Development and Validation of an Exercise Programme for Recovery Balance Impairments in Poststroke Patients

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Background: Deterioration of balance is one of the most common and disabling physical-motor deficits in patients after a stroke that have a negative impact on quality of life and increase the risk of falls. Previous studies have evaluated the effectiveness of the exercises on specific aspects of balance. However, there is no structured exercise program divided by levels for balance impairment in poststroke patients. *Methods:* Delphi method was used to design the exercise programme, and then a pilot study was performed. For the pilot study, we included 14 poststroke adults patients ($n = 7$ in each group), with balance impairment, without previous severe functional dependence, sensorial deficit or dementia. Our 4 weeks intervention (5 times/week) is based on 9 exercise of progressive difficulty, offering a multidimensional approach training (biomechanical constraints, stability limits, anticipatory, postural responses, and sensory orientation). Patients in the intervention arm received 45 minutes of usual rehabilitation plus 15 minutes of the intervention proposed. The usual-care arm received 60 minutes of usual rehabilitation. Balance impairment (Mini BESTest) was assessed at the baseline and at 4 weeks. Differences between groups were analysed using Mann-Whitney U test. *Results:* The agreement for the intervention designed was reached after 2 rounds. Participants in pilot study were 69 (SD = 9.7) years, 21.4% females. Post-treatment, median improvements in Mini BESTest were 20 (SD = 8) and 11 (SD = 10) points, $P < .01$ for intervention and control group respectively. *Conclusion:* A multidimensional approach of balance impairments in poststroke patients through the validated exercise programme proposed, may improve balance deficits.

Key Words: Balance impairment—stroke rehabilitation—Delphi method—falls prevention

Introduction

Stroke is one of the leading causes of disability, especially in older adults, in whom the incidence and prevalence reported are higher than in younger individuals.[1] According to the World Health Organization, 65% of all strokes occur in individuals aged 65 years and older.[2] Regardless the age, different studies reported that 25%-75% of all stroke survivors will have some degree of dependence to perform at least 1 activity of daily living (ADL), which has a direct impact in the social and health burden worldwide.[3,4]

The main aim of rehabilitation treatment is to reduce the impact of motor and/or cognitive deficits, in order to recover the maximum previous functional capacity.[5] Recently, the American Heart Association/American Stroke Association published a clinical guideline for acute

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Received May 24, 2019; revision received July 11, 2019; accepted July 19, 2019.

Financial Disclosure: No funding support.

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1052-3057/$ - see front matter

https://doi.org/10.1016/j.jstrokecerebrovasdis.2019.104314

stroke events, including some rehabilitation pathways.[5] Nevertheless, post-acute rehabilitation treatments are less well described. One of the most common poststroke deficits is balance impairment, which recovery is essential to maintain the autonomy in ADL[6] (eg, transfers, walk, climbing stair, etc.). Poststroke gait impairments (ie, unsafe, slow, and painful) are present in approximately 40% of stroke survivors, and it has been associated with higher rates of functional dependence, poor quality of life, and increased risk of adverse health events such as falls, hospital admissions, institutionalization, and death.[7,8] Despite the evidence that supports the importance of those deficits, no specific and structured rehabilitation guidelines to address all this deficits are available.[9]

The ability to walk is influence by a wide range of factors, among which balance is one of the most important.[8] Balance control is also a complex process that requires the coordination of sensorial, cognitive, and motor strategies. Horak et al (1996), propose a holistic and integrated balance approach based on the assessment of following neurophysiological components: biomechanical restrictions, stability or verticality limits, anticipatory postural adjustments, postural responses and sensory orientation.[10] Recently studies described the efficacy of specific rehabilitation interventions on poststroke balance impairments; however, all of them address only specific components of balance capacity.[11] Nowadays, structured rehabilitation guidelines on poststroke balance impairments, that allow a unify and holistic approach are necessary in order to decrease poststroke disabilities.[6]

The aim of our study was to design, validate, and assess the feasibility of a comprehensive exercise programme intervention to improve balance impairments in poststroke older adults.

Material and methods

Our study was divided in 2 stages: (1) Stage1: Design of the balance exercise programme which was designed by a Delphi technique based on expert judgement method; and (2) Stage 2: Pilot study to validated and assess the feasibility of the programme proposed.

1. Stage 1: Design of the exercise programme

Based on the available scientific evidence, we design a multidimensional exercise programme for poststroke balance impairments. Then, we performed the evaluation programme proposed by a Delphi technique. Delphi method is a well-recognized method to gather together expert opinion, through a repetitive, anonymous, and iterative questionnaires, which is aimed to achieve an expert's group consensus where information or questionnaires they evaluate are exhaustive and specific for the purpose.[12] Due to it characteristics, Delphi surveys are frequently used in health research, especially in topics where evidence is limited or conflicting.

Participants

Spanish experts on neurorehabilitation from all over the country, who were physiotherapists, neurologists, or geriatricians, with more than 5 years of clinical experience in the field were selected. After identifying all the possible participants, an email explaining the project and inviting them to participate in the Delphi process was sent. Eleven experts were willing and committed to participated.

Survey Process

Once all the experts gave their consent for participation, an online questionnaire was sent. The online survey was chosen instead of paper, due to the higher likelihood of participation and lower rates of missing data. Participants were requested to complete the questionnaire within 2 weeks. If any participant did not achieve this deadline, an email remainder was sent. In order to avoid possible group biases, derived from the experience of some of the team members, participation always remains anonymous.

The panel of experts were asked to fill in the questionnaire for the first time. After their responses, the data were summarized and based on the results obtained, a new questionnaire was created. The experts received this second questionnaire and they were asked to give their opinion again based on group responses. These processes were repeated until consensus was reached.[13] The number of answers in each round was monitored to control dropouts.

The Questionnaire

In order to address the different balance components described by Horak et al[10] a multidimensional physiotherapy approach for poststroke balance impairment treatment was designed. The exercises proposed must be always applied under the supervision of a physiotherapist. It was established 2 progressive levels of difficulty, the first level for patients with no sitting balance impairment and the second one for patients able to stand up at least 30 seconds, without external help. To progress to the next level, the patient must be able to perform all the exercises of the previous level, in the order proposed (Table 1).

A 9-item multiple choice questionnaire was developed in order to assess agreement of the expert with the inclusion of the specific exercise in the poststroke balance impairment rehabilitation programme proposed. Participants were requested to rank their level of agreement through a 5-point Likert scale, range from 1 to 5 ("strongly disagree", "disagree", "indifferent", "agree", and "strongly agree"). In addition, participants were asked to provide comments and suggestions after each question, if necessary.

Table 1. *Structured of the poststroke balance impairment rehabilitation exercise focused on balance systems*

Level 1 (N1): 4 Exercises

The exercises should always be performed in the same progression order.

• Stimulation by foot pressure on the foot support points (N1.1)

The physiotherapist, should press with his thumb, slightly without moving the foot on the support points used during the march (tripod plantar), respecting the order in which the footfalls (first the heel, second the head of the fifth metatarsal, and finally the head of the first metatarsus). In each of the 3 mentioned points, the following sequence must be repeated 3 times: 3 seconds of pressure, alternating with 2 seconds of rest. The approach will always be in the same order. The sequence will be performed 5 times on each foot, alternately, starting with the foot of the healthy hemibody to continue with the foot of the affected body.

The patient is asked to press the tips of the feet on the floor, slightly separating the heel from the floor. Next, you will be asked to return to the starting position (feet completely resting on the ground) and from this position press the heel against the ground trying to lift them off the ground. It will be repeated 5 times.

The movement from sitting to standing will be made a total of 6 times (3 repetitions of each change of position). In the cases that are necessary, the pauses required by the patient's functional situation will be carried out.

• The movement from sitting to standing with the paretic side food delayed will be made a total of 6 times (3 repetitions of each change of position). In the cases that are necessary, the pauses required by the patient's functional situation will be carried out.

Level 2 (N2): 5 Exercises

The exercises should always be performed in the same progression order.

•Unbalance exercise while standing (N2.1)

(*Continued*)

Before starting the imbalance exercises, the patient should be guided so that he or she is able to feel the weight of his or her body evenly on the soles of the feet and, if necessary, provide feedback on how to achieve it. When the patient is standing, a force of sufficient intensity will be applied to the anterior part of the body to cause a slight movement (disturbance of balance) and the patient will be expected to recover his balance. The disturbances will be made alternately starting with the healthy hemibody, to continue with the afflicted hemibody, the pressure can be exerted from previous to posterior or vice versa. The order will be: shoulders, lower third of the thigh and anterosuperior iliac spine. The following times, this order should not be followed since it could condition learning and anticipatory behavior.

When the patient is standing, they will be asked to hold this position for 10 seconds on the Balance-pad, it can be repeated up to 3 times as long as the patient is not fatigued.

While standing, the patient will be asked to pass all the weight of his body to the healthy side and perform a 90° flexion of the hip and a slight knee flexion of the affected side. The patient should try to maintain this monopodal posture without any external support, at least 5 seconds. Next, the patient will be asked to perform the same position, but with the affected side in full load and the healthy side in flexion. A total of 6 repetitions will be performed (3 times on each limb). If the patient could not perform this exercise, he will try to work with the help of a stool, which will be placed as a support under the leg that does not remain in full load.

•Monopodal support training with Balance-pad (N2.4)

• When the patient is standing on a Balance-pad, the patient will be asked to pass all the weight of his body to the healthy side and perform a 90° flexion of the hip and a slight knee flexion of the affected side. The patient should try to maintain this monopodal posture on the unstable cushion, without any external support, for at least 5 seconds. Next, the patient will be asked to perform the same position, but with the affected side in full load and the healthy side in flexion. A total of 6 repetitions will be performed (3 times on each limb).

Before starting the monopodal foot exercises on the Balance-pad, the patient will be guided so that he/she can feel how his body feels when he/she is in a balanced situation, with special emphasis on the distribution of the weight of the body on his/her feet. The patient should notice the weight of his body distributed on both feet equally and distributed equally throughout the foot. While the patient is standing, the patient will be asked to pass all the weight of his body to the healthy side, perform a 90° flexion of the hip and a slight knee flexion of the affected side and close the eyes. The patient should try to maintain this monopodal posture with closed eyes, without any external support, for at least 3 seconds. Next, the patient will be asked to perform the same position, but with the affected side in full load and the healthy side in flexion. A total of 6 repetitions will be performed (3 times on each limb).

In order to reach a better understanding of the answers, answers on the 5-point Likert scale were analysed as numerical scores.

Evaluation

Before the survey, experts were asked to assess (from 0 to 1) their level of knowledge on the field (Knowledge coefficient [Kc]). In parallel, the principal researcher assessed from the experts (from 0 to 1): (1) Experience on field built through the clinical practice (Exp); (2) Knowledge on the national and international scientific evidence on the field (Kno), and (3) Intuition and Knowledge of technology tools available in the field (Tec).

Based on these concepts, the expert competence coefficient (K) was calculated as the average between the knowledge coefficient (Kc) and the argumentation coefficient (Ka). Where, Ka is the weighted average of Exp (.4), Kno (.3), and Tec (.005). The weights considered were defined based on the indications of Barroso and Cabero[14] and the evaluation of the influence of each item.

$$\mathrm{Ka} = \frac{0.4 * \mathrm{Exp} + 0.3 * \mathrm{Kno} + 0.05 * \mathrm{Tec}}{0.4 + 0.3 + 0.05}$$

Statistical Analysis

The median (Me), quartiles 1 (Q1) and 3 (Q3), and answer trend of each answer were analysed. Consensus was defined as the convergence in the answers between the Me, Q1, and Q3 for each question, in each questionnaire round. The following parameters were used to defined consensus: (1) Interquartile Range (IQR): Q3 minus Q1, which is expected to decrease when the first and second round are compared and (2) Interquartile Relative Range: Q3 minus Q1 divided by Me and all multiplied 100, we defined arbitrarily a Interquartile Relative Range under 15% as an indicator of consensus.

In addition, the Fleiss kappa coefficient (γ) was calculated in order to assess the reliability of agreement between the experts ($\gamma \leq .4$: poor; $.4 < \gamma \leq .6$: moderate; $.6 < \gamma \leq .8$: good and $\gamma > .8$: excellent agreement).[15]

The analysis was performed with the R Project for Statistical software.

Regarding the Delphi method, to reach a better understanding of the experts answers, responses by the 5-point Likert scale were analysed as numerical scores.

2. Stage 2: Pilot study

After validate the exercise programme proposed by the Delphi method, a pilot study was performed to validated and assess the feasibility of the programme.

Participants

We included poststroke (ischemic or haemorrhagic) adults admitted to a rehabilitation unit of an intermediate care hospital in Barcelona, Spain. Participants must have sitting trunk control and were exclude if stroke occurred more than 3 months before admission, the presence of previous severe functional dependence (Barthel Index $\leq$ 60 points), previous orthopaedic, neurological, or other impairments that could influence balance, Wernicke aphasia or mixed aphasia previous or after stroke, delirium at admission, possible cognitive impairment (Mini Mental State Examination score $\leq$ 24 points) or previous visual deficits.

After identification of possible participants, the principal researcher was in charge to inform and offer participation to all possible participants. In case, they accept, participants were asked to sign an informed consent. The protocol was approved by the Clinical Research Ethics Committee of the Universitat Autónoma de Barcelona.

Study participants were randomly allocated to either the intervention or control group by a random computer-generated list. The randomization was managed and control by an external researcher, who was not involved in the treatment or the follow-up visit. The allocation sequence was save in sequentially numbered, sealed, and opaque envelopes.

Intervention

Participants included in the usual-care arm, received the usual poststroke rehabilitation programme, which included a 4-weeks period, 60 minutes/session, 5 times a week (20 sessions) of physiotherapy techniques and exercises (eg, tone facilitation, stretching, passive mobilization, and range-of-motion exercises for the paretic side and walking between parallel bars). As part of the multidisciplinary intervention in the intermediate care hospital, participants received also occupational therapy and nursing and medical care. Additionally, activities to promote postural control and task directed movements were performed.

Participants in the intervention group received usual-care treatment (45 minutes/day) plus 15 minutes/day of the poststroke rehabilitation programme proposed, 5 times/week, 4 weeks in total (20 sessions). All the physiotherapists performing the usual and intervention care were previously experts in neurorehabilitation, however, in order to unify the application of the intervention programme, all of them received 2 days of training.

Outcomes

The balance impairments were assessed by a blinded evaluator before (T0) and after the intervention (T1) with the Mini-BESTest, a 14-items clinical balance test[16] which aim to evaluate the 4 different balance subsystems ("Anticipatory postural adjustments," "Postural

responses," "Sensory orientation," and "Balance during gait"). Each item is scored from 0 (lowest level of function) to 2 (highest level of function) and the maximum total score is 28. This test is a reliable and valid instrument for assessing balance performance in poststroke patients.[17,18]

Sociodemographic and clinical characteristics at baseline were also collected.

Statistical Analysis

Baseline sociodemographic and clinical characteristics were described using percentages and median and IQR for categorical and continuous variables respectively. In both groups the differences between the scores obtained in T1 and T0 for the 4 subscales and total score of Mini BESTest was calculated. The Mann-Whitney U test was performed to evaluate differences between both groups. The analysis was performed with SPSS V.23 and *P* values <.05 were regarded as statistically significant.

Ethics Considerations

The present study was conducted in accordance with the ethical considerations of the Declaration of Helsinki. All experts were informed of the aim and procedures included in the present study. All participants gave their written consent before participation.

The study was evaluated by the Ethics Committee on Animal and Human Experimentation of the Universitat Autónoma de Barcelona.

The study authors have no known conflicts of interest to declare.

Results

1. Stage 1: Design of the exercise programme

A total of 11 experts were invited and accept to participate in the study. Regarding their self-assessment of their level of expertise, the mean Kc was .80 (SD = .07), while the principal researcher gave them a mean Ka of .80 (SD = .12). Thus, the mean expert competence coefficient (K) was .80 (SD = .07). According to the criteria indicated by Barroso and Cabero,[14] the level of expertise was high.

Only 2 rounds of questionnaires, applying the Delphi method, were needed to validate the designed balance exercise programme. The participation rate of experts in the first round was 100% (n = 11) and 90.91% (n = 10) in the second round.

In the first round, the participant responses were "agree" (4 points) or "strongly agree" (5 points) in 6 of the 9 questions asked, with 60% (n = X) of answers "totally agreed." The 90.91% (n = 10) of the participants were "strongly agree" in the approach of exercises N2.1, N2.3, N2.4, and N2.5. Additionally, questions related to exercises N1.3, N2.2, and N2.4 generated more discrepancy among the participants. Specifically, exercise N1.3, 63.64% (n = 7) showed "strongly agree," 27.7% (n = 3) "agree," and only 9.09% (n = 1) "indifferent." Regarding exercise N2.2, 81.82% (n = 9) of the participants were "strongly agree," 9.09% (n = 1) "agree," and 9.09% (n = 1) "disagree." Finally, in exercise N2.4, 90.91% (n = 10) of the participants were "strongly agree" and 9.09% (n = 1) rated it as "indifferent."

In the second round, 60.0% (n = 6) were "totally agree" with exercise N1.1; 70% (n = 7) with exercise N1.3; 80% (n = 8) with exercises N1.2, N2.2, and N2.3; 90% (n = 9) with exercise N1.4 and 100% (n = 10) with the exercises N2.1, N2.4, and N2.5. (Figs 1 and 2).

Except for exercise N1.1, in all the questions the IQR remained stable or decreased in both rounds. In addition, except for N1.1, during the second round the RIR was less than or equal to 15%. Despite these results, as the 100% of the participants responded "agree" or "strongly agree" with the approach of exercise N1.1, it was considered that consensus was reached. The γ coefficient was .567 in the first round and .757 in the second round, which indicates a moderate and good agreement between the experts, respectively.

2. Stage 2: Pilot study

A total of 14 consecutively poststroke patients admitted to an intermediate care hospital were included (n = 7 in each group). The mean age was 69 (SD = 9.7) years and 21.43% were females. The baseline clinical characteristics are reported in Table 2. Baseline clinical characteristics and poststroke balance impairments were comparable between both groups. Participants in both groups were generally independent for basic ADL (median Barthel Index = 100, IQR = 1) previous the stroke event and more than 64.3% had a valid caregiver.

After the rehabilitation treatment, participants included in the intervention group present greater improvements on balance, specifically in the subitems "Anticipatory postural adjustments," "Sensory orientation" and "Balance during gait," and in "Mini BESTEst total score" (Table 3). Participants who received the proposed rehabilitation exercises improved 9 points more than the usual-care group in the "Mini BESTEst total score."

Discussion

The present study proposes a comprehensive and integrated rehabilitation treatment guideline, for a multidimensional approach of poststroke balance impairments. This guideline was designed through the Delphi method, with the participation of Spanish neurorehabilitation experts. According to the pilot study conducted, participants included in the intervention group had higher improvement on balance impairments than the usual-care group. These finding suggest that the rehabilitation exercise

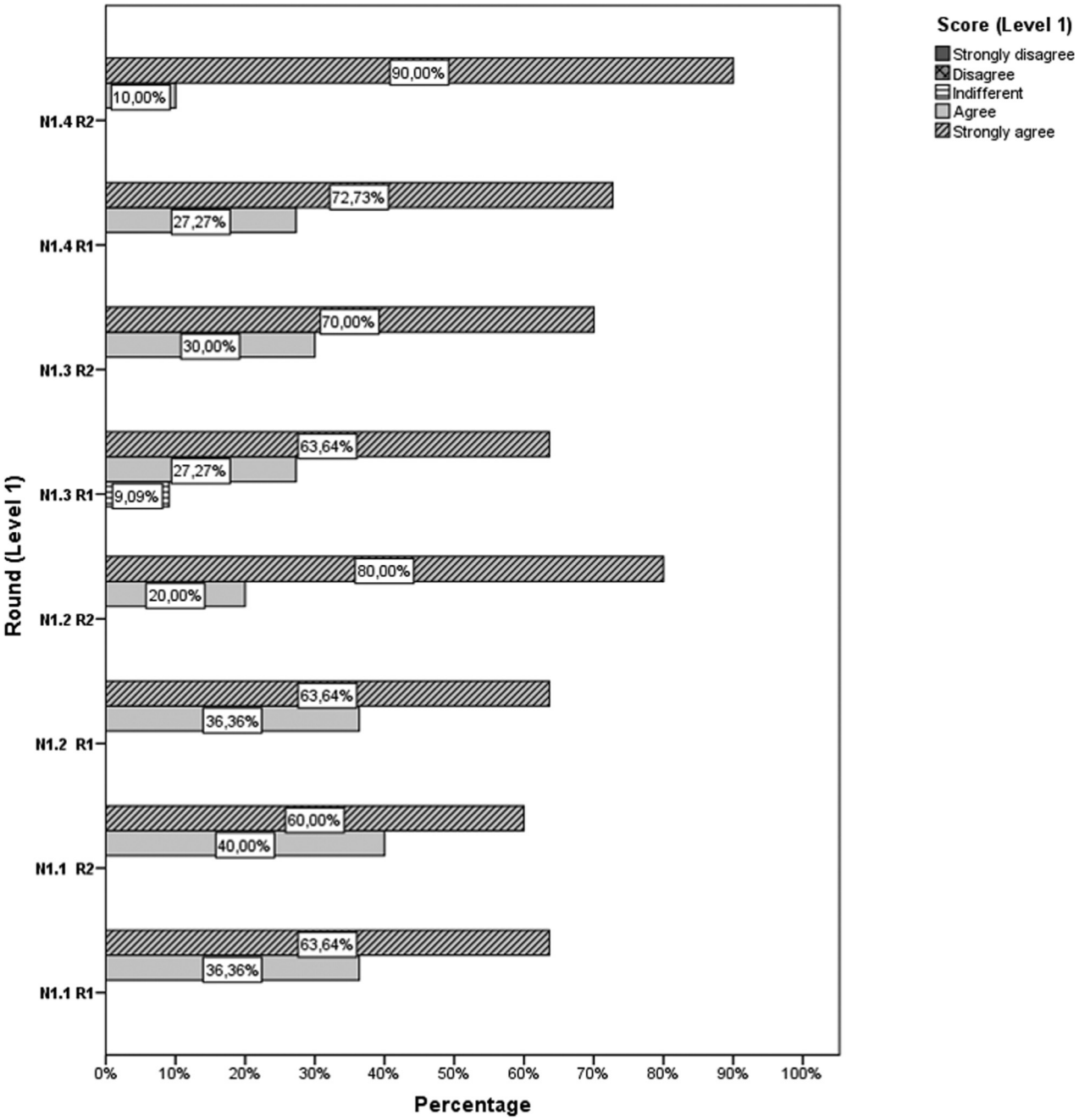

Figure 1. *Answers to the questions of the first level of difficulty in both rounds.*

programme proposed may be a valid tool to assess and treat poststroke patients with balance impairments.

The proposed guideline has been carefully designed, including exercises which have been previously described as potentially beneficial for balance impairments, according to the balance components described by Horak et al (2006).[19] Such a thorough designed and development process could be the reason of the high degree of agreement after the first questionnaire round, and that only 2 rounds were needed to reach the consensus among the experts about the rehabilitation programme proposed.

The rehabilitation exercise programme that we propose established 2 levels of difficulty progression. The first one start when the patient is able to maintain sitting trunk control, and the second one start when the patients is able to maintain standing balance. Current studies and treatment guidelines for poststroke balance impairments focus mainly on dynamic balance disorders (ie, the ability to maintain postural stability and orientation in locomotion). Thus, physiotherapy treatment does not begin until the patient is able to maintain balance while standing or even worse, when gait training has already started.[11] This could explain

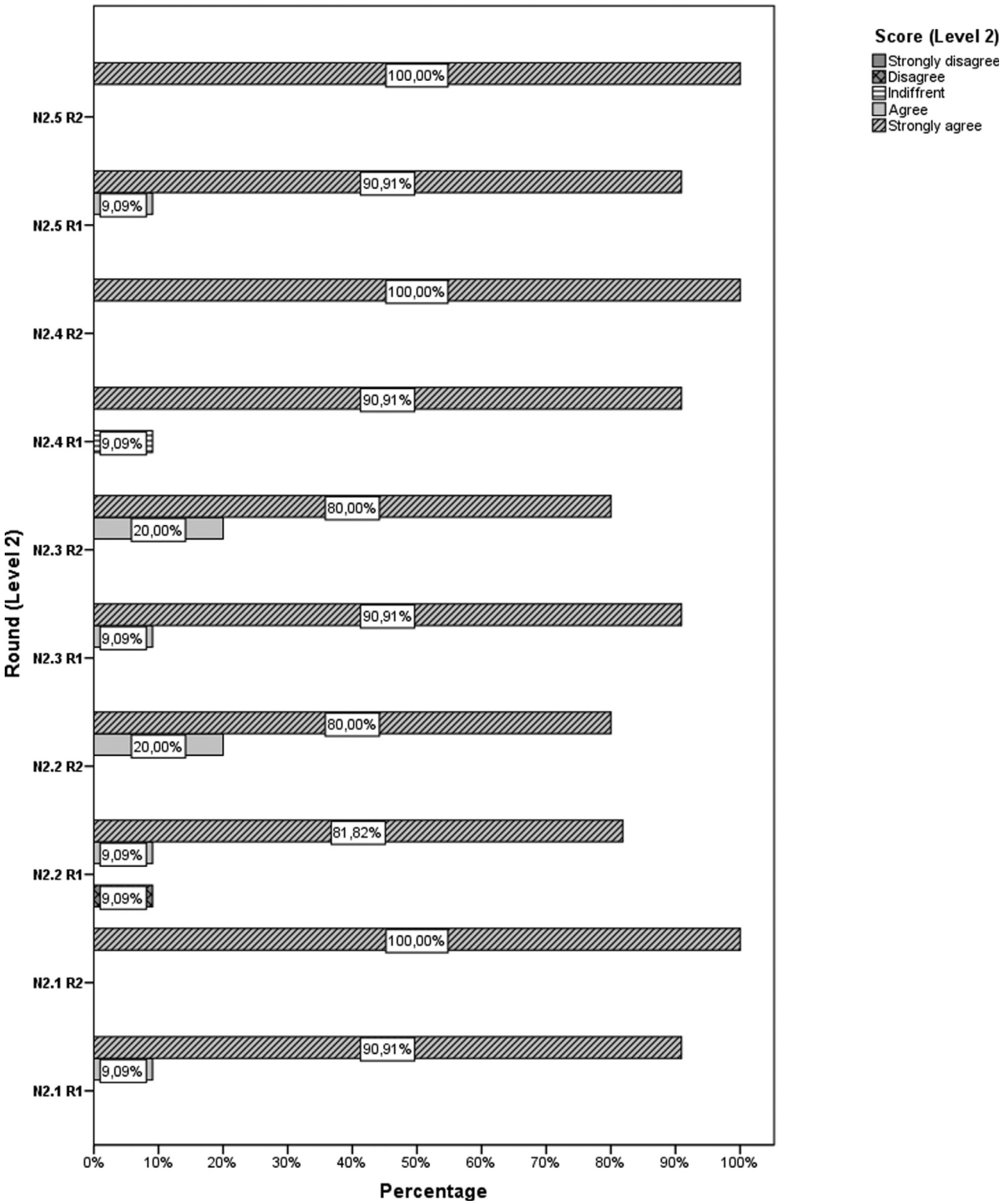

Figure 2. *Answers to the questions of the second level of difficulty in both rounds.*

why consensus was more difficult to reach on questions concerning the first level of difficulty and easily to reach for the second level. The approach proposed with 2 levels of difficulty gives the opportunity to perform a more comprehensive assessment and allows to start balance physiotherapy treatment on patients with severe neurological impairments, in whom usually this rehabilitation treatment starts later.

Moreover, the validity of the rehabilitation programme proposed was reinforce by the pilot study results, which showed that participants included in the intervention

Table 2. *Baseline characteristics of study participants*

	Group	
	Usual-care (n = 7)	Intervention (n = 7)
Age (y)	71 (23)	70 (17)
Women	28.6 (2)	14.3 (1)
Ischemic stroke	85.7 (6)	85.7 (6)
Caregiver present	71.4 (5)	57.1 (4)
Previous Barthel Index	100 (5)	100 (0)
Dominant side (right)	85.7 (6)	85.7 (6)
Survivors of transient ischemic accident (TIA)	14.3% (1)	.0% (0)
Survivors of a stroke	42.9% (3)	.0% (0
Antecedents of dyslipidemia	57.1% (4)	42.9% (3)
Antecedents of atrial fibrillation (AF)	14.3% (1)	42.9% (3)
Antecedents of high blood pressure (HBP)	85.7 (6)	85.7 (6)
Antecedents of chronic obstructive pulmonary disease (COPD)	.0% (0	28.6% (2)
Fibrinolysis	14.3% (1)	14.3% (1)
Carotid stenosis	14.3% (1)	.0% (0)
Thrombectomy	14.3% (1)	.0% (0)
Dysphagia	28.6% (2)	28.6% (2)
Affected hemisphere (left)	71.4% (5)	42.9% (3)
NIHSS before 24 h after stroke	9 (9)	9 (11)
NIHSS upon admission to the rehabilitation center	7 (2)	4 (8)

Numbers are expressed as percentage (n) or median (interquartile range).

group achieved better results on dynamic standing balance. Regarding the anticipatory subscale, the positive results in favour of the intervention group, allows this patients to be able to perform easily, independently and without support of the hands, the sit-to-stand transfer. This improvement can be explained, in part, by training on exercises N1.3 and N1.4, which attempt to train this movement with the feet in different positions (Table 1). In this sense, our results also support previous theories which ensure that specific repeated work promotes motor learning and improves muscular strength of the lower extremities, especially from the quadriceps.[20,21] Additionally, the intervention group also achieved greater improvements in the sensory orientation subscale. This improvement may be secondary to the training on unstable surfaces with exercises N2.2 and N2.4. The importance of this results relies on the neuromuscular function activation changes of the ankle, which provides information on postural control and promotes patient safety during standing and walking movements.[22]

Our study has several strengths. First, to the best of our knowledge, this is the first Delphi survey-developed

Table 3. *Differences on MiniBESTest between groups*

	Baseline (T0)	Post-treatment (T1)	Difference (T0-T1)	*P* value
Anticipatory				
Usual-care group	1 (1)	4 (3)	3 (2)	.026*
Intervention group	1 (2)	6 (0)	5 (2)	
Postural responses				
Usual-care group	1 (1)	4 (3)	3 (3)	.260
Intervention group	1 (1)	5 (2)	4 (3)	
Sensory orientation				
Usual-care group	1 (3)	5 (3)	2 (3)	.017*
Intervention group	1 (1)	6 (1)	5 (2)	
Balance during gait				
Usual-care group	(0)	3 (4)	3 (4)	.001*
Intervention group	(2)	7 (1)	7 (2)	
Total Mini BESTest				
Usual-care group	3 (3)	17 (19)	11 (10)	.004*
Intervention group	3 (7)	24 (4)	20 (8)	

Numbers are expressed as median (interquartile range); *P* values were calculated using Mann-Whitney U Test.
*P value $< .05$.

consensus on specific exercise needed as part of the balance physiotherapy treatment in poststroke patients. Second, we involved a wide range of neurorehabilitation experts with expertise in different poststroke settings. Third, the agreement was reached in only 2 questionnaire rounds, which highlights the gap of knowledge in the field and reinforces the need of a comprehensive approach of poststroke balance impairments. Finally, results from the pilot study reinforce the validity of the programme proposed. Despite this, one of the main limitations for our study is that during the development of this guidelines, we did not take into account possible age differences of the patients included, so future studies are needed in order to validate its feasibility in different populations.

Summary and Conclusion

A poststroke balance impairment treatment has been designed by a consensus of neurorehabilitation experts, which is based on a comprehensive approach of the balance systems. Future studies that evaluate the effectiveness and its suitability in different populations and phases of stroke evolution, are necessary.

Acknowledgments

We thank the experts in neurorehabilitation who help us in the exercise programme design, and also all the physiotherapists who have made this validation possible. Their professionalism and attention have made this work possible.

Conflicts of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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