The Effect of Toe-grasping Exercises on Balance Ability in Home-based Rehabilitation: A Randomized Controlled Trial by Block Randomization

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ABSTRACT. Objective: The purpose of the study was to clarify the causal effect of toe-grasping exercises on the improvement of static or dynamic balance ability in home-based rehabilitation users. Method: Our study included 34 subjects who met the criteria and were evaluable out of 98 rehabilitation service users at home nursing stations. This study was a randomized controlled trial. The intervention group performed towel gathering exercises in addition to the regular home-based rehabilitation program. The primary outcome was one-leg standing time, and the secondary outcomes were two-step test and toe grip strength. Results: Seventeen subjects were assigned to the intervention group and seventeen to the control group by block randomization. Data from 15 and 12 subjects in the intervention group and control group, respectively, who were able to complete the initial evaluation and the evaluation after 3 months, were analyzed. We compared the amount of change after 3 months of evaluation in the intervention group with the change in the control group. The results showed that the left/right mean value of oneleg standing time in the intervention group was significantly greater than that in the control group. In terms of the amount of change in the intervention period (T2-T1) within each assessment, there were significant improvements in both the toe-grip strength and the two-step values in the intervention group. Conclusion: We found that toe-grasping exercises could improve the balance ability of home-based rehabilitation users. This suggests the clinical significance of toe function in rehabilitation programs.

Key words: Toe-grip strength, Home-based rehabilitation, One-leg standing time, Two-step test, Randomized controlled trial

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As the birthrate declines and the population ages in Japan, it is becoming increasingly important to create a social system to support the elderly. Therefore the importance of home-care services, such as home-based rehabilitation, is constantly growing3,15. However, there is currently little research to accumulate evidence-based data though the society recognizes the significance of home-based rehabilitation in fall prevention and postponing the need for nursing care15. Hence, the specific benefits of home-based rehabilitation programs have not yet been completely determined.

The importance of fall prevention in daily life at home is recognized because falls in the elderly often have serious consequences such as bone fractures15. Improvement in balance ability plays an important role among fall prevention strategies16,17.

There are two types of balance ability: static and dynamic. Static balance is the ability to maintain upright posture within the limits of the base of support; dynamic balance is the ability necessary to move out of and change the base of support. Both of them are essential for fall preven-
Various systems are involved in the static and dynamic balance abilities of the musculoskeletal, neuromuscular, sensory/perceptual, and cognitive systems. It has been suggested that toe functions, such as toe grip strength, play an important role in the musculoskeletal system. However, there are few studies on how toe-grip strength affects the musculoskeletal function in the elderly with chronic diseases and those who require long-term care. Benvenuti et al. reported as the activity level of the elderly declined, the toes’ motor function, such as the toe-grip strength, declined too. Murata et al. found a significant correlation between the toe-grip strength and the occurrence of falls in a prospective study of the elderly who could walk independently. Nagai et al. investigated the effects of toe grip training on lower limb muscle strength and balance ability in elderly nursing home residents using a crossover test and found that toe grip strength and functional reach distance were improved in a pre- and post-training comparison. Thus, we are gradually becoming aware of the growing importance of toe functions, such as toe-grip strength, on balance ability. However, there is little evidence to support the necessity of incorporating training to improve toe function in rehabilitation protocols in medical institutions and home care facilities. In particular, there are no randomized controlled trials that have examined the effects of toe training on balance and the occurrence of falls in the elderly with chronic diseases and those who require long-term care. Benvenuti et al. reported as the activity level of the elderly declined, the toes’ motor function, such as the toe-grip strength, declined too. Murata et al. found a significant correlation between the toe-grip strength and the occurrence of falls in a prospective study of the elderly who could walk independently. Nagai et al. investigated the effects of toe grip training on lower limb muscle strength and balance ability in elderly nursing home residents using a crossover test and found that toe grip strength and functional reach distance were improved in a pre- and post-training comparison. Thus, we are gradually becoming aware of the growing importance of toe functions, such as toe-grip strength, on balance ability. However, there is little evidence to support the necessity of incorporating training to improve toe function in rehabilitation protocols in medical institutions and home care facilities. In particular, there are no randomized controlled trials that have examined the effects of toe training on balance performance in individuals with conditions requiring nursing care during rehabilitation.

We focused on the toe-grip strength in home-based rehabilitation. There is a relationship between the toe-grip strength and one-leg standing time, an index of static balance ability, in home-based rehabilitation users who require assistance or watchful waiting for movement, and presents significant correlation. However, although such a correlation was determined in a cross-sectional study, the causal relationship remains unclear.

The purpose of our study was to clarify the hypothesis that there is a causal effect of the toe-grasping exercises on the improvement of static or dynamic balance ability in home-based rehabilitation users. A randomized controlled trial was conducted to investigate whether the implementation of toe-grasping exercises improves the static and dynamic balance ability.

Subjects and Methods

1. Subjects

Our study included 34 subjects who met the following criteria and were evaluable out of 98 rehabilitation service users attended by physical or occupational therapists at home nursing stations from April 2018 to March 2020. The inclusion criteria were: able to ambulate at or above watchful waiting level and absence of malignant or degenerative diseases. The exclusion criteria were: a significant change of medical condition (hospitalization, etc.) and inability to perform the towel gathering exercise.

All subjects gave their consent for participation after receiving written and oral explanation on the methods and procedures involved in the study. They were informed that they could discontinue participation at any time if they felt burdened, without any consequences, and that their personal information and privacy were guaranteed. This study was designed following the Declaration of Helsinki principles and was approved by the Ethics Committee of the Japanese Physical Therapy Association (approval number: H29-001). This study was registered as a clinical trial with UMIN (acceptance number: UMIN000043984).

2. Methods

Sample size setting

The sample size design was conducted using G*power 3 (Heinrich-Heine-University, free software) with an alpha error of 0.05, a power of 0.8, and a large effect size (0.8) based on Cohen’s theory of differences in populations. The required sample size was 26 subjects in each group.

Randomization method

This study was a randomized controlled trial based on the CONSORT 2010 guidelines in which subjects were divided into an intervention group and a control group by computerized block randomization. For the method of allocation, six subjects were allocated as a block, and 20 different combinations [e.g., (a)(a)(b)(a)(b)(b)] were created in which the number of the two types of groups, intervention group (a) and control group (b), were equal. The combinations were then determined by the numbers obtained by random number generation using Excel (Microsoft Corporation). The assignments were applied sequentially according to these combinations. The assignment order was set by a physical therapist working at the visiting nursing station, who was the researcher. It was based on the subject’s schedule and the order of the new implementation of the home-based rehabilitation during the period. Another physical therapist working at the same home nursing station, who did not know the study’s contents, was responsible for generating random numbers and managing the assignment table. In this way, each group was assigned a random number. Thus, the researcher was kept uninformed until the allocation of each group was completed and the subjects distributed in groups.

Evaluation Method

The evaluation period was determined by the first evaluation (T1) and the 3-month evaluation (T2), with a duration of 3-4 months. All evaluations were conducted indoors, at the subject’s home, before the rehabilitation, and at a rehabilitation home visit. The evaluation items were toe-grip strength, one-leg standing time, and a two-step test for balance ability evaluation.
1) Toe-grip strength

The toe-grip strength was evaluated using a toe grip dynamometer (T.K.K. 3361; Takei Scientific Instruments, Niigata, Japan)\(^\text{20}\). The subjects sat on a bed, or a chair with the knee flexed at 90°, and after fixing the foot, the gripping force was measured at maximum effort\(^\text{16}\). The measurements were registered three times on each side, and the maximum value was used.

2) One-leg standing time

The subject was instructed to stand on one leg with their eyes open and with arms at their sides for a maximum of 30 sec. The maximum value of the three measurements on each leg was used for evaluation\(^\text{21,22}\). The criterion to stop the measurement was when the non-tested leg contacted the floor or when the tested leg was displaced. During the examination, subjects were closely observed for fall prevention from the side of the non-tested leg. If one-leg standing on either side was considered to be impossible or dangerous (due to skeletal conditions or pain) to perform, the test would be discontinued.

3) Two-step test

The Japanese Orthopaedic Association proposed a two-step test as one of the evaluation methods that can be easily performed for assessing the locomotive syndrome\(^\text{23,24}\). Its evaluation has been shown to have a relationship with the 10-m walking speed, 6-minute walking distance, and the degree of daily life independence\(^\text{25}\). Also, the two-step test is strongly correlated with dynamic balance assessments such as the Timed Up and Go test (TUG), indicating its usefulness as an indicator of dynamic balance ability\(^\text{26}\). The two-step test measures the length of two steps, and the two-step value for standardization is the ratio of the maximum length of two steps to the subject’s height. Measurements were performed for the maximum length at which the subject’s balance is maintained three times, and the maximum value was used for evaluation. The test should be conducted under the supervision and within the range of not losing balance and not jumping.

The above evaluations were performed by the researcher, a physical therapist working at a home-nursing station.

**Intervention method**

The control group’s usual home-based rehabilitation program was conducted for 40 minutes per visit, focusing on general coordination, range of motion, muscle strengthening, and basic movement. Based on the usual home-based rehabilitation program provided in Table 1, each therapist implemented an individual program according to the needs and conditions of the subject. They were conducted twice a week on average.

The intervention group performed towel gathering exercises twice a week for about three months in addition to the regular home-based rehabilitation program described above (Table 1). Towel gathering is the most often used exercises for improving the toe-grip strength\(^\text{27}\). According to a schedule, seven physical therapists working at a home-nursing station, including the researcher, randomly provided the control and the intervention home-based rehabilitation services to the control and intervention group.

The towel gathering exercise consisted of sitting on a bed, or a chair with the knee bent at approximately 90° with the heel on the floor, flex back the foot with a maximum effort by flexing the toes. The subject repeated the exercise to feel his lower limbs felt tired; he/she stopped for a 30-sec break and then repeated the movement. This series of exercises was performed three times in a row for approximately three minutes per set. The towel gathering exercise was performed as one set in addition to the regular rehabilitation program during the therapist’s visit. The subjects were also encouraged to voluntarily perform the towel gathering exercise the rest of the days and mark them on a calendar provided to them in advance. The number of therapists’ visits was determined by the number of days provided by the nursing care insurance during the evaluation period. The number of days of towel gathering exercises was counted based on the number of marks on the calendar handed to the subject in advance.

**Statistical analysis**

The statistical analysis was performed by a different researcher from the one who organized the data. JMP 12.0.1 software (SAS Institute, Cary, NC, USA) was used for the statistical analysis. The primary outcome was one-leg standing time, and the secondary outcomes were two-step test and toe grip strength. Statistical methods were determined based on the results of the Shapiro-Wilk test for normal distribution. Parametric methods were used for normally distributed data, and non-parametric methods were used for non-normal distribution. Wilcoxon signed-rank

| Table 1. Program content in the intervention and control groups |
|---------------------------------------------------------------|
| **Intervention Group**                                        |
| usual home-based rehabilitation program                       |
| general coordination                                         |
| range of motion exercises                                    |
| muscle strengthening exercises                                |
| basic movement exercises                                      |
| towel gathering exercises                                     |
| **Control Group**                                             |
| usual home-based rehabilitation program                       |
| general coordination                                         |
| range of motion exercises                                    |
| muscle strengthening exercises                                |
| basic movement exercises                                      |
test determined changes in data assessed before and after the intervention, and comparisons with the control group were calculated using Wilcoxon rank-sum test. The level of statistical significance was set at 5%.

**Results**

1. **Subjects**

   The flow diagram of the subjects is shown in Figure 1. Seventeen subjects were assigned to the intervention group and seventeen to the control group by block randomization. Data from 15 and 12 subjects in the intervention group and control group, respectively, who were able to complete the initial evaluation and the evaluation after 3 months, were analyzed.

2. **Baseline Characteristics**

   The baseline values were compared for the basic attributes and background factors in both groups (Table 2). There were no significant differences in age, sex, nursing care level, home-based rehabilitation period, evaluation period, number of days visited by home-based rehabilitation during the evaluation period, or frequency of visits between the groups.

3. **Comparison between the intervention and the control group (Table 3)**

   First, each assessment was compared between the intervention and control groups at the initial assessment time (T1) as a baseline. There was no significant difference in one-leg standing time, two-step values, and the toe-grip strength. Next, we compared the amount of change after 3 months of evaluation (T2-T1) in the intervention group with the change in the control group. The results showed that although there was no significant difference in the one-leg standing time in the results of both the right and left leg, the left/right mean value in the intervention group was significantly greater than that in the control group. No significant difference was observed in toe-grip strength and two-step values between the groups.

   In terms of the amount of change in the intervention period (T2-T1) within each assessment, there was no significant change in the one-leg standing time and two-step values in the control group. There were no significant intragroup changes in the one-leg standing time in either the intervention or control group.

**Discussion**

1. **Changes in toe-grip strength**

   In the present study, we compared the change in the intervention group (T2-T1) with the change in the control
group after 3 months of evaluation. There was no significant difference in toe-grip strength. This result suggests that toe-grasping exercises had no effect on toe-grip strength. However, the results of the pre/post comparison within the groups showed that there was no significant change in both the left/right values and the mean values in the control group, while there was a significant improvement in the intervention group. This result supports the usefulness of toe-grasping exercises to some extent. In previous studies, results in young people \(^{28}\) and in other older adults who require care \(^{29}\) have shown that training improves toe-grip strength regardless of age or disease status. In any case, the effect of the current toe-grasping exercises may have been small. The method and frequency of training are issues to be studied in future researches.

2. Effect of toe-grasping exercises on balance ability

We compared the amount of change after 3 months of evaluation (T2-T1) in the intervention group with the change in the control group. As a result, although there was no significant difference in one-leg standing time in the right and left leg results, the left/right mean value in the intervention group was significantly greater than that in the control group.

Since we found a significant correlation between the toe grip strength and one-leg standing time results in home-based rehabilitation users who require assistance or supervision for mobility \(^{16}\), the hypothesis of the present study, that improvement of toe-grip strength by toe-grasping exercises would affect the improvement of balance ability such as one-leg standing time, was confirmed by the results of this study. However, it is necessary to consider the reasons for the rather weak results to confirm the hypothesis, such as the fact that no significant difference was obtained in the results of the one-legged standing time measurement for the left and right sides. One of the reasons for this, as mentioned above, was that the toe-grasping exercises had little effect on toe-grip strength. Another consideration is that toe-grip strength has a small influence on one-leg standing time. Yamauchi et al. \(^{30}\) examined whether postural stability during one-legged standing, using the center of pressure, was related to the toe-grip strength in healthy young adults.

### Table 2. Baseline comparison of intervention and control groups

| Data Item                          | Intervention Group (n=15) | Control Group (n=12) | P value |
|------------------------------------|--------------------------|----------------------|---------|
| Age (years, mean±SD)              | 76.2±12.2                | 80.5±7.7             | 0.51*1  |
| Sex (male/female)                 | 5/10                     | 5/7                  | 0.71*2  |
| Level of nursing care\(^{4}\)     |                          |                      | 0.20*2  |
| Support level 1                   | 2                        | 0                    |         |
| Support level 2                   | 3                        | 4                    |         |
| Care level 1                      | 1                        | 4                    |         |
| Care level 2                      | 6                        | 3                    |         |
| Care level 3                      | 2                        | 1                    |         |
| Care level 4                      | 1                        | 0                    |         |
| Care level 5                      | 0                        | 0                    |         |
| Disease (including duplication)   |                          |                      | 0.33*2  |
| Cerebral vascular disorder        | 7                        | 3                    |         |
| Orthopedic disorders             | 4                        | 8                    |         |
| Internal disorder                | 5                        | 5                    |         |
| Hypertension                     | 5                        | 2                    |         |
| Diabetes                         | 3                        | 2                    |         |
| Self-immune disorders            | 1                        | 0                    |         |
| Mental disorder                  | 0                        | 1                    |         |
| Home-based rehabilitation period\(^{4}\) (days, mean±SD) | 928.7±993.1 | 907.1±991.9 | 0.79*1  |
| Evaluation period (days, mean±SD) | 105.5±8.1                | 107.8±7.4            | 0.51*1  |
| Number of days visited (days, mean±SD) | 26.0±11.7            | 28.0±6.4             | 0.21*1  |
| Frequency of visits (days/week, mean±SD) | 1.7±0.8          | 1.8±0.5              | 0.61*4  |

*1: Wilcoxon rank sum test
*2: Chi-squared test
*3: Level of nursing care determined by the long-term care insurance system. Patients apply for the care need assessment at the city office.
*4: Utilization period determined by the number of days from the start of use of the home nursing station to the date of the first evaluation.
Table 3. Comparison of the amount of change in measurements between the intervention group and the control group

|                        | Intervention Group (n=15) |                          | Control Group (n=12) |                          | T1         | T2         | T2-T1      | T1         | T2         | T2-T1      | r value   |
|------------------------|---------------------------|--------------------------|----------------------|--------------------------|------------|------------|------------|------------|------------|------------|-----------|
|                        | T1                        | T2                       | T2-T1                | P value*1                |            |            |            | P value*2   |            |            |            |           |
| Toe-grip strength (kgf)| Right                     | 7.3±6.7                  | 8.3±6.2              | 1.0±1.6                  | 0.04*      | 4.5±3.1    | 4.7±3.5    | 0.2±1.6    | 0.31       |            |            | 0.31      |
|                        | Left                      | 5.3±2.8                  | 6.7±3.3              | 1.4±1.6                  | 0.001**    | 5.0±2.9    | 5.1±3.6    | 0.04±2.4   | 1.00       |            |            | 0.79      |
|                        | Maximum                   | 7.7±6.6                  | 8.8±6.1              | 1.1±1.6                  | 0.02*      | 5.3±3.1    | 5.7±3.9    | 0.3±1.8    | 0.38       |            |            | 0.35      |
|                        | Average                   | 6.3±4.5                  | 7.5±4.5              | 1.2±1.4                  | 0.001**    | 4.8±2.9    | 4.9±3.3    | 0.1±1.8    | 0.69       |            |            | 0.41      |
| Two-step value         |                           |                          |                      |                          |            |            |            |            |            |            |           |
|                        | Right                     | 0.6±0.3                  | 0.8±0.3              | 0.1±0.2                  | 0.048*     | 0.6±0.2    | 0.6±0.2    | -0.02      | 0.47       |            |            | 0.71      |
|                        | Left                      |                           |                      |                          |            |            |            |            |            |            |            | 0.08      |
|                        | One-leg standing time (sec)| Right                   | 5.7±7.6              | 6.2±8.1                  | 0.5±2.8    | 0.57       | 1.8±2.6    | 2.0±3.6    | 0.2±1.6    | 1.00       |            | 0.06      |
|                        | Left                      | 7.0±10.0                 | 8.2±10.6             | 1.2±3.3                  | 0.36       | 5.0±6.5    | 2.7±3.5    | -2.3±4.7   | 0.16       |            | 0.75      |
|                        | Maximum                   | 8.1±9.8                  | 9.5±10.4             | 1.4±3.4                  | 0.16       | 5.1±6.5    | 3.2±4.0    | -1.9±4.2   | 0.23       |            | 0.48      |
|                        | Average                   | 6.3±8.0                  | 7.2±8.6              | 0.8±1.8                  | 0.19       | 3.4±4.5    | 2.3±3.2    | -1.1±2.3   | 0.19       |            | 0.34      |

**P<0.01, *P<0.05**

T1 indicates the pre-measurement, and T2 indicates the post-measurement.
Abbreviations: P=Significance probability, r=Effect size, SD=Standard deviation

#1: Before and after comparison of intervention groups
#2: Before and after comparison of control group
#3: Comparison of the measurements at T1 between the intervention group and the control group
#4: Comparison of the amount of change in measurements between the intervention group and the control group
and found no significant correlation. This result suggests that the toe-grip strength does not have a substantial role in postural stability during static standing. Therefore, it is possible that toe-grasping exercises are not effective in influencing one-leg standing time.

On the other hand, the two-step value did not show a significant difference between the intervention and control groups at the 5% level. However, it could be argued that a result of $P=0.083$ and an effect size of $r=0.51$ do not mean that there is no significant difference, but that there is a tendency for some improvement. In fact, within-group comparisons before and after the intervention showed a significant improvement in the intervention group. Fukuda et al. found that toe-grip strength training significantly improved walking speed and stride length during a 10 m walk in young, healthy subjects. They attributed the increase in toe-grip strength to an increase in stride length due to increased propulsive force and stability at the time of stepping off the toes. The present results may have affected the two-step value for the same reason. These results indicate that increasing toe-grip strength can lead to an increase in dynamic balance ability.

These results suggest the clinical significance of providing more training to improve toe function in rehabilitation programs at medical institutions and nursing facilities.

3. Limitations of this study

This study has several limitations. First, the sample size was smaller than previously estimated because of the inability to secure a sufficient number of cases within the study period and the difficulty in extending the study period due to the researchers’ change in affiliations. As a result, the power of the study was reduced, the rate of error increased, and significant differences may have been overlooked. Therefore, we did not discuss only the significant difference, but also the effect size. Second, there is a possibility that the control group may have been mixed with the intervention group. Since the home-based rehabilitation program is individualized to meet the needs and conditions of the subjects, we cannot deny the possibility that some toe-grasping exercises were conducted for the subjects in the control group. However, in the current home-based rehabilitation program, it is realized that each therapist does not provide toe-grasping exercises to all subjects by default. The fact that there was a significant difference between the two groups, even with the possibility that the control group was included in the intervention, may strengthen this significance. Third, all assessments in this study were conducted by a single physical therapist. There may be some influence of bias because other therapists participating in the intervention could grasp the study’s contents to some extent. Further study is warranted to verify our findings in larger-scale trials.

Conclusion

In this study, we found that toe-grasping exercises could improve the balance ability of home-based rehabilitation users who require assistance or supervision for mobility. This suggests the clinical significance of providing more training to improve toe function in rehabilitation programs at medical institutions and nursing facilities.

Conflict of Interest: None.

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