"AN EVALUATION OF DOMICILIARY REHABILITATION FOR STROKE PATIENTS AFTER DISCHARGE FROM HOSPITAL"

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In Memory of

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ABSTRACT

Not only can stroke kill, but it can also disable and handicap the survivors. There is no medical treatment for stroke and not all stroke can be prevented. Rehabilitation, to promote recovery, or maintenance, to support those who do not recover, is required.

Evidence about the efficacy of stroke rehabilitation is poor. There is little evidence to support many of the specific techniques used, but there is evidence to support the use of organised rehabilitation in hospitals. After leaving hospital there is some evidence that rehabilitation in out-patient departments and at home may be of further help.

In this thesis, the results of a study undertaken to add to this slender body of knowledge by comparing domiciliary to hospital-based rehabilitation after hospital discharge are presented and discussed. Overall, no difference was found in terms of survival, institutionalisation, disability or perceived health between a domiciliary and a hospital-based rehabilitation service (day hospitals and out-patient departments). However, young stroke patients who had required considerable amounts of rehabilitation in a Stroke Unit, were best given further therapy at home rather than in out-patient departments, since it improved household and leisure abilities. This result is compatible with the only other controlled study of domiciliary stroke rehabilitation after hospital discharge. For frail elderly patients, the day hospital service may have had advantages over the domiciliary service because death and institutionalisation rates were lower. The latter finding may be spurious, due to allocation bias and small sample size. In view of the expense of day hospitals, more research is required to examine their efficacy.

It is concluded that domiciliary rehabilitation is a small step forward for stroke rehabilitation and will benefit some disabled stroke survivors, and may be a more resource-efficient way of treating many others.

INTRODUCTION

1.1 GENERAL INTRODUCTION

It has been said that no single medical measure would make such a contribution to the quality of life in old age as the prevention of stroke (Garraway, 1985). Stroke is the third most common cause of death in the UK: nearly 82,000 deaths were attributed to cerebrovascular disease in 1984 (Royal College of Physicians, 1989). But death is not the only terrible feature of stroke, for half of those who survive an acute stroke for six months are disabled (Wade & Langton Hewer, 1987). Stroke is the most common cause of severe disability in the community (Harris, 1971). A third, or more, of stroke survivors are depressed (Robinson et al, 1984). The financial cost of stroke is enormous, costing the NHS £560M in the UK in 1985 (Langton Hewer, 1990) which equates with each Health District in England and Wales spending £3M on stroke annually (King's Fund Consensus Conference, 1989).

It is the purpose of this thesis to illustrate the nature of the problem facing those who attempt to restore and maintain the functional ability of stroke patients, to review the evidence for the benefit of stroke rehabilitation and to report a study evaluating a domiciliary rehabilitation service. In these initial pages the concepts of "impairment", "disability" and "handicap" are described, since they provide a sensible framework to describe the effects of stroke upon individuals, and the place of rehabilitation in the control of the effects of disease is discussed.

1.2 DISABLEMENT: IMPAIRMENT, DISABILITY AND HANDICAP

A terminology is required which allows the various effects of stroke, such as an extensor plantar response, the development of urinary incontinence and the loss of entitlement to drive to be classified.

The WHO International Classification of Impairments, Disabilities and Handicaps (WHO, 1980) provides a conceptual framework for the classification of the way in which individuals can be affected by disease. It proposes that pathological processes lead to "impairment", that is: "any disturbance of the normal structure and functioning of the body, including the systems of mental function. It is characterised by a permanent or temporary psychological, physiological or anatomical loss or abnormality, and includes the occurrence of an abnormality, defect or loss in a limb, organ, tissue or other structure of the body, or in a functional system or mechanism of the body" (Wood, 1988). For example, impairments caused by stroke include hemiplegia, hemianopia and aphasia.

As a result of impairments, patients may be unable to perform tasks or activities such as walking, dressing or eating. This is "disability" and is defined as: "the loss or reduction of functional ability and activity consequent upon impairment. It is characterised by excesses and deficiencies of behaviour and other functions customarily expected of the body or its parts, and represents objectification of impairments in everyday life and activity" (Wood, 1988).

Patients may have equal disability but its impact upon their lives may differ. For example, immobility has greater consequences for a person who lives alone without any support than it does for a person who is well supported at home. The overall impact of a disease upon an individual from their subjective point of view is referred to as "handicap". It is defined as "the disadvantage experienced as a result of impairment or disability. It is

characterised by a discordance between the individual's performance or status and the expectations of the particular group of which he or she is a member, including the individual's own expectations. Handicap thus represents the social and environmental consequences of impairments and disabilities" (Wood, 1988).

Another term which may be used is "disablement", which is a "generic term referring to any experience identified variously by the terms impairment, disability and handicap" (Wood, 1988).

The use of the concepts of impairment, disability and handicap are increasingly accepted as key concepts in the field of rehabilitation. However, confusion can arise because of the differences between these specialist definitions and the lay use of the words "impairment", "disability" and "handicap". According to the Concise Oxford Dictionary to impair is to "damage, weaken", which is close in meaning to the ICIDH definition. However, the dictionary does not distinguish between disability, a "thing or lack that prevents one's doing something", and handicap, a "thing that prevents one from doing something".

It has been suggested that the ICIDH taxonomy is conceptually unsound when used to describe psychological disturbance, because it is difficult to distinguish the pathological process of mental illness from the impairment, and that social disability resulting from mental illness is indistinguishable from handicap (Wiersma, 1986). In this thesis, impairment, disability and handicap are used in their specialist senses as far as possible, but avoided if their use leads to lack of clarity when discussing psychological disturbance.

1.3 THE CONTROL OF DISABLEMENT

Wood (1988) has suggested that there are three approaches to the control of disablement: primary control (to prevent), secondary control (to arrest) and tertiary control (to repair). Tertiary control is divided into restoration and maintenance, with restoration comprising reconstruction and rehabilitation.

Several potentially modifiable risk factors for stroke are known, such as hypertension (MacMahon et al, 1990), cigarette smoking (Shinton & Beevers, 1989) alcohol excess (Gill et al, 1986) and hyperlipidaemia (Tell et al, 1988), so there is potential for the primary control (prevention) of stroke. Patients with a high risk of stroke such as those with hypertension (Collins et al, 1990), atrial fibrillation (Stroke Prevention in Atrial Fibrillation Study Group Investigators, 1990: The Boston Area Anticoagulation Trial for Atrial Fibrillation Investigators, 1990), mitral stenosis (Gibson, 1983), carotid artery stenosis (European Carotid Surgery Trialists' Collaborative Group, 1991) and other vascular disease (Antiplatelet Trialists Collaboration, 1988) have been shown to benefit from specific preventive treatments. If the reason for the fall in the incidence (Garraway et al, 1983) from stroke were to be more fully understood, then still strokes might be prevented.

When prevention fails, secondary control (cure) or tertiary control (repair) is required. Unfortunately, there is no effective medical or surgical drug treatment which cures an acute stroke. there is no drug treatment which promotes the repair of the injured brain. Reconstruction of the central nervous system is emerging from science fiction with the use of neural transplants for Parkinson's disease, but has not been used in stroke. Other surgical procedures, such as tendon release in the management of severe spasticity, are rarely indicated and of unproven efficacy. Thus there is no secondary control of stroke, and tertiary control is required. A commitment to maintenance, either by continuing care or support in the community, is part of the

responsibility of a humane society. Maintenance is, however, the least satisfactory approach to the control of disease. A huge task therefore remains for rehabilitation services: to restore the function of stroke patients, so that the requirement for maintenance is minimised.

"Rehabilitation may be considered as the process of restoring an individual to the fullest level of function. It includes physical, mental and social well-being and independence" (Lincoln, 1991). This thesis will concentrate mainly upon the role played by physiotherapy and occupational therapy in the rehabilitation of stroke patients, because these disciplines traditionally occupy key positions in rehabilitation teams. The valuable contributions of speech therapists, nurses, clinical psychologists, social workers, doctors, lay persons and the clergy are not within the scope of this thesis.

1.4 HANDICAP DUE TO STROKE

The handicap experienced by a stroke patient results from the impairments and disabilities caused by the stroke, the effect of pre-existing impairments and disabilities, and other factors which render the patient vulnerable to the consequences of disability.

Impairments caused by stroke

There are many impairments which result from stroke and which contribute to disability and handicap, such as hemiplegia, hemianopia, aphasia, neglect, ataxia, dysarthria and dysphagia. Some patients with large strokes die soon after onset due to cerebral oedema, brain stem compression or of the complications of their deficits such as bronchopneumonia or pulmonary emboli. However, in survivors, an important characteristic of most impairments is that they tend to recover spontaneously. It is not certain how much recovery is due to the re-perfusion of "the ischaemic penumbra" (areas of brain which were merely ischaemic rather than infarcted), to diaschisis (the recovery of "stunned" parts of the brain which were functionally but not anatomically related to the area damaged by the stroke), to plasticity within the central nervous system (axonal sprouting) or the use of previously redundant neural networks.

Table 1 illustrates the falling prevalence of several impairments at different times post-stroke (Kotila et al, 1984). Patients in that study were in hospital and receiving physical therapy, so some of the recovery may have been due to rehabilitation. The tendency for patients to recover without any specific treatment is illustrated in a report from the Oxfordshire Community Stroke Project (Davies et al, 1989) where functional recovery occurred as often in those who were not admitted to hospital (24/31) as in a group matched for disability who were admitted to hospital (23/30).

Table 1 Prevalence of impairments over time in 154 stroke survivors. (taken from Kotila et al, 1984).

Impairment	Prevalence at		
	24 hrs	3 months	12 months
Hemiparesis	73%	50%	37%
Incoordination	86%	73%	61%
Dysphasia	36%	29%	28%
Dysarthria	57%	29%	21%
Visuo-perceptual disorder	-	60%	41%

It would be hoped that as the impairments and disabilities due to stroke resolve, that handicap should also be reduced. However, this might not be the case. Employment may cease permanently and the financial hardship caused by a stroke may force irrevocable changes in patients' lives, such as moving house or giving up driving.

Pre-existing impairments and disabilities

The Oxfordshire Community Stroke Project provides useful demographic information about first stroke (Bamford et al, 1988). The incidence of stroke rises with age, and the greatest number of strokes occurs in those aged 75 to 84, since there are large number of patients at risk in that age group. Despite the falling age-specific incidence of stroke, in the next three to four decades the numbers of people aged 85 years and over will double with the result that the rate of new handicap due to first stroke will change only slightly over the next few decades (Malmgren et al, 1989) This may underestimate the true amount of future stroke related handicap, since subsequent strokes which tend to occur in the very elderly, may contribute substantial additional handicap (Barer, 1989). Therefore the total number of strokes may not change much but stroke will increasingly be a disease of the very elderly.

The OPCS survey "The prevalence of disability among adults" (Martin et al, 1989) showed that the prevalence of disability rose sharply with increasing age, particularly over the age of 75: 47% of people aged 75-79 who lived in private households were disabled. The most prevalent disabilities found in this age group were locomotor, hearing, personal care and visual problems. Musculoskeletal, ear, circulatory (not including stroke) and eye complaints were the commonest cited causes of disability. Dementia, too, becomes more common with increasing age: in a community survey in Liverpool the prevalence of dementia in women rose from 2% in those aged 65-69 to 25% in those aged 85-89 (Copeland et al, 1987). It must not be forgotten that depression is a more common psychiatric condition than dementia in the elderly: in a study in Nottingham the prevalence of depression was 9.8% (Morgan et al, 1987).

Thus, since the potential victims of stroke are elderly, they are likely already to have difficulty walking, hearing and seeing. A considerable number of potential stroke victims will be depressed and some will be demented.

Vulnerability to handicap.

The majority of stroke patients therefore have to deal with the social disadvantage associated with being elderly, in addition to the disabilities resulting from pre-existing and stroke-related impairments. Poverty remains prevalent in old age: approximately 25% of all people over the age of 65 have been estimated to be poor and a further 44% to be on the margins of poverty (Victor, 1989). Poverty is associated with poor housing, and in an OPCS survey (Hunt, 1978) 12% of households with elderly people had only an outside lavatory. Imagining an elderly stroke victim shuffling through inclement weather to get to the toilet, it is not difficult to see how the impact of poor mobility is greater in the disadvantaged elderly. Poverty may also have a role in the development of the considerable social disengagement seen in the elderly. Reviewing several community surveys, Tinker (1981) has

concluded that approximately one fifth of all elderly are socially isolated. The significance of loneliness is that, in Abrams' survey of those aged 75 and over, primary social relationships were the most important determinants of life satisfaction (Abrams, 1978). If an elderly person is even more socially isolated as a result of a stroke, then this is likely to decrease quality of life yet further.

In summary, stroke victims are usually elderly and hence may frequently have been poorly mobile, hard of hearing or partially sighted before their stroke. A stroke brings impairments which may render them more immobile, less able to care for themselves and more depressed. Poverty, poor housing and social isolation further contribute to their handicap. This is the challenge for rehabilitation services.

1.5 THE CARERS OF STROKE VICTIMS

Before considering the direct effect of rehabilitation on patients' problems, it must be remembered that many stroke patients receive considerable amounts of personal care from their families (Ebrahim & Nouri, 1987), and that the husbands and wives of stroke patients come from the same population of elderly people as the stroke victims themselves, and so they may well be disabled or depressed and vulnerable to the development of handicap. Holbrook's interviews (1982) suggested that many aspects of the carers' lives were disrupted: many of them had financial worries, concerns about their own health, or felt that their social life had been adversely affected. She concluded that "stroke is a family matter". A community survey in Bristol (Wade et al, 1986) reported that carers felt they were more anxious after the patients' stroke than they were before. In Wade's Bristol survey the prevalence of depression found in stroke carers (11-13%) was found to be "significant", although this is similar to the prevalence of depression found in a normal community sample of elderly people in Nottingham (10%) (Morgan et al, 1987). There have been few studies showing which problems are more prevalent in carers of stroke patients than those who are not carers, nor many studies which identify which patient characteristics cause the most problems. In a study in Nottingham (Ebrahim & Nouri, 1987) the majority of carers who provided physical help felt that it had an adverse effect on their lives. On the other hand, a study in North Carolina (Silliman et al, 1986) showed that relatives of stroke patients in institutional care were just as distressed as those who looked after the patient at home, although in both instances the more disabled the patients were, the more emotionally distressed and less likely to engage in social activity were the carers.

Caring for stroke patients is not always detrimental: the majority of carers in Silliman's study in North Carolina reported increased self-esteem and a closer personal relationship between the carer and the patient because they had been able to manage their loved one's illness.

There is therefore likely to be a complex relationship between the emotional and physical health of the carers and patients. Rehabilitation therefore not only has the problems of the patients to deal with but also the interwoven problems of their carers.

STROKE REHABILITATION

2.1 PHYSIOTHERAPY AND OCCUPATIONAL THERAPY

Physiotherapy is concerned with the use of specific exercises or physical treatments to promote the restoration of function, particularly walking, whereas occupational therapy is concerned with the use of specific activities, particularly activities necessary for daily living and leisure, to promote recovery. The use of physical exercise and activity for stroke patients has a long history, dating back at least as far as the fifth century neurologist Caelius Aurelianus (Licht, 1975).

Physiotherapy

"Traditional" physiotherapy for stroke involves resistive exercises to improve recovering muscle strength, and active or passive exercises to maintain a full range of joint movement. Repeated activity may also encourage re-learning of abilities, and biofeedback techniques can be employed to enhance this. Postural deformities which interfere with function can be modified with braces and other mechanical or electromechanical devices. If a paralysed limb fails to recover then attempts can be made to overcome functional loss by use of the uninvolved side.

A variety of "neurophysiological" techniques have been developed in recent decades. Exponents of these techniques point out that traditional approaches are illogical, because resistive exercises are for increasing muscle bulk, yet it the control of movement which is at fault in stroke, and resistive exercise encourages pathological motor patterns rather than the re-acquisition of normal function. Neurophysiological regimes are said to interact with the complex pattern of spinal reflex activity which emerges after a hemiplegic stroke, so that pathological neurological states, particularly high muscle tone, do not develop, but instead a normal pattern emerges, allowing normal function to return. Many neurophysiological schools have developed, basing their teaching on the empirical findings of their founders (Bobath, 1978;

Johnstone, 1983; Brunnstrom, 1970). In these schools, spinal reflexes are affected by such techniques as altering the position or amount of weight bearing on the limbs, the use of pressure splints applied to limbs, or by dynamic approaches to reproduce normal sensory input (such as carefully assisted and controlled walking).

Neurophysiological regimes are not identical. Some, such as that described by Bobath (1983), intend to inhibit certain reflex patterns which emerge: "It is impossible to superimpose normal patterns on abnormal ones, and so the abnormal patterns must be suppressed" (Nathan, 1983). Brunnstrom (1970) "has come to the opposite conclusion" and saw the emerging spinal reflexes as a "necessary stage for further recovery".

Exponents of neurophysiological techniques assert that some traditional approaches are deleterious: "No patient who rehabilitates by learning to compensate with his sound side ever returns to normal living" (Johnstone, 1978). Similarly, early achievement of function by any means may not be favoured, because it may encourage the development of compensatory mechanisms which are considered to impair eventual progress (Bobath, 1983). Braces and mechanical adaptations are often seen as devices which reinforce abnormalities rather than ameliorate them, and so may also not be favoured (Bobath, 1983). On the other hand, the attention to reducing muscle tone which is so prevalent in Bobath's approach has itself been criticised (Landau, 1974) and experimental evidence has been provided to show that muscle tone may be less important than simple muscle weakness (see Bohannon et al, 1991). Despite the apparent dissent between schools, modern textbooks of physiotherapy predominantly advocate a neurophysiological approach as advocated by Bobath. It is pointed out that each patient is different, that each requires a specific and unique treatment, but the treatment should accord with the principles expounded by Bobath, "the Bobath Concept". Treatment is more than the exercises, and so advice other than the neurophysiological is given such as attention to comfort, motivation and dignity, and the need to take

co-existing disablement into account.

Occupational therapy

Whereas modern physiotherapists would therefore suggest that their therapy is effective because it has a neurophysiological basis, the efficacy of occupational therapy is attributed to its "profound psychological justification" (McDonald et al, 1976). In his description of the first curative work-shop, which he established at Shepherd's Bush Military Orthopaedic Hospital during the Second World War, Sir Robert Jones wrote "We depend largely upon the psychological element to help in the recovery....Those of us who have any imagination cannot fail to realise the difference in atmosphere and morale in hospitals where patients have nothing to do... from that found where for part of the day they have regular, useful and productive work" (McDonald et al 1976). Occupational therapy intends to promote recovery through activity, and modern therapy, especially for stroke patients, is not confined to vocational work. Thus the occupational therapist encourages the patient to practise performing activities of daily living such as feeding, dressing, toileting, household management and so on. Household tasks may be practised as they are also a part of everyday life, and leisure pursuits may be encouraged.

Physiotherapy and occupational therapy together

It is possible that a neurophysiological physiotherapy approach to a stroke patient may be contrary to that taken by an occupational therapist, such as the latter's early use of aids or adaptations to promote early return of functional independence, irrespective of the quality of movement involved in so doing.

However, there is no reason why a physiotherapist who prescribes physical exercises should not arrange it so that those exercises perform some useful function to enhance morale. Similarly, occupational therapists

prescribing activity therapy could ensure that the physical exercise implicit in the activity accords with a preferred neurophysiological approach (eg: Eggers, 1983). Therefore there should be no conflict between physiotherapists and occupational therapists. Some separation of duties is necessary to avoid duplication of roles and typically physiotherapists concentrate upon trunk control, transferring and mobility, permitting occupational therapists to train the patient in activities of daily living such as dressing.

Indeed, when working with stroke patients, both physiotherapists and occupational therapists need to have the same overall aims and both need to be aware of the same avoidable complications such as a painful shoulder or an injury from a fall (which may result from unskilled handling), limb contractures (which result from prolonged adoption of a flexed posture such as sitting), and loss of morale (Mulley, 1982). All therapists should also remember that although they may intervene to influence impairment or disability, it is handicap which they should trying to reduce, since handicap is what matters most to the patient (Tallis, 1989). As the Tunbridge Committee on Rehabilitation put it, "in addition to restoring the individual patient to the highest level of functional activity, both mental and physical, in the shortest possible time" consideration must be made of "the individual's morale, motivation and relationship to the society in which he lives and to which he will return" (Central Health Services Council, 1972).

2.2 PHYSIOTHERAPY AND OCCUPATIONAL THERAPY SERVICES

Physiotherapists and occupational therapists working with stroke patients in NHS hospitals work in medical, geriatric and neurological departments or stroke units. NHS out-patients are dealt with through the PT and OT out-patient departments, geriatric day hospitals, or at home by domiciliary services, where they exist. Little is known about how stroke rehabilitation services are used in normal practice. Using published literature to examine the provision of rehabilitation throughout the country has three problems: rehabilitation services are likely to be arranged differently in different parts of the country, so what may be true of one area may not be true elsewhere; it is likely that services which have spent the effort to examine themselves are unrepresentative of those that do not, and services are changing as geriatric services continue to develop, so published reports may be out of date. For example, day hospitals were uncommon in geriatric medicine before the 1950's but there are now over 300 of them (Forster & Young, 1989).

In-patients

In-patient studies such as the Edinburgh Stroke Unit Study (Garraway et al, 1980a&b) and the Dover Stroke Unit Study (Stevens et al, 1984) revealed that nearly all stroke in-patients entered into these studies received PT, but the provision of OT was not so widespread. Thus, in the Edinburgh study, nearly all the Stroke Unit and medical ward patients received PT (100% & 94% respectively), but more patients received OT in the Stroke Unit (88%) than on medical wards. In the Dover Stroke unit study the lower provision of OT was even more marked, as most patients in the Stroke Unit and on the ordinary medical wards received physiotherapy, yet OT was given to only 42% of the Stroke Unit patients and 23% of those treated on ordinary medical wards.

Little therapy is actually given to in-patients each day. Tinson (1989) demonstrated that stroke in-patients in the Frenchay Hospital, Bristol, received an average of only about an hour of therapy for each working day. Wade (1984) made similar observations in those patients at the Frenchay Stroke Rehabilitation Unit, who received only about an average of 20 minutes each of physiotherapy and occupational therapy. It is possible to deliver 2 1/2 hours of therapy per day (Keith & Cowell, 1987). Details of the actual practices of the therapists (ie, what PTs and OTs do during therapy sessions) have not been described.

Out-patients

Little is known about how many of the 30% to 60% of stroke patients who are not admitted to hospital (Cochrane, 1970; Brocklehurst et al, 1978; Bamford et al, 1986) receive rehabilitation. Rather more is known about how many stroke survivors discharged from hospital receive further rehabilitation. In a study from Northwick Park hospital (Smith et al, 1981) only 18% of those on a register of acute stroke who were discharged from hospital were deemed suitable for intensive rehabilitation in out-patient departments (domiciliary rehabilitation and day hospitals were not mentioned). In the Dover Stroke Unit study, 83% of those discharged from the Stroke Unit attended out-patient departments or day hospitals, compared with 45% of those on ordinary wards. A survey of all stroke patients on a hospital register of acute stroke in Nottingham showed that 37% of all discharges received further rehabilitation, 17% in a day hospital and 20% in an OPD (there was no domiciliary service) (Gladman et al, 1991).

In the Northwick Park Study, the "conventional" out-patient therapy (which was no better than no therapy) treated patients for two mornings each week, providing on average 1.5 hours of PT and 1 hour of OT each week. "Intensive" therapy in the Northwick Park study (which was significantly better than no therapy) was given on four whole days each week, and

averaged 3.5 hours of PT and 1.5 hours of OT each week. In the Nottingham survey (Gladman et al, 1991) patients attending out-patient PT or OT departments were usually seen for two mornings or afternoons each week. Patients having PT received 2 hours of therapy each week and those having OT received 3 hours each week. However only half of the patients attending OPDs received both PT and OT, and courses of treatment were given usually for about two months only.

In studies in Bradford (Forster & Young, 1989) and Nottingham (Gladman et al, 1991), stroke patients usually attended day hospitals twice each week for about 6 hours on each attendance. Only about 1/4 of the time was spent in therapy, although patients received both physiotherapy and occupational therapy. Again, details of the actual practices of the therapists (ie, what PTs and OTs do during therapy sessions) have not been described. Day hospitals are able to provide medical and nursing care, meals and sometimes hairdressing, chiropody and other services. Thus day hospitals offer a model of rehabilitation that is more suitable to elderly patients who have multiple disabilities. However, the reasons why patients are and are not selected for further rehabilitation are unclear. It is also unclear why some patients go to day hospitals and others to out-patient departments. In the Nottingham survey (Gladman et al, 1991), where approximately equal numbers of patients attended day hospitals and OPDs, patients attending an OPD or a DH had similar levels of disability at hospital discharge but more of the DH attenders had mental impairment. It must be noted that the most striking factor affecting site of rehabilitation after discharge in the Nottingham study was the ward at discharge: most patients on Health Care of the Elderly wards went to DHs and most patients on General Medical wards and the Stroke Unit went to OPDs.

Virtually nothing has been published about how often domiciliary rehabilitation is available for stroke patients, or how much therapy patients receive.

2.3 THE EVALUATION OF STROKE REHABILITATION

Research in rehabilitation

Since impairments and disabilities improve over the first few months after a stroke the need for rehabilitation may be overlooked ("It will get better on its own"), spontaneous recovery may be mistaken for an effect of therapy ("I treated him and he got better, so my treatment must have been effective), or the effect of treatment may be mistaken for spontaneous recovery ("He would have improved even if you hadn't treated him, so your treatment was a waste of time"). Controlled studies are therefore essential if rehabilitation is to be evaluated.

In stroke rehabilitation, therapists may be wary of investigation because they themselves are considered to be under test just as much as the treatment they provide. A doctor who gives an ineffective drug in a clinical trial is not considered to be ineffective himself, but after a trial of speech therapy in Nottingham reported negative results (Lincoln et al, 1984) the quality of the therapy (that is, the skill of the therapists) was questioned (De Ryder et al, 1984) and the results were said to be only applicable to Nottingham, implying that with better speech therapists elsewhere negative results would not have been obtained (Steiner, 1984). The only answer to the problem that positive or negative trials may be considered non-representative of practice elsewhere is for more and more units to subject their therapies to objective scrutiny. If several controlled trials of a treatment fail to show any benefit, then claims of efficacy from devoted exponents become less powerful, and if several trials of the treatment show that it is of use, then it becomes increasingly likely that it will work elsewhere.

Explanatory and pragmatic approaches to clinical studies

Schwartz and Lellouche (1967) used the terms "pragmatic" and "explanatory" to describe two different approaches towards the design of clinical studies. In an explanatory study, the aim is to see whether the treatment under test has any biological effect or not. In a pragmatic study, the aim is to see whether the treatment under test has any use in practice. Such approaches are complementary: there is often little point in testing a treatment in clinical conditions when there is no other evidence to show that it might be useful, but a treatment which works well under strict experimental conditions may not turn out to be of use in normal clinical practice.

In an explanatory study, factors other than the one under test must be carefully controlled, so such experiments should be performed under laboratory-like conditions. The control treatment should be chosen so that the only difference between the groups is the factor under test. To detect specific effects, explanatory studies must use specific outcome measures. For example, a specific treatment to improve muscle strength obviously requires a measure of muscle strength, rather than a measure of arm function such as dressing or feeding. It may be useful to analyse explanatory studies including only those cases who received the test treatment as intended.

In a pragmatic study, treatment must be delivered in an optimal or sensible clinical way, so that the results of the study are relevant to clinical practice. A clinically relevant choice of treatment for the control group must be made, such as no treatment or the treatment which is normally used. Outcome measures concerned with physiological details such as impairments are of little use in such studies: a global measure is required which will allow the findings of the study to indicate whether the patients have achieved an overall benefit or not. Analysis must be by "intention to treat", so the outcomes of those who drop out of the study are taken into consideration.

Explanatory studies in stroke rehabilitation are those which examine the effects of specific techniques, ie, the individual components of a treatment package. For example, to identify the specific effect of early Bobath rehabilitation, attempts must be made to control for the effects of spontaneous recovery and other rehabilitation inputs. Pragmatic approaches suit the evaluation of a complete rehabilitation package. For example, to evaluate a stroke unit using an explanatory approach when all aspects of therapy are subject to a strictly defined trial protocol might allow the separate influences of physiotherapists, doctors and occupational therapists upon rehabilitation outcome to be identified, but the artificial conditions imposed by the trial protocol will mean that the study will not answer the question "Is a stroke unit working under normal clinical conditions worth having or not?".

Explanatory studies of specific techniques are difficult to perform in stroke rehabilitation because of the nature of the treatment which is to be tested. Physiotherapy and occupational therapy for stroke patients, as advocated in modern textbooks and therefore probably as practised in ordinary clinical settings, cannot be likened to the use of a drug in a medical setting. When a patient receives physiotherapy it is difficult to say exactly what treatment is actually given, since it is given in accordance with an overall approach rather than as a specific prescription. Modern teaching emphasises that the therapist should "feel" the patient's response to treatment and modify the treatment accordingly. Thus, therapists may argue that there is little point of testing a specific procedure, since procedures are almost infinitely variable and each procedure is often only part of a large number of procedures which are only effective if employed synchronously. Furthermore, the intuitive approach which is encouraged in therapists is contrary to the objective and explicit approach required in clinical trials. Nevertheless, implicit neurophysiological and psychological hypotheses underlie techniques for stroke rehabilitation, which can be tested using explanatory studies.

Not only is it difficult to define the treatment which is given, and who should have it, but is it is difficult in clinical practice to control for the effects of other influences upon outcome. One approach is to use a single case designed study, where a single patient is studied and the treatment is alternately given and withdrawn, and so the patient acts as his own control. Since most stroke rehabilitation is given during the recovery phase, it may be impossible to distinguish between natural recovery and the effects of treatment. This severely limits the use of single-case designed studies. The other major problem of single case studies is that the results are not easily generalisable to other patients.

Randomised and non-randomised group studies

Results of group studies are more easily generalised to other patients. In such studies control and study groups should be comparable, and the best way to ensure this is by random allocation of patients to the treatment or control groups. Unfortunately, as will be reviewed later, few randomised controlled studies have been performed in research in stroke rehabilitation. In non-randomised controlled studies base-line characteristics of the treatment and control groups should be no different than might have been expected by random allocation, and allocation should occur by chance rather than by purposeful selection. This means that the criteria for entry must be carefully chosen and recorded. Even if these caveats are met, it still remains impossible to say whether the difference between the outcome of the two treatment groups was due to the treatment they received or because of a bias introduced by the selection process. Mathematical techniques such as multivariate analysis might be used to correct for any imbalance in prognostic factors between non-randomly allocated groups, but the same problem exists: an effect which appears to be associated with a certain treatment may not be due to that treatment, since patients may have been selected for that treatment on the basis of an otherwise-unmeasured prognostic feature.

Study group size

The effect of rehabilitation is likely to be, at most, moderate in size, yet this may be clinically useful. However, large group studies are required to avoid such genuine treatment effects being missed (a type II statistical error). The need for large clinical studies to detect moderate treatment effects has been well made by Yusuf and colleagues (1984).

Reduction of bias

Systematic bias must be minimised if moderate treatment effects are to be detected. Allocation bias can be reduced by random allocation to the treatment groups, but to minimise observer bias, studies whenever possible should be performed "double-blind", so that neither the patient nor the outcome assessor are aware of the treatment the patient will receive. In rehabilitation studies it is often not possible to prevent the patient from knowing which treatment he or she receives, but "single-blind" studies are possible if the person who assesses outcome is unaware of the treatment allocation. Unblindedness is a serious design flaw, because the subjective component of functional assessments makes them prone to bias, especially if the assessor also provided the treatment.

2.4 THE EFFICACY OF SPECIFIC STROKE REHABILITATION TECHNIQUES

Table 2 shows the design of five controlled trials of neurophysiological treatments for stroke against traditional methods. In none of these studies was a difference found between the two types of treatment. Several methodological flaws are evident. In three studies treatment allocation was non-random. In the California study (Lord & Hall, 1986), patients in the two groups were treated in different hospitals, so their treatment is likely to have differed in other respects than the type of therapy alone. Also it should be noted that as a result of non-random allocation to treatment, the groups were poorly matched for time from stroke to start of treatment (9 versus 25 days). In the report of the New York study (Stern et al, 1970), the prejudice of the therapists involved is actually remarked upon, and yet the treating therapists were responsible for the measurement of outcome. In the Ontario study (Basmajian et al, 1987), which was rigorously conducted, only 29 patients were recruited in three years so it was too small to have sufficient power to detect anything other than very large treatment effects. Therefore, these studies are unable to confirm whether any one of the neurophysiological techniques is superior to another or to traditional methods. Furthermore, as there are no studies using a no treatment control group, it cannot be shown that any of these techniques is of any use at all.

In view of the difficulties in conducting a satisfactory group study of treatment techniques in stroke (as is illustrated by the slow recruitment rate in the Ontario study), there has been a growing tendency to consider single-case designs, because fewer patients are required and specific techniques can be tailored to individual requirements (Sunderland, 1990). Wagenaar and colleagues in Holland (1990) reported the results of seven single case designed studies to compare two different types of neurophysiological therapy (Bobath versus Brunnstrom) in acute stroke. The trend towards natural recovery in each patient was calculated, and then the

variations from this underlying trend were deduced for each phase of treatment. Little evidence of difference between the techniques was evident. It is likely that more single-case design work will be done, but to date, even this methodology has failed to demonstrate the benefit of any one technique over another, or over no treatment.

Electromyographic (EMG) biofeedback is perhaps an exception. Crow and her colleagues (1989) showed in a group study of 40 patients in Nottingham that EMG biofeedback for six weeks improved arm function when independently measured using two validated arm function (impairment) assessments. Although the benefits did not persist for another six weeks, the study is an example of a small methodologically sound explanatory group study where positive treatment effects were detected.

Occupational therapy techniques have been subject to virtually no evaluation. In a study in Philadelphia (Smedley et al, 1986) it was proposed that arm exercise therapy using a slot machine would be less boring than traditional peg-boards, pulleys etc. They therefore suggested that using such machines in a rehabilitation regime would enhance motivation and hence enhance recovery (a hypothesis behind occupational therapy). Unfortunately, this innovative study was small (50 patients), patients were not randomly allocated to use of slot machines, the patients in each treatment group were in different hospitals and the assessors were involved in the delivery of treatment. Multivariate analysis was used in an attempt to correct for the confounding variables and it was concluded that slot machines were of benefit, but the methodological flaws must render that conclusion invalid.

In a small randomised study (only 15 patients per group, most of whom had stroke) Soderback (1988) indicated that the addition of household training to routine rehabilitation led to gains in several aspects of function such as speech, memory and praxis. Although the research findings accord with an occupational therapy hypothesis that recovery can be enhanced by

activity, the study was so small that there can be little statistical confidence in the results.

It must be concluded that most of the specific techniques used by physiotherapists and occupational therapists have not been subject to any useful evaluation, and therefore remain of unproven benefit. The dearth of information is probably due to a lack of appreciation of research methodology, a reluctance to use no treatment controls (which would presumably make treatment effects more easily detectable), a lack of research infrastructure to enable the recruitment of adequate numbers of patients, and a lack of funding to sustain studies of an adequate size.

Table 2. Controlled trials comparing traditional and neurophysiological techniques for stroke rehabilitation.

Study	Total Number of patients	Comparison	Randomised?	Outcomes	Independent assessor?
Stern New York (1970)	62	Traditional versus Neurophysiological	No	Motility , strength, ADL (Kenny Institute Self Care Evaluation)	No
Logigian Boston, Mass (1983)	42	Traditional versus Neurophysiological	Yes	ADL (Barthel) Manual Muscle Test	Not stated
Lord California (1986)	39	Traditional versus Neurophysiological	No	Unvalidated telephone functional assessment	No
Dickstein Israel (1986)	131	Traditional versus PNF versus Bobath	No	Tone, range of movement, strength, walking, ADL (Barthel)	No
Basmajian Ontario (1987)	29	Traditional + EMG versus	Yes	Upper Extremity Function Test	Yes

2.5 THE EFFICACY OF STROKE REHABILITATION SERVICES

Most studies of stroke rehabilitation services fall into two groups, either those of hospital in-patients or of out-patients. For in-patients, comparisons have been made between intensive or specialised therapy regimes, such as occurs in a stroke unit, and less intensive therapy. Table 3 summarises the design of the randomised controlled trials and important prospective non-randomised controlled trials in in-patient stroke rehabilitation. One controlled study from Bristol (Wade et al, 1985) attempted to prevent hospital admission by providing a home care team. In fact, the proportion of patients were admitted to hospital in the groups with and without the home care team was similar as were their outcomes.

The studies in Scotland (Garraway et al, 1980a), Finland (Sivenius et al, 1985), Sweden (Strand et al, 1985) and Norway (Indredavik et al, 1991) all indicated that stroke unit or intensive rehabilitation improved outcome in patients admitted to hospital with acute stroke. In the Scottish study, stroke unit patients went home sooner than medical ward patients, and at a mean of 60 days a higher proportion of stroke unit patients were functionally independent. The difference in functional ability between the groups was lost when they were re-examined at 12 months (Garraway et al, 1980b). A similar finding was made in the Finnish study where functional outcome was statistically significantly improved at one week and 3 months in those who were intensively treated, yet at 6 and 12 months post-stroke, these differences did not reach statistical significance. Care must be taken when looking at the Finnish results, because they were derived from an analysis of covariance and because results from only 74 (78%) patients were analysed (the fate of those not analysed was not reported). Although patients in the Swedish study were not randomly allocated to the stroke unit or the general medical ward, the report indicated that considerable efforts were taken to avoid bias between the groups, and the patients were well matched. Patients treated on the Swedish stroke unit were significantly more likely to be able to walk independently at

discharge, but at 12 months, once again, this difference was not statistically significant. However, benefits did persist in the Swedish study in that fewer patients who had been on the stroke unit were in residential care at 12 months. In the Norwegian study, both at 6 weeks and at 12 months, the proportion of patients in institutional care was less and the degree of functional ability was greater in the group treated by the stroke unit.

The results of five other studies in Table 3, from New York (Feldman et al, 1962), Illinois (Gordon et al, 1966), Birmingham, USA (Peacock et al, 1972), Ontario (Wood-Dauphinee, 1984) and England (Stevens et al, 1984), showed no overall difference in functional outcome between those given intensive or specialist treatment compared to those given ordinary treatment. The North American studies were small, so a negative result would be expected. The negative results of the English study (n=225) may still be explained by size alone, as it was not as large as either the Scottish (n=311) or Swedish (n=293) study. In the English study, small but not statistically significant changes were seen, in that 63% of stroke unit survivors were discharged home at 12 months compared to 52% of those who had been treated on medical wards, and at 12 months 47% of stroke unit survivors were functionally independent in ADL compared to only 38% from medical wards. The results of the English study therefore point towards a benefit of a stroke unit.

This evidence tends to show that intensive in-patient treatment for acute stroke produces improved functional outcome in the first few months when compared to less intensive treatment, but that the benefits achieved by intensive therapy may be lost or no longer as great by one year after the stroke. If this is so, two questions must be answered: how is that benefit achieved, and why might it be lost?

In the Scottish and English studies, more of the stroke unit patients received occupational therapy than did the patients on the medical wards. In

the Scottish study both physiotherapy and occupational therapy was commenced earlier in the stroke unit. In the Finnish study, more rehabilitation was given to the intensively treated group, but the nature and timing of the treatment was not described. In the Swedish and Norwegian studies the level of provision of rehabilitation was not described, but the essential features of the unit were listed as team work, staff education, very early rehabilitation, and active involvement and education of the patients' families. It is likely that the rehabilitation of acute stroke in-patients is improved with a regime which is coordinated, where therapy is started as soon as possible, and where there is emphasis on occupational therapy in addition to physiotherapy.

The reasons for the apparent loss of benefit of treatment with time are not clear. The statistical power of all studies of stroke rehabilitation is reduced over time because the number of patients remaining alive dwindles as time goes by. This may explain why only non-significant trends suggesting persistent benefit at 12 months were shown in the English, Swedish and Finnish studies. However, if the loss of benefit is genuine, two explanations are possible: less intensively treated patients eventually catch-up with their more intensively treated counterparts, or else the intensively treated group deteriorates until it matches the less intensively treated group. If the former is true, then the role of intensive therapy is merely to accelerate a natural process, but not to alter the final outcome. If the latter explanation were true, attempts should be made after discharge from hospital to maintain the achieved functional gains. In the Scottish study a higher proportion of patients discharged functionally independent from the stroke unit became functionally dependent at 12 months, ie, benefit was lost. This was attributed to overprotection by relatives, although no evidence for this was cited. In the Swedish study where a trend towards the maintenance of benefit was seen, and the Norwegian study where statistically significant benefits persisted at 12 months, it was stressed how much of the rehabilitation was done with the patients' families.

One approach towards the maintenance of the benefit of rehabilitation is therefore to enlist the help of the patients' families. Another approach is to continue rehabilitation as an out-patient. Little is known about out-patient stroke rehabilitation and few randomised studies have been reported. A study from Northwick Park hospital (Smith et al, 1981) studied 133 patients who were recruited over 6 years. Patients were randomly allocated to receive intensive out-patient rehabilitation (n=46), routine out-patient rehabilitation (n=43), or visits from a health visitor but no rehabilitation (n=44). When the changes in the mean ADL score for each group from discharge to three or twelve months were compared, the group given intensive treatment made the most improvement, followed by the group who received routine rehabilitation, but even the group not receiving rehabilitation made some improvement. The differences were statistically significant only at three months between the intensive and no treatment groups, and between the combined intensive and routine groups and the no treatment group, but not between the routine treatment and no treatment groups. At twelve months, only the ADL scores of the intensive treatment group were significantly different from the no treatment group. The number of patients who deteriorated by three months in the no treatment group (10 patients) was larger than the number in the routine (4 patients) or intensive treatment groups (1 patient), and the degree of deterioration was larger in the no treatment group. The Northwick Park study therefore provides evidence that deterioration can be prevented by out-patient rehabilitation.

Certain qualifying points have to be made about the Northwick Park study. Only the intensive regime was shown to be better than no treatment. However, since many of the patients scored near to maximal on the ADL outcome scale, it is possible that the true amount of improvement was not fully assessed. It took six years to recruit the 121 patients for the study, and this low rate suggests that the patients selected for the study may be atypical. The study report stated that only 18% of all stroke patients discharged from hospital were enroled into the study (implying an average hospital admission

rate of only 180 cases of acute stroke per year, compared to the 400-500 per year in each of the acute Nottingham hospitals), because 49% were too frail and the rest had fully recovered. It follows that only a minority of patients might be able to benefit from this intensive treatment. It should be noted that intensive rehabilitation for four whole days each week uses a large amount of resources unless it is restricted to a minority of patients. Thus the Northwick Park study does not provide a solution to the rehabilitation problems posed by the majority of stroke patients. Also rehabilitation in a hospital out-patient department is unlikely to enlist the help of the family or to help the carers directly.

A recent study in Bradford (Young & Forster, in press) compared the functional and emotional outcome of 124 stroke patients allocated on discharge from hospital to community physiotherapy or attendance at a geriatric day hospital. This is the only study to date which has addressed domiciliary and day hospital rehabilitation. At 6 months the patients treated by the community physiotherapist had greater self-care ADL ability. Home treatment can be given to all patients, whether they are frail or not. It is likely to be cheaper that day hospital treatment. Therefore it is likely that domiciliary rehabilitation is both an efficient and effective approach to the rehabilitation of stroke patients after hospital discharge. It is possible that home treatment owes its efficacy to involvement with carers, although this has not been examined.

In summary, stroke unit therapy is of benefit for in-patients with stroke. The benefits of rehabilitation may be lost after hospital discharge. Deterioration can be prevented in a minority of patients by intensive rehabilitation in out-patient departments. Recent evidence also suggests that home rehabilitation is effective, and it may also be considerably more widely applicable and efficient in its use of resources than intensive out-patient department therapy.

Table 3 **Randomised, and important non-randomised, studies of in-patient stroke rehabilitation.**

RCT = randomised controlled trial
PNRCT = prospective non-randomised controlled trial

Trial	Design	Comparison	Number of patients	Outcome Assessment	Independent assessor
USA (New York) Feldman (1962)	RCT	Full rehabilitation v medical & neurology ward	82	Motor scale 3 point ADL scale	No
USA (Illinois) Gordon (1966)	RCT	Full rehabilitation v rehabilitation nurse	91	Walking scale 5 point ADL scale	No
USA (Birmingham) Peacock (1972)	RCT	Intensive v conventional	52	6 point ADL 6 point vocational scale	No
Scotland Garraway (1980)	RCT	Stroke unit v medical ward	311	Edinburgh 7-item ADL assessment	?
England Stevens (1984)	RCT	Stroke unit v medical ward	225	4 ADL items	Yes
Canada Wood-Dauphinee (1984)	RCT	Special team care v normal care	130	Motor (Brunnstrom) ADL (Barthel)	Yes
Finland Sivenius (1985)	RCT	Intensive v normal therapy	95	Motor (Katz) ADL (Lehmann)	Yes
Sweden Strand (1985)	PNRCT	Stroke unit v medical ward	293	4 ADL items Residence	Yes
Norway Indredavik (1991)	RCT	Stroke unit v medical wards	220	Barthel ADL Residence	?

2.6 REHABILITATION AND EMOTIONAL PROBLEMS

As outlined earlier, emotional problems, and depressed mood in particular, are prominent in survivors of stroke. What part might rehabilitation play in the reduction of depression, and other emotional problems?

Factors which may play a part in the development of depressed mood and other emotional disturbances after stroke include any or all of the following: a constitutional vulnerability; a lesion damaging an anatomically discreet part of the brain controlling emotion; diffuse brain damage, producing emotional disturbance alongside impairment of other higher mental functions, or the effect of physical disability and the loss of normal social function on an intact emotional system. Emotional disturbance, when present, might be ameliorated by a resolution of the underlying condition, or by specific therapy such as drugs or psychotherapy.

Constitutional factors and the degree of brain damage caused by the stroke are unlikely to be influenced by rehabilitation. But since rehabilitation may be able to improve physical performance and encourage the restoration of social function, it may reduce the extrinsic causes or act as psychotherapy to ameliorate the condition. It is therefore necessary to examine the relative importance of intrinsic and extrinsic factors in the development of emotional disturbance after stroke, and the degree to which rehabilitation with physiotherapy and occupational therapy may act as a form of psychotherapy.

Methodological problems

Before examining these questions, it is important to consider the methodological problems which confuse research in this area. Survey instruments to detect depression have been developed in non-disabled subjects in the form of self-report symptom inventories, such as the Zung rating scale (Zung, 1965), General Health Questionnaire (GHQ) (Goldberg & Hillier,

1979) or Wakefield Depression Inventory (WDI) (Snaith et al, 1971). These all include questions about a number of psychological and psychosomatic symptoms. However, the symptoms reported by physically disabled subjects may be due to their disability rather than depression. For example, in the WDI, "I find it easy to do the things I used to do", and in the GHQ "Have you recently been taking longer over the things you do?", are clearly not specific questions for depression. This makes it difficult to distinguish between physical disability and depression, thus estimates of incidence and prevalence of true depressive illness after stroke may be too high and it is difficult to identify the influences of physical disability and depression on each other. Despite this, Robinson and Price (1982) have shown that the GHQ correlates closely with the findings of a standard psychiatric interview, the Present State Examination (Wing et al, 1977).

Although several groups have investigated the association between the intra-cerebral location of stroke and depression, unless the influence of other site-specific deficits is taken into account, a meaningful relationship between stroke location and depression cannot be made. This becomes a particular problem when only small numbers of patients are studied, and unfortunately much of the published information about the relationship between the intra-cerebral location of the stroke and depression comes from small studies of selected patients. Complicating the search for a link between the intra-cerebral location of stroke and subsequent depression yet further, it should be noted that patients with disorders of communication have difficulties with questionnaires and are likely to be excluded from such studies, thus introducing a bias.

Another problem, when examining the influence of physical disability, social activity and depression on each other, is that it is exceedingly difficult to determine which is a cause and which an effect.

Intrinsic and extrinsic factors

A constitutional vulnerability has been shown to be one of the factors in the development of depression in the elderly (Murphy, 1982), and has also been assumed to be important in stroke patients, by the failure of physical and social factors to explain the development of depression adequately (Wade et al, 1987). However, after it was proposed that depression was a specific feature of stroke (Folstein et al, 1977), the search began to implicate a specific area of the brain in the control of mood. Conflicting results have been published, some suggesting an excess of depression in left hemisphere-damaged patients (Robinson et al, 1982, 1984) whereas others have suggested that depression is equally common in left and right hemisphere lesions (Folstein et al, 1977; Robinson et al, 1983: Sinyor et al 1986; Collin et al, 1987; Ebrahim et al, 1987). Another large study (Wade et al, 1987) showed depression to be more common in left hemisphere damaged patients at an early stage after stroke (3 weeks) but that at 6 months and a year there was no inter-hemispheric difference in the prevalence of depression. Such discrepancies encouraged investigation of the relationship between the intra-hemispheric stroke location and the incidence of depression. Strokes occurring in the frontal pole of the left hemisphere (Robinson & Price, 1982: Robinson et al, 1983 & 1984; Sinyor et al, 1986), the frontal pole of the right hemisphere (Sinyor et al, 1986) and the posterior pole of the right hemisphere (Robinson et al, 1984: Sinyor et al, 1986: Finset et al, 1989) may be more commonly associated with the development of depression. Although focal damage to parts of the brain involved in the control of affect may play a part in the genesis of depression after stroke, the high prevalence of depression might be more related to the effects of brain damage in any location. A catecholamine-depletion hypothesis has been proposed (Robinson & Coyne, 1980). Analogies may be seen in the high prevalence of depression in other conditions where neurotransmitter levels are known to be low such as Parkinson's disease (Gotham et al, 1986).

It must be remembered however that depression is the commonest mental illness in old age. When the causes of depression in the elderly were examined by Murphy (1982), most cases were attributed to a combination of a vulnerable premorbid personality and an excess of adverse life events, particularly events associated with loss, threat of loss, and events with permanent or prolonged social implications. Stroke would certainly qualify as a potent adverse life event! Depression has commonly been seen in other medical illnesses (Roth & Kay, 1956: Robins, 1976), and hence it has been argued that depression is not a specific complication of stroke at all (Robins, 1976). Other psychological problems seen after stroke, such as poor memory, emotional instability and irritability, are commonly seen after other illnesses, and these findings suggest that these symptoms reflect a failure to cope with the consequences of the disease (Leegaard, 1983).

Although a close relationship between depression and physical disability might be expected, the results of the studies in stroke patients are conflicting. Three large surveys (Robinson et al, 1983: Ebrahim et al 1987: Wade et al, 1987) have found a relationship between physical disability and depression, whereas two smaller studies (Robinson & Price, 1982: Feibel & Springer, 1982) have not. The relationship between physical disability and depression is therefore supported by those studies which are large enough to detect it, but the causal role of disability upon the development of depression remains difficult to untangle.

A proportion of stroke patients who recover physical function do not return to normal social activities (Labi, Phillips & Gresham, 1980), and such patients are often depressed (Feibel & Springer, 1982). Two studies (Wade et al, 1987: Feibel & Springer, 1982) have confirmed a relationship between reduced social functioning and depression. The study by Wade and colleagues (1982) suggested that poor social functioning may lead to depression, yet another study showed that poor social functioning was caused by depression (Robinson et al, 1985). Social functioning and depression are also therefore

linked, but again, the causal role of social functioning upon the risk of subsequent depression remains unclear.

In summary, emotional disturbances seen after stroke may have both intrinsic and extrinsic causes. Extrinsic causes of emotional disturbance may be affected by effective rehabilitation.

Rehabilitation and depression

It has long been suggested that depression can be a cause of failed rehabilitation (Adams & Hurwitz, 1963), although when specifically examined in a multivariate analysis of the influence of psychological factors on rehabilitation progress, no separate influence of Zung rating scale scores was found (Novack et al, 1987). However, no studies have been performed to evaluate physiotherapy and occupational therapy as specific treatments for post-stroke depression, and most studies assessing the efficacy of rehabilitation have focused on the effect on physical disability alone.

Indirect information may however be of relevance. Goodstein's overview paper (1983) identified the importance of the behaviour of health care staff in the development of psychological problems in stroke patients and their relatives. He emphasised a family approach, suggesting that the family should be involved with treatment and the setting of goals, and that patient and family should all receive feedback about improvements. In a study where counselling and/or education of the carers of stroke patients was provided, improved patient and family adjustment was seen (Evans et al, 1988), but unfortunately the emotional state the patient was not directly measured. Physiotherapists and occupational therapists are in positions of influence and may be ideally placed to educate or to counsel the families of their patients, but most therapists are not trained in this area.

A therapy service visiting patients in their own homes would have the greatest chance of affecting the family. The Bristol home care team study (Wade et al, 1985) showed that depression in a group of stroke patients treated by a home care service was no less than in those without such a service. Unfortunately, the major aim of the study was to prevent admission to hospital, and this did not occur, so the potential for the patient's family to have been involved in the reduction of depression was not fully exploited. Rehabilitation could be counterproductive: a badly designed service may be intrusive and disrupt or prevent social engagement, or may reinforce emotional or physical dependence.

Therefore, since rehabilitation could reduce depression or make it worse, the effect of rehabilitation services on the prevalence of emotional problems after stroke needs to be examined.

2.7 REHABILITATION AND THE CARERS OF STROKE PATIENTS

Not only have there been few formal assessments made of the problems experienced by carers of stroke patients (1.5), ways to improve their well-being have not been studied. Strategies to help carers include support groups (Wade et al, 1986: Mykyta et al, 1976), improved linkage between hospital and after-care rehabilitation services (Field et al, 1983) or simply more care in the form of relief admissions, night-sitter services and so on (Ebrahim & Nouri, 1987). The value of including carers in the rehabilitation process, although strongly recommended (see 2.5 and 2.6), is not known. The Bristol home care service, which may have involved carers in the rehabilitation and may have been able to influence them directly, did not affect depression in carers (Wade et al, 1986). Day hospitals may relieve carers of the burden of looking after the patients, and the same may also be true of out-patient departments, but there is no evidence to show whether they succeed or not (Hildick-Smith, 1985). The scope for an effective rehabilitation service to improve the well-being of carers is unknown.

2.8 THE EVALUATION OF DOMICILIARY REHABILITATION

Chapter 1 explains that stroke is a major cause of physical disability and emotional disturbance, and occurs particularly in the elderly, who are vulnerable to the development of handicap. It also explains that despite the falling incidence of stroke and efforts to reduce the incidence yet further, rehabilitation is still required for stroke victims because there is no medical cure.

Chapter 2 explains that apart from the provision of aids and adaptations, stroke patients might be helped by physiotherapists and occupational therapists using neurophysiological and psychological techniques to promote physical and mental well-being. Little is known about whether any of these techniques is worthwhile. On the other hand it has been shown that a well organised rehabilitation service in a stroke unit can shorten hospital stay and promote physical recovery. It is not known whether stroke units reduce the degree of emotional disturbance of the patients, or reduce carers problems. Unfortunately the physical benefit which accrues from organised rehabilitation may be lost after hospital discharge. However, physical deterioration after hospital discharge can be prevented in a small number of young fit stroke patients if intensive rehabilitation is provided for several months in an out-patient department.

Intensive rehabilitation in hospital out-patient departments provides no solution to the problems experienced by the large number of frail and elderly patients. To meet the needs of the latter group, geriatric day hospitals may now undertake much of the further care of elderly stroke patients after discharge from hospital (Gladman et al, 1991). Day hospitals offer the opportunity for the involvement of a multidisciplinary team, social support to the patient, and relief for the carer. However, day hospitals have not been shown to be of use in stroke rehabilitation. Perhaps this should not be surprising given that day hospitals have several obvious disadvantages despite

offering the services listed above. For example, despite the long day patients spend in the day hospital much of that time is wasted and little therapy is actually delivered. Long ambulance journeys are required, and they may be poorly tolerated (Stokoe & Zuccollo, 1985). Day hospitals are expensive (Forster & Young, 1990).

Domiciliary rehabilitation could involve the patient's family. Even the most frail patients can be visited at home. Assessment at home may more accurately identify those with treatable problems, and treating patients at home may allow them to practice their treatment in a realistic setting, perhaps with the help of their carers. Carers themselves may also be helped. Treatment can be provided flexibly and according to the patients needs, rather than according to the limitations of an ambulance service. Evidence supporting the value of domiciliary rehabilitation has recently emerged from the Bradford Community Stroke Trial.

The amount of information about the rehabilitation of stroke patients remains small, particularly for out-patients. In view of the potential benefits of treatment at home, a study was performed comparing domiciliary physiotherapy and occupational therapy to the hospital-based services of day hospitals and out-patient departments.

DESIGN OF THE NOTTINGHAM DOMICILIARY REHABILITATION STUDY

3.1 SUMMARY

Patients were identified from a register of all those admitted to the City and University Hospitals, Nottingham with acute stroke. All surviving patients were entered into the study except those who required respite or terminal care, those who previously had been receiving rehabilitation as an out-patient, those not disabled by the stroke and those who were in hospital for less than 7 days. Patients were considered for entry for the study when plans for discharge were being made. Base-line characteristics were recorded, informed consent was obtained and consecutive sealed envelopes containing cards marked either "DRS" or "HRS" were used to allocate patients to receive either the Domiciliary or Hospital-based Rehabilitation Services after discharge. Ethical approval for the study was obtained.

All patients allocated to the Domiciliary Rehabilitation Service (DRS), were assessed by a member of the Domiciliary Rehabilitation Team (DRT), who also provided any therapy required and arranged other relevant help. The DRT comprised two half-time physiotherapists and an occupational therapist. The DRT treated patients for up to six months, after which those requiring further rehabilitation were referred to the hospital-based rehabilitation services. Patients allocated to the Hospital-based Rehabilitation Service (HRS), were eligible for the routine rehabilitation service in Nottingham before the development of the domiciliary service. Thus, follow-up for geriatric patients was usually in a day hospital and for those on the Stroke Unit or general medical wards further therapy was usually given in out-patient departments.

The primary endpoints were functional ability at 3 and 6 months, assessed using the postal Extended ADL, and perceived health, using the Nottingham Health Profile administered by an independent assessor at 6 months. ~~At~~ 6 months an assessment of impairment was made using the Rivermead Motor Assessment and self-care ADL ability with the Barthel ADL Index. Carers were assessed at 6 months using the Life Satisfaction Index and

the Brief Assessment of Social Engagement. The provision of therapy was determined from the routinely collected records of the rehabilitation services. Data were analysed on the University of Nottingham mainframe computer using the Statistical Package for the Social Sciences programme.

3.2 IDENTIFICATION OF PATIENTS: THE STROKE REGISTER

The findings of the Nottingham Domiciliary Rehabilitation Study (NDRS) are only likely to be applicable to stroke patients elsewhere if the patients selected for the study are typical of the generality of stroke patients. For this reason the identification process and exclusion criteria were carefully formulated and clearly defined.

The NDRS only included patients who were admitted to hospital, because the resources were not sufficient to identify, recruit and treat patients who were managed solely at home. Many of the latter are significantly disabled (Wade et al, 1985: Davies et al, 1989), and there is no reason why they should not benefit from domiciliary rehabilitation.

The Nottingham Stroke Register

In 1989 the Nottingham Health Authority covered a population of 623,600 (Nottingham Health Authority, 1989) and was served by two hospitals, the University and City hospitals, both of which had acute general medical and geriatric admission services. Accident and Emergency staff and General Practitioners referred patients with stroke to either service at their discretion. There was no admission policy for stroke patients, although the geriatric service was rarely referred patients below the age of 65. There were three geriatric hospitals (the General Hospital, Basford Hospital and Highbury Hospital), taking patients from the acute hospitals for rehabilitation. Patients were not admitted directly to the 15 bedded stroke unit at the City Hospital, but when medically stable patients were referred from medical or geriatric wards if it was decided that they might benefit from intensive rehabilitation. From August 1988 to July 1990 all patients with possible stroke who were admitted to general medical and acute geriatric wards were identified by the author. The few patients admitted directly to slow-stream geriatric wards, or the neurology wards were not screened because pilot work had shown that few

of these patients had suffered acute strokes. All 14 acute medical and 11 geriatric wards at the City and University hospitals were visited twice weekly to identify patients. The 13 slow-stream wards at the General, Basford and Highbury hospitals were contacted weekly to follow patients who had been transferred. Nurses, therapists and doctors were asked to indicate all known or possible stroke patients on the ward. Different members of the ward staff were interviewed on different occasions, depending upon their availability, and sometimes nursing records were inspected. Visits to the medical wards of the City hospital were prefaced by an inspection of the register of all acute hospital admissions, so that those admitted temporarily to non-medical wards could also be identified. Therapists attached to the medical wards were asked to help locate stroke patients admitted to non-medical wards at the University hospital.

All patients identified in this way were examined by the author, to establish whether they had suffered a stroke or not, using the WHO definition: "rapidly developed clinical signs of focal (or global) disturbance of cerebral function lasting more than 24 hours or leading to death with no apparent cause other than of vascular origin" (Aho et al, 1980). Clinical diagnostic criteria were used because they are usually correct (Sandercock, 1985), and furthermore, although CT scanning would have provided further information, in practice only a minority of all potential patients, both locally (18% on the Nottingham Stroke Register in 1988) and nationally (Langton Hewer & Wood, 1989) are scanned.

Patients with sub-arachnoid haemorrhage (sudden onset headache, photophobia and features of meningism) without focal signs, were not registered. Patients with "funny turns", "dizzy spells", "off legs" or an acute deterioration of a dementing illness were screened, but were only registered if they met the definition above. Patients who had suffered strokes in the past were not excluded. Patients developing strokes while in hospital were registered, unless the stroke was a terminal event in another illness. This

approach was taken so that most stroke patients would be registered, retaining reasonable diagnostic certainty.

3.3 SELECTION OF PATIENTS

Selection criteria were required to allow all the patients who could reasonably receive rehabilitation after discharge to be entered in the study. It was desirable to avoid the inclusion of patients who would not respond to rehabilitation, as they would have wasted resources and diluted the effects of treatment. Brocklehurst (1978) and Andrews (1982) showed that severely disabled stroke survivors often received prolonged rehabilitation, yet their chances of functional recovery, and hence, benefit were slight. Another group of patients who would not be expected to benefit from rehabilitation would be those patients with very mild strokes, who recover completely and rapidly.

If the NDRS had been performed during the acute phase of stroke, then triage on admission would have been necessary (Garraway, 1981). However, since it was a study of rehabilitation in the post-discharge phase, entry was delayed until plans for discharge were being made, when the severely affected patients had died or arrangements for the severely affected survivors to be transferred to residential or nursing care had been made. There is no reason why patients sent to nursing homes cannot benefit from rehabilitation, but a different approach and study design would be needed. Patients with non-disabling strokes and those who recovered rapidly were easily excluded. Using this simple approach, the majority of patients who obviously would not have responded to rehabilitation, or who would have been unsuitable for a domiciliary service were excluded.

Although clinical factors which predict later functional outcome have been identified, it is not known if a group of patients can be identified who will respond to treatment rather than recover spontaneously. Therefore, all remaining patients who could receive rehabilitation should be included, because all might potentially, benefit from it.

The exclusion criteria used were:

1. Death in hospital.
2. Transfer to another hospital, or discharge to residential or nursing care.
3. Stroke with no physical disability at registration.
4. In hospital for less than 7 days.
5. Not suitable for either rehabilitation service because patient lived out of the catchment area.
6. Not suitable for the domiciliary rehabilitation service because day hospital care requested for carer relief.
7. Not suitable for a rehabilitation service because of terminal care needs.
8. Not suitable for random allocation because already receiving hospital-based rehabilitation services.
9. No consent given.
10. Administrative (discharged home before entered).

3.4 CONSENT

Ethical approval for the NDRS was obtained from the local Research Ethical Committee. Patients were asked to consent to participate in this research project before they were included. The treatment provided by the domiciliary service involved no medication or invasive procedures and inclusion into the study did not significantly inconvenience patients. Using the terminology in the report of the Royal College of Physicians of London, "Research Involving Patients" (1990, p9), the study posed a "less than minimal risk" to patients. Using that report's guidelines for such studies, oral consent after oral explanation is satisfactory (p16). Therefore, oral consent was obtained and in each case this fact was recorded in the patients hospital notes. If the patient was dysphasic or confused then consent was obtained from a close relative.

The amount of information that patients should be told remains a matter of judgment. The Royal College Report states that, as a minimum, patients should know they are taking part in research and that they consent to this. From the trialist's point of view, patients should be told what is to be expected of them during the study, so that those who are unwilling or unable to comply with the protocol are not included. In the NDRS, patients were told that they would receive postal questionnaires and would be visited to complete other questionnaires and assessments so that their progress could be monitored and the value of any treatment they had received could be evaluated. Patients could either have been told that they would be randomly allocated to one of two services or merely allocated to one of the services without being told that there had been another possibility. The former approach is in keeping with the general recommendations for informed consent in the Royal College Report (p32). However, the Report's authors also admit that there are circumstances where the random basis on which treatment is allocated should not be declared (p32). This study is such a case, and the reason for this is described below. If patients were told about both rehabilitation services and if most had a strong

preference for one of them, then those allocated to the preferred service might feel lucky and grateful, and those allocated to the less popular service might be disappointed or ungrateful. It follows that giving a more complete explanation may encourage the groups to differ in their attitude towards their treatment and the study. A consequence of this is that patients in the different groups may not cooperate equally with the trial protocol and the less preferred service may be tested unfairly under sub-optimal conditions. Another consequence is that those who are disappointed may register this by exaggerating their problems, "faking bad", and those who are grateful may minimise their problems, "faking good" (Streiner & Norman 1989). This produces a systematic bias, and a strongly biased study will be useless and is unethical (Altman, 1980). Sometimes this problem can be overcome by excluding patients who have strong treatment preferences. This approach was not helpful in the NDRS because pilot work suggested that the majority of patients preferred to have their treatment at home, which was not possible outside the study. Therefore, patients were not routinely told that they would be randomly allocated to treatment, but further information was not withheld if requested.

3.5 ASSESSMENT BEFORE ENTRY TO THE STUDY

If by chance the random allocation procedure produced imbalanced groups, then the interpretation of the results would have to be made extremely carefully, alternative handling of the data might be required and fewer hard conclusions could be drawn. In view of this possibility, it was necessary to assess patients on entry to the study so that the similarity between the groups could be checked. This information could also be used to confirm that the overall study population was representative of other populations of stroke patients, to define the characteristics of patients treated by the different services and to investigate the prognostic value of various clinical features. Data were collected soon after admission (at registration) and at entry to the study.

Information collected at registration

Patient identification: name; address; date of birth; telephone number; GP; consultant; hospital ward; hospital and Korner number.

From the admission clerking notes: age; sex; residence; date of stroke and admission, and conscious level on admission.

Clinical examination: clinical location of stroke; classification of deficit; conscious level when examined; gaze palsy; motor, tactile, language, visual or bulbar impairment and urinary continence.

Information collected at entry to the study

Previous medical history: history of vascular events or risk factors; other significant medical history; previous immobility (Functional Ambulatory Category $<5/5$ (Holden et al, 1984)), continence and mental capacity; previous employment and marital status.

Current functional ability and mental capacity: Barthel ADL Index (Mahoney & Barthel, 1965: Collen et al, 1988); and the Abbreviated Mental Test Score (AMTS) (Hodkinson, 1972).

The register and study entry forms and their coding guides are shown in the appendix.

3.6 RANDOM ALLOCATION TO TREATMENT GROUP

Patients were randomly allocated to the domiciliary or hospital-based services because allocation by any other method was unlikely to produce groups of similar characteristics (Altman, 1980). Random allocation schedules were prepared in advance. The order of odd and even numbers in consecutive columns in a table of random numbers was used to determine the order in which pieces of card marked either with "DRS" or "HRS" were sealed in consecutively numbered envelopes. Patients were screened to check that they were suitable for the study, initial data was collected, consent was obtained and only then was the next envelope opened to reveal the service to which the patient was allocated. No patients allocated to the hospital-based services were subsequently treated by the domiciliary team but some patients were withdrawn from the home treatment group and followed-up in day hospitals. However, the results were analysed according to the initial allocation. In view of the large number of patients in the study, block randomisation was considered to be unnecessary.

3.7 STRATIFICATION

The process of random allocation relies upon chance to distribute prognostic factors equally between the two groups, but stratification is a process which can ensure that known prognostic factors are equally distributed between the two groups, so that only the distribution of unknown prognostic factors is left to chance (Zelen 1974). For example, in acute stroke it is known that those who are unconscious when admitted to hospital have a worse outlook than those admitted drowsy, who, in turn, do worse than those admitted alert. For a drug study of acute stroke, a separate randomisation schedule can be prepared for each of these groups (or strata), so it will be certain that equal numbers of unconscious, drowsy and alert patients will be in each group. If a second prognostic factor is known, then each of these strata can be sub-stratified by the second prognostic factor, and so on. Very complex stratification procedures can be designed if many prognostic variables are known.

Another benefit of stratification is that sub-analysis of the strata is valid, whereas the analysis of retrospectively derived sub-groups may not be. If it is known in advance that certain sub-analyses will be performed, then it is preferable to stratify patients accordingly. For example in a trial of acute stroke, it may be postulated that the effect of the new drug would be greater in patients who were drowsy on admission than those admitted either unconscious or alert. If the allocation of patients was stratified by conscious level, then each group could be analysed separately because patients would have been randomly allocated within each group.

Stratification, for either of these purposes, is particularly useful if small numbers of patients are entered into a study and if prognostic variables are known to be of importance. It becomes unnecessary with increasing numbers of patients, especially if the prognostic factors are weak (Feinstein and Landis, 1976).

Pilot work (2.3) had shown that patients discharged from the stroke unit, medical or geriatric wards received different in-patient management and differed considerably with regard to age, sex, time in hospital and previous and current disability. Furthermore, patients on the Stroke Unit and on General Medical wards usually attended out-patient rehabilitation departments for further rehabilitation whereas patients on Health Care of the Elderly wards were followed-up in day hospitals. To help ensure similarity between the two overall treatment groups and to allow separate analyses of those treated by out-patient departments and day hospitals, patients were stratified according to the type of ward from which they had been discharged. Thus three strata were created: geriatric ward (HCE), medical ward (GM) and stroke unit (SU) discharges.

3.8 THE STUDY TREATMENT: THE DOMICILIARY REHABILITATION SERVICE

No routine domiciliary service had previously existed in Nottingham, so a service had to be developed. The Domiciliary Rehabilitation Team (DRT) was recruited, comprising two half-time physiotherapists and a full-time occupational therapist. All three therapists had wide previous experience in treating stroke patients and had worked locally for some years.

A running-in phase was necessary to allow sensible working practices to be developed. Advice was sought from other domiciliary services in the country. In keeping with the principles of pragmatic study design, the DRT was encouraged to operate as it would in a normal NHS service, with minimal interference from the study protocol.

All patients allocated to the DRS were initially assessed at home by a member of the DRT. Those suitable for intervention were identified and a home treatment programme was designed and carried out by the DRT. Whenever necessary, the DRT liaised with in-patient rehabilitation staff before hospital discharge and with other agencies after discharge. The team had access to in-patient physiotherapy and occupational therapy records. Although the DRT was based at the Nottingham Stroke Research Unit no other research staff were involved in the working practice of the team. The author was consulted on matters of trial protocol only.

Details of every visit were recorded by the domiciliary therapists, but the results are not presented in this thesis.

3.9 THE CONTROL TREATMENT: THE CONVENTIONAL REHABILITATION SERVICE

As there is considerable spontaneous recovery after a stroke, a control group was necessary. The control treatment chosen was the existing rehabilitation service in Nottingham. In keeping with pragmatic study design, attempts were made to ensure that the hospital-based services operated as they usually did and were not controlled by trial protocol.

Patients allocated to the conventional rehabilitation service received out-patient physiotherapy or occupational therapy or were referred to a geriatric day hospital, as is the usual practice in Nottingham. There were two physiotherapy and two occupational therapy departments (one each at the City and University Hospitals), and three geriatric day hospitals (Sherwood, University and Gibson Day Hospitals). Before discharge from hospital the in-patient therapists usually made the decision whether or not to refer patients for out-patient therapy. Referral to a geriatric day hospital was made by or on behalf of a geriatric consultant at a multidisciplinary case conference.

Attendance registers kept in the physiotherapy and occupational therapy departments and day hospitals were regularly inspected to identify the study patients attending at each site, the number of attendances they made and the period of time over which these attendances were made. To ensure that all of those attending for further therapy had been identified, plans for further rehabilitation made before hospital discharge were noted. A questionnaire was sent to all patients at 3 months after randomisation asking whether they had received any further therapy, where it had been performed and whether they had travelled by ambulance. Patients identified by these means were specifically sought in the attendance registers. No further measure of the rehabilitation was made during the study for fear of interfering with normal practice.

3.10 ASSESSMENT OF OUTCOME

To detect a difference in the efficacy of the rehabilitation services, disability and improve well-being had to be measured. Outcome measures should be relevant, valid, reliable, sensitive and resistant to the introduction of bias.

Relevance

Outcome assessments should be pertinent to the state of health of the patients and sensitive to aspects of health related to the intervention under evaluation. Stroke patients are known to be disabled and have considerable psychological problems, and rehabilitation may affect either or both. Measures of these aspects of health were required.

Validity

This is a complex concept, but in essence a valid instrument is one which measures what it is supposed to measure. The demonstration of validity can be a difficult process and no single test can establish undeniable validity. There are several ways in which validity can be tested. A simple approach is to establish "face validity", for example, by looking at the items on a questionnaire to see if they appear to be sensible. Face validity must be established with care. For example, with an instrument to measure overall health, lay people as well as health care workers should be consulted to avoid undue prominence of medical perceptions of health. "Content validity" is similar: the instrument is inspected to see if it appears to have sampled all the relevant contents of the construct. Establishing face and content validity is subjective, and it is possible that a scale could be declared to have face validity beeause its inventor says it has.

To allow a more objective test of validity, an instrument can be compared to a "gold standard" measure, when one exists. This is referred to as "criterion validity". A new test can be compared with an older, proven test: this is referred to as "concurrent validity".

In some situations no gold standard or similar instrument exists and so another approach must be taken. This is to test whether the construct measured by the instrument accords with what is known about that construct. This is "construct validity", of which there are several different types. For example, it would be expected that a measure of functional ability in hospital patients would be related to whether they were discharged to independent or institutional care. A scale which cannot discriminate between two such groups of patients does not have "discriminant validity" and so, is unlikely to be measuring functional ability.

Most people who deal with stroke patients believe that functional recovery after stroke follows a fairly predictable pattern and that a hierarchy of increasingly difficult tasks exists: patients are expected to be able to transfer themselves before they can walk, and walk before they can run, etc. If an instrument to measure functional recovery can be shown to have a hierarchical structure, then it is more likely to be measuring functional recovery than one that does not. Items which form a hierarchical scale are likely to belong together, or be part of the same construct. The Guttman scaling procedure (Guttman, 1950) is a mathematical procedure which can calculate the degree to which a scaled instrument forms a unidimensional hierarchical scale.

There are additional benefits of a Guttman scaled instrument. An ordinal scale is formed which allows statistical tests to be used more robustly. Such scales have reproducibility: that is, when two patients have a scale score of 6/10, this will usually mean that the same 6 items on the scale have been "passed" by each patient, whereas in a non-hierarchical instrument this may

not be the case. Scores from scaled instruments therefore have clearer meanings than scores from those that do not. A scaled instrument will not include items of equal difficulty to each other, which keeps the number of items in the scale to the minimum. Hierarchical scales can be simple, whereas instruments in which the items are weighted if they are more important or difficult are more complex.

Reliability

If two or more people use the same instrument at the same time to assess the same patient then similar results should be obtained. If this is not so then the instrument has poor inter-observer reliability. If scores obtained by an instrument in a stable patient are not consistent over time then the instrument has poor test-retest reliability.

The use of an instrument with poor reliability will introduce an unnecessarily large variation in the results, thereby possibly obscuring treatment effects. Furthermore, since instruments in rehabilitation may be unreliable if they call for unduly subjective assessment, poor reliability may indicate that the instrument will be prone to the introduction of bias.

Sensitivity

It is likely the effects of rehabilitation on overall function are moderate or small. However, small changes in functional ability may be very important to patients. For example, the re-acquisition of the ability to get up and down one or two steps allows a person who had been housebound to take advantage of the outside world once more. Instruments which contain only a few relevant items are unlikely to detect the small but important changes which are to be expected of rehabilitation.

Resistance to introduction of bias

Observer bias is a considerable danger in a rehabilitation study, because the assessment procedures used frequently include a subjective component. Self-report assessments avoid observer bias, and postal assessments do not require an assessor at all. However, many assessments have not been shown to be reliable when used in this way. Bias can be reduced if assessment of outcome is made by an independent observer, who has not been involved in the care of the patient and is, as far as possible, unaware of the treatment allocation. In this study, a physiotherapist was appointed as an independent assessor since her training enabled her to make sensible use of instruments which measured impairment, disability and handicap.

How many measures?

When several outcome measures are used there is an increased likelihood of a statistically significant result occurring by chance, or of a mixture of conflicting positive and negative results. In pragmatic trial design ideally a single outcome measure should be used to give an unequivocal answer to the research question (Schwartz & Lellouche 1967). The ideal measure combining physical disability, handicap and cost does not exist. However, there have been several attempts to produce assessment procedures which take several domains of health into consideration. Examples are shown in Table 4. Although much time and effort has been taken in the development of these instruments as survey tools, most have not been widely used in intervention studies. The large number of questions most of them contain renders them difficult to administer. Many of the questions they contain may be of little interest to research project, yet asking them may tire the respondent so that the replies to more important questions may be less reliable. Despite covering many aspects of health, in several of them no overall score is obtained, and therefore multiple comparisons are not avoided.

Even if an overall score is obtained, care must have been taken to ensure that the score from each domain of health is correctly weighted. Exempt from these criticisms is the Sickness Impact Profile (SIP) (Bergner et al, 1981), which has a lesser-known English version called the Functional Limitation Profile (FLP) (Patrick & Peach, 1989). Although the SIP/FLP is long, it might may have been a suitable instrument to use in the NDRS if it was the only outcome measure. However, it was preferred to make separate assessments of impairment, disability and emotional health since we hoped that more specific enquiry into these aspects of health may more easily detect important differences between the two services under test.

Therefore measures of disability and well-being were required as primary outcome measures and other data was collected to improve the interpretation of the main findings.

Table 4. Global assessments

Name	Number of items	Patients used	Reliability	Admin method
Sickness Impact Profile (Bergner 1981)	136	any	IR TRT	interview
Functional Limitation Profile (Patrick, 1989)	136	any	IR TRT	interview
MAI IADL (Lawton 1982)	216	elderly	TRT	interview
SELF (Linn 1984)	54	over 60yrs	TRT	self-report
CARE (Golden 1984)	328	all	not adequately tested	interview

3.11 ASSESSMENT OF IMPAIRMENT

In a pragmatic study the reduction of impairment alone, without a reduction in disability or handicap, would not be a valuable outcome (Gladman, 1990). Nevertheless, a measure of impairment was made to aid the interpretation of the main findings.

Although there are several motor assessment procedures to choose from, the Rivermead motor assessment (Lincoln & Leadbitter, 1979) is simpler than many others (eg Fugl-Meyer et al, 1975: Lindmark, 1988). It consists of a gross function scale (13 items), a leg and trunk scale (10 items) and an arm scale (15 items). Reliability of formal assessments has been established and construct validity has been partially established by the Guttman scaling procedure (recovery of motor function would be expected to follow a hierarchical pattern).

3.12 ASSESSMENT OF DISABILITY

Since many patients are continent, and able to walk and dress themselves independently by the time they get home, a measure of such self-care activities alone would have been unable to detect further improvement. It follows that commonly used self-care ADL scales such as the Barthel ADL Index (Mahoney & Barthel, 1965) and the Nottingham ADL scale (Ebrahim et al, 1985) were not appropriate as primary outcome measures.

Of greater relevance to patients living at home are the activities of daily living such as shopping, cooking, outdoor mobility and leisure pursuits. In the USA they are referred to as "complex performance tasks" (Task Force on Stroke Impairment, Disability and Handicap, 1990) or "instrumental" activities of daily living (Lawton & Brody, 1969), although authors in the UK have used the terms "extended" ADL (Barer & Nouri, 1989) or "lifestyle" (Holbrook & Skilbeck, 1983). The terminology can be confusing: there is an Instrumental ADL scale, which is an instrument designed to measure the construct of instrumental ADL! In this thesis, scales including items related to personal hygiene and simple mobility are referred to as "self-care ADL" scales and those which include items about normal activities of daily life for a person living at home such as outdoor mobility, domestic management and leisure are referred to as "home life ADL" scales.

Several scales containing home life ADL items exist, as shown in Table 5. The majority of these scales are not suitable as outcome measures in a study of stroke rehabilitation. Some scales have been designed for use in patients with disorders other than stroke. An example is the Functional Status Index (Jette 1980) which was designed for arthritis sufferers, and hence includes an assessment of pain. The sort of patient for whom the Passmore Edwards Rehabilitation Centre scale (Parish & James, 1982) was developed is unclear, because its use in only two patients has been described! Some

instruments are too brief to be sensitive enough for a rehabilitation study. For example, Fillenbaum's adaptation of the OARS IADL subscale (Fillenbaum, 1985) which was designed for screening the elderly includes only five items. Other instruments lack reliability data. When using the Frenchay Activities Index (Holbrook & Skilbeck, 1983) informants are interviewed and asked to recall the number of times they have performed 10 certain tasks over the preceding 3 months and 5 other tasks over the last 6 months. In view of the high frequency of memory deficits among stroke patients, the lack of reliability data for the Frenchay Activities Index, which is so dependent upon respondents having an accurate memory over the previous few months, is an important omission.

Guttman scaled instruments are to be preferred, for the reasons outlined earlier. The Rivermead ADL (Whiting & Lincoln, 1980), the Extended ADL (Nouri & Lincoln, 1987) and an expanded Katz ADL scale (Asberg & Sonn, 1989) are all Guttman scaled and the first two of these contain sufficient items to be potentially useful as outcome measures. Unfortunately, the Rivermead ADL has only been used in formal assessments, that is, patients are observed to see if they can perform each item. This therefore makes the Rivermead ADL time-consuming, and therefore unsuitable for use in a large study. The Rivermead ADL has only recently been used in elderly subjects (Lincoln & Edmans, 1990). If the Rivermead ADL could be performed informally (ie, by asking) would make it a good outcome measure because it has the advantage of combining self-care and home-life ADL items in a single scale.

The Extended ADL (E-ADL) is a 22 item questionnaire which is sent by post to patients with a reply paid envelope and a covering letter. The items were originally described as forming four Guttman-scaled sections: outdoor mobility; kitchen management; domestic management and leisure. It has been since been shown that the kitchen and domestic sections can be combined to form a single household Guttman scale. Under certain circumstances all 22

items can be combined to form a single scale, although it does not quite meet the conventionally accepted criteria for a unidimensional scale (Lincoln & Gladman, in press). No other test of validity have been performed and items were selected because they were "thought to be important for daily living at home". Test-retest reliability has been established. A postal assessment has considerable advantages for clinical studies because it is easy to administer and it eliminates bias due an unblinded assessor. The size, scaling properties and method of administration were the reasons why the E-ADL was chosen as the primary outcome measure of disability in the NDRS. A limitation of the E-ADL, in common with all other home-life ADL scales, is the lack of extensive validation data. This is an aspect which requires further work.

The E-ADL was administered at 3 and 6 months after randomisation to examine the possible differences in functional ability during and just after the period over which post-discharge rehabilitation was given. It was also administered at 12 months to detect any differences either persisted or disappeared, but the 12 months results are not presented in this thesis.

Table 5. Comparison ADL scales containing home-life items.

Name	Home life ADL items	Patients	Reliability	Admin method	Guttman scaled	Remarks
IADL (Lawton 1969)	8	elderly	not tested	interview	yes	females only
Functional Life Scale (Sarno 1973)	23	21-70yrs	not adequately tested	interview	no	
OARS IADL (Duke Univ. 1978)	7	>65yrs	IR TRT	interview self-report	no	derived from IADL scale
Functional Status Index (Jette 1980)	11	arthritis adults	IR TRT	interview	no	measures pain
Rivermead ADL (Whiting 1980)	15	stroke, head injury	IR TRT	formal assessment	yes	
Passmore Edwards (Parish 1982)	11	unstated	not tested	formal assessment	no	
Frenchay Activities Index (Holbrook 1983)	15	stroke	not tested	interview	no	
Adapted OARS (Fillenbaum 1985)	5	elderly	not tested	interview	yes	derived from OARS I-ADL
Adapted OARS (Spector 1987)	2	elderly	not tested	interview	yes	derived from OARS I-ADL
Extended ADL (Nouri 1987)	22	stroke all ages	TRT	postal assessment	yes	
Expanded Katz (Asberg 1989)	5	elderly	IR	interview	yes	

IR: inter-rater reliability
TRT: test-retest reliability

3.13 ASSESSMENT OF EMOTIONAL DISTURBANCE

As outlined earlier (2.6), emotional disturbance, particularly depression, is common in stroke patients, and there are reasons to believe that it might be ameliorated by rehabilitation. As depression is the most common and important emotional disturbance after stroke, a measure was needed for the NDRS which was sensitive to depressed mood. The instrument also had to use a self-report approach, as a formal psychiatric interview would have been impractical and susceptible to the introduction of bias. A comparison of several self-report questionnaires which measure emotional disturbance is shown in Table 6.

Some of the instruments in Table 6 were designed as measures of depression, such as the Wakefield Depression Inventory (WDI) (Snaith et al, 1971), whereas the Nottingham Health Profile (NHP) (Hunt et al, 1980) was designed as a short and simple assessment of perceived health. The instruments designed to detect depression were validated against psychiatric interviews, whereas the NHP required validation procedures to ensure that it could discriminate between groups of patients in different states of health. Nevertheless, the NHP is sensitive to emotional disturbance (Ebrahim et al, 1986).

Questionnaires sensitive to emotional problems include lists of symptoms which have either somatic ("Felt that you are ill?") or psychological content ("Felt that life is entirely hopeless?"). A positive answer to the question "Been taking longer over the thing you do?" may suggest depression in an able-bodied person, but in a stroke patient may merely reflect their physical disability. However, questions about somatic symptoms may also be sensitive to the emotional effects of physical disability: the question "Felt on the whole you were doing things well?" may be answered with a "yes" in a well-adjusted disabled patient, but with a "no" in an equally disabled but badly-adjusted patient. It was considered that the attitude patients have towards

their disability is most likely to be the aspect of emotional problems which physical therapists can alter. Therefore it was important that the outcome measure of emotional disturbance in the NDRS included questions about somatic symptoms.

An outcome measure for elderly and frail survivors of stroke must be simple. Ebrahim and colleagues (1986) found that the NHP was simpler to use than the General Health Questionnaire (GHQ), perhaps because the former requires yes/no replies, whereas the GHQ requires the patient to choose one of four replies. The Beck Depression Inventory (Beck et al, 1961) may also be too complex for frail elderly patients, because it has up to six response categories for each question. Wade and colleagues (1987) found the 12-item WDI easier to use than the 20-item Beck Hopelessness Scale (Beck et al, 1974).

The NHP was chosen as the outcome measure of emotional disturbance in the NDRS because of its simplicity, and because it measures somatic symptoms yet it has been shown to be sensitive to depressed mood. It is a measure of subjective health status, or perceived health, in six domains: physical mobility, energy, sleep, pain, social isolation and emotional distress. It comprises 38 items, each of which is a simple statement such as "I'm tired all the time", to which a yes/no answer is required. The items are weighted, so that the score in each domain ranges between 0 and 100. The weightings for each score were calculated using Thurlstone's Method of Paired Comparisons (Hunt et al, 1986), which ensured that the weightings for each item within a domain of health reflected their relative importance. The NHP can be administered by interview, by self-completion or even by post in certain instances. It has been extensively validated in adult British samples of all ages, in a variety of states of health. Test-retest reliability has been demonstrated.

After much use of the NHP, its authors have concluded that it measures "distress" (Hunt et al, 1986, p232). In Ebrahim's study of use of the NHP in stroke patients a Total NHP score was produced, being the mean of the energy, sleep, pain, social isolation and emotional distress scores (Ebrahim et al, 1986). Using a cut-off score of 30/100 the total score could discriminate between those classified as depressed using the GHQ and those who were not. The score from the mobility section was not included in the total NHP score, presumably because the NHP mobility section is the least likely to reflect emotional disturbance. The calculation of the Total NHP score may not be a valid procedure, because it has not been shown that the six domains are of equal importance. However, a benefit of the Total NHP score is that statistical analysis is simplified and multiple comparisons can be avoided.

Table 6. Comparison of self-report measures of emotional disturbance

Test	All items	Somatic items	Psych items	Number of response categories	Test-retest reliability	Use
Beck Depression Inventory (Beck 1961)	21	7	14	4-6	no	objective measure of depression
General Health Questionnaire (Goldberg 1979)	28	7	21	4	no	screening test for psychological disorders
Wakefield Depression Inventory (Snaith 1971)	12	4	8	4	yes	measuring the severity of depressive illness
Beck Hopelessness Scale (Beck 1974)	20	0	20	2	no	to study hopelessness
Hospital Anxiety and Depression Scale (Zigmond 1983)	14	3	11	4	no	detecting depression and anxiety in hospital out-patients
Nottingham Health Profile (Hunt 1980)	38	29	9	2	yes	measuring health status, to plan services and evaluate treatments

3.14 ASSESSMENT OF CARERS

The welfare of the spouses, relatives or companions living with stroke victims is worthy of consideration not only because it may influence the outcome of the patients, but because it is a primary concern in its own right (1.5, 2.7). Measures were required to assess the overall impact of a stroke on the patients' carers. The instrument needed to be sensitive to those aspects of the carers life which might be affected by rehabilitation services so that any differences in the efficacy of the two services in this respect could be detected. Whereas for the patients it was important to measure the emotional response to their stroke using somatic symptom inventories, this was not necessary for carers, who may not have been ill.

Hospital-based services may have freed the carer from caring for a few hours, by keeping the patient occupied and out of the house for part of the day. Therefore, a measure of activity was required. The Brief Assessment of Social Engagement (BASE) (Morgan et al, 1987) was chosen, because it has been used in community studies and so is likely to be appropriate to people who are not patients. Simple yes/no answers are required. The version used in a large community survey of the elderly comprised 20 items related to involvement with society, for example, access to a car, having friends and so on. Its reliability and internal consistency has been demonstrated. Discriminant validity was demonstrated in a shorter version by showing that it distinguished between a group of elderly people who regularly visited swimming pools and less active groups of elderly people (Morgan et al, 1985). BASE and scores from an adapted Life Satisfaction Index (LSI-Z) (Wood et al, 1969) were strongly correlated and this finding was presented to illustrate construct validity.

The morale of the carers was assessed using a version of the LSI-Z, one item of which had been modified for use in British subjects to form the Nottingham version (Morgan et al, 1987). To improve the reliability and

internal consistency of the original version of the Life Satisfaction Index (LSI-A) (Neugarten, 1961) 13 of the 20 items were selected to produce the LSI-Z, and the scoring system was adjusted (Wood et al, 1969) and criterion validity for the shorter scale was demonstrated by comparison with rater judgments. Analysis of the Life Satisfaction Index in British subjects showed that it measures two factors: acceptance/contentment and achievement/fulfilment (Bigot, 1984). The internal consistency of the Nottingham LSI-Z (N-LSIZ) remains satisfactory when used in British subjects (Morgan et al, 1987).

In the Nottingham Rehabilitation Study the BASE and N-LSIZ were used in the assessment of carers at the six and twelve month visits. Specific measures of mood, anxiety and so on were not made to keep the assessment schedule short. The results at twelve months are not reported in this thesis.

3.15 ASSESSMENT OF THE USE OF RESOURCES

Stroke patients use a considerable amount of community resources other than those of the rehabilitation services (Garraway, 1981). An effective assessment by a rehabilitation service might increase the use of other services, if it exposed unmet need. On the other hand a more effective service may enable patients and carers to be more independent, thereby reducing the need for other services. Measuring the use of so many different agencies (district nurses, GPs, and all the social services) was not possible. The number of days spent in hospital between entry to the study and discharge was determined from the stroke register and the sites and duration of any readmissions during the six months after randomisation were determined by consulting the computerised hospital record of admissions and discharges. These data are not presented in this thesis.

3.16 ANALYSIS

Ideally, pragmatic studies require an analysis to be performed on an intention-to-treat basis. In a pragmatic analysis all patients entered into the study should be included, not only those who received treatment. When the outcome measure is a disability scale this is relatively easy if all patients survive and are assessed. However, some patients will die, and it has to be decided how these events will be handled in the analysis.

Several approaches are possible. In a rehabilitation study, one approach is simply not to include the patients who die in the analysis. This may be justified if the death rate is low, if the death rate is similar in both groups, and if the causes of death are unrelated to the intervention. Another approach is to assign dead patients an arbitrary disability score, such as zero or a negative number, so that all patients have a disability score and can be analysed statistically. The problem with this approach is that apparent differences in disability scores may really be due to differences in death rates, making the interpretation of the results difficult. The technique can therefore only be justified when the death rate is low and if the death rate is fairly similar in the two groups, in which case it is equally appropriate to ignore the deaths anyway.

A better approach is to define a good outcome group. Good outcome can be defined as staying alive and maintaining a certain functional level, and then all other outcomes (death or deterioration) can be considered as bad outcomes. All patients can then be classified, and the results can be described in clinically meaningful terms: the difference in proportion who achieve a good outcome. A further advantage of this approach is that other aspects of outcome can be included, such as becoming institutionalised, or becoming depressed. Thus good outcome could be defined as staying alive, at home, without depression, and maintaining a certain functional level.

There were difficulties with using this pragmatic approach in the NDRS. Death and institutionalisation were easy to define and identify, but depression was difficult measure in all patients because it was not possible to use the Nottingham Health Profile, in patients with dysphasia or other communication disorders. Therefore the absence of depression could not be included in a definition of good outcome. The main domain of health being studied in the NDRS was home-life ADL ability. If good outcome was defined as achieving a certain E-ADL score (a criterion value), then patients who improved or deteriorated at levels of ability entirely above or below the criterion value would not influence the results. Thus, having a criterion value would be an incomplete way of dealing with all the clinical information available. A more sensitive approach was to assume that maintaining the level of function reached at discharge from hospital (or improving) was a good outcome. This would require a baseline assessment of the level of function to be made before or immediately after hospital discharge, so that changes could be detected. Unfortunately it was impossible to make meaningful baseline assessments of post-stroke home-life ADL ability before hospital discharge, or even in the first few weeks after discharge. For example, it may take some weeks before a patient has had the opportunity to walk outside, go on a bus journey, write a letter or perform most of the tasks listed in the E-ADL scale. However, it was possible to measure self-care ADL ability meaningfully in hospital and at home, and thus a pragmatic analysis was possible if good outcome was defined as staying alive, at home, and not deteriorating in terms of self-care ADL ability between discharge and six months.

Although an analysis using this pragmatic outcome classification would be expected to provide a crude overall view of the efficacy of the interventions under test, other analyses were required, principally to examine the E-ADL scores in survivors, the NHP scores and the death and institutionalisation rates. The results section starts with simple presentations of the data such as the death and institutionalisation rates and the Barthel ADL, E-ADL and NHP scores in the survivors. An analysis of the proportion of patients achieving

good outcome (as defined above) is also presented. In the discussion, the overall picture revealed by these analyses is summarised.

The E-ADL and the NHP do not form interval scales, and the NHP scores are known not to be normally distributed. For these reasons non-parametric analyses were performed when comparing groups - the Mann-Whitney U-test.

The ideal method of analysis is not merely to perform significance testing, but to look at estimates of the size of the effect of treatment using confidence intervals for the size of the difference between the groups (Gardner & Altman, 1980). This was done wherever appropriate (Morris & Gardner, 1988: Campbell & Gardner, 1988).

Since a single and complete pragmatic analysis was not possible, there was great scope for multiple testing which leads to false positive results. Comparisons of all six NHP domains, one total and three E-ADL subsections in the overall group and in the three strata requires forty separate tests. One method of overcoming the problem of producing a number of false positive results is to set the level of significance at a very low level but this makes it difficult to detect any significant effects at all unless they are large. Another approach is to use an analysis of variance technique. Another approach is to perform several analyses so that the data is thoroughly examined, and to check whether statistically significant results are consistent with each other or not. If the results appear to be consistent with each other then they are likely to be genuine, but if a comparison of the statistically significant results reveals no coherent picture, then this it is likely that the statistically significant results have arisen by chance. The latter approach was used.

3.17 POWER OF STUDY

It was decided to estimate in advance how likely it was that the study would detect a difference between the home-life ADL ability of the groups. Factors which influence such estimates are the true size of the effect in question, the degree to which a result which may have occurred by chance is to be accepted as statistically significant (the probability of a type 1 error, alpha, the level of significance) the degree to which a genuine effect may be missed by chance (the probability of a type 2 error, beta), the number of patients studied and the variability of the E-ADL in the study population. It is difficult to relate these factors together using non-parametric statistics, but parametric statistics allow a simple formula to be used as an approximate estimate (Kirkwood, 1988).

Although the correct approach is to decide upon the size of the treatment effect that is expected and then to perform a study of the appropriate size, it was known that the resources for the NDRS were limited. It was therefore decided to calculate the size of treatment effect that could be expected with the available resources to check that it was acceptable.

Pilot work showed that about 20 patients might be recruited each month. Funding could support the study for 16 months. Thus 320 patients could reasonably be recruited. If 150 patients in each group completed the study, with 80% power, a significance level of 0.05, and a standard deviation for the E-ADL of 6.0 (obtained from pilot work) it was calculated that a mean difference between the groups of 2 E-ADL points could be detected. To have detected a mean difference of 1 E-ADL point would have required in excess of 1000 patients in each group, which was not feasible. In view of the lack of validity data it was difficult to decide with any certainty what amount of difference between the groups marked the boundary between clinical importance and unimportance, but it was not thought worthwhile to attempt to look for treatment effects smaller than 2 E-ADL points.

RESULTS

4.1 THE POPULATION IDENTIFIED

Over the 16 month study period between the beginning of April 1989 and the end of July 1990, 1119 strokes were registered. In 69 cases (16%) the onset of the stroke was in hospital.

The 1119 patients spent 32968 (68%) bed days on Health Care of the Elderly (HCE) wards, of which 19339 (60% of HCE total) were spent in acute wards and 13629 (40% of HCE total) were spent in slow-stream wards, 9271 (19%) were spent in General Medical (GM) wards, 6382 (13%) in the Stroke Unit (SU) and 110 (<1%) on other wards. This gave an average prevalence of acute stroke in hospital of 100 patients: 68 patients in HCE wards of whom 40 were on acute wards and 28 were on slow-stream wards; 19 patients on GM wards and 13 patients on the Stroke Unit.

Table 7 shows demographic details of the patients dying or discharged from HCE and GM wards and the Stroke Unit.

Table 7. Characteristics of patients on the stroke register.

	HCE	GM	SU	ALL
Number of patients (%)	729 (65%)	315 (28%)	75 (7%)	1119
Admission ward:				
geriatric ward	619	2	7	628
medical ward	110	313	67	490
stroke unit	0	0	1	1
Mean age (range)	78 (53-102)	67 (29-100)	60 (38-80)	74 (29-102)
Female (%)	433 (59%)	132 (42%)	38 (51%)	603 (54%)
Previous residence:				
alone	224 (31%)	67 (21%)	10 (13%)	301 (27%)
alone (warden control)	66 (9%)	8 (3%)	1 (1%)	75 (7%)
home with spouse/carer	347 (48%)	232 (74%)	64 (85%)	643 (57%)
Part 3	24 (3%)	1	0	25 (2%)
rest home	34 (5%)	2 (1%)	0	36 (3%)
nursing home	27 (4%)	3 (1%)	0	30 (3%)
other hospital	1	1	0	2
not known	6 (1%)	1	0	7 (1%)
Discharge residence:				
alone	67 (9%)	30 (10%)	7 (9%)	104 (9%)
alone (warden control)	24 (3%)	6 (2%)	1 (1%)	31 (3%)
home with spouse/carer	184 (25%)	160 (51%)	59 (79%)	403 (36%)
Part 3	12 (2%)	2 (<1%)	0	14 (1%)
rest home	21 (3%)	2 (<1%)	1 (1%)	24 (2%)
nursing home	135 (19%)	9 (3%)	5 (7%)	149 (13%)
other hospital	13 (2%)	15 (5%)	1 (1%)	29 (3%)
died in hospital	273 (37%)	91 (29%)	1 (1%)	365 (33%)
Days in hospital mean (median)	49 (30)	16 (12)	109 (110)	44 (24)

4.2 THE POPULATION STUDIED

Three hundred and twenty seven patients were recruited, 43% of all patients discharged from hospital. Figure 1 is a plot of the cumulative number of patients recruited over the study period and shows that the rate of recruitment was steady. One hundred and sixty-two patients were allocated to the domiciliary and 165 to the hospital-based service. Table 8 shows the characteristics of the overall groups and Tables 9, 10 and 11 show the characteristics of the groups in the HCE GM and SU strata respectively.

A CT scan was obtained in 94 patients (29%).

Differences between strata

Patients in the HCE stratum were older than those in the GM or SU strata (Mann-Whitney, $p<0.01$) and a higher proportion of them lived alone (Chi-square, $p<0.01$), suffered a previous stroke (Chi-square, $p<0.05$) or previously had impaired mobility (Chi-square, $p<0.01$). SU stratum patients had a longer hospital stay than those in either of the other two strata (Mann-Whitney, $p<0.01$) and a higher proportion of them had suffered a cortical stroke, as evidenced by a higher prevalence of aphasia (Chi-square, $p<0.01$). GM patients had the shortest hospital stay (Mann-Whitney, $p<0.01$). Thus, as expected, the HCE stratum was a large group of elderly and frail patients, the SU stratum included a small group of younger patients who had survived cortical strokes and who had required prolonged in-patient rehabilitation, leaving another large group of younger patients who were discharged relatively quickly in the GM stratum.

Differences between DRS and HRS groups

There were no significant differences between the treatment groups either overall or by stratum with respect to demography (age, sex, residence,

marital or employment status), previous medical history (previous vascular disease, presence of vascular risk factors), or conscious level on admission. Similarly, at randomisation there were no differences either overall or by stratum in the mental capacity (AMTS). However, the Barthel ADL scores of the HRS group were slightly higher than the DRS group overall, and when examined by stratum this difference was only seen in the GM stratum. In the GM stratum the length of hospital stay was also slightly shorter in the HRS group.

More patients in the HRS group had Barthel scores of 16-20 (65% vs 57%) whereas more of those in the DRS group had scores of 10-15 (37% vs 29%). Therefore the difference between the groups was because more HRS patients were able to perform the difficult tasks. On contingency table analysis of the individual items on each of the ADL scales the only significant difference observed between the groups was for the Barthel ADL item concerning the ability to climb stairs (Chi-square, $p=0.03$). Within the strata, the difference in stair climbing ability was most marked, but did not reach statistical significance, in the GM stratum.

Thus a comparison of the base-line characteristics of the patients showed that the only gross imbalance between the groups was that HRS patients had a higher Barthel ADL ability, and that difference arose largely in the GM stratum. The importance of this and any other less obvious imbalances is examined in later sections.

Figure 1

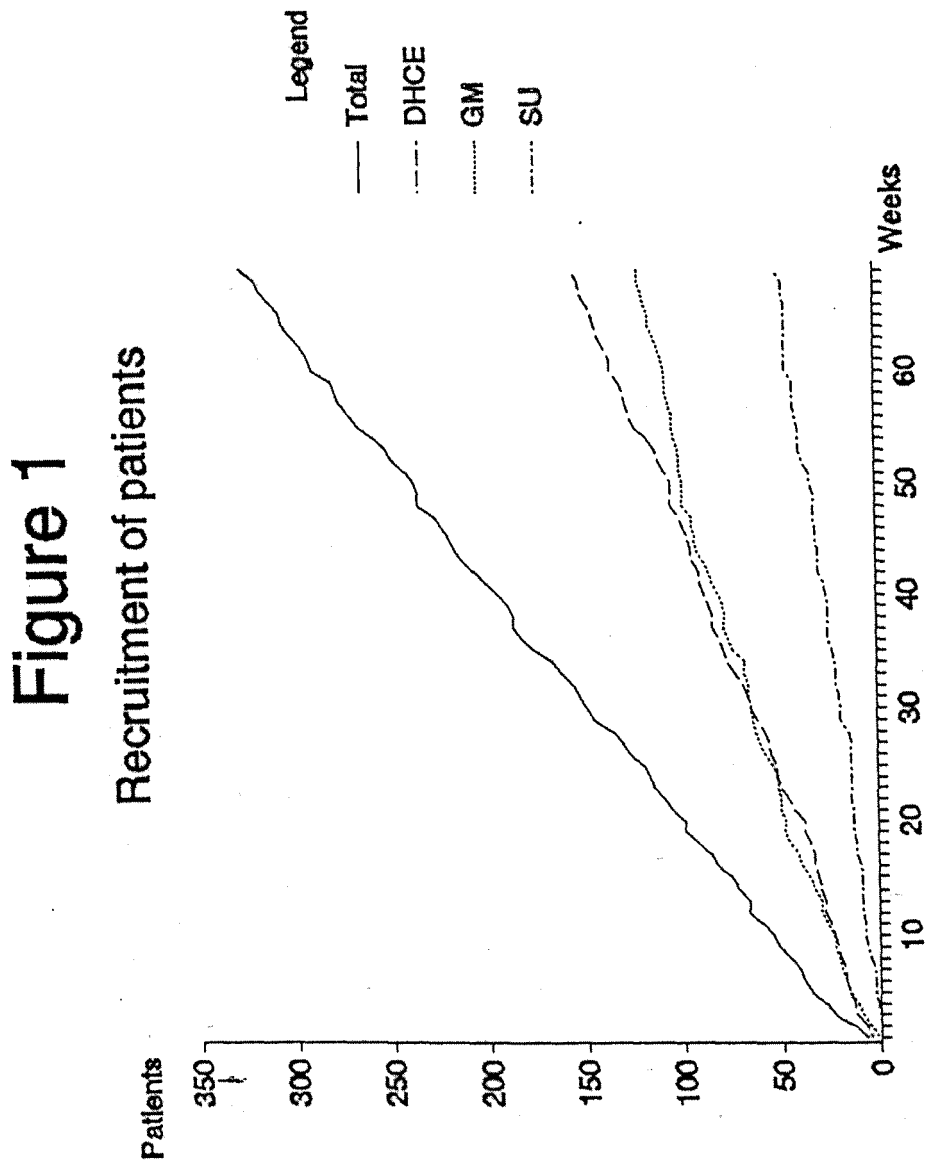


Figure 1
Recruitment of patients
Patients
350
300
250
200
150
100
50
0
10
20
30
40
50
60
Weeks
Legend
Total
DHCE
GM
SU

Table 8. Comparison of the study groups, all strata combined.

	DRS	HRS	ALL
Demography			
Number of patients	162	165	327
Mean age	70	70	70
Female	77 (48%)	77 (47%)	154 (47%)
Living alone	59 (36%)	48 (29%)	107 (33%)
Married	88 (54%)	98 (59%)	186 (57%)
Employed	17 (11%)	20 (12%)	37 (11%)
Medical history			
Previous vascular disease:			
stroke	40 (25%)	29 (18%)	69 (21%)
atrial fibrillation	26 (16%)	35 (22%)	61 (19%)
symptomatic IHD	43 (27%)	38 (23%)	81 (25%)
claudication	15 (9%)	8 (5%)	23 (7%)
abnormal ECG	81 (54%)	78 (51%)	159 (52%)
none of the above	42 (28%)	50 (33%)	92 (30%)
Vascular risk factors:			
hypertension	58 (36%)	59 (36%)	117 (36%)
diabetes mellitus	21 (13%)	22 (13%)	43 (13%)
current smoker	30 (19%)	31 (19%)	61 (19%)
none of the above	78 (48%)	74 (45%)	152 (47%)
Neither a history of vascular disease nor risk factors	23 (15%)	21 (14%)	44 (15%)
Previous immobility	35 (22%)	30 (18%)	65 (20%)
Findings at registration			
Alert when seen	144 (89%)	149 (91%)	293 (90%)
Sensory deficit	28 (17%)	24 (15%)	52 (16%)
Hemianopia	30 (19%)	39 (24%)	69 (22%)
Findings at randomisation			
Aphasia	18 (11%)	28 (17%)	46 (14%)
AMTS (median)	9	10	10
Barthel score (median)	16	17	16
Days in hospital (median)	21	18	20
Department			
HCE	79 (49%)	80 (49%)	159 (49%)
GM	55 (34%)	59 (36%)	114 (35%)
SU	28 (17%)	26 (16%)	54 (17%)

Comparisons between underlined values were statistically significant ($p < 0.05$).

Table 9. Comparison of the study groups in the HCE stratum.

	DRS	HRS	ALL
Demography			
Number of patients	79	76	155
Mean age	77	77	77
Female	41 (52%)	39 (51%)	80 (52%)
Living alone	35 (44%)	28 (37%)	63 (41%)
Married	36 (46%)	37 (49%)	73 (47%)
Employed	1	0	1
Medical history			
Previous vascular disease			
stroke	26 (33%)	16 (21%)	42 (27%)
atrial fibrillation	15 (19%)	19 (26%)	34 (22%)
symptomatic IHD	21 (27%)	13 (17%)	34 (22%)
claudication	6 (8%)	1 (1%)	7 (5%)
abnormal ECG	38 (54%)	37 (56%)	75 (55%)
none of the above	16 (22%)	19 (29%)	35 (26%)
Vascular risk factors			
hypertension	25 (32%)	18 (24%)	43 (28%)
diabetes mellitus	9 (11%)	9 (12%)	18 (12%)
current smoker	9 (11%)	8 (11%)	17 (11%)
none of the above	42 (53%)	43 (58%)	85 (55%)
Neither a history of vascular disease nor risk factors	8 (11%)	12 (18%)	20 (15%)
Previous immobility	29 (37%)	19 (25%)	48 (31%)
Findings at registration			
Alert on admission	71 (90%)	69 (91%)	140 (90%)
Sensory deficit	12 (15%)	7 (9%)	19 (12%)
Hemianopia	9 (11%)	15 (20%)	24 (15%)
Findings at randomisation			
Aphasia	8 (10%)	13 (17%)	21 (14%)
AMTS (median)	9	9	9
Barthel score (median)	16	17	16
Days in hospital (median)	21	26	25

Table 10. Comparison of the study groups in the GM stratum.

	DRS	HRS	ALL
Demography			
Number of patients	58	63	121
Mean age	64	67	65
Female	21 (36%)	27 (43%)	48 (40%)
Living alone	18 (31%)	17 (27%)	35 (29%)
Married	34 (59%)	40 (64%)	74 (61%)
Employed	12 (21%)	13 (21%)	25 (21%)
Medical history			
Previous vascular disease			
stroke	10 (17%)	9 (14%)	19 (16%)
atrial fibrillation	9 (16%)	12 (20%)	21 (18%)
symptomatic IHD	16 (28%)	19 (30%)	35 (29%)
claudication	5 (9%)	6 (10%)	11 (9%)
abnormal ECG	32 (57%)	34 (56%)	66 (56%)
none of the above	16 (29%)	20 (33%)	21 (36%)
Vascular risk factors			
hypertension	20 (35%)	29 (46%)	41 (41%)
diabetes mellitus	9 (16%)	13 (21%)	22 (18%)
current smoker	15 (26%)	27 (27%)	32 (26%)
none of the above	26 (45%)	20 (32%)	46 (38%)
Neither a history of vascular disease or risk factors	11 (20%)	5 (8%)	16 (14%)
Previous immobility	5 (9%)	10 (16%)	15 (12%)
Findings at registration			
Alert on admission	53 (91%)	59 (94%)	112 (93%)
Sensory deficit	9 (16%)	11 (17%)	20 (17%)
Hemianopia	12 (21%)	12 (19%)	24 (20%)
Findings at randomisation			
Aphasia	5 (9%)	5 (8%)	10 (8%)
AMTS (median)	10	10	10
Barthel score (median)	16	17	16
Days in hospital (median)	13	10	12

Comparisons between underlined values were statistically significant ($p < 0.05$).

Table 11. Comparison of the study groups in the SU stratum.

	DRS	HRS	ALL
Demography			
Number of patients	25	26	51
Mean age	62	58	60
Female	15 (60%)	11 (42%)	26 (51%)
Living alone	6 (24%)	3 (12%)	9 (18%)
Married	18 (72%)	21 (81%)	39 (77%)
Employed	4 (16%)	7 (27%)	11 (22%)
Medical history			
Previous vascular disease			
stroke	4 (16%)	5 (19%)	9 (18%)
atrial fibrillation	2 (8%)	4 (15%)	6 (12%)
symptomatic IHD	6 (24%)	6 (23%)	12 (24%)
claudication	4 (16%)	1 (4%)	5 (10%)
abnormal ECG	11 (46%)	7 (27%)	18 (36%)
none of the above	10 (42%)	11 (42%)	21 (42%)
Vascular risk factors			
hypertension	13 (52%)	12 (46%)	25 (49%)
diabetes mellitus	3 (12%)	0 (0%)	3 (6%)
current smoker	6 (24%)	6 (23%)	12 (24%)
none of the above	10 (40%)	11 (42%)	21 (41%)
Neither a history of vascular disease nor risk factors	4 (17%)	4 (15%)	8 (15%)
Previous immobility	1 (4%)	1 (4%)	2 (4%)
Findings at registration			
Alert	20 (80%)	21 (81%)	41 (80%)
Sensory deficit	7 (28%)	6 (23%)	13 (25%)
Hemianopia	9 (36%)	12 (48%)	21 (41%)
Findings at randomisation			
Aphasia	5 (20%)	10 (39%)	15 (29%)
AMTS (median)	10	10	10
Barthel score (median)	16	17	16
Days in hospital (median)	103	89	97

4.3 EXCLUSIONS

Table 12 lists the numbers of people in each exclusion category and Figures 2, 3, 4 and 5 are pie-charts illustrating the exclusions overall and from the HCE and GM wards and the SU respectively. The major reason why surviving patients were not entered into the study was because they were to be discharged to residential or nursing home care, especially from the HCE wards. Elsewhere it has been shown that patients discharged to residential or nursing home care are, as expected, the more severely disabled patients (Gladman et al, in press). Table 13 shows the characteristics of the patients who were discharged to private households in the Nottingham area who were and were not entered into the study. The patients requiring respite care in a day hospital were a severely affected group, since they were more likely to have had an impaired level of consciousness on admission or had cortical signs such as aphasia, and they had long hospital stays. Patients who entered the study and those who were discharged before they could be entered showed similar characteristics, except that those who were missed had shorter hospital stays.

Thus many of the very mildly and severely affected survivors were excluded from the NDRS, so that those who were included represented a "middle band" of stroke survivors. The failure to randomise all suitable patients is unlikely to have introduced an important bias.

Table 12. Reasons for exclusion.

None, included	327 (29%)
Died	364 (33%)
Residential or nursing care on discharge	211 (19%)
Non-disabling stroke	63 (6%)
Out of Nottingham Health Authority area	51 (5%)
Discharged before allocation (missed)	40 (4%)
Discharged within 7 days	29 (3%)
Day hospital required for respite	23 (2%)
Already receiving HRS	5
In pilot study	3
No consent given	2
Terminal care requirements	1
Total	1119

Table 13. Characteristics of patients entered and not entered into the study.

	Entered	Non-disabling stroke	Hospital stay <7 days	DH respite	Missed
Number	327	63	29	23	40
Age (mean)	70	71	66	72	74
Living alone	33%	28%	10%	13%	40%
Alert on admission	85%	94%	89%	71%	81%
Aphasia	29%	42%	17%	61%	31%
Paralysis (any limb MRC<3)	37%	0%	4%	57%	36%
Days in hospital (median)	50	15	5	103	33

Figure 2
Exclusions - overall

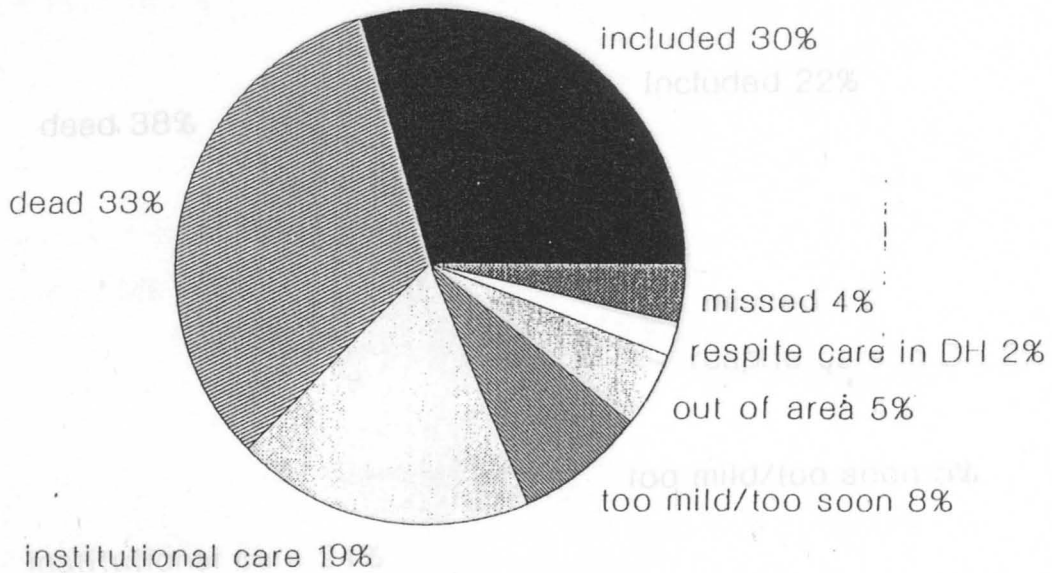


Figure 3
Exclusions - health care of the elderly

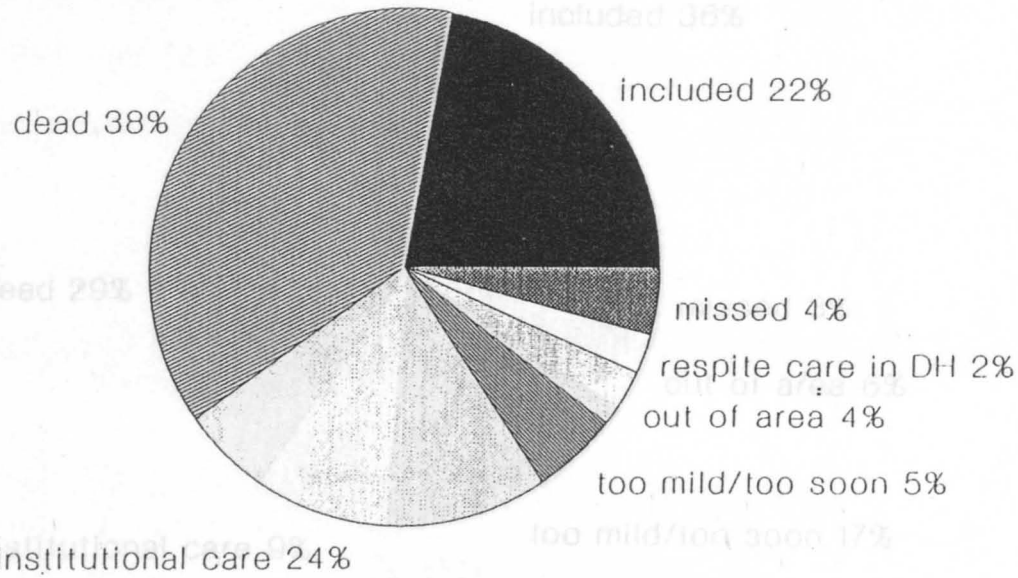


Figure 4
Exclusions - general medicine

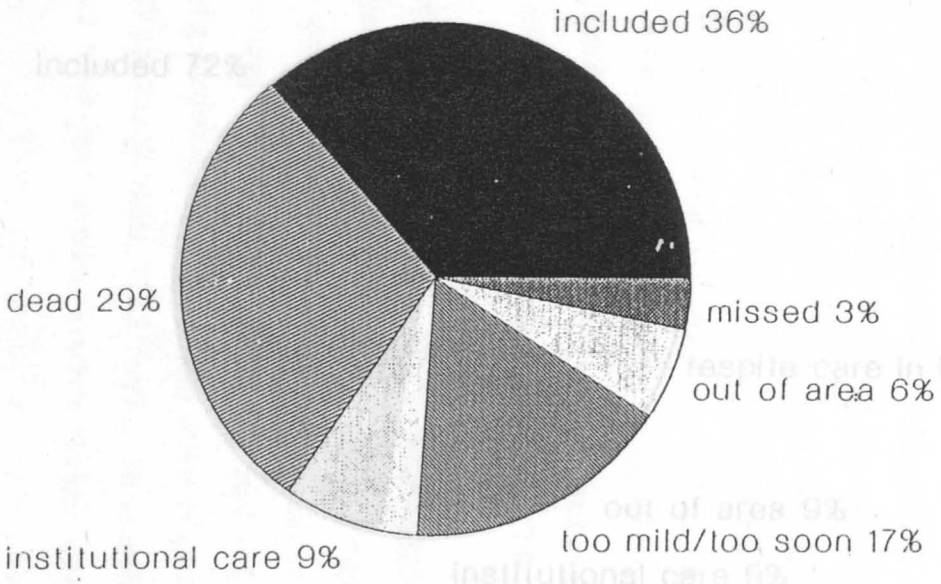
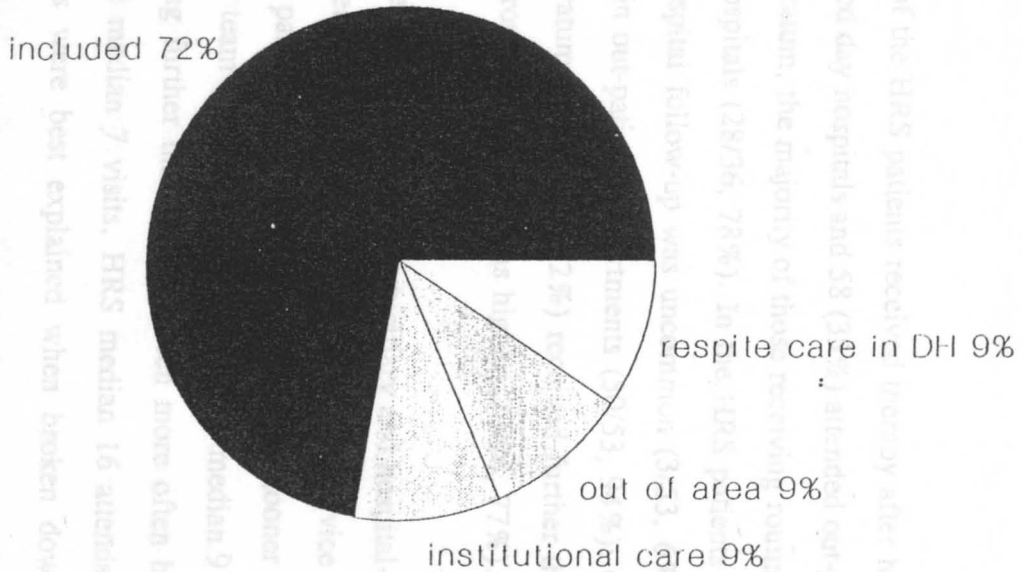


Figure 5
Exclusions - stroke unit



4.4 THE DOMICILIARY AND HOSPITAL-BASED SERVICES

Details of the services are given in Table 14. The domiciliary team assessed most patients allocated to it (154/162, 95%) for their need for further therapy, usually within a few days of discharge from hospital. Decisions to provide further therapy from the routine services were made while the patients were still in-patients.

Overall, 89 (54%) of the HRS patients received therapy after hospital discharge: 31 (19%) attended day hospitals and 58 (35%) attended out-patient departments. In the HCE stratum, the majority of those receiving routine care were followed-up in day hospitals (28/36, 78%). In the HRS patients of the GM and SU strata, day hospital follow-up was uncommon (3/53, 6%) and most patients were treated in out-patients departments (50/53, 94%). Of the HRS patients in the GM stratum only 33/63 (52%) received further therapy but in the SU stratum the proportion treated was higher (20/26, 77%).

The important differences between the domiciliary and hospital-based services were that more patients were treated by the domiciliary service (DRS 121, HRS 89, $p<0.01$), patients were contacted slightly sooner after discharge by the domiciliary team (DRS median 6 days, HRS median 9 days, $p<0.01$), but those receiving further therapy were seen more often by the hospital-based service (DRS median 7 visits, HRS median 16 attendances, $p<0.01$). These differences were best explained when broken down by stratum.

In the HCE stratum, although a smaller proportion of patients were treated by the hospital-based service, they were seen more frequently in 6 months (median 19 times) than those treated by the domiciliary team were visited (median 6 visits) ($p<0.01$). In the SU stratum more patients were followed-up by the domiciliary service, but the number of times the patients were seen in 6 months was similar. There was little difference between the

hospital-based and domiciliary services provided to the patients in the GM stratum.

Overall, both the domiciliary team and those offering hospital-based treatment tended to select younger patients, who had been hospital for a long time and who did not live alone. The domiciliary team tended to treat those with previous strokes and the hospital-based services tended to see a higher proportion of males than females.

In the HCE stratum patient characteristics increasing the likelihood of returning to a day hospital were a long stay in hospital, a previous stroke, a lower Barthel ADL score or a sensory deficit. Although the domiciliary team also tended to treat those with long hospital stays in the group, it also tended to treat younger patients and those without mental impairment. Thus, in the HCE stratum, the day hospital service was more clearly directed towards frail patients than the domiciliary service.

In the GM stratum it was not possible to detect any significant differences between the patients who were and were not treated by the DRS, but the patients returning to out-patient departments were older and had been in hospital for longer than those who were not followed-up. Thus, again, in the GM stratum the routine service was directed towards patients who were likely to have had the greatest problems.

Nine patients allocated to the domiciliary service were treated by the hospital-based services, but no cross-over took place in the other direction. Five DRS patients in the HCE stratum attended day hospitals on discharge from hospital (violating trial protocol), because their physicians decided that their carers required relief care. If this need had been identified earlier then the patients would have been excluded. Of the four other DRS patients who received hospital-based treatment, one was admitted to hospital with another stroke and attended a day hospital on discharge, another had a fractured neck

of femur and went to an OPD on discharge and two patients were referred by the DRS to an OPD, for OT workshop facilities.

Table 14. Rehabilitation provided by the DRS and HRS

	ALL		HCE		GM		SU	
	DRS	HRS	DRS	HRS	DRS	HRS	DRS	HRS
Number treated	121	89	57	36	39	33	25	20
Number treated beyond 3 months	57	50	21	23	16	15	20	12
Number treated beyond 6 months	17	17	3	8	4	6	10	3
Days to first treatment (median)	6	9	5	9	6	7	6	12
Duration of treatment in patients treated for less than 6 months (median, days)	64	57	59	65	49	29	109	58
Attendances/visits in 6 months (median, excluding DRS initial visits)	7	16	6	19	6	8	19	21
Attendances/visits 3-6 months (median, excluding DRS initial visits)	6	12	5	15	3	5	14	13
Total attendances/visits: excl. initial DRS visits	1461	1626	559	726	301	446	601	454
incl. initial DRS visits	1615	1626	631	726	358	446	626	454

Comparisons between underlined values reached statistical significance ($p < 0.05$).

4.5 OUTCOME: DEATH & PLACE OF RESIDENCE.

Table 15 shows the number of patients surviving to 6 months after randomisation and their place of residence.

There was a trend towards a higher death rate in the DRS group (relative risk 2.3, 95% confidence intervals 1.0 to 5.5, Chi-square, 3.97, p=0.05), an effect seen mainly in the HCE stratum (relative risk 3.2, 95% confidence intervals 0.9 to 11, Chi-square, 3.83, p=0.05).

When patients who had died, or who were still in hospital or who were in institutional care were considered as a single "bad" outcome category a similar trend towards more bad outcome among the DRS patients was seen (relative risk 1.7, 95% confidence intervals 1.0 to 2.9, Chi-square=3.4, p=0.07), reaching statistical significance in the HCE stratum (relative risk 2.4, 95% confidence intervals 1.1 to 5.1, Chi-square= 5.7, p=0.02).

In the overall domiciliary group "bad" outcome occurred in 19/123 (15%) patients given further therapy and 13/39 (33%) of those who were not ($p<0.05$). In the overall hospital-based group bad outcomes occurred in 6/89 (7%) of those who were followed-up and in 11/76 (14%) who were not (p=NS).

In the DRS group of the HCE stratum, 13/59 (22%) of patients given further therapy had bad outcome, compared to 9/20 (45%) who were not (p=NS). In the HRS group of the HCE stratum, bad outcome occurred in 3/40 (8%) patients followed-up and in 5/40 (13%) who were not (p=NS). In the DRS group of the GM stratum, bad outcome occurred in 5/39 (13%) given further therapy and 4/19 (21%) who were not (p=NS). In the HRS group of the GM stratum, bad outcome occurred in 5/30 (17%) who were not treated and in none of the 33 who were. In the SU stratum all DRS patients were given further therapy, one of whom had bad outcome. In the HRS group of

the SU stratum 3/20 (15%) patients who were followed-up, and 1/6 (17%) who were not, had bad outcome.

Clinical details recorded before randomisation were entered into a discriminant function model to predict death or institutionalisation at six months. The discriminant function model was accurate in only 80% of cases. Six adverse factors were identified: increasing age, previous immobility, previous stroke, living alone, a sensory deficit on admission to hospital and a lower AMTS at discharge. Table 11 illustrates the relationship between the possession of these factors and subsequent death or institutionalisation using univariate statistics and also shows the prevalence of each factor in the treatment groups. Neither the Barthel ADL score (or any of its individual items) or the level of consciousness on admission to hospital were found to have prognostic significance at this stage. This is illustrated by univariate testing: 4% of those who died or who were in an institution and 11% who stayed alive at home had been drowsy on admission; 10% with bad outcome so defined and 9% with good outcome had been incontinent of urine when entered into the study and the Barthel scores at study entry of those with bad outcome (median 15/20, interquartile range 13-17) and those with good outcome (median 17/20, interquartile range 15-17) were not significantly different (Mann-Whitney, $p > 0.05$).

Table 16 shows that 5 of the 6 risk factors including all three of the risk factors which were significant predictors of bad outcome on univariate analysis were more prevalent in the DRS group. When a discriminant model was produced taking these risk factors (and the Barthel scores) into account the expected numbers of patients with bad outcome could be calculated, and are shown in Table 15. This analysis suggests that much of the difference in bad outcome rates observed between the groups was due to allocation bias. Nevertheless, even when all these factors were taken into account by the discriminant function model, allocation to the DRS group was still found to be an additional independent prognostic factor for bad outcome.

Table 15. Overall outcome at 6 months

	ALL		HCE		GM		SU	
	DRS	HRS	DRS	HRS	DRS	HRS	DRS	HRS
Home alone	37 (23%)	25 (15%)	19 (24%)	15 (20%)	12 (21%)	10 (16%)	6 (24%)	0
Home WAF	12 (7%)	14 (9%)	6 (8%)	12 (16%)	4 (7%)	1 (2%)	2 (8%)	1 (4%)
Home + other	85 (53%)	109 (66%)	34 (43%)	41 (54%)	35 (60%)	47 (75%)	16 (64%)	21 (81%)
Hospital	3 (2%)	2 (1%)	1 (1%)	1 (1%)	2 (3%)	0	0	1 (4%)
Residential/nursing care	9 (6%)	8 (5%)	9 (11%)	4 (5%)	0	3 (5%)	0	1 (4%)
Dead	16 (10%)	7 (4%)	10 (13%)	3 (4%)	5 (9%)	2 (3%)	1 (4%)	2 (8%)
Bad	28 (18%)	17 (10%)	20 (25%)	8 (10%)	7 (12%)	5 (8%)	1 (4%)	4 (15%)
"Expected" bad *	27 (17%)	18 (11%)	22 (28%)	15 (20%)	4 (7%)	2 (3%)	1 (4%)	1 (4%)

* For an explanation of this term see page 107

Table 16. Prognostic factors for bad outcome.

	Bad outcome (n=45)	not bad outcome (n=282)	Proportion in DRS	HRS
Previous immobility	18 (40%)	47 (17%)	22%	18%
	(RR=2.7, 95% CI 1.6 to 4.6)			
Age >75 years	33 (73%)	146 (52%)	56%	54%
	(RR=2.3, 95% CI 1.2 to 4.2)			
Living alone	22 (49%)	85 (30%)	36%	29%
	(RR=2.0, 95% CI 1.1 to 3.4)			
AMTS <7/10	16 (36%)	60 (21%)	22%	24%
	(RR=1.8, 95% CI 1.0 to 3.2)			
Previous stroke	15 (33%)	55 (20%)	25%	18%
	(RR=1.8, 95% CI 1.0 to 3.2)			
Sensory deficit	11 (24%)	39 (15%)	19%	15%
	(RR=1.7, 95% CI 0.92 to 3.1)			

RR: relative risk
CI: confidence interval

4.6 OUTCOME: DISABILITY.

Barthel scores

In 300 patients the Barthel ADL Index was completed at the 6 months visit. For all patients combined the median Barthel score was 18/20.

Of the 27 patients in whom no score was available, 20 were in the DRS and of these 16 had died, 2 refused, one was in a private nursing home and one was lost to follow up. There were 7 non-respondents in the HRS group, all of whom had died.

The Barthel score was completed by the patient in 260 (87%) cases, a spouse in 22 (7%), another female relative in 9 (3%) and 9 (3%) were completed by others.

The results of the Barthel ADL scores at 6 months are shown in Table 17. No differences were detected between the raw Barthel scores at 6 months. In an attempt to correct for the imbalance in Barthel scores at discharge, the change in Barthel scores between discharge and at 6 months was computed, the group comparison were repeated and these are also shown in Table 17. In the SU stratum, the Barthel scores of the DRS improved between randomisation and 6 months later (median improvement 1, IQR 0 to 2), whereas the Barthel scores of the HRS patients deteriorated (median deterioration 0.5, IQR -1 to 1), and this difference reached statistical significance (Mann-Whitney, $p < 0.01$).

Table 17. Barthel scores.

	ALL		HCE		GM		SU	
	DRS	HRS	DRS	HRS	DRS	HRS	DRS	HRS
Barthel score at 6 months								
median	17.0	18.0	17.0	17.0	19.0	19.0	18.0	16.0
(IQR)	(14-19)	(15-20)	(12-18)	(14-19)	(16-20)	(17-20)	(15-19)	(15-18)
Improvement in Barthel score								
median	1.0	1.0	0.0	1.0	2.0	2.0	1.0	-0.5
(IQR)	(0,3)	(-1,2)	(-1,3)	(-1,2)	(1,4)	(0,3)	(0,2)	(-1,1)

IQR:Interquartile range.
Comparisons between underlined values reached statistical significance ($p < 0.05$).

E-ADL at 3 months

The E-ADL was sent by post at 3 months, and a further one was sent if no reply was obtained in 2 weeks. No further attempt was made to contact patients at 3 months, but at 6 months all patients were traced. E-ADL questionnaires were returned from 299/327 patients at 3 months. There were 17 non-respondents in the DRS group and 11 in the HRS group. At six months, 5 of the 17 DRS non-respondents at 3 months were at home, 3 were in an institution, 8 were dead and 1 was lost to follow-up: of the 11 HRS non-respondents the corresponding figures were 7 at home, 1 in an institution and 3 dead.

The identity of the respondent was clear in 268 replies. In 131 (49%) the questionnaire had been completed by the patient, 57 (21%) were completed by the spouse, 43 (16%) by another female relative, 14 (5%) by another male relative and 23 (9%) by others. Half the questionnaires were returned by 9 days and 88% were returned by 2 weeks.

The results are shown in Table 18. At 3 months there were no differences between the E-ADL scores of those treated by the DRS or the HRS, either overall or by stratum.

E-ADL at 6 months

At six months, 303 E-ADL questionnaires were returned. The respondents at 6 months were similar to those at 3 months with only 151 (50%) completed by the patient, 51 (17%) by the spouse, 28 (9%) by a female relative, 13 (4%) by a male relative, 21 (7%) by others and 39 (13%) were completed at the 6 month assessment visit, with minimal assistance from the assessor.

There were 24 non-responders: 15 of the 18 DRS non-responders had died and one was at home and refused, one was at a private nursing home too far away and did not respond, and one was lost to follow-up. All of the HRS non-responders had died (and one who responded died between returning the questionnaire and the assessment visit at six months).

The results are shown in Table 18. There were no differences in the total E-ADL scores at 6 months of those treated by the DRS or the HRS, either overall (median difference 0.0, 95% CI -1 to 1) or by stratum. In the SU stratum, in the household and leisure domains, significantly higher scores were seen in the DRS group (median difference 2.0, 95% CI 0 to 3, $p=0.02$ and median difference 1.0, 95% CI 0 to 2, $p=0.04$ respectively).

The change in E-ADL scores between 3 and 6 months were computed and compared and are also shown in Table 18. The only significant findings were that in the Stroke Unit stratum, the total E-ADL and mobility E-ADL scores of the domiciliary group improved whereas the scores for the hospital-based group tended to fall and these differences between the groups reached statistical significance (Mann-Whitney, $p<0.01$ for both).

An analysis was performed to identify base-line characteristics which predicted the total E-ADL scores at six months. This was performed so that base-line inequalities (allocation bias) could be identified. A multivariate linear logistic regression was model was required because many of the variables were likely to be related. Six independent variables were identified as predictors of the total E-ADL score: the Barthel score at discharge, decreasing age, normal mobility, a shorter time in hospital, the AMTS and living alone. Together these variables explained only 36% of the variance in E-ADL ability. Table 19 illustrates the prognostic value of each factor using univariate statistics and the prevalence of each factor in the survivors.

Multivariate analysis of covariance was performed to correct for any imbalances in the prognostic factors in the analysis of the E-ADL scores of the survivors. A square root transformation was used to give the total E-ADL score a normal distribution. When the three covariates (age, total time in hospital and Barthel score) were examined to produce their best linear relationships with the transformed total E-ADL score, a logarithmic transformation was required for the total time in hospital. The six risk factors identified from the multiple logistic regression analysis were entered into the model, as were the admission conscious level, urinary incontinence, dysphasia, sex, marital status, and stratum. Interactions between the factors and covariates were also included. Despite this manoeuvre, only 48% of the total variance was explained by the model. The effect of treatment allocation was examined, and also interactions between treatment allocation and stratum. The overall effect of treatment allocation was not significant ($p=0.29$), nor were the interactions between treatment allocation and the HCE stratum ($p=0.09$) or the GM stratum ($p=1.0$), but a significant interaction between treatment allocation and the SU stratum was found ($p=0.02$). Thus the covariance analysis again showed that there was no overall difference in the total Extended ADL scores between the services, but in the Stroke Unit stratum only the group allocated to the domiciliary team had higher scores.

Non-parametric estimates of the median difference between the groups and the 95% confidence intervals for the total E-ADL score, Barthel score and change in Barthel score are displayed in Figures 6, 7 & 8 respectively. Figures 6-8 illustrate that moderate differences in the overall group were excluded and also show the lower degree of statistical confidence achieved when the strata were analysed.

Table 18. E-ADL scores.

	ALL		HCE		GM		SU	
	DRS	HRS	DRS	HRS	DRS	HRS	DRS	HRS
TOTAL E-ADL								
3 months								
median	8.0	8.5	6.0	8.0	11.0	11.0	7.0	6.5
(IQR)	(4-13)	(4-13)	(2-10)	(2-11)	(6-16)	(6-16)	(5-11.5)	(5-9)
6 months								
median	8.5	8.0	6.0	8.0	12.5	12.0	9.5	6.0
(IQR)	(4-14)	(4-14)	(3-10)	(4-12)	(7-17)	(6-17.5)	(5-12)	(3.5-10.5)
Improvement								
median	1.0	0.0	0.5	0.0	0.0	0.0	1.5	0.0
(IQR)	(-1,2)	(-1,2)	(-1,2)	(-1,2)	(-1,3)	(-1,2)	(0,3)	(-2,1)
MOBILITY E-ADL								
3 months								
median	2.0	2.0	1.0	1.0	4.0	4.0	1.0	2.0
(IQR)	(0-4)	(0-5)	(0-3)	(0-4)	(1-6)	(1-5)	(0-3)	(1-4)
6 months								
median	2.0	2.0	1.0	1.0	4.0	4.0	1.5	1.0
(IQR)	(0-5)	(0-5)	(0-3)	(0-4)	(2-6)	(1.5-5)	(0-4)	(0-4.5)
Improvement								
median	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0
(IQR)	(0,1)	(0,1)	(0,0)	(0,1)	(-1,1)	(0,1)	(0,1)	(-1,0)
HOUSEHOLD E-ADL								
3 months								
median	4.0	4.0	3.0	4.0	4.5	5.0	4.0	3.0
(IQR)	(2-7)	(2-6)	(1-6)	(1-6)	(3-8)	(2-8)	(3-6.5)	(2-4)
6 months								
median	4.0	4.0	3.0	4.0	6.0	6.0	5.0	3.0
(IQR)	(2-7)	(2-7)	(1-6)	(2-6)	(3-7)	(2-8.5)	(3-7)	(0.5-4.5)
Improvement								
median	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0
(IQR)	(0,1)	(-1,1)	(0,0)	(0,1)	(-1,1)	(-1,1)	(0,2)	(-1,1)
LEISURE E-ADL								
3 months								
median	2.0	2.0	2.0	2.0	2.5	2.0	2.0	1.5
(IQR)	(1-3)	(1-3)	(1-3)	(1-3)	(1-4)	(2-4)	(1-3)	(1-3)
6 months								
median	2.0	2.0	2.0	2.0	3.0	2.0	2.5	2.0
(IQR)	(2-3)	(1-3)	(1-3)	(1-3)	(2-4)	(1-4)	(2-3)	(1-2.5)
Improvement								
median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
(IQR)	(0,1)	(0,0)	(0,1)	(0,0)	(0,1)	(-1,0)	(0,1)	(0,1)

Comparisons between underlined values reached statistical significance ($p < 0.05$).

Table 19. Prognostic factors of total E-ADL score at six months.

Factor	median E-ADL score	Proportion in DRS	Proportion in HRS
Discharge Barthel <17/20	7.0		
Discharge Barthel >/=17/20	10.0	42%	55%
Age 70+	7.0		
Age <70	11.0	45%	47%
Previous immobility	5.0		
Previous normal mobility	9.0	81%	82%
In hospital >2 months	5.0	17%	28%
In hospital 2 weeks to 2 months	9.0	54%	45%
In hospital 2 weeks or less	13.0	28%	26%
Abbreviated MTS <7/10	5.0		
Abbreviated MTS 7+/10	10.0	80%	75%
Living with others	8.0		
Living alone	10.0	34%	29%

Figure 6. EADL scores at 6 months:
median differences and 95% confidence intervals

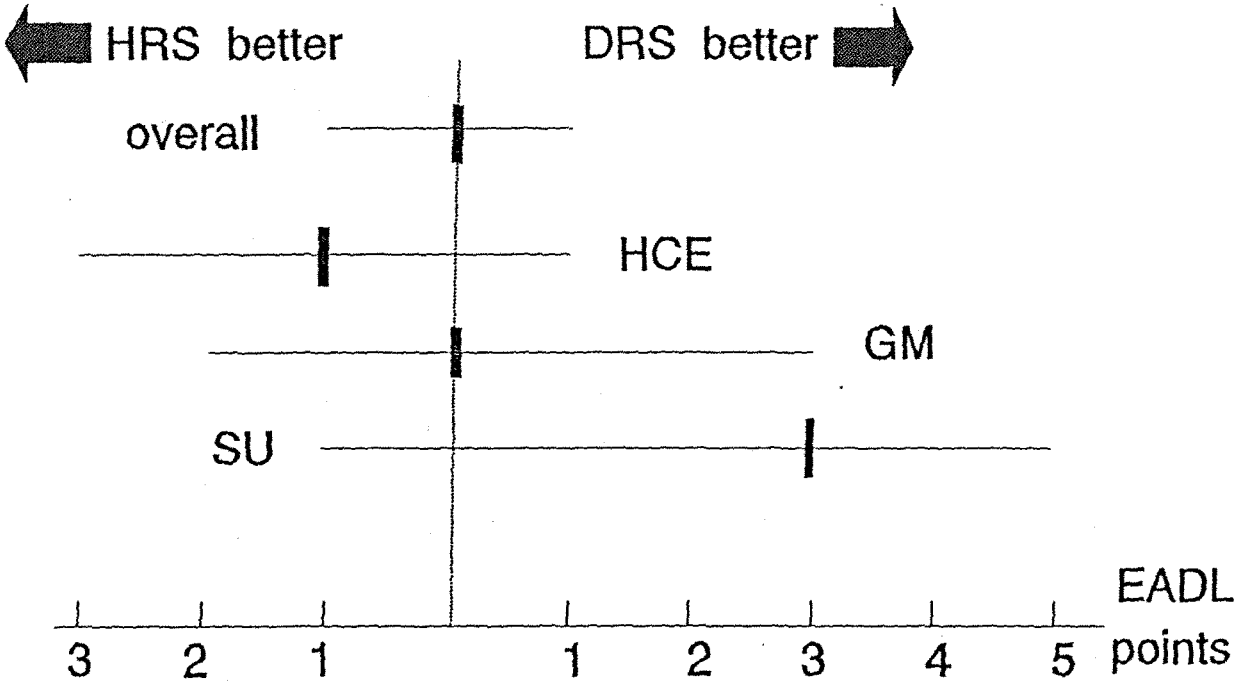


Figure 7. Barthel scores at 6 months:
median differences and 95% confidence intervals

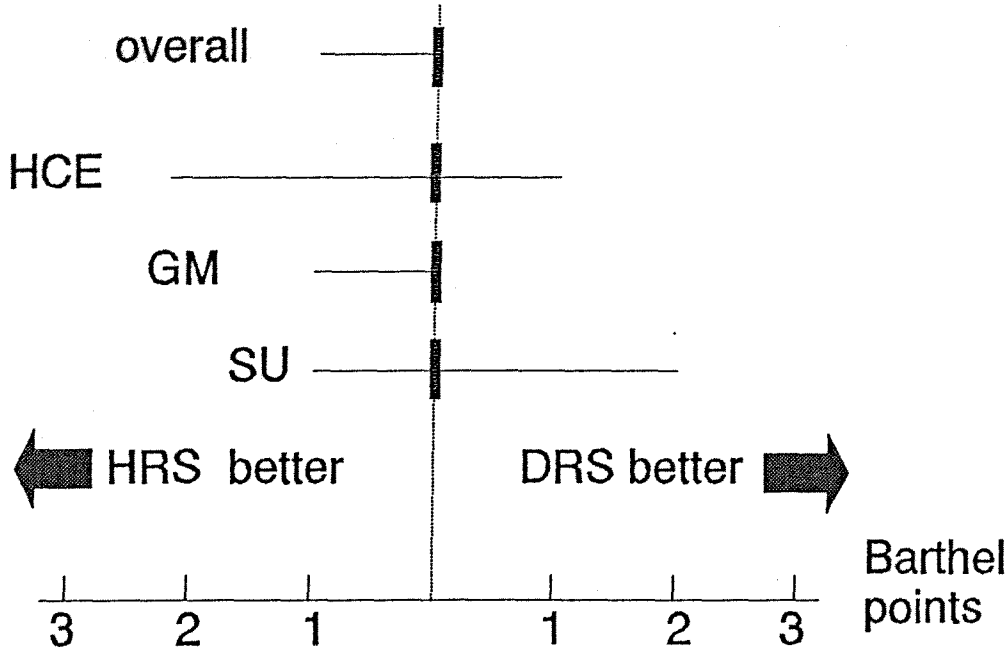
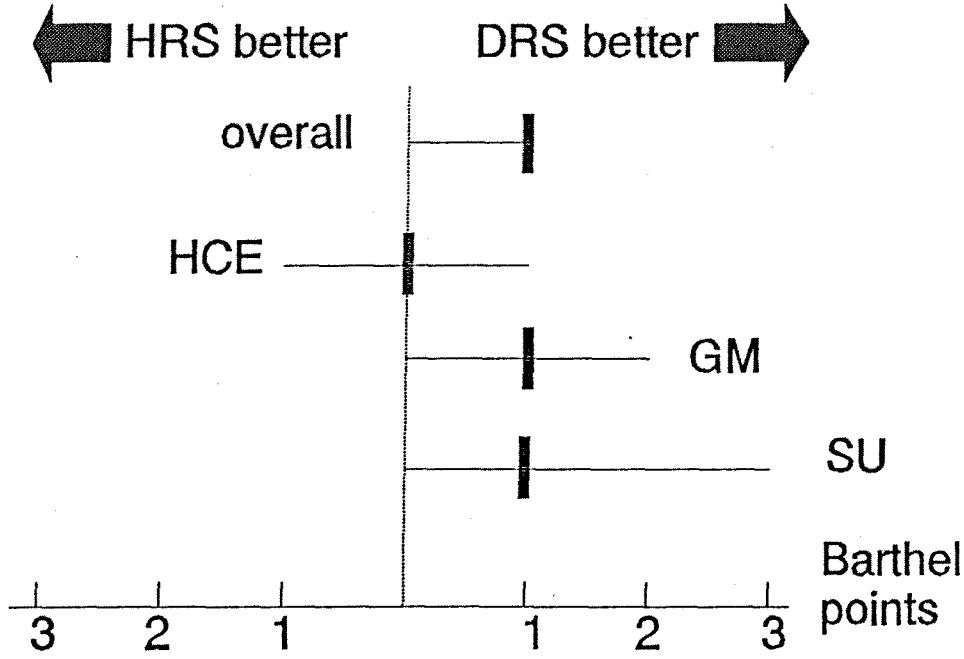


Figure 8. Improvement in Barthel score: median difference and 95% confidence intervals



4.7 OUTCOME: PREVENTING DETERIORATION

Following sections 4.5 and 4.6 it is possible to identify patients with "good" outcome if defined as those who were still at home at six months and whose Barthel ADL scores did not fall between discharge and at six months. Good outcome was equally likely in the two groups (DRS 103, HRS 108, risk ratio 1.0, 95% confidence intervals 0.8 to 1.1).

In the HCE stratum there was a trend towards good outcome being less common in the DRS group (DRS 41, HRS 48, risk ratio 0.8, 95% confidence intervals 0.6 to 1.1) and in the GM stratum there was no difference (DRS 43, HRS 48, risk ratio 1.0, 95% confidence intervals 0.8 to 1.2). Good outcome was more common in the DRS patients of the SU stratum (risk ratio 1.6, 95% confidence intervals 1.0 to 2.6, $p=0.03$).

A discriminant function analysis was performed and identified normal mental function, normal mobility, short hospital stay, no previous stroke, no sensory loss, a lower Barthel score and having been a GM patient as independent prognostic factors for good outcome. The effects of these factors upon good outcome are illustrated using univariate analysis in Table 20.

Table 20. **Univariate analyses of independent predictors of good outcome.**

	Good outcome n=211	Not good outcome n=116
Stratum		
HCE	89	66
GM	91	30
SU	31	20
	Chi-square, $p<0.01$	
AMTS >7	180 (85%)	71 (61%)
	(risk ratio 1.8, 95% CI 1.3 to 2.3)	
Normal previous mobility	182 (86%)	80 (69%)
	(risk ratio 1.6, 95% CI 1.2 to 2.1)	
Time in hospital <31 days	126 (60%)	45 (39%)
	(risk ratio 1.4, 95% CI 1.1 to 1.6)	
No previous stroke	175 (83%)	82 (71%)
	(risk ratio 1.3, 95% CI 1.0 to 1.7)	
Age <70	106 (50%)	42 (36%)
	(risk ratio 1.2, 95% CI 1.0 to 1.4)	
No sensory loss	182 (86%)	92 (79%)
	(risk ratio 1.2, 95% CI 0.9 to 1.6)	
Discharge Barthel <17	111 (52%)	56 (48%)
	(risk ratio 1.1, 95% CI 0.9 to 1.2)	

4.8 OUTCOME: PERCEIVED HEALTH

The NHP was completed at 6 months in 271 (83%) patients: 161 of these patients (59%) required no help to complete the questionnaire, but in 110 (41%), help was required - either by the use of large cards with the items on, or the recording of verbal replies for those unable to write.

Fifty six patients did not complete the NHP at 6 months: there were 35 non-respondents in the DRS, of whom 16 had died, 5 were dysphasic, 1 was confused and 13 had difficulty reading: there were 21 HRS non-respondents of whom 7 had died, 7 were dysphasic and 7 had difficulty reading.

Table 21 shows the raw results, the mean for all domains, and the proportion of patients in each group with "severe distress" (scoring >30/100 using Ebrahim's total NHP). No significant differences were seen between either group, either overall or by stratum in any NHP domain or in the mean NHP score.

Table 21. NHP scores at six months.

(Possible scores in each domain range from 0 to 100, higher scores denote worse perceived health)

	ALL		HCE		GM		SU	
	DRS	HRS	DRS	HRS	DRS	HRS	DRS	HRS
ENERGY								
median	24	24	37	38	37	24	0	0
(IQR)	(0-63)	(0-61)	(0-100)	(0-63)	(12-63)	(0-61)	(0-24)	(0-61)
EMOTIONAL DISTURBANCE								
median	10	14	10	16	23	10	0	10
(IQR)	(0-41)	(0-44)	(0-46)	(0-46)	(0-44)	(0-44)	(0-17)	(0-42)
SLEEP DISTURBANCE								
median	16	13	16	13	22	13	13	13
(IQR)	(0-50)	(0-35)	(0-50)	(0-38)	(0-67)	(0-35)	(0-35)	(0-22)
SOCIAL ISOLATION								
median	19	20	22	19	16	22	0	22
(IQR)	(0-23)	(0-42)	(0-45)	(0-42)	(0-23)	(0-41)	(0-23)	(0-55)
PAIN								
median	11	6	11	7	13	0	0	10
(IQR)	(0-30)	(0-23)	(0-30)	(0-21)	(0-31)	(0-23)	(0-15)	(0-28)
PHYSICAL MOBILITY								
median	36	33	46	35	33	23	29	33
(IQR)	(13-58)	(11-55)	(17-67)	(21-66)	(11-55)	(11-47)	(10-59)	(11-51)
MEAN NHP								
median	26	22	25	27	31	19	11	22
(IQR)	(9-42)	(9-40)	(13-47)	(10-44)	(9-46)	(9-39)	(6-30)	(4-32)
"SEVERE DISTRESS"								
number	51	51	25	30	22	16	4	5

No comparisons reached statistical significance ($p > 0.05$).

4.9 OUTCOME: IMPAIRMENT

Rivermead motor function scores were obtained at the six month visit. Gross motor scores were available for 299 patients. Gross motor scores were not available in 21 DRS patients and in 7 HRS patients. All 7 HRS and 16 of the DRS patients had died, and of the other 5 DRS patients who were not assessed, 1 was lost to follow-up, one had moved to a distant nursing home and in 3 motor testing could not be attempted or was refused.

Leg & trunk and arm scores were available in 292 cases, all of whom had gross motor scores. Leg & trunk and arm scores were not available in 7 patients (3 DRS, 4 HRS) because of dysphasia (3 cases) or other significant communication difficulties (4 cases).

The results of the Rivermead motor scores are shown in Table 22. There were no differences in the gross motor scores between the groups, either overall or by stratum. Higher arm scores were seen in the HRS group overall (Mann-Whitney, $p=0.04$), and in the GM stratum (Mann-Whitney, $p=0.02$). No differences between the groups in the HCE or SU strata were observed in any aspect of motor ability.

Table 22. Rivermead motor assessment scores

	ALL		HCE		GM		SU	
	DRS	HRS	DRS	HRS	DRS	HRS	DRS	HRS
Gross function								
median	8	9	8	8	10	11	9	9
(IQR)	(7-11)	(7-11)	(5-9)	(6-10)	(8-11)	(9-12)	(8-11)	(7-10)
Leg & trunk								
median	6	7	5	6	8	8	4	6
(IQR)	(4-9)	(4-9)	(3-8)	(4-9)	(6-10)	(6-10)	(3-8)	(4-8)
Arm								
median	10	12	10	12	11	13	3	1
(IQR)	(7-13)	(8-14)	(7-13)	(4-13)	(9-14)	(12-14)	(1-12)	(0-11)

Comparisons between underlined values reached statistical significance ($p < 0.05$).

4.10 OUTCOME: THE EFFECT OF LIVING WITH AND WITHOUT A CARER

At the start of the study it was proposed that domiciliary rehabilitation would be more effective than hospital-based rehabilitation because carers may be used as a rehabilitation resource. If this hypothesis was true, then the effect of domiciliary rehabilitation should have been greatest in the group of patients who lived with others.

Therefore the group of patients who lived alone and the group who lived with others were identified and examined separately. The proportion who were dead or institutionalised, disability scores and good outcome rates (at home without deterioration) are shown in Table 23.

Table 23 gives no support to the hypothesis that the domiciliary service was more effective in the group of patients who lived with others.

Table 23. Outcomes in patients living alone and those living with others.

	Living alone		Living with other(s)	
	DRS	HRS	DRS	HRS
Bad outcome				
Overall	15/59	7/48	13/103	10/117
HCE stratum	11/35	3/28	9/44	5/48
GM stratum	4/18	3/17	3/40	2/46
SU stratum	0/6	1/3	1/19	3/23
Total E-ADL score (median, 6 months)				
Overall	9	10	8	8
HCE stratum	7.5	10	4	6.5
GM stratum	13	13	12	11
SU stratum	11	6	8.5	6.5
Barthel ADL score (median, 6 months)				
Overall	17	18	17	18
HCE stratum	17	18	17	16
GM stratum	20	19	19	19
SU stratum	18.5	16	16	16
Good outcome				
Overall	36/59	33/48	67/103	75/117
HCE	18/35	20/28	23/44	28/48
GM	12/18	13/17	31/40	35/46
SU	6/6	0/3	13/19	12/23

Comparison between underlined values reached statistical significance (Fischer's exact test, $p < 0.05$).

4.11 OUTCOME: CARER SOCIAL ACTIVITY AND LIFE SATISFACTION

Overall, the carers of 77 patient in the DRS group were assessed using the BASE and N-LSIZ, compared to 103 in the HRS group, a significant difference ($p < 0.01$). More patients had died or gone into residential care in the DRS group (carers of the bereaved and of those in residential care were not contacted) and in fact only 11 possible carers did not respond in the DRS group compared to 8 in the HRS group. The response bias is therefore due to the difference in death and institutionalisation rates as described in 4.5. Table 24 shows that no significant differences were detected between the groups, either overall or by stratum with respect to the BASE or N-LSIZ scores.

Table 24. Median BASE and N-LSIZ scores in carers.
(Possible BASE scores range from 0 to 20, higher scores denote greater social engagement. Possible N-LSIZ scores range from 0 to 26, higher scores denoting greater life satisfaction)

	ALL		HCE		GM		SU	
	DRS	HRS	DRS	HRS	DRS	HRS	DRS	HRS
BASE	12.0	13.0	12.0	13.0	12.5	13.0	14.0	14.0
(IQR)	(11-15)	(11-15)	(10-13)	(11-15)	(11-14)	(11-17)	(11-16)	(12-16)
N-LSIZ	17.0	18.0	15.0	18.0	18.0	18.0	17.5	18.0
(IQR)	(12-20)	(12-22)	(10-19)	(11-22)	(12-21)	(14-22)	(14-22)	(12-24)

No comparisons reached statistical significance ($p > 0.05$).

DISCUSSION

Before discussing the main findings of the NDRS, the trial conduct and the degree to which the findings may be generalisable are reviewed.

Who went in the study and what rehabilitation did they receive?

Few eligible patients were not included into the study. Since all medical and geriatric wards were screened for stroke patients, the patients studied may well be representative of stroke patients discharged home from other hospitals in Britain.

Patients in the study who were discharged from Health Care of the Elderly wards were a large group of frail elderly patients: they were on average 12 years older than the patients recruited from General Medical wards and 17 years older than those from the Stroke Unit, and a large proportion of them had previous mobility problems, previous stroke, or lived alone.

In contrast to the Health Care of the Elderly patients, those discharged from the Stroke Unit were a smaller group of selected individuals, who were relatively young, who had little previous medical history or disability, and who usually had a spouse, and hence a potential carer, at home.

Patients on General Medical wards who were entered into the study had relatively short hospital stays, and were therefore a group who were less likely to have required or received much in-patient rehabilitation.

The routine hospital-based service during the study was similar to the ordinary service before the study: about half of the Health Care of the of the Elderly patients attended a day hospital but the other half received no therapy; two thirds of the patients from General Medical wards and most of the Stroke Unit patients attended an out-patient department. The day hospital service provided a relatively intense service to the frail elderly patients from Health Care of the Elderly wards (median 19 attendances), and the out-patient

departments also tended to concentrate more upon the patients from the Stroke Unit (median 21 attendances).

Although there had been no domiciliary rehabilitation service in Nottingham before the pilot phase of this study, it is evident that a domiciliary service could be set up quickly and that it could operate as planned: it assessed the needs of almost all patients at home, with little delay and provided therapy to the majority of them. The domiciliary service also gave special attention to patients from the Stroke Unit (median 19 visits), but gave relatively little attention to the frail elderly (median 6 visits).

Since the characteristics of the patients and the rehabilitation service they received were different in each stratum, in effect the NDRS was three separate randomised trials. For this reason, it was justifiable to analyse the results in this way, although this reduces the statistical confidence of the conclusions.

How was the trial conducted?

Figure 1 shows that the recruitment rate was steady throughout the study period, and is indicative of how smoothly the trial ran in practice, precisely meeting the target of 20 patients per month.

There were a few violations of trial protocol: 5 patients, all in the patients from Health Care of the Elderly wards, who were allocated to allocated to the domiciliary service were sent instead to a day hospital ("cross-over"). Some degree of cross-over is inevitable in a clinical trial which involves frail patients and carers, both of whom may have health and social problems which fluctuate unpredictably. Under these circumstances, the preferred analysis is according to initial allocation, but the unfortunate effect of cross-over is to reduce the size of any observed differences between the

services.

Nearly all surviving patients were assessed using the Barthel and E-ADL scales and very few were lost during the study (4 Barthel scores and 3 scores and 3 E-ADL scores were not obtained at six months). A loss of 1% of the patients is unlikely to have had a substantial effect on the results.

A comparison of the characteristics of the patients allocated to the two groups showed that the domiciliary group had lower Barthel ADL scores, scores, and so were more disabled, on entry to the study. Furthermore, as described in the next sub-section, other less obvious differences between the groups (eg, living alone, previous stroke and previous mobility) confirmed that the domiciliary group was more disabled and disadvantaged, mainly in the Health Care of the Elderly stratum. In view of the possible allocation bias between the groups attempts to examine the effects of base-line differences using multivariate modelling was justified.

Death and institutionalisation

In recruiting 327 patients instead of the 300 needed on the basis of power calculations, allowance had been made for some patients to die during the study. It was not expected that the death rate would be high, nor that the rehabilitation services would affect death rates. For these reasons the study was not designed to detect a difference in death rates. However, it was observed that death within 6 months of randomisation was 2.3 times more likely to occur in those allocated to the domiciliary service. The numbers of patients who died, 23 (7%), was small in statistical terms, and this is illustrated by the wide 95% confidence interval for the relative risk of death (1.0 to 5.5). Thus, the result may have occurred by chance. When all bad outcomes were considered together, a similar non-significant increased relative risk (1.7, 95% CI 1.0 to 2.9) of bad outcome in the overall domiciliary group was observed again. However, most of the bad outcomes occurred in the

vulnerable stratum of patients who had been on Health Care of the Elderly wards, and in these patients the domiciliary service did significantly worse (relative risk of bad outcome 2.4, 95% confidence interval 1.1 to 5.1). Simple deduction from these results therefore suggests that the day hospital service was more effective in preventing bad outcome than the domiciliary service in frail elderly patients.

Although these findings could be genuine, they are probably due to allocation bias. The Barthel scores at discharge and three of the most important risk factors for bad outcome (poor previous mobility, living alone and previous stroke) were more prevalent in the domiciliary group. When the imbalance in risk factors was taken into account using discriminant function analysis, it was shown that the observed bad outcome rate was very similar to the rate predicted by the model. Although the model also showed that allocation to the domiciliary service still appeared to exert a significant adverse prognostic effect for death and for bad outcome even when the other risk factors were taken into account, the limitations of the modelling technique are such that it cannot adjust completely for allocation bias.

The rate of bad outcome in the Health Care of the Elderly group allocated to the hospital-based service was low in those who attended day hospitals and also in those who were not followed-up. This is compatible with the hypothesis that the groups were biased. An alternative explanation for this finding is that the method of selection for attendance at day hospital was extremely efficient at identifying the low risk patients (who were not followed up, thus explaining the low rate of bad outcome in the untreated group) and extremely effective at preventing bad outcome in the high risk group. This hypothesis seems, at least intuitively, to be sensible since selection for day hospital follow-up was usually made after a period of in-patient assessment, with many professional staff (who were likely to know the patient in considerable detail) making the decisions about whether it was worthwhile bringing the patient back to the day hospital. This could explain the apparent

efficient identification of suitable patients. Furthermore, the day hospital follow-up was relatively intense (median of 19 attendances in 6 months) and the two larger day hospitals were on DGH sites, and thus could provide a prompt expert medical and nursing service. This could explain the effectiveness of the day hospital in reducing death rates. For this hypothesis to be true, then it should be expected that patients followed up in a day hospital should show an excess of adverse risk factors compared to those who were not followed up. This was, indeed, the case. Health Care of the Elderly patients who were followed up by the day hospital service had spent a longer time in hospital than those who were not followed up, and they were more disabled, more likely to have a previous stroke and more likely to have suffered a sensory loss as part of their stroke - all adverse prognostic factors.

In short, an interesting finding has emerged from the NDRS suggesting that a day hospital service has advantages over a domiciliary service for frail elderly patients, since death or institutionalisation was almost twice as likely with the domiciliary service. However, in view of the small number events recorded in the study and the strong possibility of allocation bias, this finding must be considered speculative.

Disability

An implication of the differing death rate in the domiciliary and hospital-based groups is that a withdrawal bias may have been introduced. If those who died were the most disabled, then the loss of these individuals would produce an apparent rise in the average scores of the remainder. Since the death rate was highest in the domiciliary group, then the artifactual rise in disability scores would have been higher in that group than in the hospital-based group, thus producing an apparent but spurious finding of an advantage of domiciliary rehabilitation. On the other hand, the allocation bias operated in the other direction and favoured the hospital-based rehabilitation group. Examination of the prevalence of prognostic factors in the survivors

of each group shows that they were well matched, so it is possible that the withdrawal bias reversed the allocation bias, and that the results of the simple group comparisons can be trusted. Furthermore, when analysis of covariance was used in an attempt to correct for baseline inequalities, the results of the simple group comparisons were confirmed.

Analysis of self-care ADL ability (Barthel scores) and home-life ADL ability (total and sub-scale E-ADL scores) showed no difference between the domiciliary and hospital-based services overall, no difference between the day hospital and domiciliary service in the frail elderly patients of the Health Care of the Elderly stratum, and no difference between the domiciliary service and the out-patient department service for the general medical patients. However, the domiciliary service did better in patients discharged from the Stroke Unit. This was evidenced by higher E-ADL household and leisure scores, a greater late improvement in total and mobility E-ADL scores and an improvement (instead of a deterioration) in the Barthel scores. The advantage of home therapy was confirmed using covariance analysis.

It can be seen from Figures 6-8 that the NDRS was unable to detect differences between the overall groups of the order of 1-2 Barthel or E-ADL points, and in the HCE and GM strata clinically important differences between the groups (up to 3 Barthel or E-ADL points) would not have reached statistical significance. In the Stroke Unit stratum it should be noted that the median total E-ADL score for the domiciliary group was 9.5 and for the out-patient group was 6.0, but nevertheless statistical significance was not reached ($p=0.10$).

A summary of the disability results is that a large overall difference between the domiciliary and hospital-based services has been excluded, and this is true in frail elderly patients from Health Care of the Elderly wards and the less frail patients from General Medical wards. However, in young patients who needed a long time in hospital, who were otherwise fit and who

had been discharged from the Stroke Unit, clinically important benefits were achieved by the domiciliary service when compared to the out-patient department service. Unfortunately, small numbers of patients were involved so the magnitude of the effect is uncertain.

Good outcome

Once the numbers of patients who died, became institutionalised or deteriorated in terms of their self-care ADL ability were known, then it was possible to calculate the proportion of patients who had a good outcome - remaining at home without deterioration. Overall, good outcome occurred with similar frequency in the groups treated by the domiciliary and hospital-based services. No differences in this respect were seen between the domiciliary service and the day hospital service in the frail elderly, or the out-patient department service in the GM group. In the younger patients from the Stroke Unit, good outcome was more commonly seen in those treated at home (Risk ratio 1.6), and although this reached statistical significance at $p=0.03$, the group size in this stratum was so small that the difference may have been clinically unimportant or very considerable (95% confidence intervals 1.0 to 2.6).

Perceived health

Patients in the home therapy group were no more likely to have better perceived health than those in the hospital-based group. Measuring perceived health in the NDRS patients was not easy, and in many patients communication difficulties made it impossible. In each domain of the Nottingham Health Profile, except Physical Mobility, there was a marked floor effect as over one quarter of respondents scored zero. Thus, differences between people with sub-threshold disturbances of their perceived health could not be detected. On the other hand, it is possible that perceived health in the NHP sub-threshold area is trivial, and best not measured. In fact, when

average scores across the domains were calculated, floor effects were not seen, and still no differences between the groups emerged.

It was not part of the study to examine satisfaction with the service in the NDRS. It was felt that this was best avoided since it would be would be difficult to prevent a response bias. In retrospect, a simple question, at the end of the interview schedule at six months, may have revealed the degree of consumer satisfaction. This would have been particularly helpful to assess in view of the absence of a clear difference between the services in terms of functional ability.

Carers

It was difficult in advance to be certain of what aspects of the carers lives might be amenable to modification by effective rehabilitation services. Several items of the Brief Assessment of Social Engagement may not have been sensitive to the effects of a rehabilitation service. For example, the possession of a telephone is unlikely to be affected by a rehabilitation service. The Life Satisfaction Index was probably a more useful measure, but it too showed no differences between the groups. In the NDRS the median Life Satisfaction Index scores for carers was 18.0, which is very similar to that found in a population of randomly selected older people (also 18.0) (Morgan et al, 1987). Similarly, Social Engagement scores for the carers in the NDRS had a median of 13, the same as that found in older people selected at random (Morgan et al, 1987). It is possible that more sensitive measures may have been needed in the NDRS, or that differences could emerge after a longer period of time. A major effect on life satisfaction and social engagement, in the short term (six months after discharge from hospital), was excluded.

What do the results show overall?

There were no important differences between the domiciliary and hospital-based services in terms of keeping patients at home without deterioration, preventing death or institutionalisation, and promoting their self-care and home-life ADL ability and their perceived health. There was no difference in the efficacy with which the services encouraged social engagement and improved life satisfaction in the informal carers of the patients.

In a group of frail elderly patients, the domiciliary and day hospital services allowed a similar proportion of patients to stay at home without deterioration. However, the day hospital service may have had a beneficial effect upon the patients who deteriorated, in that death and institutionalisation occurred more frequently in the domiciliary group. The small numbers of patients involved and the strong possibility of an allocation bias means that the latter finding may be spurious.

In the group of patients who spent little time in hospital, who had few pre-morbid health problems (GM patients), the domiciliary service and the service provided by physiotherapy and occupational therapy out-patient departments were equally effective.

In a small group of young, previously fit patients who had suffered large strokes (SU patients), the domiciliary service appeared to be better, in terms in terms of promoting and maintaining self-care and home-life ADL ability.

How can the findings of the NDRS be explained?

Recently an occupational therapy home service was evaluated in patients with rheumatoid arthritis, showing significant improvement in

functional capacity (Helewa et al, 1991). Therefore, it is not surprising that similar findings for some patients disabled by stroke should be found.

It was proposed at the start of the study that domiciliary treatment would be more effective in patients living with others, since the informal carers could provide an additional and effective rehabilitation resource. The NDRS provides no evidence to support this hypothesis.

Another explanation for the findings of the NDRS is that they relate to the intensity of the treatment rather than the site of delivery. Thus, it could be argued that the reason why some advantages of the day hospital service over the domiciliary service were seen in the frail elderly patients was because more therapy was provided overall (726 attendances vs 631 visits) and presumably more resources were invoked in each day hospital attendance. Similarly, the advantage of the domiciliary service over the out-patient service in the Stroke Unit patients could be because more of the intensity of the treatment (626 visits vs 454 attendances). However, even if the amount of treatment is more important for efficacy than the place it is delivered, what the NDRS shows is that, under normal clinical conditions, a domiciliary service is capable of providing a more effective (and intensive) service than a out-patient department service for young fit patients, and that day hospitals are capable of providing a (possibly) more effective (and intensive) service for frail elderly patients.

The NDRS was a pragmatic study and thus did not set out to answer questions about the efficacy of components of the rehabilitation packages. Other studies are required to answer questions about the value of involving carers in the rehabilitation process, and the effects of varying intensities of treatment.

How do the results of the NDRS compare to other published work?

An earlier section has shown that there is little evidence about the rehabilitation of stroke out-patients, but what there is has shown that a home-care team does not prevent stroke patients being admitted to hospital (Wade et al, 1985), that a small proportion of fit young stroke patients may benefit in terms of their ADL ability when given intensive out-patient department rehabilitation (Smith et al, 1981), and that older patients benefit in terms of their self-care ADL ability when treated at home instead of in a day hospital (Young and Forster, 1992).

Despite the lack of statistical confidence of the benefit of home therapy in the young and previously fit patients with extensive strokes in strokes in the NDRS, it was in this group of patients and in the areas of household and leisure activities that the greatest response to rehabilitation was to be expected. It is likely that this was a genuine effect. The intensity of the service provided by the out-patient departments and, indeed, by the domiciliary team, did not reach the level of intensity provided in the intensive treatment group of the Northwick Park study. Therefore, with an average of less than one visit per week over six months, home therapy is an effective and probably more resource-efficient alternative to intensive out-patient department rehabilitation for the young, previously fit patients with extensive strokes.

The Bradford Community Stroke Study suggests that the value of domiciliary therapy may extend to older patients, but this was not seen in the NDRS. One possible reason for this was that in Bradford, five physiotherapists were available, whereas in the NDRS there was the equivalent of only two therapists. In the Bradford study treatment was given for a minimum of six weeks, but no lower limit was enforced in the NDRS. Thus the lack of effect of the domiciliary service may have been because it could not provide a sufficient intensity of treatment.

"Intensive" out-patient department rehabilitation was effective in the Northwick Park study, but "conventional" rehabilitation, which was nevertheless probably more intense than that provided by the out-patient departments in the NDRS, was no better than no treatment at all. Thus it is possible that the rehabilitation of the intensity given to the patients in the General Medical stratum of the NDRS, whether in out-patient departments or at home, was also ineffective, or at least of very little effect. If there had been a no-treatment control group in the NDRS then this possibility could have been tested, but as mentioned in the methods section, this omission from the study was necessary to allow the rest of the study to have had a chance of producing any worthwhile results at all.

There have been few randomised controlled trial of day hospital care. In a study in New Zealand (Tucker et al, 1984) only 2/120 patients died in 5 months (institutionalisation rates were not quoted) and in the Bradford Community Stroke Trial (Young and Forster, 1992) only 1/200 patients went into residential care in six months (exact death rates were not quoted). The patients were younger in both the New Zealand and Bradford studies (mean age 72 and 70 years respectively) than those in the Health Care of the Elderly stratum of the NDRS (mean age 77 years). Thus, the New Zealand and Bradford studies were unlikely to have detected any effect of day hospitals upon death and institutionalisation rates because they studies younger patients who were presumably less frail. In a recent Canadian randomised controlled trial of day hospital care the average age of the patients was 79 years, nearly 1/4 (26/113) of whom had stroke (Eagle et al, 1991). The overall rate of death or institutionalisation over 12 months in the day hospital group was 35%, but in those given ordinary community care the rate was only 24% (not significantly different). The finding of the NDRS that death or institutionalisation rates are reduced when a day hospital service is provided may be spurious, but if it is a genuine effect, then it appears to be a novel observation.

In the New Zealand study, the day hospital promoted early return of function, but could not maintain this advantage, and gave rise to improved well-being, although it was suggested that this could have been achieved by simpler means such as a volunteer-run day centre. In the Bradford Community Stroke Study, there was little to commend the day hospital when compared to a more resource-efficient domiciliary service. The NDRS did not show that day hospitals improved recovery and so does not support the use of day hospitals in rehabilitation. However, if the finding of the lower death and institutionalisation rates in the day hospital group was genuine, the day hospitals may have a role in maintenance care. Whether this justifies the widespread use of day hospitals for stroke patients in Nottingham (Gladman et al, 1991) and elsewhere (Donaldson, 1986) remains uncertain.

Areas for further research

Further research is needed in all methods of the control of stroke disablement. Regarding physical rehabilitation, existing specific techniques should be tested properly, and new ones developed. Patients such as those who had been on the Nottingham Stroke Unit are suitable for initial evaluation of techniques, since they are probably the most sensitive to intervention. Techniques also have to be tested on less severely affected and more frail patients, since it must be known if treatments will benefit all patients or only a few. If a specific technique is not universally effective, then to identify those who will and those who will not respond to treatment will allow resources to be used more efficiently.

More information about the NDRS is available than has been presented in this thesis. Particular examples are the results obtained at 12 months post discharge, in which the tests performed at 6 months were repeated, and an assessment of the costs of the rehabilitation services.

The theme in the beginning of the thesis was that stroke is a disease of the elderly, and that in addition to physical disability, it causes depression and handicap. Although the area of interest in this thesis has been rehabilitation, maintenance care was also important in the care of the overall elderly stroke population, exemplified by the large proportion of patients who survived their stroke only to remain institutionalised on discharge from hospital. A smaller number of patients were ineligible for the NDRS because relief care in a day hospital was considered necessary for discharge from hospital. In those who entered the NDRS, the value of a day hospital, if any, was to prevent death or institutionalisation (without influencing functional ability), that is, they provided maintenance support to vulnerable patients. The maintenance role of day hospitals needs further investigation, to see if day hospitals alone or as part of a larger package of social care, can prevent institutionalisation.

Over one third of patients in the NDRS were severely emotionally distressed as evidenced by their Nottingham Health Profile scores, a finding in keeping with other studies. It would have been expected that the prevalence of severe emotional distress would be higher in the Stroke Unit patients than in those discharged from the General Medical wards, since Stroke Unit patients had more extensive strokes, had experienced greater loss of function and had spent longer in hospital. It was therefore interesting to find that the prevalence of severe distress was 22% in the Stroke Unit group but 35% in the General Medical group. It could be proposed that this difference was due to the in-patient experience of each group. The current trial of the Nottingham Stroke Unit (comparing Stroke Unit care to ordinary ward care) will test this hypothesis, and may elucidate the relationship between the component of therapeutic packages of care and the development of depression. Ebrahim (1990) has called for the evaluation of antidepressant drugs in this setting. Specific non-pharmacological strategies for depression and emotional distress also need to be evaluated. To make an impact upon the emotional distress of stroke patients remains one of the most important areas of stroke research.

Carers of stroke patients have problems themselves, and may yet also be an under-used rehabilitation resource. The NDRS may have failed to measure aspects of carers' lives which had been changed by their spouses' strokes. Careful, sensitive and open-minded research is required to identify the full breadth of the problems carers of stroke patients experience, how carers and patients interact, and what help they both want. Only then will it be possible to suggest sensible ways to help them, and develop the instruments to measure their success.

Domiciliary rehabilitation is a small step forward for stroke rehabilitation. Much more research is required to reduce the massive burden of stroke.

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APPENDIX

REGISTRATION FORM

NAME CONS WARD HOSP

NUMBER TRANSFERS
DOB
ADDRESS GP & TEL
PT TEL

ADM.N. [ ] DIS.N. [ ] ST.N. [ ] K.N. [ ]

DATE OF STROKE [ ] SEX [ ]
DATE OF ADMN. [ ] AGE [ ]
LOCATION [ ] RESIDENCE [ ]
ADMN. CONCS. LEVEL [ ] STROKE IN HOSPITAL [ ]

SIGNS DATE SEEN TIME A-S [ ]

CONSC. LEVEL [ ] GAZE PALSY [ ]
DEFICIT TYPE [ ] DEFICIT GRADE ARM [ ]
LEG [ ]
VISUAL [ ] SENSORY [ ]
DYSARTHRIA [ ] DYSPHASIA [ ]
INCONTINENCE [ ]
OUTCOME [ ] DATE HOSP [ ]

TOTAL TIME IN HOSPITAL [ ] TIME GM [ ] TIME DHCE-ALL [ ] TIME OTHER [ ]
DHCE-AC [ ]
TIME-SU [ ] DHCE-REHAB [ ]

TIME STROKE TO DISCHARGE [ ]

DISCHARGE ADDRESS, IF DIFFERENT:

DR STUDY/EXCLUSION [ ]

REGISTRATION FORM CODING GUIDE

HOSP	1=CHN 2=QMC-GM 3=GHN 4=SHER 5=QMC-DHCE 6=BASFORD 7=HIGHBURY
TRANSFERS	1=NONE 2=MED->DHCE 3=MED->SU 4=DHCE->SU
SEX	1=FEMALE 2=MALE
LOCATION	1=L-HEMISPHERE 2=R-HEMISPHERE 3=BILATERAL 4=BRAINSTEM 5=SUBARACHNOID 6=NOT KNOWN 9=NOT AVAILABLE
RESIDENCE	1=HOME ALONE 2= ALONE, WARDEN AID ACCOM 3=HOME WITH SPOUSE/OTHER 4=PART 3 5=PRIVATE REST HOME 6=PRIVATE NURSING HOME 7=HOSPITAL/OTHER 9=NOT AVAILABLE
ADMN. CONSC. LEVEL	1=AWAKE 2=DROWSY 3=UNCONSCIOUS 9=NOT AVAILABLE
STROKE IN HOSPITAL	1=NO 2=YES
GAZE PALSY	1=NO 2=YES 3=NOT TESTED 9=NOT AVAILABLE
DEFICIT TYPE	1=R-HEMIPLEGIA 2=L-HEMIPLEGIA 3=R-ARM MONOPARESIS 4=R-LEG MONOPARESIS 5=L-ARM MONOPARESIS 6=L-LEG MONOPARESIS 7=OTHER 9=NOT AVAILABLE
DEFICIT GRADE	0=NO MOVEMENT 1=PALPABLE FLICKER 2=MOVEMENT WITH GRAVITY ELIMINATED 3=MOVEMENT AGAINST GRAVITY BUT NOT RESISTENCE 4=MOVENT AGAINST RESISENCE BUT NOT NORMAL 5=FULL POWER 9=NOT AVAILABLE
VISUAL	1=NORMAL 2=INATTENTION 3=HEMIANOPIA 4=NOT TESTABLE 9=NOT AVAILABLE
SENSORY	1=NORMAL 2=INATTENTION 3=HEMIANAESTHESIA 4=NOT TESTABLE 9=NOT AVAILABLE
DYSARTHRIA	1=NORMAL 2=DYSARTHRIA 3=NG TUBE 4=NOT TESTABLE 9=NOT AVAILABLE
DYSPHASIA	1=NORMAL 2=YES 3=NOT TESTABLE 9=NOT AVAILABLE
OUTCOME	SEE "RESIDENCE", 8=DEATH
DR STUDY/EXCLUSION	0=INCLUDED 1=DEAD 2=RESIDENTIAL CARE ON DISCHARGE 3=NO LOSS OF LIMB FUNCTION 4=LESS THAN 10 DAYS 5=ADDRESS OUT OF AREA 6=NO PATIENT CONSENT 7=NO DOCTOR CONSENT/OTHER ARRANGEMENTS MADE 8=ADMITTED FROM DH 9=MISSED

DOMICILIARY REHABILITATION ENTRY DATE:

NAME & DISCHARGE ADDRESS

ADM. N. DIS.N. ST.N.

K.N.

CT SCAN REPORT

^BP DM IHD HIST IHD ECG A.FIB.

SMOKER PVD OTHER MEDICAL

PREV STROKE PREV MOB PREV CONF PREV INCO

AID

MARITAL STATUS CARER

WORK CARER ADDRESS

HOME VISIT DATE

PROBLEMS: DYSPHASIA

PAINFUL SHOULDER

BARTHEL

	R	R+	R+	D
Bowels				
Bladder				
Grooming				
Toilet use				
Feeding				
Transfer				
Mobility				
Dressing				
Stairs				
Bathing				
Total				

MOBILITY

AID

NOTTADL

	R	R+	R+	D
Drink				
Eat				
Wash face				
Transfer				
'Walk'				
Toilet				
Undress				
Dress				
Hot drink				
In/out bath				
Total				

MSQ

	R	D
Age		
Time		
Recall		
Hosp		
Year		
DoB		
Recog		
WW1		
Monarch		
20-1		
Total		

TIME STROKE TO RANDOMISE

TIME RANDOM TO DISCHARGE

TREATMENT OPTION

DOMICILIARY REHABILITATION ENTRY CODING GUIDE

CT SCAN 1=NO 2=YES

^BP,DM,IHD HIST,IHD ECG,A.FIB. 1=NO 2=YES 9=NOT AVAILABLE

OTHER MEDICAL

PREV STROKES 1=NO 2=ONE 3=TWO 4=3 OR MORE 9=NOT AVAILABLE

PREV MOBILITY 5=FULL 4=NOT OVER UNEVEN GROUND,OR UP STAIRS
3=NEEDS SUPERVISION ONLY 2=WALKS WITH ONE LITTLE ASSISTENCE
1=WALKS WITH ONE MUCH ASSISTENCE 0=NO WALKING/WALKS WITH TWO
9=NOT AVAILABLE

AID 1=NONE 2=ONE STICK 3=TWO STICKS 4=FRAME 5=WHEELCHAIR
9=NOT AVAILABLE

PREV CONFUSION,INCONT. WORK. 1=NO 2=YES 9=NOT AVAILABLE

MARITAL STATUS 1=MARRIED 2=WIDOW,DIVORCE 3=SINGLE
9=NOT AVAILABLE

CARER 1=SPOUSE 2=RELATIVE 3=FRIEND 4=OTHER 5=NONE 9=NOT AVAILABLE

HOME VISIT 1=NO 2=YES

DYSPHASIA, PAINFUL SHOULDER 1=NO 2=YES

TREATMENT CODE 1=CONVENTIONAL 2=DOMICILIARY REHABILITATION

BARTHEL Also see separate guidelines.

Bowels	0=incontinent 1=occasional accident 2=continent
Bladder	0=incontinent 1=occasional accident (max 1x per 24 hrs) 2=continent (for over 7 days)
Grooming	0=needs help 1=independent, face/hair/teeth/shaving
Toilet use	0=dependent 1=needs some help but can do something 2=independent (on & off, dressing and wiping)
Feeding	0=unable 1=needs help cutting,spreading butter etc. 2=independent
Transfer	0=unable 1=major help (1-2 people,physical) 2=minor help (verbal or physical) 3=independent
Mobility	0=immobile 1=wheelchair independent including corners etc 2=walks with help of one person (verbal or physical) 3=independent
Dressing	0=dependent 1=needs help,but can do about half unaided 2=independent
Stairs	0=unable 1=needs help (verbal,physical,carrying aid) 2=independent
Bathing	0=dependent 1=independent

N10PTADL, MSQ 0=NO 1=YES

TOTAL BARTHEL, N10PTADL, MSQ 98=NOT TESTABLE 99=NOT AVAILABLE

MOBILITY, AID See above.

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