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ORIGINAL ARTICLE

Effect of pulmonary training for community-dwelling frail older adults with chronic stroke: A randomized controlled pilot trial

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Abstract

Background: Decreased pulmonary function and poor deglutition are a major risk factor for poststroke aspiration pneumonia. We analyzed the benefits of pulmonary training on pulmonary function, deglutition, and quality of life (QOL) in community-dwelling, frail elderly people with chronic stroke.

Method: This study was designed as an open, randomized, controlled pilot trial. The participants, who were frail older adults with a history of stroke, were randomized to 2 rehabilitation groups: intervention group (n = 15) and control (n = 15). All participants (65–94 years) attended twelve 20-min sessions twice a week for 6 weeks of either standard rehabilitation (control group) or standard rehabilitation with pulmonary training including home pulmonary exercise (intervention group). The main outcome measures were pulmonary function (%MIP), deglutition (DRACE), and QOL (SF8·PCS), while secondary outcomes were muscle strength (grip and abdominal), thorax flexibility, 6-min walk distance, and activities in daily living. All outcomes were measured both prior to training and after the 12 sessions.

Results: The intervention group showed significant improvement in %MIP (95% CI, 2.9–31.6; $p < 0.01$), DRACE (95% CI, −4.1–0.1; $p < 0.01$), and SF8·PCS (95% CI, 2.5–7.2; $p < 0.01$) compared with controls. There were no cognitive function decline and higher brain dysfunction.

Conclusions: These results suggest that the addition of pulmonary training including home pulmonary exercise to a standard rehabilitation program could improve pulmonary function, deglutition, and QOL in frail elderly people with chronic stroke.

KEYWORDS
frailty, older adults, pulmonary rehabilitation, quality of life, respiratory function, stroke, swallowing function

Naoki Maki and Harumi Sakamoto contributed equally as co-first authors.

1 | INTRODUCTION

Worldwide, stroke is the second leading cause of death[1] and the most common cause of disability. In Japan, it is a major reason for mortality among elderly people.[2,3] Previous studies have reported that stroke affects the muscles of the upper and lower limbs, as well as those of the respiratory system, placing poststroke patients at risk of poor respiratory function and dysphagia. These patients have comorbidities, such as hemiplegia, poor sitting posture, balance, and alertness, resulting in cognitive and perceptual impairment with regard to coughing and deglutition.[4–6] Decreased pulmonary function and poor deglutition are major risk factors for aspiration pneumonia.

In Japan, pneumonia is the fifth leading cause of death among older adults. Aspiration pneumonia can lead to decreased physical and mental function, which can affect activities of daily living (ADL) and quality of life (QOL). Katzan et al.[6] reported that dysphagia, a common complication in stroke patients, is considered to be a major risk factor for poststroke pneumonia.

Our previous study investigated the pulmonary function, deglutition, and QOL of 15 chronic stroke patients and conducted rehabilitation programs that included pulmonary training.[7] Pulmonary function, deglutition, and QOL significantly improved with pulmonary rehabilitation, which is in line with previous reports of improved respiratory function from pulmonary rehabilitation in acute/subacute stroke patients.[8–12] However, the effects of pulmonary function, deglutition, and QOL in chronic stroke patients have not yet been elucidated in a randomized controlled trial. The purpose of this study was, therefore, to evaluate the effects of pulmonary training on the pulmonary function, deglutition, and QOL of community-dwelling, frail elderly people who had a history of stroke.

2 | METHODS

2.1 | Participant pool

Participants were recruited from May 2016 to July 2019 (follow-up: from July 2016 to September 2019) in a day care rehabilitation center in Ishioka city, Japan. The inclusion criteria included the following: history of stroke diagnosed by clinicians and needing rehabilitation, more than 65 years of age, 6 months since acute disease onset, and period since stroke onset of >6 months, and being in a physical condition that can be described as "frail" as defined by the Fried Frailty Criteria (Cardiovascular Health Study: CHS index).[13] Participants who could not use an auto spirometer or with moderate or severe cardiac disease (New York Heart Association[14] Classification of III or IV) [7,15] were excluded from the study.

2.2 | Study design

This study was designed as an open, randomized, controlled trial in which participants underwent 12 rehabilitation sessions (2 sessions a week for 6 weeks) that comprised either standard rehabilitation (control group) or standard rehabilitation with pulmonary training and home exercise program (intervention group). Baseline demographics, characteristics, and outcome measures for each participant were evaluated before randomization into groups.

For the intervention group, each 20-min rehabilitation session was held once a day and was made up of 10 mins of pulmonary training in addition to 10 min of standard rehabilitation.[7,15] The pulmonary training intervention comprised the following: pulmonary muscle training, stretching exercise, and home exercise.[7,15,16] Pulmonary muscle training involved the use of the Threshold PEP (Philips Company) positive expiratory pressure device set at 60% of the individual's maximal expiratory mouth pressure. Three sets of 10 breaths were performed using the Threshold PEP with resting periods of 1 min between sets.[15–20] Cough exercise was performed using 3 sets of 10 times, low-intensity (≤40% of a single repetition maximum: 1RM[17]) active coughs.[15] 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.[15]

For home training, the intervention group used the positive expiratory pressure device to do pulmonary muscle training (3 sets of 10 repeats) and cough training (3 sets of 10 repeats, low-intensity active coughs), pursed-lip breathing (3 sets of 10 repeats) every day.[7,15,21] Instruction from the physiotherapist was done before the first session of home pulmonary training. For pursed-lip breathing, the intervention group was instructed to breathe inspiratory through the nose for 2–3 s with slow expirations over 4–6 s. Participants recorded each training session in their diaries and these records were regularly checked by the physiotherapist in the rehabilitation center at least 2 days per week.

The standard rehabilitation program comprised of the following: range of motion exercises, muscle strengthening training of lower extremities, balance training, and gait training. 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.[15] Muscle strength training was performed low intensity (≤40% of 1RM[17]) using 3 sets of 10 active hip joint flex, abduction, and knee joint extension motions in the sitting position.[15] 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.[15]

2.3 | Randomization

A random group allocation sequence was generated by a computer, and randomization codes were put in opaque envelopes by the trial statistician at the University of Tsukuba. Participants who gave their informed consent to participate were assigned an identification number and the clinical occupational therapist opened the closed

envelope with the corresponding number, which included the randomization code for group allocation. The clinicians in charge of administering treatments, the assessing physiotherapists, and trial statisticians were blinded to the allocation of participants to the intervention and the controlled groups. The assessing physiotherapists were separated from the physiotherapists who provided the intervention. The physiotherapists who provided rehabilitation were not blinded to the allocation.

2.4 | Assessment

2.4.1 | Pulmonary function

Pulmonary function was evaluated using a pulmonary function test with an auto spirometer (Vitalopower KH-801; Philips Company[16]). The forced vital capacity (FVC), forced expiratory volume in 1 s (FEV1), FEV1/forced vital capacity, cough peak flow (CPF), and measurement of maximal inspiratory (MIP) and expiratory (MEP) mouth pressures were used for assessments of pulmonary muscle strength. The maximum value of 3 measurements was used for analysis. The standard regression equation published by the Japanese Respiratory Society was used to calculate all predictive values.[7,15,22,23] All respiratory parameters (excluding CPF) were used as a percentage of predicted values.

2.4.2 | Deglutition

Deglutition was evaluated using the Dysphagia Risk Assessment for the Community-Dwelling Elderly (DRACE) Test.[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 is indicative of severe dysphagia. A score of 3 points or less is considered normal deglutition, and more than a score of 4 is an indicator of being at risk dysphagia.

2.4.3 | Cognitive function

Cognitive function was measured using Mini-Mental State Examination (MMSE)[25] score. A score between 24 and 30 points is considered normal cognitive function; a score of 19 to 23 indicates borderline cognitive impairment, and anything below a score of 19 is an indicator of cognitive impairment.

2.4.4 | Muscle strength

Grip strength was measured using a hand dynamometer (Grip D TKK5401; TKK) with participants in a sitting position. Abdominal muscle was classified from levels 0 to 5 using the manual muscle test in which the body is raised from a supine position.[7,15] For knee extension strength, quadriceps strength was measured using a handheld dynamometer (HHD; EG-230 SAKAI Medical Co.). Strength was measured in kgf/kg. Each test was repeated three times, and the maximum value was used for further analyses.

2.4.5 | Thoracolumbar measurement of joint range

The range of motion (ROM) of the thoracolumbar spine rotation was measured for both the paralyzed and nonparalyzed sides using a goniometer for thorax flexibility[7,15] with participants in a sitting position. Data for the ROM measurements are presented as the mean value of both left and right sides.

2.4.6 | Exercise endurance

The 6-min walk test (6MWT), which measures the distance an individual can walk in 6 min, was used as a measure of exercise tolerance.[26] 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, and respiratory rate were also measured before and after the walk. The guideline for stopping the 6MWT was a drop in SpO_2 of 85% or less.[7,15]

2.4.7 | Activities of daily living assessment

Activities of daily living was evaluated by a physiotherapist using the Barthel Index[27] which is comprised of 10 questions and has a maximum total score of 100 points.

2.4.8 | Quality of life assessment

Quality of life was assessed using the Medical Outcome Study 8-Item Short-Form Health Survey (MOS-SF8),[28] which includes both a physical component summary score (PCS) and a mental component summary score (MCS). The MOS-SF8 measures eight health subitems: (1) general health, (2) physical function, (3) role function (body), (4) body pain, (5) social function, (6) overall sense of well-being, (7) vitality, and (8) emotional function.

In accordance with standardized assessment procedures, the measurements in this study were conducted by licensed physical therapists. Primary outcome measures were designated as %MIP for pulmonary function, DRACE for deglutition, and SF8 (PCS) for QOL. Secondary outcome measures were designated as exercise tolerance, 6-min walk distance, thorax flexibility, muscle strength, and ADL. This study was conducted in accordance with Consolidated Standards of Reporting Trials (CONSORT) statement.

2.5 | Statistical analysis

SPSS version 25.0 (IBM Corporation) was used for statistical analyses. Power analysis calculated a minimum sample size using effect size in each group with a type 1 error at 0.05 and power at 0.80. The 2-way repeated-measures analysis of variance with Cohen's partial η^2 coefficient set at 0.060 was calculated as effect size and interaction effects of the groups (time ×effect). We tested the differences between the two groups at baseline using the Chi-square test for sex, disease, type of stroke, side of paresis and comorbidity, and Mann–Whitney U test for age and other baseline assessments. The outcome measures in each group were compared with the measures by using the Wilcoxon signed rank test. Differences between groups were compared using the 2-way repeated-measures analysis of variance. Data are shown as mean ± SD, median, and interquartile range. *p* values of <0.05 were set to significance.

2.6 | Ethical considerations

This study was carried out with the approval of the Ethics Committee of the University of Tsukuba (approval # 725: 30/03/2015, Clinical Trial registered on: 27/06/2015). This study was properly and prospectively registered through the relevant clinical trial registry. All participants provided written informed consent. The authors confirm that all ongoing and related trials for this intervention are registered.

3 | RESULTS

The participant flowchart before rehabilitation is shown in Figure 1. In this study, 76 participants were assessed for eligibility and 41 were excluded for the following reasons: 27 refused consent, 6 could not use an auto spirometer, and 8 had severe cardiac disease. The remaining 35 participants were randomized into either the intervention group (n = 17) or control group (n = 18). Postintervention outcomes for 2 members of the intervention and 3 members of the control group were not available as they were discharged before completing all 12 sessions. No participants withdrew because of adverse effects. A final total of 30 participants completed the study and 15 finished the pulmonary training program. Table 1 shows the characteristics and baseline clinical data for the study participants. There were no significant differences between the 2 groups in term of age, gender, BMI, type of stroke, %FVC, FEV1% (% predicted), muscle strength, 6MWT, Barthel Index, and DRACE ($p > 0.05$). Participant shows %FVC <80%. There was no chronic obstructive pulmonary disease

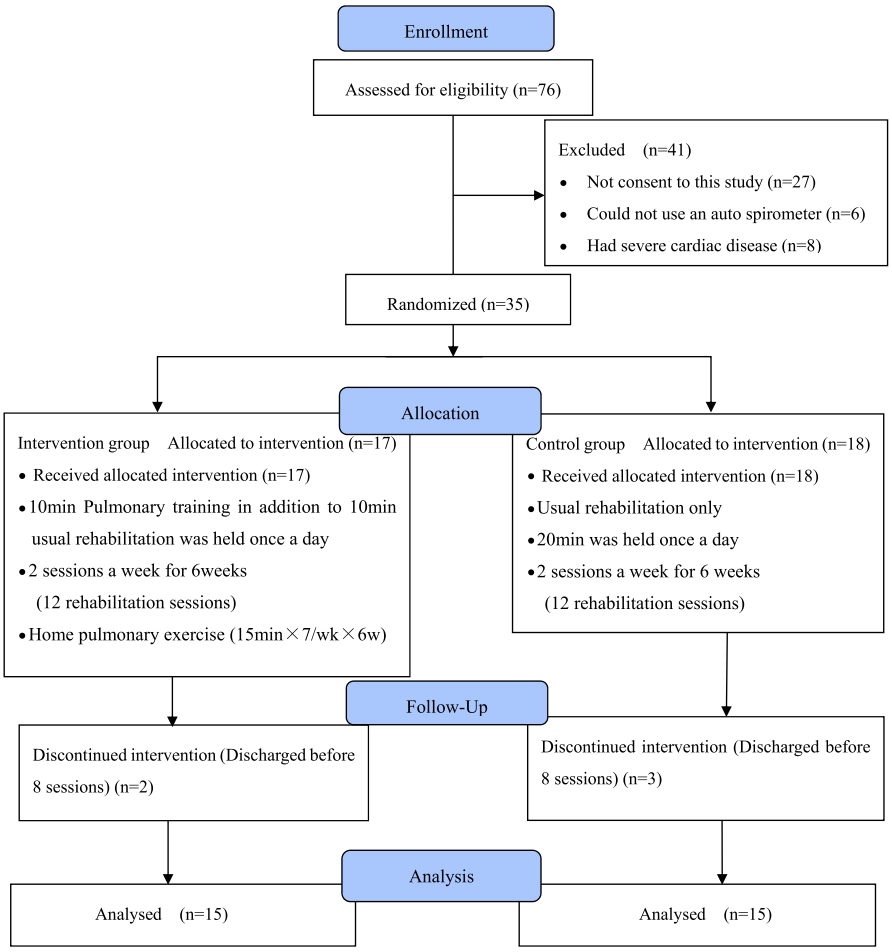

FIGURE 1 Flow of participation

TABLE 1 Demographic information of participants

Characteristics	Intervention groups ($n = 17$)	Control groups ($n = 18$)	p
Sex, Female (%)	9 (53%)	7 (39%)	0.36†
Age	81.5 (73.2–87.2)	79.0 (68.5–80)	0.25
BMI (kg/m²)	23.3 (21.1–25.6)	23.0 (20.1–26.2)	0.12
Type of stroke			0.74†
Ischemic	4 (24%)	5 (27%)	
Hemorrhagic	13 (76%)	13 (72%)	
Side of paresis			0.28†
Right	6 (35%)	8 (44%)	
Left	11 (65%)	10 (55%)	
Diseases			0.86†
COPD	0 (0%)	0 (0%)	
Chronic stable heart failure	1 (5%)	1 (6%)	
Comorbidity			
Hypertension	11 (65%)	9 (50%)	0.12
Diabetes mellitus	3 (17%)	4 (22%)	0.82
FVC (% predicted)	64.1 (58.6–75.8)	72.5 (64.7–73.3)	0.37
FEV1 (%predicted)	69.5 (55.0–83.7)	75.8 (55.3–96.1)	0.16
FEV1%	89.6 (78.3–98.1)	89.4 (79.9–99.0)	0.23
MIP (%predicted)	27.8 (14.9–32.4)	31.6 (25.1–42.4)	0.18
MEP (%predicted)	21.5 (14.0–31.7)	18.9 (14.6–24.5)	0.29
CPF (L/min)	230.8 (161.7–300.5)	243.0 (185.0–264.2)	0.46
Grip strength (kg)	16.9 (13.2–22.5)	19.3 (11.5–23.9)	0.55
Knee extension (kgf/kg)	21.5 (18.3–24.7)	23.5 (16.9–29.7)	0.13
6MWT (m)	75.0 (20–170)	60.0 (50.0–80.0)	0.86
MMSE	26.4 (25.0–28.0)	26.0 (24.5–28.0)	0.31
DRACE	6.5 (4.2–9.2)	5.5 (5.0–6.7)	0.43
Barthel index	60.5 (45.0–75.5)	62.5 (43.0–78.5)	0.47

Abbreviations: 6MWT, 6-min walk test; BMI, Body mass index; COPD, Chronic obstructive pulmonary disease; CPF, cough peak expiratory flow; DRACE, Dysphagia risk assessment for community-dwelling elderly; FEV1, forced expiratory volume at 1 s; FVC, forced vital capacity; MEP, PEmax = maximal expiratory mouth pressure; MIP, PImax = maximal inspiratory mouth pressure; MMSE, Mini-Mental State Examination.

*$p < 0.05$.

**$p < 0.01$ Median and interquartile range. *N* (%)

†Chi-square test, Mann–Whitney *U* test.

(COPD) within the two groups, but chronic stable heart failure was present in both the intervention group ($n = 1$) and control groups ($n = 1$). There were no cognitive function decline and higher brain dysfunction.

The outcome measures of the two groups are shown in Table 2. The intervention group showed significant increases in %FVC, %MIP, %MEP, CPF, thoracolumbar ROM, 6MWT, DRACE, and SF8 (PCS). On the other hand, the control group had no significant differences. The intervention group was significantly greater than the control group in the %FVC (95% CI, 2.1–14–7; $p < 0.01$), %MIP (95% CI, 2.9–31.6; $p < 0.01$), CPF (95% CI, 12.8–48.3; $p = 0.02$), thoracolumbar ROM (95% CI, 1.5–29.6; $p < 0.01$), 6MWT (95% CI, 15.3–46.1; $p < 0.01$), DRACE (95% CI, −4.1–0.1; $p = 0.01$), and SF8 (PCS) (95% CI, 2.5–7.2; $p < 0.01$). Significance between the two groups with regard to %FEV1, FEV1%, and SF8 (MCS) was not found ($p > 0.05$).

Compared with standard rehabilitation for participants with chronic stroke, the effect size for pulmonary training was 0.227 for the %MIP, 0.325 for the DRACE, and 0.202 for the SF8 (PCS). Power analysis calculated a minimum total sample size of at least 28 participants for the %MIP, 16 participants for the DRACE, and 36 participants for the SF8 (PCS) in the participants with a type 1 error at 0.05 and power at 0.80.[29] In this study, the sample size of 30 had sufficient detection power for the %MIP and DRACE; however, it was slightly short of that needed for the SF8 (PCS).

TABLE 2 Evaluation of differences within groups and differences between groups

	Intervention Group ($n = 15$)			Control Group ($n = 15$)				
Measures	**Pre**	**Post**	**Differences within groups (95%CI)†**	**Pre**	**Post**	**Differences within groups (95%CI)†**	**Differences between two groups (95%CI)‡**	**Effect size**
FVC (% predicted)	64.3 ± 11.1	70.7 ± 10.5	6.4 (2.1–11.2)**	69.2 ± 8.9	67.8 ± 9.5	−1.4 (−1.7–1.9)	7.8 (2.1–14.7)**	0.211
FEV1 (% predicted)	71.6 ± 20.1	77.9 ± 21.3	6.2 (−2.1–18.7)	76.3 ± 17.5	78.1 ± 18.0	1.8 (−3.8–2.7)	4.4 (−1.2–10.6)	0.003
FEV1%	93.6 ± 13.9	93.8 ± 19.8	0.2 (−2.5–5.7)	94.5 ± 16.1	96.1 ± 18.8	1.3 (−0.6–1.8)	1.4 (0.1–3.0)	0.019
MIP (% predicted)	27.8 ± 21.7	38.2 ± 25.4	10.4 (3.1–21.5)**	34.5 ± 13.5	30.6 ± 13.3	−3.9 (−5.1–1.2)	14.3 (2.9–31.6)**	0.227
MEP (% predicted)	22.5 ± 9.3	30.8 ± 11.6	8.3 (2.7–17.0)**	18.9 ± 7.9	17.5 ± 6.6	−1.4 (−3.9–0.9)	9.7 (2.1–20.5)**	0.318
CPF (L/min)	230.8 ± 83.5	273.0 ± 32.3	42.1 (18.2–70.3)*	235.2 ± 59.3	234.1 ± 55.7	12.6 (−1.3–16.3)	29.5 (12.8–48.3)*	0.273
Muscle strength								
Grip strength (kg)	18.2 ± 8.3	16.8 ± 8.7	−1.3 (−2.8–0.4)	20.1 ± 9.8	20.2 ± 9.2	0.1 (−2.4–2.2)	−1.2 (−2.3–1.2)	0.068
MMT (Abdominal)	2.7 ± 0.9	2.8 ± 0.9	0.1 (−1.1–1.2)	2.8 ± 0.9	2.9 ± 0.9	0.1 (−1.0–1.1)	0.1 (−1.0–1.1)	0.074
Thoracolumbar								
Spine ROM (°)								
Rotation	13.5 ± 5.3	30.3 ± 7.1	16.4 (5.1–21.5)**	19.2 ± 7.8	21.5 ± 6.5	2.3 (−5.2–5.5)	14.1 (1.5–29.6)**	0.508
6MWT (m)	91.2 ± 78.4	125.5 ± 106.3	38.3 (19.4–57.7)**	75.0 ± 58.4	74.2 ± 61.5	7.5 (−4.0–14.0)	30.8 (15.3–46.1)**	0.292
Deglutition								
DRACE	6.9 ± 4.5	4.4 ± 2.4	−2.5 (−2.9–0.5)**	5.5 ± 1.5	5.5 ± 1.6	0.1 (−0.1–0.2)	−2.6 (−4.1–0.1)**	0.325
ADL								
Barthel index	60.2 ± 19.7	61.9 ± 20.8	1.7(−3.2–6.5)	62.0 ± 18.7	62.0 ± 18.7	0 (0.0)	1.7(−3.2–6.5)	0.028
QOL								
SF8 (PCS)	32.1 ± 7.9	38.6 ± 8.3	6.5 (1.5–11.5)**	40.7 ± 7.8	38.8 ± 10.2	−1.9 (−2.1–0.1)	4.8 (2.5–7.2)**	0.202
SF8 (MCS)	44.0 ± 8.2	44.1 ± 9.3	0.1 (−1.7–1.8)	44.7 ± 5.4	45.6 ± 6.1	0.9 (−0.1–1.3)	−0.8 (−1.2–0.4)	0.017

*$p < 0.05$.

**$p < 0.01$. mean ± SD.

†Wilcoxon signed rank test.

‡2-way repeated-measures analysis of variance.

Abbreviations: 6MWT, 6-min walk test; Borg scale, rate of perceived exertion; DRACE, Dysphagia risk assessment for community-dwelling elderly; FEV1, forced expiratory volume at 1 s; FVC, forced vital capacity; MEP, PEmax = maximal expiratory mouth pressure; MIP, PImax = maximal inspiratory mouth pressure; MMT, Manual Muscle Test; PCF, cough peak expiratory flow; ROM, range of motion; SF8MCS, Mental component summary; SF8PCS, Physical component summary.

4 | DISCUSSION

The findings of our study suggest that rehabilitation programs, which include pulmonary training, can improve the respiratory function, deglutition, and QOL of community-dwelling frail elderly people who have a history of chronic stroke. Our data indicate that pulmonary training (including home exercise) sessions as part of a standard rehabilitation program can aid the recovery of pulmonary function, deglutition, and QOL more efficiently than standard rehabilitation alone. Therefore, we recommend that for frail elderly people, even for those in whom stroke has decreased pulmonary function, pulmonary training has many benefits for preventive care and improvement of QOL.

Reduced deglutition and pulmonary functions are reported to be major risk factors for aspiration pneumonia as weak coughing, which is reflective of poorly coordinated activation of respiratory and intrinsic laryngeal muscles, is a leading cause of this disease.[15,30] Our data show that maximal inspiratory mouth pressure and cough peak flow are improved by pulmonary training in frail elderly people with histories of stroke. Thus, the addition of pulmonary training could be an effective way to improve pulmonary function and deglutition in this vulnerable population.

Our data show that, even after a stroke, the %FVC and thoracolumbar ROM of frail elderly persons with restrictive ventilation disorder were significantly improved by respiratory rehabilitation training. Baruch et al.[31] evaluated the pulmonary function of 32 idiopathic pulmonary fibrosis patients with restrictive ventilation disorder and reported that their %FVC improved with respiratory exercise training. Baruch et al. also suggested the possibility that "repetitive stimulus of high ventilatory demands during exercise sessions, chest expansion during deep breathing exercises, and stretching of the thoracic muscles[31] result in a more efficient breathing pattern, improved strength of respiratory muscles, enhanced pleural elasticity, pulmonary compliance within the lung tissue, and decreased dyspnea perception following the [exercise training] program" used in their study.[31] Our data were consistent with this report and suggest that standard rehabilitation programs without a pulmonary training component are insufficient for frail elderly persons with a history of stroke to maintain their pulmonary function, deglutition, and QOL.[7,15]

International guidelines regarding pulmonary rehabilitation for those with COPD and other respiratory diseases suggest that the rehabilitation is most effective when held 5 days per week for 6–8 weeks.[32] In our study, the participants received only 2 weekly rehabilitation sessions and the duration of each session was short (for both pulmonary training and standard rehabilitation). However, our intervention included daily home pulmonary training in addition to the in-facility pulmonary rehabilitation sessions. Moreover, our trial had no COPD patients within either group. According to a previous, randomized controlled trial with chronic stage stroke, Bang et al.,[33] Seo et al.,[34] and Jung et al.[35] reported improvements in respiratory function from pulmonary training held 5 days per week for 4 weeks. Additionally, Kim et al.[36,37] described improvements in respiratory function through respiratory muscle training held 3 days per week for 4 weeks.[38] Our data were similar to these reports and show that pulmonary function, deglutition, and QOL of chronic stroke patients are improved by the addition of pulmonary training to a standard rehabilitation program.

We must acknowledge some limitations in the present study. Firstly, the intervention group, which included home pulmonary training, exercised more than the control group. It was difficult to determine whether the improvement seen in the intervention group was because of the effects of the pulmonary training or the greater amount of training. Secondly, the physical therapists who conducted rehabilitation and the participants were not blinded to the participants' allocation to the two groups; therefore, it is difficult to exclude the possibility of experimenter bias. Thirdly, while our results showed the benefit of pulmonary training in the intervention group versus the control across many of the outcome measures, we did not evaluate whether the changes were clinically important for the parameters that were statistically significant difference. Future studies that include a thorough evaluation of Minimal Clinically Important Difference (MCID) would therefore be of useful. Finally, the sample size of 30 participants in this study was low because of the single center design. Power analysis for the outcome measures showed that this number was sufficient for %MIP and DRACE; however, a sample size of at least 36 required for the SF8 (PCS). Because of this shortfall, the validity of findings with regard to the SF8 (PCS) results remain in question. Therefore, because the size of the study groups was statistically insufficient to make concrete conclusions, this study should be considered as a randomized pilot study, that, despite its limitations, lays the groundwork for future larger-scale studies. For future studies, the utilization of blinded, randomized, controlled trials with an effective regression framework would increase the generalizability and feasibility of the findings.

5 | CONCLUSIONS

The results of this study suggest that the addition of pulmonary training, including home exercise regimens, to a standard rehabilitation program could improve pulmonary function, deglutition, and QOL in frail older adults with a history of chronic stroke.

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CONFLICT OF INTEREST

Authors declare no conflict of interests for this article. All authors have read and approved submission of the original manuscript, and

the manuscript has not been published and is not being considered for publication elsewhere in whole or in part in any language.

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REFERENCES

1. World Health Organization Home Page. The top 10 causes of death. 2021. https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death. Accessed March 14, 2019.
2. Ministry of Health, Labour and Welfare Home Page Specified Report of Vital Statistics in Japan. http://www.mhlw.go.jp/english/topics/elderly/care/ (2012, Accessed February 5, 2021).
3. Morimoto K, Suzuki M, Ishifuji T, Yaegashi M, Asoh N, Hamashige N, et al. The burden and etiology of community-onset pneumonia in the aging japanese population: a multicenter prospective study. PLoS One. 2015;10(3):1–18.
4. Murray J, Scholten I. An oral hygiene protocol improves oral health for patients in inpatient stroke rehabilitation. Gerodontology. 2018;35:18–24.
5. Billinger SA, Coughenour E, MacKay-Lyons MJ, Ivey FM. Reduced cardiorespiratory fitness after stroke: biological consequences and exercise-induced adaptations. Stroke Res Treat. 2012;2012:1–11.
6. Katzan IL, Cebul RD, Husak SH, Dawson NV, Baker DW. The effect of pneumonia on mortality among patients hospitalized for acute stroke. Neurology. 2003;60:620–5.
7. Maki N, Harumi Sakamoto YU, Takata SW, Sato Y, Yanagi H, et al. The effect of respiratory rehabilitation for the frail elderly: a pilot study. General Medicine. 2016;17(4):289–98.
8. Kulnik ST, Birring SS, Moxham J, Rafferty GF, Kalra L. Does respiratory muscle training improve cough flow in acute stroke? Pilot Randomized Controlled Trial. Stroke. 2015;46(2):447–53.
9. Sutbeyaz ST, Koseoglu F, Inan L, Coskun O. Respiratory muscle training improves cardiopulmonary function and exercise tolerance in subjects with subacute stroke: a randomized controlled trial. Clin Rehabil. 2010;24(3):240–50.
10. Guillén-Solà A, Messagi Sartor M, Bofill Soler N, Duarte E, Barrera MªC, Marco E. Respiratory muscle strength training and neuromuscular electrical stimulation in subacute dysphagic stroke patients: a randomized controlled trial. Clin Rehabil. 2017;31(6):761–71.
11. Kulnik ST, Rafferty GF, Birring SS, Moxham J, Kalra L. A pilot study of respiratory muscle training to improve cough effectiveness and reduce the incidence of pneumonia in acute stroke: study protocol for a randomized controlled trial. Trials. 2014;15:123.
12. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J Psychiat Res. 1975;12:189–98.
13. Qian-Li X. The frailty syndrome: definition and natural history. Clin Geriatr Med. 2011;27:1–15.
14. Raphael C, Briscoe C, Davies J, Ian Whinnett Z, Manisty C, Sutton R, et al. Limitations of the New York heart association functional classification system and self-reported walking distances in chronic heart failure. Heart. 2007;93:476–82.
15. Maki N, Sakamoto H, Takata Y, Kobayashi N, Kikuchi S, Goto Y, et al. Effect of respiratory rehabilitation for frail older patients with musculoskeletal disorders: a randomized controlled trial. J Rehabil Med. 2018;50:908–13.
16. Tout R, Tayara L, Halimi M. The effects of respiratory muscle training on improvement of the internal and external thoraco-pulmonary respiratory mechanism in COPD patients. Ann Phys Rehabil Med. 2013;56:193–211.
17. Mangine GT, Hoffman JR, Gonzalez AM, Townsend JR, Wells AJ, Jajtner AR, et al. The effect of training volume and intensity on improvements in muscular strength and size in resistance-trained men. The effect of training volume and intensity on improvements in muscular strength and size in resistance-trained men. Physiol Rep. 2015;3(8):1–17.
18. Pontifex E, Williams MT, Lunn R, Parsons D. The effect of huffing and directed coughing on energy expenditure in young asymptomatic subjects. Aust J Physiother. 2002;48:209–13.
19. Pryor JA, Webber BA, Bethune D. Physiotherapy techniques. In: Pryor JA, Prasad SA, eds. Physiotherapy for Respiratory and Cardiac Problems: Adults and Paediatrics. 3rd ed. Churchill Livingstone: Edinburgh; 2002:161–242.
20. Merrick J, Axen K. Inspiratory muscle function following abdominal weight exercises in healthy subjects. Phys Ther. 1981;61(5):651–6. https://doi.org/10.1093/ptj/61.5.651. PMID: 7232502.
21. Inagaki T, Terada J, Tanabe N, Kawata N, Kasai H, Sugiura T, et al. Home-based pulmonary rehabilitation in patients with inoperable or residual chronic thromboembolic pulmonary hypertension: a preliminary study. Respir Investig. 2014;52(6):357–64.
22. Quanjer PH, Stanojevic S, Cole TJ, Baur X, Hall GL, Culver BH, et al. Multi-ethnic reference values for spirometry for the 3–95-year age range: the global lung function 2012 equations. Eur Respir J. 2012;40(6):1324–43.
23. Tamura G, Aizawa H, Nagai A, Inoue H. Common prediction equations of respiratory function tests from children to adults in Japan (in Japanese). J Jpn Respir Soc. 2007;42(7):535–42.
24. Miura H, Kariyasu M, Yamasaki K, Arai Y. Evaluation of chewing and swallowing disorders among frail community-dwelling elderly individuals. J Oral Rehabil. 2007;34:422–7.
25. Crum RM, Anthony JR, Bassett SS, Folstein MF. Population based norms for the mini-mental state examination by age and educational level. JAMA. 1993;269(18):2386–91.
26. American Thoracic Society. ATS statement: guidelines for the six-minute walk test. Am J Respir Crit Care Med. 2002;166:111–7.
27. Higuchi S, Kabeya Y, Matsushita K, Taguchi H, Ishiguro H, Kohshoh H, et al. Barthel index as a predictor of 1-year mortality in very elderly patients who underwent percutaneous coronary intervention for acute coronary syndrome: better activities of daily living, Longer Life. Clin Cardio. 2016;39:83–9.
28. Fukuhara S, Ware JE, Kosinski M, Wada S, Gandek B. Psychometric and clinical tests of validity of the Japanese SF-36 health survey. J Clin Epidemiol. 1998;51:1045–53.
29. Cohen J. A power primer. Psychol Bull. 1992;12:155–9.
30. Hammond CA, Goldstein LB, Zajac DJ, Gray L, Davenport PW, Bolser DC. Assessment of aspiration risk in stroke patient with quantification voluntary cough. Neurology. 2001;56:502–6.
31. Vainshelboim B, Oliveira J, Yehoshua L, Weiss I, Fox BD, Fruchter O, et al. Exercise training-based pulmonary rehabilitation program is clinically beneficial for idiopathic pulmonary fibrosis. Respiration. 2014;88:378–88.
32. ACCP/AACVPR pulmonary rehabilitation guidelines panel. Pulmonary rehabilitation: joint ACCP/AACVPR evidence-based guidelines. Chest. 1997;112:1363–96.
33. Bang D-H, Son Y-L. Effect of intensive aerobic exercise on respiratory capacity and walking ability with chronic stroke patients: a randomized controlled pilot trial. J Phys Ther Sci. 2016;28(8):2381–4.
34. Seo KC, Lee HM, Kim HA. The effects of combination of inspiratory diaphragm exercise and expiratory pursed-lip breathing exercise on pulmonary functions of stroke patients. J Phys Ther Sci. 2013;25(3):241–4.
35. Jung JH, Shim JM, Kwon HY, Kim HR, Kim BI. Effects of abdominal stimulation during inspiratory muscle training on respiratory function of chronic stroke patients. J Phys Ther Sci. 2014;26(1):73–6.
36. Kim K, Fell DW, Lee JH. Feedback respiratory training to enhance chest expansion and pulmonary function in chronic stroke:

a double-blind, randomized controlled study. J Phys Ther Sci. 2011;23(1):75–9.
37. Kim J, Park JH, Yim J. Effects of respiratory muscle and endurance training using an individualized training device on the pulmonary function and exercise capacity in stroke patients. Med Sci Monit. 2014;20:2543–9.
38. Menezes KK, Nascimento LR, Avelino PR, Alvarenga MTM, Teixeira-Salmela LF. Efficacy of interventions to improve respiratory function. Respir Care. 2018;63(7):920–33.

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