# **ORIGINAL ARTICLE**

# Effect of Vestibular Rehabilitation Program Using a Booklet in Patients with Chronic Peripheral Vestibular Hypofunction: A Randomized Controlled Trial

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Objectives: This study investigated the effects of a supervised home-based vestibular rehabilitation program using a booklet on gait function and dizziness in patients with chronic peripheral vestibular hypofunction. Methods: This was a non-blinded, randomized, controlled trial. Patients (n=42) with chronic peripheral vestibular hypofunction were randomly divided into the vestibular rehabilitation group (VR group; n=20) or the control group (n=22). Patients in the VR group received a supervised home-based vestibular rehabilitation program using a booklet in addition to physician care for 4 weeks. The physical therapist checked the home program when the VR group visited the outpatient clinic once a week. Patients in the control group received physician care only during the trial period. The primary outcome was functional gait assessment (FGA). The secondary outcomes were the dynamic gait index (DGI) and the dizziness handicap inventory (DHI). Results: Two-way repeated measures analysis of variance showed a significant interaction for FGA, DGI, DHI total, and DHI emotional scores (P<0.05) with the VR group improving more than the control group. No significant interactions were found for DHI physical and DHI functional scores ( $P \ge 0.05$ ). Conclusions: The home-based vestibular rehabilitation program in this study was effective in improving gait function and dizziness in patients with chronic peripheral vestibular hypofunction. Regular supervision may have improved adherence to home exercise and contributed to the effectiveness of vestibular rehabilitation.

Key Words: booklets; dizziness; gait; rehabilitation; vestibular diseases

#### INTRODUCTION

Dizziness is a risk factor for falls and has a negative impact on quality of life (QOL).<sup>1-3)</sup> According to a survey in the United States, 35.4% of adults aged over 40 years have vestibular dysfunction.<sup>3)</sup> Peripheral vestibular hypofunction (PVH) causes dizziness, gait disorder, postural instability, and visual blurring.<sup>4–7)</sup> There are several types of treatment for people with PVH, such as medications, surgical interventions, and vestibular rehabilitation (VR). VR has been recommended as a safe and effective intervention for patients with chronic PVH.<sup>4,8)</sup>

Current VR consists of adaptation, substitution, habituation, and balance and gait exercises.<sup>8)</sup> Home-based VR is performed using a booklet that explains how to do home exercise. Prior studies reported that home-based VR using a

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booklet for chronic dizziness was more effective than usual medical care.<sup>9–11)</sup> They found that it improves dizziness and static balance,<sup>9–11)</sup> but they did not examine its effects on gait function and dynamic balance.

The problem of home-based VR using a booklet is low adherence.<sup>10,11</sup> Adherence is an important factor affecting the efficacy of VR.<sup>10</sup> To improve adherence to home exercises, a home program should be customized according to the severity of dizziness, gait function, balance function, and capability for home exercise. Ideally, VR should be individualized to the patient,<sup>8,12</sup> and the exercises should be customized by the therapist, may contribute to improved adherence and may reduce the chance of drop-out. Accordingly, the aim of this study was to investigate the effects of a supervised home-based VR program using a booklet on gait function and dizziness in patients with chronic PVH.

#### MATERIALS AND METHODS

#### **Study Design and Procedure**

This study was based on a non-blinded, randomized, controlled clinical trial. Before patient enrollment, the study was registered with the University Hospital Medical Information Network Clinical Trials Registry (Registration number: UMIN000036608). This study conformed to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Prior to the start of the study, participants received an explanation of the purpose of this research and data use. Written informed consent was obtained from all participants. This study was approved by the ethical review committee of Mejiro University, Japan (Approval number: 18 medicine-009).

#### **Participants**

Participants were diagnosed with chronic PVH at our institution between May 2019 and June 2021. There were three inclusion criteria for this study. (1) Unilateral or bilateral PVH was diagnosed based on pathological results on the bithermal caloric test, and/or the video head impulse test (vHIT).<sup>13,14</sup> Unilateral PVH was defined as canal paralysis of greater than 20% on the bithermal caloric test, and/or the horizontal angular vestibular-ocular reflex (VOR) gain was less than 0.8, and catch-up saccade was observed on the vHIT.<sup>13,15</sup> Bilateral PVH was confirmed when the sum of the maximum slow-phase velocities of the bithermal caloric test was less than 6°/s in both ears<sup>14</sup>) or when horizontal angular VOR gain was less than 0.6 on both sides in the vHIT.<sup>14</sup> (2) Duration of symptoms of dizziness was longer than 3 months. According to a previous study, patients who had experienced dizziness for more than 3 months were defined as being in the chronic phase.<sup>8)</sup> (3) Ability to walk independently. Patients that met any of following criteria were excluded: (1) had previously undergone VR; (2) had benign paroxysmal positional vertigo; (3) showed central neurological symptoms; (4) had cognitive impairment; (5) showed inability to understand instructions; or (6) took medications that cause vestibular symptoms.

#### Randomization

Participants were randomly assigned to two groups: the supervised home-based VR program using a booklet with physician care (VR group) or physician care only (control group). Allocation was based on block randomization (block size, 4) after stratification for age (<65 years or  $\geq$ 65 years). Allocation of the patients was performed by the receptionist of the research facility who was not involved in this study. The allocation table was created before the start of this study using a RAND function in Microsoft Excel 2010 (Microsoft, Redmond, WA, USA). The authors were blinded to the allocations, which were managed by the receptionist.

#### Intervention

The VR group underwent a supervised home-based VR program using a booklet in addition to physician care for 4 weeks. The booklet contained simple illustrations (**Fig. 1**) and exercise instructions written in simple language for the general public. A physical therapist (PT) provided direct instruction during each intervention to ensure that the exercises were performed correctly.

The exercises in the booklet consisted of five exercise components: adaptation, substitution, habituation, gait, and balance exercises. Exercises 1-4 were offered to all patients in the VR group during the intervention period. Exercise 5 was provided by selecting three dizziness-inducing movements in order of symptom severity; however, in absence of dizziness-inducing movements, Exercise 5 was not performed (Table 1). The habituation exercise section (Exercise 5) of the home program was based on the Motion Sensitivity Quotient/Test.<sup>16,17</sup>) Each exercise type had several levels of difficulty that could be selected based on the state of the patient. A PT customized the home program for each individual based on the patient's functional status. The level of exercise was determined according to the following considerations: (1) the exercise could be performed correctly, and (2) mild to moderate dizziness occurred, and the symptoms disappeared within 20 min. If the patient did not feel dizziness after the exercise, the next level was selected. If the dizziness

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Fig. 1. All illustrations used in the booklet. No illustrations were attached to Exercise 5.

persisted for more than 20 min, the PT instructed the patient to reduce the duration and speed of the exercise.<sup>18)</sup>

The time required to perform home exercises at home was approximately 15 minutes per session. Participants were asked to perform the home program every day, with more than two sessions per day during the 4-week intervention period. Participants were asked to use a booklet to record the number of sessions of the home program they performed. The PT checked the home program once a week when participants visited the outpatient clinic. The VR group performed the exercises in the booklet according to the PT's instructions.

The control group received physician care only during the trial period. Physician care consisted of an explanation of the disease, reassurance, symptomatic relief (e.g., medication), and general recommendations for physical activities.

## **Outcome Measures**

The outcome measures were assessed at baseline and at 4 weeks. The primary outcome was a score on the Functional Gait Assessment (FGA). The secondary outcomes were scores on the Dynamic Gait Index (DGI) and the Dizziness

Handicap Inventory (DHI). One PT measured the FGA and DGI.

## **Functional Gait Assessment**

FGA was used to assess gait and balance function. It was developed to improve the ceiling effect of DGI and can be applied to patients with high balance ability. The FGA consists of ten items: gait on level surface, change in gait speed, gait with horizontal head turns, gait with vertical head turns, gait and pivot turn, step over an obstacle, gait with narrow base of support, gait with eyes closed, ambulating backward, and steps (stairs). Each item was scored from 0 to 3 points for a maximum total of 30 points.<sup>19)</sup> There is no reported cut-off value for the FGA score in vestibular dysfunction, but a score of less than 23 points is associated with an increased risk of falling in elderly persons.<sup>20)</sup>

# **Dynamic Gait Index**

The DGI is used to assess gait and balance function. The DGI consists of eight items: gait on level surface, change in gait speed, gait with horizontal head turns, gait with vertical head turns, gait and pivot turn, step over an obstacle, step

Table 1. B	Booklet used for home exercise
Exercise 1.	Move your head from side to side/up and down while focusing on the target (for 1 minute in each direction)
Level 1.	While sitting
Level 2.	While standing
Level 3.	While stepping in place
Level 4.	While walking
Exercise 2.	. Maintain your balance while performing the following stances (for 1 minute)
Level 1.	Stand with your feet shoulder-width apart with eyes closed
Level 2.	Stand with your feet together (with eyes open or closed)
Level 3.	Stand with your feet shoulder-width apart. Then shift your weight back and forth/left and right as far as possible (with eyes open or closed)
Level 4.	Stand with your feet together. Then shift your weight back and forth/left and right as far as possible (with eyes open or closed)
Exercise 3.	. Maintain your balance standing on one leg (for 1 minute with each leg)
Level 1.	Eyes open
Level 2.	Eyes closed
Exercise 4.	. Repeat walking 3 m (for 1 minute)
Level 1.	Walk at your normal speed
Level 2.	Look to the side (left or right) while walking
Level 3.	Alternate turning your head from side to side while walking
Exercise 5.	From 1 to 11, choose three movements that make you feel dizzy and repeat them at least three times each:
1. Sitting to	o supine
2. Supine to	o left side (roll from supine to left side)
3. Supine to	o right side (roll from supine to right side)
4. Supine to	o sitting
5. Right or	left Dix-Hallpike (sitting to supine with the head rotated to 45 degrees to the right or left)
6. Head up	from right or left Dix-Hallpike (supine to sitting with the head rotated to 45 degrees to the right or left)
7. Head tip	ped to right or left knee while sitting
8. Head up	from right or left knee while sitting
9. Head tur	ns while sitting (side to side or up and down)
10. Head ti	lts while sitting (right or left or front or back)
11. Turn 18	0 degrees to right or left while standing

around obstacles, and steps (stairs). Each item was scored from 0 to 3 points for a maximum total of 24 points.<sup>21)</sup> The fall risk in patients with vestibular dysfunction increases when the DGI score is less than 19 points.<sup>22)</sup>

#### **Dizziness Handicap Inventory**

The DHI is a 25-item multidimensional self-assessment that is used to assess disability and handicap caused by dizziness.<sup>23)</sup> It is divided into the DHI physical (seven items), DHI emotional (nine items), and DHI functional (nine items) subscales. The participants answered "yes" (4 points), "sometimes" (2 points), or "no" (0 points) to each question. The possible range of scores was from 0 to 100 points, and the severity was categorized as mild (0–30), moderate (31–60), or severe (60–100).<sup>5)</sup>

#### **Statistical Analysis**

The appropriate sample size was estimated by power analysis using G\*power (Version 3.1.9.2)<sup>24)</sup> for the unpaired *t*-test. The estimated sample size was calculated based on the DGI result in a previous study.<sup>25)</sup> The sample size calculation was set at a significance level of 5%, power of 80%, allocation ratio of 1:1, and effect size of 0.89. The calculated sample size was 42, but because of a predicted dropout rate of 20%, the target sample size was set at 50.

All statistical analyses were performed using SPSS Statistics version 27.0 (IBM, Armonk, NY, USA). An intentionto-treat approach was used for data analysis. For participants





Fig. 2. Flow diagram of the study.

who dropped out during the study period, the value at baseline was used as the value at the end of the study, and a value of 0 was assigned to the amount of change.<sup>26)</sup> The differences in baseline data were analyzed using the unpaired *t*-test and Fisher's exact test. Differences in the effects of each intervention on FGA, DGI, and DHI scores were analyzed using a two-way repeated measures analysis of variance with time (baseline and 4 weeks) and group (VR group and control group) as factors. The threshold for significance was set at P<0.05.

#### RESULTS

#### **Participant Characteristics**

From a total of 43 potential participants assessed for eligibility, 1 participant refused to participate in this study (**Fig. 2**). A total of 42 participants were randomly assigned to either the VR group (n=20) or the control group (n=22). During the intervention period, 7 participants had difficulty continuing the intervention (VR group, n=4; control group, n=3). The characteristics of the VR and control groups are presented in **Table 2**. There were no significant differences (P $\ge$ 0.05) in age, sex, time since onset, and affected side of the participants at baseline between the VR group and the control group (**Table 2**). The FGA, DGI, and DHI (total, physical, emotional, functional) scores at baseline were not

significantly different between the VR group and the control group (all  $P \ge 0.05$ ).

# Gait Function: Functional Gait Assessment and Dynamic Gait Index

The two-way repeated measures analysis of variance showed a significant interaction for FGA (F=18.339, P<0.05) and DGI (F=15.758, P<0.05) scores (**Table 3**). There were main effects of time for FGA (F=13.031, P<0.05) and DGI (F=13.075, P<0.05) scores (**Table 3**).

#### Dizziness: Dizziness Handicap Inventory

The two-way repeated measures analysis of variance showed a significant interaction for DHI total (F=4.112, P<0.05) and DHI emotional (F=5.351, P<0.05) scores (**Table 3**). No significant interaction was found for DHI physical (F=1.318, P=0.258) and DHI functional (F=2.276, P=0.139) scores (**Table 3**). There were main effects of time for DHI total (F=6.768, P<0.05), DHI physical (F=6.051, P<0.05), and DHI emotional (F=6.588, P<0.05) scores (**Table 3**). There was no significant main effect of time on the DHI functional (F=2.276, P=0.139) score (**Table 3**).

# Adherence and Changes in Exercise Level and Type

Sixteen patients performed the home program for an av-

Characteristic	VR group (n=20)	Control group (n=22)	Total (n=42)	P-value			
Age, years (mean ± SD)	$70.5\pm10.1$	$71.6 \pm 11.0$	$71.1\pm10.4$	0.717			
Sex (male/female), n (%)	12 (60.0%) / 8 (40.0%) 7 (31.8%) / 15 (6		19 (45.2%) / 23 (54.8%)	0.120			
Time since onset, days (mean $\pm$ SD)	$361.9\pm517.5$	$897.4 \pm 1352.6$	$642.4 \pm 1065.1$	0.104			
UVH / BVH, n (%)	19 (95.0%) / 1 (5.0%)	19 (86.4%) / 3 (13.6%)	38 (90.5%) / 4 (9.5%)	0.608			
Diagnosis of UVH							
Vestibular neuritis, n	10	6	16				
Inner ear disease, n	1	6	7				
Sudden deafness, n	2	2	4				
Acoustic neuroma, n	1	1	2				
Hunt syndrome, n	-	1	1				
Ototoxicity, n	-	1	1				
Unknown cause, n	5	2	7				
Diagnosis of BVH							
Inner ear disease, n	1	-	1				
(Right) Unknown cause + (left) sudden deafness, n	-	1	1				
Unknown cause, n	-	2	2				

#### Table 2. Patient characteristics

SD, standard deviation; UVH, unilateral peripheral vestibular hypofunction; BVH, bilateral peripheral vestibular hypofunction.

 Table 3. Changes of mean values between baseline and 4 weeks

			_	Time effect		Interaction	
Outcome measure		Baseline	4 weeks	F-value	P-value	F-value	P-value
FGA	VR group	$21.75\pm4.18$	$24.95\pm3.25$	13.031	$0.001^{*}$	18.339	$0.000^{*}$
	Control group	$22.68\pm5.12$	$22.41\pm5.60$				
DGI	VR group	$19.95\pm2.56$	$21.90\pm2.15$	13.075	$0.001^{*}$	15.758	$0.000^*$
	Control group	$19.82\pm3.49$	$19.73\pm3.69$				
DHI total	VR group	$44.30\pm15.96$	$35.50\pm21.11$	6.768	0.013*	4.112	$0.049^{*}$
	Control group	$40.45\pm21.04$	$39.36\pm22.15$				
DHI physical	VR group	$14.70\pm5.55$	$12.20\pm4.98$	6.051	$0.018^{*}$	1.318	0.258
	Control group	$12.36\pm6.75$	$11.45\pm6.71$				
DHI emotional	VR group	$14.40\pm7.56$	$10.90\pm9.10$	6.588	$0.014^{*}$	5.351	$0.026^{*}$
	Control group	$14.82\pm7.47$	$14.64\pm8.01$				
DHI functional	VR group	$15.20\pm9.00$	$12.40\pm9.77$	2.276	0.139	2.276	0.139
	Control group	$13.27\pm9.63$	$13.27\pm10.89$				

Data given as mean score  $\pm$  standard deviation.

\* P<0.05.

erage of  $2.0\pm0.3$  (mean  $\pm$  standard deviation) sessions per day. The mean adherence rate for exercising at home was 94.9 $\pm$ 6.7% in the VR group. **Table 4** shows the number of patients provided with each exercise during the first and fourth weeks of intervention in the VR group. The level and type of booklet exercises performed by the patients changed between the first and fourth weeks of intervention.

## DISCUSSION

This study investigated the effects of a supervised homebased VR program using a booklet for patients with chronic PVH. The results showed that patients who performed our home-based VR program had improved gait function (FGA, DGI) and dizziness (DHI).

		Number of patients		
		First week	Fourth week	
Exercise 1	Level 1	5	0	
	Level 2	10	1	
	Level 3	0	5	
	Level 4	0	9	
Exercise 2	Level 1	0	0	
	Level 2	3	0	
	Level 3	7	3	
	Level 4	5	12	
Exercise 3	Level 1	14	10	
	Level 2	1	5	
Exercise 4	Level 1	6	0	
	Level 2	6	2	
	Level 3	3	13	
Exercise 5	1	0	0	
	2	2	1	
	3	1	0	
	4	1	0	
	5	4	1	
	6	1	0	
	7	1	0	
	8	2	2	
	9	4	5	
	10	3	0	
	11	13	9	

**Table 4.** Level and type of exercises performed in the firstand fourth weeks in the VR group

The data did not include 4 dropouts and 1 missing (n=15).

This is the first study to show the effect of a home-based VR program using a booklet on gait function and dynamic balance. In particular, FGA and DGI scores showed a significant interaction between time and group factors and greater improvements in the VR group than in the control group. The home-based VR program in the present study included adaptation and substitution exercises. Adaptation exercises promote the improvement of VOR function and gaze stability.<sup>27,28)</sup> Whitney et al. reported that there were significant positive correlations between VOR function and the DGI score in patients with vestibular disorders.<sup>29)</sup> Gait and dynamic balance of the patients in the VR group may be related to the adaptation of VOR function. In addition, substitution exercises promote the use of individual sensory inputs or combinations of them to substitute for missing or decreased vestibular function.<sup>4,30</sup> Sensory substitution may improve postural stability, which may also be a factor in the improvement of gait function.

The home-based VR program in this study was found to improve DHI. Patients in the VR group showed significantly greater improvements in the DHI total and DHI emotional scores than those in the control group. The DHI results of this study agree with previous studies.<sup>9,12,31,32</sup>) Previous studies reported that VR promoted vestibular compensation and improved dizziness.<sup>31,32)</sup> Several reasons were considered for the improvement in the DHI score. First, habituation exercises in the home-based VR program may lead to a reduction in dizziness over time by repeated exposure to a specific stimulus that provokes symptoms.<sup>8)</sup> Second, the improvement in the DHI emotional aspect may be caused by a decrease in anxiety about dizziness caused by exercise. In the home-based VR program of the present study, the difficulty of the exercises was adjusted according to symptoms during weekly visits to the clinic. Therefore, patients could perform daily repetitions of exercises that provoked a manageable degree of symptoms so that VR did not cause increased anxiety and fear of dizziness.

With the home-based VR program, the VR group achieved high adherence to the treatment. A previous study of VR using a booklet showed that only 37.5% observed high adherence to home exercises because of worsening symptoms after the initiation of voluntary exercises.<sup>10</sup> Another previous study reported that adherence to the full program of exercises was 34% for the booklet-only intervention.<sup>11</sup> In the present study, the VR program was customized to the individual needs of the patients and their rate of progression. As seen in the VR group of the present study, our home-based VR program effectively improved gait function and dizziness in patients with chronic PVH with high adherence to the program.

An important factor that may have contributed to the effectiveness of home-based VR in this study was that the PT checked the home program when the patients visited the outpatient clinic. Previous studies reported that supervised exercise is more effective for dizziness than home exercise alone.<sup>31,33</sup> The PT was able to check adherence to home exercises and instruct the appropriate level of exercises when patients visited the outpatient clinic. These procedures may have improved gait function, dizziness, and adherence. Regular supervision by PT may have been an important factor in the effectiveness of the VR program in this study.

No statistically significant difference was found in time since onset between the VR and control groups in this study. However, the control group had a longer mean time since onset than the VR group. Previous studies have shown no relationship between the effect of VR and the time since This study had some limitations. First, it had a non-blinded design. Patients may have been psychologically affected by being provided with VR, and the bias of the measurer was not eliminated. The home-based VR program in this study needs to be examined in single- or double-blind, randomized trials to further validate its effectiveness. Second, the long-term effects of the home-based VR program developed in this study are unknown because the results of the study were analyzed immediately after the 4-week intervention. Follow-up data after 6 months and 1 year should be assessed to verify whether the effect is maintained. Despite these limitations, the relative simplicity of our home-based VR program makes it ideal for use by a PT with patients who have difficulty making frequent visits to the hospital.

# CONCLUSIONS

The results of this study suggest that the home-based VR program can improve gait function and dizziness in patients with chronic PVH to a greater extent than usual care by physicians. It is possible that adherence was improved by allowing the exercise difficulty to be adjusted and by providing regular instruction. Future research is needed to investigate the long-term effects of the VR program used in this study. In conclusion, performing the supervised home-based VR program using a booklet for 4 weeks is effective in improving gait function and dizziness in patients with chronic PVH.

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# **CONFLICTS OF INTEREST**

The authors declare no conflicts of interest.

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