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Vestibular rehabilitation training in patients with subacute stroke: A preliminary randomized controlled tria

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Abstract.
BACKGROUND: Vestibular rehabilitation (VR) consists in a customized exercise program patient-centred that includes a combination of different exercise components with the aim to promote gaze stability, improve balance and gait, and facilitate somatosensory integration.
OBJECTIVE: The aim of this study was to investigate the effect of customized vestibular rehabilitation training on gait stability of patients with subacute stroke.
METHODS: Twenty-five inpatients (12 M, age: 64.1 ± 12.1 years) with diagnosis of subacute stroke were enrolled and randomized in two groups. All patients were evaluated before and after 4 weeks of training sessions. An instrumented 10-Meter Walk Test together with traditional clinical scales were used to assess VR effects. To investigate if any fall event occurred after patients' dismissal, they were followed-up at three and twelve months after dismissal.
RESULTS: Higher values of walking speed and stride length were observed in the VR group. Conversely, no significant difference was found in terms of trunk stability. The results of between-group comparison highlight significant differences between the two groups for different clinical scale scores.
CONCLUSION: VR could be included into a rehabilitation program for patients with stroke for improving their gait and dynamic balance acting on their vestibular system as facilitator of recovery.

Keywords: Vestibular rehabilitation, stroke, instrumented assessment, dynamic balance and gait

1. Introduction

Vestibular rehabilitation (VR) is an exercise program patient-centred that includes a combination of different exercise components with the aim to promote gaze stability, improve balance and gait, and facilitate somatosensory integration (Han et al., 2011). Recent reviews report evidence to support the use of VR in people with unilateral peripheral vestibular disorders (McDonnell et al., 2015) and with bilateral vestibular loss, for supporting balance and gaze stability training (Hall et al., 2016). In addition, some efficacy of VR in reducing risk of fall in patients with vestibular hypofunction and in older adults has been reported (Martins et al., 2016).

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Neurological patients, such as those with Parkinson's disease, multiple sclerosis, and cerebral palsy, who undergo a VR program, show an improvement in static and dynamic balance (Acarer et al., 2015), quality of life (Hebert et al., 2011), functional capacity (Hebert et al., 2011), and motor control (Tramontano et al., 2017).

Among neurologic diseases, stroke is one of the most common cause of long-term adult disability (Duncan et al., 2003) leading to cognitive and motor function impairments. Particularly, gait and balance disorders may contribute to immobility and falls (Marsden et al., 2005). The design of personalized rehabilitation protocols, especially in the subacute phase of the stroke event, focused on the recovery of dynamic balance ability would be fundamental to reduce these deficits and, consequently, the risk of falling, thus improving patients' quality of life (Iosa et al., 2012; Iosa et al., 2012). In this respect, a recent study indicated that vestibular rehabilitation might improve vestibulo-ocular reflex (VOR) in patients with stroke, highlighting a positive effect of this VOR improvement also on gait performance (Mitsutake et al., 2017). This result was also supported by neurophysiological findings: the vestibular cortical network, in fact, contributes to modulate space, body, and self-awareness, spatial navigation, and reflex generation for posture and oculomotor control (Lopez et al., 2016). This network is in close convergence with other sensory and motor signals, attention, memory, mental imagery, and even social cognition (Angelaki et al., 2008; Angelaki et al., 2009). In addition, subliminal galvanic vestibular stimulation induces long-term reduction of hemispatial neglect and improves vertical perception in stroke patients (Oppenländer et al., 2015). Despite this evidence, no studies have considered the use of VR programs to improve dynamic balance in gait in patients with stroke.

Under these premises, the aim of this study was to investigate the effect of customized vestibular rehabilitation training on gait stability of patients with subacute stroke. We hypothesized that a neurorehabilitation training including vestibular rehabilitation might improve gait and dynamic balance also in patients with subacute stroke.

2. Methods

2.1. Participants

Twenty-five inpatients (12 M, age: 64.1 ± 12.1 years) with diagnosis of subacute stroke were enrolled in this study and randomized in two groups (Fig. 1). This sample size complied with the minimum number of participants recommended by a power analysis purposely performed ($\alpha = 0.05$; $\beta = 0.8$; $ES = 0.5$) for non-parametric between-groups comparisons (Cohen, 1977). According to this sample size estimation procedure, the inclusion of at least 8 patients for each group is recommended. Therefore, a Vestibular Group (VG) was composed of 13 inpatients (8 M, age: 63.1 ± 8.5 years) and a Control Group (CG) was composed of 12 inpatients (4 M, age: 65.1 ± 15.5 years, $p = 0.700$, t-test). Demographic characteristics of the sample are reported in Table 1.

Inclusion criteria were: stroke with unilateral hemiplegia occurred within the previous six months and ability to walk without any device or need of continuous physical assistance to support body weight or maintain balance (Functional Ambulation Classification $\geq$3). Exclusion criteria were: cognitive deficits affecting the capacity of patients to understand the task instructions (Mini Mental State Examination >24); severe unilateral spatial neglect (diagnosed with a battery of test including Letter Cancellation test, the Barrage test, the Sentence Reading test and the Wundt-Jastrow Area Illusion Test), severe aphasia (diagnosed with neuropsychological assessment), and presence of neurological, orthopedic or cardiac comorbidities (all of them clinically evaluated).

This study was approved by the Local Independent Ethics Committee and all participants gave their written informed consent to participate in the study.

2.2. Experimental protocol

The study was conducted at the Neurorehabilitation Hospital "Fondazione Santa Lucia" from March 2015 to January 2017. All patients were evaluated before the training (T0) and at the end of the training (T1) sessions. To investigate if any fall event occurred after patients' dismissal, they were followed-up by phone interviews, made by the same physiotherapist, at three and twelve months after their dismissal (Morone et al., 2014). Patients were asked if they experienced any fall and, eventually, to describe how and why it happened. Both VG and CG performed a standard physiotherapy program (2 times/week for 4 weeks). In addition, 12 rehabilitation sessions (3 times/week for 4 weeks) of 20 minutes were administered to both groups: VG performed vestibular

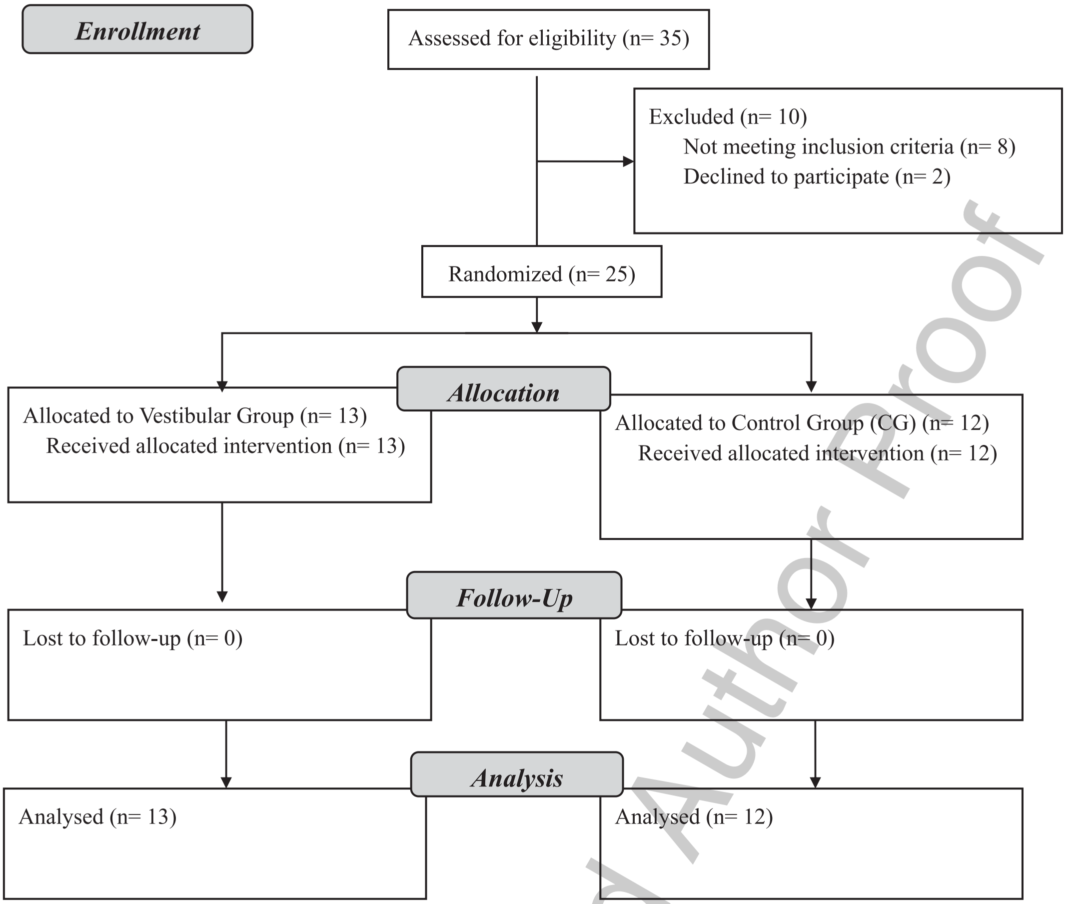

Fig. 1. Flow Diagram.

Table 1
Demographic and clinical characteristics at baseline

	VR	*CG*
Age	63.1 ± 8.5	65.1 ± 15.5
Gender	8M; 5 F	4M; 8F
Mass (kg)	65.6 ± 13.3	68.4 ± 13
Stature (cm)	171.3 ± 9.1	165.7 ± 7.5
Stroke location	6 right; 7 left	7 right; 5 left

VR: Vestibular Rehabilitation Group, CG: Control Group.

rehabilitation with exercises aiming at enhancing gaze stability and upright postural control (Han et al., 2011) (cfr. Interventions section). For CG additional rehabilitation training was focused on trunk stabilization and weight transfer to the paretic leg.

An expert physician, blind to patients' allocation, assessed each patient using the following clinical scales: Functional Ambulation Classification (FAC) (Holden et al., 1984), Tinetti Balance and Gait (TBG) (Tinetti et al., 1986), Berg Balance Scale (BBS) (Berg 1992), and Barthel Index (BI) (Collin et al., 1988).

All patients provided written informed consent and accepted to perform an instrumented 10-Meter Walk Test (10-MWT), for three times consecutively, on a straight pathway at their self-selected walking speed, at both T0 and T1. The experimental protocol of this instrumented assessment was selected according to a previous study (Bergamini et al., 2017) using five Inertial Measurement Units (IMUs) (Opal, APDM Inc., Portland, Oregon, USA) and 3D linear accelerations and angular velocities were collected. Each unit embedded three-axial accelerometers and gyroscopes (±6 g with $g = 9.81$ m×s^{-2}, and ± 1500 °/s of full-range scale, respectively) and provided the measured quantities with respect to a unit-embedded system of reference. To assess gait stability, three IMUs were secured to the participants' upper body: one on the occipital cranium bone of the head (H), one on the center of the sternum body (S), and one at L4-L5 level, slightly above the pelvis (P) (Fig. 2). The other two units were located on both distal tibiae (lateral malleoli) and were used to perform stride segmentation.

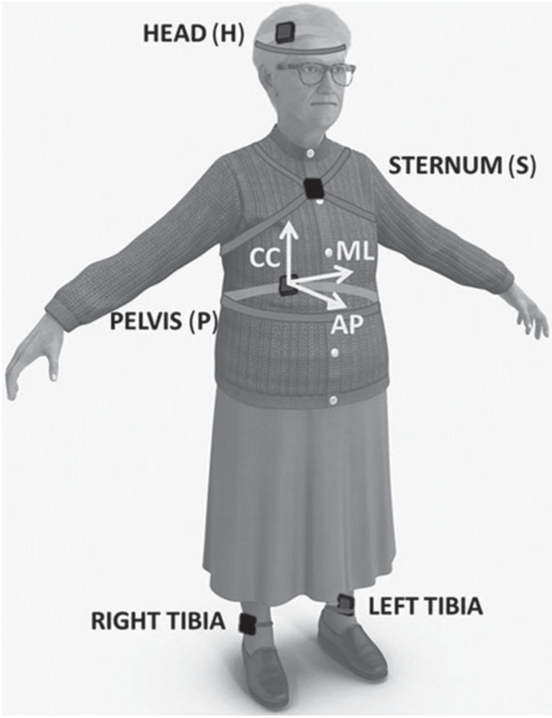

Fig. 2. Location of the Inertial Measurement Units (IMUs) attached on the participants' body segments. The axes orientation of the pelvis (P), sternum (S), and head (H) IMUs was the same during the static phase at the beginning of each trial. For the sake of clarity only the orientation of the pelvis unit is depicted (AP, antero-posterior; ML, medio-lateral; CC, cranio-caudal). Adapted from "Multi-sensor assessment of dynamic balance during gait in patients with subacute stroke" by Bergamini E et al. J. Biomech. (2017), http://dx.doi.org/10.1016/j.jbiomech.2017.07.034.

To limit the relative movement between the units and the underlying skin, IMUs were secured to the relevant body segment using *ad hoc* supports (a swim cap with a tailored pocket for the head IMU and elastic straps for the other units). To guarantee a repeatable reference system for the three IMUs located on the upper body, each unit was aligned with the corresponding anatomical axes (antero-posterior: AP, medio-lateral: ML, and cranio-caudal: CC) following the procedure proposed by (Bergamini et al., 2017).

For each 10-MWT, the following spatiotemporal parameters were obtained: average walking speed (WS = 10 m/time to complete the test), average stride length (SL = 10 m/total number of strides), and stride frequency (SF = total number of strides/time to complete the test). For what concerns gait stability, only steady-state strides were analyzed, and the following parameters were estimated:

- Attenuation Coefficients (Mazzá et al., 2008) (AC) between each level pair (H, S, P), for each acceleration component (AP, ML, CC). Each coefficient represents the variation of the acceleration from lower to upper levels of the upper body. A positive coefficient indicates an attenuation of the accelerations from the lower to the upper level, whereas a negative coefficient indicates an amplification.
- Improved Harmonic Ratio (Pasciuto et al., 2017) (iHR) for each acceleration component (AP, ML, CC) measured at the pelvis level. This index is a measure of gait symmetry and is based on a spectral analysis of the acceleration signals (0%, total asymmetry; 100%, total symmetry).

2.3. Interventions

2.3.1. Balance exercises (CG only)

The balance exercises were focused on trunk stabilization and weight transfer to the paretic leg and consisted of three exercises. First, patients were seated blindfolded on a Bobath ball for 5 minutes with an expert physiotherapist supporting them in keeping the right position. Second, patients were asked to maintain balance in a standing position on a Freeman board for 5 minutes. The third exercise consisted in transferring body weight to the paretic leg using parallel bars for 10 minutes (Morone et al., 2014).

2.3.2. Gaze stability exercises (VG only)

Exercises were performed staring at a static object while participants turned their head side to side and up and down (VORx1) (Herdman et al., 1989) for one minute for each axis. The exercises were carried out for no more than 10 min including quick rest period and were performed seated, standing and during a step on the spot. One physiotherapist, specifically trained in VR, checked that patients maintained gaze stability during each task.

2.3.3. Upright postural control (VG only)

Each patient was asked to get on a 5 cm thick foam cushion and then was blindfolded. Once the patient was in a stable posture, he/she was given the following instruction: "step on the spot for one minute". At the end of the first minute, remaining blindfolded, the patient made 90° clockwise turn and repeated the exercise for another minute. The same procedure was carried out at 180° and 270° for a total of four minutes. In case patients rotated (left/right) or moved (forward/backward) during the stepping execution, the physiotherapist helped them to recover the original position using verbal cues (e.g., "you are turning left/right" and "you are moving forward/backward") (Tramontano et al., 2016). The maximum exercises duration was of 10 min, including quick rest periods.

2.4. Statistical analyses

The IBM SPSS Statistics software (v23, IBM Corp., Armonk, NY, U.S.A.) was used. A normality check was performed using the Shapiro-Wilk test. Due to lack of normality for all the above-mentioned parameters, median and inter-quartile ranges were used to summarize all the computed parameters and all data were then analyzed using non-parametric statistics. In particular, Mann-Whitney U-test was used to compare data between groups and Wilcoxon Signed Ranks test was used for within-group analyses. The alpha level of statistical significance was set at 0.05 for all the tests.

3. Results

Table 2 shows the scores of the clinical scales administered before (T0) and after (T1) the rehabilitation program. At T0, no statistically significant differences were observed between the two groups. The results of between-group comparison at T1 highlighted that all clinical scale scores were higher in VG than in CG. Specifically, significant differences were found for the Tinetti total score and Tinetti gait subscore ($p = 0.011$ and $p = 0.014$, respectively). In addition, the results of the Wilcoxon Signed Ranks test showed that the scores of all scales increased for both groups ($p < 0.05$), for the sake of clarity, the within-group analysis results are not displayed in Table 2.

In Table 3, the results of the instrumented gait analysis are reported. For what concerns the between groups analysis, VG and CG resulted homogenous at T0 also in terms of walking ability. At T1, significant differences were found for both WS ($p = 0.043$) and SL ($p = 0.009$), which resulted higher in VG than

Table 2
Median and interquartile range (IQR) of clinical scale scores pre- and post-rehabilitation (MBI: Modified Barthel Index, FAC: Functional Ambulation Classification, T-Total: Tinetti scale, T-Balance: Tinetti Balance subscale, T-Gait: Tinetti gait subscale, BBS: Berg Balance Scale, RMI: Rivermead Motricity Index). *P*-values report the results of Mann-Whitney u-test (in bold and with asterisk if statistically significant)

Scale	Pre – Rehabilitation (T0)			Post – Rehabilitation (T1)		
	VG	CG	*p*-value	VG	CG	*p*-value
MBI	89.1 ± 11.1	85.8 ± 12.7	0.503	97.8 ± 4.7	95.8 ± 5.2	0.137
FAC	3.6 ± 0.5	3.5 ± 0.5	0.650	4.4 ± 0.5	4.1 ± 0.5	0.270
T-total	21.9 ± 3.9	20.2 ± 3.1	0.137	26.5 ± 1.5	23.8 ± 2.8	**0.011***
T-Balance	12.7 ± 2.6	11.8 ± 2.2	0.295	15.2 ± 1.4	13.8 ± 1.7	0.060
T-Gait	9.2 ± 1.5	8.3 ± 1.4	0.137	11.4 ± 1.0	9.9 ± 1.4	**0.014***
BBS	44.8 ± 6.4	40.9 ± 6.1	0.137	51.5 ± 3.3	48.0 ± 4.7	0.060
RMI	9.7 ± 2.0	9.3 ± 2.4	0.769	13.2 ± 1.2	12.5 ± 1.5	0.186

Table 3
Median and interquartile range (IQR) values of instrumented gait parameters pre- and post-rehabilitation (WS: walking speed, SF: stride frequency, SL: stride length, AC_{PH}: coefficient of attenuation of acceleration between pelvis and head, iHR: improved harmonic ratio, AP: antero-posterior axis, ML: medio-lateral axis, CC: cranio-caudal axis). *P*-values report the results of Mann-Whitney U-test (in bold and with asterisk if statistically significant)

Gait Parameter	Pre – Rehabilitation (T0)			Post – Rehabilitation (T1)		
	VG	CG	*p*-value	VG	CG	*p*-value
WS	0.71 ± 0.14	0.57 ± 0.15	0.083	0.78 ± 0.14	0.61 ± 0.14	**0.043***
SF	0.67 ± 0.07	0.66 ± 0.06	0.999	0.68 ± 0.08	0.68 ± 0.10	0.700
SL	1.06 ± 0.17	0.87 ± 0.20	0.100	1.15 ± 0.17	0.90 ± 0.15	**0.009***
AC_{PH}-AP	25.1 ± 40.4	11.8 ± 28.5	0.178	31.8 ± 29.1	8.97 ± 41.8	0.211
AC_{PH}-ML	–3.6 ± 48.8	17.1 ± 12-1	0.501	10.5 ± 37.2	–1.6 ± 44.9	0.386
AC_{PH}-CC	2.6 ± 9.7	2.2 ± 16.0	0.847	2.8 ± 10.5	3.2 ± 10.0	0.923
iHR-AP	85.6 ± 10.3	77.0 ± 11.6	0.083	89.5 ± 5.8	72.5 ± 30.0	0.923
iHR-ML	69.9 ± 9.5	68.4 ± 5.5	0.501	67.5 ± 13.9	62.5 ± 26.0	0.124
iHR-CC	85.5 ± 5.4	75.0 ± 13.6	0.102	87.3 ± 7.1	73.5 ± 30.4	0.211

in CG. When considering the within-group analysis, no significant differences were found, even if an increasing trend was observed in VG for all gait parameters. Conversely, CG displayed only a decreasing trend of the AP and ML components of AC as well as of all three components of iHR.

Three patients of CG fell at least two times twelve months after their dismissals and one patient of VG fell one time twelve months after his dismissals.

4. Discussion

This study tested the use of a vestibular rehabilitation protocol aimed at enhancing gait and dynamic balance in patients with subacute stroke. Results show a significant improvement in Tinetti Balance Gait scores in patients who underwent a customized vestibular rehabilitation program. These results are in accordance with those of Mitsutake and co-workers showing that 3 weeks of vestibular rehabilitation in subacute stroke subjects have positive effects on patients' balance ability during walking (Mitsutake et al., 2017). Instrumented analysis of walking showed higher values of walking speed and stride length in the VR group. Conversely, no significant difference was found in terms of trunk stability. This result could be due to the actual reduced sample size, because only a subgroup of patients accepted to be tested using instrumented gait analysis. Interestingly, despite the higher speed at which the VR group walked at T1, they were able to maintain similar upper body stability and symmetry with respect to the slower control group. The above-mentioned trend observed in the VR group goes towards increased AC and iHR that are typical of mild severity in stroke (Bergamini et al., 2017; Belluscio et al., 2017).

Hence, VR showed some slight higher effect than conventional therapy. A possible role played by the reflex mechanism related to vestibular function in postural control and gait performance could be at the basis of these results, as confirmed by previous studies showing the relationship between gaze stabilization function and gait performances (Whitney et al., 2009; Hillman et al., 1999) in patients with vestibular deficit. Moreover, the vestibular-spinal tract is thought to play a significant role during the execution of voluntary forward steps (Bent et al., 2002) in a specific stance phase (Bent et al., 2005). Vestibular information is weighted more heavily during double support than at any other time of the gait cycle (Bent et al., 2005) giving more stability during all gait cycle. In other words, the vestibular system can primarily induce a modulation of antigravitary muscles and balance reactions (Nallegowda et al., 2004) that, in turn, can be learned and used by feedforward mechanisms prior to voluntary movements during gait. Patients with stroke often experience balance disorders (Iosa et al., 2012), furthermore they may also have difficulties in an adequate utilization of vestibular information and their balance and gait function is mainly based on visual input (Bonan et al., 2004). VR, modulating neuroplasticity in the vestibular network, might have promoted a sensory reweighting in our patients improving their walking performance. Even in absence of a specific vestibular damage, as in the sample enrolled in the present study, VR seems to act as a facilitator for improving a compensation strategy based on the enhancement of vestibular functions for managing a correct trade-off between stability and advancement during gait (Iosa et al., 2016).

Despite the increased interest in evaluating and investigating the effects of vestibular network on balance and waking dysfunction (Van Wyk et al., 2016), so far, only one study analysed the effects of VR in stroke (Mitsutake et al., 2017). Our study suggests that the integration of vestibular rehabilitation in a standard post stroke rehabilitation protocol has the possibility to boost dynamic balance and walking recovery. Another key to interpretation of our results is that the mechanisms of experience-dependent plasticity contribute to post-stroke neuronal reorganization and to the efficacy of rehabilitative training, so it could be speculated that a need of stimulating the vestibular system exists for obtaining an increase in stability or, as our results suggest, the capacity of patients to walk faster without decreasing their upper body stability (Allred et al., 2014).

The idea of stimulating an undamaged apparatus to favour the recovery of a multi-systemic ability such as walking is not entirely new. A recent RCT (Van Wyk et al., 2014) investigated the effects of visual scanning exercises with saccadic eye movement training during task-specific activities for patients with Neglect following a stroke. As suggested by the authors, although the intervention was focused on the visual system (visual scanning exercises integrated with task-specific activities), they found more general positive effects, probably due to the inner integration of visual system with the vestibular and the somatosensory (proprioceptive, cutaneous, and joint receptors) systems in maintaining postural orientation and stability during functional movement.

An encouraging result was the lower trend in number of falls observed in the VG group twelve months after dismissals. Presumably, this result reveals that a dynamic balance training could improve the balance confidence and the self-perception reducing the risk of falls (Morone et al., 2014).

Our study has some important limitations. Although the sample size was defined according to the results of a power analysis, it was shown to be rather small. It can be speculated that the number of significant differences would increase if the sample size would be enlarged. This is particularly evident for what concerns the instrumented analysis results, where not all patients signed the informed consent for that test. Another limitation is the absence of a neurophysiological measure of potential vestibular deficits. This measure was not considered because it has been hypothesized that VR had an effect on dynamic balance regardless a specific damage of the vestibular system. However, as this measure could be helpful for obtaining a clearer patients' clinical picture, further studies should take this aspect into account. Another limitation concerns vestibular training, because we used only active horizontal and vertical head movements. Indeed, previous studies indicate that compensatory strategies should incorporate passive rotations (Cullen et al., 2004; Schubert et al., 2008) and it could be interesting for further studies to investigate also the effects of a new rehabilitation paradigm with passive rotations training.

In conclusion, VR could be included into a rehabilitation program for patients with stroke for improving their gait and dynamic balance acting on their vestibular system as facilitator of recovery, hopefully reducing their risk of falling.

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Conflict of interest

The authors declare no competing financial interests.

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Ethics approval

The study was approved by Local Ethics Committee of IRCSS Fondazione Santa Lucia.

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