

EFFECTS OF DAY-HOSPITAL REHABILITATION IN STROKE PATIENTS: A REVIEW OF RANDOMIZED CLINICAL TRIALS

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ABSTRACT. The purpose of this study was to review the literature on the effects of day-hospital rehabilitation (DHR) in stroke patients. In The Netherlands DHR concerns a multidisciplinary approach to decrease disability and handicap and to optimize quality of life in an outpatient setting. Data were collected by a computer-aided search of published randomized trials. Fifteen articles reporting on seven randomized controlled trials were selected. Data extraction included a score for quality of the methods, based on four categories: "study population", "interventions", "effects" and "data presentation and analysis". To each criterion a weight was attached and the maximum score was set at 100 points. In judging the methodological quality of the selected studies, one study proved insufficient. Of the remaining studies the sum score varied from 34 to 67, with a mean of 50. Comparison of the results of the studies is complicated by different definitions of DHR, different natures of the control group and the study population, and the variety of measurement instruments applied. Often instruments were applied whose reliability and validity was not proven. As of now it is not possible to prove that DHR for stroke patients is effective. In future research a standardized definition of DHR, a uniform control group, an acceptable research methodology and adequate measurement instruments must be applied.

Key words: day-hospital rehabilitation; stroke.

INTRODUCTION

In the Western world stroke is the most important cause of disability and handicap (3). If a stroke patient, who lives at home, still encounters disabilities and/or handicaps, day-hospital rehabilitation (DHR) may be the right treatment strategy. DHR aims at

reduction in disability and handicap (26) through a dedicated programme by a multidisciplinary approach (physiotherapy, psychology, speech therapy, social work, rehabilitation engineering, occupational therapy and rehabilitation medicine).

Day-hospital rehabilitation for stroke patients is considered effective when impairments, disabilities, handicaps and/or quality of life are significantly improved after treatment (1). A review of effectiveness of DHR has been performed before (5), but it concerned geriatric populations. Effectiveness of DHR with stroke patients of all ages has not yet been subject to review.

In this review a literature search was performed to select all studies concerning DHR with stroke patients, without the restriction of age. The studies were judged according to their methodological merits, and finally the effects of DHR in the selected studies were discussed.

METHODS

Selection of literature

Articles were selected by a computer literature search (MEDLINE) using the key words: "rehabilitation", "day care", "stroke" and "randomized controlled trial".

Structured review

A structured procedure based on general principles of intervention research (2, 23) was used to evaluate literature, both on methodological qualities and on effects of DHR.

A judgement of the studies was carried out by three reviewers, independently. Initial agreement was 86%. Disagreement existed on the items "baseline data" (randomization and drop outs) and "effects" (blinding, follow-up period). After sharpening the review instructions agreement was achieved up to 96%. Complete agreement was achieved after consulting together.

Four clusters of criteria were distinguished (Table I): "study population", "intervention", "effects" and "data presentation and analysis". To each criterion a weight was attached, as published before by Chalmers et al. (2) and

Table I. Criteria list for the methodological assessment of randomized trials of day-hospital rehabilitation for stroke patients (for details, see footnotes)

	Criteria	Weight	
<i>Study population:</i>	A. Homogeneity	2	
Baseline data	B. Delay stroke-DHR	1	
	C. Age/sex	1	
	D. Lateralization	1	
	E. Starting values	1	
	F. First-ever stroke	1	
	G. Randomization	4	
	H. Drop outs	3	
	I. <20% loss to follow-up	2	
	<10% loss to follow-up	2	
	J. >50 subjects in the smallest group	8	
	>100 subjects in the smallest group	9	
	<i>Intervention:</i>	K. Interventions described in DHR and control group	10
		L. Control group adequate	5
M. Co-interventions avoided		5	
N. Compliance measured		5	
<i>Effects:</i>	O. Patients blinded	5	
Instruments	P. Impairment	1	
	Q. Disability	3	
	R. Handicap	3	
	S. Quality of life	3	
	T. Research worker blinded	10	
	U. Follow-up period adequate	5	
	<i>Data presentation and analysis:</i>	V. Intention-to-treat analysis	5
W. Data presentation		5	

Operationalization of criteria:

- A: Description of inclusion and exclusion criteria (1 point); restriction to a homogenous population (1 point).
 B-F: Comparability for delay appearance of stroke until DHR; age and sex; left or right hemisphere of stroke; initial scores of measurement instruments; first-ever stroke or relapse (1 point each, if taken into account in study).
 G: Randomization procedure described (2 points); randomization procedure which excludes bias (2 points).
 H: Information from which group and with reason for withdrawal. No drop outs is 3 points.
 I: Loss to follow-up: all randomized patients minus the number of patients at main moment of effect measurement for the main outcome measure, divided by all randomized patients, times 100.
 J: Smallest group immediately after randomization.
 K: DHR explicitly described (5 points); all reference treatments explicitly described (5 points).
 L: Comparison with an existing treatment modality.
 M: Other medical interventions avoided.
 N: Compliance measured in each study group and satisfactory.
 O: Attempted blinding patients with respect to the content of the interventions (3 points); blinding evaluated and fully successful (2 points).
 P-S: Use of instruments concerning items: impairment (1 point, 0 points if no or non-valid or reliable instruments are applied); disability, handicap, quality of life (3 points each if valid and reliable instruments are applied, 1 point if instrument only covers part of the item, 0 points if no or non-valid or reliable instruments are applied).
 T: Effect measurement by blinded assessor (10 points).
 U: Including an effect measurement after six months or longer (5 points).
 V: When loss to follow-up is less than 10%: all randomized patients for most important outcome measures, and on the most important moments of effect measurement minus missing values, irrespective of non-compliance and co-interventions. When loss to follow-up > 10%: intention-to-treat as well as an alternative analysis for missing values.
 W: For most important outcome measures and the most important moments of effect measurement.

Koes et al. (23). The maximum score for each study was set at 100 points. Higher sum scores indicate a better methodological quality. Adaptations, which will subsequently be discussed, were carried out to make the criteria applicable for DHR and stroke patients (Table I).

In the cluster "study population" the variable "baseline data" was changed with respect to the definition by Koes et al. (23). A set of five criteria was chosen. The first is the delay between stroke onset and start of DHR. Although there are differences of opinion (16, 19–22, 27, 32) as to whether or not the length of the delay is of influence on the effect of DHR, having knowledge of the amount of delay was found to be important. The second criterion, the combination of age and sex, is a basic one, enabling comparability between studies. The third is the site of the lesion; the fact that the left or right hemisphere is damaged is of great influence on the nature of the clinical symptoms. The fourth criterion concerns the starting values of the measurement instruments used in the studies. It is essential to judging follow-up and outcome results. Finally, the distinction between a first-ever or a repeated stroke is important.

The criterion "intervention" was used to standardize the control groups and to judge whether the definition of the DHR applied in the studies met our DHR criteria. These criteria are: a multidisciplinary outpatient approach; and at least three therapies involved per treatment, coordinated by a rehabilitation physician. The treatment aims at impairments, disabilities, handicaps and quality of life.

In the cluster "effects", according to Chalmers et al. (2), blinding of the patient and research worker is of great importance. Since the effects of DHR concern impairments, disabilities, handicaps and quality of life, the selected studies are judged on the use of relevant, reliable and valid measurement instruments.

A follow-up period of six months or longer is thought to be necessary to gather sufficient data for further analysis.

The cluster "data presentation and analysis" consists of two variables; an intention-to-treat analysis and data presenting. Applying these variables increases the methodological quality of the trial (2).

Finally, an inventory is made of the effects concerning DHR with stroke patients, contributed to the selected studies. This also concerns cost-effectiveness.

RESULTS

A number of studies (7, 9, 24, 28, 35) investigate DHR without being randomized clinical trials, and therefore they are not included in this review. Fifteen articles (4, 6, 10–15, 18, 31, 33, 38–41) concerning seven randomized clinical trials were finally selected (Table II).

Methodological criteria

All the included studies are controlled clinical trials. In judging the methodological quality of the selected studies, one study (4) turned out to be insufficient, with a sum score of only 9 (Table III). Therefore, the

study was not taken into account for this review. Of the remaining six studies the sum score varied from 34 to 67, with a mean of 50 (Table III).

Control groups

The constitution of the control groups varies among the different studies. This complicates comparison of results. Two studies (18, 33) compare DHR with conventional care. A third study (31) describes a comparison between intensive DHR, regular DHR and no actual treatment, except for practice instructions. Eagle et al. (6) compared in- and outpatient treatment, whereas in the "Bradford" study (10, 38–41) DHR was compared with home physiotherapy. In the "Domino" study (11–15) the efficacy of domiciliary rehabilitation (treatment by a physiotherapist and/or occupational therapist in the patient's own environment) was studied in comparison to routine hospital based rehabilitation services, for instance, outpatient physiotherapy and occupational therapy.

Definition of day-hospital rehabilitation

In all studies the multidisciplinary character of DHR was stressed but hardly defined. In most studies the rehabilitation consisted of physiotherapy and occupational therapy only, sometimes in combination with nursing (10, 38–41). In two studies (6, 33) speech therapy, social work, and in one study (6) a pharmacist and a dietician took also part in the treatment.

Frequency and duration of treatment were often not exactly described (6, 11–15, 18). Tucker et al. (33) treated his patients twice or three times per week, from 8:00 until 14:00. Duration and contents of the specific parts of the DHR were not described. In the study published by Smith et al. (31) patients were treated in two groups: the first group was treated four days per week, the second group three half days per week. The composition of the DHR was not described.

In the "Bradford" study (10, 38–41) patients were treated for eight weeks, twice per week. This study lacks specification of the DHR.

Measurement instruments

Since DHR aims at treating impairments but above all aims at a decrease in disabilities and handicap and optimizing quality of life, instruments measuring

Table II. Details of trials studying the effectiveness of day-hospital rehabilitation in stroke patients

Authors	Name of study/year of publication	Study design	Number of patients and age (years), study and control group	Results and conclusions
Smith et al. (31)	Northwick Park 1981	Randomized controlled intensive treatment with conventional rehabilitation and with a third regimen which included no routine rehabilitation	133 patients, mean age 63, 66 and 65	Improvement was greatest and significant in those receiving intensive treatment, intermediate in those receiving conventional treatment and smallest in those receiving no routine treatment. Decreasing intensity was associated with a significant increase in the proportions of patients who deteriorated and in the extent to which they deteriorated
Tucker et al. (33)	1984	Randomized controlled comparison of DHR with conventional management	120 patients, mean age 72.5 and 71.5	Day-hospital patients showed a significant improvement in performance of activities of daily living at six weeks but not at five months; however, they had sustained improvement in mood, significant at five months. The cost of DHR was one third greater than that of rehabilitation by alternative means
Cummings et al. (4)	1985	Comparison of DHR and routine hospital rehabilitation	96 patients, mean age unknown	The patients in DHR were taken to the hospital for treatment five days a week. The control group remained in hospital on rehabilitation as inpatients and received the routine care. No significant difference was found between the two groups. However, at full capacity, with the research cost removed, the day-hospital method proved the more cost-effective
Young & Forster (10, 38-41)	Bradford, 1989-1993	Randomized comparison of DHR and home physiotherapy	124 patients, mean age 72 and 70	After eight weeks, home physiotherapy is not significantly more effective than DHR. After six months both treatment groups had improved. These improvements were significantly better for patients treated at home. Home physiotherapy also seems to be more resource-efficient
Eagle et al. (6)	1991	Randomized controlled trial comparing patients managed in day-hospital and those receiving conventional care	113 patients, mean age 79.6 and 78.2	Functional status deteriorated over time in the two groups; although the difference was not significant, there was less deterioration in the control group. The care received at the day-hospital did not improve functional status or quality of life of elderly patients as compared with the otherwise excellent geriatric outpatient care
Gladman et al. (11-15)	Domino, 1991-1994	Randomized controlled comparison of hospital based and domiciliary rehabilitation	327 patients, mean age 70	Overall there was no significant difference in effectiveness of the domiciliary and hospital based services, although younger stroke unit patients appeared to do better with home therapy while some frail elderly patients might have benefitted from day-hospital attendance
Hui et al. (18)	1995	Prospective randomized study to compare the outcome of elderly stroke patients managed by a geriatric team using a day-hospital facility vs conventional medical management	120 patients, mean age 74.1 and 73.1	Functional improvement was significantly greater in the group managed by the geriatricians with a day-hospital facility compared with the conventional group at three months but not at six months. There were also fewer outpatient visits among the day-hospital patients at six months. No significant difference was found in costs between the two treatment groups

Table III. Results of methodological review

Authors	Study name and year of publication	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	Total score
Smith et al. (31)	Northwick Park, 1981	2	1	1	0	1	1	2	0	0	8	10	5	0	0	0	0	3	0	0	0	5	0	5	34
Tucker et al. (33)	1984	1	0	1	0	1	0	4	3	4	0	10	5	0	0	0	3	0	0	0	10	0	0	0	42
Cummings et al. (4)	1985	1	0	0	0	0	0	2	0	2	0	0	0	0	5	0	0	1	0	0	0	0	0	0	9
Young & Forster (10, 38-41)	Bradford, 1989-1993	2	1	1	1	1	1	4	3	2	17	10	5	0	0	0	3	3	3	0	5	0	5	0	67
Eagle et al. (6)	1991	1	0	1	0	1	0	4	3	2	8	10	5	0	0	0	3	0	0	0	0	5	0	5	48
Gladman et al. (11-15)	Domino, 1991-1994	2	0	1	0	1	1	4	3	2	17	10	5	0	0	0	3	3	3	0	5	0	5	0	65
Hui et al. (18)	1995	2	1	1	0	1	1	2	0	0	8	0	5	0	0	0	3	0	0	0	0	5	0	5	34

According to Koes et al. (23), a sum score of 50 or more is to be considered relatively high.

these items should be part of the testing procedures. None of the studies applied a set of instruments covering all the variables mentioned above (Table IV).

Impairments were taken into account in most studies (6, 10, 18, 33, 38-41) but never covered all the possible impairments. Furthermore, only some of the instruments in this field have a proven reliability and validity (Table IV) (25, 34).

In the field of disabilities most studies (6, 10-15, 18, 31, 33, 38-41) applied a valid and reliable instrument: the "Rand" (6), the "Barthel index" (6, 18), the "Abbreviated Northwick Park Activities of Daily Living" (33), the "Frenchay Activities Index" (10, 38-41), the "Extended Activities of Daily Living" (11-15) and the "Nottingham Health Profile" (10-15, 38-41). Validity and reliability of these instruments are reported elsewhere (25, 34).

Instruments measuring handicap are the "Frenchay Activities Index" (10, 38-41) and the "Brief Assessment of Social Engagement" (11-15). Both instruments are reliable and valid.

By using the "Life Satisfaction Index (Nottingham Version)" (11-15) and the "Geriatric Quality of Life Questionnaire" (6) in two studies, the quality of life was intended to be measured. There is no proof of validity or reliability for either instrument.

Effects

Two studies (18, 33) investigated DHR within a geriatric population. Most studies concerned stroke patients only (10-15, 18, 31, 38-41), whereas two studies (6, 33) also involved other patients.

In general, no difference in effects was seen in the two studies (6, 11-15), although in the Domino study (11-15) younger stroke patients seem to be better off after domiciliary rehabilitation, while older patients are likely to benefit more from DHR.

In identifying the effects of DHR only the valid and reliable measurement instruments are taken into account. Six studies applied an instrument measuring disability (Table V).

Smith et al. (31) concluded that improvement was greatest and significant in patients receiving intensive rehabilitation, intermediate in those receiving conventional rehabilitation and smallest in those receiving no routine treatment. Decreasing intensity of treatment was associated with a significant increase in the proportion of patients who deteriorated and in the

extent to which they deteriorated. Tucker et al. (33) and Hui et al. (18) showed that functional improvement was significantly better after six weeks and three months, respectively, after DHR but was no longer significant after five and six months. No significant changes were seen by Eagle et al. (6) or Gladman et al. (11–15), whereas Young & Forster (10, 38–41) found significant improvement after six weeks and six months in the DHR group as well as in the group receiving home physiotherapy. At eight weeks the latter improved even significantly more but no further after six months.

Three studies applied an instrument measuring emotional status/depression. A significant improvement in mood was concluded five months after DHR, by Tucker et al. (33), while after six weeks a non-significant improvement was seen. Young & Forster (10, 38–41) and Hui et al. (18) found no significant changes.

Some studies (10–15, 18, 33, 38–41) analysed the cost-effectiveness of DHR. Hui et al. (18) found no difference, whereas Tucker et al. (33) and the Bradford study (10, 38–41) concluded that DHR

was less resource-efficient. Hospital based rehabilitation was more cost-efficient than domiciliary rehabilitation (11–15).

DISCUSSION

In view of the fact that stroke is an important cause of disability and handicap, the number of randomized controlled studies concerning DHR for stroke patients is low.

The methodological quality of the selected studies was assessed by applying an adapted version of a structured procedure, based on general principles of intervention research. The adaptation concerned in particular two subcriteria: "baseline data" and "instruments". The adaptations were based on literature studies and clinical experience.

Although there are no strict rules for judging the sum score, the selected studies seem to have acceptable methodological qualities.

In none of the studies taken into account in this review is DHR applied as defined in the introduction. A thorough multidisciplinary approach is an essential

Table IV. *Outcome measures and validity*

Authors	Study name and year of publication	Outcome measures	Valid
Smith et al. (31) Tucker et al. (33)	Northwick Park, 1981 1984	Activities of Daily Living Index	Yes
		Abbreviated Northwick Park Activities of Daily Living (ADL) Index	Yes
		Zung Depression Index	Yes
Cummings et al. (4)	1985	Abbreviated mental test	No
		Modified Kenny self-care evaluation protocol	No
		ADL questionnaire	No
		Mental status questionnaire	No
		Linkowski's acceptance of disability instrument	No
		Dupuy well-being measure	No
		Patient satisfactory questionnaire	No
Young & Forster (10, 38–41)	Bradford, 1989–1993	Barthel index	Yes
		Motor Club assessment	No
		Frenchay Activities Index	Yes
		Nottingham Health Profile	Yes
		General health questionnaire	Yes
Eagle et al. (6)	1991	Barthel index	Yes
		Rand questionnaire	Yes
		Global Health Question	No
		Geriatric Quality of Life Questionnaire	No
Gladman et al. (11–15)	Domino, 1991–1994	Extended Activities of Daily Living	Yes
		Barthel index	Yes
		Nottingham Health Profile	Yes
		Brief Assessment of Social Engagement	Yes
		Life Satisfaction Index (Nottingham version)	No
Hui et al. (18)	1995	Barthel index	Yes
		Self-rated health scale score	No
		Geriatric Depression Scale	Yes

Table V. Results of day-hospital rehabilitation (A) versus control group (B): ADL

Authors	Study name and year of publication	6-8 weeks		3 months		5-6 months		1 year	
		A	B	A	B	A	B	A	B
Smith, D. S. et al. (31)	Northwick Park, 1981			++	+	++	+		
Tucker, M. A. et al. (33)	1984	++	+	n.s.	n.s.				
Young, J. B. & Forster, A. (10, 38-41)	Bradford, 1989-1993	+	+			+	++		
Eagle, D. J. et al. (6)	1991			n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Gladman, J. R. F. et al. (11-15)	Domino, 1991-1994			n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Hui, E. et al. (18)	1995			++	+	n.s.	n.s.		

++ considerable increase, + increase, and n.s. no significant change.

condition for optimal efficacy of DHR, as already proven in inpatient rehabilitation for stroke patients (8, 17, 19, 22, 30). Particular expertise for mobility, personal care, communication, cognitive skills and coping strategies is essential. Future research concerning DHR for stroke patients should be based on this principle.

Measurement of the effects of DHR was, according to the goal of DHR, never complete, and frequently instruments were applied whose validity and reliability are not proven.

It is difficult to summarize the effects resulting from the selected studies. First of all, as mentioned, the nature of the DHR differs strongly per study; there is no consensus about the number and sort of applied treatments in DHR, and the amount of treatment differs per study. Second, the composition of the control groups differs. Third, no uniform set of measurement instruments was applied covering the goals of DHR. Furthermore, a lot of studies used measurement instruments with no proven validity and reliability.

In conclusion, there is, in the field of disability, little significant yet conflicting information on the efficacy of DHR. Furthermore, there is an indication that five months after DHR, improvement in mood can be achieved. In other sections of disability and impairment as well as in the field of handicap and quality of life, no (significant) effects of DHR were observed.

Although there are some studies (10-15, 38-41) of good methodological quality, it is as of now not possible to prove whether or not DHR for stroke patients is effective. It is obvious that more research is necessary.

For future research the starting point should be an adequate definition of DHR, enabling a clear distinction between DHR and other forms of rehabilitation.

For instance, "home rehabilitation" (29, 36, 37) for stroke patients differs from DHR in such a way that it was not taken into account in this study. This difference and the fact that there are up to now no randomized clinical trials performed on this form of rehabilitation made it impossible to include it in our review.

Furthermore, a uniform control group has to be defined and the research design should be of a good methodological quality. Last but not least, adequate, valid and reliable measurement instruments must be applied.

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Accepted July 7, 1997

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