

RESEARCH PAPER

## The development of a clinical practice stroke guideline for physiotherapists in The Netherlands: A systematic review of available evidence

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### Abstract

**Purpose.** To develop a clinical practice guideline for the physiotherapy management of patients with stroke as support for the clinical decision-making process, especially with respect to the selection of appropriate interventions, prognostic factors and outcome measures.

**Introduction.** Physiotherapists have a high caseload of patients with stroke, so there is a need to identify effective evidence-based physiotherapy procedures. The availability of a guideline that includes information about prognostic factors, interventions, and outcome measures would facilitate clinical decision-making.

**Method.** A systematic computerized literature search was performed to identify evidence concerning the use of: (i) prognostic factors related to functional recovery; (ii) physiotherapy interventions in patients with stroke; and (iii) outcome measures to assess patients' progress in functional health. Experts, physiotherapists working in the field of stroke rehabilitation, and a multidisciplinary group of health professionals reviewed the clinical applicability and feasibility of the recommendations for clinical practice and their comments were used to compose the definitive guideline.

**Results.** Of 9482 relevant articles, 322 were selected. These were screened for methodological quality. Seventy-two recommendations for clinical practice were retrieved from these articles and included in the guideline: Six recommendations concerned the prediction of functional recovery of activities of daily living (ADL), including walking ability and hand/arm use; 65 recommendations concerned the choice of physiotherapy interventions; and 1 recommendation concerned the choice of outcome instrument to use. A core set of seven reliable, responsive, and valid outcome measures was established, to determine impairments and activity limitations in patients with stroke.

**Conclusions.** The guideline provides physiotherapists with an evidence-based instrument to assist them in their clinical decision making regarding patients with stroke. As most of the recommendations included in the guideline came from studies of patients in the post acute and chronic phase of stroke, and in general involved patients with less severe and uncomplicated stroke, more needs to be learned about the more complex cases.

**Keywords:** Clinical practice guideline, physiotherapy, rehabilitation, stroke, prognostic factors, interventions, outcome measures

### Introduction

Stroke is a major health problem with high societal costs due to its increasing prevalence and the long-term disability it causes. In The Netherlands,

the incidence of cerebrovascular disorders is estimated at 34,500 (~2.2/1000/year) and the prevalence at 190,000 (~1.2% of Dutch population), and nowadays more patients are admitted to hospital (admission for stroke has increased from 22,717 in

1980 to 32,623 in 2003) [1]. It is intrinsic to healthcare to continuously look for evidence-based rehabilitation services. Recently, the 'best evidence' for stroke management, derived from methodologically sound clinical research, has been collected in systematic reviews and converted into several multi-disciplinary stroke guidelines [2–6]. However, physiotherapists would probably prefer to have more detailed information about making a valid functional prognosis, designing the most effective intervention program, and selecting the most appropriate measures to evaluate outcome, to facilitate clinical decision making in each individual patient in line with his or her specific functional health status [7]. As yet, there are no specific guidelines for physiotherapy in the management of stroke, even though physiotherapy accounts for a substantial proportion of the total therapy time provided by stroke rehabilitation services [8,9].

The aim of the present article was to describe the available evidence to guide the clinical decision-making process of physiotherapists dealing with the rehabilitation of patients with stroke regarding: (a) the best determinants of the ultimate functional recovery of patients diagnosed with stroke; (b) the effectiveness of applicable physiotherapy interventions; and (c) a core set of reliable, valid, and responsive outcome measures to assess patients' progress in functional health at fixed moments after stroke. This evidence is presented as the Clinical Practice Guideline in

Physiotherapy management of patients with Stroke (CPGPS) in The Netherlands [10].

## Method

### Development of guideline

A systematic literature search was conducted to determine evidence (i.e., the 'state-of-the-art') for three aspects of the physiotherapy management of patients with stroke: (i) prognostics; (ii) interventions; and (iii) outcomes. Subsequently, the methodological quality of the included studies was investigated. Levels of evidence were determined on the basis of the 'best evidence' from systematic reviews, randomized controlled trials (RCTs), controlled clinical trials (CCTs), and pre-experimental studies. The best evidence was then converted into graded recommendations for clinical practice.

Figure 1 shows how the recommendations for physiotherapy-related interventions were developed. Recommendations for each intervention were based on: (i) description of the intervention; (ii) systematic literature search; (iii) analysis of methodological quality of the studies, according to the PEDro scale [11]; (iv) quantitative analysis of the effects of the individual studies, and, if the studies were comparable with respect to type of intervention and measurement of outcome (for methods see van Peppen et al. 2004) [12]; (v) levels of evidence based

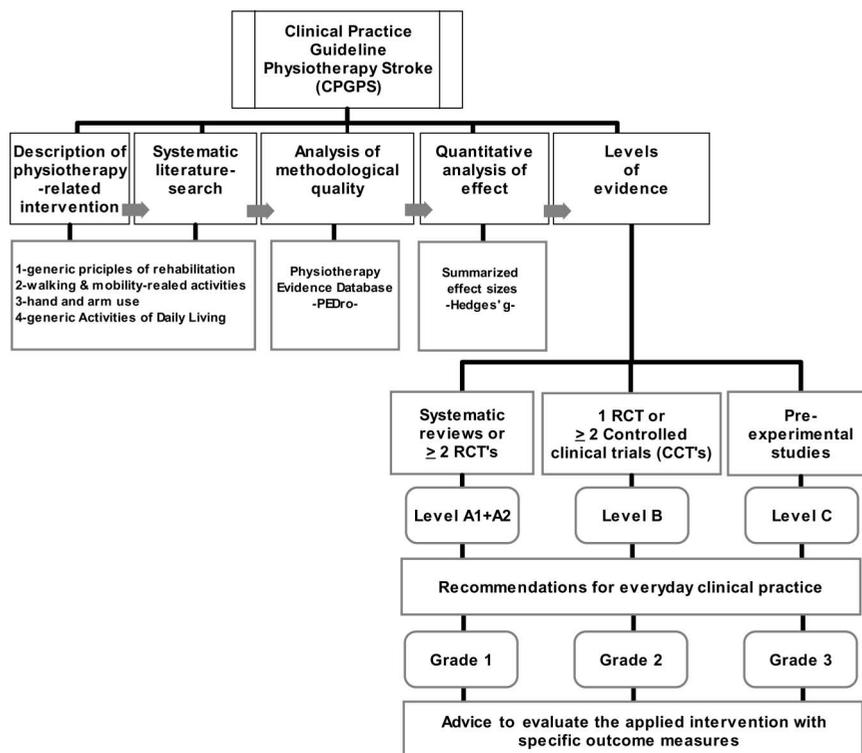


Figure 1. Flow chart concerning the selection and grading of the available evidence of each therapeutic intervention in the CPGPS.

on evidence from the literature; (vi) formulation of recommendations for using the described intervention in clinical practice; and (vii) advice regarding the use of valid, reliable, and responsive outcome measures to describe the functional health status of patients with stroke and to evaluate the effects of a physiotherapy intervention. The interventions are described in terms of general principles of rehabilitation, walking and mobility-related activities, hand and arm use, and activities of daily living (ADL).

#### *Participants in the development process of CPGPS*

Seven groups of participants contributed to the development of the guidelines during the development period March 2002 to March 2004:

- (1) The board of the Royal Dutch Society for Physical Therapy (Koninklijk Nederlands Genootschap voor Fysiotherapie: KNGF), which initiated the development of the guideline and approved the definitive version.
- (2) The Department of Physical Therapy of the VU University Medical Center (VUmc) in Amsterdam, the Netherlands, which developed the guideline and formed a steering committee and task group.
- (3) A steering committee ( $n=5$ ), which planned and coordinated the activities of the task group.
- (4) A task group (GK and RPSvP), which developed the format of the guideline; wrote the draft versions; invited the expert group, multiprofessional group, and pilot group to comment on these draft versions of the guideline; and wrote the definitive version of the CPGPS.
- (5) An expert group ( $n=8$ ), consisting of clinical experts, especially on stroke, who commented on the guideline or parts of it during its development, assessed the draft versions of the guideline and its applicability in daily physiotherapy practice. The experts were all physiotherapists experienced in stroke rehabilitation, representative for Dutch institutions treating stroke patients.
- (6) A pilot group, consisting of randomly selected physiotherapists ( $n=169$ ), who tested and commented on the draft version of the outcome measures and their applicability. Their comments, together with information on the clinical utility and overlap of the outcome measures, were used to develop the final version of the outcome measures.
- (7) A multi-professional group ( $n=9$ ), consisting of clinicians from various specialties providing care in this setting (neurologist,

rehabilitation physician, general practitioner, nursing home doctor, geriatrician, psychologist, (district) nurse, occupational therapist, and speech therapist) and a patient representative of the Dutch Stroke Association, assessed the quality of the final draft version, and its applicability to everyday clinical practice. They also determined whether the physiotherapy guideline conflicted with the recommendations of their own disciplinary guidelines [2,3].

#### **Definitions**

Stroke was defined according to the World Health Organization as 'a clinical syndrome typified by rapidly developing signs of focal or global disturbance of cerebral functions, lasting more than 24 hours or leading to death, with no apparent causes other than of vascular origin' [13]. Three phases of stroke were identified, namely, acute/sub-acute, post acute, and chronic phase. The acute phase of stroke was considered to be the first week after stroke onset, the sub-acute phase from the 2nd to the 4th week after stroke, and the post acute phase from the 2nd to the 6th month after stroke. The chronic phase started 6 months after stroke [12]. Physiotherapy was defined as the skilled use of physical interventions (in contrast to medical or surgical treatments) to restore physical functioning and to improve activity and participation in daily-life situations after injury or disease [4]. Physiotherapy interventions for patients with stroke commonly include exercise therapy, neuromuscular electrical stimulation, mechanical devices, such as balance trainers and treadmills, as well as assistive devices (canes and walkers) along with instructions for their proper use.

#### *Literature search*

An extensive computerized search of the Dutch, English, or German literature included in the MEDLINE (1966 through January 2004), CINAHL (1982 through January 2004), and EMBASE databases (1988 through January 2004), Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews (The Cochrane Library, Issue 4, 2003), DocOnline (Database of the Dutch Institute of Allied Health Care) (1987 through January 2004) and PEDro (January 2004) was conducted, using the keywords 'cerebrovascular disorders', 'cerebrovascular accident', 'stroke', 'hemiplegia', and 'rehabilitation'. Two researchers (GK and RPSvP) independently searched these electronic databases for relevant articles. The bibliographies of review articles and narrative reviews, and the abstracts of conferences were also screened. In

addition, the references of the retrieved studies were reviewed. Inclusion of articles was based on agreement between the two independent reviewers. This search strategy was the core search which served as the basis for further refinement according to the three topics: prognostic factors, physiotherapy-related interventions and outcome measures.

#### Prognostic factors

To determine prognostic factors, the following keywords were used: 'prognostic factors', 'prognosis', 'prediction', 'functional outcome', 'outcome assessment', and 'follow-up'. Factors were included if they fulfilled the following three selection criteria: (i) the prognostic factors were described to affect the functional outcome of patients with stroke; (ii) the prognostic factors were correlated with walking ability, hand and arm use, or ADL; and (iii) the study was a systematic review or meta-analysis. Quality assessment of studies of prognostic factors was based on 11 criteria for methodological quality for prognostic research [14,15] (Table I).

#### Physiotherapy-related interventions

The following keywords and MeSH were used to identify the interventions: 'physiotherapy', 'physical therapy', 'exercise therapy', 'electrotherapy', and 'occupational therapy'. Systematic reviews (SR), randomized and controlled clinical trials (RCTs and CCTs), and (non-controlled) pre-experimental studies were included for review. Studies that investigated robotics or the effects of physiotherapy

in combination with acupuncture or drug therapies were excluded.

Articles were considered relevant and selected if the study population included adults of 18 years or older, diagnosed with stroke, and the study evaluated the effectiveness of physiotherapy-related interventions. The quality of the studies was assessed with the PEDro criteria [11] for methodological quality and the levels of evidence were based on the criteria of Sacket et al. [7] (Table II).

#### Outcome measures

The following keywords were used to identify outcome measures: 'measurement', 'measure', 'assessment', 'instrument', 'scale', 'test', 'questionnaire', 'classification', 'evaluation', and 'outcome'. The following keywords were used to determine the quality of the outcome measures: 'reliability', 'validity', and 'responsiveness'.

For inclusion in the analysis, the outcome measures needed to be consistent with the International Classification of Functioning, Disability and Health (ICF) [16]; to show high-level psychometric properties, i.e., reliability (inter- and intra rater), validity and responsiveness [17] in studies with adult stroke patients, and to have good clinical utility (easy and quick to administer) (Table III); to minimally overlap each other; and to be consistent with current physiotherapy practice. Excluded were outcome measures that evaluated the cognitive impairments

Table I. Criteria used to assign levels of evidence to studies on prognostic factors [14,15].

#### Level of scientific evidence for studies on prognostic factors

- (I) Studies that satisfy all items for internal and statistical validity ( $\geq 8$  points);
- (II) Studies that satisfy all items for internal validity ( $\geq 5$  points);
- (III) Studies that do not satisfy all items for internal validity.

#### Level of scientific evidence of the systematic reviews on prognostic factors

- (A) Systematic reviews (meta-analyses) that include at least 5 studies at quality level I, which investigate the same prognostic factor;
- (B) Systematic reviews (meta-analyses) that include at least 3 studies at quality level I, which investigate the same prognostic factor;
- (C) Systematic reviews (meta-analyses) that include at least 2 studies at quality level I, II, or III, which investigate the same prognostic factor.

#### Grades of recommendation of the studies on prognostic factors

- 1. Supported by research at level A;
- 2. Supported by research at level B;
- 3. Supported by research at level C.

Table II. Criteria used to assign levels of evidence to intervention studies [7].

#### Level of scientific evidence to intervention studies

- A1. Systematic reviews (meta-analyses) that include at least 2 or more RCTs at quality level A2, which show consistent results between studies;
- A2. At least 2 RCTs of a good methodological quality (PEDro-score  $\geq 4$  points) with sufficient power and consistency;
- B. At least 2 RCTs of a moderate methodological quality (PEDro-score  $\leq 3$  points) or with insufficient power, or at least 2 CCTs, or one RCT with PEDro-score  $\geq 4$  points;
- C. Pre-experimental studies;
- D. Expert opinion\*.

#### Grades of recommendation to intervention studies

- 1. Supported by one systematic review at level A1 or at least 2 independent trials at level A2;
- 2. Supported by research at level B;
- 3. Supported by research at level C;
- 4. Not supported by research; based on expert opinion\*.

CCT = Controlled Clinical Trial; PEDro = Physiotherapy Evidence Database; RCT = Randomized Controlled Trial; \*In contrast to other guidelines, no recommendations of grade 4 were entered in the CPGPS. The grade 4 recommendations were recently established in the Dutch multidisciplinary guidelines for stroke rehabilitation [3].

Table III. Criteria used to assign levels of evidence to outcome measures [18].

*Level of scientific evidence for outcome measures*

## (A) 6 criteria:

- Validated in a stroke patient population: 0 = no; 1 = yes;
- Test-retest reliability: 0 = ICC < 0.69; 1 = ICC ≥ 0.70;
- Concurrent validity, Spearman rho ( $r_s$ ) or Pearson correlation coefficient: 0 =  $r < 0.69$ ; 1 =  $r \geq 0.70$ ;
- Responsiveness: 0 = low; 1 = high;
- Clinical use: 0 = time to administer > 16 min, and 1 = time to administer ≤ 15 min;
- Test-protocol: 0 = test-protocol not available; 1 = test-protocol available.

(B) Meets 5 of the level A criteria;

(C) Meets 3 or 4 of the level A criteria;

(D) Meets 1 or 2 of the level A criteria.

*Grades of recommendation for outcome measures*

1. Supported by research at level A;
2. Supported by research at level B;
3. Supported by research at level C;
4. Supported by research at level D.

ICC = intra class correlation coefficient; SDD = smallest detectable difference.

of stroke patients. Quality assessment of outcome measures was based on the criteria for outcome measures formulated by Bot et al. [18] (Table III).

## Results

### *Evidence to be included in the guideline*

In total, 322 articles (out of 9482 citations) were used to establish the content of the guideline: Six studies [14,15,19–22] to establish prognostic factors to predict functional recovery in patients with stroke; 284 studies to establish physiotherapy interventions for stroke rehabilitation (for references: see [10]); and 32 studies [23–54] to establish outcome measures to assess patient progress. In total, 72 possible guideline elements were identified: Six relevant to prognostic factors, 65 relevant to physiotherapy interventions, and 1 relevant to outcome measures (Table IV).

### *Prognostic factors of functional recovery*

The identification of prognostic factors was based on six systematic reviews [14,15,19–22].

### *Walking ability*

A number of factors to predict walking ability (defined in the guideline as regaining a Functional Ambulation Categories score ≥ 4) at 6 months after stroke were identified. The best explanatory factors were initial walking ability in the first 2 weeks after stroke, degree of motor paresis of the paretic leg,

homonymous hemianopia, sitting balance, urinary incontinence, high age, initial functioning (activities of daily living; ADL) in first 2 weeks after stroke [14] (Grade 3 evidence). These factors were generally similar to those predicting ADL 6 months after stroke.

### *Activities of Daily Living (ADL)*

The best predictor of recovery of independence in ADL at 6 months after stroke was the Barthel Index score in the first 2 weeks after stroke. Other predictors were urine incontinence in the first 2 weeks after stroke, level of consciousness in the first 48 hours after stroke, high age, status following recurrent stroke, degree of motor paresis, sitting balance in the first 2 weeks after stroke, orientation in time and place, and level of perceived social support [14,15] (Grade 3 evidence).

### *Hand and arm use*

The dexterity of the hemiplegic arm can best be predicted within 4 weeks after stroke [55]. The best clinical predictor of recovery of dexterity of the paretic arm 6 months after stroke was severity of arm paresis at 4 weeks after stroke, as assessed with the Fugl-Meyer Assessment [55]. Other strong predictors of recovery of dexterity after stroke were severity of the upper extremity paresis, voluntary grip function of the hemiplegic arm [37,56] or voluntary extension movements of the hemiplegic's wrist and fingers [57] within the first 4 weeks after stroke, and muscle strength of the paretic leg [55] (Grade 3 evidence). By using these prognostic factors in an early stage of rehabilitation, physiotherapists should be able to predict the functional outcome of their patients 6 months after stroke [58] (Grade 3 evidence). An example of a model to predict the recovery of walking ability after stroke is given in the Appendix.

### *Physiotherapy interventions*

The choice of physiotherapy interventions to include in the guideline was in part based on a recent review of the efficacy of physiotherapy interventions on functional outcome in stroke patients [12]. The literature search identified 284 relevant studies (25 SR, 16 critical reviews, 153 RCTs, 49 CCTs, and 41 pre-experimental studies) [10]. We used PICO search questions (Patient, Intervention, Comparison, and Outcome) [7] to identify 46 relevant physiotherapy interventions, as outlined in Figure 1 [10]. An example of a PICO question is: 'What is the evidence for constraint-induced movement therapy compared to regular arm/hand therapy on dexterity of the

Table IV. Summary of 72 recommendations of the CPGPS: Type of intervention and corresponding grade of recommendation and grades of recommendation refer to different criteria (see Tables I, II, and III).

Type of intervention	Grade of recommendation	Type of intervention	Grade of recommendation
<i>Prognostic factors (grades of recommendation, see Table I)</i>		36. Functional electro stimulation (paretic leg)	1*
1. Prognosis walking ability	3	37. Biofeedback to the paretic lower limb	1*
2. Prognosis dexterity paretic arm in first 4 weeks after onset stroke	3	38. Applying Ankle-Foot-Orthosis	2
3. Prognostic factor arm: paretic leg	3	39. Using walking aids	3*
4. Prognostic factor arm: Barthel index	3*	40. Limb loading	2*
5. Prognosis ADL	3	41. External auditory rhythms	2
6. Prognosis recovery of sequence in ADL	3	42. Therapeutic positioning paretic arm	2
<i>Physiotherapy-related interventions (grades of recommendation, see Table II)</i>		43. Stretching paretic wrist and fingers	2
7. Treatment in stroke teams (stroke unit)	1	44. Immobilization techniques (arm/hand)	2
8. Incorporating stroke unit in stroke service	3	45. Sensory training paretic arm and hand	3
9. Adherence to evidence-based guidelines	3	46. Using air-splints	2
10. Intensity of exercise therapy	1	47. Wrapping paretic arm	3
11. Task-specific training	1	48. Exercise training the paretic arm	1*
12. Context-specific training	1	49. Bilateral training cyclic arm movements	3
13. Neurological treatment approaches	1*	50. Constraint-induced movement therapy: dexterity	1
14. Treating with basic principles of the NDT-concept	3**	51. Constraint-induced movement therapy: somatosensory deficits	1
15. Motor learning (variation and repetition-without-repetition)	3	52. NMS of the paretic forearm without EMG-triggering: muscle strength and ROM	3
16. Early start of rehabilitation (within 72 hours after onset stroke)	3	53. NMS of the paretic forearm: dexterity (absence of active wrist and finger extension)	2*
17. Positioning paretic site in bed	3*	54. NMS of the paretic forearm: dexterity (with active wrist and finger extension)	2
18. Prevention decubitus	3	55. NMS of the paretic forearm with EMG-triggering	2
19. Prevention of broncho-pneumonia	3	56. Biofeedback to the paretic upper limb	1*
20. Pulmonal ventilation	3	57. TENS paretic arm	1
21. (Assistive) active movements	3	58. NMS for GHS and HSP	1
22. Prevention deep venous thrombosis	3	59. Exercises for reducing HSP	1*
23. Informing partner of patient	3	60. Shoulder exercises with pulleys in HSP	3**
24. Training sitting balance	1	61. Treatment of hand oedema: intermittent pneumatic compression	2*
25. Asymmetric wheelchair self-propelling	2*	62. Treatment of hand oedema: other treatments	3*
26. Using paretic hand during wheelchair propelling	3	63. Mirror therapy paretic arm	2
27. Training transfers from sit-to-stand and vice versa	1	64. Slings and supportive devices for reducing GHS and HSP	3
28. Preventing falls during standing up and sitting down	2	65. Strapping techniques for reducing GHS and HSP	3
29. Training standing balance on force plates	1	66. Strategy training for apraxia	2
30. (Functional) strengthening paretic muscles	1	67. Training leisure activities	1*
31. Strengthening paretic leg and spasticity	2*	68. Training attention deficits	1
32. Aerobics (combination of strength- and endurance training)	3	69. Training memory deficits	1*
33. Body-weight supported treadmill training	1	70. Neglect: visual scanning training	1
34. Treadmill training without body weight support and walking ability	1	71. Visual scanning training: prism glasses	2
35. Treadmill training without body weight support and gait speed	2	<i>Outcome measures (grades of recommendation, see Table III)</i>	
		72. Monitoring outcomes (systematically)	3

\*No or insufficient evidence was found for this intervention; \*\*Negative effect was found for this intervention; ADL= activities of daily living; EMG= electromyogram; HSP= hemiplegic shoulder pain; GHS= glenohumeral subluxation; NDT= neurodevelopmental treatment; NMS= neuro muscular stimulation; ROM= range of motion; TENS= transcutaneous electrical nerve stimulation.

paretic arm in patients with stroke?' (Table V). We grouped these interventions as being consistent with the general principles of rehabilitation, or as influencing walking and mobility-related activities, hand and arm use, and generic ADL.

We included 65 recommendations/interventions in the guideline, 24 of grade 1 evidence (Table V); 18 of grade 2 evidence [10], and 23 of grade 3 evidence [10]. In this way, the guideline recommends task-oriented and context-specific exercise

Table V. The 24 'Grade 1' recommendations of intervention studies (level A evidence), in detail described in the CPGPS [10].

PICO	Patients: In stroke patients ...	Intervention: ... the effectiveness of ...	Comparison: ... compared to ...	Outcome: ... is effective for ...
1. Generic principles: Working in stroke teams		... multidisciplinary interventions in a stroke-units ...	... conventional rehabilitation settings ...	... increasing survival, decreasing length of stay and increasing ADL-independency in the (sub)acute phase after stroke.
2. Generic principles: Intensity of exercise training		... augmented exercise therapy time spent in the first 6 months after stroke ...	... regular time spent in rehabilitation ...	... increasing the rate of recovery of ADL in the (sub)acute and postacute phase after stroke.
3. Generic principles: Task-specific training		... tasks directly trained (such as training balance in standing position) ...	... the not-trained tasks ...	... increasing the trained task in the (sub)acute, postacute and chronic phase after stroke; generalizability to other trained tasks is hardly found.
4. Generic principles: Context-specific training		... training in a well-known context ...	... training in a not-well known context ...	... increasing the effectiveness of task-learning in the (sub)acute, postacute and chronic phase after stroke.
5. Generic principles: Neurological treatment approaches		... one specific neurological treatment approach (such as NDT, PNF, MRP, Brunnstrom etc.) ...	... another specific neurological treatment approach (such as NDT, PNF, MRP, Brunnstrom etcetera) ...	... is <b>not</b> effective on outcomes at activity-level.
6. Walking and mobility-related activities: Sitting balance		... reaching with the paretic arm, while sitting, with the arm reaching outside the bearing surface ...	–	... increasing the sitting balance.
7. Walking and mobility-related activities: Standing up and sitting down		... training symmetrically standing up and sitting down ...	–	... increasing the symmetric weight-bearing during standing-up and sitting-down between the 2 legs, and the speed of these transfers in the postacute and chronic phase after stroke.
8. Walking and mobility-related activities: Standing balance on force plates		... additional training of standing balance on force plates with visual feedback while bilateral standing ...	... conventional standing balance training ...	... increasing symmetrical weight-bearing between both legs while bilateral standing in the postacute phase after stroke. Unclear if effects will generalize to better walking ability.
9. Walking and mobility-related activities: Strength training paretic leg		... (functional) strength training of the paretic leg (using fitness-apparatus of functional training), 2 to 3 times a week ...	–	... increasing muscle strength of the paretic leg and increasing gait speed in the postacute and chronic phase after stroke.

(continued)

Table V. (Continued).

PICO	Patients: In stroke patients...	Intervention: ...the effectiveness of...	Comparison: ...compared to...	Outcome: ...is effective for...
10. Walking and mobility-related activities: BWSST		... BWSST (< 40% body-weight support) in stroke patients who cannot walk in the first 6 weeks after stroke and decreased physical condition...	-	... increasing endurance.
11. Walking and mobility-related activities: Treadmill training without body-weight support		... intensive treadmill training without body-weight support in patients with a decreased walking ability...	-	... increasing walking ability in the postacute phase after stroke.
12. Walking and mobility-related activities: FES (paretic leg)		... FES on the paretic leg...	-	... is not effective on gait speed and walking ability.
13. Walking and mobility-related activities: Biofeedback to the paretic lower limb		... biofeedback to the dorsiflexion muscles of the paretic lower limb during gait...	-	... is not effective on ROM of the dorsiflexion of the paretic ankle and gait speed.
14. Hand and arm use: Exercise training the paretic arm		... exercise training of the paretic upper limb based on a specific neurological treatment approach...	... another specific neurological treatment approach...	... is not effective for faster recovery of the dexterity the paretic arm.
15. Hand and arm use: CIMT		... constraint-induced movement therapy (= forced use) in combination with an intensive functional training programme in patients with active wrist extension (20 degrees) and finger extension (10 degrees)...	-	... increasing dexterity of the paretic arm. The effect can be increased on behalf of the increasing trainings intensity of CIMT.
16. Hand and arm use: CIMT		... constraint-induced movement therapy (= forced use)...	-	... is more effective in patients with somatosensory deficits.
17. Hand and arm use: Biofeedback to the paretic upper limb		... biofeedback to the muscles of paretic arm...	-	... is not effective on active ROM and muscle strength of the paretic arm.
18. Hand and arm use: TENS		... transcutaneous nerve stimulation of the paretic arm...	-	... decreasing spasticity in the postacute phase after stroke, but the effects will not generalize to a better dexterity.
19. Hand and arm use: NMS with GHS and HSP		... neuromuscular stimulation in patients with glenohumeral subluxation of the paretic shoulder and hemiplegic shoulder pain...	-	... increasing passive ROM of lateral rotation of the paretic shoulder (13 degrees) and reducing the glenohumeral subluxation (5 mm) in the (sub)acute and postacute phase after stroke. However these effects are temporary. NMS doesn't result in a reduction of the hemiplegic shoulder pain.

(continued)

Table V. (Continued).

PICO	Patients: In stroke patients ...	Intervention: ... the effectiveness of ...	Comparison: ... compared to ...	Outcome: ... is effective for ...
20. Hand and arm use: Exercises for reducing HSP		... passive of assisted active shoulder exercises with the paretic arm ...	—	... is not more effective to other physiotherapy interventions aimed at reducing hemiplegic shoulder pain.
21. ADL: Training leisure activities		... home-based therapy aimed at increasing leisure activities (such as regaining gardening or painting) ... ... attention training ...	—	... increasing ADL-independency, participation in leisure activities, and mood of the patient.
22. ADL: Training attention deficits		... attention training ...	—	... increasing alertness and sustained attention in the postacute phase after stroke. The effects will not result in improving ADL.
23. ADL: Training memory deficits		... memory training ...	—	... is not effective to reduce memory problems in the postacute phase after stroke.
24. ADL: Neglect: visual scanning training		... treating neglect, daily 30 to 60 minutes during a few weeks in patients with right hemispherical stroke ...	—	... increasing the negligible body side, measured with visual scanning tests. The effects will not result in improvement of scanning in daily life.

ADL = activities of daily living; BWSTT = Body-weight supported treadmill training; CIMT = constraint-induced movement therapy; FES = Functional Electrical Stimulation; GHS = glenohumeral subluxation; HSP = hemiplegic shoulder pain; MRP = motor relearning programme; NDT = neurodevelopment treatment; NMS = neuromuscular stimulation; PNF = proprioceptive neuromuscular facilitation; ROM = range of motion; TENS = transcutaneous electrical nerve stimulation.

training, in particular when applied intensively and early after stroke onset (Grade 1 evidence). The interventions/recommendations (together with the level of evidence) are given in Table IV [12].

#### *Outcome measures*

The recent emphasis on 'evidence-based practice' means that extra attention should be paid to the validity of outcome measures [59]. Thirty-three studies [23–54] of outcome measures were identified, yielding 32 potential outcome measures. An independent sample of 169 physiotherapists not involved in guideline development were asked to measure outcome according to the three ICF domains (functions, activities, and participation) [16], and to indicate which of the 33 outcome measures they would prefer to use to assess treatment outcome in patients who had had a stroke. The definitive test battery (25 outcome measures) was established in consensus meetings with the experts and task group. These outcome measures were considered to reflect the three ICF activity categories, namely, walking and mobility-related activities; hand and arm use; and ADL. The outcome measures were divided into two sections. The first section, consisting of the core set of outcome measures, should be applied to all stroke patients, since these measures were considered to evaluate whether physiotherapy care was adequate in all phases after stroke. These core outcome measures had minimal overlap and were (1) the Motricity Index (MI) [29,33] (Grade 2 evidence), (2) Trunk Control Test (TCT) [29,35] (Grade 2 evidence), (3) Berg Balance Scale (BBS) [23] (Grade 1 evidence), (4) Functional Ambulation Categories (FAC) [40,41] (Grade 2 evidence), (5) comfortable Ten Meter Walk (TMW) [54] (Grade 1 evidence), (6) Frenchay Arm Test (FAT) [34,37,54] (Grade 2 evidence), and (7) Barthel Index (BI) [28] (Grade 2 evidence). The psychometric properties and level of evidence of these selected measures of outcome are summarized in Table VI.

#### *Optional outcome measures*

The second section consisted of 18 optional outcome measures, to be used to evaluate a specific function or activity in individual patients with stroke. For instance, if the hand of the paretic arm becomes edematous, it would be desirable to measure the volume of the hand. This is not necessary if the hand is not edematous. The optional outcome measures are: Modified Rankin Scale [52], Neutral-0-Method (Range of Motion) [49], Numeric Pain Rating Scale [42], Nottingham Sensory Assessment [30,44], Modified Ashworth Scale [24,60], testing

the cranial nerves [32], Brunnstrom Fugl-Meyer assessment [36], Hand volumeter [47], Trunk Impairment Scale [53], Action Research Arm Test [45], Nine Hole Peg Test [37], Timed Balance Test [25,43], Rivermead Mobility Index [27], Falls Efficacy Scale for Stroke [38,39], Timed Up&Go Test [48], Six Minutes Walk [26], Nottingham Extended ADL-index [46,54], and Frenchay Activities Index [31,50].

#### *Moments of assessment after stroke*

The task group and expert group reached agreement on when the core outcome variables should be measured. Since the information acquired can assist physiotherapists in their clinical reasoning and decision making, it is important to measure these variables at the start and end of a course of treatment, before each (multidisciplinary) stroke team meeting (actual information about patients' status and progress), and at 3 and 6 months after stroke (to use in future prognostic research).

## **Discussion**

In general, the use of evidence-based guidelines improves patient care [7,61]. The same is true regarding clinical decision-making in physiotherapy [9,62]. To improve physiotherapy care for patients with stroke in The Netherlands, we developed a clinical practice guideline for physiotherapy for patients with stroke (CPGPS). We first performed a literature review, identifying 322 relevant articles that covered three aspects of the physiotherapy management of stroke patients, namely, prognostics, interventions, and outcomes. The methodological quality of these studies was assessed, as was the content of the interventions used. Seventy-two recommendations for clinical practice for physiotherapists were distilled from these articles: Six recommendations concerned the prediction of functional recovery of generic ADL, including specific ADLs such as walking ability and hand/arm use (grade 3 evidence); 65 recommendations concerned physiotherapy interventions (24 of grade 1 evidence; 18 of grade 2 evidence; and 23 of grade 3 evidence); and 1 recommendation concerned when to assess functional outcome, using reliable, responsive, and valid outcome measures. According to the guideline, physiotherapists should assess each stroke patient with the core set of 7 high-quality outcome measures (grade 1 or 2). Most (6 of 7) of these outcome measures assessed activities of the ICF framework [59,63,64]. As such, the guideline should be used by physiotherapists in clinical decision-making [65].

The guideline was constructed according to international standards [66–68]. The main electronic

Table VI. Characteristics of the primary set of outcome measures included in the CPGPS (for explanation of the used criteria see Table III).

Outcome measure	Brief description	Validated in stroke patient population:	Concurrent validity:	Test-retest reliability:	Responsiveness:	Clinical use	Number of criteria max 6 criteria, see Table III	Level of evidence
Motricity index	Evaluates voluntary motor activity or maximal isometric muscle strength of (paretic) arm as well as (paretic) leg muscles. Reliable, valid, and quick to perform, and poor responsiveness. Six items scored on an ordinal rating scale (sum score 0–200 points)	Demeurisse et al. (1980) [33] Collin & Wade (1990) [29]	MI-leg vs. FM-leg: $r_s = 0.69^{**}$ MI-arm vs. FM-arm: $r_s = 0.71^{**}$ (Koolstra 2004) [94]	$r_s$ (inter) = 0.91** $r_s$ (intra) = 0.98** (Koolstra 2004) [94]	Low SDD (MI-arm) = 12 points SDD (MI-leg) = 13 points (Koolstra 2004) [94]	TPA: yes TTA: 10–15 min.	5	2
Trunk Control Test	Evaluates the stability of the trunk. Reliable, valid, simple to administer, and poor responsiveness. A 3-point ordinal rating scale (0, 12, or 25 points for each item) is used to score four axial movements (sum score: 0–100 points)	Collin & Wade (1990) [29] Franchignoni et al. (1997) [35]	TCT vs. MI-leg: $r_s = 0.71^{**}$ TCT vs. FAC: $r_s = 0.69^{**}$ (Koolstra 2004) [94]	$r_s$ (inter) = 0.96** $r$ (intra) = 0.87** (Koolstra 2004) [94]	Low SDD = 25 points (Koolstra 2004) [94]	TPA: yes TTA: 5–10 min.	5	2
Berg Balance Scale	Evaluates static and dynamic balance in a functional way. The scale is valid, reliable, and responsive, and takes about 15 min to administer. The BBS consists of 14 items, scored on 5-point ordinal rating scale (0–4 points). The sum score varies between 0 and 56 points	Berg et al. (1995) [23]	BBS vs. TUG: $r_s = -0.70^{**}$ BBS vs. FRT: $r_s = 0.88^{**}$ (Koolstra 2004) [94]	ICC (inter) = 0.96** ICC (intra) = 0.98** (Koolstra 2004) [94]	High SDD = 6 points (Stevenson 2001)	TPA: yes TTA: 15 min.	6	2
Functional Ambulation Categories	Evaluates the degree of dependence in walking ability. The FAC is a valid, reliable assessment tool, easy to administer, and poor responsiveness. It contains 6 items, scored on a 2-point ordinal scale (sum score, 0–5 points)	Holden et al. (1984) [40] Holden et al. (1986) [41]	FAC vs. TMWconf.: $r_s = 0.79^{**}$ FAC vs. BI: $r = 0.89^{**}$ (Koolstra 2004) [94]	$r_s$ (inter) = 0.79** ICC (intra) = 0.96** (Koolstra 2004) [94]	Low SDD = 1 point (Koolstra 2004) [94]	TPA: yes TTA: 1 min.	5	2

(continued)

Table VI. (Continued).

Outcome measure	Brief description	Validated in stroke patient population:	Concurrent validity:	Test-retest reliability:	Responsiveness:	Clinical use	Number of criteria max 6 criteria, see Table III	Level of evidence
Ten Meter Walk	Gives a valid and reliable indication of the comfortable walking speed. It is responsive and simple to administer, and can be tested in patients with a FAC score of 3 or more points. The mean of 3 walking trials is recorded. Patients can be tested wearing orthotics or using walking aids	Waide 1992 [54]	TMWcomf. Vs. FAC : $r_s = 0.79^{**}$ (Koolstra 2004) [94]	$r_p$ (inter) = 0.97** ICC (intra) = 0.97** (Koolstra 2004) [94]	High SDD = 0.16 m/s (Koolstra 2004) [94]	TPA: yes TTA: 5–10 min.	6	1
Frenchay Arm Test	Evaluates the use of paretic hand and arm. The FAT is a reliable and valid tool with poor responsiveness. Items scored on a 2-point ordinal rating scale (0–1 point), with a total score of 0–5 points	Waide (1992) [54] DeSouza et al. (1980) [34]	FAT vs. UAT : $r_p = 0.93^{**}$ (Koolstra 2004) [94]	ICC = 0.90** (Hoogstraat unpubl.)	Low SDD = 1.3 points (Hoogstraat unpubl.)	TPA: yes TTA: 5–10 min.	5	2
Barthel Index	Evaluates the degree of dependence on ADL. The BI is a valid, reliable assessment tool, and is easy to administer with poor responsiveness. There are several different versions of the test; we chose the 20-point Collin version. <sup>28</sup> This version contains 10 items, some of which are scored on a 2-point (0–1 point) and others on a 4-point ordinal rating scale (0–3 points)	Collin et al. (1988) [28]	BI vs. FAC: $r_s = 0.89^{**}$ BI vs. ARAT: $r_s = 0.46^*$ (Koolstra 2004) [94]	$r_s$ (inter) = 0.95** $r_s$ (intra) = 0.95** (Koolstra 2004) [94]	Low SDD = 4 points (Koolstra 2004) [94]	TPA: yes TTA: 3–5 min.	5	2

\*\*  $p < 0.001$ ; \*  $p < 0.01$ ; ARAT = Action Research Arm Test; BBS = Berg Balance Scale; BI = Barthel Index; FAC = Functional Ambulation Categories; FAT = Frenchay Arm Test; FM = Fugl-Meyer Assessment; FRT = Functional Reach Test; ICC = Intraclass Correlation Coefficient; MI = Motricity Index;  $r_p$  = Pearson's correlation coefficient;  $r_s$  = Spearman correlation coefficient; SDD = Smallest Detectable Difference; TCT = Trunk Control Test; TMW = Ten Meter Walk; TPA = test protocol available; TTA = time to administer; TUG = Timed Up&Go Test; UAT = Utrecht Arm Test; vs. = versus.

databases were searched and the methodological quality of the included studies was analysed [7,11,14,15,18]. Although sometimes arbitrary choices were made when scoring the methodological quality of the studies [69], our choices seem to have been justified, according to recent stroke rehabilitation literature [70]. Furthermore, where possible, we analysed the effects of the interventions (and if possible statistical pooling of comparable interventions) [10,12]. Most of the intervention studies included were small and hence had a low statistical power to reveal statistically significant effects [12]. The differences in methodological quality resulted in an almost significant negative trend between the calculated effect sizes in 123 of the included RCTs and the quality rating according to the PEDro scale [12]. In addition, the generalizability of the results of studies of prognostic factors is often limited due to methodological flaws and the often arbitrary timing of predicting outcome post stroke [14]. Recently, a new longitudinal regression model was developed in which the longitudinal relationship of observed changes in body functions, such as strength and synergism, is related with observed improvements in activities such as gait [71]. The advantage of such longitudinal regression models is that time is used as a covariate that independently determines the accuracy of outcome [71]. In addition, most regression models have not been cross-validated in an independent group of stroke patients, which makes the generalizability of the derived model questionable. There is a need for long-term studies of the chronic phase in order to identify those patients who are susceptible for functional decline, for example in gait performance [72].

Each step in the clinical decision-making process should incorporate the patient's wishes and be based on the patient's functional prognosis. However, physiotherapists should use their clinical experience to critically appraise treatment goals and evaluative measurements in term of activities and participation [65,73,74]. In other words, when treating patients, there is always a compromise between existing evidence on the one hand, and the patients' clinical state and circumstances, the patients' preferences, including cultural and ethical factors, and constraints, such as time available to apply the guideline and available equipment and expertise [65,73], on the other. Consequently, clinical practice guidelines cannot be seen as a simple cookbook in which steps are taken automatically. Moreover, such guidelines do not always cover all the aspect or events that occur in 'real life'.

While many of the physiotherapy interventions included in the guideline were restricted to exercises [10], in practice physiotherapists often use combined interventions or interventions which, to our knowl-

edge, have never been investigated in well-designed studies [10,12]. For example, there are few RCTs of the effect of physiotherapy on stair climbing, of the use of walking aids, of training transfers (bed to chair), or of instructions for fall prevention [10,12]. In addition, a discussion is warranted on which research design is most appropriate for generating evidence to improve everyday physiotherapy practice [75–77]. It might be useful to consider non-linear dynamics [78,79], and psychological constructs in physiotherapy research and stroke rehabilitation, such as control perceptions [80].

Recently, a number of multidisciplinary stroke guidelines have been developed in the UK [6], Scotland [4], USA [81], Canada [82], New Zealand [83], and The Netherlands [2,3]. To date, to our knowledge, beside our guideline [10], no physiotherapy-specific stroke guideline has been published, except extracts of the physiotherapy elements of the UK stroke guideline [84]. However, the development of a monodisciplinary stroke guideline has been criticized recently [85], because stroke rehabilitation is a team activity and therefore cannot be split up into the effects of specific professional therapies [85]. We consider monodisciplinary guidelines an extension of existing multidisciplinary guidelines, offering more detailed information related to a certain discipline [86].

We are aware, however, that the applications of CPGPS are not restricted to the discipline 'physiotherapy' alone. Moreover, it should be emphasized that the content of physiotherapy differs in each institutional setting and heavily depends on the available expertise in each multidisciplinary team as well as the context of healthcare system in general. Therefore, the present CPGPS should not be seen as an attribution of certain interventions to a certain discipline but rather as a collection of available knowledge about the effectiveness of interventions applicable by physiotherapists working in the Dutch healthcare system.

*Posthoc* analyses of the content of the guideline demonstrated that almost 90% of the recommendations were based on the results of intervention studies involving patients in the post acute and chronic phase of stroke, and patients who had experienced a less severe or uncomplicated stroke. We have to conclude that evidence-based interventions are based on only a minority of patients, given the complexity of stroke. In fact, it could be queried whether individual stroke patients will benefit from this guideline and evidence-based interventions in everyday physiotherapy practice. To our knowledge, this gap between evidence-based knowledge and the real world has not been investigated.

We are also aware that developing CPGPS does not automatically result into a changed behaviour of

physiotherapists in their daily practice by lack of knowledge about the factors impeding successful implementation. For example, the present CPGPS showed moderate evidence for a reduced length of stay in favor of Motor Relearning Programme (MRP) or traditional care, compared to a rather impairment focused neuromuscular treatment approach such as neurodevelopmental treatment (NDT). No evidence was found for applying a specific neurological treatment program in terms of muscle strength, synergism, muscle tone, walking ability, dexterity or ADL [12]. Achieved consensus of the dubious role of strictly applying NDT concept after stroke has resulted in an implementation research programme for 2 years paid by the Dutch Government [87]. In this implementation project NDT teachers are educated how to apply the evidence-based guidelines into practice, how to measure change and how to estimate prognosis in patients with stroke. Since recently, all NDT teachers in The Netherlands accepted to participate in this implementation project of the CPGPS and endorsed to change their name into 'Neurorehabilitation-CVA'.

The conceptual evidence-based model for clinical decision-making composed by Haynes et al. [65] emphasizes the central role of clinical expertise in this process. Clinical expertise has three components, namely, research evidence, patients' clinical state and circumstances, and patients' preferences and actions. In developing the guideline, we concentrated on one component, research evidence, and paid less attention to the other two components [65]. To improve the guidelines, we suggest that in the future: (a) Patients with stroke should be stratified into different functional profiles according to their prognosis in their recovery of functional health status [71,88,89]; (b) Clinical decision rules for each stratum or group should be developed [90]; and (c) Concepts concerning clinimetric monitoring of functional health status of patients with stroke should be developed [91]. In addition, we need to know more about the time dependence of functional recovery after stroke [71,88], about the mechanisms underlying therapy-induced functional improvement, and the time dependence of predictors of functional outcome [71,88,89]. The recent shift in physiotherapy toward task-oriented and context-specific training means that outcome measures may need to be developed in order to evaluate patients with stroke in their real-life activities [64,92]. These improvements can be integrated in an update of the CPGPS. The board of the Royal Dutch Society for Physical Therapy stipulated that the guideline should be revised every 5 years. As one of the aims of developing this guideline was to improve everyday physiotherapy

practice, in the future attention should be paid to factors that hinder the implementation of the guideline.

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## Appendix

### **An example of using outcome measures to predict functional recovery after stroke**

Kwakkel [93] developed a model to predict the degree of walking ability, as measured with the Functional Ambulation Categories (FAC), 6 months post stroke, using the initial Barthel Index (BI) score at 2 weeks after stroke in a linear regression model:

$FAC = 1.860 + (0.03 * (BI * 5)) + (1.236 * SB)$ , where sitting balance (SB) is defined as ability to maintain sitting balance for minimally 30 seconds without support (score = 1, maintaining SB is possible, score = 0, maintaining SB is not possible). As an example, a stroke patient has a BI score of 5 points 2 weeks after stroke, then the FAC score at 6 months would be calculated as follows:  $FAC = 1.860 + (0.03 * 25) + (1.236 * 1) = 3.846$ .