PA was not affected by the intervention. A significant group-by-time interaction was observed for loneliness, with a medium effect size ($p < 0.05$), indicating that loneliness was significantly reduced in the intervention group compared to the control group.

Conclusion: The multi-component program aimed at promoting PA may contribute to the building of social relationships and reducing loneliness in older adults with social frailty and pre-frailty.

Keywords: community-dwelling older adults, loneliness, multi-component program, physical activity, social frailty

Introduction

Social frailty is defined as an individual's increased risk of experiencing a decline in social functioning and is characterized by a lack of social resources, weak social networks, and low levels of social engagement.[1] During the COVID-19 pandemic, social distancing measures have had adverse effects on the mental and physical health of older adults.[2] Physical activity (PA) decreased among older adults.[3] In addition, older adults experience more loneliness compared to the pre-pandemic period.[4] Our previous study revealed that during the pandemic, community-dwelling older adults who went out less frequently reported lower PA and increased feelings of loneliness.[5] A lower frequency of going out, a factor of social frailty, could also be a risk factor for incident disability among community-dwelling older adults.[6] The frequency of going out is used as a screening measure for housebound status[7] and is associated with social and environmental factors such as non-participation in organizational activities and a lack of close friends.[8,9] Therefore, promoting PA may provide an opportunity for older adults with social frailty to form social networks that encourage them to go out more frequently and reduce their loneliness.

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PA can extend the years of active independent living, reduce disability, and improve the quality of life in older adults.[10] Moreover, it is beneficial for mental health.[11] A previous study demonstrated that those with social frailty had poorer mental health during the pandemic and that forming exercise habits at home helped maintain a healthy mental health status.[12] Furthermore, an increase in social support due to participation in an exercise intervention directly predicted a reduction in loneliness.[13] Therefore, it is necessary to provide interventions that focus on PA in older adults with social frailty.

To our knowledge, only a few randomized controlled trials (RCTs) on social frailty have been conducted. For instance, Pollak et al[14] examined the effects of lending robotic pets to older adults with social frailty, focusing on outcomes such as social frailty, cognitive function, and depression. However, they found no significant effects. This intervention was delivered individually and did not involve strategies to encourage social engagement. In contrast, Kim et al[15] implemented a "Social Nutrition Program", which involved home visits by social workers and dietitians. These professionals provided dietary advice, individual counseling, and encouragement for social participation. Their program demonstrated effectiveness in improving physical frailty and performance. However, it primarily relied on home-based professional visits and did not actively promote social interactions, such as going out, meeting others, or engaging in conversations. Given the characteristics of social frailty, interventions that encourage going out and foster social interactions and participation are critical. Effective programs should aim to enhance PA and reduce loneliness by promoting going out and social connections. Nevertheless, evidence on effective intervention methods specifically targeting PA and mental health in older adults with social frailty remains limited.

Multi-component interventions have been demonstrated to be more effective than mono-domain interventions in older adults.[16–18] Regarding loneliness, multi-component interventions or exercise in group settings may help build social relationships and lead to less loneliness.[19] To build social relationships, older adults with social frailty increase their participation rates. According to previous research,[20] the key factors for increasing adherence are as follows: (a) the duration of the exercise intervention is not too long; (b) initial exploration of participants' characteristics and barriers; (c) participants' education; (d) integration in daily living; (e) social support from professional relatedness; (f) communication and feedback; (g) participants' active role (ie, self-monitoring); and (h) available progress information and monitoring. Considering these key factors, we developed a multi-component program that includes health education, exercise, and self-monitoring, focusing on promoting a more active life for older adults with social frailty and pre-frailty. In other words, we hypothesized that a multi-component program focusing on PA could improve PA and reduce loneliness. Using an RCT design, this study examined the effects of a multi-component program among older adults with social frailty and pre-frailty.

Materials and Methods

Study Design

A single-parallel-group RCT was conducted in an urban community in Japan between February 2023 and September 2023. The study flowchart is shown in Figure 1, which summarizes the processes of participant enrollment, allocation, and analysis. This study was conducted following the CONSORT guidelines. A computerized block randomization with randomly selected block sizes of 4 was used to assign participants enrolled to the control group (CG) or the intervention group (IG) in a 1:1 allocation ratio. Participants were stratified according to social frailty and pre-frailty using Makizako's Social Frailty Index.[6] The group allocation was hidden from the outcome assessors.

Participants

We invited men and women aged 60 years and older who lived in nine buildings in UR Morinomiya housing complexes and four apartment complexes in the surrounding area (3266 units) to participate in the study. All the participants were located in Morinomiya, Osaka, Japan. Envelopes containing participation information and social frailty assessment forms were distributed to all the households in the target area. This RCT included older adults with social frailty and pre-frailty, defined according to Makizako's Social Frailty Index.[6] Social frailty was defined as meeting ≥2 of the following criteria, and pre-frailty as meeting one: living alone (yes), going out less frequently compared with the previous year (yes),

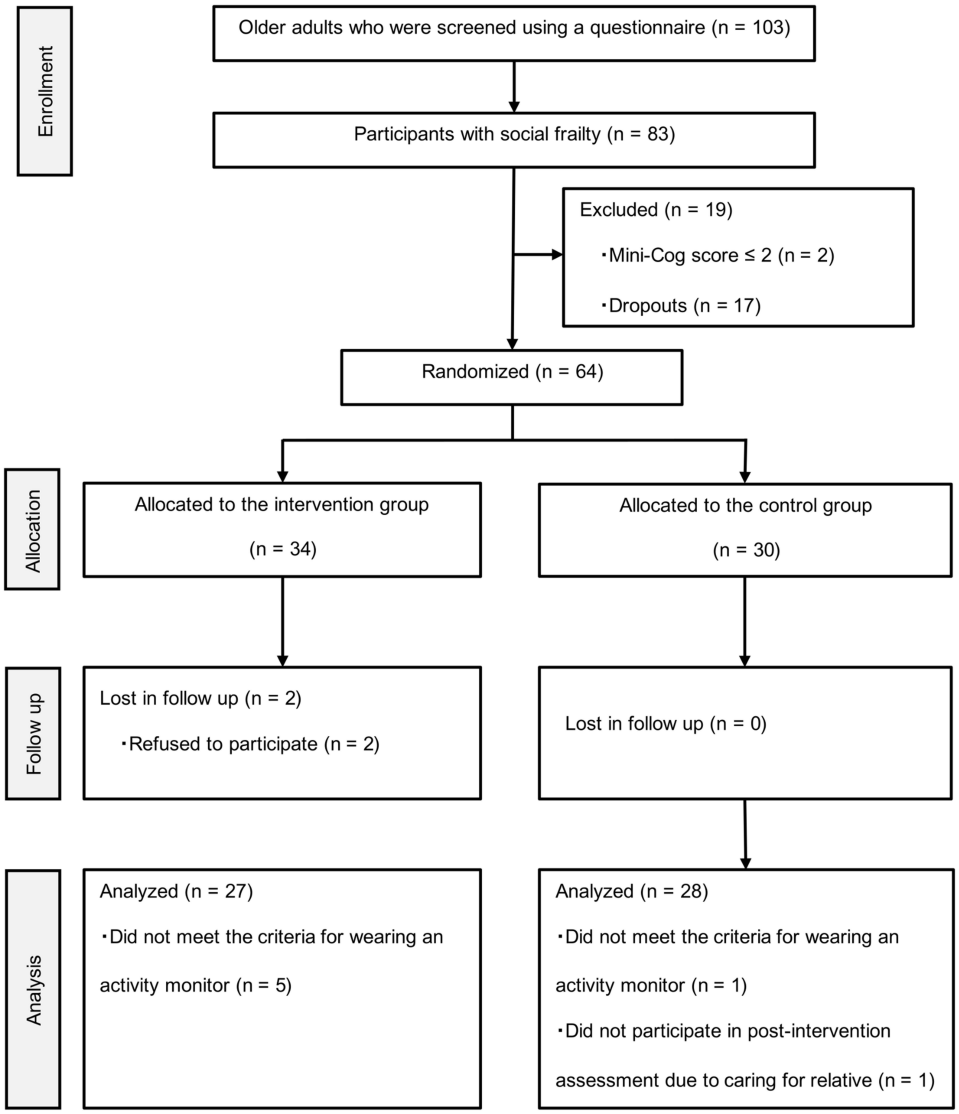

Figure 1 Study flowchart depicting the flow of participants through the randomized controlled trial.

sometimes visiting friends (no), feeling helpful towards friends or family (no), and talking to someone every day (no). This is the most common assessment method developed by Makizako et al and is widely used in older adults.[6] The exclusion criteria were as follows: (a) severe cardiac and pulmonary diseases that can limit PA; (b) difficulty walking independently without assistance; and (c) suspected cognitive impairment (Mini-Cog score $\leq$ 2 points).[21] The study protocol was reviewed and approved by the Graduate School of Rehabilitation Science, Osaka Metropolitan University (2022–116) and registered with the University Hospital Medical Information Network Clinical Trials Registry (No. UMIN000050306) on February 1. Written informed consent was obtained from each participant before they participated in the study.

Content of Intervention

We conducted a baseline assessment in both groups at the start of the study. This was followed by the implementation of an 8-week program in the IG. At the end of the 8 weeks, both groups were assessed again (post-intervention). For ethical reasons, in the CG, a simple exercise booklet was distributed after the baseline assessment. A similar program was conducted for those who wished to participate in the post-intervention assessment. In the IG, the 8-week multi-component program (60 min, 1 day/week) consisted of three components: (a) health education, (b) exercise, and (c) self-

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monitoring (Table 1). For health education, we delivered lectures on the importance of PA, the effects of walking, the management of low back pain, and muscle strength in older age. As for the exercise interventions, methods of walking, stretching exercises, back pain exercises, and body weight training were provided. Regarding self-monitoring, the participants wrote and reflected on how they spent their days on a sheet during the first and last class sessions. At the end of each session, we distributed a daily log sheet that included questions on whether and where to go, daily steps, brisk walking, exercise, and physical and mental conditions. Participants were asked to submit their sheets in the following session and receive individual feedback from the main implementer. In addition, we shared the results of the physical function and PA assessments before the intervention. Program booklets were distributed to the IG participants so that they could review and exercise at home. In each session, one physical therapist, the main implementer, and three physical therapists provided support to groups of five to nine participants.

Outcome Measures

Primary Outcome

The primary outcome was PA. A triaxial accelerometer (HJA-750C, OMRON) was used to collect daily PA data.[22] The participants were asked to wear the accelerometer for a week, except when they were bathing and sleeping. The accelerometer displays were masked to prevent the participants from checking their data. Step counts, sedentary behavior time (1.0–1.5 METs), light PA (1.6–2.9 METs), and moderate-to-vigorous PA (≥ 3.0 METs) were measured.[23] Considering that the participants were older adults, we used the data to determine if they wore the accelerometer for more than 10 h a day and three days or more a week, which was in line with previous research.[24] Non-wear time was defined as the total time with an intensity of 1 METs or less, lasting 90 min or more.[25]

Secondary Outcome

Secondary outcomes were loneliness, health-related quality of life, low back pain, and physical performance. Loneliness was measured using the Three-Item Loneliness Scale (TIL Scale) based on the Revised UCLA Loneliness Scale.[26] The participants were asked how frequently they "felt left out", "felt isolated from others", and "felt like they lacked companionship". Their responses were rated on a three-point scale (one = hardly ever; two = sometimes; and three = often). The scores for all items were summed to generate a loneliness score ranging from three to nine, with higher scores indicating higher levels of loneliness.

The participants' perceived health-related quality of life was assessed using the EuroQol-5Dimention-5Leve.[27] This questionnaire consists of five dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and five levels of problems. It also includes a visual analog scale ranging from 0–100, with higher scores

Table 1 Contents of the 8-Week Multi-Component Program

Week	Contents	Components		
		Health Education	Exercise	Self-Monitoring
1st	The importance of physical activity.	○		○
2nd	Walking tips: changes due to aging and countermeasures	○		○
3rd	Walking tips: walking practice		○	○
4th	Management of low back pain: mechanism and countermeasures for low back pain	○	○	○
5th	Management of low back pain: stretching instruction		○	○
6th	Muscle strength in older age: countermeasures for sarcopenia	○		○
7th	Muscle strength in older age: strength training guidance		○	○
8th	Walking tips: individual walking instruction	○	○	○

Notes: The 8-week multi-component program (60min, 1day/week) consisted of three components: health education, exercise, and self-monitoring. As for the self-monitoring, participants reflected on how they spent their day in the 1st and 8th weeks. In addition, they were given a daily log for each session to record their physical activity and mental and physical condition over the week, and feedback was provided the following week.

indicating better quality of life. The results of the five dimensions were transformed into an index value using a calculator with different value sets, depending on the country, which was validated in our context.[28]

For low back pain, the visual analog scale scores ranged from "no pain = 0 mm" to "worst pain imaginable = 100 mm". Scores were calculated to the nearest millimeter using a ruler. A score of 30 mm or more was considered as having moderate or severe back pain.[29]

Physical performance was assessed using the Short Physical Performance Battery,[30] which consists of three tests (gait speed, chair standing, and balance skills). Gait speed was tested using a 4-m walk with or without mobility devices (the fastest time of the two trials was used). The ability to stand up from a chair and return to a seated position five times with crossed arms was also tested. Balance was assessed using the feet in side-by-side, semi-tandem, and tandem stands. The final scores ranged from 0 (worst performance) to 12 (best performance).

Sample Size

The sample size was determined using G*Power version 3.1.9.7, as previously described.[31] Assuming a the within-between interaction of group and time in repeated-measurements analysis of variance with 2 groups and 2 points of measurement, we set the effect size, α level, and power as 0.25, 0.05, and 0.80, respectively. The calculated required total sample size was 34 participants across both groups. To account for an anticipated dropout rate of 25%,[32] we recruited 50 participants for both groups.

Statistical Analyses

Baseline characteristics were compared using Mann–Whitney U and χ^2 tests for continuous and categorical variables, respectively. The effectiveness of the multi-component program was verified using repeated-measures analysis of variance with group-by-time interaction, and partial η^2 values were calculated as measures of effect size. The analysis was conducted according to the intention-to-treat protocol. All analyses were conducted using IBM SPSS Statistics for Windows, version 29.0 (IBM Corp., Armonk, NY, USA). Differences were considered statistically significant at $p < 0.05$.

Results

Enrollment and Baseline Data

Figure 1 shows a flowchart of the RCT selection process. A total of 103 men and women aged ≥ 60 years were enrolled in this study, of whom 83 had social frailty or pre-frailty. However, we excluded two participants with suspected cognitive impairment (Mini-Cog score ≤ 2) and 17 who did not participate in the baseline assessment. The remaining 64 participants, all of whom met the inclusion criteria, were randomly assigned to the IG (n = 34; 8 men and 26 women; mean ± standard deviation age, 78.7 ± 4.8 years) and the CG (n = 30; 10 men and 20 women; 78.9 ± 7.4 years) (Figure 1). Table 2 shows the baseline demographic and

Table 2 Baseline Demographic and Clinical Characteristics of the Participants

	All (n = 64)	**Intervention Group (n = 34)**	**Control Group (n = 30)**	**p value**
Age, years	78.8 ± 6.1	78.7 ± 4.8	78.9 ± 7.4	0.88
Female	46 (71.9)	26 (76.5)	20 (66.7)	0.42
Mini-Cog scores (range 0–5)	4.3 ± 0.8	4.4 ± 0.8	4.3 ± 0.8	0.81
Living alone	48 (75.0)	23 (67.6)	25 (83.3)	0.25
Duration of living Less than 10 years 10–29 years Over 30 years	 28 (43.8) 23 (35.9) 13 (20.3)	 11 (32.4) 14 (41.2) 9 (26.5)	 17 (56.7) 9 (30.0) 4 (13.3)	0.13

(*Continued*)

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Table 2 (Continued).

	All (n = 64)	Intervention Group (n = 34)	Control Group (n = 30)	p value
Number of floors				
First floor to 10th floor	42 (65.6)	19 (55.9)	23 (76.7)	0.08
11th floor and above	22 (34.4)	15 (44.1)	7 (23.2)	
Highest education				
Middle or senior high school	43 (67.2)	25 (73.5)	18 (60.0)	0.29
College	21 (32.8)	9 (26.5)	12 (40.0)	
Chronic conditions	51 (79.7)	26 (76.5)	25 (83.3)	0.50
Hypertension	22 (34.8)	9 (26.5)	13 (43.3)	0.16
Arthritis	19 (29.7)	13 (38.2)	6 (20.0)	0.11
Lumbar	11 (17.2)	7 (20.6)	4 (13.3)	0.44
Hip joint	3 (4.7)	2 (5.9)	1 (3.3)	0.55
Knee joint	12 (18.8)	9 (26.5)	3 (10.0)	0.12
Osteoporosis	12 (18.8)	5 (14.7)	7 (23.3)	0.38
Diabetes mellitus	8 (12.5)	3 (8.8)	5 (16.7)	0.34
Hyperlipidemia	8 (12.5)	4 (11.8)	4 (13.3)	0.57
Respiratory disease	6 (9.4)	3 (8.8)	3 (10.0)	0.60
Malignant tumor	5 (7.8)	3 (8.8)	2 (6.7)	0.56
Heart disease	4 (6.3)	2 (5.9)	2 (6.7)	0.64
Stroke	1 (1.6)	0 (0.0)	1 (3.3)	0.47
BMI	22.4 ± 3.7	22.1 ± 3.6	22.8 ± 3.8	0.54
Primary outcome				
Daily steps	5692.0 ± 3598.9	6478.8 ± 3839.9	4850.8 ± 3174.3	0.09
SB (min/day)	405.8 ± 111.6	380.8 ± 81.8	432.5 ± 132.9	0.32
LPA (min/day)	232.9 ± 69.1	236.4 ± 70.3	229.2 ± 68.9	0.33
MVPA (min/day)	64.5 ± 44.5	70.9 ± 51.0	57.7 ± 36.0	0.29
Secondary outcome				
TIL Scale (score)	4.2 ± 1.4	4.4 ± 1.5	3.9 ± 1.3	0.20
Felt a lack of companionship; often	12 (18.8)	9 (26.5)	3 (10.0)	0.13
Felt left out; often	1 (1.6)	1 (2.9)	0 (0.0)	0.51
Isolated from others; often	2 (3.1)	1 (2.9)	1 (3.3)	0.41
EQ-5D-5L VAS	75.3 ± 17.3	73.6 ± 18.2	77.2 ± 16.2	0.38
EQ-5D-5L score	0.9 ± 0.1	0.9 ± 0.1	0.9 ± 0.1	0.83
LBP; VAS	22.4 ± 23.1	24.2 ± 21.7	22.1 ± 25.2	0.69
SPPB (score)	11.1 ± 1.3	11.2 ± 1.1	10.9 ± 1.6	0.45

Notes: Data are presented as mean ± SD or n (%). p values were calculated using the Mann–Whitney *U*-test or a χ^2 test.
Abbreviations: BMI, body mass index; EQ-5D-5L, EuroQol-5Dimention-5Level; LBP, low back pain; LPA, light physical activity; min, minutes; MVPA, moderate-to-vigorous physical activity; SB, sedentary behavior; SPPB, Short Physical Performance Battery; TIL Scale, Three-Item Loneliness Scale; VAS, visual analog scale.

clinical characteristics of the participants. There were no significant differences in the participants' baseline demographic and clinical characteristics between the two groups. The participation rate in the 8-week multi-component program was 93.8%. No adverse events were observed during the study.

Primary Outcome

Table 3 shows the results for each variable at baseline and after intervention in both groups. There were no significant differences between pre- and postintervention in any variable related to PA within either group, nor was there a significant group-by-time interaction.

Table 3 Comparison of Outcome Variables at Baseline and Post Intervention

		Baseline	Post-Intervention	p value[a]	F value[b]		
					Main effect (group)	Main effect (period)	Interaction (group × period)
Primary outcome							
Daily steps	IG	6478.8 ± 3839.9	6649.1 ± 4138.2	0.15	1.62	2.13	0.01
	CG	4850.8 ± 3174.3	5371.7 ± 3629.3	0.41			
SB (min/day)	IG	380.8 ± 81.8	392.2 ± 89.9	0.81	1.16	1.64	2.66
	CG	432.5 ± 132.9	384.2 ± 95.9	0.08			
LPA (min/day)	IG	236.4 ± 70.3	238.9 ± 74.7	0.50	0.09	0.23	0.29
	CG	229.2 ± 68.9	229.6 ± 86.5	0.74			
MVPA (min/day)	IG	70.9 ± 51.0	72.0 ± 47.3	0.66	1.01	0.05	0.03
	CG	57.7 ± 36.0	60.0 ± 40.7	0.76			
Secondary outcome							
TIL Scale (score)	IG	4.4 ± 1.5	3.8 ± 1.0	0.03	0.09	0.96	7.42*
	CG	3.9 ± 1.3	4.1 ± 1.5	0.15			
Felt a lack of companionship; often	IG	9 (26.5)	2 (5.9)	0.03	0.34	0.21	8.37*
	CG	3 (10.0)	4 (13.3)	0.11			
Felt left out; often	IG	1 (2.9)	0 (0.0)	0.48	0.00	0.24	0.24
	CG	0 (0.0)	1 (3.3)	1.00			
Isolated from others; often	IG	1 (2.9)	0 (0.0)	0.10	0.00	1.42	1.42
	CG	1 (3.3)	2 (6.7)	1.00			
EQ-5D-5L VAS	IG	73.6 ± 18.2	79.4 ± 12.7	0.05	0.00	3.54	2.01
	CG	77.2 ± 16.2	77.3 ± 14.5	0.81			
EQ-5D-5L score	IG	0.88 ± 0.10	0.86 ± 0.11	0.33	0.43	0.14	1.28
	CG	0.89 ± 0.11	0.89 ± 0.14	0.54			
LBP; VAS	IG	24.2 ± 21.7	21.4 ± 22.8	0.17	0.88	1.52	0.12
	CG	22.1 ± 25.2	17.4 ± 22.9	0.65			
SPPB (score)	IG	11.2 ± 1.1	11.2 ± 1.0	0.83	1.11	0.03	0.19
	CG	10.9 ± 1.6	10.8 ± 1.7	0.61			

Notes: Data are presented as mean ± SD and n (%). [a]Calculated using the Wilcoxon signed-rank test. [b]Calculated using repeated-measures analysis of variance. *Significant at 0.05%.

Abbreviations: CG, control group; EQ-5D-5L, EuroQol-5Dimention-5Level; IG, intervention group; LBP, low back pain; LPA, light physical activity; min, minutes; MVPA, moderate-to-vigorous physical activity; SB, sedentary behavior; SPPB, Short Physical Performance Battery; TIL Scale, Three-Item Loneliness Scale; VAS, visual analog scale.

Secondary Outcome

The TIL Scale scores decreased significantly ($p = 0.03$) in the IG but not in the CG ($p = 0.15$) (Table 3). Furthermore, a significant group-by-time interaction was observed in the TIL Scale score ($F = 7.42$, $p < 0.05$; Table 3). Additionally, regarding the sub-items of the TIL Scale, the percentage of participants who often felt like they lacked companionship decreased significantly in the IG ($p < 0.05$; Table 3). Moreover, a significant group-by-time interaction was observed for "felt like they lacked companionship" ($F = 8.37$, $p < 0.05$; Table 3). No significant changes were observed in any of the other variables.

Discussion

This study assessed a multi-component program aimed at improving PA and loneliness levels among community-dwelling older adults with social frailty and pre-frailty in a Japanese urban area. The primary outcome, PA assessed using an accelerometer, was not specifically affected by the intervention. Among the secondary outcomes, loneliness had a significant interaction between group and duration, with a medium effect size. Moreover, the mean adherence to this program was 93.8%, and there were no adverse events.

To our knowledge, the current study is the first RCT of community-dwelling older adults with social frailty involving a multi-component program to improve PA and loneliness. The studies by Pollak et al[14] and Kim et al[15] share similarities with the current study in that they target social frailty older adults; however, their intervention methods and program

designs differ. Pollak et al employed a home-based intervention using a robotic pet, which did not involve direct social interaction with other individuals.[14] In contrast, Kim et al implemented an individualized home-visit model in which social workers and dietitians provided social counseling and nutritional support.[15] Our program provided more opportunities for participants to go out and interact with others than these previous studies. Moreover, in designing our program, we aimed to enhance adherence by incorporating key factors known to support adherence in older adults, as highlighted in a previous review.[20] Specifically, we focused on integrating the program into participants' daily lives, facilitating communication and feedback, providing supervision during exercise sessions, and encouraging participants to take an active role.[20] These elements likely contributed to the high adherence observed among participants in our program.

As previously mentioned, the mean adherence to this program was 93.8%, and there were no adverse events. A previous systematic review indicated that the mean adherence rate to community-based group exercise interventions in older adults was 69.1%.[33] Based on previous research,[5,20] we ensured that (a) the duration of the program was not too long; (b) we had information about the loneliness and PA levels of older adults in the target area; (c) there was good accessibility, adequate location, and flexibility in the schedule for this program; (d) our staff provided intra-session positive feedback and bilateral and fluid communication with participants; (e) in a session, we provided the results of baseline PA and physical function for the IG; and (f) in the self-monitoring part, we asked participants to submit weekly daily logs and provide personalized feedback. We considered that these factors might have encouraged participation in the 8-week program for older adults with social frailty who lived alone, were less likely to go out, and had little interaction with others.

We investigated whether PA, assessed using accelerometers, affects social frailty in older adults through an 8-week multi-component program. To our knowledge, this is the first study to measure PA in older adults with social frailty using an accelerometer. No statistically significant effects of the intervention on PA were observed, as both the IG and the CG sustained their relatively high baseline activity levels throughout the study period. In the present study, the mean daily step count in the IG was 6478.8 steps, and the mean duration of moderate-to-vigorous PA was 70.9 minutes per day. Comparatively, a previous study reported that community-dwelling older adults in Japan had a mean daily step count of 4474 steps and an average of 37.8 minutes per day of MVPA.[34] These findings suggest that our participants exhibited relatively high baseline activity levels, which may account for the lack of significant changes observed in their PA levels.

Our program effectively reduced loneliness in the IG. In particular, the proportion of participants who often felt a lack of companionship decreased significantly in the IG, contributing to a reduction in loneliness. Social frailty is moderately and positively correlated with loneliness.[35] The generation of negative emotions such as loneliness affects the emotional regulation ability and participation in social activities of older adults, resulting in a decline in their physical function and life satisfaction as well as the occurrence of a social psychological crisis.[36,37] Multi-component interventions or exercise in a group setting may help build social relationships associated with decreased loneliness.[19] Previous research has indicated that increases in social support due to participation in exercise interventions directly predict reductions in loneliness.[13] Moreover, PA programs, regardless of exercise mode, may be effective in reducing loneliness in older adults.[38] Therefore, we suggest that our program, which includes health education, exercise, and self-monitoring with feedback, could help build social relationships and positively affect loneliness among the participants.

The present study has some limitations. First, because it was conducted in an urban area of Japan, it is difficult to generalize the results due to the regional nature of the study. Second, many participants had high PA levels, whereas we expected the population to have lower PA levels. In the future, it will be necessary to monitor PA levels and verify the effectiveness of the program in older adults with social frailty. Third, the sample size was too small to conduct a sub-analysis, and multiple participants did not meet the criteria for wearing an activity accelerometer. Although the standards for wearing the PA monitor were set for older adults in the community, following previous research,[24] there were six people in each group. Considering the impact on analytical power, it may be necessary to consider wearable device technology, which is easier to use.[39] Finally, this study did not use the social frailty index as the primary outcome because one of the social frailty indicators, living alone, is not modifiable through intervention. Furthermore, assessing changes in the indicator's reduction in the frequency of going out compared to one year ago would require long-term follow-up,

which was beyond the scope of this two-month study. We acknowledge this limitation and have identified long-term effect evaluation as an important area for future research.

To address social frailty in the post-COVID-19 era, early detection and intervention remain critical to prevent its progression and lower the incidence of nursing care needs. This study's multi-component program, designed with the specific characteristics of socially frail older adults in mind, may facilitate improved social interactions. Future research should explore the long-term effects of this program on social frailty status and the rates of nursing care certification.

Conclusion

In this study, we implemented an 8-week multi-component program aimed at promoting PA, which included health education, exercise, and self-monitoring, for older adults with social frailty and pre-frailty. The results indicated no specific effect on PA, although loneliness was reduced. Therefore, our intervention may help older adults with social frailty and pre-frailty build social relationships and contribute to reducing loneliness. Future research is needed to examine the long-term intervention effects of the program and to clarify whether the state of social frailty can be changed.

Abbreviations

CG, control group; IG, intervention group; PA, physical activity; RCT, randomized controlled trial; TIL Scale, Three-Item Loneliness Scale.

Data Sharing Statement

The data supporting the findings of this study are available upon request from the corresponding author. The data are not publicly available due to ethical restrictions.

Ethics Approval Statement

This study was approved by the Committee on Research Ethics of the Graduate School of Rehabilitation Science at the Osaka Metropolitan University (approval number: 2022-116). All participants provided signed informed consent before participating in this study in accordance with the 1975 Declaration of Helsinki and were free to withdraw their consent at any time without any detrimental consequences. This study adhered to the principles of the Declaration of Helsinki (updated version 2008).

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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The authors report no conflicts of interest in this work.

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