[Environmental Health and Preventive Medicine 11, 221–227, September 2006]

Original Article

Randomized Controlled Trial to Evaluate Effectiveness of Exercise Therapy (Takizawa Program) for Frail Elderly

Mitsuyo MAKITA[1], Hiroto NAKADAIRA[2] and Masaharu YAMAMOTO[3]

[1]*Department of Physical Therapy, School of Health Science, Niigata University of Health and Welfare, Niigata, Japan*
[2]*Department of Nursing, Faculty of Nursing, Social Welfare, and Psychology, Niigata Seiryo University, Niigata, Japan*
[3]*Department of Community Preventive Medicine, Graduate School of Medical and Dental Sciences, Niigata University, Niigata, Japan*

Abstract

Objective: Although exercise therapy intervention for frail elderly people was not of great interest in the past, it has recently drawn attention as a method to prevent and improve conditions requiring care since the enforcement of the Long-Term Care Insurance Law and the revision of the long-term care insurance system. This randomized controlled trial was performed to evaluate the effects of exercise therapy using the Takizawa Program.

Methods: In this randomized controlled trial, we evaluated the effects of exercise therapy on the frail elderly, including those who need a high level of care, in terms of two factors: the range of motion and the functional independence measure. The subjects were 145 females admitted to special nursing homes for the elderly. They were stratified according to their care levels and randomly assigned to either the exercise therapy intervention group or the control group.

Results: The range of motion values in the flexions of both shoulders, the right knee extension, and the dorsal flexions of both ankles significantly increased only in the exercise therapy intervention group. The functional independence measure score did not improve in the exercise therapy intervention group.

Conclusion: Exercise therapy should be used for the frail elderly requiring a high level of care.

Key words: randomized controlled trial, exercise therapy, frail elderly, range of motion (ROM), functional independence measure (FIM)

Introduction

Exercise therapy for the frail elderly was previously considered to be of little interest. However, the Long-Term Care Insurance Law enforced in 2000 has raised interest in exercise therapy for disabled elderly people in the maintenance phase (1–5). Furthermore, the long-term care insurance system will be changed to a care prevention-oriented system in 2006 (6). The goal of this system is to maintain and improve the conditions requiring long-term care and to prevent the aggravation of their conditions. Exercise therapy for the frail elderly is necessary to achieve this goal. However, this therapy is only applied to at-home patients who require light care or who are at a high risk of disabilities requiring care.

For patients admitted to special nursing homes, trials to change the "activity of daily living (ADL) to perform possibly" to "ADL to perform definitely" (7, 8) are conducted, but exercise therapy for maintaining and improving motor functions that are essential for ADL is not yet regularly performed. Many long-term-care facilities use recreation as a substitute for exercise therapy, although it is often, for safety reasons, performed while sitting, which limits its effects on the functions of the lower limbs and trunk and promotes disuse atrophy (9). Thus, exercise therapy for the frail elderly has increasingly drawn attention, but it has generally only been applied to patients requiring light care.

We have developed the Takizawa Program as an exercise therapy for the bedridden elderly with marked hypofunction (10–14), and we have used it for approximately 15 years. The Takizawa Program (11), which was used in this study, is designed so that the frail elderly can perform essential physical exercises to achieve upright position and gait. The program uses exercises ranging from assistive to resistive, according to the

Received Dec. 21, 2005/Accepted May 31, 2006
Reprint requests to: Mitsuyo MAKITA
Department of Physical Therapy, School of Health Science, Niigata University of Health and Welfare, 1398 Shimami-cho, Niigata 950-3198, Japan
TEL & FAX: +81(25)257-4451
E-mail: makita@nuhw.ac.jp

conditions of the subjects, to increase the range of motion values of large joints and the movements of large muscles in the trunk and limbs. Most of these exercises, however, are active assistive exercises.

The program is performed three times per week while sitting or standing. The program includes the following exercises:

1. Upper limb range of motion exercise using a movable pulley
2. Trunk flexion and twisting exercise with abdominal breathing
3. Ankle plantar-dorsal flexion exercise using the instrument "PATA"
4. Knee flexion-extension exercise using the instrument "KORO"
5. Shoulder and elbow flexion-extension exercise
6. Knee extension exercise
7. Hip flexion exercise
8. Standing balance exercise using parallel bars or stall bars.
9. Hip abduction, hip flexion, hip extension, squat, and tip-toe standing using parallel bars.
10. Walking forward, backward, and sideward using parallel bars.
11. Ambulatory exercise using a walker developed specifically for this program (15). It has "sleds" on the front wheels to prevent the user from reaching high speeds.

This program is now widely practiced as an individual exercise therapy for the frail elderly in some special nursing homes for the elderly and in geriatric hospitals, but no data has been obtained from studies including a randomized controlled trial (RCT). Clarifying the efficacy of this exercise therapy for the patients in these facilities may draw more attention to exercise therapy for the frail elderly.

Therefore, this RCT was performed to evaluate the effects of exercise therapy using the Takizawa Program in terms of two factors: range of motion (ROM) and functional independence measure (FIM).

Subjects and Methods

Subjects

The subjects were female patients in three special nursing homes for the elderly in the Tokyo Metropolitan area and Niigata Prefecture who were in stable health and agreed to participate in this study. The subjects in each nursing home were stratified in terms of their care levels and then randomly assigned to either the exercise therapy intervention group (Ex group) or the control group (Co group).

Care levels are defined in the Long-Term Care Insurance Law, and are determined on the base of the total time required for assistance with ADL's, Instrumental ADL's, functional training, and medical services. The care levels and corresponding estimated times per day required for care are as follows (6).

Assistance needed: from 25 to 30 minutes (because the patients classified in this level are not admitted to facilities, they were not included in this study).

Care level 1: from 30 to 50 minutes.

Care level 2: from 50 to 70 minutes.

Care level 3: from 70 to 90 minutes.

Care level 4: from 90 to 110 minutes.

Care level 5: 110 minutes or longer.

This study was reviewed and approved by the ethics committee of each of the participating facilities and the ethics committee of Niigata University of Health and Welfare. The purpose of this study and the contents of the exercise program were explained in detail by the health care staff to each subject or her appropriate family member when a subject could not understand by herself. All the subjects or their families gave written informed consent before participating in this study.

Exercise therapy and procedure

Exercise therapy interventions were performed three times per week for three months at all the facilities. Even though these facilities are special nursing homes for the elderly, they can provide organized physical exercise and have nurses and careworkers who serve as physical exercise instructors.

Endpoints and measurers/evaluators

ROM value was measured, and FIM score was obtained to evaluate the effects of the exercises.

ROM value was measured for shoulder flexion, knee extension, ankle dorsal flexion, and ankle plantar flexion using the method recommended by the Japanese Orthopedic Association and the Japanese Association of Rehabilitation Medicine. Measurements were made before and after the exercise therapy intervention. At the nursing homes in Niigata, the patients exercise sessions were led by one physical therapist, whereas at the nursing home in Tokyo, the exercise sessions were led by physical exercise trainers and the exercises were checked by the same physical therapist who visited the Niigata nursing homes once a month. The evaluators of ROM were physical therapists working for other facilities, who were not involved in the exercise therapy.

The FIM method is used to evaluate ADL in the integrated data system that was developed in 1979 through the Stroke Outcome Study, which was conducted by the American Congress of Rehabilitation Medicine in cooperation with the American Academy of Physical Medicine and Rehabilitation, primarily involving 17 facilities. FIM consists of 18 factors, and is characterized by examining the details of self-care and transfer activities and also by addressing issues of communication and social cognition (16). Saitoh et al. (17) have reported that the time needed for care is 1.61 minutes per item.

The functional levels and scores of FIM include the following seven grades:

7: No assistance from others is needed in performing ADLs. (Complete independence)
6: One or more of the following are needed to perform any ADL: use of assistive devices, longer time than usual, and safety considerations. (Modified independence)
5: Assistance including monitoring patients or setting up necessary devices is needed in performing ADLs. (Supervision, Setup)
4: Patients exerting 75% or greater effort to perform the exercises and need no more assistance than just mild physical support. (Minimal assistance)
3: Patients exerting between 50 and 75% effort to perform

the exercises and need more assistance than mild physical support. (Moderate assistance)
2: Patients exerting between 25 and 50% effort to perform the exercises. (Maximal assistance)
1: Patients exerting less than 25% effort to perform the exercises. (Total assistance)

The evaluators of FIM in this study were the careworkers who provided daily care to the patients, and were blind to the patient's assignments to the Ex or Co group.

Statistical analyses

The distribution of the care levels was analyzed using the chi-square test. Mean ages were compared using Student's t-test. ROM values before and after the exercise therapy intervention were compared in each group using the paired-t test and between both groups using Student's t-test. FIM scores were compared between the two groups before and after the exercise therapy interventions using Mann-Whitney's U test, and those before and after the exercise therapy intervention were compared in each group using the Wilcoxon signed-rank sum test.

Results

Characteristics of subjects from three facilities

The number of subjects and the timing of the study in each facility were as follows:

Facility A in Niigata admitted 72 patients, and 60 of them were female, of whom 52 participated in a study performed from May to August in 2003. Facility B in Tokyo admitted 104 patients, and 84 of them were female, of whom 59 participated in a study performed from November, 2003 to January, 2004. Facility C in Niigata admitted 50 patients, and 40 of them were female, of whom 38 participated in the study performed from June to September in 2004. The total number of subjects from the three facilities was 149 (Ex group 74; Co group 75), of whom 145 subjects (Ex group 71; Co group 74) participated throughout their entire intervention period. FIM score was measured for all the subjects, but ROM value was measured only for 67 subjects in the Ex group and 58 subjects in the Co group (Table 1). ROM value was not measured in some subjects because they were absent as a results of hospitalization or were sick on the day of the measurement.

Table 1 shows the distribution of care levels for the subjects in the Ex and Co groups whose FIM score and ROM value were measured before and after the exercise therapy intervention. There was no significant difference in the distribution of care levels between the Ex and Co groups (for the subjects whose FIM score was measured, p=0.965; for the subjects whose ROM was measured, p=0.357).

For all the subjects, the mean period from admittance to the beginning of the intervention study was 1256 days (30–11940 days), and the median of the period from admittance to the beginning of the intervention study for the Ex group was 1160.5 days and that for the Co group was 1280.5 days. The mean ages were 84.85±7.30 in the Ex group and 86.25±6.59 in the Co group (p=0.114).

Comparison of ROM values

(1) Comparison of ROM values between groups before exercise therapy intervention

The baseline differences in ROM values between both groups were not significant except right shoulder flexion (p=0.048) (Table 2).

(2) Comparison of ROM values between groups after exercise therapy intervention

The ROM values for right shoulder flexion (p=0.001), left shoulder flexion (p=0.005), right knee extension (p=0.022), and left knee extension (p=0.047) were significantly higher in the Ex group than in the Co group (Table 2).

(3) Comparison of ROM values between before and after exercise therapy intervention for each group

The Ex group showed improvements in ROM values for right shoulder flexion (p=0.009), left shoulder flexion (p=0.028), right knee extension (p=0.001), right ankle dorsal flexion (p=0.005), and left ankle dorsal flexion (p=0.006) compared with those before the exercise therapy intervention (Table 2). On the other hand, the Co group showed no significant improvements.

(4) Difference in amount of change in ROM value between before and after exercise therapy intervention

As for differences in the amounts of change in ROM value, the values of right knee extension (p=0.069), and left ankle dorsal flexion (p=0.018) markedly increased in the Ex group (Table 3).

Table 1 Distribution of care levels for subjects

Care level[$]	Length of time for care per day[$]	Number of subjects whose FIM* was measured			Number of subjects whose ROM[#] was measured		
		Ex group[¥]	Co group[¥]	p value[&]	Ex group[¥]	Co group[¥]	p value[&]
1	from 30 min. to 50 min.	5	4		5	3	
2	from 50 min. to 70 min.	9	10		9	2	
3	from 70 min. to 90 min.	19	17		16	15	
4	from 90 min. to 110 min.	16	17		15	15	
5	110 min. or longer	22	26		22	21	
Total		71	74	0.965	67	58	0.357

* Functional Independence Measure.
[#] Range of motion.
[$] Care level is defined in the Long-Term Care Insurance Law, and determined on the bases of the total time required for assistance.
[¥] Value indicates number of subjects.
[&] p value by chi-square test for independence test.

Table 2 Differences in range of motion values between groups before and after exercise therapy intervention

	Before intervention		p value	After intervention	p value[#]	After intervention	p value	p value
	Ex group*	Co group*	Before	Ex group*	Before-after	Co group*	Before-after	After
Right shoulder flexion	109.6±38.5	95.3±40.2	0.048[#]	116.3±34.5	0.009[$]	93.4±43	0.471	0.001[##]
Left shoulder flexion	109.6±34.3	97.1±39.1	0.070	114.7±31.6	0.028[$]	95.8±39.7	0.899	0.005[#]
Right knee extension	−24±21	−29.3±27.3	0.244	−19.1±18.7	0.001[$$]	−29.9±30.1	0.615	0.022[#]
Left knee extension	−20.6±23.7	−25±25.1	0.330	−18.9±20.8	0.565	−28.8±31.4	0.347	0.047[#]
Right ankle dorsal flexion	1.8±25.2	4.6±13.8	0.249	5.1±9.6	0.005[$$]	3.8±15.4	0.825	0.630
Left ankle dorsal flexion	0.9±15.5	3.3±14	0.416	4.7±16.5	0.006[$$]	2.7±13.2	0.806	0.464
Right ankle plantar flexion	35.7±11.7	33.9±15.8	0.498	36.5±10.9	0.583	36.2±12.2	0.353	0.872
Left ankle plantar flexion	37.2±9.9	34.5±11.9	0.202	36.7±11.5	0.212	37.0±11.9	0.089	0.479

* Value indicates average range of motion in degrees of subjects.
[#] $p<0.05$, [##] $p<0.01$ by Student's t-test.
[$] $p<0.05$, [$$] $p<0.01$ by paired t-test.

Table 3 Comparison of amounts of change in range of motion (ROM) values between groups before and after exercise therapy intervention by care level

Care level	Right shoulder flexion			Left shoulder flexion		
	Ex group*	Co group*	p value	Ex group*	Co group*	p value
All subjects	6.7	−1.9	0.188	5.2	−1.3	0.182
Levels 1 and 2	2.3	1.0	0.439	4.3	9.0	0.196
Level 3	4.7	1.3	0.288	7.8	8.3	0.476
Level 4	10.3	−10.3	0.016[#]	5.0	−12.0	0.064
Level 5	8.6	−3.3	0.070	4.1	−2.9	0.185
	Right knee extension			Left knee extension		
	Ex group	Co group	p value	Ex group	Co group	p value
All subjects	4.9	−0.6	0.069[#]	1.8	−3.8	0.290
Levels 1 and 2	1.3	−3.0	0.090	5.7	−4.0	0.1547
Level 3	7.2	−0.3	0.036[#]	2.8	−5.7	0.0804
Level 4	8.7	6.7	0.328	4.7	7.3	0.3340
Level 5	3.2	−5.5	0.120	−3.6	−10.2	0.2676
	Right ankle dorsal flexion			Left ankle dorsal flexion		
	Ex group	Co group	p value	Ex group	Co group	p value
All subjects	3.3	−0.8	0.166	3.8	−0.6	0.018[##]
Levels 1 and 2	0.7	−1.0	0.364	3.3	0.0	0.178
Level 3	4.7	−1.3	0.035[#]	5.3	−3.3	0.006[##]
Level 4	3.7	3.7	>0.95	−0.7	−1.0	0.457
Level 5	3.9	−3.6	0.123	5.9	1.4	0.113
	Right ankle plantar flexion			Left ankle plantar flexion		
	Ex group	Co group	p value	Ex group	Co group	p value
All subjects	0.8	2.3	0.610	0.4	2.5	0.212
Levels 1 and 2	1.3	−2.0	0.281	3.7	6.0	0.358
Level 3	7.5	5.0	0.279	5.9	6.7	0.441
Level 4	6.0	2.0	0.153	−8.0	−2.0	0.096
Level 5	0.2	4.3	0.257	−1.5	1.8	0.447

* Value refers to average change in range of motion degrees.
[#] $p<0.05$, [##] $p<0.01$ by Student's t-test.

(5) Difference in amount of change in ROM value between before and after exercise therapy intervention by care level

For care level 3, statistically significant differences in ROM values were observed for right knee extension (p=0.036), right ankle dorsal flexion (p=0.035), and left ankle dorsal flexion (p=0.006) in the Ex group. For care level 4, a significant difference in ROM values was observed for right shoulder flexion (p=0.016) in the Ex group (Table 3).

Comparison of FIM scores

(1) Comparison of FIM scores between groups before exercise therapy intervention

No difference in the baseline FIM scores before exercise therapy intervention was observed between the groups except for that in the baseline FIM scores for expression which was significantly higher in the Ex group (p=0.034). The mean FIM scores for eating were within the range of 4 (minimal assistance

Table 4 Differences in funcional independence measure (FIM) score between groups before and after exercise therapy intervention

	Before intervention		p value[#]	After intervention	p value[$]	After intervention	p value[$]	p value[#]
	Ex group*	Co group*	Before	Ex group*	Before-after	Co group*	Before-after	After
FIM motor items								
(Self-care)								
Eating	4.1±2.0	3.5±2.3	0.089	4.0±2.0	–0.942	3.4±2.2	–0.988	0.043[#]
Grooming	2.9±2.1	3.2±2.0	0.105	3.2±2.0	0.500	2.7±2.1	–0.944	0.054
Bathing	2.4±1.7	2.0±1.6	0.050	2.4±1.8	–0.679	2.1±1.6	0.564	0.113
Dressing, upper body	2.7±2.0	2.5±2.1	0.072	2.7±2.0	–0.800	2.5±2.1	0.500	0.084
Dressing, lower body	2.5±2.0	2.3±2.0	0.073	2.4±1.9	–0.935	2.3±2.0	–0.603	0.097
Toileting	2.7±2.4	2.3±2.0	0.110	2.6±2.3	–0.928	2.4±2.2	–0.948	0.246
(Sphincter Control)								
Bladder management	2.4±2.0	2.3±2.0	0.373	2.4±2.0	–0.531	2.3±1.9	–0.557	0.354
Bowel management	2.7±2.3	2.6±2.2	0.466	2.7±2.3	–0.531	2.5±2.1	–0.926	0.324
(Transfers)								
Bed, chair, wheelchair transfers	3.2±2.2	3.0±2.4	0.231	3.0±2.3	–0.895	2.8±2.3	–0.992	0.178
Toilet transfer	3.1±2.3	2.9±2.3	0.145	3.0±2.3	–0.973	2.7±2.3	–0.978	0.234
Tub, shower transfers	2.1±1.6	2.2±1.7	0.392	2.2±1.6	–0.705	2.1±1.6	–0.864	0.319
(Locomotion)								
Walk/wheelchair	3.1±2.2	2.8±2.3	0.142	3.0±2.1	–0.804	2.8±2.1	–0.703	0.157
Stairs	1.8±2.5	1.6±1.5	0.144	1.6±1.4	–0.877	1.6±1.3	–0.658	0.580
FIM cognitive items								
(Communication)								
Comprehension	2.9±1.9	2.6±1.9	0.068	3.0±1.8	0.856	2.5±1.7	–0.622	0.045[#]
Expression	3.0±1.8	2.6±1.9	0.034[#]	2.8±1.8	–0.967	2.5±1.7	–0.749	0.110
(Social cognition)								
Social interaction	2.9±2.0	2.6±2.1	0.078	2.8±1.9	–0.564	2.3±1.8	–0.978	0.014
Problem solving	2.3±1.8	2.0±1.6	0.118	2.1±1.8	–0.993	1.9±1.5	–0.976	0.131
Memory	2.4±1.9	2.2±1.9	0.195	2.4±1.8	0.562	2.2±1.8	–0.704	0.110
Total	49.6±30.1	44.9±30.2	0.059	48.4±29.6	0.970	43.4±29.6	–0.998	0.050

* Value indicates mean score of FIM.
Scoring criteria of FIM, full score of FIM is 126 (18 items × 7).
7: Complete independence. 6: Modified independence. 5: Supervision, Setup. 4: Minimal assistance. 3: Moderate assistance. 2: Maximal assistance. 1: Total assistance.
[#] $p<0.05$ by Mann-Whitney's U test.
[$] p value by Wilcoxon signed-rank sum test.

Table 5 Differences in total score of functional independence measure (FIM) between groups before and after the exercise therapy intervention for each care level

Care level	Before intervention		p value[#]	After intervention	p value[$]	After intervention	p value[$]	p value[#]
	Ex group*	Co group*	Before	Ex group*	Before-after	Co group*	Before-after	After
Levels 1, 2	99.7±14.3	85.8±22.9	0.089	98.9±12.2	0.500	83.3±22.3	0.271	0.033[#]
Level 3	53.9±22.4	62.4±23.7	0.270	52.6±20.5	0.325	61.5±23.9	0.362	0.182
Level 4	40.5±15.9	32.4±14.8	0.092	37.5±16.6	0.070	29.8±12.4	0.059	0.108
Level 5	24.8±9.04	21.3±8.25	0.072	24.5±8.95	0.972	20.6±7.07	0.056	0.075

* Value indicates mean of total FIM score.
[#] p value by Mann-Whitney's U test.
[$] p value by Wilcoxon signed-rank sum test.

is needed) to 3 (moderate assistance is needed) in both groups, and the mean scores for most of the other items were approximately 2 (maximal assistance is needed) (Table 4).

(2) Comparison of FIM scores between groups after exercise therapy intervention

Comparison between groups after the exercise therapy intervention showed that FIM scores for eating ($p=0.043$) and comprehension ($p=0.045$) were significantly lower in the Co group than in the Ex group (Table 4).

(3) Comparison of FIM scores between before and after exercise therapy intervention for each group

Comparison between before and after the exercise therapy intervention showed no significant differences for any items in either group (Table 4).

(4) Comparison of total FIM scores by care level

As for the total FIM scores by care level, a comparison between the two groups after the exercise therapy intervention showed a significant decrease in FIM score for care levels 1 and 2 in the Co group ($p=0.033$) (Table 5).

(5) Difference in amount of change in FIM

The mean amounts of change in total FIM scores were compared, but there was no significant difference between the

Table 6 Average differences in functional independence measure (FIM) scores before and after exercise intervention

	Ex group*	Co group*	p value#
Total	−1.2±6.9	−1.5±5.49	0.823
Care levels 1, 2	−2.2±7.6	−2.4±9.59	0.948
Care level 3	−0.3±9.16	−1.0±5.32	0.765
Care level 4	−3±6.32	−2.4±5.05	0.770
Care leve 5	−0.2±4.19	−0.7±1.97	0.642

* Value indicates average change in FIM scores before and after intervention.
# p value by Mann-Whitney's U test.

Ex and Co groups for all subjects and for each care level (Table 6).

Discussion

In this study, we evaluated the effects of exercise therapy (Takizawa Program) intervention on the frail elderly using RCT with two factors: ROM and FIM.

The ROM values of the subjects admitted to the special nursing homes for the elderly were very low at the baseline. Normal ROM values have been determined by the Japanese Orthopedic Association and the Japanese Association of Rehabilitation Medicine, but several studies have shown that the normal ROM values vary depending on age and sex (18, 19). Okabe et al. (19) have reported the mean ROM values of women aged from 70 to 80 as follows: shoulder flexion, 161°; knee extension, −3°; ankle dorsal flexion, 21°; and ankle plantar flexion, 53°.

Our baseline measurements were lower than the standards of the Japanese Orthopedic Association and the Japanese Association of Rehabilitation Medicine (1995). Furthermore, these values were lower than the averages by age, which may be due to the effect of disuse atrophy. Fukuya (9) has reported that the failure to stand up and remain in an upright position as independent actions for longer than 1 minute per day in daily life results in limitations in ankle dorsal flexion. Fukuya has also reported that people who remain in a sitting position for more than 1 hour have limitation in knee extension. The subjects of this study had difficulty standing up and remaining in an upright position as independent actions, as described by Fukuya (9), and spend most of the day sitting in a wheelchair. In addition, because raising the upper limbs overhead is not required in their daily lives, such action was thought to be limited mainly owing to disuse atrophy.

After the exercise therapy intervention, ROM values only in the Ex group increased except for tthat of ankle plantar flexion. The ankle plantar flexion value did not change in the Ex group but increased in the Co group. In contrast, the ankle dorsal flexion value decreased in the Co group, which indicated that the drop foot symptom was aggravated in the subjects of the Co group and improved in those of the Ex group.

The exercise therapy intervention used in this study, which is called the Takizawa Program, is characterized by the use of simple instruments. These instruments include a "movable pulley" for the shoulders, PATA for plantar and dorsal flexion of the ankles, and "KORO" for flexion and extension of the knee. According to Endo et al. (20), the motion range of PATA for ankle dorsal flexion is 0–25° and the motion range of KORO for knee flexion is 30–110°. These instruments were used to assist with repetitive exercise within the subjects' individual ROM. Repetitive exercises were performed with the help of assistants when the subject could not move, and assistance was reduced as the numbers of spontaneous actions of the subject increased. The instruments were equipped with springs and blocks so that users could move them with little effort, thus, the subjects were also assisted by the instruments. Such spontaneous action reportedly promotes secretion of extracellular fluid in the matrix of tissues that constitute joints and prevents changes in cell functions (21). Therefore, this exercise therapy intervention with the aid of instruments (Takizawa Program) is considered suitable for improving ROM. In this study, the subjects showed a difference in the baseline ROM values between the right and left joints, and they also showed a difference in the amount of change in ROM value after the exercise therapy intervention between the right and left joints. These findings were observed from the subjects having disorders such as hemiplegia and rheumatoid arthritis, which do not occur symmetrically in the right and left joints.

FIM score did not significantly increase or decrease after the exercise therapy intervention in either group. However, the Co group showed lower scores for eating and comprehension than those of the Ex group after the exercise therapy intervention. Additionally, the comparison of the total scores by care level between the groups indicated that the total score of the Ex group was higher than that of the Co group for care levels 1 and 2. This finding indicates that an appropriate exercise therapy intervention for people who need light care may delay the aggravation of their function.

In this study, the exercise therapy intervention could not increase the FIM score or improve ADL of the frail elderly. ADL of the frail elderly is difficult to improve, and, in particular, the more difficult the improvement in ADL in patients with a chronic cerebrovascular disorder becomes, the longer the disease persists (22–24). Intensive training could improve actions such as sitting up, standing up, and gait, whereas improvements in ADL probably require not only improvement of actions but also various factors such as the motivation of patients, the consciousness of caregivers, and environmental factors, including the residential environment. For 80.4% of the subjects of this study who were 80 years old and over, who were in need of long-term care and who on average fell into care level 5, achieving apparent improvement seemed particularly difficult. In addition, an improvement in ADL was not apparent probably because the subjects of this study included patients with dementia.

In this study, five stratified care levels seemed to be too high for the number of subjects, thus, studying subjects at the same care level may better reveal the effects and problems of the program.

The maintenance of the function level acquired through rehabilitation is reported to be influenced by not only motor function factors but also by psychosocial factors (23). In one study, it was found that 15 to 20% of patients who need a high level of care could improve their ADL if they have motivation

(2). Decreases in the levels of gait function and some other functions were reported to become evident after a certain period of time after discharge (24). In this study, we examined the amounts of changes in ROM value and FIM score after exercise therapy intervention, but a multifaceted analysis involving psychological factors, environmental factors, and time of the start of exercises may be necessary to more accurately determine the effects of various exercises on the frail elderly.

In conclusion, the exercise therapy intervention used in this study, which is called the Takizawa Program, was found to be effective for the frail elderly, regardless of the types of disorder and disease. Future studies of this exercise therapy intervention should also include the frail elderly at high care levels as the target population.

References

(1) Chino N. Investigation into the actual condition of rehabilitation medicine for chronic cerebral vascular accident. Nagoya, Japanese Foundation for Aging and Health, 2002. (Article in Japanese)

(2) Japanese Physical Therapy Association (ed.) The Report on the Ability of Activity of Daily Living in Elderly People and Rehabilitation Care. Tokyo: Japanese Physical Therapy Association; 2004. (Article in Japanese)

(3) Yamazaki H. A study of the effect of rehabilitation training for the physically disabled in hospital. Journal of Transportation Medicine. 2002;56:12–18. (Article in Japanese)

(4) Hosoe M, Takahasi Y, Matsuo A, Nisiwaki M. Rehabilitation of chronic stroke elderly patients. Gero onsen hospital annual report. 2001;28:1–6. (Article in Japanese)

(5) Kusakabe K, Arata S, Nisiwaki M, Kiriyama K, Maeda K, Shimura I, et al. Effect of medical rehabilitation for chronic stroke patients. Gero onsen hospital annual report. 2000;27: 79–82. (Article in Japanese)

(6) Health and Welfare Statistics Association (ed.) Journal of Health and Welfare Statics. 2005;52:173–184. (Article in Japanese)

(7) Morita H, Sionaka M, Hurui T, Miyakawa Y, Shimada T. The psychology and environmental factor affecting the gaps between capability ADL and performance ADL in the home-bound post stroke hemiplegic elderly-analysis by structural equation model. Sogo Rehabilitation. 2003;31:167–174. (Article in Japanese)

(8) Sakurada M, Suzuki S, Asanuma T, Chiba M, Nanami T, Uemura S. The analysis of difference between the residents in health service facility for aged-who do and don't to do daily activity. The Akita Journal of Physical Therapy. 2002;10:47–50. (Article in Japanese)

(9) Fukuya Y. Disuse syndrome and physical therapy for the disabled living at home. The Japanese Journal of Physical Therapy. 1995;29:852–857. (Article in Japanese)

(10) Society for the Study of Rehabilitation in the 21st century (ed.) Re-acquirement of the Gait of Bedridden Elderly. Fujisawa, Civil; 1996. (Article in Japanese)

(11) Takizawa S, Kimura T, Kijima H, Okamoto Y, Nagaoka K, Morita Y, et al. Biophilia rehabilitation and proposition of the solution to the aging crisis. International Society of Physical and Rehabilitation Medicine. 2001;729–734.

(12) Takizawa S, Kimura T, Kijima H, Okamoto Y, Nagaoka K, Kanai Y, et al. Ambulation from bedridden. International Society of Physical and Rehabilitation Medicine. 2001;747–752.

(13) Takizawa S. An application of the civil technology to the sustainable aged society. Biophilia Rehabilitation Journal. 2004;2:1–24.

(14) Usizawa K, Takizawa S, Nagasawa H, Makita M, Kimura T, Takizawa K. Statistical evaluation of rehabilitation to the disabled elderly based Takizawa-program. Biophilia Rehabilitation Journal. 2004;2:71–80.

(15) Morita Y. Clinical evaluation of new type of walker with a seat and two fore sleds. Biophilia Rehabilitation Journal. 2004;2:51–56.

(16) Data management service of the uniform data system for medical rehabilitation and the center for functional assessment research. Guide for use of the uniform data set for medical rehabilitation. New York: State University of New York; 1990.

(17) Saitoh E. New assessment tool for stroke, FIM and SIAS. Journal of Clinical and Experimental Medicine. 1992;163: 275–291. (Article in Japanese)

(18) Watanabe H. The range of motion of the extremities in healthy Japanese people. Journal of Orthopedic Science. 1979;53:275–291. (Article in Japanese)

(19) Okabe T, Watanabe H, Amano T. The range of motion of the extremities in healthy Japanese people—The differences according to the sex. Sogo Rehabilitation. 1980;8:41–56. (Article in Japanese)

(20) Endo S, Makita M, Nagasawa H, Takizawa K, Kobayasi K, Shoji K. Rehabilitation training with two simple machines. Proceeding of 13th International Congress of World Confederation for Physical Therapy. 1999;539.

(21) Nakamura T. Joint contracture. Japanese Journal of Geriatric Psychiatry. 2002;13:360–365. (Article in Japanese)

(22) Sayama I. Current status of post-stroke patients at home and follow-up results of their sequential functional changes. Sogo Rehabilitation. 1998;26:1127–1134. (Article in Japanese)

(23) Nakamura R. Functional Assessment and Prognosis of the Stroke. Tokyo: Ishiyaku; 1997. (Article in Japanese)

(24) Sunakoda A. Prediction of functional state in stroke patients living at home. Sogo Rehabilitation. 1998;26:1119–1125. (Article in Japanese)