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ORIGINAL ARTICLE

Vestibular rehabilitation in elderly patients with postural instability: reducing the number of falls—a randomized clinical trial

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Abstract

Background Our previous study had shown the effectiveness of vestibular rehabilitation (VR) in improving balance in elderly patients, assessed immediately afterwards.

Aims The main goal of the present study is to consider whether this improvement in balance assessment turns out in a reduction of the number of falls.

Methods 139 elderly patients with high risk of falls were included and randomized to one of the following study arms: computerized dynamic posturography (CDP) training, optokinetic stimulus, exercises at home or control group. Patients were assessed with objective outcome measures (sensorial organization test and limits of stability of CDP, number of falls and number of hospital admissions due to falls) and subjective outcome measures (dizziness handicap inventory and short falls efficacy scale-international) during a 12-month follow-up period.

Results Average number of falls significantly declined from 10.96 (before VR) to 3.03 (12-month follow-up) in the intervention group ($p < 0.001$); meanwhile, in the control group, the average number of falls changed from 3.36 to 2.61 during a 12-month follow-up period ($p = 0.166$).

Discussion The present study provides evidence that VR can decisively improve balance in elderly patients with instability, which can lead in turn to a significant reduction of falls.

Conclusion We recommend performing VR in any older person with high risk of falls.

Keywords Elderly · Falls · Computerized dynamic posturography · Optokinetic · Vestibular rehabilitation

Introduction

Accidental falls, specifically in elderly patients, are a very important public health problem from both clinical and economic perspectives [1]. Falls also have significant social and psychological consequences, as patients tend to lose self-confidence, limiting their physical activity due to fear of falling again [2].

It is well known that balance becomes more precarious with age. Even without pathological disorders, the physiological decline in balance due to the ageing of the different body systems involved (visual, vestibular and proprioceptive) [3] is a factor that also leads to falls [4].

However, vestibular rehabilitation (VR) protocols have been shown to be effective in improving balance affected by different neurological [5] and vestibular disorders [6–8].

Specifically, different rehabilitation protocols have improved postural control and confidence in elderly people with instability [9, 10].

Anyway, to the author's knowledge there are no randomized clinical trials of whether VR is effective in reducing the number of falls in elderly [11].

Different rehabilitation techniques that have proven to be effective in improving balance are available: computerized

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dynamic posturography [5–7], optokinetic stimulus [6, 12] or exercises focused on stabilizing eye position and gait training [13], but there is insufficient evidence to discriminate between their efficacy and productivity.

Our earlier study has shown the effectiveness of VR in improving balance in the elderly, assessed immediately afterwards [14]. So, the aims of the present paper are

a. To verify whether the improvement in balance achieved persists in the medium term (6–12 months).
b. To consider whether this improvement in balance assessment turns out in a reduction in the number of falls suffered by elderly patients.
c. To compare the effectiveness of three different methods of VR in improving balance in the medium term and to explore whether there are also differences between them in reducing the number of falls.

Materials and methods

This study was funded by the project PI11/01328, integrated into the State Plan for R + D + I 2008–2011 and funded by *the ISCIII—Subdirección General de Evaluación y Fomento de la Investigación* and the European Regional Development Fund: "Reduction of falls in the elderly by improving balance through vestibular rehabilitation".

Design

Experimental study, single-center, open-label, randomized (balanced blocks of patients) in four parallel branches, in 139 elderly patients with high risk of falls. The complete protocol of this research project has been published [15]. This study was registered in http://ClinicalTrials.gov (Identifier NCT03317353).

Study population: inclusion and exclusion criteria

The age of the study subjects was 65 years or more, and they presented balance impairment without a vestibular disease. A neurotological examination was performed to rule out other causes, including assessment for the absence of spontaneous or induced nystagmus with the head shake test, and the absence of saccades by the Halmagyi test. The study was completed with videonystagmography or imaging tests when necessary. They also presented a high risk of falling, fulfilling at least one of the following inclusion criteria [15]:

- Have fallen at least once in the last 12 months.
- Taking more than 15 s, or needing support, in the modified timed up-and-go (TUG) test. In the standard test [16], the seated subject stands up, walks 3 m to a wall, turns around, walks back and sits down again. In the modified test [17], the subject was required to walk around the chair before sitting down again (an additional 180° turn).
- Obtaining a score of less than 68 in the average score of the sensory organization test (SOT) of the computerized dynamic posturography (CDP).
- Have fallen at least once during the SOT.

The study's exclusion criteria were

- Cognitive decline that prevents the patient from understanding the assessment, vestibular rehabilitation exercises and granting informed consent. None of the patients included had dementia and the score in the mini-mental test [18] was 25 points or greater.
- Balance disorders caused by conditions other than age (neurologic, vestibular, etc.).
- Organic conditions that prevent standing on two feet, which is necessary for a complete postural assessment and performance of vestibular rehabilitation exercises.

Pre-screening visit 0

Complete balance examination and interview that enable us to select individuals with balance disorders and a high risk of falling who are candidates for inclusion in the study.

This visit includes the following tests:

a. Questionnaires that measure disability due to imbalance and risk of falling:

    - Dizziness Handicap Inventory (DHI), validated in Spanish [19]: it assesses disability perceived by the patient in relation to instability. It consists of 25 items with three possible answers: "yes" (4 points), "sometimes" (2 points), and "no" (0 points). Highest perception of disability would be 100 and the lowest one could be 0.
    - Short falls efficacy scale-international (FES-I) [20, 21]. It is a shortened version to assess fear of falling during seven activities with four possible answers (we use a modification in the score): not at all concerned (0 points), somewhat concerned (1 point), fairly concerned (2 points) and very concerned (3 points). The highest score (severe concern about falling) is, therefore, 21.

b. Computerized dynamic posturography (CDP), sensory organization test (SOT) (we used the Neurocom Smart Equitest platform): The SOT includes quantitation of the patient's center of gravity displacements in six different sensorial information conditions [22]:

1. Fixed surface and visual surround, eyes open.
2. Fixed surface, eyes closed.
3. Fixed surface, eyes open, moving visual surround.
4. Moving surface, eyes open, fixed visual surround.
5. Moving surface, eyes closed.
6. Moving surface, eyes open, moving visual surround.

Each of the six conditions was repeated three consecutive times, with the patients completing a total of 18 tests per record. The time established for each of these tests was 20 s.

Analysing and comparing the responses to the different sensorial conditions, we can quantify the contribution of sensorial receptors to maintaining balance. The study analysed the following variables:

- Average balance score, obtained by weighting the means scores of each sensorial condition.
- Somatosensory input, which is the percentage value that results from the following formula: (mean score of condition 2/mean score of condition 1) × 100.
- Visual input, calculated as the result of (mean score of condition 4/mean score of condition 1) × 100.
- Vestibular input, calculated as (mean score of condition 5/mean score of condition 1) × 100.
- Visual preference, calculated as [(mean scores of conditions 3 + 6)/(mean scores of conditions 2 + 5)] × 100. It is a measure of the patient's reliance of visual information, even when that information is incorrect.

c. CDP, limits of stability (LOS): Following visual feedback, the patient has to voluntarily move his or her center of gravity (CoG) without moving his or her feet on the platform to reach eight points around him/her [22]. These points represent 100% of the displacement limit of the subject's center of gravity, according to height and age [22].

   We analysed the following parameters:

   - Time reaction (TR): time from signal movement to start of patient movement.
   - Mean velocity (MV): mean speed of CoG movement as degrees per second.
   - Endpoint excursion (EPE): distance travelled by CoG in first attempt to attain the target.
   - Maximum excursion (MXM): longest distance travelled by CoG during the test. It can differ from the above if corrective movements are attempted because the first attempt fell short.
   - Directional control (DC): comparison between quantity of movement in the object's direction and the quantity of movement in another direction.

d. Direct question about the number of falls and hospital admissions due to falls in the last 12 months.

The subject's eligibility was verified upon completion.

Randomization and intervention

Visit 1

After the first screening visit, subjects who provided informed consent were included in the study and randomized to one of the following study arms:

a. Intervention with CDP exercises: The Smart Equitest program was used with a protocol of 10 exercises per session, which were customized depending on each patients deficit. The exercises involve visual biofeedback together with sensitive, real-time monitoring of movement. In addition, the support surface and/or visual surround may also move in response to the patients' own movement. The exercise difficulty was progressively increased throughout the rehabilitation sessions (by increasing the LOS, the transition rate or the movement of the posturography platform). The duration of each session was approximately 15 min. The distribution of sessions was one per day and five per week (2 weeks).
b. Intervention with exposure to optokinetic (OKN) stimuli: The patients stood, with their feet symmetrically positioned, in a dark room, 2 m from the wall displaying the optokinetic stimulus generated by the planetarium. The exercise difficulty was progressively increased throughout the rehabilitation sessions with gradually increase of:

   - Stimulus speed: from 30°/s the first day to 100°/s the last.
   - Duration of session: from 5 min the first day to 15 min the last.
   - Stimulus complexity: horizontal stimuli in the first sessions, progressively adding vertical and rotating stimuli.
   - Support surface difficulty: initially hard surface, last sessions on foam.
   - The distribution of sessions was one per day and five per week (2 weeks).

c. Intervention with exercises at home: The patient is given a list of exercises program (and explained how to do them) based on Cawthorne–Cooksey vestibular rehabilitation exercises [23, 24] to stabilize eye position and improve postural control. Patients performed them twice a day for 2 weeks and the approximate duration of each session was 15 min. A family member must supervise the exercises to verify the programs' adherence.
d. Control group: Patients did not receive any vestibular rehabilitation intervention; however, they were encouraged to walk to improve their general physical condition as in the other groups. Determinations were made also at the same time as in the other groups.

Randomization was performed by C.H.U de Santiago Clinical Epidemiology and Biostatistics Unit. Once the informed consent form is signed, the investigator contacts the unit, which gave him the code of the arm to which the patient was assigned. A $n=20$ block balanced randomization sequence was used.

The balance study described in the first visit (baseline record) is repeated, with all the tests (questionnaires and CDP assessment) 3 times:

- Visit 2: Immediately after completion of VR (3 weeks after baseline record, in control group).
- Visit 3: 6 months after VR.
- Visit 4: 12 months after VR. The number of falls and the number of hospital admissions due to falls in 12 months after completion of VR programme were also recorded (or equivalent time in control group).

Statistical analysis

Chi-square statistic was used to analyze differences by gender and ANOVA was used to analyze differences by age and body mass index (BMI) between treatment groups.

Depending on data distribution (it was tested by Kolmogorov–Smirnov test), the analysis to examine the mean differences between before treatment, 6-month follow-up and 12-month follow-up was carried out performing *t* test for dependent sample or Wilcoxon's test. To compare the effectiveness of the three different methods in reducing the number of falls, Kruskal–Wallis test was used. Finally, we have also analyzed the correlations between the different quantitative variables before training and the reduction of falls in the intervention groups (using Spearman's correlation test).

Multivariate analysis

Generalize linear model (GLM) was used to analyze the efficacy of the intervention in reducing the falls from baseline considering each subject's group and the covariables of interest (age, gender, BMI, number of previous falls and number of previous admissions resulting from those falls). The efficacy (dependent variable) was defined as the change of the number of falls between 12-month follow-up (visit 4) and pre-screening (visit 0).

Level of statistical significance in all the tests applied was p value < 0.05. All analyses were carried out with SPSS version 22.0 (IBM, Armonk, NY) for Windows.

Calculation of sample size

The sample size was estimated with reference to the results of previous studies conducted by the group [5] in which there was a 10-point change in the mean average balance score of the SOT (CDP), (baseline value: 64; post-rehabilitation value: 73; value after 12 months: 74). Considering a security level (1—∞) of 95% and a type II (b) error likelihood of 0.2, 53 subjects were needed in each arm. With these considerations, the sample size would be 212 subjects, and it was increased to 220 (55 in each arm) in case of any loss to follow-up. However, after a formal interim analysis with 139 patients that had shown benefits with specific interventions compared to control group, and bearing in mind that participants were at risk of falls, we decided not to recruit more patients in the present study.

Ethical aspects

The study was conducted according to the Declaration of Helsinki and all the patients granted their consent to participate in the study in writing. The study protocol was approved by the Independent Ethics Committee of Galicia (protocol 2010/139).

Results

139 elderly people with instability were initially included in the study and the drops-out is shown in Fig. 1.

106 patients completed the 12-month follow-up and were analyzed in the final study.

The final sample was made up of 22 females and 5 males in the CDP group, 22 females and 8 males in the OKN group, 18 females and 3 males in the exercises at group home, and 27 females and 1 male in the control group.

Demographic data and results of clinical assessment are summarized in Table 1.

There was no statistically significant difference in gender (Chi square, $p=0.116$), nor age or BMI (ANOVA with post hoc Dunnett's, $p>0.05$ in both of them).

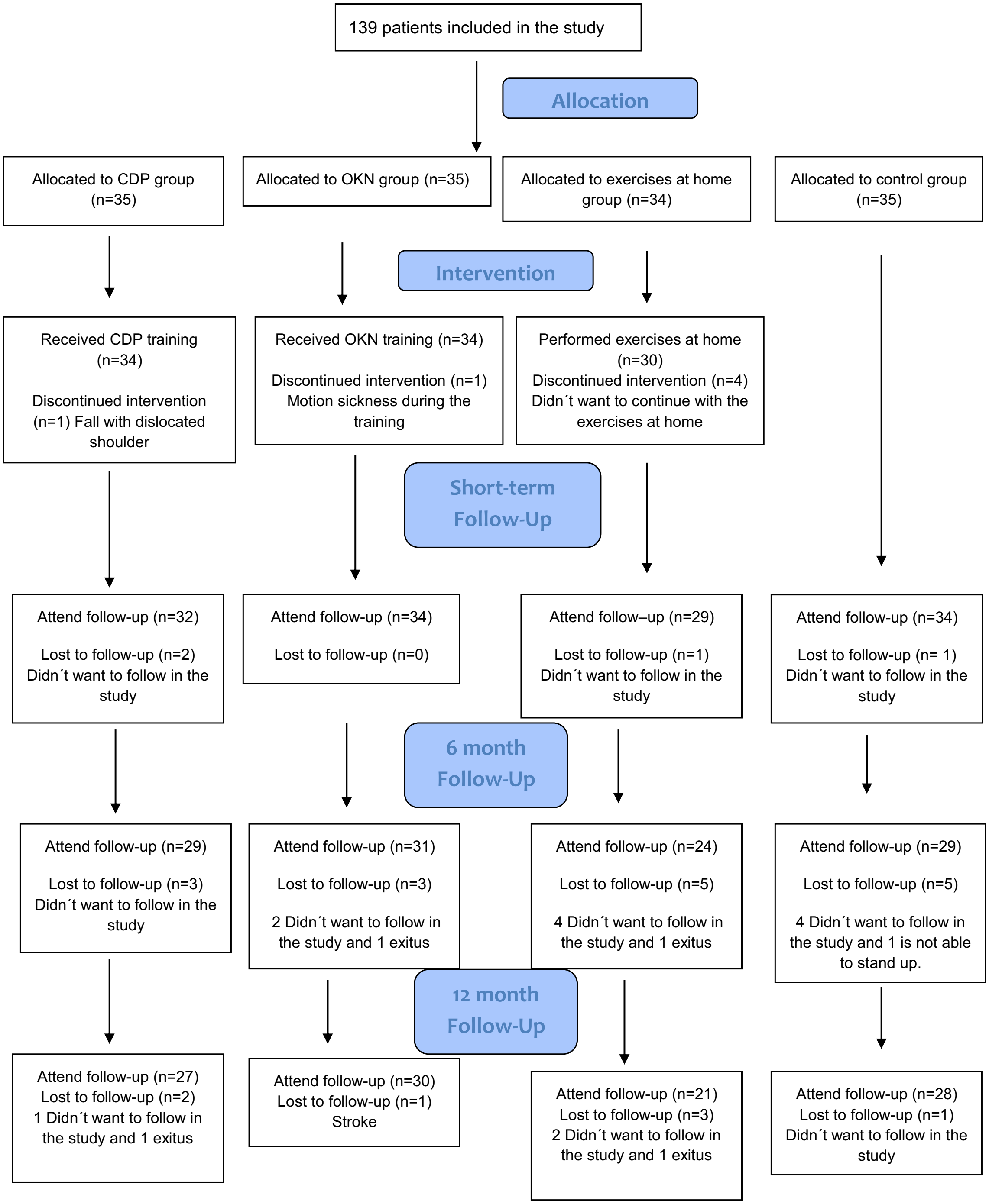

Fig. 1 Flowchart of the study

Objective outcome measures

SOT

The average score in the different groups is summarized in Fig. 2. There was a statistical significantly improvement in the 6- and 12-month follow-up in the CDP group ($p < 0.001$ in both assessment), in the OKN group ($p = 0.001$ and $p = 0.015$, respectively) and in the control group ($p < 0.001$ and $p = 0.002$, respectively).

In the CDP group, there was a statistically significant improvement at 6-month follow-up in the visual and vestibular input ($p = 0.005$ and $p = 0.01$, respectively), and number of falls in the SOT ($p = 0.001$). In the 12-month follow-up, there was also a statistically significant improvement in the visual and vestibular input

Table 1 Demographic data and results of clinical assessment in the study groups

	CDP group $N=27$	OKN group $N=30$	Exercises at home group $N=21$	Control group $N=28$
Age	76.98 ± 7.16	74.34 ± 5.77	76.83 ± 6.62	76.82 ± 5.74
BMI	29.34 ± 3.85	30.65 ± 5.10	30.60 ± 3.42	30.19 ± 4.00
Previous falls[a]	3.52 ± 6.98	17.07 ± 66.72	11.81 ± 23.96	3.36 ± 5.93
Previous hospital admissions[a]	0.67 ± 2.32	0.10 ± 0.305	0.62 ± 1.35	0.29 ± 0.81
Average balance score (SOT)	53.74 ± 12.67	55.93 ± 13.05	55.90 ± 9.78	58.79 ± 12.36
Somatosensorial input (SOT)	95.48 ± 6.36	93.67 ± 8.25	96.52 ± 5.21	94.93 ± 4.97
Visual input (SOT)	66.63 ± 21.44	68.47 ± 15.44	69.10 ± 15.13	67.68 ± 23.25
Vestibular input (SOT)	30.89 ± 25.88	30.33 ± 25.74	27.57 ± 23.34	37.93 ± 23.17
Vestibular preference (SOT)	92.74 ± 16.96	99.03 ± 14.86	100.48 ± 20.17	95.79 ± 13.78
Number of falls (SOT)	3.37 ± 2.51	2.70 ± 2.21	2.95 ± 1.91	2.39 ± 2.69
TR (LOS)	1.18 ± 0.35	1.07 ± 0.29	1.24 ± 0.36	1.12 ± 0.36
VM (LOS)	2.34 ± 0.90	2.22 ± 0.64	2.39 ± 0.79	2.37 ± 0.88
EPE (LOS)	51.59 ± 11.20	50.07 ± 11.64	48.00 ± 10.71	45.61 ± 9.95
MXM (LOS)	67.44 ± 13.72	68.80 ± 11.23	64.05 ± 10.67	63.89 ± 11.65
CD (LOS)	64.41 ± 16.13	70.47 ± 9.66	64.62 ± 10.90	60.93 ± 12.44
Time (TUG)	20.81 ± 4.86	20.49 ± 6.69	21.27 ± 8.26	22.16 ± 13.45
Steps (TUG)	28.00 ± 7.75	24.73 ± 5.82	26.57 ± 7.81	27.54 ± 11.53
DHI	54.22 ± 21.16	57.87 ± 24.32	54.57 ± 22.13	55.57 ± 15.89
Short FES-I	8.81 ± 4.95	10.20 ± 6.04	8.00 ± 4.33	8.71 ± 4.77

[a]Number in the last 12 months

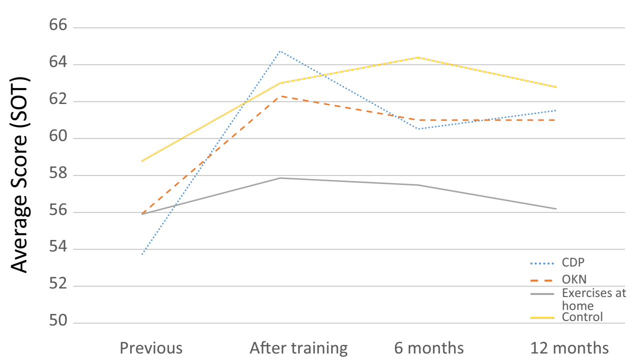

Fig. 2 Change of average balance score (SOT) after training in the different groups

Fig. 3 Change of maximum excursion (LOS) after training in the different groups

($p < 0.001$ and $p = 0.046$, respectively) and number of falls ($p < 0.001$).

In the OKN group, there was a statistically significant improvement at 6-month follow-up and 12-month follow-up in the vestibular input ($p = 0.003$ and $p = 0.008$, respectively) and number of falls in the SOT ($p = 0.001$ and $p = 0.008$, respectively).

In the exercise-at-home group, there was no significant improvement in the CDP parameters at 6- and 12-month follow-up. However, in the control group, there was a statistically significant improvement at 6-month follow-up in the visual and vestibular input ($p = 0.03$ and $p < 0.001$, respectively), and number of falls in the SOT ($p = 0.014$). In the 12-month follow-up, there was also a statistically significant improvement in the visual and vestibular input ($p = 0.006$ and $p = 0.027$, respectively) and number of falls ($p = 0.037$).

LOS

MXM in the different groups is summarized in the Fig. 3. There was a statistically significant improvement in the 6- and 12-month follow-up in the CDP group ($p = 0.006$,

$p = 0.011$, respectively), but there was no significant improvement in the other groups.

In the CDP group, there was also a statistically significant improvement in the following parameters of LOS at the 6- and 12-month follow-up: TR ($p = 0.015$ and $p = 0.006$, respectively) and DC ($p = 0.009$ and $p = 0.003$, respectively). EPE shows a statistically significant improvement at 6 months ($p = 0.013$).

In the OKN group and the exercises at home group there was only a statistically significant improvement in TR at 12-month follow-up ($p = 0.005$, $p = 0.001$, respectively).

The control group showed a significant improvement in the EPE at 6-month follow-up ($p = 0.015$).

Number of falls and hospital admissions due to falls

The average number of falls in the intervention group (CDP, OKN and exercises at home) significantly declined from 10.96 (before VR) to 3.03 (12 months follow-up) ($p < 0.001$). Meanwhile, in the control group the average number of falls changed from 3.36 to 2.61 during 12-month follow-up period but it was not statistically significant ($p = 0.166$) (Fig. 4).

In the CDP group, previous falls were 3.52 and at 12-month follow-up were 2.19 ($p = 0.175$). In the OKN group the falls reduced from 17.07 to 4.43 ($p = 0.011$) and in the exercises at home group from 11.81 to 2.10 ($p = 0.006$).

However, when we compare the effectiveness of the three different methods of vestibular rehabilitation in reducing the number of falls, the analysis did not show statistically significant differences ($p > 0.05$). On the other hand, GLM analysis did not reveal any statistically significant effect in the different groups ($p > 0.05$).

In the intervention group, the reduction of falls has only shown a statistically significant correlation with the number of previous falls (0.684, $p < 0.001$) and previous admissions due to falls (0.299, $p = 0.008$).

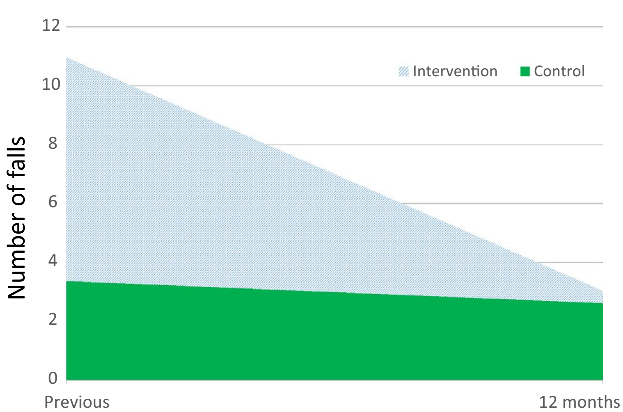

Fig. 4 Mean number of falls in the intervention group and control group

Regarding the number of hospital admissions to hospital due to falls, in the intervention groups there was a reduction from 0.44 ± 1.55 to 0.27 ± 0.87 but there was not a statistically significant difference ($p = 0.389$). In the control group, there was a reduction from 0.29 ± 0.81 to 0.18 ± 0.39 but it was not statistically significant ($p = 0.782$).

Subjective outcome measures

DHI and short FES

No group has shown statistically significant improvement in the questionnaires (DHI or short FES-I) at 6- and 12-month follow-up ($p > 0.05$).

Discussion

The present results provide evidence that vestibular rehabilitation can decisively improve balance in elderly patients with instability, which can lead in turn to a significant reduction of falls.

In addition, the study shows that the improvement in balance assessment achieved persists in the medium term (6–12-month follow-up). However, in the CDP group, a learning effect has to be taken in count when we perform the assessment also with posturography [25, 26], especially in the short-term evaluation. On the other hand, findings of a previous study indicate that an average score change of greater than 8 points would indicate change due to rehabilitation [25]; and only CDP group is close to a clinically significant improvement at the 12-month follow-up.

It is a noteworthy finding that a simple advice of walking to improve their general physical condition and gain confidence (control group) may improve the balance in elderly people, unfortunately the falls did not significantly reduce in these patients.

Regarding the improvement in the sensorial analysis of the SOT, with the help of CDP training, we can develop exercises that stimulate the hypofunctional sensory system, so we can expect to find evident benefits in the use of vestibular and visual information, as was observed in these patients. Although it is remarkable, that this improvement is also achieved with the simple advice of walking (control group). In a previous study in patients with unilateral vestibular hypofunction trained with OKN stimuli, improvement was greater in visual preference [6]; but in our present study with elderly patients, the improvement is greater in the vestibular input. Another study showed that complex repeated optokinetic stimulation in standing humans has been used successfully for the treatment of unsteadiness in presbyastasic elderlies [27].

In the CDP group, improvement was greater in the limits of stability, because with the help of visual biofeedback, we are able to increase them.

An important finding was that, despite improvement in balance and the reduction in falls, there were no significant improvements in the subjective outcome measures. This fact has also been reported by other studies [6, 28, 29].

Another aim of the present study is to compare the effectiveness of different methods of VR. In our previous study regarding the short-term results, supervised and customized exercises with CDP resulted in significantly greater improvement in the posturographic short-term assessment [14]; however, this holds not enough in reducing significantly the falls at 12-month follow-up. On the other hand, OKN and exercises at home group had a statistically significant reduction of falls.

Nevertheless, the attrition ratio in the exercise-at-home group is much higher than in the other groups, and this could induce the possibility of a bias [30]. It is likely that in the future we could perform the exercises at home with the Wii® Balance Board that provides a more enjoyable method of balance training [31] or assisted with audio-visual media [32], to avoid so many drop-outs in the follow-up.

Regarding better outcomes with VR in the reduction of falls, there is only a moderate correlation with previous falls and a weak correlation with previous hospital admissions due to falls. So subjective questionnaires or posturography assessment is not able to predict which elderly patients with instability could benefit more from VR. OKN and exercise-at-home groups have higher previous falls, this fact may also influence the better outcomes in this variable (regression towards the mean) [33], as the multivariate analysis did not show statistically significant differences between the VR groups.

VR is an effective technique to reduce falls in elderly patients with instability, and age did not affect potential improvement after training. Therefore, we recommend performing VR in any older person with high risk of falls. To know what is the most effective technique of VR in these patients, we are currently performing a new study, which compares the effectiveness between two different biofeedbacks (visual and vibrotactile).

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Compliance with ethical standards

Conflict of interest The authors report no conflicts of interest.

Research involving human participants and/or animals The study was performed according to the protocol approved by the Independent Ethics Committee of Galicia (Protocol 2010/139).

Informed consent Signed informed consent was obtained from all participants.

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