

Clinical Study

Development and Process Evaluation of a 5-Week Exercise Program to Prevent Falls in People after Stroke: The FALLS Program

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Falls are a common complication after stroke, with balance and gait deficits being the most important risk factors. Taking into account the specific needs and capacities of people with stroke, we developed the FALLS program (FALL prevention after Stroke), based on the “Nijmegen falls prevention program” (a proven-effective 5-week exercise program designed for community-dwelling elderly people). The program was tested in twelve community-dwelling persons with stroke, and a process evaluation was conducted with patients, trainers, health care professionals, and managers. The FALLS program was considered suitable and feasible by people with stroke in the study and relevant health care professionals, and recommendations for implementation in clinical practice have been suggested.

1. Introduction

Approximately 610,000 people in the United States and 41,000 in The Netherlands sustain a first-ever stroke each year [1, 2]. Although (partial) functional recovery is seen in a majority of those who survive their stroke, disabling cognitive, sensory, and motor deficits persist in many subjects. Due to these deficits, falls are a common complication after stroke. A recent paper showed that at one-year followup, 43–70% of the stroke survivors have fallen once, with a fall incidence rate of 1.4–5.0 falls each person-year [3]. Furthermore, it stated that community-dwelling stroke survivors report walking as the most important activity leading to falls and that balance and gait deficits are identified as the most important risk factors [3].

Although numerous papers have reported on the epidemiology of falling and fall risk factors after stroke, few studies have addressed the prevention of falls in people with

stroke. A recent paper identified a total of 13 randomised controlled trials in which falls had been included as an outcome measure, but in the vast majority of these studies, falls only constituted a secondary outcome [4]. Hence, the interventions were not designed with the primary aim to prevent falls, and, in addition, most of the studies were not adequately powered to identify potential reductions in falls.

Given the central role of balance and gait deficits in the etiology of falls after stroke, exercise programs seem to be the most promising approach to prevent falls. It is known that task-specific exercise programs improve balance and gait abilities in people with stroke, and there is some preliminary evidence that they can reduce the number of falls as well [3]. Marigold et al. demonstrated that an agility exercise program improved quiet-stance stability, responses to balance perturbations, and walking under challenging circumstances [5]. The fall rate for the agility exercise group was 0.10 falls/month per person versus 0.26 falls/month per

person for the group receiving stretching and weight-shifting exercises (sham intervention), but this difference was not significant due to the relatively small group sizes. However, for a subgroup of participants (75% of the total group) with an increased fall risk, that is, those with a history of falls, the authors found a significantly lower proportion of fallers in the experimental group (53%) compared to the sham group (87%) at one-year followup. Another study of a small group of people with stroke ($n = 10$) also yielded promising results of exercise with respect to falls prevention [6].

In the general elderly population, there is overwhelming evidence for exercise programs to be the most effective single intervention to reduce falls. Specifically multimodal programs including strength, balance, endurance, and flexibility have shown to be effective [7–10]. One such exercise program is the “Nijmegen falls prevention program” (NFPP), which was found to reduce the number of falls by 46% and to improve balance confidence and walking skills [11]. This program consists of three elements: (1) negotiating obstacles based on obstacles mimicking hazards in daily life; (2) walking exercises simulating walking in crowded environments; (3) training of fall techniques, derived from martial arts. The program is designed to include the most challenging circumstances of daily life, with the highest fall risk. With the introduction of the practice of fall techniques, the program not only aimed at a reduction in the number of falls, but also at the prevention of fall-related injuries and at a decrease of fear of falling [12]. An adjusted version of the NFPP (designed for persons with osteoporosis) was demonstrated to reduce the number of falls by 39% in conjunction with improved balance confidence [13]. We expect that an adjusted version of the NFPP, that takes into account the specific needs and capacities of people with stroke, will also be effective in preventing falls in this population.

Thus, the first aim of the present study was to develop a stroke-specific version of the NFPP, named the “FALL prevention after Stroke” (FALLS) program. The program was tested in two groups of six community-dwelling persons with stroke. As a second aim, we conducted a process evaluation in patients, trainers, health care professionals, and managers to identify the suitability of the FALLS program for people with stroke and its feasibility in clinical practice.

2. Material and Methods

2.1. Intervention. The “FALLS program” is based on the NFPP, a proven-effective 5-week exercise program, designed for community-dwelling elderly people with a history of falling [11]. To adjust the NFPP to the specific needs and capacities of people with stroke, a project committee was formed. The committee consisted of three physiotherapists specialized in stroke rehabilitation and the two primary investigators (H. J. R. van Duijnhoven, resident in rehabilitation medicine; V. Weerdesteyn, movement scientist and physiotherapist). Two members of the committee (W. Hellebrand and V. Weerdesteyn) were also involved in the development of the original NFPP. The members studied the NFPP training protocol in detail and proposed a number



FIGURE 1: Obstacle course.

of adjustments, additions, and deletions of exercises. These were discussed among the committee members during three sessions of two hours, after which consensus was reached on the final protocol. The committee met a fourth time after the first group had finished the training program to discuss suggested changes on the basis of the observations and experience of the trainers.

The size of the training groups was reduced from 10 to 6 persons, because people with stroke were expected to need more intensive guidance and supervision. The number of supervisors was set at 2-3 physiotherapists per group, depending on the specific exercises. The walking exercises were revised to match with the smaller group size. The duration of the sessions was extended from 1.5 to 2 hours, and the number of repetitions of exercises was reduced because of the slower walking and movement speed of people with stroke. In addition, the higher physical and mental fatigability of people with stroke was taken into account by introducing a resting break of approximately 15 minutes. Furthermore, the rate at which the exercises increase in complexity was reduced (and, as a consequence, the final level of complexity) because of the physical impairments and the reduced speed of learning after stroke. Finally, solutions were formulated for the difficulties participants might encounter in several exercises due to paresis of the upper extremity. No specific homework exercises were included in the program, but participants were encouraged to implement the skills and knowledge as acquired during the sessions in their daily life. It was evaluated at the beginning of each session whether the participants had been able to do so.

The final FALLS program consists of 10 sessions (two sessions per week) of 2 hours each. A detailed overview of its contents is presented in Table 1. The first session of the week is dedicated to an obstacle course that challenges balance, gait, and coordination (Figure 1). The obstacles mimic ADL activities with a high fall risk, like walking over doorsteps, stepping stones, or various kinds of ground surface. In addition, the obstacle course contains elements to practice reaching sideways while sitting or standing and standing up without using the hands. It emphasizes on dynamical balance training but also contains training of strength (e.g., m. quadriceps while standing up without using the hands). To further simulate the complexity of daily life, these balance and gait tasks are executed simultaneously with additional

TABLE 1: Final content of the FALLS program.

	Session	Content	Min
(1)	<i>Obstacle course</i>	Uneven pavement, slopes, balance beam, walking under clothing line, various ground surfaces with doorsteps, narrow passage, stepping over a bench, stepping stones, transfer from stance to kneeling position, reaching, rotating, slalom with stepping over obstacles in lateral direction, walking backwards, and sitting down and standing up from a chair without arm use.	105
(2a)	<i>Fall techniques</i>	Trunk stability while sitting, falling sideways from a sitting position, and safely standing up from ground.	60
(2b)	<i>Walking exercises</i>	Walking in a row: changing walking speed and direction; throwing and catching a ball while walking; changing direction and avoiding collision with other participants; balance exercise: standing in a circle while pulling an elastic rope and walking in different directions.	45
(3)	<i>Obstacle course</i>	Motor dual task: walking in pairs holding a stick; visual deprivation: walking with dimmed light; cognitive dual task: count 1 specific sound in a piece of music while walking over the obstacle course.	105
(4a)	<i>Fall techniques</i>	Trunk stability, falling sideways and backwards from a sitting position, and rolling exercises to prepare for a forward fall.	60
(4b)	<i>Walking exercises</i>	Walking in a row or square: changing walking speed and direction and backward walking; walking in a crowd with a balloon balancing on the hand; walking in pairs with badminton rackets and balloons.	45
(5)	<i>Obstacle course</i>	Motor dual task: walking with a serving tray; cognitive dual task: listening to a story and counting words while walking over the obstacle course.	105
(6a)	<i>Fall techniques</i>	Falling sideways and backwards from a sitting position, falling sideways and forwards from kneeling position.	60
(6b)	<i>Walking exercises</i>	Shuttle walk exercise: walking at gradually increasing speeds (1.5–6 km/h); playing a balloon with a badminton racket and one leg trapped in a hoop. Ball tunnel: walking through hoops while other participants throw balls.	45
(7)	<i>Obstacle course</i>	Different arrangement of the obstacles and walking in two groups in opposite directions; motor dual tasks: walking with serving tray with cups, walking with umbrella and filled bag.	105
(8a)	<i>Fall techniques</i>	Falling forwards and sideways from a kneeling position, falling backwards from a standing position.	60
(8b)	<i>Walking exercises</i>	Turning hoops: working together in a group to keep hoops turning; hockey game.	45
(9)	<i>Obstacle course</i>	Motor dual task: walking with serving tray, walking with a hockey stick and ball; cognitive dual task: count one specific sound in a piece of music.	105
(10a)	<i>Fall techniques</i>	Falling forwards and sideways while standing beside a thick mattress and falling backwards from a standing position.	60
(10b)	<i>Evaluation</i>	Evaluation of the total program.	45

cognitive or motor tasks (20 and 25% of the time, resp.) and under visual constraints, for example, dimmed light (15% of the time). While negotiating the obstacles, participants not only practice their balance and coordination, they also learn to recognize and cope with potentially hazardous situations. The second session comprises walking exercises (45 minutes) and the practice of fall techniques (60 minutes). The walking exercises mimic walking in a crowded environment, where adjustment in walking speed and direction are required, and collisions with other people or objects may perturb one's balance. Because participants are physically active during the exercises, endurance is trained as well. The practice of fall techniques is based on martial arts techniques and includes falling in forward, backward, and lateral directions. The difficulty is gradually enhanced by increasing the height from which subjects fall (from sit to stance) [11]. These

techniques have previously been demonstrated to be safe, even for persons with osteoporosis [14]. Furthermore, they are trainable in older adults and reduce the impact forces on the hip during sideways falls (as measured in a movement laboratory), which may reduce the risk of hip fractures when applied in real-life falls. The participants also perceived less fear of falling after intervention [12].

2.2. Participants. The final FALLS program was tested on twelve community-dwelling persons with stroke (divided over two consecutive groups of 6 participants). All participants had sustained a stroke more than 6 months ago, thereby eliminating spontaneous recovery processes to interact with training effects. They had all received (and completed) inpatient rehabilitation within the past two years and had a functional ambulation categories (FAC) score of 4

TABLE 2: Characteristics of the twelve participants. The means and standard deviations are given, as well as the frequencies and percentages (between brackets). Maximum scores are 100 for motricity index, 100% for Fugl Meyer lower extremity, 56 for berg balance score and 23 for trunk impairment scale.

Participant characteristics	Mean \pm SD
Age	60.5 \pm 3.1
Months after stroke	16.2 \pm 1.9
Gender (%)	
Male	7 (58)
Female	5 (42)
Type of stroke (%)	
Haemorrhage	4 (33)
Infarction	8 (67)
Side of lesion (%)	
Right	5 (42)
Left	7 (58)
Motricity index leg	77.2 \pm 16.1
Fugl Meyer lower extremity scores	74.3 \pm 18.1
Berg balance score	50.5 \pm 5.0
Trunk impairment score	17.8 \pm 3.4

TABLE 3: Participant satisfaction regarding the FALLS program.

Component	Pleasant* Yes (%)	Instructive* Yes (%)	Time spent* Good (%)	Guidance* Good (%)
Obstacle Course	91	100	100	91
Fall Techniques	91	100	73	100
Walking Exercises	100	100	73	100

* Questions asked with answer possibilities: did you find the component pleasant? (yes/no); did you find the component informative? (yes/no); how do you judge the time spent on the component? (too little/good/too much); how do you judge the guidance of the trainers during this component? (too little/good/too much).

or more (the capacity to walk independently on even terrain). Exclusion criteria were other musculoskeletal conditions that affect balance or gait abilities, conditions in which physical activity is contraindicated, use of psychotropic drugs, and severe cognitive/behavioral problems (mini-mental state examination below 24).

The protocol was approved by the regional medical-ethical committee. All participants gave written informed consent.

2.3. *Process Evaluation.* The process evaluation was conducted at the level of the participants, the trainers (who developed the program and trained the subjects), other health care professionals, and the management. With regard to the participants, attendance rates were registered, and participant satisfaction was assessed by means of groupwise

discussions and an anonymous questionnaire to be filled in at home after completion of the program.

The trainers (the physiotherapists who trained the participants) discussed in depth their observations and comments immediately after each session. They also established whether the session had been delivered according to protocol and whether the intended goals had been reached. Points for improvement were noted and applied to the following lessons.

Health care professionals' opinion on the suitability and feasibility in clinical practice of the program was assessed by interviewing physiotherapists, rehabilitation physicians, and team managers. Thirteen physiotherapists from the rehabilitation centre (not involved in the training) filled in a questionnaire, after having seen a presentation of the contents of the FALLS program. Subsequently, the answers to the questions were further discussed among the group members. Two rehabilitation physicians who have specialized in the treatment of people with stroke at the same rehabilitation centre were interviewed on these topics as well. A face-to-face structured interview was held with two team managers to identify organizational opportunities and barriers for implementation of the program in clinical practice.

2.4. *Data Analysis.* Descriptive statistics were used to analyse quantitative data from the questionnaires (answers to "yes/no" questions and to multiple-choice questions). The answers to the "open" questions were categorised and presented separately. The same procedure was followed for the qualitative data from the group discussions and the interviews.

3. Results

3.1. *Participants .* The characteristics of the participants are presented in Table 2. The attendance rate to the training sessions was 97.5%. Only 2 subjects missed one or two sessions, because of hospital visits or vocational obligations. There were no dropouts, and no adverse physical effects were reported.

Eleven participants returned the evaluation questionnaires. The results are presented in Table 3. In general, participants were satisfied with the frequency of the training sessions (91%), the duration of the sessions (100%), and the time of the day at which the sessions were planned (3 p.m. to 5 p.m., 100%). The majority (73%) was satisfied with the duration of the program. Two people considered the program too short, whereas one person thought the program was too long. With respect to the contents of the program, the three elements were generally judged pleasant and instructive. In addition, the guidance was considered to be good for all elements. The time spent per element was also judged positively although for the fall techniques and walking exercises, three people reported that the time spent on this element could be shorter (20%) or longer (10%). In the groupwise discussions, it was pointed out that the participants were interested in booster sessions (a short session a couple of months after the end of the intervention, repeating the most important elements, particularly of the fall techniques).

In general, the different elements of the obstacle course, walking exercises, and fall techniques were considered feasible by the participants, which demonstrates that the exercises matched their level of physical abilities. The balance beam and the stepping stones (see Table 1) were reported as the most difficult elements of the obstacle course, falling sideways towards the affected side for the fall techniques and increasing speed for the walking exercises. For the obstacle course, the slalom and slopes were considered relatively easy. All participants who walked with a cane were able to eventually complete the program without it.

As a result of the program, participants reported to have extended their range of physical abilities. The majority of the participants (73%) had been able to implement the training advice and acquired skills while walking under challenging circumstances in daily life. Seventy-three percent reported to feel less at risk of falling and to have lower fear of falling. Those persons who did not perceive these benefits were the ones without initial fear of falling and who did not consider themselves at high fall risk prior to the intervention. Furthermore, all participants would recommend the FALLS program to other persons with stroke.

3.2. Trainers. In general, the elements of the original FALLS program were considered to be feasible for the participants; however, some adaptations were made based on the trainers' evaluations. These were discussed and agreed upon during the meeting of the project committee after the first group of participants had been trained. On the obstacle course, observing other participants was instructive for healthy persons, but not for persons with stroke due to attentional deficits. As a compensation, a set of optional balance exercises was offered to participants who had to wait for a supervisor.

The most important changes in the walking exercises were based on the observed cognitive and attentional problems of the participants. Cognitive elements were added, and the number of exercises was limited to a maximum of 3 per session. To adapt the training to the variable abilities of the participants, each exercise consisted of a basic element of which the intensity or complexity was gradually increased. The fall training was feasible in its original design, as the participants were capable of executing the exercises according to the protocol. Therefore, no substantial adaptations had to be made.

3.3. Health Professionals. All 13 physiotherapists completed the questionnaires. They all considered the FALLS program to be a good addition to the existing treatment programs. The majority considered it feasible (85%) for implementation in routine clinical practice. They judged the content of the program well adjusted to the target group and did not expect organisational problems. A rehabilitation centre was identified as the most suitable setting for the program (93%), whereas 70% thought it would also fit in a primary care physiotherapy practice.

In general, the program was deemed most suitable for outpatients directly following discharge from inpatient

rehabilitation, or in the chronic phase after stroke (85%). Forty-six percent considered the program feasible for inpatients as well. They agreed on independent walking ability (FAC 4 or 5) to be the necessary entry level for the program. In addition, balance problems and/or fear of falling were considered the main inclusion criteria, whereas participants should not suffer from severe cognitive and/or behavioral problems, which influence basic understanding and cooperation. All the therapists deemed themselves capable of delivering the training sessions, but prior to working as a trainer, they would like to receive education on the specific contents of the program.

The interviews with the rehabilitation physicians yielded similar results. They suggested that the program was suitable both for patients in the chronic phase of stroke and for patients who are recently discharged from inpatient rehabilitation. If the program would be implemented, it should be delivered by physiotherapists specialized in stroke treatment, if necessary, with the help of other disciplines. In addition, they also advised participants to be screened for cognitive and/or behavioral problems by a rehabilitation physician prior to entering the program, who should also determine whether additional support would be needed.

3.4. Management. The managers considered the FALLS program to be a good addition to the present rehabilitation program. They also indicated that it would fit within the reimbursement system for health care costs in The Netherlands, such that the costs for delivering the program would be sufficiently covered. Experience with comparable projects did not show large barriers for implementation, besides planning.

The program could probably be offered 3 to 4 times a year, depending on the number of persons eligible for participation. Trainers could be educated in the specific elements of the program, and interns could learn from more experienced trainers.

4. Discussion

In the present paper, we described the development and process evaluation of the FALLS program, a 5-week exercise falls prevention program designed for persons with stroke. The NFPP was adjusted to meet the special needs and capacities of people with stroke. The program was offered to two groups of six participants.

From the results of the present study, we can conclude that the FALLS program is safe and feasible for participants in the chronic phase of stroke. There were no adverse events, and the duration and frequency of the program were considered appropriate by the participants. There was an excellent attendance rate, which is important given the progressive nature of the program. These results are comparable to the original NFPP and to an adjusted version for persons with osteoporosis [11, 13]. Although data on the effectiveness of the program are not yet available, the experiences of the participants are promising. Most of them reported that their fear of falling was reduced after the program and that they felt to have improved balance maintenance while walking under

challenging circumstances. The original NFPP has already been proven to be effective in reducing the fall incidence after implementation in clinical practice [15].

Although the effectiveness of the FALLS program still needs to be established in a randomised controlled trial, the results of the questionnaires and interviews with the health care professionals and managers indicate that there appear to be no major hurdles for eventual implementation of the program in clinical practice. The program should preferably be offered to outpatients, in the chronic phase after stroke or shortly after discharge from inpatient rehabilitation. It is known that fall incidence rates increase strongly in the first 8 weeks after discharge [3]. It is suggested that this increase is due to the fact that people with stroke are not optimally prepared for the challenges they have to face in daily life. Nevertheless, patients who have not followed the program after discharge from the rehabilitation centre may still benefit from it in a later phase. These persons are likely to have experienced one or more falls and thus may feel a higher necessity to prevent falls. According to the health care professionals, the program should be embedded in specialized outpatient facilities of a rehabilitation centre. In that case, trainers have elaborated experience with treatment of persons with stroke, and there is a possibility of additional support from other disciplines (e.g., language and speech therapists or psychologists) for advice on guidance of participants with specific problems.

Furthermore, it was suggested that, to be included in the program, participants should be at increased fall risk, that is, have balance and/or gait problems, fear of falling, or a positive fall history. Participants should be independent walkers (FAC 4 or 5, with or without walking cane) and should not have severe cognitive, behavioral, or language problems, which could interfere with basic understanding and cooperation. Screening by a rehabilitation physician prior to the program is therefore necessary.

A limitation of the present study is that it was conducted on a small group ($N = 12$) of people with stroke. In addition, participants were mildly affected and had no or little cognitive problems. Therefore, the results can only be applied to this specific population. A second limitation is that the effectiveness of the FALLS program has not yet been established in a randomised controlled trial (with fall rate as the main outcome). Hence, the conclusions and recommendations regarding potential implementation of the program are somewhat premature.

Furthermore, although the management indicated that the costs of the program would be covered under the current reimbursement system in The Netherlands, the cost-effectiveness of the program should ultimately be demonstrated as well in order to support its implementation in the poststroke rehabilitation program. At this moment, it is hard to estimate the potential cost effectiveness due to the lack of information on the effectiveness of the program and on the average costs per fall in the population of people with stroke. The main costs for delivering the program would be the start-up costs (training of physiotherapists; ~2000 Euro material costs for the obstacle course and the walking exercises, assuming safety mats and regular physiotherapy equipment

to be present) and personnel (~600 Euro per participant). If a reduction in fall rates could be achieved similar to the two prior studies on the Nijmegen falls prevention program [11, 13], an average of more than one fall per participant could likely be prevented based on the previously reported fall rates of 1.4–5.0 falls per year in people with stroke [3]. In the general elderly population, the average costs per fall amount 1,059 to 10,913 US Dollars [16]. Hence, if the FALLS program would be effective in reducing the number of falls, these numbers indicate that it has good potential to be cost effective as well.

In conclusion, with this process evaluation, we have demonstrated that the FALLS program is perceived, both by the users and relevant health care professionals, to be safe and suitable for the specific group of people with stroke as included in this study. Implementation of the program within a specialized rehabilitation centre is considered feasible by physical therapists, rehabilitation physicians, and team managers, but this should be preceded by a large randomized controlled trial to establish the effects of the program on fall rates. The perceived improvements in balance control and confidence are promising, and it is for future research to objectify these effects as well.

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Conflict of Interests

The authors declare that there is no conflict of interests.

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