Effect of respiratory rehabilitation for frail older patients with musculoskeletal disorders: a randomized controlled trial

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ORIGINAL REPORT

EFFECT OF RESPIRATORY REHABILITATION FOR FRAIL OLDER PATIENTS WITH MUSCULOSKELETAL DISORDERS: A RANDOMIZED CONTROLLED TRIAL

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Objective: **To investigate the effects of respiratory rehabilitation on respiratory function, swallowing in community-dwelling frail older patients with musculoskeletal disorders.**

Design: **Randomized open-label controlled trial.**

Setting: **Day-care facility in a rehabilitation hospital in Japan.**

Subjects: **A total of 63 participants with musculoskeletal disorders (intervention group: *n* = 31; control group: *n* = 32) completed the randomized controlled trial.**

Interventions: **All participants received 12 20-min sessions twice a week for 6 weeks of either typical rehabilitation (control) or typical rehabilitation with respiratory rehabilitation (intervention).**

Main measures: **Outcome measures were assessed prior to rehabilitation and after 12 sessions. The measures included: respiratory function, swallowing function, exercise tolerance, 6-min walk distance, thorax flexibility, muscle strength (grip and abdominal), activities of daily living, and quality of life.**

Results: **Participants in the intervention group showed significantly greater improvement in respiratory function (95% confidence interval (CI), 3.8–6.6; *p* = 0.01), swallowing function (95% CI −1.8–0.6; *p* = 0.01), and quality of life (SF8 Physical Summary Score) (95% CI 2.4–7.1; *p* = 0.01) compared with those in the control group.**

Conclusion: **Addition of respiratory rehabilitation to a typical rehabilitation programme could improve not only respiratory and swallowing function, but also quality of life, in frail older patients.**

Key words: respiratory rehabilitation; community-dwelling frail older patients; respiratory function; swallowing function; quality of life.

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LAY ABSTRACT

Older persons can be susceptible to respiratory-related conditions, particularly pneumonia. This study examined the effects of breathing training on respiratory function, swallowing function, and quality of life in community-dwelling frail older persons with musculoskeletal disorders. The participants were divided into 2 groups. One group performed a regular rehabilitation programme, and the other group performed breathing training exercises, including a coughing exercise, respiratory muscle stretching exercise, and respiratory muscle training using a hand-held resistance device. The exercises improved respiratory function, swallowing, and quality of life. Such breathing training might be effective in helping to prevent pneumonia in frail older patients with musculoskeletal disorders.

Pneumonia is a major cause of death in elderly people (1, 2). Pneumonia caused by aspiration, generally known as aspiration pneumonia, can lead to a decrease in activities of daily living (ADL) and quality of life (QoL), accompanied by a decrease in physical and mental functions (3, 4). The most common causes of aspiration pneumonia are aspiration while eating, chewing, or swallowing; decrease in oral function; and decrease in respiratory function associated with ageing (5, 6).

Respiratory disabilities and lack of exercise in older persons can lead to conditions such as disuse syndrome and pneumonia (7). Long-term care rehabilitation institutions should therefore ensure that their patients are appropriately protected against pneumonia. Improvement in respiratory function is considered important to maintain ADL and QoL in older persons.

In general, respiratory rehabilitation improves respiratory function and QoL for patients with chronic obstructive pulmonary disease (COPD) (8). However, the effects of respiratory rehabilitation on respiratory function and QoL in community-dwelling frail older persons is unknown. Our previous study evaluated respiratory function in older persons, including those with suspected COPD, for whom respiratory rehabilitation might be particularly effective (9). Therefore, in this study, to clarify the effects of respiratory rehabilitation on community-dwelling frail older persons in general, we excluded older patients whose forced expiratory volume in 1 s (expressed as a percentage) was less than 70%. The findings of our previous study suggest that even older patients without respiratory disease can benefit significantly from pulmonary rehabilitation (9). Therefore, the current study sought to clarify the effects of respiratory rehabilitation

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on community-dwelling frail older persons without respiratory diseases. Several trials of pulmonary rehabilitation have been performed in elderly patients with decreased respiratory and swallowing functions due to Parkinson's disease or cerebrovascular disease (10). However, the effects of respiratory rehabilitation on respiratory function, swallowing, and QoL of frail older persons with musculoskeletal disorders without COPD have yet to be established. Our previous pilot study (9) evaluated the respiratory function of 30 participants (15 with musculoskeletal disorders and 15 with cerebrovascular disorders) and offered a rehabilitation programme that included respiratory training. Respiratory function, swallowing function, and QoL significantly improved during respiratory rehabilitation. However, to increase the generalizability of our findings, a randomized controlled trial was needed. In the present study, a randomized controlled trial was conducted to examine the effects of respiratory rehabilitation on respiratory function, swallowing, and QoL of community-dwelling frail older patients with musculoskeletal disorders, but without COPD.

METHODS

Participants

Participants were recruited from a day-care facility in Yasato Rehabilitation Hospital, Ibaraki Prefecture, Japan, from September through December 2015. The inclusion criteria were as follows: (*i*) patients with musculoskeletal disorders, such as osteoarthritis or fracture, diagnosed via clinical and image findings; (*ii*) frail person, according to Fried Frailty Criteria (11); (*iii*) aged 65 years or older; (*iv*) certified as requiring support levels 1 and 2 or care levels 1 to 3 according to the Japanese Long-term Care Insurance criteria (1); (*v*) $\geq$6 months since acute disease onset; (*vi*) Mini-Mental State Examination (MMSE) (12) score $>$21; (*vii*) absence of COPD or any other respiratory disease; and (8) forced expiratory volume in 1 s of $\geq$70%. Exclusion criteria were as follows: (*i*) forced expiratory volume in 1 s (expressed as a percentage) was less than 70% (suspected COPD); (*ii*) moderate or severe cardiac disease (New York Heart Association (9, 13) Classification of III or IV); (*iii*) ischaemic or haemorrhagic stroke; or (*iv*) neurodegenerative disease.

Study design

This study was designed as an open-label randomized controlled trial. Participants understood 12 rehabilitation sessions that included respiratory rehabilitation (2 sessions a week, for 6 weeks). Each 20-min session was held once a day and comprised 10 min of respiratory rehabilitation in addition to 10 min of typical rehabilitation (9). Baseline measures of each of the subject's demographics and characteristics and outcome measures were assessed before the subjects were randomized into groups. A computer-generated allocation sequence was used, whereby odd-numbered patients were placed in the respiratory rehabilitation group and even-numbered patients were placed in the control group. The intervention consisted of the following: (*i*) respiratory muscle training, (*ii*) coughing exercise, (*iii*) diaphragmatic muscle training, (*iv*) stretching exercise, and (*v*) home exercise (14). For respiratory muscle training, participants performed 3 sets of 10 breaths through a commercially available hand-held resistance device (Threshold PEP; Philips Co., Tokyo, Japan) set at 60% of the individual's maximal expiratory mouth pressure, with resting periods of 1 min between sets (14–16). The cough exercise was performed using 3 sets of 10 active coughs (17, 18). For diaphragmatic muscle training, each participant performed 30 maximal voluntary diaphragmatic contractions while in the supine position with a moderately heavy weight (1–3 kg) placed on the anterior abdominal wall to resist diaphragmatic descent (19). For the stretching exercise, respiratory muscles stretches were performed under instruction of a physical therapist. Patients were placed in a supine or lateral position, with knees bent to correct the lumbar curve. The patients were asked to move their arms in flexion, horizontal extension, abduction, and external rotation motions. As for home exercise, the participants received guidance on pursed-lip breathing and cough training and were asked to perform 30 sets of each training exercise per day (9, 20).

The typical rehabilitation programme consisted of the following: (*i*) range of motion exercise, (*ii*) muscle strength training, (*iii*) balance training, (*iv*) gait training, but no respiratory rehabilitation. Participants performed range-of-motion exercises of the major joints of the lower extremities (hip, knee, and ankle) under the guidance of a physical therapist. Muscle strength training was performed using 3 sets of 10 active hip joint flex, abduction, and knee joint extension motions in the sitting position. Balance training involved the participants standing on alternate legs for durations of 30 s with upper-limb support from a physical therapist. This exercise was repeated 3 times on each foot (20).

Assessment

For standardized assessment procedures, the measurements in this study were made by trained physical therapists. Primary outcome measures were as follows: respiratory function and swallowing function. Secondary outcome measures were: exercise tolerance, 6-min walk distance, thorax flexibility, muscle strength (grip and abdominal), ADL, and QoL. The assessing physical therapists were not totally blinded to the allocation of participants to the intervention and control groups.

Respiratory function. Respiratory function was evaluated using a respiratory function test with an auto spirometer (Vitalopower KH-801; Philips Co., Tokyo, Japan) (14). The following parameters related to respiratory function were measured: (*i*) vital capacity (VC), (*ii*) forced vital capacity (FVC), (*iii*) forced expiratory volume in 1 s percent predicted (FEV1)%predicted, (*iv*) FEV1/FVC (FEV1%), (*v*) peak expiratory flow rate (PEF), and (*vi*) cough peak flow (CPF). Respiratory muscle strength was assessed through measurement of maximal expiratory mouth pressure (MEP) and maximal inspiratory mouth pressure (MIP). CPF was defined as the highest point of the flow volume curve obtained during a cough, and the maximum value of 3 measurements was used for analysis. All predictive values were calculated using the standard regression equation published by the Japanese Respiratory Society (9, 21, 22).

Swallowing function. Swallowing function was evaluated using the Dysphagia Risk Assessment for the Community-Dwelling Elderly test (DRACE) (23) and the Repetitive Saliva Swallowing Test (RSST) (24). The DRACE test includes 12 questions with possible answers of "not at all" (scoring 0 points), "sometimes" (scoring 1 point), and "frequently" (scoring 2

points). A high score indicates severe dysphagia. In the RSST, the participant is instructed to repeatedly swallow for 30 s. Successful swallowing is confirmed by placing a finger over the participant's hyoid bone and palpating the downward movement of the laryngeal elevation that occurs during swallowing. We measured the number of times the participant swallowed in 30 s (9).

Strength evaluation. Grip, abdominal muscle strength were measured with the participant in a sitting position. Each test was repeated 3 times, and the maximum value was used for further analyses.

Grip strength was measured using a hand dynamometer. Rectus abdominal muscle and right and left oblique muscle strengths were measured using the Manual Muscle Test (MMT). Muscle strengths were measured at levels 0 to 5 (9).

Thorax flexibility. As trunk measurement of joint motion, the range of motion of the thoracolumbar spine (flexion and extension, side bending, and rotation) was measured using a goniometer (9).

Exercise tolerance. Exercise tolerance was measured using the 6-min walk test (6MWT) (25), which measures the distance an individual can walk in 6 min (also called the ambulatory distance). Percutaneous oxygen saturation (SpO_2) was measured before and after the 6-min walk using a saturation pulse oximeter. Heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate, and rate of perceived exertion (Borg Scale) were also measured before and after the walk (9). The stopping guidelines were as follows: subjective symptoms such as dyspnoea of intensity; percutaneous oxygen saturation (SpO_2) drops by 85% or less; it was assumed that the heart rate increased to 85% or more of the predicted maximum heart rate.

ADL evaluation. ADL were evaluated by a physiotherapist, using the Functional Independence Measure (FIM) scale. The FIM comprises 18 items, each with a maximum score of 7 and a minimum score of 1, and the maximum total score is 126 points. The 18-item FIM can be divided into 13 items assessing motor ADL (including 6 items for self-care, 2 items for sphincter control, 3 items for transfer, and 2 items for locomotion) and 5 items assessing cognitive ADL (including 2 items for communication and 3 items for social cognition) (9, 26).

QoL evaluation. We assessed QoL using the Medical Outcome Study 8-Item Short-Form Health Survey (MOS-SF8). The MOS-SF8 measures 8 health domains: (*i*) general health, (*ii*) physical function, (*iii*) role function (body), (*iv*) body pain, (*v*) social function, (*vi*) overall sense of well-being, (*vii*) vitality, and (*viii*) emotional function. The SF8 scores include both a physical component summary score (PCS) and a mental component summary score (MCS) (9, 27, 28).

Statistical analysis

SPSS version 21.0 (IBM Corporation, NY, USA) was used for all statistical analyses. Sample size was calculated resulting in a minimum sample size of 26 in each group with a power of 80% and an alpha error of 5%. Effect size was calculated using Mann–Whitney *U* testing, with Cohen's d coefficient set at 0.8. The sample size ($n=63$) of this study, therefore, has sufficient detection power. To ensure balanced randomization, the differences between the intervention and control groups at baseline were tested using the Fisher's exact test for sex and unpaired *t*-tests for age, time since stroke, and other baseline assessments. The outcome measures in each group were compared with the baseline measures using the Wilcoxon signed-rank test. Differences between groups were compared using the Mann–Whitney *U* test. Significance was set at $p<0.05$.

Ethical considerations

This investigation was performed with the approval of the ethics committee of the University of Tsukuba (approval number 944). All participants provided written informed consent after receiving a full written description of the trial. The trial was prospectively registered through Clinical Trial Registry (ID: UMIN/2017/000027650; registered on: 6/06/20017).

RESULTS

Fig. 1 shows a flow chart of patients' participation in this study. A total of 77 patients were assessed for eligibility. Of thes, 7 did not consent to the study, 2 had forced expiratory volume in 1 s of ≤70%, and 1 had severe cardiac disease; the remaining 67 patients were randomized. Of the 33 patients allocated to the intervention group, 2 could not continue the rehabilitation because they were discharged before completing all 12 sessions. Likewise, 2 of the 34 patients allocated to the control group could not continue rehabilitation because they were discharged before completion of the sessions. We could not obtain the post-intervention outcomes for these 4 patients who withdrew. No subjects withdrew because of adverse effects. A final total of 63 patients completed the study, and 31 of them completed the respiratory rehabilitation programme. No differences in patient characteristics or baseline clinical data were observed between the 2 groups (Table I). The secondary measures did not differ between the 2 groups. The amount of rehabilitation during the

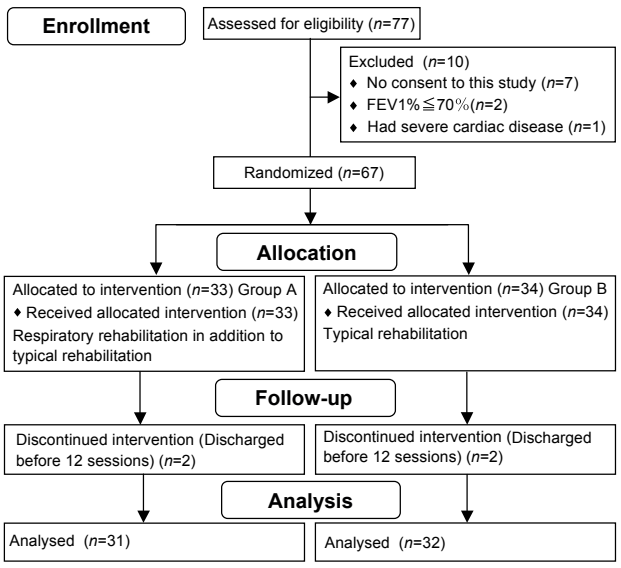

Fig. 1. Flow chart of patients' participation.

Table I. Demographic characteristics of subjects who completed the study

Characteristics	Intervention groups ($n = 33$)	Control groups ($n = 34$)	p-values
Sex; female, *n*, %	22 (68)	25 (72)	0.16[a]
Age, years, mean (SD)	83.1 (7.7)	81.8 (8.4)	0.24[b]
BMI, kg/m^2, mean (SD)	23.1 (3.5)	22.9 (3.9)	0.12[b]
Certified as requiring support or care (levels), mean (SD)	1.1 (0.8)	1.2 (0.7)	0.69[b]
Main diseases, *n*			
Femoral neck fracture	7	6	0.87[b]
Compression fracture of spine	8	10	0.74[b]
Humeral fracture	1	2	0.91[b]
Tibial fracture	2	1	0.91[b]
Osteoarthritis	17	14	0.28[b]
Comorbidity, *n*			
Hypertension	4	7	0.12[b]
Diabetes mellitus	1	2	0.92[b]
Variables, mean (SD)			
VC, %predicted	84.9 (5.6)	86.7 (8.3)	0.23[b]
FEV1%, %predicted	85.1 (10.9)	84.5 (9.2)	0.39[b]
Grip strength, kg	15.2 (7.9)	16.7 (8.4)	0.27[b]
Knee extension, kgf/kg	14.5 (7.8)	13.1 (6.1)	0.13[b]
DRACE	7.0 (3.4)	6.8 (2.9)	0.44[b]

*$p < 0.05$, **$p < 0.01$.
[a]Fisher's exact test. [b]Mann–Whitney *U* test.
BMI: body mass index; DRACE: Dysphagia Risk Assessment for Community-dwelling Elderly; SD: standard deviation.

intervention period did not differ between the 2 groups (Table I).

Table II shows the outcome measures of the 2 groups. The intervention group showed significant increases in forced expiratory volume in 1 s, maximal expiratory mouth pressure and maximal inspiratory mouth pressure, cough peak flow, the range of motion of thoracolumbar spine rotation, the 6-min walk test, the Dysphagia Risk Assessment for the Community-Dwelling Elderly test, and the Medical Outcome Study 8-Item Short-Form Health Survey a physical component summary score, whereas the control group did not. The intervention group showed significantly greater improvement than the control group in the forced expiratory volume in 1 s, maximal expiratory mouth pressure and maximal inspiratory mouth pressure, cough peak flow, the range of motion of thoracolumbar spine rotation, the 6-min walk test, the Dysphagia Risk Assessment for the Community-Dwelling Elderly test, the Medical Outcome Study 8-Item Short-Form Health Survey, physical component summary score.

DISCUSSION

To the best of our knowledge, this is the first randomized controlled trial to address the efficacy and show the beneficial effects of respiratory rehabilitation in improving respiratory function, swallowing, and QoL in frail older patients with musculoskeletal disorders and without COPD. Our results indicate that including a respiratory rehabilitation session in a programme of typical rehabilitation could improve respiratory function, swallowing, and QoL more efficiently than could usual rehabilitation. Our results further suggest that respiratory rehabilitation is effective even for community-dwelling frail older persons without

Table II. Differences within groups, differences between groups

Measures	Intervention groups ($n = 31$)			Control groups ($n = 32$)				
	Pre Mean (SD)	Post Mean (SD)	Differences within groups (95% CI)[a]	Pre Mean (SD)	Post Mean (SD)	Differences within groups (95% CI)[a]	Differences between two groups (95% CI)[a]	Effect size
VC, %predicted	84.9 (5.6)	85.7 (5.2)	0.7 (0.1–1.6)	86.7 (8.3)	86.2 (9.1)	–0.4 (–1.0–0.1)	1.2 (0.5–2.3)	0.225
FVC, %predicted	84.0 (4.5)	84.6 (4.2)	0.5 (–0.2–1.4)	83.2 (10.6)	82.8 (10.0)	–0.4 (–0.9–0.1)	1.0 (–1.1–2.9)	0.114
FEV1, %predicted	83.6 (11.4)	88.6 (12.8)	5.0 (3.8–6.2)**	83.8 (11.5)	83.9 (11.0)	–0.06 (–0.6–0.8)	5.2 (3.8–6.6)**	0.901
FEV1%	85.1 (10.9)	86.2 (10.8)	1.1 (0.5–1.6)	84.5 (9.2)	84.2 (9.0)	–0.3 (–0.8–0.1)	1.4 (0.01–3.0)	0.597
PEF, %predicted	72.7 (13.3)	73.0 (12.3)	0.3 (–0.1–0.7)	70.6 (13.5)	70.4 (14.0)	0.2 (–0.3–0.6)	0.4 (–0.2–1.0)	0.059
MIP, %predicted	20.6 (6.9)	25.8 (5.9)	5.2 (3.7–9.7)**	21.6 (8.0)	22.0 (8.9)	0.3 (–0.6–1.3)	4.8 (3.0–6.5)**	1.113
MEP, %predicted	22.4 (6.7)	29.0 (6.8)	6.5 (4.7–8.5)**	23.9 (8.1)	23.5 (7.4)	–0.3 (–0.7–1.4)	6.8 (4.8–8.8)**	1.302
CPF, l/min	189.1 (28.2)	217.1 (32.3)	27.3 (21.3–34.5)**	182.0 (23.5)	181.0 (24.2)	–0.9 (–3.0–1.0)	34.5 (22.8–46.3)**	1.176
Muscle strength								
Grip strength, kg	15.2 (7.9)	15.3 (8.7)	0.1 (6.8–23.8)	16.7 (8.4)	17.1 (9.9)	0.4 (7.1–27.2)	–0.3 (–1.5–1.2)	0.082
Thoracolumbar spine ROM (°)								
Rotation	15.1 (6.7)	25.6 (6.0)	10.4 (8.6–12.4)**	17.5 (8.9)	17.3 (8.0)	–0.1 (–1.4–1.2)	10.3(8.0–12.6)**	0.941
6MWT, m	100.6 (71.9)	134.1 (65.3)	33.5 (25.8–41.2)**	95.7 (74.2)	97.2 (71.7)	1.5 (–4.0–7.0)	34.5(25.1–44.0)**	1.055
Swallowing function								
DRACE	7.0 (3.4)	5.8 (2.4)	–1.1 (–1.6–0.6)**	6.8 (2.9)	6.9 (2.6)	0.1 (–0.1–0.3)	–1.2 (–1.8–0.6)**	0.898
RSST	2.2 (1.2)	2.6 (1.2)	0.4 (0.2–0.6)*	2.0 (1.3)	2.1 (1.4)	0.1 (–0.1–0.2)	0.3 (0.1–0.6)	0.664
ADL								
FIM	108.1 (12)	108.4 (10)	0.3 (–1.5–1.8)	109.5 (11)	109.1 (9	–0.4 (–1.6–1.2)	0.7 (–1.8–2.5)	0.170
QOL								
SF8 (PCS)	43.9 (6.3)	48.8 (4.8)	4.8 (2.3–7.3)**	46.3 (4.6)	46.1 (4.5)	0.1 (–0.1–0.3)	4.8 (2.4–7.1)**	0.991
SF8 (MCS)	47.3 (6.7)	47.4 (6.4)	0.1 (–1.2–1.3)	45.8 (4.8)	45.9 (4.9)	0.1 (–0.1–0.2)	0.2 (–1.0–1.4)	0.237

[a]Wilcoxon signed-rank test. [b]Mann–Whitney *U* test. *$p < 0.05$, **$p < 0.01$.
VC: vital capacity; FVC: forced vital capacity; FEV1: forced expiratory volume at 1 s; PEF: peak expiratory flow; CPF: cough peak expiratory flow; MIP: PImax=maximal inspiratory pressure; MEP: PEmax=maximal expiratory pressure; ROM: range of motion; Borg scale: rate of perceived exertion; 6MWT: 6-Minute Walk Test; RSST: Repetitive Saliva a Swallowing Test; DRACE: Dysphagia Risk Assessment for Community-dwelling Elderly; FIM: Functional Independence Measure; SF8PCS: Physical Component Summary; SF8MCS: Mental Component Summary; SD: standard deviation; 95% CI: 95% confidence interval.

COPD. In light of these results, we recommend that frail older persons, even those without COPD or with decreased respiratory function, receive respiratory rehabilitation for preventive care.

Reduced swallowing and respiratory functions are major risk factors for aspiration pneumonia. The cough mechanism is important to prevent aspiration, and poor coughing is a leading cause of aspiration pneumonia. Coughing requires coordinated activation of the respiratory muscles and intrinsic laryngeal muscles (9, 29).

Our data indicate that maximal expiratory mouth pressure and maximal inspiratory mouth pressure, cough peak flow are improved in frail older persons by respiratory rehabilitation. Addition of respiratory rehabilitation could be effective in protecting against aspiration pneumonia in frail older persons.

Respiratory function in frail older persons can easily deteriorate. Lepeule et al. (30) evaluated the pulmonary function of 858 community-dwelling older persons and reported that their forced expiratory volume in 1 s decreased by approximately 1% every year (9). Previously, we conducted a longitudinal study of 30 community-dwelling frail older patients using rehabilitation services. Our study showed that, over a period of approximately one year, respiratory function, swallowing function, and QoL were significantly reduced. However, after 6 weeks of a rehabilitation programme that included respiratory training, the respiratory function, swallowing, and QoL of participants in our intervention group had significantly improved. Our results suggest that a typical rehabilitation programme without respiratory training does not suffice for frail older persons to maintain their respiratory function, swallowing, and QoL (9). This current randomized controlled trial provides further evidence that rehabilitation programmes that include respiratory rehabilitation are more effective for frail older persons than typical rehabilitation.

Study limitations and conclusion

The present study has some limitations. Although every effort was made to keep the assessors and participants blind to group allocation, due to the nature of the rehabilitation and assessment environment, this cannot be guaranteed. Thus, we cannot exclude the power of the placebo effect, observer bias, or experimenter bias in the current study. In addition, we used only a single centre to recruit participants. Further blinded studies across multiple centres are needed to address these limitations. However, despite these limitations, our results suggest that respiratory function, swallowing and QoL of frail older persons are improved by the addition of respiratory rehabilitation to a typical rehabilitation programme.

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