Aging Clinical and Experimental Research

Fall prevention in the young old using an exoskeleton Human Body Posturizer. A Randomized Controlled Trial.

--Manuscript Draft--

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Author Comments:	Dear Dr. Maggi, We appreciate the opportunity to address comments from the journal editors and referees on our manuscript (ACER-D-15-00365), "Fall prevention in the elderly using an exoskeleton Human Body Posturizer." We have responded to each point on the following pages. The revised manuscript has

	been uploaded to the submission website. We believe that the revisions have improved the quality of the manuscript and we are grateful for the Reviewer's and Editor's time spent in evaluating this article. Sincerely, Walter Verrusio

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Fall prevention in the young old using an exoskeleton Human Body Posturizer. A Randomized Controlled Trial.

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Abstract

Background: Fall risk in elderly has been related with physical decline, low quality of life and reduced survival. **Aim**: to evaluate the impact of Exoskeleton Human Body Posturizer (HBP) on the fall risk in the elderly. **Methods**: 150 subjects (mean age: 64.85; 79 M/71 F) with mild fall risk were randomized into two groups: 75 for group treated with Human Body Posturizer (HBP group) and 75 for physical training without HBP group (Exercise group). The effects of interventions were assessed by differences in tests related to balance and falls. Medically eligible patients were screened with Tinetti Balance and Gait Evaluation Scale, Short Physical Performance Battery and Numeric Pain Rating Scale in order to determine fall risk in elderly people. **Results**: In the HBP group there was a significant improvement in Short Physical Performance Battery, Tinetti Scale and Pain Numeric Rating Scale with a significant reduction in fall risk ($p<0,05$). In the Exercise group we observed only minimal variations in the test scores. **Discussion**: The results at the sixth and twelfth month show a twofold positive effect in the HBP group reducing fall risk and improving quality of life by reducing pain. **Conclusion**: The use of exoskeleton Human Body Posturizer seems to be a new significant device for prevention of fall in elder patients. Further research should be carried out to obtain more evidence on effects of robotic technology for fall prevention in the elderly.

Keywords: fall prevention, elderly, exoskeleton, posture, quality of life.

Introduction

Fall risk has been related to a number of factors such as history of falls, muscle weakness, gait and balance deficit, use of assistive device, visual and mobility impairment, fear of falling, cognitive impairment, depression, age, number of medications, psychotropic and cardiovascular drugs, malnutrition, urinary incontinence, arthritis, home hazards and footwear. The natural ageing process combined with inactivity can gradually lead to decreased physical performance with the result that many elder people are at increased risk of falling [1,2]. In 2009, 2.2 million nonfatal fall injuries among older adults were treated in emergency departments and more than 581,000 of these patients were hospitalized in USA [3]. Twenty to thirty percent of people who fall suffer moderate to severe injuries such as lacerations, hip fractures, or head traumas. These injuries can make it hard to get around or live independently, and increase the risk of early death [4,5]. However, older adults can remain independent and reduce their chances of falling. Physical exercise plays an essential role in this sense. It is also important that the exercises focus on increasing leg strength and improving balance. Exoskeleton technology has potential benefits for wheelchair users' health and mobility [6]. Exoskeletons are employed successfully in stroke rehabilitation and Food and Drug Administration has recently approved the home use of an exoskeleton's model with supervision of a specially trained assistant [7,8]. However difficulty donning and doffing, problems transferring or slow movement may limit use of this supports [9], for this reason we tested the "Human Body Posturizer" (HBP) system that is much lighter and compact (e.g., portable in a case) than other available orthoses.

The Human Body Posturizer (HBP) is a fully articulated orthesis, consisting of four basic elements which come into contact with different anatomical zones, and able to adapt themselves to the physical characteristics of each individual. As a result, users enjoy great freedom of movement and continuous central reprogramming of the users' postural attitude. Given the versatility of the innovative HBP system, it may be worn by the user in its entirety or, alternatively, only choosing to wear some of its elements. The HBP may be used for rehabilitation therapy in water. It is constructed entirely of extremely light and durable plastic materials and metal alloys. These materials are hypoallergenic, therefore the HBP may be worn in contact with the skin. It may be washed with detergent and liquids for sterilization. The complete system weighs 1.5 kg (Fig.1).

A recent study showed that the HBP rehabilitation device may improve response accuracy, walking and posture in Multiple Sclerosis patients by stimulating the Prefrontal Cortex (PFC), which is fundamental in motor control [10]. It has been proposed that age-related decline in executive processes and motor functions is due to alterations in brain activity. In elderly, compensatory response to neuronal deficits or loss of neuronal specialization produce hyperactivation of specific brain areas, particularly in the PFC [11]. Physical exercise appears to reduce this overrecruitment of PFC in elderly patients, with benefits in executive functions mediated by the PFC [12]. Di Russo et al . alternatively, showed in Multiple Sclerosis patients a new pathway for the improvement of executive and motor functions by hyperstimulation of compensation mechanisms (e.g. hyperactivity PFC) using HBP [10].

The aim of this study is to determine whether exposure to physical training with exoskeleton HBP can have a positive effect in elderly with moderate risk of fall in terms of reduction of fall risk and improvement of Quality of life.

Materials and methods

This was a randomized controlled trial conducted in the Sapienza University of Rome in collaboration with Foro Italico University of Rome. The trial, according to Declaration of Helsinki, was approved by the ethics committee of our University and patient anonymity was preserved. All participants gave their written informed consent prior to enrolment.

Eligible participants were young old (60 to 69 years; mean ±standard deviation 64.85± 4.6 ys). The exclusion criteria were the following: medical condition that prevented safe participation in an exercise programme; peripheral artery occlusive disease, diabetic neuropathy, history of stroke, history of inflammatory arthritis, history of vertebral fragility fractures and/or hip or leg fractures in the previous 24 months, Systolic blood pressure (SBP) >200 mmHg and/or diastolic blood pressure (DBP) >110 mmHg. All participants had normal and/or corrected vision. The study took place at the Geriatric Day Service of Department of Cardiovascular, Respiratory, Nephrologic and Geriatrics Sciences of Policlinico Umberto I in Rome.

Older community-dwelling patients who visited the ambulatory of our Department between June, 2014, and September, 2014, for evaluation of cardiovascular risk factors, were considered for this

study. Patients with moderate fall risk (Tinetti score 19-24) were recruited in the trial. Participants were randomly assigned into two groups following simple randomization procedures (computerized random numbers) to 1 of 2 treatment groups. In the first group (HBP group), subjects were assigned to receive physical exercise training using HBP; the second group (Exercise group) subjects were assigned to receive physical exercise training without HBP. At the gym of our Department, each patient was engaged in three sessions of physical exercise a week, with each session lasting approximately 1 hour, under instruction of a therapist. All patients followed a personal exercise program , characterized by walking and balance test and posture strengthening exercises. The physical activity was moderately intense so as not to exceed the target pulse rate, meaning 75% of the maximum pulse rate for the patient being treated (based on the theoretical maximum pulse rate by age, or on the Borg scale) [13]. Blood pressure, resting heart rate and pulse oximetry were assessed before and after exercise.

All subjects of HBP group were trained in the use of exoskeleton. HBP is a fully articulated orthesis, consisting of four basic elements The first modular and plastic element is that which rests on the back. Its central part is adjustable and is secured to the shoulders with braces. It adheres to the trunk, thanks to two flexible lateral supports which adapt to the chest and which are frontally fixed with straps. The second, cranio-cervical, element is characterized by a helmet placed on the wearer's head and on the top of which is inserted a cervical spring mechanism which connects the helmet to the dorsal element, thus enabling complex head and neck movements. The third, modular and plastic, lombo-sacral, element is positioned at the centre of the sacrum. This, in turn, is articulated with the dorsal element and, through the adjustable lateral supports that surround the pelvis, is frontally secured with straps. This element is also characterized by the presence of a mobile and adjustable support which allows users to apply thrust, of greater or lesser intensity, to the lumbar region. It should be noted that the internal sacral part is characterized by forward thrust which is required in order to reposition the pelvis. The fourth and final, modular and plastic, element is that which relates to the lower limbs. Each limb is inserted into the lateral pelvic supports and, placing them at the height of the hip joint, the brackets are laterally positioned at the thigh and the leg. It is important to position the articulated joint between the thigh and leg at knee height. The two moulded brackets are fixed to the limbs by means of straps.

Baseline evaluation included: a complete physical examination, Body Mass Index (BMI), Blood Pressure measurement, Short Physical Performance Battery (SPPB), SF 36 Life Quality Questionnaire, Tinetti Balance and Gait Evaluation Scale and Numeric Rating Pain Scale (NRS).

BMI was calculated by dividing the weight for the square of height (Kg/m2).

Blood pressure was measured twice to the right arm after a rest of 10 minutes with subjects in sitting position, using a mercury sphygmomanometer. Systolic and diastolic blood pressure levels were defined as first and fifth Korotkoff phases.

SPPB is an objective assessment tool for evaluating lower extremity functioning in older persons [14,15] by measuring balance, gait speed, lower limb strength and endurance, all crucial in performing activities of daily living. It consists of the 3 components: balance (3 different standing balance tests); gait speed (4-meter walk at a usual pace); chair stand test (time required to rise 5 consecutive times from a chair without arm rests). Each component was scored from 0 (not possible) to 4 (best performance) and summed in a total score ranging from 0 to 12.

Health-related quality of life was measured using SF 36 Life Quality Questionnaire [16]. It consists of 36 questions, organized into eight domains. The eight domains are physical functioning, Role physical (problems with work or daily acitivites as a results of physical health), Bodily pain, general health evaluation, Vitality, Social functioning, Role emotional; severe problems with work or daily acitivites as a result of emotional health and mental health. All items are coded, scaled and transformed linearly from 0 (worst health) to 100 (best health).

We analyzed the balance and the risk of falls using the Tinetti Balance and Gait Evaluation Scale [17] (28-point scale: <19 indicates a high risk for falls; 19–24 indicates a moderate risk for falls). The NRS (scored 0–10) was used to quantify the pain subjectively.

Although it's known that skeletal factors together with non-skeletal factors may increase the risk of falls, we assessed in the two groups the Bone Mass Density (BMD). Indeed, there is a strong inverse relationship between bone density and fracture risk [18]. BMD of the hip (femoral neck) and spine (L1-L4) was measured by DXA using a QDR 4500 Discovery densitometer (Hologic, Inc., Waltham, MA) in the array

(fan beam) mode by the same technician at each visit. At the screening visit, subjects underwent a single measurement of the left hip and spine.

The primary endpoint was to evaluate the incidence and relative risk of falls in the two groups. The number of falls will be monitored with daily fall diaries. Diaries will be collected monthly through the mail. Details of each registered fall will be ascertained by the investigator. The definition of a fall is "an unexpected event in which the participant come to rest on the ground, floor or lower level" [19].

Secondary efficacy endpoints included change in SPPB, NRS, Tinetti Gait and Balance Scale and SF-36 Quality of life after 6 and 12 months of treatment.

All parameters were checked for normality using the Kolmogorov-Smirnov test. All values are expressed as mean ± standard deviation (SD). Differences between groups were tested using ANOVA test (continuous variables) or chi-square test (categorical variables). $P<0.05$ (for ANOVA) and 0.025 (for Chi Square) were considered to be significant. Significances were adjusted using the Bonferroni method. All analyses were carried out using the SPSS 15.0 statistical package for Windows (SPSS Inc., Chicago, Illinois).

Results

One hundred fifty patients were randomized into two groups: seventy-five subjects into the HBP group (mean age: 64.5 ± 5; males/females: 39/36) and seventy-five subjects into the Exercise group (mean age: 66.5 ± 3.8; males/females: 40/35).

There were no significant differences between the groups regarding the distribution of age and gender. Ninety-eight percent of patients completed 12 months of treatment and had end-of-study clinical parameters. Three patients withdrew from the trial because of new diagnosis of hip fracture (1 subject) and stroke (2 subjects). Participants attended clinic visits at the time of randomization (baseline), at 6-month and at 12-month interval (Fig. 2).

Baseline evaluation didn't show significant differences between the two groups (Table 1). Subjects showed a mean BMI compatible with a diagnosis of overweight. High-normal blood pressure was seen in the two groups of the trial. BMD hip and spine values didn't differ between the two groups, showing normal values

adjusted for age and sex (Range 0.4-1). Subjects showed a moderate pain to the NRS (sites of pain: hips, knees, neck, lower back).

According to primary endpoint, we investigated the fall incidence in the two groups of our trial (Table 2).

The fall relative risk in the HBP group was significantly lower than Exercise group ($p< 0.025$), with a reduction of 68%. In particular, significant decrease was shown in fall risk adjusted for age (65-69 years p value = 0.006) and for sex (Male p value = 0.014). All falls resulted in pain that lasted 3 days or more without others consequences.

At 6 month's and 12 month's evaluation, HBP group revealed a significant improvement in Tinetti Balance Scale, NRS and SPPB ($p<0.05$). The 73 subjects treated with HBP also demonstrated a better quality of life and proprioception, associated with a decreased pain sensation at the NRS (Fig.3). Besides, HBP group showed a good compliance with the exoskeleton.

Discussion

The aim of this study is to determine whether exposure to physical training with HBP support can have a positive effect for fall reduction in elderly. The results at the sixth and twelfth month show a twofold positive effect in the HBP group reducing fall risk and improving quality of life by reducing pain.

On the contrary, in the Exercise group we observed only minimal variations in the test scores. There are many distinct and multifactorial causes for falls in elderly people, including low muscle strength, balance and gait disturbances, cognitive function decline, environmental hazards, and low or high activity levels [20]. So the physical exercise programs on fall prevention should include more interventions aiming at multiple fall risk factors [21]. Although there was limited evidence that multi-factorial interventions, including exercise, were more beneficial than exercise alone, two exceptions should be noted. Campbell et al [22] found that an exercise intervention delivered in the home was not as effective as a home safety intervention for fall reduction in older adults with visual impairment. Further, combining exercise and home safety was no better than the home safety programme alone. However Perula et al. [23] also demonstrated that the multifactorial intervention program (individual advice, information leaflet, physical exercise workshop and home visits) is no more effective than the brief intervention (brief individual advice and information leaflet)

to reduce the overall risk of falls. Poor adherence to the exercise programme may have influenced their results. Several studies showed that exercise programs should particularly include strength, balance, gait, coordination training and cognitive training to effectively reduce falls [24-26]. We hypothesize that the lack of some components in our exercise progam (e.g. coordination training and cognitive training) may underlie this minimal variations in the Exercise group. Contrariwise the use of HBP seems to mitigate the limits of our exercise program. In light of these results, we hold that physical training associated with use of HBP could be a useful instrument for the prevention of falls in the elderly. We also observed progressive improvement linked to an increase in the number of sessions. We believe that physical training can encourage the elderly subject to take a more active role in the health care and prevention of falls. So, our trial highlighted that the use of exoskeleton could improve compliance with physical activity, with a better sense of body and reduction of fall risk. Indeed, our training with HBP support seems more efficacious also in improving quality of life of patients by reducing pain. This is the reason why we intend to further investigate the role of physical exercise with HBP also in depressed subjects, assuming that physical training seems efficacious on control of subjects with light to moderate depression [27].

Nevertheless the current study faces certain limitations. Firstly, the lack of more multidimensional evaluation of patients (i.e. walking speed test, test for mood, etc…). Secondly, the duration of follow up. Further trials will be needed in order to verify the impact of HBP on long-term outcomes, such as fracture risk, survival and quality of life. Thirdly, the lack of instrumental evaluation of Prefrontal Cortex that is implicated in executive and motor control. Fourthly, we tested HBP in a sample with a medium risk of fall; further research should be carried out including elderly with high risk of fall.

Conclusions

The use of Human Body Posturizer (HBP) could be a useful instrument for the prevention of falls in the elderly. Further research is needed to elucidate whether exercise training using HBP can reduce falls or fall risk factors in older adults with chronic conditions including a investigation of possible biological action mechanism (e.g., effects on the Prefrontal cortex).

Compliance with ethical standards Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Conflict of Interest: The authors declare that they have no conflict of interest. Informed consent was obtained from the patients.

Conflict of interest statement

On behalf of all authors, the corresponding author states that there is no conflict of interest.

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Table 1. Baseline evaluation of the two groups of the study

Table 2. Incidence and relative risk of falls adjusted for age and sex in the 12 months of the trial

* Indicates change from baseline to 12 months significantly different from Exercise group at P < 0.025 (Chi-square test); (n)= number.

Figure 1. Characteristics of exoskeleton Human Body Posturizer.

Figure 2. The study flow chart.

Figure 3. 6th month and 12 month evaluation of the two groups of the study.

Values represent group means (standard deviation) at baseline (W0), 6 (W24) and 12 (W48) months.(SPPB = Short Physical Performance Battery; NRS = Numeric Rating Pain Scale; SF-36 QoL = SF 36 Life Quality Questionnaire; * p< 0,05; ** p < 0.01)

Figure 1

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Fig. 2 The study flow chart.

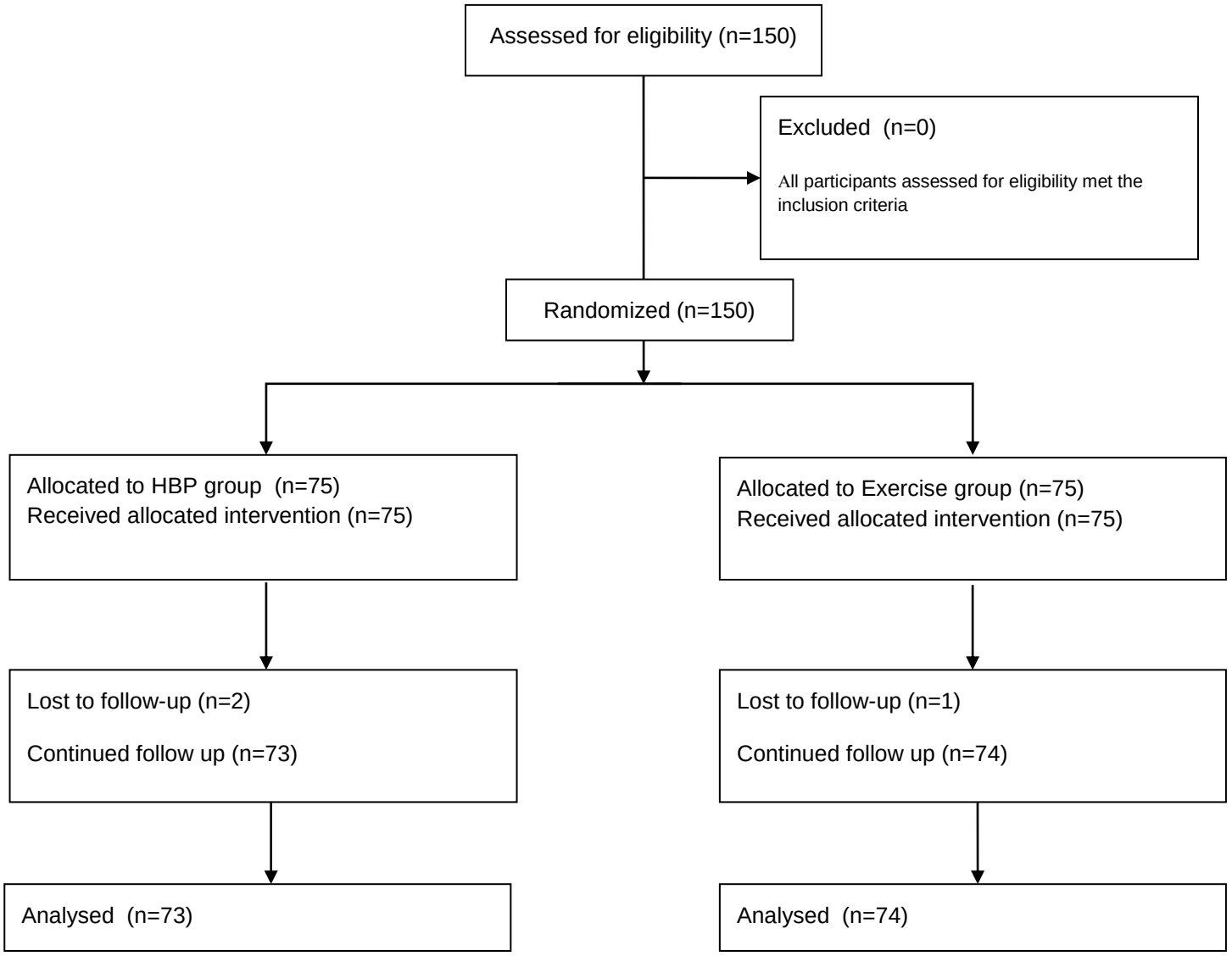

Figure 3

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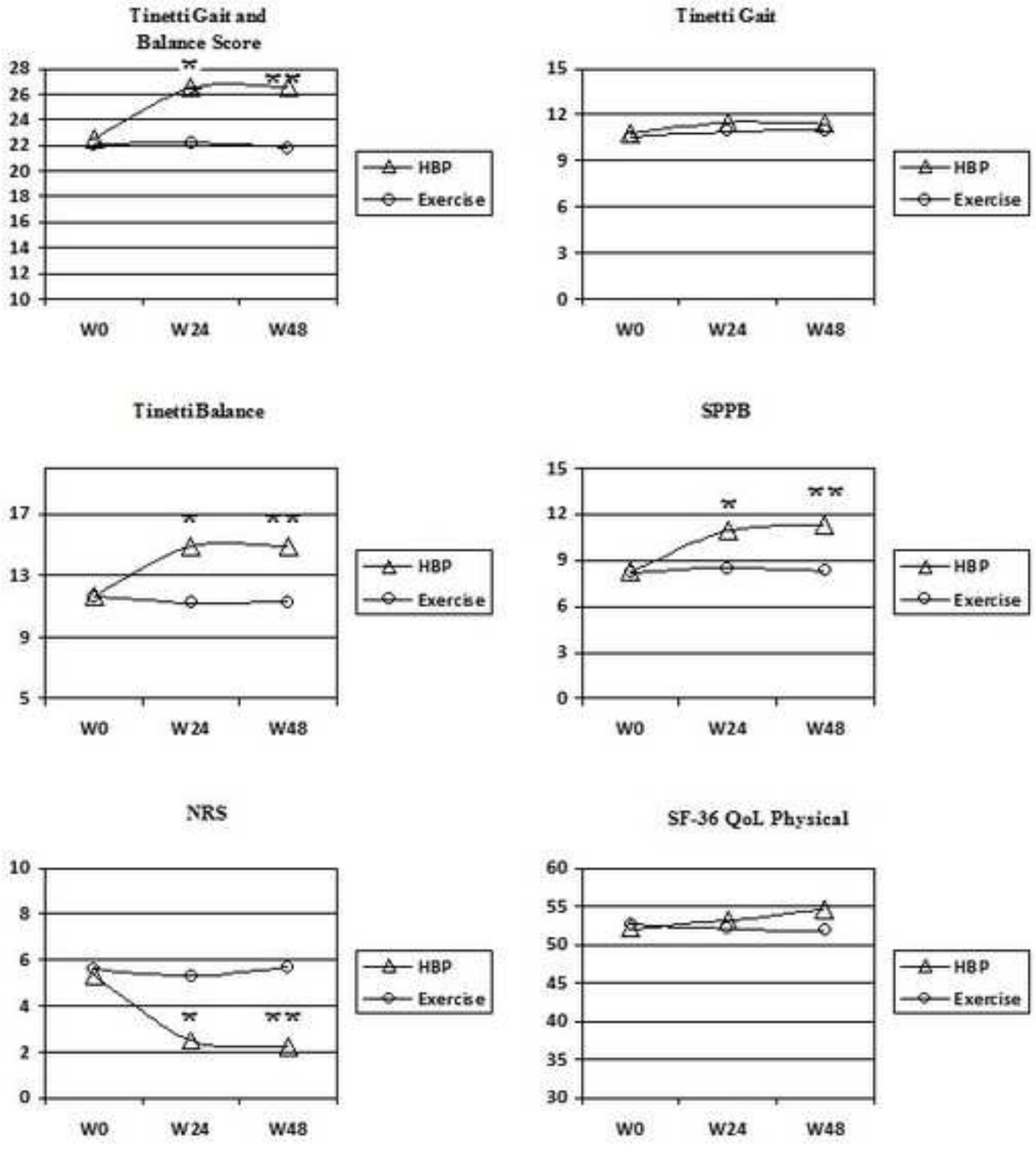

Table 1. Baseline evaluation of the two groups of the study

Baseline	HBP Mean (SD)	EXERCISE Mean (SD)	ANOVA p value
Sex (M/F)	39/36	40/35	> 0.05
Age (years)	64.5 (5)	66.5 (3.8)	> 0.05
BMI (kg/mq)	25.7 (4.1)	25.3 (3.3)	> 0.05
Systolic pressure (mmHg)	133.8 (16)	135.4 (13)	> 0.05
Diastolic pressure (mmHg)	83.5 (7)	85.1 (6)	> 0.05
BMD Hip (g/cm^2)	0.81 (0.1)	0.83 (0.09)	> 0.05
BMD Spine (g/cm^2)	0.88 (0.12)	0.92 (0,13)	> 0.05
Tinetti Gait and Balance Score	22.5 (2.7)	22.1 (3.9)	> 0.05
Tinetti Gait	10.8 (1.7)	10.5 (1.5)	> 0.05
Tinetti Balance	11.7 (1.4)	11.6 (1.9)	> 0.05
SPPB	8.3 (1.4)	8.2 (1.3)	> 0.05
NRS	5.3 (2.1)	5.6 (2.3)	> 0.05
SF-36 QoL Physical	52.1 (6)	52.7 (7.1)	> 0.05
SF-36 QoL Mental	52.2 (5.4)	53.1 (5.3)	> 0.05

Table 2. Incidence and relative risk of falls adjusted for age and sex in the 12 months of the trial

Group	***Number of patients* (HBP/Placebo)**	***Falls*** **HBP (n)**	**Exercise (n)**	**RR (95% CI)**	**P value**
	147 (73/74)	6	19	0.32 (0.14-0.76)	0.022*
Age (years)					
60-64	75 (38/37)	2	6	0.32 (0.07-1.51)	0.08
65-69	72 (35/37)	4	13	0.33 (0.12-0.9)	0.006*
Sex					
Male	77 (38/39)	4	12	0.34 (0.12-0.97)	0.014*
Female	70 (35/35)	2	7	0.29 (0.06-1.28)	0.03

* Indicates change from baseline to 12 months significantly different from Placebo group at $P < 0.025$ (Chi-square test); (n)= number.

December 29, 2015

Stefania Maggi, M.D

Editor in Chief

Aging Clinical and Experimental Research

Dear Dr. Maggi,

We appreciate the opportunity to address comments from the journal editors and referees on our manuscript (ACER-D-15-00365), "*Fall prevention in the elderly using an exoskeleton Human Body Posturizer.*"

We have responded to each point on the following pages. The revised manuscript has been uploaded to the submission website.

We believe that the revisions have improved the quality of the manuscript and we are grateful for the Reviewer's and Editor's time spent in evaluating this article.

Sincerely,

Walter Verrusio, M.D., Ph.D.

"Sapienza" University of Rome

Department of Cardiovascular, Respiratory, Nephrologic, Anesthesiologic and Geriatric Sciences, Viale del Policlinico 155, 00162, Rome, Italy.

Reviewer #1:

In this paper, authors performed a randomized controlled trial to investigate the efficacy of exoskeleton Human Body Posturizer in elderly for fall prevention. There are quite substantial criticisms to be addressed which make the paper unsuitable for publication in the present form. Although of potential interest, this work suffers from several limitations.

First, the population did not include elderly individuals (age ranged from 60 to 69 years, mean age was 64.85 years old).

We have amended the title regarding to the Reviewer's comments.

In the second paragraph of the "Materials and methods" section, we have added this change.

Furthermore, you have to report the prevalence of osteoarthritis and/or visual impairments in your population, in order to investigate the role of confounding factors.

In the second paragraph of the "Materials and methods" section, we have added this information.

Finally you should report the number of falls in the last 12 months and related consequences.

Table 2 shows the number (n) of falls in the last 12 months.

In the sixth paragraph of the "Results" section, we have added this information.

We recommend you to make the following substantial corrections:

1. You have to refer to the CONSORT 2010 checklists to improve the manuscript

We have further amended the manuscript regarding to the CONSORT 2010 checklist .

TITLE and ABSTRACT

2. For RCT the study design must be included in the title

We have amended the title regarding to the Reviewer's comments.

3. At the line 3 page 2 put a semicolon after the mean age 69,95. Moreover replace 69,95 with 69.95

We have made this change.

INTRODUCTION

4. Page 4, line 1. Check the sentence ("accuracy"?)

In the fourth paragraph of the "Introduction" section, we have re-formulated this sentence.

METHODS

5. Describe how sample size was determined

In the third paragraph of the "Materials and methods" section, we have added this information.

6. Define the recruitment period.

In the third paragraph of the "Materials and methods" section, we have added this information.

7. Provide rationale for blood pressure and BMD measurements.

In the second and eleventh paragraphs of the "Materials and methods" section, we have added this informations and cited the reference n. 18

8. Page 6. The primary endpoint is not clear. You should clarify the objective of the study.

In the twelth paragraph of the "Materials and methods" section, we have added this information.

9. Page 5. You have to specify the skeletal site of BMD measurements at hip (femoral neck, total hip or both?) and spine (L1-L4 or L2-L4;

In the eleventh paragraph of the "Materials and methods" section, we have added this informations.

did you exclude patients with history of vertebral fragility fractures?).

In the second paragraph of the "Materials and methods" section, we have added this informations.

Moreover, why did you measure BMD of the right hip? Measurement of the non-dominant limb should be more appropriate.

We apologize for this error and in the eleventh paragraph of the "Materials and methods" section, we have corrected the text as suggested.

10. Page 5. You have to better define the personal daily exercise program. Provide further details (eg. setting, frequency, duration, intensity).

In the third paragraph of the "Materials and methods" section, we have added this informations and cited the reference n. 13.

RESULTS

11. Replace 150 with "One hundred fifty".

We have made this change.

12. "There were no significant differences between the groups regarding the distribution of age, gender, diseases and pharmacological treatment". This assertion is not supported by your methods because you did not report any comorbidity burden assessment neither details about pharmacological treatment.

We have amended the second paragraph of the "Results" regarding to the Reviewer's comments.

13. "The 73 subjects treated with HBP also demonstrated a better quality of life and proprioception, associated with a decreased bone pain sensation". Clarify this sentence: what does it mean "bone pain sensation?".

In the last paragraph of the "Results" section, we have edited this sentence to comply with this request.

Furthermore, what are the causes of pain in your population?

In the fourth paragraph of the "Results" section, we have added this information.

DISCUSSION

14. "…in the Exercise group we observed only minimal variations in the test scores". Your results are not in line with those reported in literature and should be discussed.

15. "In light of these results, we hold that physical training associated with use of HBP could be a useful instrument for the prevention of falls in the elderly". This sentence is does not support what you said earlier.

We have edited the section of "Discussion" to comply with this request and cited the references n 21, 24-26.

16. "We also observed progressive improvement linked to an increase in the number of sessions. Interventions lasting longer than 6 months reduce the rate of falls [20]. Shorter exercise interventions (i.e., less than 6 months) also have shown positive results in fall risk reduction. In the shortest exercise intervention (2 weeks), the authors reported improvement in getting up from the floor, a specific functional task related to falling and fall recovery [21]. Another trial showed that adapted physical activity plays a relevant role in secondary prevention of osteoporosis, also when performed in swimming pools [22]. However Perula et al. [23] also demonstrated that the multifactorial intervention program (individual advice, information leaflet, physical exercise workshop and home visits) is no more effective than the brief intervention (brief individual advice and information leaflet) to reduce the overall risk of falls. We believe that physical training can encourage the

elderly subject to take a more active role in the health care and prevention of falls. Our training with HBP support seems more efficacious also in improving quality of life of patients, this is the reason why we intend to further investigate the role of physical exercise with HBP also in depressed

subjects, assuming that physical training seems efficacious on control of subjects with light to moderate depression [24].". This part should be removed because it is not relevant to your study.

We have edited the section of "Discussion" to comply with this request

17. Page 8. "Our training with HBP support seems more efficacious also in improving quality of life of patients…". This sentence is not supported by your results.

We have amended the first paragraph of the "Discussion" regarding to the Reviewer's comments

REFERENCES

18. Review the references because we found some errors in how they are written and structured.

We have edited the section of "References" to comply with this request. Please note that, with the inclusion of the new references which we believe would be of interest to readers the manuscript now contains 27 references.

Reviewer #2:

Dear Authors, your article is well done. Your work is interesting. It provides results that can give new therapeutic possibility for the management of elderly in order to be able to prevent falls and consequently improve their daily living. The article does not need of any main revision; there are only a criticism about the administration of rehabilitation program: what about the dose and time of administration of physical exercise program. How many time a day? Alone or with a therapist? It is an home rehabilitation program?

In the third paragraph of the "Materials and methods" section, we have added this informations.

Finally it would be interesting to evaluate the effects of exoskeleton HPB also in elderly with high risk of fall; why did you test only in people with a medium risk?

Reviewer is right in stating that it would be interesting to evaluate the effects of exoskeleton HPB also in elderly with high risk of fall. However, in this study we preferred assess the effect of HBP in a sample of young old (60 to 69 years), so this may explain the medium risk of falls of subjects.

We have considered the Reviewer's comments and have highlighted this point in the last paragraph of the "Discussion" section.

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The corresponding author should be prepared to send the potential conflict of interest disclosure form if requested during peer review or after publication on behalf of all authors (if applicable).

☑ We have no potential conflict of interest.

Category of disclosure	Description of Interest/Arrangement

Article title Fall prevention in the young old using an exoskeleton Human Body Posturizer. A Randomized Controlled Trial.

Manuscript No. (if you know it) _____

Corresponding author name Walter Verrusio

Herewith I confirm, on behalf of all authors, that the information provided is accurate.

Author signature _____ Date 30/12/2015