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Impact of Shaking Exercise on Functional Recovery in Patients with Chronic Post-Stroke Upper Limb Impairment: A Multicenter, Open-Label, Quasi-Randomized Controlled Trial

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Abstract: Stroke causes disability and significantly affects patient quality of life. Post-stroke rehabilitation of upper limb function is crucial, as it affects daily activities and individual autonomy. Traditional rehabilitation methods often require frequent visits to specialized centers, which can be costly and challenging. This study investigated the effectiveness of a home-based self-training device, "Kenko Yusuri", in improving upper limb function in patients with chronic stroke. This multicenter prospective intervention study used a quasi-randomized controlled trial design. Ninety-three outpatients from five hospitals in Japan were enrolled and assigned to either the intervention group which used the "Kenko Yusuri" device or the control group which underwent conventional rehabilitation. All patients received botulinum toxin type A (BoNT-A) injections to treat upper limb spasticity. The primary outcome measure was the Fugl–Meyer Assessment (FMA) of upper-extremity motor function. Secondary outcomes included the modified Ashworth scale (MAS) score, range of motion (ROM), and chronic pain assessments. The intervention group demonstrated significantly greater improvements in FMA total scores than the control group. Patients with moderate impairment experienced the greatest benefits from the intervention. There were no significant between-group differences in MAS scores or ROM measurements. Pain and wrist ROM showed improvement in the intervention group. Home-based training with a shaking device significantly improved upper limb function in patients with moderate chronic post-stroke paralysis. This approach aligns with the principles of use-dependent plasticity and offers a feasible and cost-effective alternative to traditional rehabilitation methods.

Keywords: stroke rehabilitation; upper limb impairment; home-based training; self-training device; botulinum toxin type A

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1. Introduction

Strokes remain a leading cause of disability globally, profoundly affecting the quality of life of millions each year [1,2]. Rehabilitation of post-stroke upper limb function is crucial [3,4], as it directly affects patients' ability to perform daily activities and enhances individual autonomy [5–7]. Although traditional rehabilitation methods such as physical therapy and pharmacological interventions are effective, they typically require frequent visits to specialized centers. This can be costly and logistically challenging for many patients, particularly those who may require prolonged therapy [8,9].

Spasticity is a common complication in patients with severe stroke that leads to pain and significant motor dysfunction. Treatment often involves long-term management strategies, including the use of botulinum toxin type A (BoNT-A), which has been widely adopted for its efficacy in reducing muscle hypertonicity and associated discomfort [8–13]. However, botulinum therapy is repetitive and invasive, and when administered alone it

may not improve upper limb function; it must be combined with occupational therapy [10]. Patients with chronic stroke are required to exercise at home to improve their upper limb function and require assistance from their family members [11]. This long-term, daily independent training may be physically and mentally demanding for patients and their families [12].

Recent advancements in noninvasive cerebral stimulation therapies such as repetitive transcranial magnetic stimulation (rTMS) combined with intensive upper limb training have shown promise in improving functions previously considered irreversible [4,13–17]. Despite these advancements, the accessibility of innovative treatments in home settings remains limited, which poses a significant barrier to sustaining patient engagement and recovery. The integration of home-based training devices into standard post-stroke rehabilitation protocols could therefore represent a transformative approach to care, reducing the burden on healthcare systems, while simultaneously improving patient outcomes.

Occupational therapists manually perform rehabilitation to treat upper limb dysfunction as an after-effect of stroke [18,19], and the concept of user-dependent plasticity is particularly relevant in patients with chronic stroke [20,21]. This suggests that the nervous system can functionally reorganize itself in response to the demands placed upon it, implying that consistent, repetitive use of the affected limbs can lead to improved motor function and recovery over time. Therefore, the development of home-based self-training devices, like the "Kenko Yusuri", is not only innovative but essential. These devices enable patients to engage in regular structured training at home without continuous professional supervision and align with the principles of use-dependent plasticity by facilitating frequent and repetitive use of the impaired limbs. This approach not only makes rehabilitation more accessible and cost-effective but also allows for therapy customization to meet individual needs, thereby enhancing the potential for recovery. These devices also ensure continuity of care, enabling patients to maintain and improve the long-term gains achieved in clinical settings. Additionally, the "Kenko Yusuri" shaking device is expected to offer therapeutic benefits in the management of spasticity. Its vibrational features are expected to relieve muscle tension, potentially complementing or reducing the need for invasive treatment. This could significantly enhance the quality of life and functional independence of stroke survivors by providing a nonpharmacological option for managing one of the most challenging complications of stroke recovery.

Integrating home-based training devices into standard post-stroke rehabilitation protocols may represent a transformative approach to care; it may alleviate the burden on healthcare systems, while simultaneously improving patient outcomes. The aim of this study was to evaluate the effectiveness of the "Kenko Yusuri" shaking device in improving upper limb function in patients with chronic stroke, thereby reducing the physical and mental burden on patients and caregivers.

In this study, the primary focus was on improving patients' upper limb impairments with the shaking device. Previous studies have demonstrated the sensitivity of the Fugl–Meyer Assessment (FMA) in detecting changes in motor function after therapeutic interventions, supporting its use as a primary outcome measure [22,23]. On the other hand, the modified Ashworth scale (MAS) is a valuable tool for assessing spasticity, specifically measuring muscle tone and spasticity, which are important aspects of stroke recovery. However, the primary focus of the intervention was to improve overall motor function, encompassing a broader range of abilities than spasticity alone. To capture the functional improvements in voluntary movement and coordination targeted by the shaking exercise, the FMA was determined to be more appropriate to assess the overall impact of the intervention [24,25]. Previous studies have shown that the shaking exercise enhances proprioceptive feedback and motor control, improving motor function [26,27]. The primary goal of the intervention was to improve voluntary movement and coordination, which are key components of the FMA.

2. Materials and Methods

2.1. Study Participants

This multicenter prospective intervention study adopted a randomized trial design and included outpatients enrolled between December 2020 and June 2023 at five hospitals in Japan. Patient data were collected from Jikei University Hospital [Tokyo], Aomori Shintoshi Hospital [Aomori], Izumi Memorial Hospital [Tokyo], Gosho Minami Rehabilitation Clinic [Kyoto], and Nishi Hiroshima Rehabilitation Hospital [Hiroshima] and were subsequently analyzed.

Participants were included if they (1) were stroke patients with upper limb impairment who were aged >20 and <80 years; (2) had stroke onset at least 6 months prior; (3) had upper limb Brunnstrom recovery stage III to V; (4) were undergoing ongoing botulinum therapy for upper limb spasticity; (5) did not have cognitive impairment; and (6) had been fully informed of the study and provided voluntary written consent based on their full understanding of the study.

Patients were excluded if (1) they had implanted medical devices (pacemakers, cochlear implants, etc.); (2) had serious cardiac disease; (3) were pregnant or suspected of being pregnant; (4) had unstable or urgent medical conditions (acute heart failure, acute renal failure, acute liver failure, severe diabetes, infectious diseases, etc.); (5) had unstable or urgent medical conditions (acute heart failure, acute renal failure, acute liver failure, severe diabetes, infectious diseases, etc.); or (6) had participated in other clinical studies within 4 months.

2.2. Study Participants

This study was conducted as a multicenter, open-label, quasi-randomized controlled trial. Participants were consecutively enrolled at five medical institutions and assigned to an intervention group using a vibration exercise device or a control group receiving conventional treatment. Participants were assigned to the intervention or control group alternately based on the order of enrollment. This quasi-randomized approach was chosen due to the logistic constraints of the participating institutions.

All participants were informed of how the study results would be used and signed an informed consent form agreeing to participate. This study was performed over 12 weeks. The study group underwent voluntary training using the shaking device, whereas the control group underwent conventional voluntary training (Figure 1). The shaking device used in this study was a "Kenko Yusuri" (JMH100, Top Run Corporation, Tokyo, Japan) [28,29].

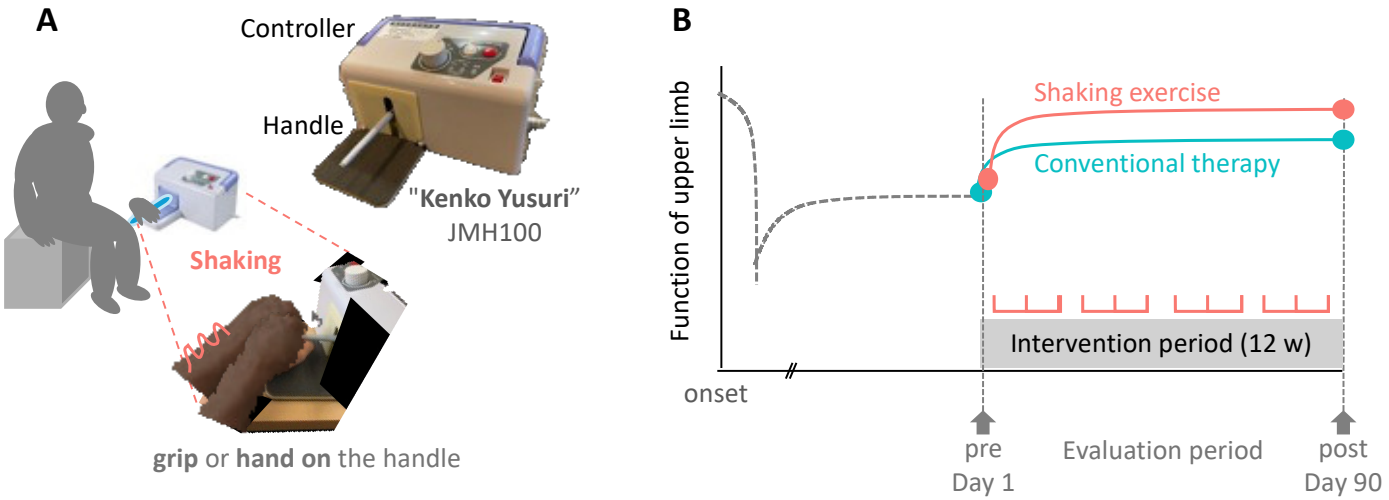

Figure 1. Conceptual diagram and protocol of this study designed to examine the differences in the effects of shaking exercise and conventional therapies on functions of upper limb in participants with

paralysis: (**A**) The patient places or grips his or her hand on the handlebar, and the device uses the principle of leverage to generate a pendulum-like motion that swings the affected hand. (**B**) Patients in the intervention group performed daily shaking exercises at home, three times a day, for 10 min each time. The control group performed self-training at home that was guided by outpatient rehabilitation. Both groups continued outpatient treatment for 3 months.

2.3. Addressing Potential Biases

To mitigate potential selection bias inherent in a quasi-randomized design, we ensured that all eligible patients within the study period were included, regardless of the institution at which they received treatment. In addition, baseline characteristics between groups were compared to ensure comparability of the intervention and control groups. To minimize training variability, specifications were used to standardize the treatment protocol across all sites, and the study was performed by dedicated therapists at each institution.

Given the nature of the intervention involving the use of the shaking device, blinding of the therapists and patients was not feasible. The following measures were implemented to mitigate potential information bias in FMA-UE scores due to the failure to blind to treatment allocation: (1) All evaluators received standardized training to ensure consistent and objective administration of FMA-UE assessments. (2) FMA-UE assessments were performed according to strict objective criteria detailed in the assessment protocol. Evaluators were instructed to adhere to these criteria to minimize subjective interpretation and ensure consistency in scores.

A change from the baseline FMA-UE score was the primary focus of the analysis to reduce the impacts of any baseline imbalances. The baseline FMA-UE score was considered to be a confounding factor affecting the results, as was the patient's impairment severity. Similarly, the patient's age, sex, time since onset, receipt of BoNT-A treatment, stroke type, and paralyzed side were investigated as factors influencing baseline imbalance. These were analyzed to mitigate their influence on the results.

2.4. Self-Training Using the Shaking Device

The shaking device was used by gripping the handle with the affected upper limb. Patients who could not grip the handle were allowed to use it by placing their palms or distal forearms on the handle.

The handle was moved by approximately 13 cm vertically at 1 Hz continuously for 10 min. If the upper limb dropped off during the exercise, the patient was allowed to stop the device once and resume use. However, if the patient was unable to complete the exercise after multiple attempts, they were advised to rest and try again later. Ten min of use was allowed per self-training session, and self-training was conducted three times a day (30 min in total). The self-training status was recorded by the patients on a form, which was collected and checked by the physician in charge at the end of each study period.

2.5. Adjunctive Therapy

All patients received BoNT-A injections for upper limb spasticity (up to 400 units for the upper limb) as adjunctive therapy. BoNT-A injections were administered once before the start of the 12-week intervention program, and no additional doses were administered during the study period, which concluded at the end of the 12-week evaluation. The following concomitant therapies were prohibited: (1) electrical stimulation therapy, (2) repetitive transcranial magnetic stimulation therapy, (3) transcranial direct-current electrical stimulation therapy, and (4) robotic rehabilitation therapy. They were prohibited during the entire study period (from the date consent was obtained until the last observation date). In addition, the initiation of new muscle relaxants was prohibited during the study period (from the date of consent to the date of final observation). If patients were taking them routinely, the dosage and administration method were not changed during the study period.

This study was approved by the Clinical Review Board of Jikei University Educational Corporation (CRB3180031). This study was registered in the Japanese Registry of Clinical Trials (jRCTs032200164) by the Ministry of Health, Labor, and Welfare.

2.6. Outcome Measures

The Fugl–Meyer assessment (FMA) score was used as the main outcome in this study. It evaluates motor function, sensory function, balance, range of motion, and joint pain and is divided into 66 points for the upper extremity. The FMA method was chosen because of its high reliability, reproducibility, and validity [22,30,31]. It comprises four subscales: Part A (Shoulder/Elbow/Forearm) assesses movements involving the shoulder, elbow, and forearm. Part B (Wrist) evaluates wrist movements, including flexion, extension, and circumduction. Part C (Hand) assesses hand movements, grip ability, and finger coordination. Part D (Coordination/Speed) evaluates rapid alternating and coordinated upper extremity movements. Each item is scored on a 3-point scale (0–2), where higher scores indicate better motor recovery.

The severity of motor function impairment according to the FMA score is as follows: $\leq$20, severe; 21–45, moderate; and 46–66, mild paralysis [32]. Secondary outcomes included the modified Ashworth scale (MAS), which was used to assess the degree of spasticity [24]; range of motion (ROM), using active and passive joint movement; and subjective chronic pain, using the visual analog scale (VAS) [33].

2.7. Statistical Analysis

A generalized linear mixed model (GLMM) approach was employed to evaluate the effect of the shaking exercise device on upper limb functional recovery in patients with chronic stroke [34]. This method was selected due to the repeated measures nature of the data and the inclusion of both fixed and random effects to account for within-subject correlation and between-subject variability.

If the GLMM analysis revealed a significant interaction effect between the intervention group and study periods, pairwise comparisons between groups at each period were performed to verify that the groups were significantly different. This would provide insight into the temporal pattern of disability recovery and the potential effectiveness of the vibration exercise device during the intervention period.

A stratified analysis was conducted using baseline FMA-UE scores to examine the potential impact of impairment severity on intervention effectiveness. Patients were categorized into the following subgroups based on their initial disability level: (A) severe paralysis: $\leq$20, (B) moderate paralysis: 21–45, and (C) mild paralysis: 46–66 [32]. This stratification enabled (1) a comparison of intervention effects among subgroups, (2) an assessment of the vibration exercise device's effectiveness relative to initial upper limb motor impairment, (3) a more precise evaluation of the intervention's impact within homogeneous clinical severity groups, and (4) specific model adjustments for each severity group.

The primary outcome variable was the FMA-UE total score, which measures motor function recovery [35]. The fixed effects in the model included the intervention periods, the intervention group, and their interaction. Additionally, the model controlled for several covariates: age, sex, type of diagnosis, affected side, initial FMA score at baseline, and the dose of Botulinum Toxin A treatment. The GLMM can be expressed as follows:

$$\text{FMA-UE total} = \beta_0 + \beta_1 \times \text{periods} + \beta_2 \times \text{group} + \beta_3 \times (\text{periods} \times \text{group}) + \beta_4 \times \text{age} + \beta_5 \times \text{sex} + \beta_6 \times \text{diagnosis} + \beta_7 \times \text{affected side} + \beta_8 \times \text{BoNT-A dosage} + u_i + \epsilon$$

where u_i represents the random intercept for each subject, accounting for within-subject correlation, and ϵ is the residual error. The model was fitted using the Restricted Maximum Likelihood (REML) method to provide unbiased estimates of the variance components. The significance of fixed effects was evaluated using Wald z-tests.

Model assumptions, including normality of residuals and homoscedasticity, were thoroughly checked. The normality of residuals was assessed using the Shapiro–Wilk test,

and visual inspections of histogram and Q-Q plots. Homoscedasticity was evaluated using residuals vs. fitted values plots and confirmed by the Breusch–Pagan test.

We performed both intent-to-treat (ITT) and per-protocol (PP) analyses. In the ITT analysis, we included all participants initially assigned, regardless of adherence or missing data, to maintain the benefits of randomization. Where data were missing from our study, we applied multiple imputation techniques to estimate and replace the missing values, ensuring comprehensive data analysis. This approach aligns with the recommended practices for handling missing data in clinical research, as detailed by Sterne et al., who emphasized the importance of addressing such gaps to maintain the validity of statistical inference [36]. In the PP analysis, we included only participants who completed the study without significant deviations from the protocol to assess the effectiveness of the intervention for those who adhered to the protocol and had complete data.

Post hoc comparisons of changes in between-group differences were performed using the Mann–Whitney U-test. In addition, intragroup comparisons were performed using the Wilcoxon signed-rank test. All statistical tests were two-sided, and significance was set at $p < 0.05$. No statistical sample size calculations were performed. However, we performed post-hoc power and effect size analyses on the results of the 93 patients in this study using G*Power version 3.1 (Heinrich-Heine-Universität, Düsseldorf). This indicates that this study was underpowered, and future studies should consider larger sample sizes to ensure adequate power. We calculated the post hoc power critical z = 0.19, $1 - \beta = 0.48$, and effect size $h = 0.40$ using the z-test.

Data analysis was conducted using Python (version 3.8, Anthropic, Wilmington, DE, USA). We used the "pandas" library (version 1.2.0) for data preprocessing and the "statsmodels" library (version 0.12.0) to construct GLMM using the "mixedlm" function. The flexibility of Python allows for rigorous data manipulation and detailed modeling.

3. Results

3.1. Participants and Baseline Characteristics

Ninety-three patients with stroke were prescribed rehabilitation treatment at five medical institutions during the study period. The number of patients varied among the participating hospitals, ranging from 9 to 41 per institution. All eligible patients were included (Table 1). Data from all 93 patients were analyzed (Figure 2).

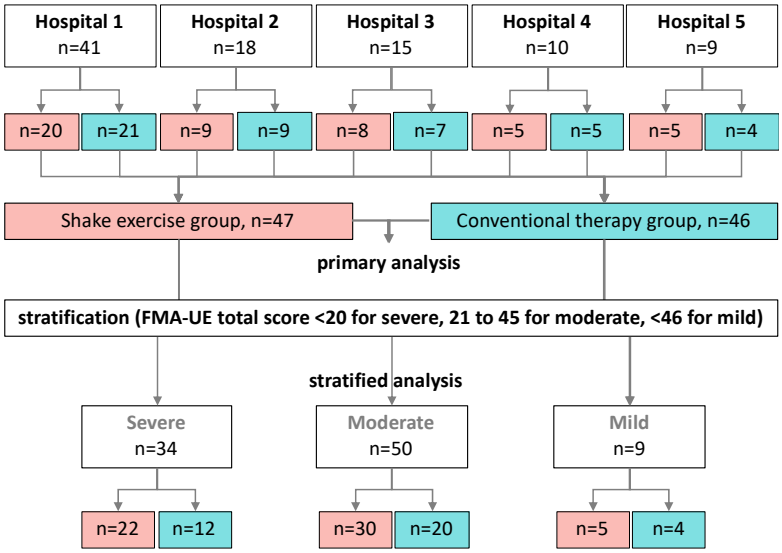

Figure 2. Flow chart of the processing protocol applied in this study for the inclusion and categorization of the participants. The included study participants from five hospitals ($n = 93$) underwent shaking exercise or conventional therapy. The same patients were also divided into 3 groups according to the function score of the upper extremity. Pink; Shaking group, Light blue; Controls.

Table 1. Pretreatment baseline characteristics of the shaking exercise and control groups.

Variables	All (n = 93)	Shaking (n = 47)	Control (n = 46)	Statistics χ^2 or U	p-Value	r or V
Sex (Female/Male)	50/43	26/22	24/21	0.00	1.00	0.00
Age (median, [Q1, Q3])	59 [53, 68]	59 [53, 67]	59 [53, 68]	1065	0.91	0.49
Diagnosis (CI/ICH/other)	33/55/5	16/30/2	17/25/3	0.59	0.75	0.08
Affected side (L/R)	46/47	27/21	19/26	1.31	0.25	0.12
Month from onset	131 [92, 175]	136 [98, 177]	126 [81, 175]	1487	0.36	0.56
FMA-UE	24 [18, 30]	27 [23, 31] *	20 [17, 23]	1343	0.04	0.62
BoNT-A treatment (times)	14 [10, 18]	14 [11, 19]	13 [9, 17]	1124	0.81	0.49
BoNT-A dose (Unit)	250 [200, 350]	250 [200, 400]	250 [200, 300]	1208	0.32	0.56

Data are presented as median [1st, 3rd quartile]. Chi-square test with Cramer's V for effect size is used to compare the number of patients, diagnosis, and affected side in each group. Month from onset, FMA-UE, BoNT-A are compared with Mann–Whitney U-test. * $p < 0.05$ compared with controls. Pink; Shaking group, Light blue; Controls. CI; cerebral infarction, ICH; intra cerebral hemorrhage, FMA-UE; Fugl–Meyer assessment of the upper extremity, BoNT-A; Botulinum toxin type A.

3.2. Results from GLMM for FMA-UE Score

Table 2 presents the estimated factor levels for the FMA-UE score derived from the Generalized Mixed Linear Model. The analysis included all 93 patients, with fixed effects comprising the intervention period (Periods), intervention group (Group), and their interaction (Periods × Group). The group coefficient (β = 1.363, SE = 0.447, p = 0.002) indicated that the shaking group had a significantly higher baseline FMA-UE score than the control group. The period coefficient (β = 0.467, SE = 0.298, p = 0.118) showed the overall change in FMA-UE score over time across both groups, which was not statistically significant. Importantly, the interaction term (β = 1.359, SE = 0.419, p = 0.001) indicated that the shaking group experienced a significantly greater improvement in FMA-UE scores over time than the control group, demonstrating the effectiveness of the intervention.

Table 2. Estimated factor levels by Generalized Mixed Linear Model for FMA-UE score.

Variable	β	SE	z-Value	p-Value		95% CI	
Intercept	0.467	0.550	0.849	0.396		0.611	1.545
Periods	0.467	0.298	1.565	0.118		−0.118	1.051
Group	1.363	0.447	3.048	0.002	*	0.486	2.239
Periods × Group	1.359	0.419	3.242	0.001	*	0.538	2.181
Group Variance	25.368	4.721	5.373	0.000	*	16.115	34.621
Periods Variance	25.057	4.150	6.038	0.000	*	16.923	33.191
Group × periods Covariance	23.963	4.300	5.572	0.000	*	15.534	32.391

The model includes data from 186 observations across 93 periods. Fixed effects included the intervention period (Periods), shaking group (Group), and their interaction (Periods × Group). Statistical significance is set at * $p < 0.05$. SE; Standard Error, β; estimated coefficient.

Variance components were significant with group variance (Group Var = 25.368, SE = 4.721, $p < 0.001$, 95% CI [16.115, 34.621]), period variance (Periods Var = 25.057, SE = 4.150, $p < 0.001$, 95% CI [16.923, 33.191]), and the covariance between group and period (Group × Periods Cov = 23.963, SE = 4.300, $p < 0.001$, 95% CI [15.534, 32.391]).

3.3. Changes in FMA-UE Scores Pre- and Post-Intervention

Table 3 summarizes the changes in FMA-UE scores pre- and post-intervention for both the shaking and control groups. The intervention group demonstrated a significant improvement in the FMA-UE total score (median change = 1.8, 95% CI [0.8, 2.8]) compared with the control group (median change = 0.4, 95% CI [−0.1, 1.0], U = 823, p = 0.04, indicating a significant difference (r = 0.24) (Figure 3A). For the FMA-UE part A subscale, the intervention group showed a median change of 1.2 (95% CI [0.6, 1.8]) versus the control group's 0.3 (95% CI [−0.2, 0.9]), with a U-value of 769.5 and a p-value of 0.01, indicating a statistically

significant difference (r = 0.29). The FMA-UE part B did not show significant changes between the intervention and control groups (U = 1014.5, $p = 0.56$, r = 0.06). Similarly, the FMA-UE part C and D changes were not significant between the interventions.

Table 3. Changes in FMA-UE scores pre- and post-intervention, compared with control and intervention groups.

FMA-UE	Shaking (n = 47)			Control (n = 46)			U	p		r
	Pre	Post	Delta	Pre	Post	Delta				
Total	26.8 [23.0, 31.2]	28.4 [24.4, 33.0]	1.8 [0.8, 2.8]	20.0 [17.1, 23.3]	20.3 [17.4, 23.7]	0.4 [−0.1, 1.0]	823	0.04	*	0.24
part A	21.4 [19.4, 23.5]	22.6 [20.6, 24.7]	1.2 [0.6, 1.8]	17.5 [15.5, 19.6]	17.9 [15.8, 20.0]	0.3 [−0.2, 0.9]	770	0.01	*	0.29
part B	2.9 [2.1, 3.7]	3.1 [2.3, 3.9]	0.2 [−0.2, 0.6]	1.7 [0.9, 2.4]	1.9 [1.1, 2.7]	0.2 [−0.1, 0.6]	1015	0.56		0.06
part C	4.1 [2.9, 5.2]	4.2 [3.1, 5.4]	0.2 [−0.3, 0.6]	3.5 [2.4, 4.7]	3.3 [2.2, 4.5]	−0.2 [−0.5, 0.1]	977	0.37		0.10
part D	1.3 [0.8, 1.7]	1.4 [1.0, 1.9]	0.2 [0.0, 0.4]	0.8 [0.3, 1.2]	0.7 [0.3, 1.2]	0.0 [−0.2, 0.1]	964	0.16		0.11

A Mann–Whitney U-test comparing the changes (Δ values) in FMA scores before and after treatment between control and intervention groups. Δ values are calculated as the difference between pre- and post-intervention scores for each measure. * p-values less than 0.05 indicate statistically significant differences between the groups. Effect size (r) is reported to quantify the magnitude of the difference, with values closer to −1 or 1 indicating a stronger effect. Data are presented as medians and 25th–75th percentile values. Pink columns indicate the Shaking group data, while the Control group is shown in light blue.

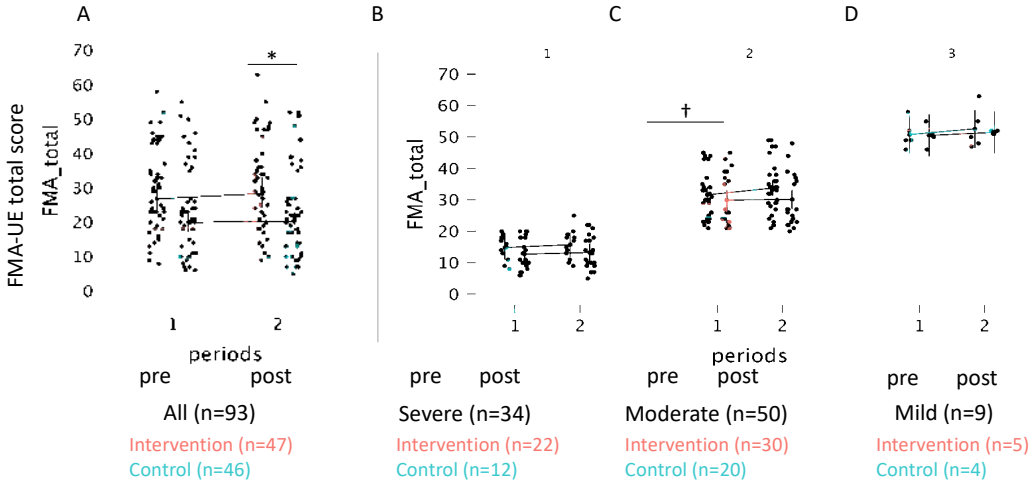

Figure 3. Comparison of FMA-UE scores pre and post intervention between shaking exercise and conventional therapy groups. The plots include data for all patients and are stratified by the severity of impairment at baseline (mild, moderate, and severe): (**A**) Changes in FMA-UE scores for all patients. (**B**) For patients with mild impairment at baseline. (**C**) For patients with moderate impairment at baseline. (**D**) For patients with severe impairment at baseline (Intervention n = 5, Control n = 4). * $p < 0.05$ for between groups based on Mann–Whitney U-test. † $p < 0.05$ for within groups by Wilcoxon test.

3.4. Baseline Characteristics According to Severity

The baseline characteristics of the shaking exercise and control groups, stratified by the severity of upper limb impairment in stroke patients (severe, moderate, and mild) are shown in Table 4.

Table 4. Baseline data for shaking exercise and control groups for upper limbs of patients with stroke according to severity.

Variable	Severe (n = 34)		Moderate (n = 50)		Mild (n = 9)	
	Shaking	Control	Shaking	Control	Shaking	Control
Sex (Female/Male)	8/5	13/8	16/14	13/7	3/2	4/0
Age	66 [52, 74]	59 [54, 70]	56.5 [53, 66.5]	56.5 [52.75, 64]	58 [57, 61]	69 [58, 73]
Diagnosis (CI:ICH; Other)	7:6:0	7:13:1	8:3:2	8:11:1	1:4:0	2:1:1
Affected Side (L/R)	9/4	11/10	15/15	7/13	3/2	1/3
Month of Onset	167 [94, 248]	138 [92, 176]	134 [103, 174]	116 [80, 169]	122 [110, 137]	88 [79, 136]
FMA-UE Total	15 [11, 18]	11 [10, 18]	30.5 [24.25, 34.75]	26 [23, 37.5]	49 [49, 52]	50.5 [49, 52]
BoNT-A treatment (times)	14 [11, 23]	13 [10, 17]	15 [10, 21]	10 [6, 15]	18 [14, 27]	14 [6, 22]
BoNT-A (unit)	275 [200, 300]	250 [250, 400]	250 [200, 400]	200 [197.5, 250]	250 [100, 250]	175 [138, 250]

Data are presented as median [1st, 3rd quartile]. CI; cerebral infarction, ICH; intra cerebral hemorrhage, L; left, R; right, FMA-UE; Fugl-Meyer assessment of the upper extremity, BoNT-A; Botulinum toxin type A. Pink; Shaking group, Light blue; Controls.

3.5. Stratified Analysis of FMA-UE Score by Severity Level

Statistical results are shown in Table 5. For patients with severe impairment (n = 34), the intervention group showed a median change of 1.0 [−0.25, 1.0], while the control group's was 0.0 [0.0, 1.25]. The differences were not statistically significant, with U-values of 16.00 (p = 0.22, r = 0.43) for the intervention group and 21.50 (p = 0.09, r = 0.00) for the control group (Figure 3B). In the moderate impairment category (n = 50), the shaking device group exhibited a median change of 1.0 [0.0, 4.0], significantly greater than the control group's change of 0.0 [0.0, 1.0] (U = 59.50, p = 0.01, r = 0.25) (Figure 3C). The control group's result was not significant, with a U-value of 25.50 (p = 0.50, r = 0.00). Among mildly impaired patients (n = 9), the intervention group showed a median change of 2.0 [0.5, 3.5], compared with the control group's 1.5 [−0.5, 2.75]. Neither group's results were statistically significant for the intervention group, and they were 3.50 (p = 0.63, r = 0.36) for the control group (U = 1.50, p = 0.25, r = 0.77) (Figure 3D). These findings indicate that the shaking device intervention significantly improved FMA-UE scores in patients with moderate impairment, while no significant improvements were observed in patients with severe or mild impairments.

Table 5. Stratified analysis results of FMA-UE score changes in stroke patients: comparison of shaking device intervention and control groups by severity level.

Severity	Group	Pre	Post	Delta	U	p		r
Severe (n = 34)	Shaking	15.0 [11.0, 18.0]	16.0 [12.5, 18.3]	1.0 [−0.25, 1.0]	16.00	0.22		0.43
	Control	11.0 [10.0, 18.0]	13.0 [9.75, 17.0]	0.0 [0.0, 1.25]	21.50	0.09		0.00
Moderate (n = 50)	Shaking	30.5 [24.3, 34.8]	33.5 [29.0, 37.5]	1.0 [0.0, 4.0]	59.50	0.01	*	0.25
	Control	26.0 [23.0, 37.5]	27.0 [23.0, 37.3]	0.0 [0.0, 1.0]	25.50	0.50		0.00
Mild (n = 9)	Shaking	49.0 [49.0, 52.0]	51.5 [47.75, 57.0]	2.0 [0.5, 3.5]	1.50	0.25		0.77
	Control	50.5 [49.0, 52.0]	51.0 [51.0, 52.0]	1.5 [−0.5, 2.75]	3.50	0.63		0.36

The severity levels are divided into Severe, Moderate, and Mild based on initial FMA scores. Shaking refers to the intervention group using the jiggling device, and Control refers to the control group. The change in FMA score (delta) from pre to post intervention. The Wilcoxon signed-rank test for comparing the changes within the Shaking and Control groups. Data are presented as medians and 25th–75th percentile values. * $p < 0.05$ for comparison. Pink; Shaking group, Light blue; Controls.

3.6. Analysis of Secondary Outcomes and Data Imputation

An intention-to-treat analysis was performed for secondary outcomes. The collection of MAS, ROM, and VAS data for the eight patients at one participating clinic was not feasible owing to the constraints imposed by the Japanese insurance system. To overcome this limitation and ensure the continuity and completeness of our dataset for secondary outcome analysis, missing MAS, ROM, and VAS data were imputed using multiple techniques.

To examine the effects of the intervention on chronic pain using the VAS, Wilcoxon signed-rank tests were performed to compare the pre- and post-intervention scores within each group (Table 6). In the control group, a significant difference in the VAS scores was observed from pre- to post-intervention (W = 23.00, p = 0.02, Cohen's d = 0.00). Conversely, no significant changes were observed in the intervention group (W = 8.00, p = 0.60, Cohen's d = 0.00). A comparison of changes in the MAS scores, joint ROM, and pain perception measurements pre- and post-intervention between the shaking exercise and control groups showed no statistically significant differences for any of the parameters measured (Appendix A).

Table 6. Comparative analysis of motor function outcomes between the control and intervention groups: Assessing efficacy through modified Ashworth scale and range of motion measurements.

Variables			Intervention Group			Control Group			Δ Control vs. Δ Intervention		
			Pre	Post	Delta	Pre	Post	Delta	U	p	r
modified Ashworth scale	shoulder	flex	1 [1, 2]	1 [1, 2]	0 [0, 1]	1 [1, 2]	1 [0, 2]	0 [0, 0]	908	0.14	−0.16
		ext	1 [0, 2]	1 [0, 2]	0 [0, 0]	1 [0, 2]	1 [0, 2]	0 [0, 0]	1028	0.62	−0.05
	elbow	flex	1 [1, 2]	1 [1, 2]	0 [0, 1]	1 [1, 2]	1 [1, 2]	0 [0, 0]	1202	0.31	0.11
		ext	2 [1, 2]	2 [1, 2]	0 [0, 1]	2 [1, 2] *	1 [0, 2]	0 [0, 1]	930	0.20	−0.14
	wrist	flex	1 [0, 2]	1 [0, 2]	0 [0, 1]	1 [1, 2]	1 [1, 2]	0 [0, 0]	1082	1.00	0.00
		ext	2 [1, 2]	2 [1, 2]	0 [0, 1]	1 [0, 2]	1 [1, 2]	0 [0, 0]	1087	0.97	0.01
	finger	flex	2 [0, 2]	1 [0, 2]	0 [0, 1]	1 [0, 2]	1 [0, 2]	0 [0, 0]	1091	0.93	0.01
		ext	0 [0, 2]	1 [0, 2]	0 [0, 0]	1 [0, 2]	1 [0, 2]	0 [0, 0]	1037	0.68	−0.04
Active Range of Motion	shoulder	flex	110 [125, 80]	110 [125, 88]	0 [−5, 10]	83 [110, 43]	83 [120, 50]	0 [−5, 9]	1094	0.92	0.01
		ext	40 [40, 20]	40 [50, 30]	0 [−5, 5]	35 [40, 25]	35 [40, 20]	0 [−5, 5]	1311	0.06	0.21
		abd	75 [120, 60]	85 [113, 60]	5 [0, 10]	60 [85, 50]	60 [80, 41]	0 [−5, 5]	1187	0.41	0.10
		add	0 [10, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]	999	0.46	−0.08
	elbow	flex	115 [130, 103]	115 [130, 100]	5 [−10, 0]	100 [114, 76]	100 [120, 83]	0 [−5, 5]	1036	0.73	−0.04
		ext	−15 [−38, 0]	−10 [0, −30]	5 [0, 10]	−18 [−49, 0]	−15 [−39, −6]	5 [0, 10]	1214	0.30	0.12
	wrist	flex	15 [40, 0]	15 [40, −5]	0 [−5, 5]	13 [0, 30]	18 [−10, 30]	0 [−5, 5]	941	0.27	−0.13
		ext	30 [40, 0]	30 [45, 5]	0 [0, 0]	5 [−28, 35]	8 [−20, 34]	0 [−10, 0]	1141	0.64	0.06
Passive Range of Motion	shoulder	flex	140 [125, 155]	140 [120, 160]	0 [−5, 10]	138 [120, 160]	135 [120, 154]	0 [−5, 9]	1048	0.80	0.03
		ext	50 [45, 60]	50 [48, 58]	0 [−5, 5]	50 [41, 50]	50 [40, 50]	0 [−5, 0]	1006	0.55	0.07
		abd	135 [130, 140]	140 [130, 143]	0 [0, 5]	140 [130, 145]	133 [125, 145]	0 [−5, 0]	892	0.12	0.18
		add	0 [−10, 0]	0 [−5, 0]	0 [0, 0]	0 [−9, 0]	0 [−5, 0]	0 [0, 0]	1054	0.81	0.03
	elbow	flex	120 [95, 150]	120 [98, 155]	5 [−10, 10]	118 [90, 145]	110 [90, 144]	0 [−14, 5]	898	0.16	0.17
		ext	0 [0, 13]	0 [0, 0]	0 [0, 0]	0 [0, 12]	0 [0, 0]	0 [0, 0]	1187	0.27	−0.10
	wrist	flex	70 [60, 80]	70 [60, 80)	0 [−8, 5)	70 [65, 80]	70 [60, 80]	0 [0, 5]	1144	0.62	−0.06
		ext	60 [45, 70]	70 [48, 80)	0 [0, 10)	68 [50, 75]	68 [55, 74]	0 [0, 9]	1029	0.68	005
Pain VAS			2 [0, 5]	2 [0, 6]	0 [0, 0]	3 [0, 6]	2 [0, 5] *	0 [−1, 0]	914	0.10	0.10

A Mann–Whitney U-test was used to compare changes in MAS and ROM between groups, quantified by calculating the difference (Δ values) between pre- and post-intervention measurements. p-values are presented for the results of comparisons between the shaking exercise and control groups. * $p < 0.05$ for within-group comparisons were performed using a Wilcoxon signed-rank test. Data are presented as medians and 25th–75th percentile values. Pink; Shaking group, Light blue; Controls.

Significant within-group changes in the control group were particularly notable in MAS elbow extension (W = 19.5, p = 0.005, effect size r = −0.839) and MAS wrist flexion (W = 6.0, p = 0.083, effect size r = −0.861). The other scores in the control group did not show statistically significant differences. In the intervention group, although there were no statistically significant overall changes, the MAS wrist flexion score showed a moderate effect size (W = 97.5, p = 0.206, effect size r = −0.720).

In within-group comparisons of the intervention group, the most significant change was observed in active shoulder extension ROM (W = 93.0, p = 0.011, effect size r = −0.727), indicating a statistically significant decrease in shoulder extension ROM following the intervention. Other ROM measurements showed no significant changes, with effect sizes indicating slight to moderate reductions, such as in passive elbow extension ROM (W = 97.0, p = 0.512, effect size r = −0.721) and passive wrist extension ROM (W = 162.5, p = 0.056, effect size r = −0.620). In the control group, no significant changes were observed in most ROM measurements after treatment. However, notable changes with moderate effect

sizes were identified for several measurements, although they did not reach statistical significance at conventional thresholds.

This method allowed us to statistically estimate missing data based on available patient information and characteristics observed in complete cases. Table A1 presents the results of the PP analysis of the secondary outcomes. Using nonimputed data, patients in the intervention group maintained a significantly greater active ROM in shoulder extension (Δ5.4 vs. Δ−1.3) and wrist active flexion (6.6 vs. 1.5; $p = 0.03$), as well as less pain (−0.61 vs. 0.15) than the control group.

All participants adhered to the assigned intervention or control group throughout the study, and no crossover between groups occurred. Although participants were absent from training sessions and adhered to the prescribed regimen, some protocol deviations were observed. For example, participants were sometimes unable to grasp the lever of the shaking device with their affected hand. These deviations were addressed by providing assistance to therapists or by installing a holding jig to prevent any impact on the training. Only 1/47 patients (2.1%) in the test group experienced an adverse event that was undeniably related to the shaking device. The patient experienced mild pain in the clavicular area, which improved with follow-up. There were no adverse events in the control group.

4. Discussion

This study evaluated the effects of home-based training using a vibrational device, termed the "Kenko Yusuri", on functional recovery in patients with chronic post-stroke upper limb impairment. According to the FMA-UE scores, the shaking exercise group showed significantly greater improvements than the control group that engaged in conventional training. Notably, this intervention was particularly effective in patients with moderate impairment, suggesting that vibrational stimulation can enhance neuroplasticity and sensory–motor integration [37], potentially facilitating motor function recovery [38,39]. The efficacy of the intervention was further supported by the results derived from the GLMM analysis, which provide a predictive model for quantification of the intervention's impact on functional improvements.

Jiggling and vibratory exercises also reduce muscle spasticity, which is commonly observed among stroke survivors [40]. In this study, the use of a home-based shaking device significantly improved the total FMA scores of patients with moderate impairment, demonstrating the efficacy of the device in activating sensorimotor pathways [41], which are often underused in paralyzed upper limbs [42]. Vibratory stimuli enhance proprioceptive feedback, which is essential for the motor learning and rehabilitation of individuals with neurological impairments. Recent studies have investigated the effects of vibration stimulation on upper limb spasticity after stroke, specifically comparing the effectiveness of vibration stimulation of the tendons and muscle bellies [43]. Vibration applied directly to the flexor tendon showed significantly greater reductions in spasticity than when it was applied to the muscle belly or after regular stretching. Vibratory stimulation is consistent with the hypothesized mechanism that tendon stimulation is more effective because of its effect on the Golgi tendon organ, which plays an important role in regulating muscle tone [44].

Improvements in upper limb impairment with spasticity often necessitate the continuation of BoNT-A treatment for at least four sessions, alongside regular training [45]. However, progression toward functional improvement tends to plateau with prolonged treatment. Patients who have undergone >10 sessions of BoNT-A therapy typically show minimal functional enhancement, reaching a plateau in their recovery. For these long-term treatment patients, pain reduction is the primary goal and outcome, while spasticity control is essential for maintaining quality of life [46]. The patients in the present study underwent multiple BoNT-A treatments, suggesting that their upper limb function may have reached a plateau despite consistent self-training. These patients often continued regular BoNT-A treatment and self-training. Although initial improvements in motor function may have

been observed, these gains plateaued over time. Therefore, the unchanged MAS scores in the present study may be attributed to a plateau effect. Nonetheless, similar to the control of spasticity achieved with BoNT-A treatment, continuous self-training remains crucial.

In our study, patients with stroke used a shaking device at home, either independently or with family assistance. This approach aligns with emerging research suggesting that the engagement of patients in active movement is beneficial for recovery from paralysis. Recent research supports the idea that active participation in rehabilitation by patients with stroke can significantly enhance recovery outcomes [47]. This includes patients taking an active role in their recovery through home-based interventions, as these interventions have been shown to be effective for motor function recovery after stroke. Incorporating exercise and functional task practices into daily routines, as emphasized in recent guidelines, is crucial for motor recovery. These activities are most effective when they involve high repetition and are tailored to an individual's specific needs, allowing for the patient's active participation in the rehabilitation process (National Clinical Guideline for Stroke, 2023) [48]. The importance of patient-driven activities in stroke rehabilitation suggests that interventions should not only be guided by healthcare professionals but also encourage self-practice and active involvement in therapeutic activities to maximize recovery outcomes.

In the results of this study, in which varying degrees of stroke severity demonstrated different responses to shaking device interventions, it is important to consider the influence of initial impairment severity on rehabilitation outcomes. This differential response aligns with previous findings in stroke rehabilitation, suggesting that the initial severity of motor function impairment can significantly dictate the potential and rate of functional recovery [16,46]. Severe and mild cases often present with distinct challenges. Severe cases may involve extensive neurological damage, which limits the efficacy of peripheral stimulation interventions, as the central pathways may be too impaired to translate peripheral sensory inputs into meaningful motor outputs. Mild cases, on the other hand, may not show dramatic improvements simply because their baseline function is already high, and the ceiling effect limits observable changes [49]. These observations underscore the necessity for a stratified approach to treatment and tailoring interventions to match the severity of impairment. Understanding and integrating severity-specific responses into rehabilitation protocols can optimize recovery trajectories and ensure that each patient receives the most appropriate and effective intervention tailored to their needs [50].

The intervention group in our study exhibited a mean increase in FMA-UE scores; however, these gains did not surpass the minimum clinically important difference (MCID) threshold [51]. The use of a shaking device represents a novel approach that provides specific neuromuscular stimulation, which may not be traditionally targeted in conventional stroke rehabilitation. Although neuroplasticity can still be promoted in the chronic phase of stroke recovery, the extent to which it can be influenced is often constrained by the severity and location of brain injury. Consequently, even modest improvements in the FMA-UE scores could indicate beneficial neurological adaptations [2,13]. The concept of MCID is critical for assessing the efficacy of interventions. However, it is inherently a population-based measurement that may not capture subtle yet clinically meaningful improvements at the individual level. Future studies should consider a personalized approach to therapy, emphasizing prolonged intervention durations and comprehensive outcome measures to fully capture the benefits of rehabilitation interventions.

While our study did not include a placebo device control group, the potential for a placebo effect remains a consideration. The belief in the efficacy of the rehabilitation advice provided in a clinical setting might lead patients to use their affected limbs more frequently, thus contributing to functional improvements. This psychological boost, stemming from trust in the treatment and increased engagement in rehabilitation activities, could enhance outcomes independently of the mechanical benefits of the device. Future studies should consider ethical and practical ways to incorporate placebo controls to better isolate the therapeutic effects of such interventions.

This study, while innovative in its approach to post-stroke rehabilitation, has several limitations. First, a key limitation of this study was the relatively small sample size, which might limit the generalizability and robustness of our findings. Our post hoc power analysis indicated a lower statistical power, suggesting that the study was underpowered to detect small to moderate effects. Future research should aim to include a larger sample size to ensure adequate power and provide more definitive conclusions on the efficacy of the shaking device for upper limb rehabilitation in stroke patients. Second, our findings indicated the variable efficacy of the intervention across different levels of severity of impairment. The intervention showed significant benefits in patients with moderate severity but not in those with mild or severe impairments. This suggests that the effectiveness of the intervention is contingent on the patient's initial functional status, necessitating further investigation of tailored therapeutic approaches for different severity levels. Third, all the participants received BoNT-A treatment, which may have confounded the effects of the shaking device on motor recovery. Future studies should consider separate groups for those receiving BoNT-A and those who do not to isolate the effects of the shaking device. Fourth, variability in adherence to the intervention protocol owing to the home-based nature of the therapy may have influenced the outcomes. Ensuring the consistent application of the intervention in such settings remains a challenge, and methods for monitoring and improving home-based intervention fidelity should be integrated into future studies. Fifth, the primary outcome measure, the FMA-UE, may not have captured all relevant aspects of functional improvement owing to its susceptibility to ceiling effects [49], particularly in patients with mild impairment. Including additional functional and patient-centered outcome measures could provide a more comprehensive assessment of the intervention's impact.

Continued BoNT-A treatment combined with daily training in the chronic phase can improve shoulder and arm motor function, even in patients with moderate-to-severe paralysis. The findings of this study support this hypothesis. Additionally, patients who underwent shaking training exhibited reduced chronic pain, a previously unreported benefit. Although the motor function improvements were small, they were clear, leading to greater patient motivation and activity, which, in turn, can further enhance motor function. The stratified analysis indicated that the intervention had significant effects, particularly in patients with moderate impairment. For patients capable of isolated movement, treatments such as transcranial magnetic stimulation may further enhance functional recovery. In patients with severe or moderate impairment, implementing a home-based training regimen using a shaking device can reduce pain and improve motor function. Conducting this training for 10 min, three times a day, while engaging in other activities, such as watching TV or talking, can be beneficial. This method offers a safe and sustainable treatment option that allows patients to continue treatment without excessive strain, thereby potentially reducing the economic burden on families and healthcare systems.

5. Conclusions

Our multicenter quasi-randomized controlled trial provides evidence supporting the use of home-based voluntary training using the "Kenko Yusuri" shaking device to enhance functional recovery in patients with chronic post-stroke upper limb impairment. While the improvements in FMA-UE scores in the intervention group did not exceed the MCID, they were statistically significant compared with those of the control group. Our findings suggest that even modest gains in motor function can substantially affect the quality of life and independence of stroke survivors. Home-based interventions, such as the "Kenko Yusuri", provide a feasible and effective option to supplement traditional care strategies, making a meaningful difference in the management of chronic stroke rehabilitation.

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Appendix A

Table A1. Comparisons of the modified Ashworth scale and range of motion using active and passive movements within the shaking exercise and control groups, analyzed using raw data.

	Intervention Group (n = 39)		Control Group (n = 39)		Between-Group	Mean Change	
Secondary Endpoints (n = 78)	**Pre-Test**	**Post-Test**	**Pre-Test**	**Post-Test**	***p*-Value (95% CI)**	**Intervention Group**	**Control Group**
MAS (shoulder flexion)	1 [1, 1] ‡	1 [1, 1] ‡	1 [1, 2]	1 [1, 1] ‡	0.574	0 [1, 0]	0 [0, 0]
MAS (shoulder extension)	1 [0, 1] ‡	1 [0, 1] ‡	1 [0, 1] ‡	1 [0, 1] ‡	0.59	0 [0, 0]	0 [0, 0]
MAS (Elbow flexion)	1 [1, 1] ‡	1 [1, 1] ‡	1 [1, 1] ‡	1 [1, 1] ‡	0.215	0 [−1, 0]	0 [0, 0]
MAS (Elbow extension)	1 [1, 1] ‡	1 [1, 1] ‡	1 [1, 1] ‡	1 [0, 1] ‡	0.297	0 [−1, 0]	0 [, 1, 0]
MAS (Wrist flexion)	1 [0, 1] ‡	1 [0, 1] ‡	1 [1, 2]	1 [1, 1] ‡	0.367	0 [−1, 0]	0 [0, 0]
MAS (Wrist extension)	1 [1, 2] ‡	1 [1, 1] ‡	1 [1, 2]	1 [1, 1] ‡	0.57	0 [−1, 0]	0 [0, 0]
MAS (Finger flexion)	1 [0, 2] ‡	1 [0, 2]	1 [0, 1] ‡	1 [0, 1] ‡	0.64	0 [−1, 0]	0 [0, 0]
MAS (Finger extension)	0 [0, 1] ‡	1 [0, 1] ‡	1 [0, 1] ‡	1 [0, 1] ‡	0.461	0 [0, 0]	0 [0, 0]
Sholder flexion active ROM	102.50 ± 32.39 †	102.78 ± 35.65	80.00 ± 46.73	81.03 ± 47.69	0.808 (−5.33, 6.83)	0.28 ± 10.07	1.03 ± 15.06
Sholder flexion passive ROM	138.47 ± 23.11	140.28 ± 22.86	131.76 ± 29.56	134.12 ± 29.04	0.796 (−3.71, 4.81)	1.81 ± 10.36	2.35 ± 7.10
Sholder extension active ROM	32.08 ± 15.92	37.50 ± 13.91	30.88 ± 15.54	32.21 ± 25.14	0.019 (−12.39, −1.09) †	5.42 ± 14.31	−1.32 ± 8.47
Sholder extension passive ROM	49.58 ± 11.97	51.06 ± 11.54	45.15 ± 11.38	43.82 ± 11.68	0.162 (−6.78, 1.19)	1.47 ± 9.67	−1.32 ± 6.66
Sholder abduction active ROM	88.19 ± 38.29 †	88.89 ± 36.80	65.29 ± 33.93	65.15 ± 35.52	0.819 (−8.19, 6.51)	0.69 ± 16.13	−0.15 ± 14.59
Sholder abduction passive ROM	122.50 ± 35.73	124.86 ± 35.89	113.68 ± 37.42	112.06 ± 40.99	0.381 (−12.86, 4.90)	2.36 ± 14.42	−1.62 ± 22.22
Sholder adduction active ROM	7.36 ± 20.86	7.50 ± 20.79	3.09 ± 12.67	3.09 ± 12.43	0.937 (−3.65, 3.37)	0.14 ± 8.58	0.00 ± 5.77
Sholder adduction passive ROM	10.56 ± 20.24	10.28 ± 19.82	7.24 ± 12.06	7.21 ± 13.15	0.885 (−3.20, 3.70)	−0.28 ± 8.10	−0.03 ± 6.16
Elbow flexion active ROM	111.33 ± 21.52	109.03 ± 29.71	102.50 ± 23.07	104.56 ± 21.30	0.366 (−5.37, 14.09)	−2.31 ± 26.06	2.06 ± 11.69
Elbow flexion passive ROM	135.14 ± 8.49	136.25 ± 8.14	132.21 ± 16.34	131.47 ± 15.45	0.197 (−4.66, 0.97)	1.11 ± 6.29	−0.74 ± 6.29
Elbow extension active ROM	−22.78 ± 22.57	−20.69 ± 21.22	−24.71 ± 25.88	−25.29 ± 27.33	0.281 (−7.60, 2.26)	2.08 ± 11.17	−0.59 ± 9.36
Elbow extension passive ROM	−5.69 ± 12.14	−5.28 ± 12.07	−5.15 ± 12.94	−5.29 ± 13.14	0.647 (−3.05, 1.92)	0.42 ± 6.48	−0.15 ± 3.37

Table A1. *Cont.*

Secondary Endpoints (n = 78)	Intervention Group (n = 39)		Control Group (n = 39)		Between-Group	Mean Change	
	Pre-Test	Post-Test	Pre-Test	Post-Test	p-Value (95% CI)	Intervention Group	Control Group
Wrist flexion active ROM	23.33 ± 28.23	16.67 ± 27.95	16.18 ± 30.00	17.65 ± 29.47	0.026 (0.94, 15.34) †	−6.67 ± 17.81	1.47 ± 11.52
Wrist flexion passive ROM	68.47 ± 13.46	66.94 ± 14.80	70.44 ± 13.62	72.06 ± 12.86	0.106 (−0.70, 7.00)	−1.53 ± 8.69	1.62 ± 7.36
Wrist extension active ROM	13.47 ± 38.24	23.33 ± 28.88	7.65 ± 30.83	9.41 ± 28.81	0.14 (−19.05, 2.86)	9.86 ± 28.55	1.76 ± 14.87
Wrist extension passive ROM	58.33 ± 21.18	60.14 ± 23.25	60.15 ± 18.47	63.53 ± 15.15	0.522 (−3.33, 6.49)	1.81 ± 10.77	3.38 ± 9.75
Pain VAS	3.17 ± 3.04	2.56 ± 2.50 *	2.65 ± 2.84	2.79 ± 3.05	0.03 (−1.44, 0.07) †	−0.61 ± 1.59	0.15 ± 1.26

The pretest was performed before the intervention, and the post-test was performed after 12 weeks. The Mann–Whitney U-test was performed for MAS. Significantly differences were found * within groups and † between groups. ‡ in the pretest comparisons between the intervention and control groups, a significant difference was observed ($p < 0.05$). The significance level was set at $p < 0.05$ for differences between the two groups. CI; confidence interval, SD; standard deviation, 1Q and 3Q 25th–75th percentile values, MAS; modified Ashworth scale, ROM; range of motion. Pink; Shaking group, Light blue; Controls.

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