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ORIGINAL ARTICLE

Safety and Feasibility of Dual-task Rehabilitation Program for Body Trunk Balance Using Virtual Reality and Three-dimensional Tracking Technologies

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Objective: The ability to walk is one of the most important basic functional activities of daily living, and the number of patients with walking disability who need rehabilitation is increasing worldwide. The purpose of this first-in-man study was to evaluate the safety and feasibility of an off-label, tailor-made, dual-task rehabilitation program for body trunk balance using the mediVR01 system (mediVR, Inc. Osaka, Japan), which incorporates virtual reality (VR) and three-dimensional tracking technologies. **Methods:** We prospectively enrolled 31 healthy volunteers to take part in the trial (Trial Registration UMIN000029659). After an assessment of body trunk balance, a tailor-made, dual-task, rehabilitation training program lasting 10–15 min was provided. The primary endpoint was the postprocedural number of simulator sickness questionnaire (SSQ) symptoms. The secondary endpoints were adverse events and satisfaction with the program. **Results:** The median age of participants was 68 years, with 67.7% being elderly (>65 years) and 54.8% being male. The number of SSQ symptoms immediately after the rehabilitation programs significantly increased from 0 (interquartile range 0–0) to 0 (0–1.5) (P=0.009), with a significant difference between the young and elderly participants (P-interaction<0.001). The most frequent symptom was sweating (22.6%), followed by fatigue (19.4%). All participants successfully completed the rehabilitation programs without significant adverse events such as fall or injuries. Moreover, all participants considered the VR rehabilitation programs to be enjoyable, and 93.5% of participants reported a sense of achievement. Group attendance was associated with higher levels of satisfaction (P=0.049). **Conclusion:** The tailor-made, dual-task rehabilitation training programs for body trunk balance using VR and three-dimensional tracking technologies were safe and feasible even for elderly participants.

Key words: body trunk balance; dual-task rehabilitation; first-in-man; mediVR01; virtual reality

INTRODUCTION

The ability to walk is one of the most important basic functional activities of daily living (ADLs). This ability can be impaired by various conditions, including cerebrovascular diseases such as stroke, neurodegenerative diseases such as Parkinson's disease and dementia, sarcopenia, and frailty; in geriatric patients, even hospitalization can have an adverse effect.[1–6] As the world's population ages, the number of patients with walking disability increases. In many countries, this may result in a demand–supply mismatch in the clinical setting caused by inadequate human resources, such as insufficient numbers of physical therapists or caregivers, or problems with the costs of home and outpatient healthcare.[2,7–9]

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To maintain or regain walking ability so that ADLs can be performed safely, exercise rehabilitation focusing on body trunk balance and muscle strengthening of the lower extremities is recommended by international guidelines, such as those for stroke survivors.[10] Whereas, muscle strengthening can be provided using a fixed program, it is difficult to provide tailor-made rehabilitation programs for body trunk balance without an experienced physical therapist because real-time quantitative instructions and tools for concomitant assessment are lacking.[8,11] Moreover, exercise rehabilitation programs should ideally use technology also to stimulate the cognitive function to help prevent falls (so-called "dual-task" training) and should include an element of entertainment to discourage discontinuity or withdrawal from the rehabilitation intervention.[12–17]

To meet these ideal criteria for body trunk balance training, we developed a tailor-made, dual-task, rehabilitation training program using virtual reality (VR) and three-dimensional tracking technologies to provide patients with an exercise rehabilitation program with an element of gamification. This study aimed to evaluate the safety and feasibility of this approach by focusing on the incidence of VR sickness in subjects using a new off-label VR rehabilitation training program for body trunk balance, namely the mediVR01.

METHODS

Participant Involvement

This study was a prespecified phase I clinical study that aimed to evaluate the safety and feasibility of an off-label medical device, the mediVR01 (mediVR, Inc., Osaka, Japan). The mediVR01 provides patients with a standardized, tailor-made, dual-task exercise rehabilitation program for body trunk balance using VR and three-dimensional tracking technologies (HTC Vive®, HTC Corporation, New Taipei City, Taiwan). All subjects were healthy adult volunteers, and the exclusion criteria were a medical history of (1) vertigo, dizziness, Meniere's disease, or other semicircular canal or inner ear problems; (2) untreated poor vision; (3) epilepsy; (4) postural dizziness or hypotension; (5) participation in another clinical study within 3 months; (6) and psychiatric disorder or loss of the ability to understand; (7) further, volunteers considered to be inappropriate candidates based on the attending physician's discretion were also excluded. Of 33 healthy volunteers enrolled between November 1 and December 28, 2017, one volunteer disagreed with our privacy policy and another candidate with Meniere's disease met one of the exclusion criteria of the present study. Finally 31 participants completed the study and enrolled in the final analysis. The study protocol complied with the standards of the Declaration of Helsinki and was approved by the Ethics Committee of the Japan Society of Clinical Research (approval number 201706). Written informed consent was obtained from all study participants, and participants were informed that the study results would be disseminated as a journal article. This study was registered at the University Hospital Medical Information Network Clinical Trials Registry (UMIN000029659) and meets the criteria of the International Committee of Medical Journal Editors (ICMJE).

Study Protocol

As shown in **Fig. 1A**, participants sit on an upright chair, wear a head-mounted display (HMD) and a central tracker located near the supraclavicular fossa, and grasp two handheld controllers. The VR system locates participants in a motion-tracked three-dimensional space called "room scale" of the HTC Vive set. HTC Vive can provide users with graphics at >90 frames/s (fps) with an approximately 110° viewing angle and includes accurate three-dimensional tracking technology.

For calibration, we evaluated conventional reaching distances (colored blue in **Fig. 1A and 1B**) and maximum reaching distances (colored red in **Fig. 1A and 1B**) at 0°, 45°, and 90° for the left hand (0L, 45L, and 90L) and at 90°, 135°, and 180° for the right hand (90R, 135R, and 180R) with the subject in the sitting position. Conventional reaching distances were measured with each hand level with the shoulders, as shown in **Fig. 1C**. The maximum reaching distance was measured with the hands at the same level but with the subject reaching as far possible, as shown in **Fig. 1B**. Participants were then instructed to catch a virtual square box at the thoracic level (**Fig. 1C**). The box fell from a 3 m height at pre-determined horizontal distances tailor-made for each participant. The horizontal distances were classified into two categories, namely long and middle, and were calculated using the following formulas: 0.9 * maximum reaching distance and 0.9 * (conventional + maximum reaching distances)/2, respectively. If the participant failed to catch a virtual square box, for safety reasons, the box disappeared at a height of 20 cm above the floor. The censoring area of the square box was 4 cm per side for measurement accuracy, and this was indicated by an outlined pale box with 20 cm on a side for visibility. The censoring area of the handheld controllers had a 2 cm spherical diameter. The purpose of the reaching tasks was to stimulate body trunk balance, and to train participants to balance for stable walking. During the

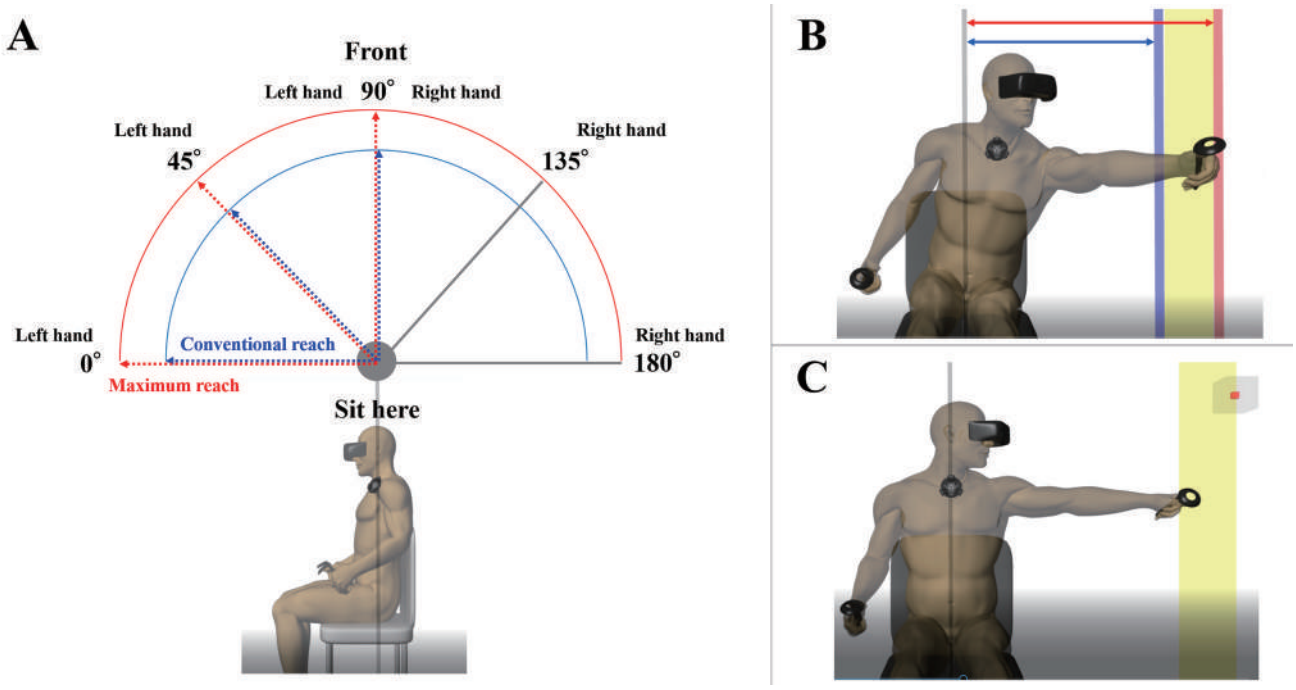

Fig. 1. Concepts of the mediVR01 system. After assessment of the subject's body trunk balance (A and B), a tailor-made rehabilitation training program was provided with the subject in the sitting position (C). The purpose of reaching with the hands was to stimulate body trunk balance and to train participants to balance. With VR and three-dimensional tracking technologies, the stimulation inputs for body trunk balance could be quantitatively provided by setting the reaching distances. Cognitive function was also stimulated to provide dual-task training in a uniform VR environment.

program, the direction and horizontal distance of the box in the following task was indicated by the HMD. We expected that the provision of this information would cause the participants to internalize the nature of the next task and would therefore result in a higher success rate. By repeatedly allowing the participants to think about the timing and distance of the next target, cognitive function was simultaneously stimulated to provide dual-task training.[12–14] We measured the horizontal distances for each handheld controller and the central tracker during each training exercise to evaluate the achievement rate for each task. We thereby provided participants with quantitative information about trunk control and quantitatively evaluated their achievement for each task during the tailor-made, dual-task, rehabilitation training program.

The four parameters of the rehabilitation programs in the present study were as follows: (1) distance (middle or long), (2) direction (0L, 45L, 90L, 90R, 135R, or 180R), (3) falling speed of the square box (55 or 75 cm/s), and (4) the interval between tasks (1, 3, or 5 s). To provide another parameter for cognitive function stimulation, it is possible to change the size of the center or outline of the falling box or the sensing sphere. However, these sizes were fixed in the present study. Participants first underwent two practice rehabilitation programs to familiarize themselves with VR rehabilitation, followed by two exercise rehabilitation programs (normal and hard). If participants could understand how to use the system after the first practice rehabilitation program, the second practice program could be skipped. Detailed protocols are shown in **Table 1**. Elderly participants (≥65 years old) required approximately 15 min to complete all the programs, whereas young participants took 10 min. If a falling square box was caught by the participant, the task was recorded as a success. For each subject, we evaluated the total success rates of Exercise 1 and Exercise 2 as defined in **Table 1**. Provision of the rehabilitation programs was either personalized or in groups. In group sessions, three or more participants came together, with one undergoing the rehabilitation program while the other participants observed. To prevent subjects falling from the chair, safety management was provided by a caregiver positioned by the participant during the rehabilitation session.

Table 1. Practice and exercise rehabilitation programs carried out using the mediVR01 system

Program	Falling speed	Interval	Tasks	Protocol
Practice 1	Elderly 55 cm/s Young 75 cm/s	5 s	24	Middle distance 0L–0L–45L–45L–90L–90L–180R–180R–135R–135R–90R–90R Long distance 0L–0L–45L–45L–90L–90L–180R–180R–135R–135R–90R–90R
Practice 2	Elderly 55 cm/s Young 75 cm/s	3 s	24	Middle distance 0L–0L–45L–45L–90L–90L–180R–180R–135R–135R–90R–90R Long distance 0L–0L–45L–45L–90L–90L–180R–180R–135R–135R–90R–90R
Exercise 1 (normal)	Elderly 55 cm/s Young 75 cm/s	3 s	24	Long distance 90R–0L–135R–45L–180R–90L–135R–0L–90R–45L–135R–90L–180R–0L–90R–45L–180R–90L–135R–0L–90R–45L–180R–90L
Exercise 2 (hard)	Elderly 55 cm/s Young 75 cm/s	1 s	24	Long distance 90R–0L–135R–45L–90R–0L–135R–90L–180R–45L–180R–90L–180R–0L–135R–90L–135R–45L–90R–0L–90R–45L–180R–90L

Each program had four parameters: (1) horizontal distance (middle or long), (2) direction (0L, 45L, 90L, 90R, 135R, or 180R), (3) falling speed of the square box (55 or 75 cm/s), and (4) the interval between tasks (1, 3, or 5 s). Participants first underwent two practice rehabilitation programs to familiarize themselves with VR rehabilitation. This was followed by two exercise rehabilitation programs (normal and hard). 0L, 45L, and 90L are orientations of 0°, 45°, and 90° for the left hand, whereas 90R, 135R, and 180R are orientations of 90°, 135°, and 180° for the right hand.

Endpoints and Statistical Analysis

The primary endpoint was the safety of mediVR01, which was evaluated based on the number of simulator sickness questionnaire (SSQ) symptoms.[18] SSQ was administered before, immediately after, and 3 days after the VR rehabilitation programs. SSQ consisted of 16 parameters that were each evaluated in four categories: none, slight, moderate, and severe.[18] The secondary endpoints were adverse events (such as falls from the chair, any injuries, or unexpected discontinuation of the rehabilitation program) and the feasibility of mediVR01, which was evaluated using a five-point Likert scale questionnaire on satisfaction and sense of achievement. These secondary endpoints may reflect the overall severity of SSQ symptoms and describe the degree of safety. Continuous variables were summarized using medians and interquartile ranges (IQRs, quartiles 1 to 3), whereas categorical variables were summarized using counts and percentages. The statistical significance of the pre- and postprocedural number of SSQ symptoms in each participant was evaluated using the Wilcoxon signed-rank test considering parity. We defined elderly participants as those aged ≥65 years. The P-interaction between the elderly and young participants was also evaluated using linear regression analysis by including the postprocedural number of symptoms as the objective variable and preprocedural number of symptoms as the explanatory variable, with the elderly participants as the interaction term. Differences in the prevalence of secondary endpoints between the elderly and young participants or types of attendance were evaluated using the chi-square test. All statistical analyses were performed using Microsoft R Open Software (version 3.3.2, Microsoft Corporation, Redmond, WA, USA).

RESULTS

Participant characteristics are shown in **Table 2**. The median age was 68 years (IQR 57–73 years), with 67.7% being elderly and 54.8% being male. None had used a VR device before the study, and 32.3% wore eyeglasses. Eleven (35.5%) participants had experienced car sickness in their daily life, 9 (29.0%) played video or smartphone games, and 20 (64.5%) underwent the rehabilitation program in groups.

The total success rate for the normal exercise rehabilitation program defined as Exercise 1 in **Table 1** was 95.8% (85.4%–100.0%). There was a statistically significant difference between the elderly and young participants (87.5% [75.0%–95.8%] vs. 100.0% [96.9%–100.0%]; P=0.005). In contrast, the total success rate for the hard exercise rehabilitation program, defined as Exercise 2 in **Table 1**, was 45.8% (33.3%–58.3%). There was no statistically significant difference between the elderly and young participants (45.8% [33.3%–58.3%] vs. 54.2% [39.6%–57.3%]; P=0.497).

With respect to the primary endpoint (**Table 3**), the postprocedural number of SSQ symptoms, especially the

75th percentile value, significantly increased from 0 (0–0) to 0 (0–1.5) (P=0.009). Furthermore, there was a significant difference in the postprocedural number of SSQ symptoms between young participants (from 0 [0–0] to 1 [0–2.75]) and elderly participants (from 0 [0–0] to 0 [0–0]) (interaction effect, P<0.001). All SSQ symptoms were reported to be slight, except for those in the youngest participant (29 years old), who had preprocedural symptoms of slight fatigue and had slight eyestrain and who, after rehabilitation, had moderate eyestrain, moderate difficulty in focusing, moderate sweating, moderate blurred vision, and moderate stomach awareness. The most frequent symptom was sweating (22.6%), followed by fatigue (19.4%), eyestrain (12.9%), difficulty in focusing (12.9%), and blurred vision (12.9%). However, subsequently, all SSQ symptoms improved, and no participants showed any SSQ symptom 3 days after the rehabilitation program.

With respect to the secondary endpoints, no falls from the chair or injuries occurred. One 72-year-old participant unexpectedly discontinued the rehabilitation program because he unintentionally pushed the emergency stop button, with which the device was equipped for safety reasons. He then redid the normal exercise rehabilitation program after a computer reboot; the total procedural time was extended to 20 min (i.e., an additional 5 min). Consequently, all participants completed the rehabilitation programs without any adverse events. **Figure 2** shows the results of the five-point Likert scale questionnaire survey on satisfaction and sense of achievement. All participants considered the VR rehabilitation programs to be enjoyable, and the majority (93.5%) reported a sense of achievement. However, some participants complained about the short duration of the rehabilitation programs. Interestingly, group attendance was associated with higher satisfaction levels (P=0.049).

DISCUSSION

In the present study, we evaluated the safety and feasibility of a new off-label medical device intended to improve body trunk balance. The device provided participants with a standardized, tailor-made, dual-task, exercise rehabilitation program with a level of gamification. The main findings were as follows: (1) The number of SSQ symptoms significantly increased immediately after the rehabilitation program, and this was mainly attributable to increased symptoms in young participants. (2) All participants successfully completed the rehabilitation programs without any adverse events such as falls or injuries. (3) All participants considered the VR rehabilitation programs to be enjoyable, despite their lack of previous VR experience, and most participants reported a sense of achievement. (4) Group attendance was associated with higher satisfaction levels.

VR-induced Sickness Assessed by SSQ

To provide participants with quantitative instructions and to quantitatively evaluate achievements, we employed VR and three-dimensional tracking technologies. The most important safety problem of VR in the clinical setting is VR-induced sickness, which is believed to occur as a result of discrepancies among sensory inputs, such as those between visual and vestibular senses, known as sensory conflict.[19] To minimize VR-induced sickness, we selected HTC Vive because its HMD can operate at >90 fps, which may be sufficient to avoid frame delay and visual lag during the rehabilitation program.[19] In our rehabilitation program, we fixed the landscape to avoid sensory conflict and stimulated the cognitive function using the following four parameters of the falling box: horizontal distance, direction, falling speed, and interval between tasks. Even with these efforts to minimize VR-induced sickness, the number of SSQ symptoms significantly increased immediately after the rehabilitation program, and this was mainly attributable to an increase in symptoms in young participants. However, we believe that the two most frequent SSQ symptoms, namely sweating and fatigue, are natural responses to exercise rehabilitation and do not require caution in our view. Therefore, one of the important lessons from our study with respect to VR-induced sickness is that we need to exercise caution during rehabilitation, especially when providing programs for young participants. The increase in SSQ symptoms in younger participants may partly be explained by their tendency to become enthusiastic to successfully catch the square boxes.

We intentionally provided an exercise rehabilitation program within a field greater than the 110° field of view of the HTC Vive HMD because restricting the body trunk balance exercises within 110° is not realistic in the clinical setting. For example, several tasks such as 0L–135R or 180R–0L need body trunk balance at 135° or 180°, respectively. It is possible that this type of exercise rehabilitation program may have elicited sensory conflict and resulted in increased SSQ symptoms in this study. Increasing the field of view of the VR HMD could potentially result in a reduction in VR-induced sickness in the future.

Other Safety Problems

To safely operate a standardized rehabilitation program

Table 2. Participant characteristics

Parameter	n=31
Age, years	68 (57–73)
Elderly (≥65 years old)	21 (67.7)
Male	17 (54.8)
Height, cm	160 (155–166)
Weight, kg	61.0 (50.8–72.5)
Previous VR experience	0 (0.0)
Wearing eyeglasses	10 (32.3)
Vision problem (questionnaire)	
Myopia	12 (38.7)
Hyperopia	3 (9.7)
Astigmatism	8 (25.8)
Presbyopia	12 (38.7)
Car sickness	
Often	1 (3.2)
Sometimes	4 (12.9)
Rarely	6 (19.4)
Never	20 (64.5)
Playing video/smartphone games	
Often	0 (0.0)
Sometimes	4 (12.9)
Rarely	5 (16.1)
Never	22 (71.0)
Type of attendance	
Personalized	11 (35.5)
Group (≥three participants)	20 (64.5)

Continuous variables are given as medians and interquartile ranges, whereas categorical variables are summarized using counts and percentages.
VR, virtual reality.

without human medical resources, our program was executed with the participants sitting on an upright chair, rather than standing. The rationale for this was the fact that two-thirds of the total body weight is centered in the upper body, which results in inherent balance instability in humans.[20] Consequently, we speculated that upper body balance training, even in a sitting position, may exhibit reasonable degrees of both efficacy and safety, although efficacy was not evaluated in this study. All participants successfully completed the rehabilitation programs without significant adverse events such as fall or injuries. We believe that the disappearance of the square boxes at a height of 20 cm also contributed to safety.

To proactively evaluate the safety of our exercise rehabilitation program, participants finished with a hard exercise rehabilitation program (**Table 1**) that was expected to be very difficult to deal with. As anticipated, the overall success rate for the hard exercise rehabilitation program, defined as Exercise 2 in **Table 1,** was less than 50%, and there was no statistical difference between the elderly and young participants. This finding suggests that our exercise rehabilitation program was intentionally interruptible and did not result in adverse events such as a fall.

Feasibility Evaluation

Contrary to our expectations, all participants, including the elderly, found the VR rehabilitation programs enjoyable, despite their lack of previous VR experience. Compared with the young participants, the elderly participants tended to consider the VR rehabilitation programs as very enjoyable, although the difference was not statistically significant. The reason for this may have been that our main targets were the

Table 3. Results of the simulator sickness questionnaire survey

	Before VR rehabilitation programs	Immediately after VR rehabilitation programs	Three days after VR rehabilitation programs
No. of symptoms in each participant	0 (0–0)	0 (0–1.5)	0 (0–0)
Elderly	0 (0–0)	0 (0–0)	0 (0–0)
Young	0 (0–0)	1 (0–2.75)	0 (0–0)
Detailed components			
1. General discomfort	0 (0.0)	2 (6.5)	0 (0.0)
2. Fatigue	1 (3.2)	6 (19.4)	0 (0.0)
3. Headache	0 (0.0)	0 (0.0)	0 (0.0)
4. Eyestrain	1 (3.2)	4 (12.9)	0 (0.0)
5. Difficulty in focusing	1 (3.2)	4 (12.9)	0 (0.0)
6. Increased salivation	0 (0.0)	1 (3.2)	0 (0.0)
7. Sweating	0 (0.0)	7 (22.6)	0 (0.0)
8. Nausea	0 (0.0)	0 (0.0)	0 (0.0)
9. Difficulty in concentrating	0 (0.0)	0 (0.0)	0 (0.0)
10. Fullness in the head	0 (0.0)	1 (3.2)	0 (0.0)
11. Blurred vision	2 (6.5)	4 (12.9)	0 (0.0)
12. Dizziness with eyes open	0 (0.0)	3 (9.7)	0 (0.0)
13. Dizziness with eyes closed	0 (0.0)	1 (3.2)	0 (0.0)
14. Vertigo	0 (0.0)	1 (3.2)	0 (0.0)
15. Stomach awareness	0 (0.0)	1 (3.2)	0 (0.0)
16. Burping	0 (0.0)	0 (0.0)	0 (0.0)

Continuous variables are given as medians and interquartile ranges, whereas categorical variables are summarized using counts and percentages.

All symptoms were reported to be "slight," except for those in a 29-year-old man with preprocedural symptoms of slight fatigue and slight eyestrain who had moderate eyestrain, moderate difficulty in focusing, moderate sweating, moderate blurred vision, and moderate stomach awareness immediately after rehabilitation.

elderly participants, and the normal exercise rehabilitation program was likely too easy or left much to be desired for the young participants, as suggested by the very high success rate. Furthermore, we showed that group attendance was associated with higher satisfaction. It appears that the concept of mutual-help group participation, applied as a treatment strategy for alcohol or drug abuse, may also be applicable to the field of rehabilitation.[21,22]

Clinical Implication

Recently, gamification has been widely introduced into many medical disciplines, especially in the digital healthcare fields, including e-learning and self-administered physical training programs.[16,17] Moreover, the remarkable success of the augmented reality game Pokémon GO (Niantic, Inc., San Francisco, CA, USA), which might inadvertently contribute to public or psychiatric health, shows the potential for the new healthcare approach of entertainment with a hidden healthcare agenda.[23–25]

Study Limitations

This study has several limitations that should be considered during data interpretation. First, the number of participants is low. Second, a significant selection bias exists because enrolments were made based on voluntary participation. Lastly, we did not evaluate the efficacy of the mediVR01 system in this study. Some physicians have suggested that the use of two-dimensional programs, such as Nintendo Wii Fit™ (Nintendo, Kyoto, Japan), that encourage physical activities or exercise, cannot with certainty lead to an intended therapeutic effect. The reason they give is the inability of such programs to provide accurate instructions and quantitative assessments, despite such programs exhibiting a certain level of efficacy, especially on Berg balance scores and the timed-up-and-go test, and despite their very high levels of safety and feasibility (similar to those found in the current study).[17,26,27] However, our novel quantitative tailor-made rehabilitation approach has the potential to resolve this problem by providing accurate instructions and quantitative

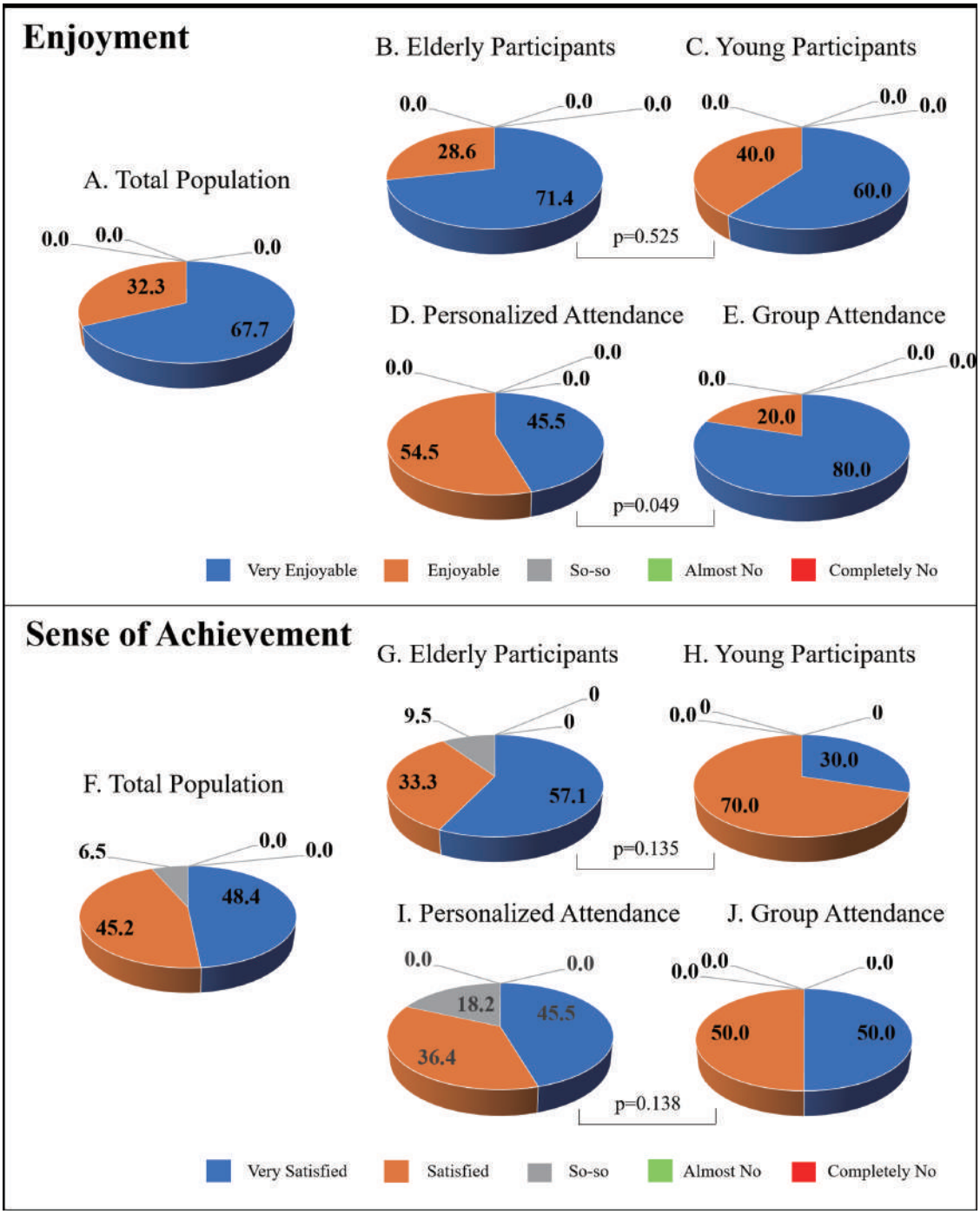

Fig. 2. Satisfaction and sense of achievement. Results of a 5-point Likert scale questionnaire on satisfaction (A–E) and sense of achievement (F–J).

assessments. The efficacy and effect of our system on the recovery of walking ability, the alleviation of human resource problems, and cost reduction are pertinent issues for future research.

CONCLUSIONS

Our tailor-made, dual-task rehabilitation training program for body trunk balance using VR and three-dimensional tracking technologies was safe and feasible, even for elderly participants.

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CONTRIBUTORS

Masahiko Hara, Tetsuhisa Kitamura, Yuichiro Murakawa, Kyosuke Shimba, Shimpei Yamaguchi, and Masatake Tamaki (1) provided substantial contributions to the conception or design of the study or the acquisition, analysis, or interpretation of data; (2) drafted the paper or revised it critically for important intellectual content; (3) provided final approval of the version to be published; and (4) agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CONFLICT OF INTEREST

Masahiko Hara, Kyosuke Shimba, Shimpei Yamaguchi, and Masatake Tamaki are stock holders of mediVR, Inc., a company with unlisted stock and ongoing international Patent Cooperation Treaty applications that holds a patent on dual-task training and updating the target value of rehabilitation based on achievement rates (patent no. 6200615 in Japan). However, this research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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