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STROKE REHABILITATION IN THE ELDERLY: A CONTROLLED STUDY OF THE EFFECTIVENESS AND COSTS OF A MULTIDIMENSIONAL INTERVENTION

Doctoral dissertation

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ABSTRACT

Stroke is one of the most important causes of disablement among elderly people. As the prevalence of stroke is predicted to increase in the near future the impact of chronic disablement will pose a great challenge to the health care systems of developed countries. At present, there is little data on the effectiveness of long-term rehabilitation of stroke patients living in the community. The aim of the present study was to examine the effects of a multidimensional intervention on older stroke patients and their caregivers living in their own homes.

Stroke patients with residual disability aged 65 or more were randomised to the intervention program or the control group. The intervention consisted of three annual courses with physical activity, psychological and social support and counselling support between the courses. Social interaction beyond the intervention program was promoted. Outcome was assessed at 1, 2 and 3 years after study entry with measures of physical performance, ADL, mood, behavior and caregiver strain. The use of health care services was recorded and the costs were evaluated. A total of 117 stroke patients were included in the study. The mean time interval from the most recent stroke to study entry was 4 years 2 months. The two groups were comparable at randomisation with regard to all assessment measures. There were no significant differences between the groups with regard to the Barthel Index, the Brunnström-Fugl-Meyer scale, the Functional Ambulation Categories or gait speed over 10 meters at the follow-up assessments. The median total NOSGER score was significantly ($p=0.014$) lower in the intervention group at three years suggesting an improvement in IADL, mood and social behavior. Similarly, the MADRS revealed slight improvement in the mood of the patients in the intervention group. There was no difference between the groups in caregiver strain assessed with GHQ-12. During the second and third year of follow-up the attendance to day center was less frequent ($p=0.005$ and $p=0.039$, respectively) in the intervention group. Moreover, the number of bed days in health centers was significantly ($p=0.041$) lower in the intervention group over the three-year follow-up. In spite of the increased amount of resources for the rehabilitation of the patients in the intervention group, the overall cost of health care services was not higher compared to the control group.

The multidimensional rehabilitative intervention improved the IADL and the mood of elderly stroke patients, but it had no effect on their physical performance or caregiver strain. Moreover, there was a decrease in the use of community services. Rehabilitation of older stroke patients with residual disabilities is beneficial and resource-efficient when aimed at enhancing skills of extended ADL and social integration.

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To Tiina, Roope and Joonas

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Toivala, November 2000

Kauko Pitkänen

ABBREVIATIONS

ADL	activities of daily living
ANOVA	analysis of variance
BFM	Brunnström-Fugl-Meyer scale
BI	Barthel Index
CI	confidence interval
COPD	chronic obstructive pulmonary disease
CT	computerized tomography
DM	diabetes mellitus
DSM	Diagnostic and Statistical Manual of Mental Disorders
FAC	functional ambulation categories
FIM	Finnish marks
GHQ	General Health Questionnaire
IADL	instrumental activities of daily living
IQR	interquartile range
MADRS	Montgomery-Åsberg Depression Rating Scale
MMSE	Mini Mental State Examination
NOSGER	Nurses' Observation Scale for Geriatric Patients
NYHA	New York Heart Association
QALY	quality adjusted life year
QoL	quality of life
SD	standard deviation
SII	Social Insurance Institution
TIA	transient ischaemic attack
VAS	visual analogue scale

CONTENTS

1. INTRODUCTION

Stroke is a leading cause of disability among elderly people. In addition to physical, emotional and social consequences, the economic impact of stroke is tremendous (Rissanen et al. 1995, Dobkin 1995, Taylor et al. 1996). As the incidence of stroke increases markedly with age (Sivenius 1982, Geddes et al. 1996), ageing populations expose an increasing number of people to the risk of stroke in western countries. Therefore, a considerable amount of resources are required to provide long-term care for stroke patients.

Little is known about the effectiveness of long-term stroke rehabilitation. There are no generally accepted guidelines that determine the optimal timing, intensity or duration of rehabilitation (Stason 1997). Moreover, we lack data on what type of rehabilitation is most beneficial and resource-efficient for the patients with residual disabilities living in their homes. Several reports have addressed the need for psychological support and enhancing social activities in order to reach the ultimate goal in stroke rehabilitation (Evans et al. 1992, Young 1994, Parker et al. 1997). Many stroke patients fail to resume full lives, and a major negative impact of stroke on family functioning is not an infrequent phenomenon. Therefore, stroke rehabilitation requires a long-term perspective, extending to several years after the onset of stroke.

There are several factors that may have adverse effects on long-term recovery after stroke. Many of the factors are modifiable, if adequate attention is paid to them. Most of the studies on poststroke depression have found that impaired mood has a negative impact on recovery (Thompson et al. 1989, Schubert et al. 1992, van de Weg et al. 1999). Considering the relatively high prevalence of depression in stroke patients, the importance of identification and treatment of clinically significant depression cannot be overemphasized (Parikh et al. 1990). Social factors have been reported to be as much a determinant of good outcome as the severity of disability after stroke (Kelly-Hayes et al. 1988). The assessment of the patient's family and social support system is important to achieve the best possible outcome in stroke rehabilitation - social integration and return to normal life (Evans et al. 1992, Glass et al. 1993).

The incentive for the present study was the clinical experience gathered over several years on the unequal distribution of rehabilitation services for stroke patients in the Northern Savo region, Finland. Especially elderly stroke patients often find it difficult to receive adequate attention to their disabilities late after stroke. A referral system with proper assessment of need for rehabilitation and sound timing of interventions would most likely reduce the resource-consuming use of health care and support services in the community.

The aim of this study was to examine the effects of a multidimensional rehabilitation, based on intervention courses and counselling support, on the functioning of elderly stroke patients with residual disabilities and their caregivers living in their own homes. This was a cost-effectiveness study with an intention to find out whether the new approach would be more resource-efficient than conventional care, which would have implications to the development of rehabilitation practices for elderly stroke patients.

2. REVIEW OF LITERATURE

2.1. General aspects of stroke

Stroke is defined as rapidly developing clinical signs of a focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than vascular origin (Aho et al. 1980). Stroke can be classified into four pathogenetically different categories. Thrombotic strokes represent 40% of all strokes; embolic strokes are the second commonest type (30%) followed by lacunar (20%) and haemorrhagic strokes (10%). Major risk factors include advanced age, male gender, hypertension, atrial fibrillation, coronary artery disease, diabetes, hypercholesterolemia and cigarette smoking (Benson & Sacco 2000). Stroke prevention focuses on the modifiable risk factors by means of education and medical attention.

2.2. Impact of stroke on health care system

The increasing magnitude of the stroke-induced burden on the health care systems of developed countries has not been recognized to its full extent until the past decade. The incidence as well as the prevalence of stroke increases sharply with age. The data of a community-based survey in the UK yielded an age-specific prevalence rate of 46, 8 per 1000 for men and 33,9 per 1000 for women in the age group of 65-74 whereas the overall rate for both men and women over 75 rose to 95,1 per 1000 (Geddes et al. 1996). The sharp rise in incidence rates by age has been reported also in several domestic studies in the past decades (Aho 1975, Sivenius 1982, Rissanen 1992). On the other hand, there has been a declining trend in the overall incidence rates in Finland since the 1970s (Kotila 1986, Sarti et al. 1994, Numminen et al. 1996, Fogelholm et al. 1997). Convincing evidence from the FINMONICA study showed that whereas the incidence of stroke has declined during a ten-year period since the early 1980s, the stroke mortality has dropped even more resulting in a rising total prevalence of stroke in Finland (Tuomilehto et al. 1996). There exists ample data gathered e.g. in the Minnesota Stroke Survey, that indicate a significant improvement of survival of stroke patients during the 1980s (Shahar et al. 1995). The reasons for the declining mortality rate have not yet been comprehensively explained but the improved supportive and rehabilitative care and a change in the natural history of the disease have been postulated (Geddes et al. 1996). Consequently, this newly established trend may cause substantial and long-term effects on the costs of stroke care (Scott et al. 1994, Terent et al. 1994). According to the estimates of Rissanen et al. (1995) referring to the figures for the year 1989, the needs of stroke survivors for institutional care will grow by 50% by the year 2010. Up to 2,1 million in-patient days per year would then be required unless the dismal course can be reversed. The direct annual costs of care of stroke survivors in Finland were estimated to total 2,5 billion FIM in

1989, constituting 6% of the total health care expenses in the state budget for the year 1991. Apparently, there has been some growth in the figures in recent years, but, to my knowledge, we lack a detailed up-to-date analysis on the costs of stroke to Finnish society.

A report on stroke care in England unveiled the fact that the 12 per cent of patients who are highly dependent and moving towards long-term care account for 56 per cent of the total expenditure on stroke care in the first year (Bosanquet & Franks 1998). Estimates on the lifetime costs showed that patients needing long-term care can cost 30 times more than patients enjoying a rapid recovery. Furthermore, as the report lamented, there is little evidence that these huge costs of long-term care can actually improve quality of life. A considerable amount of resources are required to provide long-term care for stroke survivors in Finland. It was estimated that a total of 5550 beds were occupied in health centers and 4550 stroke survivors were accommodated in homes for the aged and the total costs of institutional long-term care amounted to 948 million FIM in 1989 (Rissanen 1992).

Despite the declining stroke incidence in Finland in the 1980s, it has been predicted that the incidence rates will eventually assume the opposite trend as the aging populations expose an increasing number of people to the risk of stroke (Malmgren et al. 1989). In fact, an increase in stroke incidence has already been observed in Sweden and in North America (Terent 1988, Brown 1996, Johansson et al. 2000). It is likely that survival will continue to improve as suggested by the epidemiological data from the 1980s (Shahar et al. 1995, Tuomilehto et al. 1996), which combined with increasing incidence would result in growing prevalence rates for stroke. The disease burden of stroke will thus pose a major challenge to the health care systems of developed countries in the coming decades.

2.3. Sequelae of stroke

Stroke is the third commonest cause of death after coronary heart disease and all cancers on a global scale (Murray 1997). About 20 % of patients with first-ever strokes die in a month, and among survivors at one year about one-third are dependent on others for activities of daily living (ADL) (Aho 1975, Kotila 1986, Bamford et al. 1990). In Finland, about one-quarter of stroke survivors at one year require institutional care and more than one-tenth of the patients are bedridden (Rissanen 1992).

Stroke is one of the most important causes of chronic disablement. It may affect virtually all functions: motor and sensory functions, autonomic nervous system, balance, ambulation, speech, perception, cognition and mood as well as the ability to carry out ADL and social activities. Hemiparesis is apparently the most striking characteristic of stroke with a frequency of 70% to 85% in the acute stage (Sivenius 1982, Kotila 1986, Rissanen 1992) and even higher frequencies have been reported among the elderly (Kalra et al. 1993a). Although 60% of stroke survivors regain independence in walking by three months, many hemiplegic patients have continuing problems with mobility due to impaired balance and motor weakness (Wade et al. 1987). According to Mayo et al. (1999) 78% of persons had not reached age-specific norms for upper extremity function at 3 months after stroke and 85% were still impaired on gait speed.

Loss of arm function is one of the most devastating features of stroke. Broeks et al. (1999) found that most of the improvement occurred during the first 16 weeks after stroke and half of the patients had fair to good functional abilities of the hemiplegic arm 4 years after stroke. The affected limb may cause severe disablement when accompanied with sensory loss and spasticity. Intact sensory function of the affected upper limb has been found in only one in four of the long-term survivors of stroke (Broeks et al. 1999). Many individuals with sustained hemiparesis suffer from spasticity interfering with functional mobility and ADL (O'Brien et al. 1996). Treatment choices must be taken into consideration when spasticity produces pain, results in impairment of mobility, threatens to produce joint deformities or contributes to the development of skin ulcers (Lehmann et al. 1987, Langlois et al. 1991, Dimitrijevic et al. 1994, Hesse et al. 1998, Lagalla et al. 2000). Shoulder subluxation is another common sequel in hemiplegic patients. Although pain is a frequent problem in patients with hemiplegic shoulder, it has been suggested that adhesive capsulitis rather than shoulder subluxation is a main cause of pain (Ikai et al. 1998). Shoulder subluxation, however, has been suggested to be a causative factor for reflex sympathetic dystrophy (RSD). According to Dursun et al. (2000) glenohumeral subluxation was found in three-quarters of the patients with RSD. Central poststroke pain is often recognised as a difficult problem to manage. Supratentorial lesions of the somatosensory pathway may produce pain that is more likely to be greatest in an extremity, whereas pain caused by infratentorial lesions is often localized in the face. The thalamic pain syndrome, predominantly associated with right diencephalic lesions, is more likely to produce half-body pain (Bowsher et al. 1998).

Poststroke seizures have been estimated to occur in about 10% of long-term survivors (Moskowitz et al. 1972, Burn et al. 1997). The risk of seizures has been found to be greater in patients with haemorrhagic strokes (Burn et al. 1997, Paolucci et al. 1997). Early seizures (within 14 days following the stroke) are more common, but the risk of recurrence is greater in patients with late (after the first 14 days following the stroke) seizures (Asconape & Penry 1991, Berges et al. 2000). In a study of Rumbach et al. (2000) status epilepticus (SE) was recognised in 19% of the patients with poststroke seizures and SE was the first epileptic symptom in 11% of cases. Although poststroke seizures may be followed by persistent worsening of the previous neurologic deficit (Bogousslavsky et al. 1992), no significant association has been found between occurrence of seizures and outcome of rehabilitation (Paolucci et al. 1997). When poststroke seizures develop, treatment is indicated, and in cases of late seizures with an increased risk of recurrence, long-term anticonvulsant therapy is highly recommendable especially for the elderly stroke patients (Asconape & Penry 1991).

Incontinence is an important measure of stroke severity that not only affects the lives of stroke survivors but also of their caregivers (Brittain et al. 1998). Incontinence has been recognised as one of the main prognostic features after stroke (Anderson et al. 1994 , Taub et al. 1994, Ween et al. 1996, Sze et al. 2000). Studies on outcome after stroke in the elderly have found that urinary incontinence is significantly associated with place of living after hospital discharge (Kalra et al. 1993a, Thommessen et al. 1999). The prevalence of full urinary incontinence was 8% and that of partial incontinence 11% six months after stroke in the study of Nakayama et al. (1997). The prevalence rates for fecal incontinence were 5% and 4%, respectively.

Aphasia is a frequent specific cognitive deficit followed by stroke. Approximately one in every three stroke patients in the acute phase suffer from dysphatic problems (Kotila et al. 1984, Wade et al. 1986). Aphasia, a typical characteristic of a left hemispheric lesion, is often associated with other cognitive deficits such as apraxia (Kertesz 1979, Alexander et al. 1992), memory deficits (Gainotti et al. 1978, Ween et al. 1996) and visuospatial disorders (Kertesz 1979). Severe apraxic disorder, manifesting itself as a difficulty to produce a series of movements according to given instructions (ideomotor apraxia) or as a difficulty to use familiar objects (ideational apraxia), is a major challenge in the acute phase of stroke rehabilitation. The prevalence data of apraxia in the postacute phase of stroke is rare. In the cohort study of Pohjasvaara et al. (1997), only 2% of the patients had apraxic disorder three months after stroke.

Hemianopsia, unilateral neglect, anosognosia and specific deficits of perception and attention are frequent consequences of hemispheric lesions. Neglect, an impaired ability to react to stimuli on the opposite side of the brain lesion, has been reported in 43% of the patients with stroke in the right hemisphere (Pedersen et al. 1997). Deficits in spatial perception have been found in 60% of patients 3 months after the onset of stroke (Kotila et al. 1984). In a stroke cohort studied by Pohjasvaara et al. (1997) 22% of patients had attention disorder and 37% of patients sustained impairment in visuospatial and constructional functions. The prevalence of anosognosia, the unawareness of deficits caused by stroke, was 28% among patients with right hemispheric lesion in a study reported by Starkstein et al. (1992) and 36% in the study reported by Pedersen et al. (1996). The severity of anosognosia varies and it often occurs simultaneously with unilateral neglect (Starkstein et al. 1992). Mild forms of neglect and anosognosia may easily go undetected unless neuropsychological tests are applied, but nevertheless, can hamper the patient´s motivation and result in slow progress in rehabilitation. Both the duration of hospitalization and therapy input have been found to be significantly greater in patients with visual neglect (Kalra et al. 1997).

Memory disorders have been reported in 10-55% of stroke patients (Kotila et al. 1984, Tatemichi et al. 1994, Pohjasvaara et al. 1997). Estimating the prevalence of memory disorders among stroke patients is questionable since patients with aphasia are often excluded. General intellectual decline characterised by impairment in several cognitive domains is not uncommon after stroke. Pohjasvaara et al. (1997) reported that 27% of patients had impairment at least in three cognitive functions three months after stroke. Older patients, in particular, are susceptible for the deleterious effects of stroke on cognitive functions and even a single incident of stroke can be of crucial importance in the development of cognitive decline. Kase et al. (1998) studied a cohort of older stroke patients and found a correlation between large, left-sided stroke and cognitive decline. Furthermore, a finding of lower prestroke Mini-Mental State Examination (MMSE) scores among cases with poststroke intellectual decline has been reported.

A wide range of emotional and behavioral disturbances occur following stroke (Robinson 1997). Some of these neuropsychiatric disorders, such as depression and apathy, have a potential impact on rehabilitation efforts and recovery from stroke. Other disturbances, such as poststroke anxiety and pathological crying may affect social functioning. However, both depression and pathological crying have been shown to respond to treatment with antidepressant medication (Andersen et al. 1993, Robinson et al. 1993, Andersen et al. 1994). An interesting syndrome that is often overlooked as a stroke-induced behavioral disturbance is abnormal illness behavior. It occurs when the patient persists in the sick role and withdraws from responsibility and cooperating with caregivers. According to Clark and Smith (1997) abnormal illness behavior was apparent in nearly 30% of the patients at discharge and the disturbance persisted for 12 months.

2.3.1. Poststroke depression

Depression is the most common emotional and behavioral disorder following stroke. There is large variation in the prevalence rates of depression after stroke due to patient selection and diagnostic methods. Wade et al. (1987b) concluded that depressed mood was present in about one-quarter of survivors up to one year after stroke. Previous studies have identified two types of depressive disorders associated with stroke: major depression, which occurs in up to 25% of patients; and minor depression, which occurs in 10 -30% of patients following stroke (Robinson et al. 1983, Eastwood et al. 1989). The frequency of major depression (DSM-III-R criteria) was 26% in a cohort at three months from the onset of ischemic stroke (Pohjasvaara et al. 1998). In the study of Kauhanen et al. (1999), depression was diagnosed in 53% of the patients at three months and in 42% at 12 months after stroke, but the frequency of major depression increased from 9 to 16% during the first year. Similar prevalence rates for major depression among long-term stroke survivors have been presented in several other studies (Wade et al. 1987, Parikh et al. 1990, Åström et al. 1993, Sharpe et al. 1994). More than half of the patients who are depressed in the acute phase of stroke are at risk of chronic depression (Wade et al. 1987).

Association between specific lesion location and poststroke depression has been a subject of debate in recent decades. There are several reports that suggest a higher rate of depressed mood in those with a lesion in the left frontal region (Robinson et al. 1984, Morris et al. 1992, Herrmann et al. 1993), although Wade et al. (1987) failed to confirm any association between right-sided weakness and depression.. Left hemispheric preponderance in poststroke depression was also evident in the work of Kauhanen (1999) who demonstrated higher frequency of depression among aphasics than non-aphasics following stroke. Sharpe et al. (1994) found evidence that depression in long-term survivors of stroke may be associated with the size of the lesion. A more recent study (Kim & Choi-Kwon 2000) could not confirm the relationship between poststroke depression and laterality or the size of the lesion, but revealed the major influence of anterior lesion location and poststroke mood disorders. Other factors that have been reported to be associated with poststroke depression include functional dependence and female sex (Sharpe et al. 1994), younger age (Robinson et al. 1983) and social impairment (Robinson et al. 1987). Obviously, the etiology of poststroke depression is multifactorial including both prestroke personal and social factors and stroke induced factors (Herrmann et al. 1993, Andersen et al. 1995, Lyketsos et al. 1998).

The effect of depression on outcome following stroke has been examined in a number of studies. Parikh et al. (1990) demonstrated that patients with acute poststroke depression had an impaired recovery in activities of daily living over two years compared with nondepressed patients. Similar findings of a negative effect of depression on functional recovery have been reported by Sinyor et al. (1986), Diamond et al. (1995) and van de Weg et al. (1999). Furthermore, Parikh et al. (1990) pointed out that in most of the patients with major depression, delayed recovery was apparent even after the depression had alleviated.

An important aspect related to long-term outcome and depression following stroke was demonstrated by Morris et al. (1993), who found an increased mortality among patients with poststroke depression when compared with nondepressed patients. Early detection and treatment of depression has been underlined by many investigators (Reding et al. 1986, Clark et al. 1998, van de Weg et al. 1999) and a possible beneficial effect of antidepressant medication on recovery after stroke has been suggested.

2.3.2. Stroke and quality of life

An accumulated body of literature has shown evidence that stroke affects the long-term quality of life (QoL) and the well-being of the family. Stroke victims frequently complain of social isolation, increased dependence on relatives and poor life satisfaction (Isaacs et al. 1976, Viitanen et al. 1988, Santus et al. 1990). Despite methodological variations and different types of instruments available, most of the recent studies have involved components of physical, psychological and social functioning as well as role performance and incidence of pain and other symptoms in evaluating QoL after stroke (Fitzpatrick et al. 1992). Physical disablement and psychological maladjustment have been found to be significant determinants of deteriorated QoL in stroke survivors (Ahlsiö et al. 1984, Niemi et al. 1988, King 1996, Jonkman et al. 1998, Kauhanen 1999, Nyrkkö 1999). Most of the studies have underlined the importance of depression as a prime correlate of decreased QoL. In a few studies, improvement in QoL has occurred during the first year (Åström et al. 1992, Jonkman et al. 1998), and in the study of Hackett et al. (2000) patients who had survived six years after stroke perceived their mental health to be comparable to that of normal controls. Other studies have reported a decline in some domains of QoL over time (Viitanen et al. 1988, Nydevik 1994) even when the disability level remains unchanged or improves (Béthoux et al. 1999).

Sexual dysfunction and dissatisfaction with sexual life are common phenomena among stroke survivors and their spouses (Monga et al. 1986, Boldrini et al. 1991, Korpelainen et al. 1999). Psychosocial factors, depression, physical disability and the presence of concomitant diseases influence the quality of sexual life of stroke survivors (Korpelainen et al. 1999). There are only a few studies on the prevalence of sexual disorders after stroke. According to Korpelainen et al. (1999) 33% of patients and 27% of spouses enjoy no coital activity after stroke, but also higher percentages have been reported (Monga et al. 1986). Urinary incontinence, occurring in up to 10% of long-term stroke survivors (Wilkinson et al. 1997, Brittain et al. 1999), may play an important role in contributing to inferior QoL as a result of restrictions in social activities.

The quality and the frequency of social contacts are often abruptly decreased after stroke (Trigg et al. 1999). Former friends and workmates may cease to visit, contributing to the experience of social isolation (Isaacs et al. 1976). Dependence on relatives can cause conflicts within the home which in turn can undermine the supportive role of the family and weaken the odds for social reintegration. Anderson et al. (1995) reported that almost one half of the one-year stroke survivors with residual disability were dependent on family members for their social functioning.

Lack of leisure activities has been reported to be a frequent problem that impedes stroke patients from resuming full lives (Sjögren 1982, Widén-Holmqvist et al. 1993). Impaired physical function and deficient communication skills may lead to feelings of stigma and loss of confidence which could explain the decline in participation in social activities after stroke (Parker et al. 1997). Role changes within the family, non-supportive attitudes and emotional reactions can result in family dysfunction and major changes in lifestyles (Robinson et al. 1985, Evans et al. 1994). Caregivers may adopt an unnecessarily protective attitude and thus discourage efforts towards independence. It has been reported that among physically well recovered stroke victims, those who live alone are more likely to resume social and leisure activities than those who live with a caregiver (Labi et al. 1980). On the other hand, the importance of the family was clearly demonstrated in the study of Davidoff (1992) who showed the presence of a family member to be a predictor of residential outcome after stroke.

2.3.3. Burden on caregivers

A growing number of reports over the past decade have focused on caregiver strain following stroke. A study of Bugge et al. (1999) revealed that 37% of caregivers experienced considerable strain 6 months after stroke. In another report, one-fifth of the caregivers still found themselves under strain 5 years after their spouse's stroke (Wilkinson et al. 1997). Anderson et al. (1995) studied a group of stroke survivors with a residual disability one year after the stroke. They found that 55% of the caregivers showed evidence of emotional distress and almost all caregivers reported adverse effects on social activities and leisure time. As many as three-quarters of the caregivers responsible for the caring of stroke patients in the last year of life, have reported that caring had restricted their own activities and only one-third had found it a rewarding experience (Addington-Hall et al. 1998). Poor sleep quality, fatigue, pain and gastrointestinal disorders have been reported to be frequent symptoms among caregivers (Williams 1993). There are a number of factors that explain the caregiver strain. A few studies have suggested that disablement and cognitive deficits following stroke have an adverse effect on marital relations and family adjustment (Brocklehurst et al. 1981, Williams et al. 1986). Caregivers are more likely to become depressed if the patients are severely dependent (Dennis et al. 1998). It has also been argued that it is the behavioral changes occurring in the patient rather than the physical impairment which contributes to the caregivers′ ill-being (Anderson et al. 1995). Those caring for depressed or anxious stroke patients have found caring to be particularly stressful (Addington-Hall et al. 1998). Role changes within the family, the loss of companionship, financial difficulties and disruption of social life can induce anxiety in the caregiver. Whatever the reason, stroke is one of the most traumatic diseases affecting the patient and the family. As Anderson et al. (1995) stated the family members "must overcome the initial shock of stroke, reassess their values, and readjust their own lives and those of their families so that they can provide what is often an extraordinary level of care".

2.4. Stroke outcome

2.4.1. Outcome measurement

Outcome can be defined as "the state or situation that arises as a result of some process or intervention" (Wade 1999). Outcome measures are commonly chosen on the basis that they should reflect relevant rehabilitation goals (Keith 1995). In addition to validity, i.e. the process of rehabilitation is related to an outcome measured, it is important that the measures are reliable, sensitive and easy to administer (Fitzpatrick et al. 1992).

Discharge placement is one of the most important indicators of the effectiveness of rehabilitation because it reflects the patient's capability to resume previous roles and engage in activities of daily living. Resource use involving the use of social and health care services, medication, etc., has become an increasingly important outcome measure for various health care decisions. Traditional functional status measures are widely used in assessing outcome. Numerous such measures have been developed for specific assessment of physical, psychological, behavioral and social parameters of the individual. The applicability of different functional outcome measures is variable. The poor sensitivity of the measures is a frequent problem in the long-term stroke rehabilitation. Productive activity that has economic or social contributions can also be considered in choosing an outcome measure for rehabilitation. The ability to pursuit leisure activities has been considered as a relevant goal in stroke rehabilitation (Parker et al. 1997). Finally, satisfaction with outcomes and services by patients, relatives, referrers and purchasers is a relevant point in judging the quality of service and should be taken into account in health care decisions (Keith 1995).

Impaired mobility and volitional movements of the extremities are often the most visible consequences of stroke. Several measures are available to rate these physical disabilities. The Functional Ambulation Categories (FAC) (Holden et al. 1984), which records the amount of personal assistance needed, is feasible in rehabilitation, although it has a limited sensitivity. Another useful scale is the Rivermead Mobility Index (Collen et al. 1991), which concentrates on 15 fundamental aspects of mobility. Walking skills can also be evaluated by measuring the time taken to move a certain distance. Gait speed has been shown to relate to many other attributes of walking, and its validity and reliability has been established in many studies (Holden et al. 1984, Wade et al. 1987a, Bohannon & Andrews 1990). Widely used measures of voluntary motor control include the Motricity Index (Demeurisse et al. 1980), the Motor Club Assessment (Ashburn 1982), the Rivermead Motor Assessment (Lincoln & Leadbitter 1979) and the Motor Assessment Scale (Carr et al. 1985). The Brunnström-Fugl-Meyer scale (BFM) (Fugl-Meyer et al. 1975) measures volitional movements of the extremities, range of motion, postural stability and sensory function. It has proved to be useful in many controlled trials of stroke therapies (Garraway et al. 1980, Smith et al. 1981, Feys et al. 1998, Volpe et al. 2000).

There are numerous methods for evaluating activities of daily living (ADL) in stroke patients. Most ADL indices measure the need for help, which is useful in judging the patient's ability to live alone. The Barthel Index (BI) (Mahoney & Barthel 1965) includes the ten most common areas within ADL and it is a widely used, well validated measure. It has a good test-retest reliability and it has been used in different settings (Wade & Collin 1988, Chino et al. 1988, d'Olhaberriague et al. 1996). The scoring is simple and it is quick to complete. One notable limitation is its poor sensitivity to detect small differences (Wade 1992). Other alternative measures of ADL are the Katz Index (Katz et al. 1963), the Northwick Park Index (Benjamin 1976) and the Nottingham Ten-point Index (Ebrahim et al. 1985). In addition to the indices of basic ADL there are a number of scales that have been designed to measure extended ADL. Such measures include the Functional Independence Measures (Keith et al. 1987), the Rivermead ADL Index (Whiting & Lincoln 1980), the Nottingham Extended ADL Index (Nouri & Lincoln 1987) and the Frenchay Activities Index (Holbrook & Skilbeck 1983). The Nurses' Observation Scale for Geriatric Patients (NOSGER) (Spiegel et al. 1991) is a new behavioral assessment scale for elderly patients. It is constructed to observe the frequency of behavioral phenomena that are meaningful and relevant both in a hospital setting and at home. Investigations in several countries and different settings have shown that the NOSGER is a valid and reliable measure (Brunner & Spiegel 1990, Wahle et al. 1996).

Mood disorder is a frequent sequel of stroke and may often have a major influence on outcome. Most of the depression scales have been designed for psychiatric use and only a few have been developed for use with the disabled (Wade 1992). Among the measures used in stroke patients are the Beck Inventory (Beck et al. 1961), the Zung Self-rating Depression Scale (Zung 1965), the Wakefield Self-assessment Depression Inventory (Snaith et al. 1971), the Hamilton Rating Scale (Hamilton 1967) and the Montgomery-Åsberg Depression Rating Scale (MADRS) (Montgomery & Åsberg 1979). The MADRS, like the four other depression scales has been developed for use with the general population, but secondarily all of these scales have been applied to detect mood disorders in the disabled and the elderly. There are several stroke studies in which the MADRS has proved to be useful and the relevant rating scale for evaluating depressive patients (Herrmann et al. 1995, Béthoux et al. 1996, Neau et al. 1998, Penrod et al. 1998, Wiart et al. 2000).

The General Health Questionnaire (GHQ) (Goldberg 1972) has gained many advocates for its use with disabled patients. The original GHQ contains 60 questions and various shorter versions have been developed. The GHQ-28 has been frequently used to screen emotional impairment. It can also be used to measure stress on caregivers. The Finnish version of the GHQ-12 has been previously used to screen psychological distress in the Finnish general population (Näyhä 1986, Hintikka et al. 1998).

The assessment of QoL after stroke has become increasingly popular in recent years. Studies on QoL have concentrated on the assessment of clinical value of treatments or on the evaluation of different interventions from an economic point of view (Fitzpatrick et al. 1992, Wade 1992). Measuring QoL is problematic since the validity of any unidimensional or composite scale is difficult to establish. According to Wade (1992), if an overall measure of the QoL is to be looked for, one should take account of the particular phenomena that are in relation to the hypothesis being tested, and then use the appropriate measures. Instruments used in the assessment of the QoL can be divided into generic and disease-specific scales. The more commonly used instruments include the Sickness Impact Profile (Bergner et al. 1981) and the Nottingham Health Profile (Hunt et al. 1986). Also other generic instruments, applicable to a wide variety of health problems, have been used in assessing the QoL, such as the SF-36 (Ware & Sherbourne 1992) and the RAND-36 (Hays et al. 1993). A visual analogue scale (VAS) for the QoL in stroke patients has been previously used in two observational studies (Ahlsiö et al. 1984, Béthoux et al. 1996) and in a controlled trial (Indredavik et al. 1998). It is a simple method, but has not been validated for use with stroke patients, and therefore it has been utilized only as a secondary outcome measure of the QoL.

2.4.2. Factors influencing stroke outcome

The majority of spontaneous recovery of function occurs during the first 3 months after stroke

(Skilbeck et al. 1983, Sivenius et al. 1985, Jorgensen et al. 1995a). There is an extensive body of literature on factors that are associated with functional outcome. The severity of stroke has been found to be negatively correlated with functional recovery in a number of studies (Lehmann et al. 1975, Feigenson et al. 1977, Kotila et al. 1984, Westling et al. 1990). A previous stroke, the presence of cognitive deficits, urinary and/or bowel incontinence, low functional admission scores and a delay from the onset of stroke to hospital admission have been reported to be predictors of unfavourable outcome (Wade et al. 1983, Galski et al. 1993). As stated above, poststroke depression has an adverse effect on functional recovery. Family support has been shown to play a crucial role in determining residential outcome (Andrews et al. 1984, Kelly-Hayes et al. 1988, Davidoff 1992, Ween et al. 1996). Moreover, the presence of a spouse at home has been found to be a prognostic indicator of good functional outcome in patients with the most severe stroke.

2.4.3. Stroke outcome and old age

The effect of age on stroke outcome is not unambiguous. Older age has been reported to be an adverse prognostic indicator of functional outcome by several studies (Ahlsiö et al. 1984, Kotila et al. 1984, Wade et al. 1985, Westling et al. 1990, Jorgensen et al. 1999). No association between age and improvement in function has been found in a few other studies (Lehmann et al. 1975, Adler et al. 1980, Heinemann et al. 1987, Kong et al. 1998). This inconsistency may be explained by various factors such as differences in rehabilitation procedures and the measures used in evaluating functional recovery. According to Ferrucci et al. (1993), older patients with severe disability had greater functional recovery than younger ones after completion of a rehabilitation program, possibly due to better compensatory strategies. Prestroke level of function may play an important role in predicting stroke outcome in the elderly. Fewer limitations in physical function before stroke have been found to be associated with better physical outcome 6 months after the stroke and a lower risk of institutionalization (Colantonio et al. 1996).

Wyller et al. (1998) found that older age was related to a higher subjective well-being in stroke patients. A firm social network was one of the most important factors predicting a favourable outcome in terms of subjective well-being after stroke. A concordant finding of a good psychological well-being among older patients late after stroke was also reported by Pound et al. (1999) and Löfgren et al. (1999). Urinary incontinence and cognitive dysfunction among elderly stroke patients are associated with more frequent placements in sites other than their own homes (Kalra et al. 1993a, Thommessen et al. 1999). The importance of social support for the elderly has been recognised in many studies that have examined variables associated with good outcome (Åström et al. 1992, King 1996). In the study of Santus et al. (1990), more than half of the elderly patients had problems in social and family integration one year after stroke. Provision of support may therefore adopt a crucial role in cases of older stroke survivors. Andrews et al. (1984) pointed out that although older patients have equal functional recovery, social factors may result in more frequent placement in institutional care for the elderly. Therefore, it is not surprising that early discharge from hospital and provision of family support have been reported to be associated with higher patient satisfaction (Pound et al. 1999, Mayo et al. 2000).

2.5. Effects of acute stroke rehabilitation

The role of rehabilitative efforts has been widely recognised as being essential in the acute stage of stroke (Heinemann et al. 1987). The beneficial effects of stroke unit rehabilitation have been well documented by several workers (Strand et al. 1985, Indredavik et al. 1991, Kalra et al. 1993b and 1995). Treatment of acute stroke patients in stroke units has been shown to reduce mortality, length of hospital stay, discharge rate to nursing homes and cost (Jorgensen et al. 1995b). Functional recovery has been significantly greater and more rapid in a stroke unit compared with general wards (Kalra 1994). Treatment in stroke units has increased the proportion of patients able to live at home long after their stroke (Indredavik et al. 1999). Elderly stroke patients may equally benefit from the well-organized management of stroke (Kaste et al. 1995, Jorgensen et al. 2000).

2.6. Long-term rehabilitation following stroke

There is a widespread belief that most of the recovery occurs within a few months after a stroke and little improvement takes place thereafter (Wade et al. 1985). For that reason, no further rehabilitative efforts may be provided after the acute period. Some patients, however, would need prolonged therapy to reach the recovery target that may occur up to two years after the stroke (Kelly et al. 1985, Tangeman et al. 1990). The major problem has been to identify those individual patients who will benefit from long-term rehabilitation programs (Dam et al. 1993). Novel restorative programs that focus on the functional improvement of the upper extremity (Taub et al. 1993 and 1998, Miltner et al. 1999) or on the recovery of gait (Hesse et al. 1994) have provided promising tools for the treatment of selected stroke patients with residual disability.

It has been argued that the outcome of physical recovery has been overemphasized in planning therapy programs for stroke patients (Young 1994). The needs for education, psychological support, and enhancing social integration should also be addressed adequately to ensure an optimal long-term outcome (Evans et al. 1992, Flick 1999). There are relatively few studies that have examined the effectiveness of a long-term rehabilitation for stroke survivors and consequently, we do not know the best possible approach to the management of patients with a remote stroke. We know that functional decline occurs in some patients over a long period of time after the stroke (Reutter-Bernays & Rentsch 1993, Addington-Hall et al. 1996, Wilkinson et al. 1997). Older stroke survivors, in particular, are vulnerable to functional deterioriation over time, often due to other causes than stroke. Nonetheless, access to rehabilitation, especially in Finland, is limited for people aged 65 or over mainly because of meager supply of services available in the community. A similar imbalance between demand and service provision for the elderly disabled people has been found also in Sweden and England (Johansson et al. 1992, Wilkinson et al. 1997).

2.6.1 Home versus hospital

It has been postulated that unless the patient is seen as a part of his familiar context, i.e. home, including its physical, psychosocial and cultural elements it will be hard to achieve the target of rehabilitation (Cant 1997, von Koch et al. 1998). Furthermore, hospital stay with routine rehabilitation measures is resource consuming and that is why several authors have proposed less expensive approaches to provide treatment for stroke patients (Brocklehurst et al. 1981, Young et al. 1993). In 1980's there was a growing interest in home rehabilitation studies to establish more cost-effective strategies. Despite the rather discouraging report of Wade et al. (1985) a number of further studies have compared the effects of home rehabilitation with those of hospital treatment over the past 15 years. The results of the Bradford Community Stroke Trial suggested that home physiotherapy is slightly more effective and more resource efficient than day hospital attendance and should be the preferred rehabilitation method for the aftercare of stroke patients (Young et al. 1992). In the Domino Study, the domiciliary and hospital-based services were found to be as effective at three and six months after discharge (Gladman et al. 1993) but in the follow-up at one year the benefits of domiciliary rehabilitation for the patients discharged from a stroke unit were lost (Gladman et al. 1994). A study conducted in Southwest Stockholm (Widén-Holmqvist et al. 1998) suggested that early supported discharge after stroke followed by home rehabilitation services for 3-4 months was as beneficial as routine hospital rehabilitation for the majority of moderately disabled patients. Considerable savings in resource use were reported to the advantage of home rehabilitation. These findings were supported by the recent Australian study of Anderson et al. (2000).

The effects of day hospital attendance on the functional recovery of stroke patients over 65 years of age were studied after discharge from a stroke rehabilitation ward (Hui et al. 1997). Care in the geriatric day hospital hastened functional recovery and reduced outpatient visits. However, the patients who received conventional medical management caught up in progress from 3 months on and the final outcome at 6 months was similar in both groups.

Baskett et al. (1999) found that a programme of continuing self-directed exercises for patients discharged home after a stroke, supervised once a week by therapists, was as effective as outpatient or day hospital therapy.

2.6.2. Other home-based interventions

Stroke patients with a mild functional disability who are not admitted to hospital are often judged not to require rehabilitation. However, in the work of Walker et al. (1999) this group of patients (the BI score 15 -20) benefitted from occupational therapy at home in terms of improved performance of instrumental activities of daily living (IADL). It was suggested that independence in housework, walking over uneven ground, or in crossing a road would make a difference for any stroke patient.

A need for better post-discharge support and counselling and more information rather than more rehabilitation has been expressed by patients interviewed three years after stroke (Greveson et al. 1991). Older stroke patients with a mild residual disability who are living at home may improve in social activities as a result of specialist nurse support (Forster & Young 1996).

Readmission to inpatient care is common among disabled stroke patients. According to Andersen et al. (2000), follow-up home visits by a physician or a physiotherapist after discharge can significantly decrease the readmission rate. The finding supported the results of a previous report by Corr et al. (1995) who studied the effect of a follow-up service by an occupational therapist on stroke patients after discharge from a stroke unit. The scheme of accelerated hospital discharge after acute stroke followed by multidisciplinary home-based rehabilitation specifically targeted toward the individual needs of the patients reduced significantly the length of hospital stay but did not have any impact on their general health or physical or psychological outcomes different from that of conventional care (Anderson et al. 2000). The major disadvantage was the finding of worse mental health among caregivers in the intervention group and therefore an increased focus on emotional support for caregivers was addressed for future interventions.

To facilitate adjustment to disability and reintegration to normal life a few social support interventions have been tried but the results have been modest (Towle et al. 1989, Friedland & McColl 1992, Dennis et al. 1997). Evans et al. (1988) reported that counselling intervention improved adjustment, caregiver knowledge and family function one year after stroke but did not have any influence on the use of social services.

The Leeds Family Placement Scheme was an interesting approach providing short term support for vulnerable stroke patients on discharge from intensive hospital rehabilitation (Geddes et al. 1989). The patients were placed into substitute families for an average of 8 weeks under the supervision of an occupational therapist to receive care from trained lay caregivers. Although the study had several weaknesses, the placement scheme proved to be more effective in improving and maintaining basic ADL than the conventional approach.

Leisure activities have been found to decrease after stroke (Feibel & Springer 1982, Drummond 1990). In the study of Drummond and Walker (1995), leisure rehabilitation was found to be an effective way of maintaining and increasing leisure participation after stroke. Since a previous study (Jongbloed & Morgan 1991) could not establish a positive effect of occupational leisure rehabilitation, it is not clear whether such intervention is more effective than counselling alone.

2.6.3. Support in the community

Returning to the community can be a traumatic experience to the stroke patient and various support services have been developed beyond primary health care to enhance coping with the illness and to facilitate return to normal life. In addition to national organizations involved in providing information to stroke survivors, there are a growing number of locally based self-help groups for stroke patients and their caregivers which provide care and support. The general opinion is, however, that there is a low level of service provision especially for older stroke survivors living in the community and more rehabilitation and co-operation with primary and secondary health care would be required to ensure an optimal long-term outcome.

To facilitate access to rehabilitation, an open referral system, in which referrals are accepted from any relevant person or agency, has been examined in a restricted urban area of Southeast England (Maheswaran et al. 1998). Even though only 9% of patients were considered to have been inappropriately referred, the possible disadvantage of low cost-effectiveness may eventually dampen the broader interest in an open system.

Since most elderly patients prefer to stay at home, community care has acquired a greater relevance (Salvage et al. 1989, Steel 1991). An important requirement of good health care and social services for older people living in the community would be flexibility of provision, implying the need for patient assessment before admission to the appropriate service (Black & Bowman 1997). An integrated social and medical care with case management programmes may be one way to reduce admission to institutions and prevent the functional decline in the elderly (Bernabei et al. 1998).

2.7. Cost-effectiveness of stroke rehabilitation

The economic burden of stroke involves a vast amount of direct costs due to healthcare, social and rehabilitation services and indirect costs like the loss of productivity. The direct costs alone consume considerable portions of national healthcare budgets in industrialised countries. Therefore, healthcare authorities, policymakers and above all purchasers continually stress the importance of economic efficiency in service provision. Consequently, the assessment of cost-effectiveness has become more common in the field of stroke-related interventions in recent years (Holloway et al. 1999).

A full economic evaluation study involves the comparison of both the costs and the consequences between two or more program alternatives (Drummond et al. 1997). In a cost-effectiveness analysis, the outcome can be assessed in different ways, such as life-years gained, decreased length of hospital stay or decreased readmission rate. This variety of outcome measures is a major limitation making comparisons between the various studies difficult to perform. In a cost-utility analysis, on the other hand, health improvement is expressed in quality-adjusted life years (QALYs) which is a uniform measure. Although QALYs are regarded as the most sophisticated way of quantifying effects, they are rarely used in economic evaluation studies concerning cerebrovascular disease (Evers et al. 2000).

Several studies have compared the effects and the costs of a home-based rehabilitation scheme and an alternative treatment strategy after discharge from acute stroke care. The results of the Bradford Community Stroke Trial showed that home physiotherapy was slightly advantageous over day hospital attendance and the former was significantly less expensive (Young & Forster 1993). In the DOMINO study (Gladman et al. 1994), the patients discharged from geriatric wards were shown to be less likely to die or to be transferred to permanent care when they received day hospital service, but the cost of this service was 25% more than that of home-based rehabilitation. Domiciliary service, on the other hand, was significantly more expensive than hospital outpatient rehabilitation for the patients discharged from general medical wards or from a stroke unit. Previous reports have demonstrated that specialized stroke units can improve outcome after stroke without increasing the cost of health care services (Eason et al. 1995, Jorgensen et al. 1995b). Hui et al. (1995) examined the effects and costs of a geriatric day hospital treatment and conventional medical management for the elderly stroke patients in Hong Kong. They found that early discharge from a stroke ward followed by rehabilitation at the day hospital hastened functional recovery and reduced outpatient visits without increasing costs. However, based on the data of the Perth Community Stroke Study, Anderson et al. (2000) reported that early hospital discharge and a home-based rehabilitation scheme were less costly than conventional care, and if provided for the mildly disabled only, such services might well be most cost-effective.

Currently, we lack information about which model of rehabilitation is the most efficient in reducing the disease burden late after stroke. The few studies that have examined the cost-effectiveness of stroke rehabilitation have focused on the subacute phase of stroke and the follow-up period has not extended beyond six months after hospital discharge (Table 1). Based on the data of the previous studies, a tentative conclusion can be made that home-based rehabilitation might be more economical with comparable effects in terms of functional gains.

Table 1. Earlier cost evaluation studies in stroke rehabilitation. RCT = randomised controlled trial

Author	Intervention	Period	n	Main results
Anderson et al. 2000a,b	Hospital vs. home-based rehabilitation (RCT)	6 months	86	No difference in outcomes, lower costs in rehabilitation

Byford et al. 1995	Short-term family placement scheme	3 months	120	Increased functional outcome, decreased cost
Gladman et al. 1994	Domiciliary vs. hospital-based rehabilitation (RCT)	6 months	327	No difference in outcome, increased cost in domiciliary service
Hui et al. 1995	Day hospital vs. conventional care (RCT)	6 months	120	No difference in functional outcome, no difference in cost
Keith et al. 1995	Acute vs. subacute rehabilitation	Hospital	428	Decreased functional gains, decreased costs in subacute service
Young & Forster 1993	Home physiotherapy vs. day hospital	8 weeks	95	No difference in functional outcome, decreased cost in home physiotherapy

3. AIMS OF THE STUDY

The purpose of the present study was to evaluate the effects of a long-term rehabilitation program on elderly stroke patients' well-being and to enhance our knowledge so as to develop ways to improve the rehabilitation of stroke patients. More specifically, the aims were:

1. To determine whether elderly patients with residual disability can benefit from increased physical and social activity and counselling support late after stroke.

2. To study the effects of the rehabilitation program on the caregivers´ psychological distress.

3. To measure the impact of the intervention on the use of health care services in the community.

4. To evaluate the cost-effectiveness of the rehabilitation program and its applicability to the present health care environment.

4. PATIENTS AND METHODS

4.1. Study population

The patients were selected from among the population of 12 municipalities in the Northern Savo region (250 000 inhabitants) in Eastern Finland. Following the recommendation of the Finnish National Board of Health (Simonen et al. 1989) the stroke patients previously independent in their daily life are almost invariably examined by a neurologist and hence admitted first to Kuopio University Hospital or one of the district hospitals, Iisalmi or Varkaus. Older patients with acute stroke, however, are often admitted to smaller hospitals or, if referred to the neurological clinic, they tend to be transferred to a general medical ward of a health center soon after the diagnosis has been confirmed. After returning home, patients aged 65 or more with functional disability compromising their management of daily activities are eligible for receiving a pensioner's care benefit from the Social Insurance Institution (SII).

The recruitment of the patients was started in May 1995 and completed in May 1996. The initial goal for the sample size was 140 subjects. The subjects were recruited from two sources. The files of 514 patients receiving a care benefit for the disabled were examined in the local SII offices to search for eligible subjects. The search yielded 196 cases who were contacted by mail through the official channels of the SII and sent essential information about the upcoming study and a consent form. A total of 116 patients provided informed consent. Additional three patients who had received rehabilitation in Brain Research and Rehabilitation Center Neuron were recruited by telephone and each of them consented. The study was approved by the ethics committee of Kuopio University Hospital.

The eligibility was verified in a clinical examination by a neurologist before randomisation. Two subjects were eventually dropped out on the basis of clinical findings (other chronic diseases with severe disability). Thus, a total of 117 patients were selected to proceed in the 3-year follow-up scheme (Figure 1).

4.2. Inclusion criteria

The list of inclusion criteria is shown in Table 2. Patients aged 65 or more and those having their 65th birthday by the end of the year of study entry were included. Patients were eligible if they had had one or more strokes at least six months prior to study entry. Patients with severe chronic diseases affecting markedly on performance or compliance were not included. For example, patients with progressive rheumatoid arthritis or uncompensated cardiac or pulmonary insufficiency were omitted. Likewise those individuals with alcoholism or a recent history of a psychotic disorder were excluded. The files of each patient were thoroughly examined to exclude those with progressive cognitive decline as the main cause of dependence. Patients with "mild" cognitive impairment were not excluded. The degree of cognitive impairment was evaluated first by the notes in the patient files and eventually at the patient interview. Patients with stroke from subarachnoid haemorrhage or a brain trauma were also excluded. All patients were entitled to one of the three SII care benefits for the disabled. The benefits are granted according to the degree of disability. Patients entitled to the lowest benefit are mostly independent in self-care but need help in some house chores or outside the home. The middle benefit means that the patient needs regular help in basic ADL and is dependent in home maintenance. To be entitled to the highest benefit, the patient requires constant surveillance and help to be able to live at home.

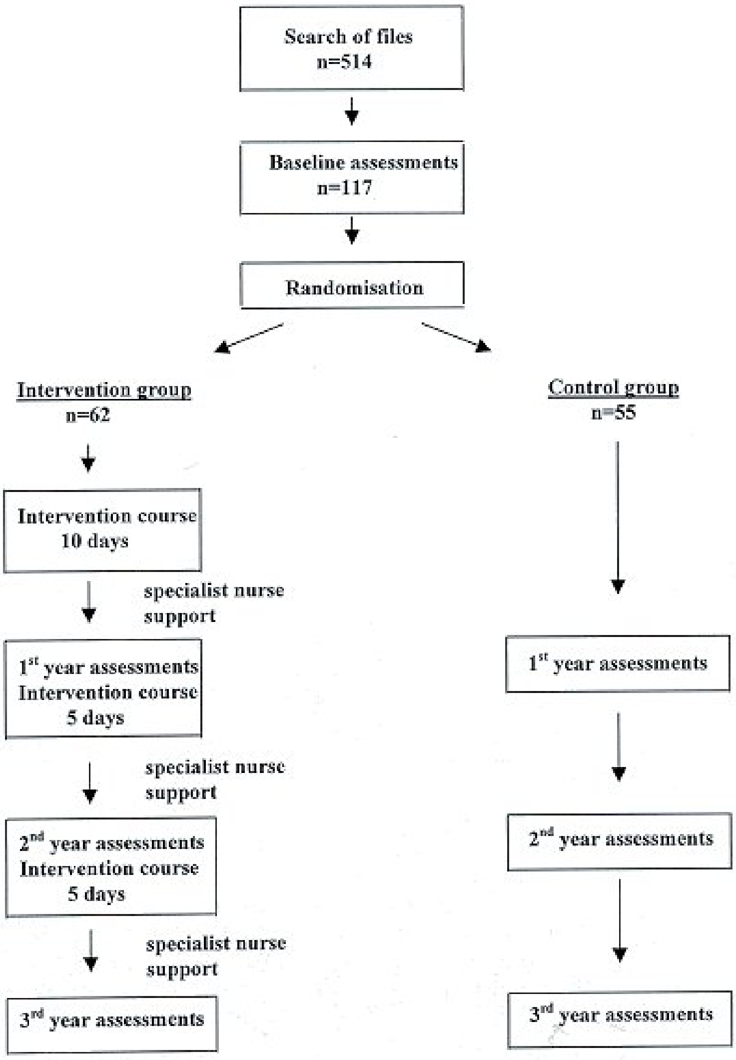
Table 2. Inclusion criteria.

Age	65 or older
Stroke chronicity	6 months or more
Living environment	Home
Comorbidity	No marked effect of performance
Level of disability	Entitled to SII care benefit

4.3. Study design

The present study was a randomised controlled trial with a 3-year follow-up scheme. Each patient underwent the baseline assessments before randomisation. The simple randomisation method of sealed envelopes containing one of two figures was used to allocate patients either to the intervention or the control group. The follow-up assessments were performed at one, two and three years from the baseline in both groups. The chart flow in Figure 1 presents an overview of the study scheme.

Figure 1. Study design.



4.4. Baseline assessments

4.4.1. Clinical examination

As soon as the patients returned the informed consent form they were invited for baseline assessments. All the patients were first examined by a neurologist to confirm eligibilty. A comprehensive clinical examination included inquiry of medical history, collecting the data on the characteristics of stroke from the patient files, assessment of mental state and mood, evaluation of atherosclerotic problems and cardiopulmonary symptoms and measurement of blood pressure. The clinical examination was recorded as shown in Appendix I.

4.4.2. Patient interview

All subjects were interviewed at study entry using a structured questionnaire. In addition to demographic characteristics, the interviewer (a specialist nurse) collected extensive data on housing, cohabiting, social activities and characteristics of daily life. The use of ambulation aid and any form of support from the community was recorded. The use of health care services was inquired. See Appendix II for further details.

4.4.3. Assessment measures

In addition to comprehensive clinical assessments, the patients were evaluated with a number of instruments widely used in assessing patients´ physical, psychological and social performance. The BFM (Fugl-Meyer et al. 1975) was applied to measure physical performance. Walking was classified by the FAC (Holden et al. 1984). The speed of gait was measured by asking the patient to walk a distance of 10 meters indoors (Wade et al. 1987). The BI (Mahoney & Barthel 1965) was selected as a measure of basic ADL and the NOSGER (Spiegel et al 1991) was utilized to evaluate coping from a behavioral point of view. The MADRS (Montgomery & Åsberg 1979) and the MMSE (Folstein et al. 1975) ratings were collected to assess mood and cognitive function, respectively. Caregivers´ strain was assessed by a short version of the GHQ (Goldberg & Hillier 1979). Finally, quality of life of the patients and their caregivers was measured with a visual analogue scale (VAS) (Huskisson 1974) after they had completed the three-year follow-up.

The evaluations of the subjects at the study entry were performed at Säveri Medical Clinic in Kuopio or at a medical setting nearest to each patient to avoid possible distress and fatigue due to transportation. Once the baseline assessments were completed, the patients were randomly allocated either to the intervention or the control group.

4.4.3.1. Physical performance

The assessment scales for physical performance were the BFM, the FAC and gait speed over 10 meters. Even though the study was not specifically designed to obtain evidence of physical recovery, the BFM served as a tool for assessing the impact of the increased physical activity included in the study.

The BFM includes a three-point grading for motor function, balance, sensation and passive range of motion. In this study only motor function and balance were evaluated. The maximum score for motor function in the standard BFM is 100. The maximum score for balance is 14. Scores for the unaffected side were not expressed. The BFM has been proven to be a valid and a reliable measure for testing motor performance in patients following stroke (Fugl-Meyer et al. 1975, Sanford et al. 1993).

The FAC is a six-grade classification of gait ranging from "unable to walk" to "can walk independently" The classification does not take account of the use of walking aids. It is a useful classification and sensitive to change during active rehabilitation in which progress in walking occurs. The validity and reliability of the FAC has been demonstrated in earlier reports (Holden et al. 1984, Collen et al. 1990).

Gait speed over 10 meters is a simple but a valid and a reliable measure of walking ability in a stroke patient (Wade et al. 1987). The patient is asked to walk 10 meters on a level surface using any aid he or she wishes. In such a situation, realizing the speed being measured, the patient is prone to try his or her best. The use of a walking aid was recorded. Gait speed has been shown to relate to other measures such as the FAC and the use of walking aids (Holden et al. 1986). Its validity and reliability have been established in many studies (Holden et al. 1984, Wade et al. 1987a, Bohannon & Andrews 1990) and its additional advantages are simplicity and reasonable sensitivity.

All the above mentioned assessment measures were performed by an experienced physiotherapist excluding the sections of reflexes and volitional movements in the BFM, which were performed by a neurologist.

4.4.3.2 Activities of daily living

The BI was used to assess functional disability in self-care, mobility and sphincter control. The BI is a 10-item scale including feeding, dressing, grooming, bathing, bladder and bowel continence, chair and toilet transfer, walking on level surface and stairs. Each item is rated on a scale ranging from 0 to 15 points depending on the need for help. The maximum score is 100. The BI was selected since it is known to have good reliability and validity in assessing ADL among stroke patients (D'Olhaberriague et al. 1996). It has been used in different settings (Wade & Collin 1988, Chino et al. 1988) and it is quickly administered as a screening instrument. The major disadvantage of the BI is its low sensitivity in assessing the patients with residual disabilities late after stroke (Shah et al. 1989).

To compensate for the limitations of the BI, an additional scale, the NOSGER, was selected to assess self-care and functional competence in daily living. The NOSGER consists of 30 items divided into six dimensions assessing memory, instrumental activities of daily living, self-care, mood, social behavior and disturbing behavior. Each item is rated according to the frequency of their occurrence using a five-point score labeled "all the time", "most of the time", "often", "sometimes", "never". The order of each item score is arranged to produce low dimension scores for little or no disturbance and high scores for severe dysfunction in the respective dimension. The NOSGER has been proven to be a reliable and valid rating scale for the behavioral characterization of geriatric patients (Wahle et al. 1996). All of the NOSGER dimensions have shown high correlations with other measures designed to evaluate the same areas of mental functioning in geriatric patients (Spiegel et al. 1991). Since there are no previous reports on the use of the NOSGER in stroke rehabilitation intervention, it was appropriate to test correlations with other measures possessing related items of behavior, especially mood and self-care.

Both the BI and the NOSGER scales were performed by a specialist nurse.

4.4.3.3. Social behavior

Since the present study was designed to enhance social activities among stroke patients, it was relevant to incorporate an assessment scale to evaluate any possible effects of the intervention on social behavior. However, there are practical limitations in applying a large number of instruments on a clinical encounter with elderly patients. For that reason the social parameters of the NOSGER were applied to indicate possible changes in social behavior.

Stroke-induced disability may contribute significantly to an impaired coping. Unsuccessful coping with the disease may result in higher dependence in ADL and, eventually, in greater dissatisfaction. To determine the underlying attributes for the impaired coping, we asked the patient and the caregiver to name one or more major problems that impeded their functioning at home.

Many studies have found a reduction in leisure activities following stroke (Sjögren 1982, Feibel & Springer 1982, Drummond 1990). The present study charted the patterns of leisure activities before and during the follow-up. We were interested to find out whether the patients could maintain or even increase their involvement in leisure pursuits with the help of long-term support.

4.4.3.4. Psychological assessment

High prevalence rates of depression among stroke patients and the often detrimental effect of stroke on QoL provided a meaningful basis for assessment of psychological well-being among the study subjects. The MADRS was selected to evaluate mood and the MMSE was performed to assess cognitive functions. The mood and memory dimensions of the NOSGER served as parallel assessment instruments to detect changes in mood or cognitive functions. DSM-classification was not used in the evaluation of depression due to lack of psychiatric expertise in the research team.

The MADRS consists of 10 items with a score ranging from 0 to 6 for each item. The higher the score the more severe is the depression. The maximum score is 60. A score of 20 or more has been considered indicative to a clinical (major) depression whereas scores ranging from 7 to 19 suggest the possibility of a minor depression (dysthymic disorder). The MADRS is short and easy to apply in a clinical examination but is nevertheless relevant with good validity and reliability in detecting depressive symptoms (Maier et al. 1988, Peyre et al. 1989). One important advantage of the MADRS is its high sensitivity for change (Snaith 1993, Galinowski & Lehert 1995). The global score of the MADRS is not influenced by age or sex (Pellet et al. 1987). Like all other depression rating scales, the MADRS has been developed primarily for psychiatric purposes in general population. However, it has proved to be very useful in a variety of interventions assessing the severity of poststroke depression (Herrmann et al. 1998, Wiart et al. 2000) and the treatment effects in the elderly (Pitt 1993).

The MMSE includes cognitive abilities such as orientation, registration, attention, calculation, recall, language and copying. Language functions are tested by naming, repeating, following commands, reading and writing. The maximum score is 30 and a score of 23 or less indicates significant cognitive impairment. The MMSE is not designed for diagnostic purposes. It has been widely used as an instrument for screening for cognitive impairment in community-based studies (Tombaugh &

McIntyre 1992, Fratiglioni et al. 1993, Ganguli et al. 1993, Koivisto 1995).

4.4.3.5. Caregiver strain

The emotional distress of the main caregivers was examined with a 12-item Finnish version of the GHQ. The questionnaire is based on the respondent's appraisal of his or her psychological well-being and coherence. The caregivers were instructed to answer the questions regarding how they had felt recently and over the past few weeks. Each question produces four alternative responses scoring 0-0-1-1 (the usual method). The first alternative indicates either the absence of a negative phenomenon or the presence of better than usual condition. The second alternative means that the condition has been unchanged over the past few weeks. The last two alternatives signify the degrees of inferiority to the usual condition. Thus, the maximum score for the 12-item GHQ would be 12 indicating the worst possible condition. A total score of three or more indicates a probable minor mental disorder and the score of five or more has been considered as an indicator of a major stress. In the present study the cut-off point of 4/5 was applied to identify the caregivers with clinically significant stress. The form was given to the caregiver by the specialist nurse to be filled in at home in order to reduce any possible "face-to-face effect". The short 12-item GHQ has been found to be a robust tool in screening for psychological distress, producing results comparable with longer versions (Goldberg et al. 1997). According to that report, the validity of the instrument was not influenced by sex, age or education level.

4.5. Follow-up assessments

The follow-up assessments were performed one year, two years and three years after the study entry. The time window for the follow-up assessments was +/- 1 month. Patients in the intervention group were assessed while participating in the second and third course in Neuron. Patients in the control group were assessed in Säveri Medical Clinic in Kuopio at one and two years. The assessment procedure was similar in both groups. The patient underwent three successive measurement sessions separated by a short break. The duration of each follow-up assessment ranged from 2 to 3 hours. The last follow-up assessments of the patients in both groups at three years were performed during an outpatient visit in Neuron.

All the assessment scales reported above were performed at the follow-up times. The assessors were unaware of the contents of the previous recordings but could not be blinded to the group. The baseline data and the follow-up data were collected by the same neurologist and the same specialist nurse. The assessor (a physiotherapist) of the physical performance measures (BFM, FAC and gait speed) at the baseline had a substitute physiotherapist for the follow-up assessments. Adequate training was provided to assure conformity in the ratings.

4.6. Use of health care services

The use of health care services was recorded at each follow-up. The data were based on the inquiry of the patient and the caregiver and on the hospital documents of the inpatient stay. A health care professional in the community was contacted, if appropriate, to verify data concerning the use of services. The specialist nurse kept a record of the outpatient and home physiotherapy visits included in the intervention. Admission to permanent inpatient care was recorded. Death and institutionalization were regarded as the end-point events. The following data were collected on the structured questionnaire (see Appendix II):

1. The use of institutional care (hospital inpatient stay)
2. Inpatient rehabilitation
3. Outpatient visits to doctor
4. Physiotherapy (outpatient or home)
5. Attendance to day center

6. The use of home help service (including night call)

7. House-calls by a nurse (home nursing)

8. The use of community support (transportation, meals on wheels, safety phone).

The use of special therapy (occupational therapy, speech therapy and neuropsychological rehabilitation) was also inquired, although it was unlikely that an elderly patient with a remote stroke would receive that type of service. The number of physiotherapy sessions in the year before study entry could not be reliably assessed.

The statistics from the National Research and Development Centre for Welfare and Health (STAKES) were available to check the acquired data concerning the use of inpatient stay in hospitals and rehabilitation institutes in the year prior to the study and over the years to the end of 1998.

4.7. Quality of life

For several years researchers have approached QoL assessment by measuring different dimensions of physical, psycholocigal and social well-being. The present study included each of the dimensions and an additional way of simply asking the patient and the caregiver to measure their QoL by drawing a mark on a visual analogue scale (VAS). The VAS was performed by the participants who completed the three year follow-up. The patients and the caregivers were given instructions to include physical, psychological as well as social performance in the respondent´s view of his or her QoL after they had completed the study. The VAS used in the present study was a 100 -mm long bar graded with "worst possible quality of life" at the bottom and "best possible quality of life" at the top. The respondents were instructed to draw an intersecting mark on the bar enabling the rater to measure the length in millimeters from the bottom of the bar.

The VAS for QoL has not been validated, and therefore it was used in the present study as a secondary outcome measure. Correlations with other functional measures were tested.

4.8. Patient satisfaction with intervention

Along with the QoL assessment, a structured questionnaire was utilized to evaluate satisfaction with various aspects of the intervention. The following questions were included:

1. In your opinion the most important effects of the intervention were

☐ Physical condition improved
☐ Mood improved
☐ Social activity increased
☐ Access to support and care improved
☐ No effects

2. How would you rate the information and the support provided by the specialist nurse?

☐ Excellent
☐ Good
☐ Too little
☐ Not at all

3. How do you rate the intervention courses as a form of rehabilitation ?

☐ Excellent
☐ Good
☐ Too little

☐ Not at all

4. As the caregiver of a stroke patient what kind of attention did you receive during the follow-up ?

☐ Excellent
☐ Good
☐ Too little
☐ Not at all

All the participants that completed the study were asked the following question:

5. How important do you find the existence of a support worker for stroke survivors?

☐ Very important
☐ Less important
☐ Not necessary

4.9. Economic evaluation

The data on the direct costs of health care and social services were collected as shown in Table 3. The intervention team kept account of the travel costs of home visits. The travel costs incurred by the use of health care services could not be collected reliably and were thus excluded. The costs of the intervention protocol (patient assessments, data collection, etc.) were not included in the evaluation. Home visits and counselling support for the patients and caregivers was estimated to take 35% of the working time of the specialist nurse, which was included in the costs of the intervention (Pitkänen 2000). The costs of walking aids or adaptive instruments were excluded. The indirect costs incurred by informal care were not calculated in the present study. Pensioner's care benefits and caregiver benefits are considered as income transfers and not real costs to society (Luce et al. 1996) and hence were not analyzed or compared between the groups.

The annual reports for collecting the unit costs for the economic evaluation were available from the following sources: the Office of Social and Health Affairs of the city of Kuopio, Kuopio University Hospital, the municipalities of Kiuruvesi and Leppävirta and the Municipal Consortium for Health Care of Siilinjärvi and Maaninka. The average unit cost of the three latter sources was used to calculate the costs of health center in-patient stay in all of the rural communities. The unit costs of hospital in-patient stay in the two district hospitals, Iisalmi and Varkaus, were included in the annual reports of Kuopio University Hospital. The annual reports of all of the above mentioned municipalities were used to calculate the average unit cost for social services in the community. The average unit costs were applied simply because annual reports were not available from all of the municipalities involved or the specific data were missing. The overall costs of the follow-up years were compared to those of the year before the study. See Appendix III for further details.

Table 3. Assessment of direct costs.

Service item	Cost item	Source of data
Institutional care:	Average cost of bed day	Annual reports: Kuopio university hospital, the city of Kuopio, the municipalities of Kiuruvesi, Leppävirta, Siilinjärvi & Maaninka
Hospital inpatient stay		
Rehabilitation		
Nursing homes		
Homes for the aged		
Outpatient health care:	Average cost of visit:	Annual reports as above
Hospitals	doctor, all therapists	Makkonen & Asikainen 1998
Health centers	doctor, all therapists	
Private clinics	doctor, all therapists	
Home visits	physiotherapist	
Community support		
Day hospital	Average cost of visit	Annual reports as above
Home help service	Average cost of visit	
Home nursing	Average cost of visit	
Meals on wheels	Monthly cost	
Transportation	Monthly cost	
Safety phone	Monthly cost	
Intervention		
Courses (patient & caregiver)	Cost per day	Annual reports of Neuron
Specialist nurse support	35% of the annual salary	Pitkänen 2000
Travel costs	Cost per km	Driving diary
Phone	Monthly cost	Phone bills

4.10. Rehabilitation in the intervention group

4.10.1. Intervention courses

The purpose of the study was to investigate whether a long-term rehabilitation with short annual courses of increased physical and social activity and counselling support had beneficial effects on patients aged 65 or more, who received a pensioner's care benefit. The initial courses started 1-3 weeks after the baseline assessments. The length of the course was 10 days and each course consisted of 6-8 stroke patients and their caregivers. The rehabilitation program was conducted by a multidisciplinary team including a specialist nurse, a social worker, a physiotherapist and a neurologist. The core of the intervention course consisted of functional group therapies. Functional tasks like expressing the feelings by painting and group discussions, art and crafts, games, glass painting and printing of a t-shirt were included in each course. Lectures and discussions in the group aimed at increasing the knowledge of stroke and the post-stroke recovery. The more informal part of the course consisted of shared leisure activities, e.g. a trip to a nearby tourist attraction.

An assessment by a speech therapist was provided to the patients with dysphatic problems. An occupational therapist taught the group of participants new skills to facilitate independence in ADL, counselled them on the use of special equipment and encouraged the patient and the caregiver to pursue social and leisure activities. The patients did not receive individual physiotherapy or occupational therapy. A neuropsychologist counselled on the adjustment processes involved in recovery after stroke and on methods to cope with the disability.

The follow-up courses were carried out one and two years after entry to the study and each follow-up course lasted 5 days. Both the initial and the follow-up courses included a 30-45 minute daily session of group exercise. The functional group therapies and discussions on topics related to coping with disability were included in a similar manner as during the initial course. The participants were informed and counselled on the various forms of support available in the community. Patients sharing the same geographical locations were invited to join the courses together, if possible, in order to promote social interaction beyond the study program. Social and leisure activities were provided and the advantage of group dynamics was used to create bonds between participants. Again, as many of them as possible were directed to join the follow-up courses to strengthen the sense of togetherness.

Outpatient or home physiotherapy was provided between the courses as required. If there was some urgent need, e.g. if living at home was jeopardized, an inpatient rehabilitation period of 10-14 days could be arranged in Neuron.

4.10.2. Counselling support

The specialist nurse and the physiotherapist visited the patient and his or her caregiver within two weeks after they had completed the initial course. Problems that compromised independence in ADL were investigated. The need for special aids, reconstruction of house interior or the use of social services was evaluated. The patient or the caregiver was instructed to contact the specialist nurse whenever their concern was related to coping with the disability. Additional home visits were arranged by the specialist nurse as required, keeping an account of all visits. After the follow-up courses, the specialist nurse alone visited the patient and encouraged him or her to maintain telephone contact. Start-ups of local self-organizing exercise or social activity groups were encouraged to provide a network of relationships and the sense of togetherness within the intervention group.

4.10.3. Staff and setting

The intervention courses were conducted by a team with established skills in functional group therapies, an essential method in facilitating adjustment and improving coping with disability. The core team consisted of four specialist nurses and a social worker. One of the nurses was in charge of coordinating the appropriate group of patients in the courses, counselling and providing the support between the courses and collecting and recording the data of the assessments performed by himself or by the physiotherapist or the neurologist. The team was supplemented by a physiotherapist and a neurologist contributing their experience of stroke rehabilitation to the courses. An occupational therapist, a speech therapist and a neuropsychologist, all professionals in stroke rehabilitation, provided expert assistance to the patients and their caregivers during the initial courses. The staff members were not changed during the follow-up except for the physiotherapist (after the baseline assessments). All the courses took place in the Brain Research and Rehabilitation Center Neuron, Kuopio, an institute specializing in stroke rehabilitation.

4.11. Rehabilitation in the control group

Patients in the control group received no special intervention. They had no contact with the study members between the follow-ups except for a pre-Christmas get-together party once in the middle of the project. The control subjects did not receive any detailed counselling but, to meet the demands of good clinical rapport, they were provided with general information on available services in the community, if such a need clearly emerged. Otherwise the control subjects were assumed to receive whatever was the form of service or care provided by the current care policies in their home community.

4.12. Statistical analysis

The categorical data of the subjects were compared between the groups using the Chi-square and Fisher's exact test. Independent samples t-test was applied in cases with continuous data. The Mann-Whitney U test was used to compare the differences in the median values of the functional scales whenever the variable was not normally distributed. Repeated measures ANOVA was used to test the significance of differences for functional assessment scales from baseline to 3-year follow-up. ANOVA of general factorial model using the baseline scores as covariates was also applied to examine the significance for the change of scores with the functional instruments. The Wilcoxon signed rank test was used to examine significances within groups. The Kaplan-Meier method combined with the log rank test was applied to compare the mean survival times with regard to end-point events between the groups. The Spearman correlation was calculated between the results of the functional scales and the QoL measure of VAS.

All statistical procedures were performed using the SPSS version 6.1.4. and the StatXact version 4.0.1.

4.13. Funding

The present study was funded by RAY, a Finnish organization administering gaming activities, which then allocates the revenues to non-profit purposes.

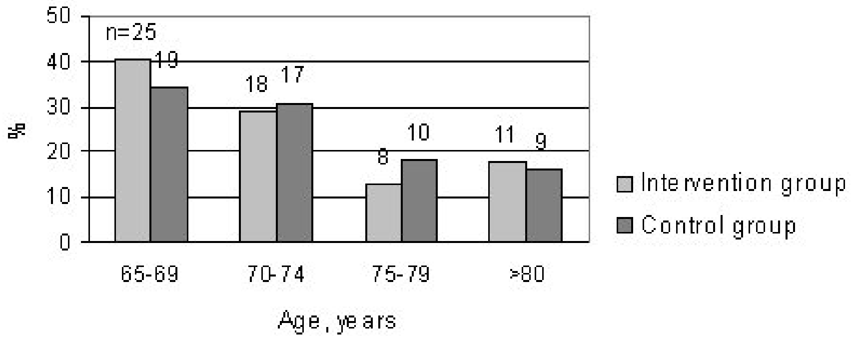
5. RESULTS

5.1. Clinical characteristics

5.1.1. Age and gender

A total of 117 patients were included in the study and underwent the baseline assessments. Sixty-two patients were randomized to the intervention group and fifty-five to the control group. One patient in the intervention group dropped out before entering the initial course due to fatigue. The median age of the patients in the intervention group was 71,3 years (range 64,3 - 84,3 years) and in the control group 72,6 years (range 64,8 - 85,4 years). The proportion of patients aged 80 years or older was almost equal in both groups (17,7% vs. 16,2%). The age distribution of the patients in the two groups is shown in Figure 2. The percentage of male subjects was 69,4% in the intervention group and 50,9% in the control group.

Figure 2. Age distribution of the patients in intervention group and control group.



5.1.2. Social characteristics

The intervention and the control groups were comparable with regard to demographic parameters at the study entry. The proportion of female caregivers was greater in the intervention group (83,3% vs. 63,9%). One-fifth (19,4%) of the patients in the intervention group and one -fourth (25,5%) in the control group had a professional education. A majority of the patients in both groups considered their economical status as moderate and only about one-tenth of the patients found themselves in a poor economical situation. In both groups 16% of the participants considered themselves as well-off. Only one patient in the intervention group and five patients in the control group listed social pursuits as their main hobbies. Approximately half of the patients in both groups reported a distressing life event such as the decease or a serious illness of a spouse or a close relative or some other tragic event had affected their life less than five years before study entry. The percentage of non-smokers was high in both groups (93,5% vs. 96,5%). There was no difference in alcohol consumption between the groups. Forty-two patients (68,0%) in the intervention group and forty-one (74,5%) in the control group were non-users and only a small minority (11,3% and 5,5%, respectively) consumed alcohol at least once a week. All of the basic characteristics of the patients are presented in Table 4.

Table 4. Basic characteristics of the patients.

	Intervention group	**Control group**
	n (%)	**n (%)**
Patients	62	55
Age, mean (SD)	72,2 (5,7)	72,1 (5,7)
Male sex, all	43 (69,4)	28 (50,9)
>=75 years	14 (22,6)	10 (18,2)
Marital status		
married	43 (69,4)	38 (69,1)
unmarried	3 (4,8)	2 (3,6)
widowed	15 (24,2)	15 (27,3)
divorced	1 (1,6)	-
Education		
elementary school only	50 (80,6)	41 (74,5)
Poor economical status	6 (9,7)	7 (12,7)
Hobbies		
sedentary	52 (83,9)	42 (76,4)
exercise	9 (14,5)	8 (14,5)
Living alone	13 (21,0)	10 (18,2)

Frequency of contacts with friends		
<=once a week	32 (54,8)	34 (61,8)
Distressing life event	33 (53,2)	25 (45,5)
Smokers	4 (6,5)	2 (2,6)
Alcohol >= once a week	7 (11,3)	3 (5,5)

5.1.3. Source of information

Only fifteen (24,2%) patients in the intervention group and sixteen (29,1%) patients in the control group provided all of the relevant information by themselves. Thus, the majority of the patients needed support from their caregivers when interviewed to provide the data according to the structured questionnaire (Appendix I). The need for support was not explained solely by dysphatic problems and, overall, the finding may reflect the level of dependence in social activities in the majority of the patients.

5.1.4. Medical history

Twenty-three patients (37,1%) in the intervention group and fourteen (25,5%) in the control group had had prior myocardial infarction but the difference was not significant (p=0.180). A history of two or more strokes was found in 17,7% of the patients in the intervention group and 14,5% in the control group. There were no statistically significant differences in comorbidity between the two groups. The prevalence of concomitant diseases is shown in Table 5.

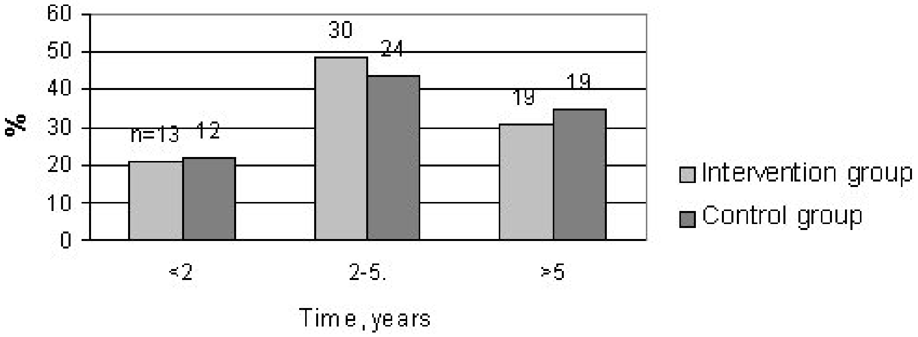
Table 5. The prevalence of concomitant diseases at study entry.

	Intervention group n=62	**Control group n=55**
	n (%)	**n (%)**
Myocardial infarction	23 (37,1)	14 (25,5)
Coronary heart disease	38 (61,3)	26 (47,3)
Hypertension	43 (69,4)	42 (76,4)
Atrial fibrillation	10 (16,1)	12 (21,8)
Arterisclerosis obliterans	12 (19,4)	9 (16,4)
Diabetes	13 (21,0)	16 (29,1)

5.1.5. Time interval from stroke to study entry

The mean time interval from the most recent stroke to the baseline of the study was 4 years 2 months (range 7 months to 11 years 1 month) in the intervention group and 4 years 1 month (range 6 months to 12 years 4 months) in the control group. The percentage of subjects with a stroke less than two years before entering the study was equal in both groups (21,0% vs. 21,8%). The distribution of time interval from stroke to study entry is shown in Figure 3.

Figure 3. Distribution of time interval from the most recent stroke to study entry.



5.1.6. Characteristics of stroke

Thirty-five patients in both groups (56,4% vs. 63,6%) had been diagnosed as having an atherothrombotic brain infarction. There were slightly more intracerebral haemorrhages (16,1% vs. 7,3%) and less embolic infarctions (14,5% vs. 23,6%) in the intervention group, but the difference between the two groups was not statistically significant. Only six patients in the study population had a cerebellar infarction and thirteen patients had suffered a brain stem infarction. The two groups were comparable with regard to the localisation of brain infarction as shown in Table 6.

Table 6. Type and localisation of brain infarction among the study subjects.

		Intervention group n=62	**Control group N=55**
		n (%)	**n (%)**
Type of lesion			
	Atherothrombotic	35 (56,4%)	35 (63,6)
	Embolic	9 (14,5)	13 (23,6)
	ICH	10 (16,1)	4 (7,3)
	Unknown	8 (12,4)	3 (5,5)
Site of lesion			
	Left hemisphere	28 (45,2)	23 (41,8)
	Right hemisphere	23 (37,1)	24 (43,6)
	Cerebellum	4 (6,5)	2 (3,6)

	Brain stem	7 (11,3)	6 (10,9)

5.1.7. Clinical findings

Overall, the two groups were well matched with the clinical findings (Table 7). A total of twenty-four patients in the study population were dysphatic and two-fifth of the patients had clinically hypesthetic sensory dysfunction. The data of the occurrence of one or more epileptic seizures following stroke was acquired by inquiry or from the hospital files of the patients. The number of patients with recurrent seizures was not assessed. Patients with prestroke epilepsy were excluded from the prevalence rate. Shoulder pain was recorded when occurring persistently but also if the patient reported a frequent (daily) feeling of pain related to a specific arm position or movement. The prevalence of bladder dysfunction was higher in the control group but the difference was not statistically significant (25,8% vs. 41,8%; p=0.067).

Physical performance was classified using the NYHA-scale (New York Heart Association, 1964) based on the patient´s or the caregiver´s verbal report. The percentage of patients classified to NYHA >2 was slightly higher in the intervention group, but the difference was not significant (50,0% vs. 38,2%, Chi-square; p=0.270).

Table 7. Clinical findings in baseline examination.

	Intervention group n=62	**Control group n=55**
	n (%)	**n (%)**
Aphasia / dysphasia	14 (22,6)	10 (18,2)
Hemianopia	5 (8,1)	6 (10,9)
Hemihypesthesia	25 (40,3)	22 (40,0)
Seizures	7 (11,3)	5 (9,1)
Shoulder pain	18 (29,0)	12 (21,8)
Contractures	3 (4,8)	2 (3,6)
Bladder dysfunction	16 (25,8)	23 (41,8)
Performance NYHA >=2	31 (50,0)	21 (38,2)
Major complaint: disability in ADL	25 (40,0)	24 (45,5)
Blood pressure, mean (SD)		
Systolic	154 (21,7)	155 (24,2)
Diastolic	87 (11,7)	90 (11,2)
Weight, mean (range)		
Men	77,2 (57-100)	75,3 (60-101)
Women	73,0 (53-100)	74,2 (36-135)

5.2. Baseline data of functional assessments

5.2.1. Motor function and ambulation

Reflex activity, volitional movements, coordination and speed of the upper and lower extremities as well as postural stability were assessed with the Brunnström-Fugl-Meyer scale. Seventeen patients (27,5%) in the intervention group and eighteen (33%) in the control group scored less than 35. The analysis of postural stability of the patients revealed no difference between the two groups. The median value of the total score for balance was 9 in both groups.

Walking skills were analysed by measuring gait speed in a 10 meter indoor track and by classifying the patients into different ambulation categories according to Holden et al. (1984). There was great variability in the speed of walking in both groups. The fastest time was 8 seconds in the intervention group and 5 seconds in the control group whereas the slowest performance took 228 seconds and 295 seconds in the respective groups. Eight patients would have needed such firm support that they could not be tested. In addition, three patients in both groups were categorized as `non-functional´, i.e. not being able to walk or requiring assistance from more than one person. Half of the patients (50,0%) in the intervention group and 43,5 % in the control group were fully independent in walking on any surface. Forty-four patients (71,0%) in the intervention group and forty-one (74,5%) in the control group needed the assistance of a walking aid while being tested.

5.2.2. Activities of daily living

Twenty-five patients in both groups (40,0% vs. 45,5 %) viewed their disabilities in daily activities as the major problem encountered in living at home (Table 7). The next most frequent complaint among the patients in the intervention group was pain (14,5%) whereas in the control group dizziness was reported (14,5%). The caregivers' opinions on the major problems for the patients to live at home were in accordance with the patients' views.

Functional ability in daily activities was evaluated by using the Barthel Index and the NOSGER scale. The median value of the total score for the BI was 75 in both groups. In order to compare different levels of functional disability the patients were distributed into three categories of the BI according to Sulter et al. (1999). There were no differences in the distribution of patients to the BI categories between the groups. The proportion of patients scoring <60 in the BI indicating higher degree of dependence was comparable in the two groups (22,6% in the intervention group and 27,3% in the control group). The highest level of BI scores (85-100) was achieved by 21 (33,9%) patients in the intervention group and 22 (40,0%) in the control group. The two groups were also comparable with regard to the analysis of individual items of the BI.

The median value of the total score for the NOSGER was 62,5 (range 33,0-87,0) in the intervention group and 60,0 (range 33,0-92,0) in the control group. The two groups were also comparable with regard to the different NOSGER dimensions.

5.2.3. Mood and cognitive function

There were 34 (54,8%) patients in the intervention group with a score of 7 or more for the MADRS. whereas the respective number of patients in the control group was 25 (45,5%). The percentage of moderately or severely depressed patients as indicated by the MADRS score of 20 or more was equal in both groups (Table 7).

Twelve (19,4%) patients in the intervention group and fifteen (27,3%) in the control group could not be tested with the MMSE mainly because of dysphatic problems. Sixteen out of the fifty patients (32,0%) in the intervention group assessed with the MMSE achieved a score of 23 or less indicating clinically significant cognitive impairment. In the control group, nine (22,5%) patients scored 23 or less in the MMSE. The mean value of the total score for the MMSE was 24,5 (SD + 4,4) in the intervention group and 25,4 (SD + 3,5) in the control group.

Table 8. Summary of the functional assessments at baseline. There were no statistical differences

between the groups. IQR=interquartile range.

		Intervention group n=62	Control group n=55
BI	median, IQR	75,0 (60,0-90,0)	75,0 (50,0-90,0)
	>=85, number of patients (%)	21 (33,9)	22 (40,0)
	<60, number of patients (%)	14 (22,6)	15 (27,3)
NOSGER	median, IQR	62,5 (53,0-73,0)	60,0 (52,0-68,0)
	<50, number of patients (%)	9 (14,5)	10 (18,2)
	>=70, number of patients (%)	19 (30,6)	12 (21,8)
MADRS	median, IQR	8,0 (2,0-14,0)	6,0 (2,0-14,0)
	<7, number of patients (%)	28 (45,2)	30 (54,5)
	>=20, number of patients (%)	7 (11,3)	6 (10,9)
MMSE	median, IQR	25,0 (22,0-28,0)	25,0 (23,0-28,0)
	<=23, number of patients (%)	16 (32,0)	9 (22,5)

5.2.4. Caregiver strain at study entry

The emotional distress of the caregivers was evaluated using the 12-item Finnish version of the General Health Questionnaire. The caregiver was instructed to complete the questionnaire at home to provide the familiar context to his or her judgements. The median values of the GHQ were comparable in the two groups (5,0 vs. 4,5) at the initial assessment. The proportion of caregivers scoring 5 or more on the GHQ was equal in the two groups (50,9% vs. 50,0%). The age, the degree of disability in basic ADL or the severity of depression of the patient were not associated with caregiver strain.

5.2.5. Use of health care and social services

The need for community support before entering the study was compared between the groups. There were no significant differences in the need for home help service, nursing service, meal service, transport service or in attendance to day hospital between the two groups. The need for safety phones was also similar in both groups. Assistive devices for basic activities were used by 45,2% of the patients in the intervention group and 38,2% in the control group. The use of community support and social services in the year before study entry is presented in Table 9. There was no data available on the use of out-patient health care services (i.e. visits to doctor and physiotherapy). The number of in-patient days in institutional care and rehabilitation facilities was collected over the period of one year preceding the baseline assessment of the study. No significant differences could be found between the groups with regard to their need for in-patient stay prior to the study (Table 10).

Table 9. Use of community support over the year preceding the study. The figures for the last five items represent the number (%) of patients using the service or support.

	Intervention group n=62 n (%)	Control group n=55 n (%)

Home help service, patients visits	16 (25,8) 2992	15 (27,3) 2922
Home nursing, patients visits	18 (29,0) 341	17 (30,9) 214
Day center, patients visits	10 (16,1) 372	17 (30,9) 214
Meal service	8 (12,9)	11 (20,0)
Transport service	27 (43,5)	21 (38,2)
Safety phone	6 (9,7)	7 (12,7)
Caregiver benefit	14 (22,6)	7 (12,7)
Pensioner's care benefit		
lower	24 (38,7)	23 (41,8)
middle	29 (46,8)	23 (41,8)
higher	6 (9,7)	8 (14,5)

Table 10. Use of inpatient hospital and rehabilitation services prior to the study.

	Intervention group n=62 n (%)	**Control group n=55 n (%)**
Kuopio University Hospital		
Patients	19 (30,6)	14 (25,5)
Periods	25	22
Days	155	165
District hospitals		
Patients	5 (8,1)	5 (9,1)
Periods	5	10
Days	116	62
Health Centers		
Patients	21 (33,9)	26 (47,3)
Periods	46	41
Days	339	806
Intitutional care, total		

Patients	34 (54,8)	30 (54,5)
Periods	76	73
Days	670	1033
Rehabilitation institutes		
Patients	12 (19,4)	8 (14,5)
Days	178	152

5.3. Outcome of 3-year follow-up

5.3.1. Case fatality and institutionalization

Seventy-two (61,5%) subjects out of 117 completed the last follow-up assessments (Table 11). For three patients in both groups the final assessments were performed in their homes since their weak condition did not permit them to be transported to the assessment venue. For practical reasons these particular patients were not assessed with the BFM scale and the FAC. Gait speed over 10 meters was not measured. They did not undergo clinical neurological examination.

Eleven patients (17,7%) in the intervention group and nine patients (16,4%) in the control group died during the three year follow-up period. Six (9,7%) patients in the intervention group and ten (18,2%) in the control group were transferred to permanent institutional care. The mean time interval to institutionalization was 560 days (95% CI; 332 days to 787 days) in the intervention group and 632 days (95% C I; 442 days to 823 days) in the control group. The difference was not statistically significant (Kaplan -Meier log rank 0,52, p=0.469). Four (6,5%) and five (9,1%) patients in the respective groups dropped out. The number of patients dying or being transferred to permanent care during each year of follow-up are shown in Table 11. Gender and living conditions were of no predictive importance for institutionalization (Table 12). The age of 75 or older, on the other hand, was associated with increased number of transfers to permanent care in the whole study population (Chi-square=7,62; p=0.006). There were no significant differences in the number of patients dying during the three year follow-up between the two age populations in either of the two groups.

Two patients out of sixteen (12,5%) in the intervention group and five out of seventeen (29,4%) in the control group who needed assistance in walking at study entry were institutionalized by the end of the follow-up. Within the control group those who needed assistance or surveillance in walking were more likely to be transferred to permanent care compared to those who were independent (35,3% vs. 10,5%, Fisher's exact test; p=0.054). In the intervention group no such tendency was observed (12,5% vs. 8,7%).

Table 11. Number of participants at each assessment and number of end-point events during each year of follow-up in intervention (IG) and control group (CG).

	1. year		**2. year**		**3. year**	
	IG (%)	**CG (%)**	**IG (%)**	**CG (%)**	**IG (%)**	**CG (%)**
Participants	55 (88,7)	49 (89,1)	45 (72,6)	39 (70,9)	41 (66,1)	31 (56,4)
Drop-outs	2 (3,2)	3 (5,5)	3 (5,5)	3 (6,1)	-	-
Institutionalized	2 (3,2)	3 (5,5)	3 (5.5)	4 (8,2)	1 (2,2)	3 (7,7)
Deceased	3 (4,8)	1 (1,8)	5 (9,1)	3 (6,1)	3 (6,7)	5 (12,8)

Table 12. Number of patients transferred to permanent care and number of deaths in three years by age, gender, living conditions and walking dependency at study entry. IG=intervention group; CG=control group.

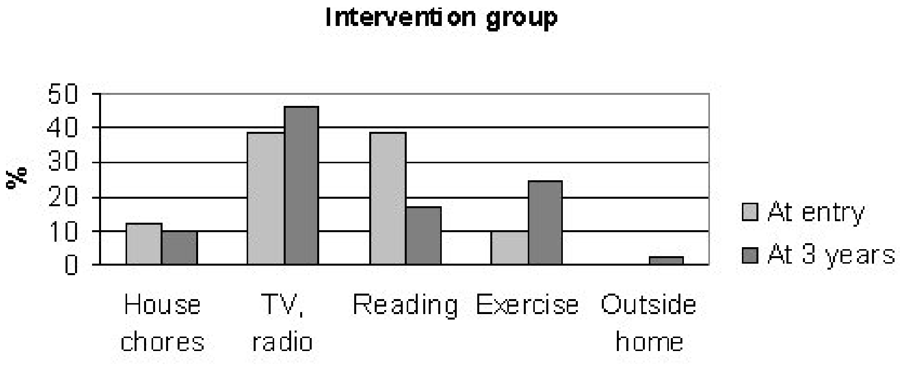
	Permanent care		**Deceased**	
	IG n (%)	**CG n (%)**	**IG n (%)**	**CG n (%)**
Men	5 (11,6)	5 (17,9)	9 (20,9)	5 (17,9)
Women	1 (5,3)	5 (18,5)	2 (10,5)	4 (14,8)
Age<75	2 (4,7)	4 (11,1)	7 (16,3)	5 (13,9)
Age>=75	4 (21,1)	6 (31,6)	4 (21,1)	4 (25,0)
Living alone	2 (14,3)	2 (14,3)	1 (7,1)	4 (28,6)
Cohabiting	4 (8,3)	8 (19,5)	10 (20,8)	5 (12,2)
Ambulation				
Dependent	2 (12,5)	6 (35,3)	4 (25,0)	4 (23,5)
Independent	4 (8,7)	4 (10,5)	7 (15,2)	5 (13,2)

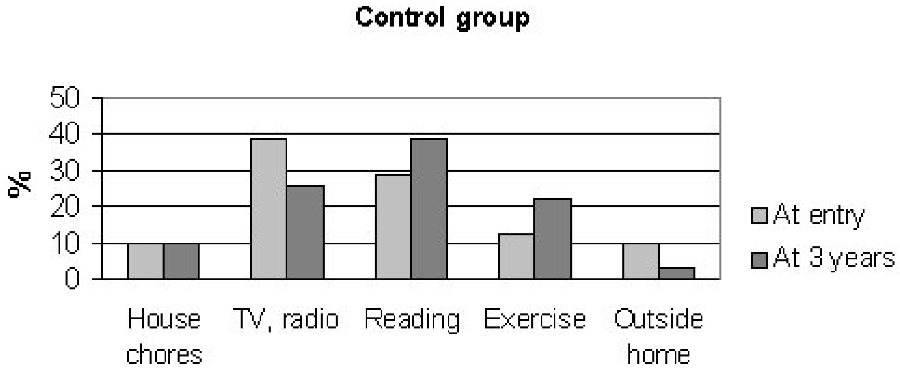
5.3.2. Changes in social circumstances

Dramatic events in social circumstances such as death of a spouse or a close relative did not have any effect on the need for permanent institutional care. Only three patients out of thirty-eight who underwent such changes in personal life were eventually admitted to institutional care. An opposite trend was actually seen since none of the nine patients who had two or more dramatic life events needed to be transferred to permanent care. The occurrence of events among the patients did not differ between the study groups: 35,5% of the patients in the intervention group and 36,4% in the control group had at least one event considered as a major distress.

The profiles of leisure activities were charted at study entry and at the follow-ups to examine the influence of the intervention on the social functioning of the patients. The proportion of patients who reported exercise as their major leisure activity increased in both groups during the follow-up. Otherwise, no substantial changes in the patterns of leisure activity were seen between the baseline and the end of the follow-up (Figure 4). An exercise group and a leisure club were established during the first year of follow-up with the help of counselling support by the staff. Six patients and ten caregivers were involved in the exercise group which was run on a voluntary basis. A network of five patients and their caregivers supervised by a nurse established a leisure club in another locality. None of the patients in the control group reported that they had part in any comparable group activities.

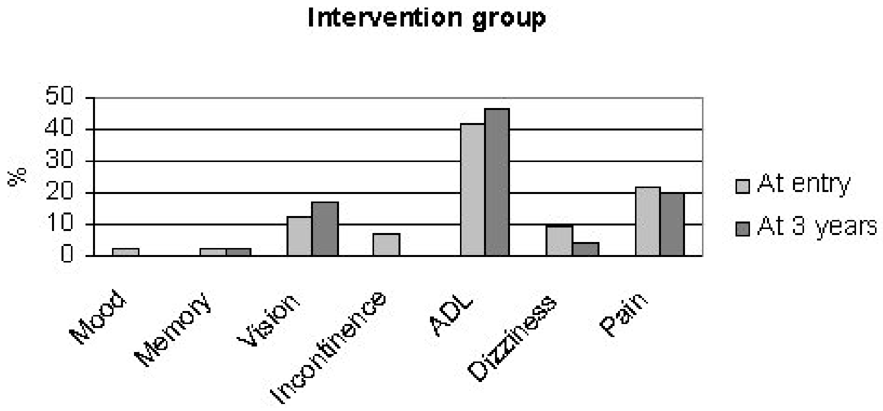
Figure 4. Leisure activity patterns in the intervention and the control groups at study entry and at 3 years. Five domains of leisure pursued by the proportion of patients who completed the follow-up (intervention group: n=41; control group: n=31) are shown below.

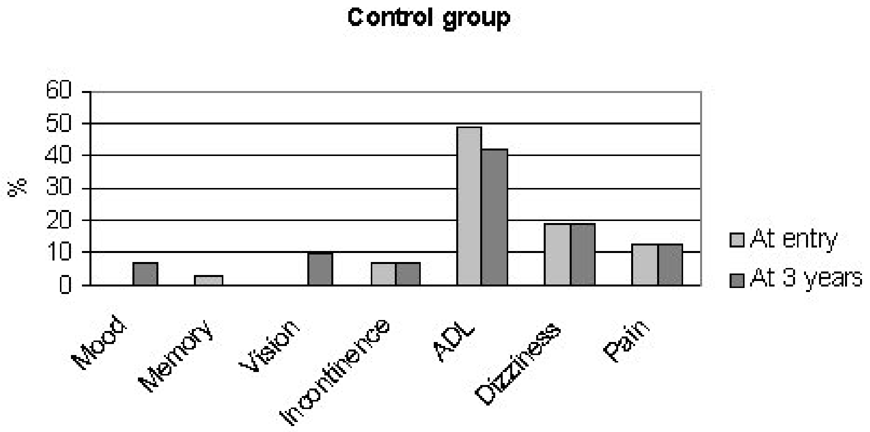




Another interest was to monitor the factors that were considered by the patients as their main problems in coping in their living environments. The most frequent problem hampering with coping at study entry was disability in ADL, and this remained the main problem at the end of the follow-up. No marked changes could be found in the patterns of responses of the patients concerning their main problems in coping (Figure 5).

Figure 5. Frequency of the factors considered by the patients as their main problem in coping at study entry and at 3 years (intervention group: n=41; control group: n=31).





5.3.3. Functional outcome

5.3.3.1. Motor function and ambulation

Forty patients (64,5%) in the intervention group and thirty-one (56,4%) in the control group could be assessed with the BFM and classified by the FAC at 3 years. No significant differences could be established between the groups regarding the change of median scores for motor function and balance by the BFM. The proportion of the patients independent in walking in the intervention group at three years was smaller than that at the baseline. Overall, the changes during the follow-up were marginal (Table 13).

Table 13. Comparison of the Functional Ambulation Categories (FAC) at entry and at 3 years. There were no significant differences between the groups in the distribution of the patients into different categories analyzed by contingency tables.

	At entry		**3 years**	
	Intervention group (n=62) n (%)	**Control group (n=40) n (%)**	**Intervention group (n=40) n (%)**	**Control group (n=31) n (%)**
FAC				
0 = Non-functional	3 (4,8)	3 (5,5)	4 (10,0)	2 (6,5)
1 = Dependent-level 2	1 (1,6)	3 (5,5)	4 (10,0)	2 (6,5)
2 = Dependent- level 1	7 (11,3)	5 (9,1)	5 (12,5)	4 (12,9)
3 = Dependent-supervision	5 (8,1)	6 (10,9)	2 (5,0)	2 (6,5)
4 = Independent-level surface	15 (24,2)	14 (25,5)	7 (17,5)	8 (25,8)
5 = Independent	31 (50,0)	24 (43,6)	18 (45,0)	13 (41,9)

Gait speed was measured for 33 patients (80,5%) in the intervention group and for 28 (90,3%) in the control group at three years. The median time to walk 10 meters indoors improved slightly in both groups. The control group outperformed the intervention group, but as the measured times varied considerably, the difference between the groups was not statistically significant (Table 14).

Table 14. Median scores (IQR) for motor function and balance by BFM and median time (IQR) to walk 10 m. The Mann-Whitney U- test revealed no significant differences between the groups. IQR = interquartile range.

	At entry		**At 3 years**	
	Intervention group n=62	**Control group n=55**	**Intervention group n=40**	**Control group n=31**
BMF				
Motor function	64,0 (32,0-83,0)	72,0 (26,0-89,0)	67,5 (33,5-84,0)	73,0 (19,0-89,0)
Balance	9,0 (7,0-10,0)	9,0 (7,0-11,0)	9,0 (6,5-11,0)	9,0 (7,0-12,0)
	(n=57)	**(n=50)**	**(n=40)**	**(n=28)**
Gait speed 10 m, s	21,0 (16,0-44,0)	22,5 (13,0-44,0)	19,0 (12,0-44,0)	15,5 (11,0-44,0)

5.3.3.1. Activities of daily living

There were no significant changes in functional ability within or between the groups during the three year follow-up regarding the BI scores. The mean value of the total score of the BI decreased slightly in both groups (4,7% in the intervention and 2,0% in the control group) among the seventy-two subjects who completed the study. The analysis of variance controlling the effect of baseline scores by defining them as covariates found no statistically significant differences in the change of scores between the two groups among the patients who completed the study. Changes in mean values of the BI scores for all the subjects assessed at study entry and at three years were negligent. Finally, the distribution of the patients into three BI categories (Sulter et al. 1999) revealed no significant differences between the groups (Table 15).

Table 15. Distribution of the patients into three BI categories and mean values of the total BI scores at entry and at 3 years.

	At entry		**3 years**	
	Intervention group (n=62) n (%)	**Control group (n=55) n (%)**	**Intervention group (n=41) n (%)**	**Control group (n=31) n (%)**
BI score >=85	21 (33,9)	22 (40,0)	19 (46,3)	13 (41,9)
BI score 60-80	27 (43,5)	18 (32,7)	12 (29,3)	7 (22,6)
BI score <60	14 (22,6)	15 (27,3)	10 (24,4)	11 (35,5)
Mean +/- SD	72,9 +/- 21,1	71,6 +/- 23,6	71,6 +/- 25,6	71,8 +/- 24,8

A severe disability in ADL indicated by a BI score of less than 60 was associated with more frequent transfers to permanent care. In the whole study population, nine (10,2%) patients with the BI score of 60 or more were institutionalized compared with the seven (24,1%) who scored less than 60 (Chi-square=3,58; p=0.059).

The NOSGER scale which measures several essential domains of human behavior as well as functional abilities revealed significant differences between the groups over three year period (Table 16, Figure 6). The NOSGER total score at three years was significantly better in the intervention group (independent t-test; p=0.026). Repeated measures ANOVA for the NOSGER showed a significant difference between the two study groups for the assessments over three years (p=0.007). Within-subjects analysis of the repeated assessments indicated that a significant improvement had occurred in the intervention group (p=0.010/Bonferroni). The analysis of the different dimensions showed an improvement for IADL, mood, memory and social behavior. The change of mean scores for the first two of these items between the base line and the final assessment was statistically significant (Wilcoxon; p=0.016 and p=0.002, respectively). The differences in the change of scores for three items (IADL, mood and disturbing behavior) between the groups were also significant (Figure 7). In the control group, there was a significant change only concerning disturbing behavior with the change in the scores being positive indicating an unfavorable development in the follow-up period.

Lower functional capabilities measured with the NOSGER scale (>70) were associated with more frequent admissions to permanent care (Chi-square=5,26; p=0.022).

Table 16. Summary of the evaluation of the NOSGER scale with mean values and SDs at entry and at three years.

	At entry		**3 years**	
	Intervention group (n=62) n (%)	**Control group (n=55) n (%)**	**Intervention group (n=41) n (%)**	**Control group (n=31) n (%)**
NOSGER, total	62,9 +/- 13,3	60,8 +/- 11,8	55,7 +/- 14,9	62,9 +/- 13,7
IADL	13,5 +/- 3,3	13,1 +/- 3,2	12,1 +/- 3,2	13,5 +/- 3,4
Self-care	7,9 +/- 2,9	7,8 +/- 2,6	7,6 +/- 3,1	8,5 +/- 3,2
Mood	11, 8 +/- 2,9	11,4 +/- 2,5	10,0 +/- 2,5	11,3 +/- 2,6
Memory	10, 5 +/- 3,2	10,2 +/- 2,9	9,2 +/- 2,7	10,4 +/- 3,3
Social behavior	11,2 +/- 3,2	11,0 +/- 3,1	9,8 +/- 2,7	10.8 +/- 2,6
Disturbing behavior	7,9 +/- 2,5	7,3 +/- 2,5	7,6 +/- 2,3	8,4 +/- 2,3

Figure 6. Mean total scores for the NOSGER over three years of follow-up. The difference in the change of scores from baseline to 3-year follow-up between the groups was significant (ANOVA; p=0.003).

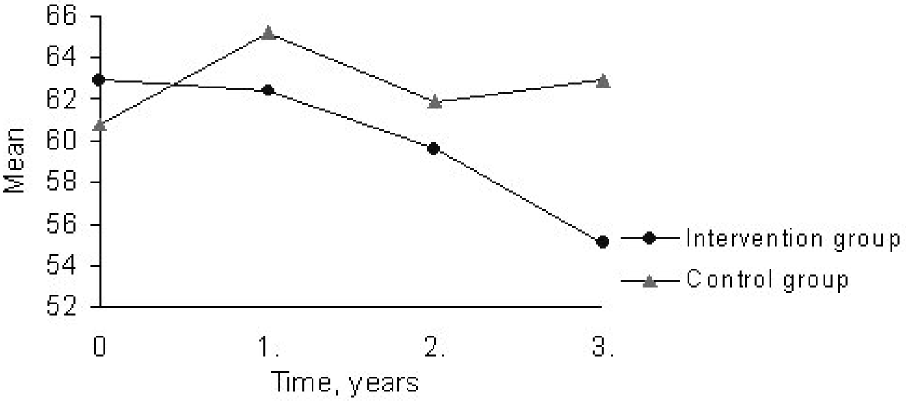
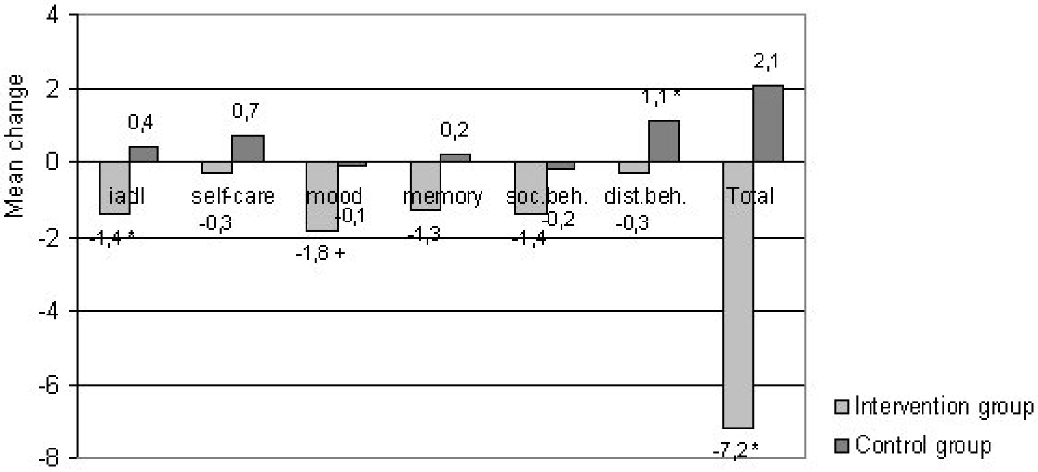


Figure 7. Change of mean scores for different NOSGER dimensions from baseline to 3-year follow-up. The significance of difference between the groups for each dimension was calculated through the use of ANOVA General Factorial Model with baseline scores as covariates. * p<0.005; + p<0,05.



5.3.3.2. Mood and cognitive abilities

There was a decline in the median scores for the MADRS among the patients in the intervention group over the three year follow-up suggesting an amelioration in mood. The difference between the baseline and the 3-year scores, however, was not statistically significant (Wilcoxon matched pairs test; p=0.228). In the control group, no actual change in the median values for the MADRS scores was detected. Analysis of variance was used to compare the two groups with regard to the change of median scores between baseline and three years (p =0.056). In all, 34,1% of the patients in the intervention group and 45,2% in the control group experienced disturbance of mood (MADRS score >7) at the three-year follow-up assessment. Only three (7,3%) patients in the intervention group and five (16,1%) in the control group scored 20 or more at three years (Table 17).

The rate of institutionalization was slightly higher for the depressed patients (MADRS score >20) than for the non-depressed (30,8% vs. 11,5%; Fisher's exact test, p=0.078). The patients in the intervention group who scored 7 or more for the MADRS were admitted more frequently to permanent institutional care than the patients who scored less than 7 (Fisher's exact test; p=0.028).

Table 17. Evaluation of baseline and 3-year scores for MADRS. The last row shows median scores at entry for the patients who completed the follow-up.

	At entry	**3 years**

	Intervention group (n=62) n (%)	Control group (n=55) n (%)	Intervention group (n=41) n (%)	Control group (n=31) n (%)
MADRS < 7, %	45,2	54,5	65,9	54,8
7-19, %	43,5	34,6	26,8	29,1
>=20, %	11,3	10,9	7,3	16,1
MADRS, median (IQR)	8,0 (2,0-14,0)	6,0 (2,0-14,0)	4,0 (0-11,0)	5,0 (2,0-17,0)
	(n=41)	**(n=31%)**		
median (IQR)	6,0 (2,0-12,0)	6,0 (2,0-11,0)		

The MMSE did not establish any significant changes between the groups or within the groups during the follow-up period. Ten (27,8%) patients in the intervention group and six (21,4%) in the control group scored less than 24 for the MMSE. The mean value of the MMSE was 24,7 + 5,2 in the intervention group and 25,7 + 3,6 in the control group at three years. There was actually no change in the mean values of the MMSE in either of the two groups over 3 years of follow-up (Table 18).

Cognitive impairment at study entry assessed with the MMSE had a strong association with institutionalization later on. Nine patients out of twenty-five (36,0%) who scored less than 24 were eventually transfered to permanent care, whereas the respective proportion of patients among those who scored 24 or more was only 4,6% (Fisher's exact test; p<0.001). The difference between high scorers (>24) and low scorers (<24) within the groups in regard to institutionalization was considerable both in the intervention and the control group (Fisher's exact test; p=0.031 and p=0.003, respectively).

Table 18. Evaluation of the MMSE.

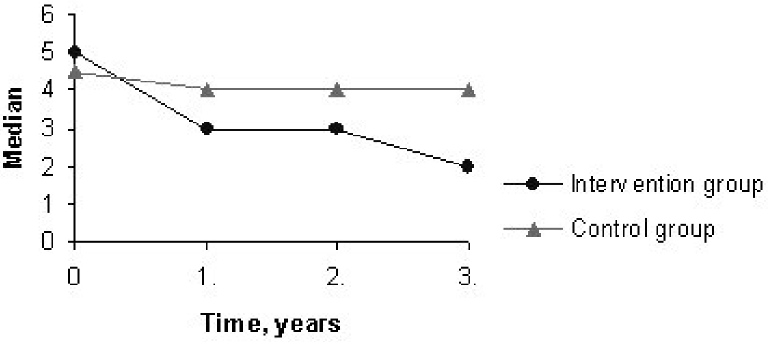
	At entry		3 years	
	Intervention group (n=50) n (%)	Control group (n=40) n (%)	Intervention group (n=36) n (%)	Control group (n=28) n (%)
MMSE, mean +/- SD	24,5 +/- 4,4	25,4 +/- 3,5	24,7 +/- 5,2	25,7 +/- 3,6
MMSE < 24, %	32,0	22,5	27,8	21,4

5.3.3. Caregiver strain

Caregivers' feelings of strain were evaluated throughout the study with a 12-item GHQ. The caregiver received the form at the end of each assessment with a prepaid postage envelope and instructions to express the responses regarding his or her feelings over the past couple of weeks. Since some of the patients did not have anyone who could be considered as a caregiver, it was obvious that some missing cases would be encountered. Nevertheless, the percentage of responses remained high throughout the follow-up varying within the range of 83,6% -90,3% in the intervention group and 79,5%-87,1% in the control group. The median score for the GHQ at study entry was 5,0 (IQR 1,0-

8,0) in the intervention group and 4,5 (IQR 1,0-8,0) in the control group. The respective values at three years were 2,0 (IQR 1,0-7,0) for the intervention group and 4,0 (IQR 1,0-7,0) for the control group. The difference between the groups at three years was not significant (Mann-Whitney U, p=0.769). Furthermore, the difference in the change of scores between the groups over three years was not significant (repeated measures ANOVA; p=0.877) (Figure 8). The proportion of caregivers scoring 5 or more was equal (50,9% vs. 50,0%) at entry and remained equal (44,4%) in the two groups at 3 years.

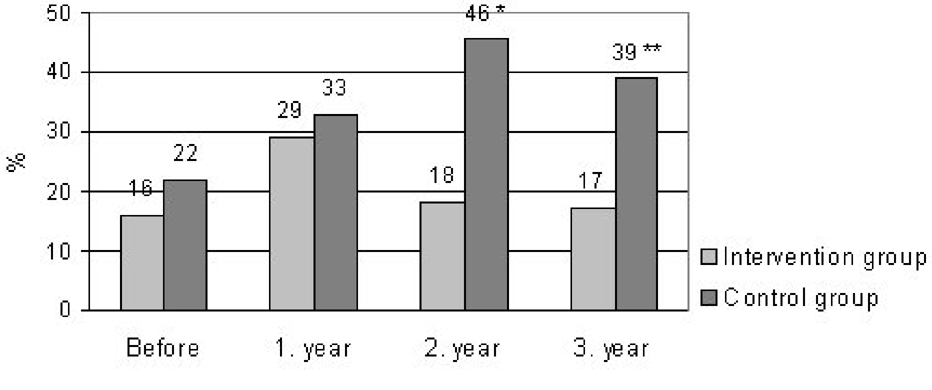
Figure 8. The median scores for the GHQ over three years. The difference in the change of scores over 3 years was not significant between the groups (repeated measures ANOVA; p=0.877).



5.3.4. Need for community support

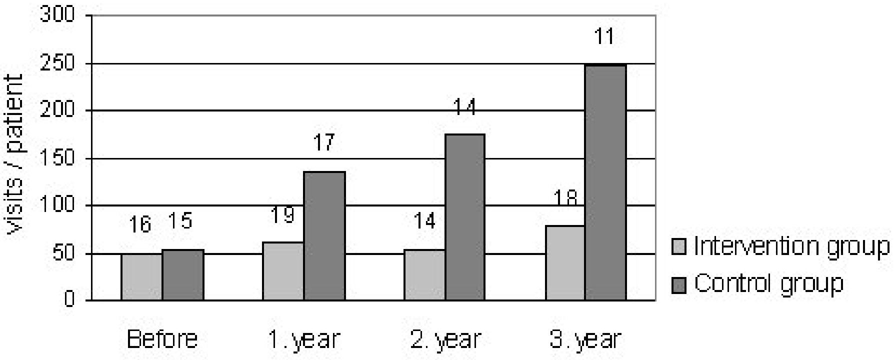
As reported above, there were no significant differences between the groups in need for community services before the intervention was launched. At the one year recordings, an apparent trend in attendance to day center was seen. The number of visits to day center increased by 40,0% in the control group compared with a 30,8% increase in the intervention group (Table 9, Table 20). During the second year of follow-up, the percentage of patients attending the day center decreased from 29,1% to 17,8% in the intervention group (five out of nine patients lost to follow-up, one new attendee), while in the control group an increase from 32,7% to 46,7% was recorded (two patients lost to follow-up, four new attendees). A total of 20 patients (40,8%) in the control group were attending the day center by the end of the three-year follow-up compared to 17 (30,9%) in the intervention group. However, the difference in the total number of visits to day center during 3 years was not significant between the groups (Mann Whitney U; p=0.092).

Figure 9. Percentage of patients attending to day center during the year before study entry and each year of follow-up. The data of the patients lost to follow-up were not available. *Chi-square = p=0.005; ** Chi-square = p=0.039.



There was no significant difference in the need for home help service between the groups with regard to the number of patients expressing such a need. In the control group, however, the total number of home help service visits increased in each year of follow-up in spite of the decreasing number of patients that needed the service after the first follow-up year as shown in Figure 10. A total of 29 (59,2%) patients in the control group needed home nursing during the 3 year follow-up while in the intervention group the respective number of patients was 25 (45,5%). The need for safety phones was significantly greater in the control group (4,4% vs. 23,1%, Fisher's exact test; p=0.020) during the second year of follow-up. No significant differences were seen between the groups with regard to the need for meal service or transport service. The number of patients receiving a caregiver benefit was higher in the intervention group in the first year of follow-up (Table 19). Eight (14,5%) patients in the intervention group and nine (18,4%) in the control group were provided with new assistive devices to help with basic activities. None of the patients were provided with home adaptations.

Figure 10. The number of home help visits per case before study entry and in each year of follow-up. The figure above each column represents the number of patients receiving the service. There were no significant differences between the groups.



5.3.6. Use of health care services

Figure 11 and Table 20 depict the use of in-patient care during the three-year follow-up. The percentage of patients that needed hospital treatment or in-patient care in health centers was similar in both groups throughout the entire follow-up period. Patients in the control group were admitted 67,5% more frequently to health centers (in-patient periods per case: 2,0 vs. 3,4; Mann-Whitney U; p=0.122) and the number of bed days in health centers was nearly three times as high in the control group than in the intervention group by the end of the follow-up (bed days per life year: 12,5 vs. 37,2; Mann-Whitney U; p=0.069). The total number of bed days in hospitals and health centers was 85,8% higher in the control group (bed days per life year: 24,0 vs. 44,6) but no difference was found in the number of in-patient care periods per case (4,2 vs 4,8). Bed days in rehabilitation centers were recorded separately to elicit the impact of the intervention in the light of standard use of rehabilitation services by the control group. By the end of the follow-up 16 (29,1%) patients in the intervention group compared to12 (24,5%) in the control group had received standard rehabilitation. The number of bed days in rehabilitation facilities was also similar in the two groups (bed days per life year: 4,4 vs. 3,7). The intervention courses yielded a total of 980 days (18,5 days per life year). The total number of bed days per life year in institutional care (hospitals, health centers, rehabilitation facilities and courses together) was 46,9 in the intervention group and 48,4 in the control group. Thus, in spite of the considerable number of bed days due to intervention courses no significant difference could be found between the two groups with regard to total in-patient stays.

Table 19. Use of community support during the 3-year follow-up. The number of patients attending to day center is significantly higher in the control group in the second and third year of follow-up. There is also significant difference in need for safety phone in the second year.
Chi-square tests; * p=0.005, ** p=0.039, ***p=0.012
Mann-Whitney U tests; § p=0.005, §§ p=0.0029

	1. year		**2. year**		**3. year**		**Total**	

	IG n=55	**CG n=49**	**IG n=45**	**CG n=39**	**IG n=41**	**CG n=31**	**IG n=55**	**CG n=49**
Home help service								
Patients (%)	19 (34,5)	17 (34,7)	14 (31,1)	14 (35,9)	18 (43,9)	11 (35,5)	26 (47,3)	23 (46,9)
Visits	3310	6600	2367	6761	3160	7634	8837	20995
Home nursing								
Patients (%)	16 (29,1)	19 (38,8)	18 (40,0)	16 (41,1)	18 (43,9)	16 (51,6)	25 (45,5)	29 (59,2)
Visits	252	219	257	167	388	282	897	668
House-calls in intervention	55		45		41		141	
Day center								
Patients (%)	16 (29,1)	16 (32,7)	8 (17,8)	18 (46,7)*	7 (17,1)	12 (38,7)**	17 (30,9)	20 (40,8)
Visits	432	720	288	848 §	240	478 §§	960	2046
Meals on wheels								
Patients (%)	9 (16,4)	11 (22,4)	8 (17,8)	10 (25,6)	8 (19,5)	6 (19,4)	12 (21,8)	13 (26,5)
Transport service								
Patients (%)	34 (61,8)	26 (53,1)	26 (57,8)	23 (59,0)	25 (61,0)	18 (58,1)	35 (63,6)	29 (59,2)
Safety phone								
patients (%)	5 (9,1)	7 (14,3)	2 (4,4)	9 (23,1) ***	3 (7,3)	6 (19,4)	6 (10,9)	11 (22,4)
Caregive benefit								
Patients (%)	16 (29,1)	7 (14,6)	12 (26,7)	11 (28,2)	14 (34,1)	10 (32,3)	19 (34,5)	12 (24,5)

Table 20. Use of in-patients health care services during the 3-year follow-up. Data of the patients who dies, were institutionalized or interrupted participation were not available. Consistently, intervention courses were included only for those who underwent each follow-up assessment.
* Mann-Whitney U; p=0.041

	1. year		**2. year**		**3. year**		**Total**	
	IG n=55	**CG n=49**	**IG n=45**	**CG n=39**	**IG n=41**	**CG n=31**	**IG n=55**	**CG n=49**
Kuopio University Hospital								
Periods	28	13	24	12	27	16	79	41
Days	165	90	120	74	127	57	412	221
Patients treated (%)	14 (25,5)	9 (18,4)	12 (26,7)	9 (23,1)	10 (24,4)	13 (41,9)	26 (47,3)	23 (46,9)

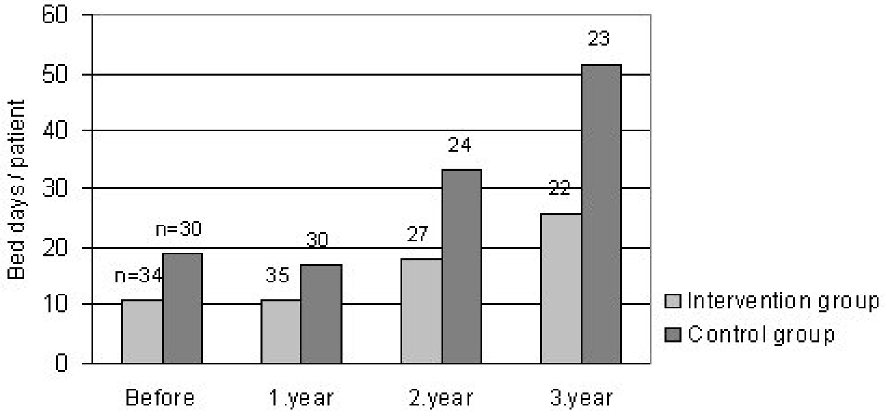
District hospitals								
Periods	11	5	4	6	5	3	20	14
Days	113	18	18	67	44	30	175	115
Patients treated (%)	6 (10,9)	3 (6,1)	4 (8,9)	5 (12,8)	2 (4,9)	2 (6,5)	9 (16,4)	7 (14,3)
Health centers								
Periods	42	60	34	43	21	32	97	135
Days	332	713	174	493	159	484	656	1690*
Patients treated (%)	22 (40,0)	25 (51,0)	17 (37,8)	19 (48,7)	14 (34,1)	19 (61,3)	34 (61,8)	37 (75,5)
Rehabilitation								
Days	179	131	49	43	13	13	241	187
Patients treated (%)	14 (25,5)	8 (16,4)	4 (8,9)	4 (10,3)	2 (4,9)	1 (3,2)	16 (29,1)	12 (24,5)
Intervention courses								
Days	550	-	225	-	205	-	980	-
Patients treated (%)	55	-	45	-	41	-	55	-
Total								
Days	1330	952	586	677	548	584	2464	2213
Days / life year	22,8	17,8	11,5	14,9	12,6	15,7	46,9	48,8

Table 21. Out-patient health care services during the 3-year follow-up.
Chi-square; * p= 0,012, ** p=0,008, ***p=0,020
f p=0,046, *ff* p=0,025, § p=0,003

	1. year		**2. year**		**3. year**		**Total**	
	IG n=55	**CG n=49**	**IG n=45**	**CG n=39**	**IG n=41**	**CG n=31**	**IG n=55**	**CG n=49**
Physician								
Private; visits	14	18	19	4	10	3	43	26
Private; patients	6 (10,9)	6 (12,2)	12 (26,7)	3 (7,7)	4 (9,8)	3 (9,7)	15 (27,3)	10 (24,4)
Health center; visits	133	114	96	98	112	69	341	281
Health center; patients	50 (90,9)	43 (87,8)	42 (93,3)	35 (89,7)	37 (90,2)	29 (93,5)	54 (98,2)	47 (95,9)
Hospital; visits	55	43	48	38	54	24	157	105
Hospital; patients	30 (54,5)	22 (44,9)	27 (60,0)	20 (51,3)	25 (61,0)	18 (58,1)	41 (74,5)	36 (73,5)
TOTAL; visits / life year	3,5	3,3	3,2	3,1	4,0	2,6	10,7	9,0
	55		45	38	39	30	55	

TOTAL; patients	(100)	40 (100)	(100)	(97,4)	(95,1)	(96,8)	(100)	40 (100)
Physiotherapy								
Clinic; visits	354	394	250	154	167	59	771	607
Clinic; patients	25 (45,5)	15 (30,6)	20 (44,4)	7 (17,9) *	9 (22,0)	4 (12,9)	33 (60,0)	16 (32,7)**
Home; visits	321	297	147	277	185	93	653	667
Home; patients	19 (34,5)	7 (14,3) ***	9 (20,0)	7 (17,9)	9 (22,0)	4 (12,9)	20 (36,4)	11 (22,4)
TOTAL; visits / life year	11,6	12,9	7,8	9,5	8,1	4,1	27,5	26,5
TOTAL; patients	36 (65,5)	22 (44,9) *f*	26 (57,8)	13 (33,3)*ff*	17 (41,5)	8 (25,8)	44 (80,0)	24 (49,0)§

Figure 11. Bed days of in-patient care (rehabilitation not included) before study entry and cumulative number of bed days over three years in proportion to the group size at each recording. N stands for the number of patients that needed institutional care during each year of follow-up.



The overall use of outpatient health care services in both groups is shown in Table 21. The number of patients that received physiotherapy each year of follow-up was higher in the intervention group. The difference was significant in the first (Chi-square=3,97; p=0.046) and second year (Chi-square=5,02; p=0.025) and over the 3-year period (Chi-square=8,94; p=0.003). No differences were found between the groups in regard to the outpatient visits to doctor during the follow-up. None of the patients received speech therapy or occupational therapy during the follow-up. The house-calls and physiotherapy provided by the intervention staff are shown in Table 22.

Table 22. House-calls by specialist nurse, in-patient rehabilitation in Neuron and outpatient physiotherapy initiated by referrals from intervention.

	Ist reay n=55	**2nd year n=45**	**3rd year n=41**
House calls	75	62	49
In-patient rehabilitation			
bed days	67	60	16

patients	7	6	3
Outpatient physiotherapy			
sessions, home or clinic	158	148	112
patients	21	19	14

5.3.7. Quality of life

The patients and the caregivers who completed the final follow-up assessments were asked to judge their QoL after the study by drawing a mark on the visual analogue scale (VAS) graded with "worst possible" at the bottom and "best possible" at the top. The median time delay from the end of the study to the judgement was 196 days (range: 7 - 379) in the intervention group and 195 days (range: 0 - 344) in the control group. Thirty-six patients (87,8%) and thirty-five caregivers (85,4%) in the intervention group and twenty-five patients (80,6%) and twenty-four caregivers (77,4%) in the control group gave their judgements. One response in the intervention group could not be interpreted and was thus omitted.

The VAS results were produced by the distance of the mark in millimeters from the bottom of the bar. Mean distances measured with the poststudy VAS were 57,3 + 18,9 for the patients in the intervention group and 56,8 + 31,5 in the control group. The mean values for the caregivers were 67,5 + 20,7 in the intervention group and 57,3 + 30,3 in the control group (Table 23). Eight (19,3%) caregivers in the intervention group and ten (34,5%) in the control group marked their QoL less than 50 mm from the bottom of the scale. The time delay from the end of the study to the time when the responses were made had only a small effect on the judgements. Those patients who gave their responses more than six months after the end of the study had slightly better judgements on their scales. In the intervention group the mean distances were 54,4 + 21,6 for the patients (n=17) with a time delay of less than six months and 60,9 + 16,2 for those (n=17) with more than six months. In the control group, the corresponding figures were 50,9 + 35,3 and 64,4 + 26,4. No actual difference between early and late responses was seen in the groups of caregivers (intervention group; 67,7 + 25,5 vs. 67,6 + 16,1 and control group; 56,7 + 32,0 vs. 58,2 + 31,3).

Table 23. QoL at 3 years measured with the VAS (millimeters) by patients and their caregivers. No statistical differences were found between the groups.

	Patients		**Caregivers**	
	Intervention group	Control group	Intervention group	Control group
	(n=34)	(n=24)	(n=34)	(n=23)
VAS, mean +/- SD	57,3 +/- 18,9	56,8 +/- 31,5	67,5 +/- 20,7	57,3 +/- 30,3
	(n=17)	(n=10)	(n=17)	(n=10)
Answered within 6 months	54,4 +/- 21,6	50,9 +/- 35,3	67,7 +/- 25,5	56,7 +/- 32,0
	(n=17)	(n=14)	(n=17)	(n=13)
Answered in > 6 months	60,9 +/- 16,2	64,4 +/-26,4	67,6 +/- 16,1	58 +/- 31,3

5.3.8. Correlations between functional abilities and quality of life

No statistically significant correlations could be established between the VAS and the BI, the MADRS or the NOSGER. A weak negative correlation between the VAS and the NOSGER suggested that the patients with better coping were prone to give a more positive appraisal of their QoL. The VAS for QoL did not correlate with the BI or the MADRS scores. The Spearman correlation coefficients are shown in Table 24.

Table 24. Spearman correlation coefficients between functional status and QoL.

	Barthel Index	**MADRS**	**NOSGER**
VAS for QoL	0,1849, p=0,157	-0,1206, p=0,359	-0,2424, P=0,062
NOSGER	-0,5031, p<0,001	0,4631, p<0,001	
MADRS	-0,2600, p=0,027		

5.3.9. Patient satisfaction with intervention

Satisfaction with the intervention was evaluated with a short structured questionnaire exploring the patient's or the caregiver's subjective experience with the intervention (Figure 12-15). A total of 36 (87,8%) patients out of 41 who completed the study in the intervention group returned their responses. All the patients who completed the study were asked for their opinion on the importance of recruiting a support worker for stroke survivors. The number of respondents was 61 (84,7%). The vast majority (86,9%) of them considered the idea as "very important" and only 11,5% of the respondents considered it as "less important".

Figure 12. Patient's opinion on the most important effects of the intervention. The question consisted of the five alternatives shown below. One or more alternatives could be selected. Total numbers (N) of selected alternatives are presented.

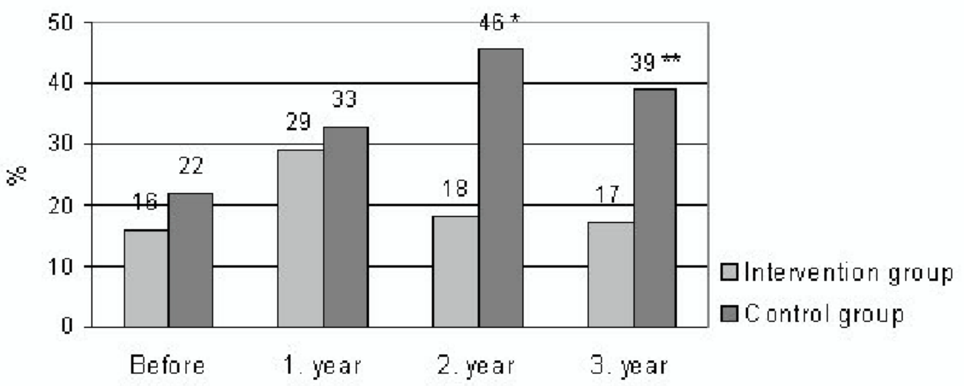


Figure 13. Quality of information and support received from the specialist nurse. The percentage of respondents selecting each alternative is presented. Only one alternative could be selected.

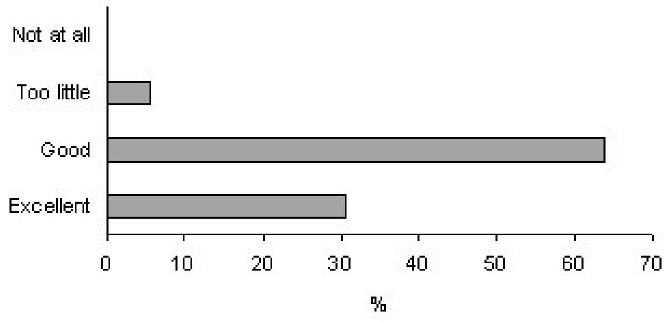


Figure 14. Sufficiency of intervention courses as rehabilitation service. Columns represent the percentage of respondents selecting each alternative. Only one alternative could be selected.

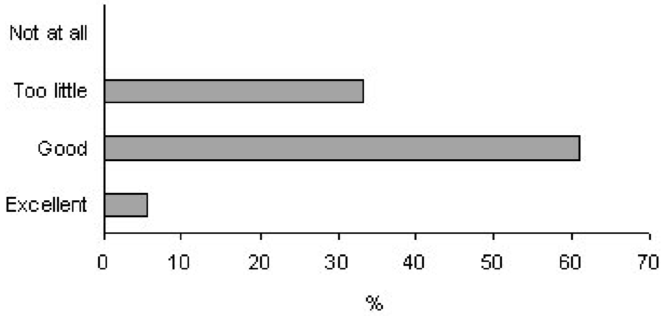
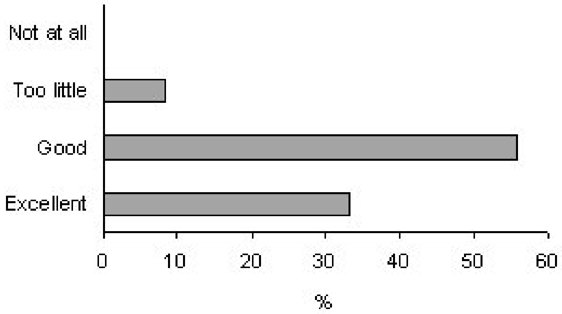


Figure 15. Caregiver's opinion on the quality of attention received during the follow-up. The percentage of caregivers selecting each alternative is presented. Only one alternative could be selected.



5.4. Costs of rehabilitation, community support and health care services

The evaluation of costs of the use of community support and health care services was based on the unit costs provided by the annual reports of Kuopio University Hospital and four municipal Offices of Social and Health Affairs (Kuopio, Kiuruvesi, Leppävirta and Siilinjärvi). The costs of the specialist nurses' home visits and phone calls incurred by the intervention were included in the total expenditure of outpatient services. The expenses of 35% of the working time of the specialist nurse which represented the time spent in home support for the patients and their caregivers was also included. The bed day costs of the intervention courses for the patients and their caregivers were included in the total expenditure of the inpatient rehabilitation. The costs of travel incurred by the intervention courses or the follow-up visits or the regular use of health care services were not included. All the cost items and the unit costs are shown in Appendix III.

The overall cost per case for health care services during the year before the follow-up was 31500 FIM in the intervention group and 38400 FIM in the control group. Nearly half of these costs in both groups were attributed to community support (46,1% vs. 44,6%) and only a small portion was spent in rehabilitation (12,7% vs.10,3%). In the intervention group, the costs of intervention courses and specialist nurse support together accounted for 34,6% of all costs in the first year and 26,0% in the second year. In the control group the proportion of rehabilitation services of all costs in the first year was equal (10,8%) to that before the study, but only 5,9% in the second year. The overall costs of the intervention during the 3-year follow-up were 2214600 FIM (45700 FIM/patient) constituting 28,9% of the total costs in the intervention group.

In the third year of follow-up the cost per case of community support for the patients in the intervention group was 50,7% higher than prior to the study. In the control group, the growth of the corresponding cost was 132,7% from the baseline. The overall costs of community services for the three-year follow-up was 61000 FIM/patient in the intervention group and 105400 FIM/patient in the control group (Figure 17). Outpatient health care (physiotherapy included), on the other hand, was less expensive in the control group (15400 FIM/patient vs. 9900 FIM/patient) over the three-year follow-up (Figure 18).

Figure 17. Cost of community support before the study and over 3-year follow-up.

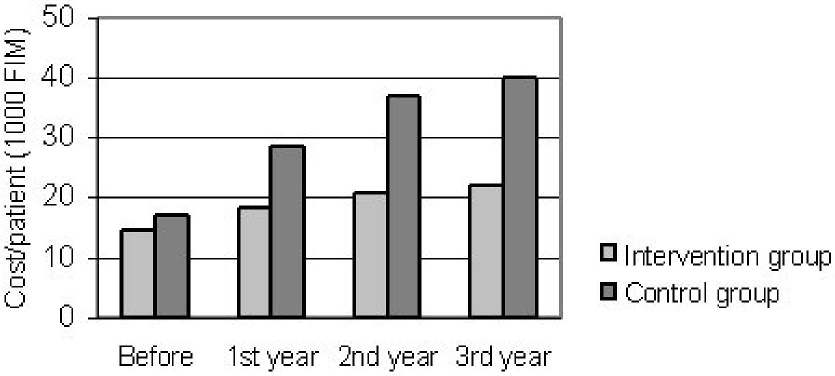
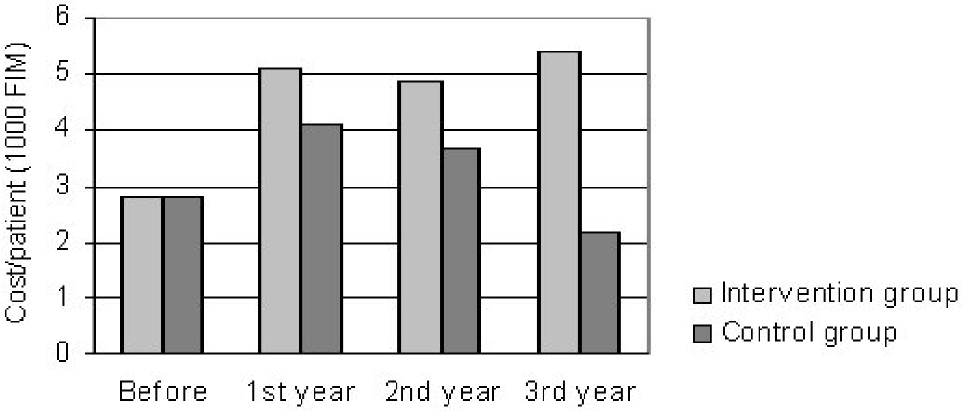
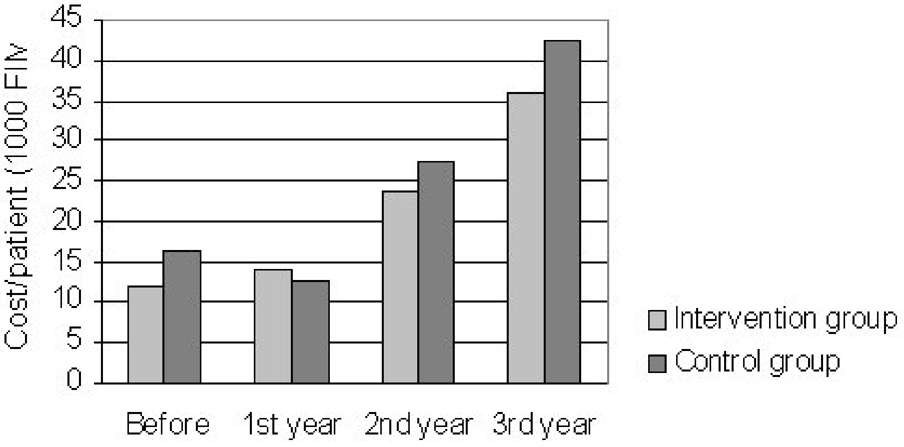


Figure 18. Costs of outpatient health care services before and during the 3-year follow-up.



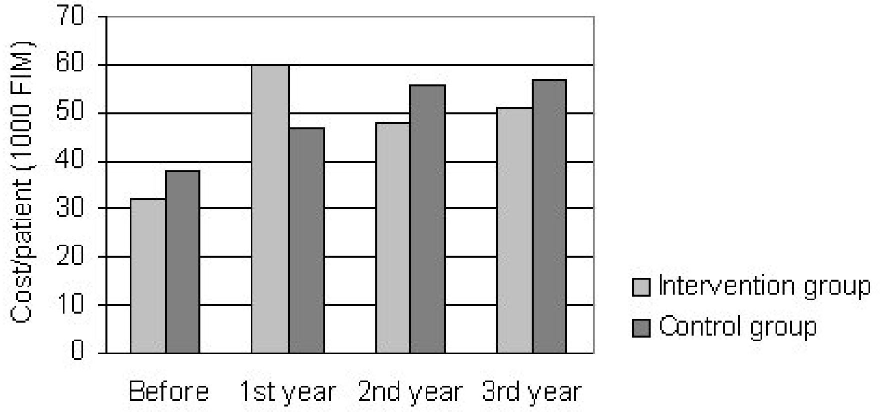
Inpatient health care was more expensive in the control group during the year before the study (11900 FIM vs. 16 300 FIM) and no actual change in the difference occurred by the end of follow-up. The overall cost per case for inpatient health care was 36000 FIM in the intervention group and 42100 FIM in the control group (Figure 19).

Figure 19. Costs of inpatient health care services in the year prior to study and cumulative costs per case over 3 years of follow-up.



The relatively high cost of the intervention accounts for most of the difference in the overall costs between the groups in the first year of follow-up. In the second and third year, however, the overall cost per case was higher in the control group with a difference similar to that before the study (Figure 20). The overall cost per case for the 3-year follow-up was 158500 FIM in the intervention group and 160900 FIM in the control group.

Figure 20. Costs of all health care services before and during the follow-up.



6. DISCUSSION

There is little scientific data on the actual benefits of long-term stroke rehabilitation. Empirical data based on clinical experience suggests that many stroke patients need rehabilitation or social services for a long time after their stroke to cope with problems in daily living. The lack of clinical practice guidelines results in an uneven distribution of rehabilitation services in the long-term care of stroke. The elderly, in particular, may often find that the services are inaccessible even though there is an indisputable need for rehabilitation. Inappropriate referrals, on the other hand, result in poor cost-effectiveness of the services and may give rise to skepticism among those who make decisions on service provision. One of the principle aims of the present study was to find out whether elderly stroke patients and their caregivers would benefit from rehabilitation late after stroke. Keeping in mind the ultimate goal was a return to normal life, a multidimensional approach was applied, involving both rehabilitative therapies for the patients and counselling support for the caregivers. The feasibility of the approach was evaluated through the analysis of the effectiveness and costs over a period of 3 years and comparing the results with those of a control group. Due to the patient selection and the restricted catchment area, one must be cautious in applying the results of the present study to the whole population of stroke patients in Finland.

6.1. Patients and methods

The study population was based on the selection criteria described in the methods section to minimize the effects of a serious concomitant disease on the functional ability of the patient. Secondly, to avoid the confounding effect of spontaneous recovery on levels of functioning, at least six months had to have elapsed since the stroke. The age of 65 or more was considered appropriate for two reasons. First, that is the age of retirement and therefore the loss of job productivity could be neglected in the evaluation of costs. Second, the SII serves as the main rehabilitation provider for the disabled under the age of 65. People aged 65 or older in general have to rely on the services provided by the community. The majority of the patients were found from the files of the local SII offices. The patients had been awarded a pensioner's care benefit to compensate for a specific level of functional disability. The case finding strategy was not comprehensive. A number of patients with mild disability were clearly overlooked because they were not registered in the files of the SII. The advantage of the strategy was the discreet procedure of acquiring informed consent through official inquiry to the beneficiaries. The process of consent to randomization, on the other hand, might have biased the results, because some patients and caregivers were clearly disappointed at being allocated to the control group. However, the number of patients who dropped out during the first year was comparable in the two groups, and thereafter it was unlikely that the feeling of disappointment continued to play a significant role.

The initial goal for the sample size was 140 patients. Since 40,2% of the eligible patients did not return the informed consent form and two more individuals were excluded at the baseline examination, the actual sample size was 117. The difference in the number of patients between the groups (intervention group: n=62; control group: n=55) was attributed to the simple randomisation technique designed to allocate all of the 140 patients.

The time elapsing since the stroke was two years or more in the great majority of the patients (78,6%). In one-third of the patients the time interval was five years or more. It is possible that the patients who had had stroke long before entering into the study had adopted coping strategies compatible with their domestic environment and hence no further positive outcome could be achieved by the intervention. Adjustment to stroke-induced disabilities may improve so much that, in the long run, the effects of other factors may be emphasized in the need for help in activities of daily living. Possibly, a greater proportion of patients with a more recent stroke would have had an effect on the results. It may well be argued that, in spite of the exclusion criteria, controlling for the effects other than those of stroke on the performance of the patient was not adequate. On the other hand, it must be accepted that a typical stroke patient at an older age has a number of concurrent diseases. Apart from the shortcomings, the present study population can be considered as a fair sample of the disabled, elderly stroke patients living at home in Eastern Finland.

The proportion of males in the present study population was slightly larger than that in some other stroke rehabilitation studies (Gladman et al. 1993, Drummond & Walker 1995, Forster & Young 1996, Anderson et al. 2000) but equal to that in the Swedish study of Widén-Holmqvist et al. (1996). There was an imbalance of gender distribution, with an excess of males in the intervention group, which may indicate a faulty randomisation. However, none of the assessment scales contained sex-specific domains, so it was unlikely that the observed gender imbalance had any significant impact on the results. Rehabilitation outcome, on the other hand, has been shown to be independent on sex (Heinemann et al. 1987, Dam et al. 1993, Jorgensen et al. 2000). All the other characteristics of the patients in each group were well matched at the baseline.

A possible source of bias can be found in the method of performing the follow-up assessments. The assessors were blinded to the scores of the previous assessments but not to the group. The raters were thus aware of the possible bias involved in assessing the follow-up scales and therefore rigorous objectivity was stressed.

The patients in the intervention group were assessed in Neuron at the first and the second follow-up while participating in the courses, whereas the patients in the control group were assessed at Säveri Medical Clinic in Kuopio. The ongoing intervention course may have influenced the attitudes and expectations of the patients when giving responses in the assessment of NOSGER scale, which is based on the patient or the caregiver interview. A possible contamination effect must be taken into account when interpreting the results of the control group. During the assessment process, the patients could ask for information concerning stroke care and available services. The assessment of physical performance, on the other hand, could have encouraged some individuals in the control group to do more physical exercise. The assessment procedure per se was similar in both groups. At each assessment the patient underwent three successive measurement sessions performed by a neurologist, a physiotherapist and a specialist nurse.

In the present study, a rather simple and crude method was used to assess QoL. To obtain more detailed information one of the multidimensional health-related QoL measures would have been more appropriate (de Haan et al. 1993). However, there is a limit in the number of instruments which can be conveniently performed in the assessment of elderly stroke patients. The average assessment time to complete the measures used in the present study was 2 hours and 30 minutes per case for each follow-up. Although it was possible to have a break between the three distinct measurements it was obvious in some cases that going through the multitude of measures was physically demanding if not exhausting. The VAS used in the present study was applied only after the patients had completed the 3-year follow-up. It was regarded as sufficiently quick and easy to complete at home to minimize the number of possible non-responders. The lack of baseline assessment with the scale was unavoidable.

Although the BI has been proven to be a valid and a reliable measure in assessing activities of daily living in stroke patients (d'Olhaberriague et al. 1996) it does suffer a few limitations. The BI concentrates solely on the level of independence in basic activities and is seldom informative enough to meet the multidimensional requirements of functional assessment. Moreover, in the case of long-term stroke rehabilitation the changes in the functional abilities of the patients are usually so small that the BI is not sensitive enough to detect them. The BI, however, may serve as a reference measure for a more specific and more sensitive instrument, such as the NOSGER.

While a number of clinical trials have used the NOSGER scale in the assessment of psychogeriatric patients, there are no previous reports of its application in a stroke intervention. Despite the similarities of the items with the BI, the basic structure of the NOSGER is totally different examining the frequency of occurrence of a given behavior. Nevertheless, the NOSGER has been found to be a reliable and valid assessment scale (Spiegel et al. 1991, Wahle et al. 1996). Interestingly, it has been suggested that the NOSGER dimensions memory, IADL, self-care and social behavior, which have been shown to have a close correlation with other similar tests, may function as parameters of being "cognitively intact" (Wahle et al. 1996). In the present study, correlations between the NOSGER and the BI, the MADRS and the VAS for QoL were calculated.

It may also be argued that the present study applied assessment instruments that were not relevant with respect of the chronicity of impairments after stroke and to the type of intervention. Admittedly, the intervention did not contain such elements that could have possibly resulted in detectable changes in the dimensions of the BFM, i.e. motor function and balance. On the other hand, keeping in mind the relatively long duration of the follow-up, there was some foundation for the hypothesis that the support and the encouragement provided by the intervention to increase physical activity could maintain or enhance a general level of physical condition and mobility assessed with the FAC and the gait speed.

A few details in the evaluation of the use and costs of health care services are worth mentioning. The number of outpatient visits to doctor and physiotherapy could not be reliably collected with respect to the year preceding study entry. Again, during the follow-up, the recording of the visits to outpatient services was based on the interview of the patient or the caregiver and obviously some data were missed. However, the effect of the missing data was likely to be of little importance and does not disqualify the comparison of costs between the groups.

The present study excluded the costs of informal care and travel costs incurred by the use of services. Both cost items are of great importance in the domiciliary care of stroke survivors and their inclusion in the present study would have provided a valuable aspect for the evaluation of costs.

The intervention was not intended to influence the use of medication. A new drug was prescribed only on rare occasions and the routine check-ups of medication continued to take place in the consulting rooms of the patient's general practitioner. Thus, the exclusion of medication from the evaluation of costs was unlikely to distort the difference in overall costs between the groups.

The intervention method and arrangements used in the present study have not been published earlier. Previous randomised controlled trials in the field of long-term stroke rehabilitation have investigated the effects of follow-up home visits by a health care professional (Forster & Young 1996, Andersen et al. 2000), or occupational therapy at home (Corr & Bayer 1995, Drummond & Walker 1995, Logan et al. 1997), or compared a day -hospital rehabilitation with home-based therapies (Young & Forster 1992, Gladman et al. 1993, Baskett et al. 1999).

The duration of the intervention and the length of the follow-up are important factors in evaluating the functional outcome late after stroke. In earlier studies, the length of follow-up has varied from 3 to 12 months. According to many health care professionals, a much longer follow-up period is needed to evaluate the effects of an intervention on the use of services. Thus, the present study provided a 3-year perspective to observe such effects. However, there is a clear problem of drop-outs as one prolongs the length of the follow-up in a study involving the elderly. The problem could be controlled by increasing the number of subjects, but in the case of an intervention study, increasing the study population would be restricted within the economical boundaries of the study finances.

6.2. Clinical characteristics

The socioeconomic and clinical characteristics were similar in both groups with the exception of the gender imbalance. The fact that a relatively small number of patients had had their stroke less than 2 years prior to the study (intervention group, n=13; control group, n=12) must be considered both as a weakness and a strength of the present study. Earlier studies have started an intervention immediately after hospital discharge (Young & Forster 1992, Gladman et al. 1993, Corr & Bayer 1995, Baskett et al. 1999, Andersen et al. 2000) or within six weeks of the acute stroke (Forster & Young 1996). A few studies that involved patients with a remote (>6 months) stroke focused on improving a specific motor function (Wade et al. 1992, Miltner et al. 1999, Smith et al. 1999). The present study, to my knowledge, is the first randomised controlled trial published to date to investigate the effects of a multidimensional intervention long after the stroke.

The median age of the study population was 72 years which is similar to the finding in an epidemiological study in Central Finland (73 years, Rissanen 1992). In an earlier intervention study, the median age has been comparable (73 years, Forster & Young 1996), and in a number of other studies the average age has ranged from 70 to 80 years (Gladman et al. 1993, Kaste et al. 1995, Corr & Bayer 1995, Logan et al. 1997, Widén-Holmqvist et al. 1998).

The prevalence of a previous myocardial infarction was slightly higher in the intervention group (37% vs. 25%). The difference was not statistically significant and was unlikely to affect the profiles of functional performance in the two groups. The proportions of patients with atrial fibrillation (16% vs. 22%) and diabetes (21% vs. 29%) were slightly higher in the control group but, again, the differences were insignificant. In previous Finnish studies, the prevalence rates for atrial fibrillation and diabetes among stroke patients have been comparable (Rissanen 1992, Ilmavirta 1994, Kaste et al. 1995) even though the present study involved a selected group of patients.

The proportion of patients with a right-sided brain lesion was slightly lower in the intervention group (37%) than in the control group (44%). Furthermore, slightly higher frequencies of embolic infarctions (15% vs. 24%, p=0.208) and fewer intracerebral haemorrhages (16% vs 7%, p=0.141) were found in the control group. Lesion type and laterality, however, have not been shown to have any impact on functional recovery (Jongbloed 1986, Kong et al. 1998) or on emotional well-being late after stroke (de Haan et al. 1995). The data of bladder dysfunction were collected in the clinical examination with the help of inquiry only, and the number of patients with incontinence was not specified in either group. Therefore the frequencies (26% in the intervention group; 42% in the control group, p=0.067) must be interpreted with caution. The BI item bladder control, on the other hand, did not reveal differences between the groups.

6.3. Functional abilities at baseline

Both groups were comparable with regard to the functional measures at the initial assessment. Twenty-one (34%) patients in the intervention group and twenty-two (40%) in the control group scored 85 or more on the Barthel Index indicating independence with minimal assistance. The percentage of patients who were dependent in basic activities was relatively high because of the patient selection. Only 12 (19%) patients in the intervention group and 13 (24%) in the control group were able to perform gait speed test over 10 meters indoors without a mobility aid. Assistive devices to facilitate basic activities in the home had been provided to 45% of patients in the intervention group and to 38% in the control group. The patient characteristics regarding functional dependency were in accordance with the findings of a previous study on severely affected stroke survivors (Löfgren et al. 1999).

Despite their ongoing physical disability most long-term stroke survivors seem to cope well psychologically (Löfgren et al. 1998, Hackett et al. 2000). In earlier studies, the prevalence of major depression (DSM-III-R criteria) has been 16% at 12 months (Kauhanen et al. 1999) and 8% among longer term stroke survivors (Sharpe et al. 1994). In the present study, only 11% of the patients were considered to have major depression (MADRS score >20) at study entry. The median score for the MMSE was 25 in both groups, which is comparable with the findings of earlier studies on elderly patients late after stroke (Santus et al. 1990, Löfgren et al. 1999). The proportion of patients with significant cognitive impairment (MMSE <24) was slightly higher in the intervention group (32%) than in the control group (22%). Patients with severe aphasia could not be tested with the MMSE.

No difference in caregiver strain between the groups could be established. The proportion of caregivers scoring 5 or more in the GHQ-12 indicating clinically important distress was equal (50%) in both groups. The prevalence of emotional distress among the caregivers has been similar in previous studies (Anderson et al. 1995, Dennis et al. 1998) although comparisons are difficult to make because of differences in assessment methods.

The use of community services prior to the study entry was similar in the two study groups. One-fourth of the patients were receiving home help service and approximately 30% of the patients were provided with home nursing. Attendance at a day center was slightly more frequent in the control group but the difference was not significant. The most common type of community support was the transportation service, which was provided for 40% of the patients. Eight (13%) patients in the intervention group and eleven (20%) in the control group received meals on wheels. The presence of a safety phone was rather uncommon (ca. 10%) among the study population. The number of patients admitted to and the number of in-patient care periods in hospitals and health centers was similar in both groups. The lack of data of outpatient health care visits was considered of little importance for the subsequent comparisons of overall use of services between the groups.

6.4. 3-year follow-up results

The following chapters elucidate the main results, i.e. the effectiveness and costs of the multidimensional intervention.

6.4.1. Functional outcome

In the present study no actual changes occurred in gait speed over 10 meters or in the FAC or in the BFM. The ability in the basic activities of daily living remained also unchanged during the 3-year follow-up. These findings are in accordance with the fact that functional recovery has plateaued by six months after stroke and there is little subsequent further improvement. In the present study most of the patients had had the stroke at least 2 years earlier and by that time they had clearly adopted well established basic routines of daily living. However, a growing number of studies have demonstrated that more focused efforts may improve mobility or even the functional skills of the upper extremity in selected groups of patients treated more than one year after stroke (Wade et al. 1992, Hesse et al. 1994, Miltner et al. 1999).

One of the main interests in the present study was to evaluate the effects on extended ADL such as social behavior and leisure activities. The ability to pursue social activities has been stressed by many researchers as an indicator of good recovery after stroke (Evans et al. 1994, Young 1994). An improvement in behavioral patterns indicated by the change of scores for the NOSGER scale was evident among the patients in the intervention group (Table 16). A more detailed examination of the different NOSGER dimensions revealed the positive effect to be located in the domains IADL, mood and social behavior (Figure 7), which obviously have a pivotal role in indicating social coherence. No deterioriation was observed in the rest of the NOSGER dimensions in the intervention group, whereas in the control group a significant worsening in disturbing behavior was seen. The finding may have implications for the caregivers' psychological well-being. Two studies have suggested that the occurrence of psychological and behavioral disturbances more than physical disability of the stroke survivor are the factors determining the caregiver's distress (Anderson et al . 1995, Addington-Hall et al. 1998).

Social isolation is a common and a well-recognised feature of life after stroke (Isaacs et al. 1976). A few earlier studies have demonstrated a positive effect of home-based rehabilitation on social activities among stroke survivors (Widén-Holmqvist et al. 1998, Mayo et al. 2000). The positive change in social functioning detected by the NOSGER scale in the present study may well reflect the satisfaction expressed by many participants after they had completed the 3-year follow-up. An important component of the present intervention was the emergence of local group activities to enhance physical well-being and to provide a way to maintain social relations spawned during the intervention courses. As Parker et al. (1997) pointed out, leisure activities have an important role in stroke rehabilitation with their potential impact on life satisfaction. The present intervention did not change significantly the patterns of leisure activities (Figure 4). The proportion of patients reporting exercise as their main leisure activity increased slightly in both groups. The slight increase in the control group may be explained by the contaminating effect of the study. When speculating on the beneficial effects of the intervention, it can be assumed that the need for acquiring community support became less frequent due to the continuous support provided by the specialist nurse and the new relationships formed within the group.

The NOSGER total score had significant correlations with the MADRS and the BI. This finding would support the concept of the usefulness of the NOSGER in evaluating the effectiveness of stroke rehabilitation.

Only weak support for an improvement in mood of the patients in the intervention group was provided by the observed decrease in the MADRS scores in three years (Table 17). Although the magnitude of change in the MADRS scores was not great, the importance of psychological support for the stroke survivors cannot be ignored. The need for support has been emphasized in previous studies. In the study of Kotila et al. (1998), the provision of outpatient rehabilitation and social activities resulted in a considerable decrease in the proportion of depressed patients. Anderson et al (2000), on the other hand, failed to detect any significant impact of an early hospital discharge and home-based rehabilitation scheme on the patients' psychological outcome. Time delay from the onset of stroke to the beginning of intervention obviously dictates the type of support that can be applied successfully. Adjustment to the loss of functions due to stroke takes time and the patient may not be able to cope with multimodal counselling and support in the first weeks after the stroke. Only after the adjustment process has advanced to the stage of approval, which may take up to 2 years or more from the onset of stroke, will the patient be more receptive to extend his or her interest in such domains as social or leisure pursuits. That may be a reason why no positive effects on social functioning have been achieved in some of the earlier studies (Friedland & McColl 1992, Gladman et al. 1993, Logan et al. 1997).

More than half of the patients were assessed with the MMSE at three years. As mentioned earlier, the MMSE is a screening test for dementia and gives only a rough estimate of the cognitive function of a subject. According to the final assessments at three years, no cognitive decline had occurred during the follow-up period in either of the two groups in the present study. Although in earlier studies (Wade et al. 1989, Tatemichi et al. 1994, Pohjasvaara 1998) decline in one or more cognitive domains has been found to be prevalent following acute stroke, there is a scarcity of reports that have examined the development of cognitive functions in long-term stroke survivors.

6.4.2. Caregiver strain

The caregivers' feelings of distress were evaluated throughout the 3-year follow-up using the self-reported GHQ-12 scale. The percentage of respondents was high at each assessment (79,5%-90,3%) and a number of missing cases was expected as some of the patients did not have a family member or a caregiver. The median score for the GHQ at study entry was on the borderline to indicate significant stress for the caregivers in both groups (5,0 for the intervention group; 4,5 for the control group). The severity of strain was not associated with the age, the level of ADL-ability or the mood of the patient. During the follow-up, a consistent decline in the median scores occurred in the intervention group but not in the control group (Figure 8). However, the proportion of caregivers scoring 5 or more, indicating clinically significant distress, remained high (44,4%) in both groups at three years.

The present study offered a unique opportunity to observe the burden of caregiving in the families of stroke survivors. The common opinion of the staff members was that, in general, the caregivers were doing psychologically well throughout the 3-year follow-up. In the older age group (>75 years), however, a greater tendency to feel anxiety or discomfort over caregiving was experienced, although the empirical finding was not translated into the GHQ. It can be assumed that more extended and thorough measures would have possibly detected the detailed alterations in their psychological well-being. Little is known about which factors are associated with caregiver strain. The study of Hodgson et al. (1996) suggested that caregivers' stress appraisal, physical health and satisfaction with service provision were significant predictors of the caregivers' psychological well-being. The amount of time the caregiver spends with the patient has been reported to be an important factor (Bugge et al. 1999). The data concerning the relationship between the physical disability of a stroke survivor and caregiver strain are controversial. Most studies have failed to confirm a significant relationship (Anderson et al. 1995, Dennis et al. 1998, Scholte op Reimer et al. 1998). The patient's dependency before the stroke, on the other hand, may be more important in predicting the caregiver's emotional distress (Dennis et al. 1998).

The present intervention included not only supportive therapies for the participants but also rather extensive flow of information on stroke rehabilitation and new instructions to apply in daily living. In many cases it was the caregiver who bore the main responsibility for the implementation of the new ideas. An important finding of the present study was that the effects of the intervention were not gained at the expense of increasing the caregiver burden. In the earlier study of Elmståhl et al. (1996), the highest caregiver burden was found among those patients who enjoyed the greatest improvements in basic ADL at three years after stroke.

6.4.3. Quality of life

QoL measured with a VAS scale was identical for the patients in the two study groups at the end of the follow-up. There was a tendency for a better QoL appraisal among the patients who gave their answers more than 6 months after the end of the follow-up. Almost 40% of the patients considered their QoL to be poor (distance of the mark less than 50 mm from the bottom of the scale). The QoL of the caregivers was comparable with that of the patients. A slightly higher proportion of the caregivers in the control group considered their QoL as poor compared with the intervention group (19% and 34%, respectively). The VAS for QoL had only a weak correlation with the NOSGER and no correlation with the MADRS or the BI was found.

Stroke survivors' QoL has become the subject of great interest during the past two decades. The importance of QoL has been advocated for a broad range of decision making in health care policy, which implies that the effectiveness and cost-effectiveness of treatments should be measured in terms of the QoL (Katz 1987, Fitzpatrick et al. 1992). In two previous studies the QoL of stroke patients has been found to improve in the one year period after the stroke (Åström et al. 1992, Jonkman et al. 1998). In one study of 6-year stroke survivors (Hackett et al. 2000) in New Zealand the health-related QoL appeared to be relatively good when compared with controls, confirming earlier data of a Swedish study (Löfgren et al. 1998) showing good psychological well-being among those who survived several years after the stroke. However, the data of the long-term QoL remains controversial since one study (Kauhanen 1999) failed to confirm improvement in the QoL in the one year period after the stroke and a few other studies have reported a deterioriation over time (Ahlsiö et al. 1984, Niemi et al. 1988, Béthoux et al. 1999).

The severity of impairment and disability as well as depressed mood have been shown to correlate with the post-stroke QoL (Ahlsiö et al. 1984, Niemi et al. 1988, Jonkman et al. 1998). However, the present study could not establish any such correlation. The possible influence of the degree of disability on QoL should be taken into account in order to provide an appropriate type of support to the right target. The study of Forster & Young (1996), in which a specialist nurse support had a positive effect on social outcome for the mildly disabled patients, but not for the moderately or severely disabled ones, is obviously an example of the above mentioned phenomenon.

6.4.4. Patient satisfaction with intervention

An important means of assessing the results of a rehabilitation intervention is to evaluate the patient's satisfaction with the outcomes and the services (Keith 1995). Satisfaction assessments have been shown to reflect real differences in the provision of care, so that the patients who receive more therapy and help are more likely to be satisfied (Pound et al. 1999). According to Clark & Smith (1998a) satisfaction with progress in rehabilitation is influenced by several factors, such as the return to previous lifestyle activities, the presence of depression, family functioning and adequate information on stroke.

In the present study, satisfaction with the intervention was evaluated after the patients had completed the 3-year follow-up. The amount and sufficiency of information and support received from the specialist nurse was considered good or excellent by 94% of the respondents. The majority (67%) of the patients found the intervention courses alone sufficient as a rehabilitation service. Improvement of psychological well-being or increased social activity were expressed in 56% of responses to the question " What was the most important effect of the intervention?". Almost one-fourth (23%) of the responses highlighted the improvement of physical condition suggesting that the measures used in assessing the physical performance were not sensitive enough to detect the self-reported positive changes. One-fifth of the responses emphasized the importance of improved accessibility to support and help.

Psychological distress among the caregivers of stroke patients is common (Anderson et al. 1995, Dennis et al. 1998, Bugge et al. 1999) and many caregivers have unmet needs. Caregivers need information about stroke-related problems, about availability of help and social services, and most importantly, they need someone to share the experience of caring for a stroke patient. The present intervention clearly successfully addressed those needs, since 89% of the respondents expressed satisfaction with the amount and quality of attention received during the follow-up.

The important role of the support worker was mentioned by 87% of the patients. They recommended that a support worker should be available as a standard service provided by the community.

6.4.5. Use of social and health care services

A few findings of the present study regarding the use of community services need to be discussed. First, attendance to day center increased significantly in the control group compared with the intervention group by the end of the second year and the use of the service remained at a significantly higher level in the control group to the end of the follow-up (Table 19). Although the intervention courses were of short duration and were arranged only once a year, they obviously served as a much-needed and good opportunity to meet other people experiencing the same feelings of coping with the sequelae of a devastating illness. Furthermore, the courses offered the caregivers a unique opportunity to receive valuable information about stroke-related problems. The multidisciplinary team introduced the participants to various forms of social activity and local exercise groups were encouraged to be established to maintain social interaction beyond the courses. This multifaceted approach might have influenced the need for day center service in the intervention group. However, it is not certain whether the significant difference in the attendance to day center between the groups was due to the multimodal support or to the effect of an unrecognised factor. It is possible that the slightly greater proportion of female caregivers in the intervention group (83,3% vs. 63,9%) had an effect on the use of services.

The proportion of patients that received home help service was similar in both groups throughout the follow-up period. The number of service visits per patient increased in the control group from the first year on, but three quarters of the total number of visits were accumulated by five individuals. It is an interesting question whether the increased need for home help service by these five individuals would have been prevented by the multimodal support had they been allocated to the intervention group. Living alone and male sex were associated with more frequent use of home help, as expected.

The need for safety phones was greater in the control group from the second year on. Only one patient in the intervention group was provided with a safety phone during the 3-year follow-up, while in the control group four more people were connected to this type of community support. Since the number of cases was small, it is not possible to draw any definite conclusions on whether the lesser need for safety phones in the intervention group was influenced by the multidimensional support. One plausible explanation would be the improved feeling of security through the knowledge that they could always access counselling from their specialist nurse.

The proportion of patients that needed house-calls by a primary care nurse during the 3-year follow-up was slightly greater in the control group (45,5% vs. 59,2%), but the difference was not significant. The use of meals on wheels and transport service was similar in both groups. Transport service was the most frequently (61,5%) received community support among the study population followed by home nursing (51,9%), home help service (41,7%) and attendance to day center (35,6%). Meals on wheels was provided for 24,0% of the patients. The use of services was comparable with that reported in a study conducted in Perth, Western Australia (Anderson et al. 1995). In an earlier Finnish study (Rissanen 1992), the need for home nursing and home help service was slightly more frequent than in the present study.

No significant differences could be found between the groups in the use of in-patient health care services. The total number of bed days per life year was 46,9 in the intervention group and 48,4 in the control group. An apparent trend, however, was seen in the control group to more frequent admissions to health centers throughout the 3-year follow-up. In addition to the number of in-patient care periods, the number of patients admitted to and the number of bed days in health centers were consistently higher in the control group (Table 20). Another observation to be found in Table 20 is the modest amount of standard in-patient rehabilitation in both groups, especially from the second year on. Significantly more patients received out-patient or home physiotherapy in the intervention group (80,0% vs. 49,0%; Chi-square: p=0.003). More than one-quarter (29,4%) of all physiotherapy sessions were initiated by referrals from the intervention. Each referral was preceded by a goal-setting evaluation by staff members. Although physiotherapy was aimed at improving mobility or relieving spasticity, no evidence on its effectiveness was found in terms of assessment measures (BFM, FAC, gait speed). Moreover, it was unlikely that the higher frequency of referrals to physiotherapy in the intervention group had a significant impact on the use of social services. Generally, the provision of outpatient or home physiotherapy did not abolish the need for home help or other services. No difference between the groups could be found regarding the number of visits to a physician.

The intervention courses constituted 39,8% of the total number of bed days in the intervention group. In spite of the accumulation of bed days due to intervention courses the total number of bed days was no greater in the intervention group, in fact rather the opposite. It might have been possible that the intervention had an effect on the need for in-patient health care services in the community. As mentioned earlier, the present study was the first to explore the effects of a multidimensional intervention on elderly patients' well-being and their use of services late after a stroke. Therefore more studies are needed to obtain further evidence to support these findings.

6.4.6. End-point events

There were no significant differences between the groups with regard to the end-point events. Few patients dropped out (4=6,5% in the intervention group and 5=9,1% in the control group) and no drop-outs occurred during the last year of follow-up.

Eleven (17,7%) patients died during the 3-year follow-up in the intervention group and 9 (16,4%) in the control group. Slightly more patients were transferred to permanent care in the control group

(10=18,2%) compared with the intervention group (6=9,7%). According to Reutter-Bernays & Rentsch (1993) 16,3% of the patients discharged from a rehabilitation unit in Luzern, Switzerland, had been admitted to institutional care 2-5 years later. A similar prevalence rate (15%) of institutionalization for the long-term stroke survivors was also found in the Framingham Study in Massachusetts, U.S.A. (Gresham et al. 1979).

Certain factors were found to be associated with admissions to permanent care. The age of 75 or more ($p=0.006$), poor functional performance assessed with NOSGER ($p=0.022$), depressed mood (0.028) and impaired cognitive ability ($p<0.001$) at study entry were related to more frequent admissions to permanent care. These findings are in accordance with an earlier report (Reutter-Bernays & Rentsch 1993). In contrast to the report of Rockwood et al. (1996) the present study found no relationship between gender or the presence of a caregiver and the risk of institutionalization. Similarly, changes in social circumstances, such as traumatic life events, were not associated with admissions to permanent care

6.4.7. Evaluation of costs

The costs of community services over the 3 years of follow-up were 72,8% more expensive in the control group (61000 FIM/patient vs. 105400 FIM/patient). The two most resource consuming types of services were home help service and transport service (Appendix III). The costs of home help service constituted 33,8% of all social service expenses in the intervention group and 52,4% in the control group, whereas the proportion of transport service of all social service costs was 37,5% and 20,8% in the respective groups. Outpatient health care was costlier in the intervention group (15400 FIM/patient vs. 9900 FIM/patient). Inpatient health care, on the other hand, was 16,9% more expensive in the control group (36000 FIM/patient vs. 42100 FIM/patient).

The costs of the intervention itself constituted 28, 9% of the total expenses in the intervention group. Standard rehabilitation resources spent during the 3-year follow-up were 7,6% of the total costs in the intervention group and 6,7% in the control group.

In spite of the relatively great amount of resources consumed by the intervention courses in the three years (40900 FIM/patient) , the overall per capita cost was not higher in the intervention group (158400 FIM vs. 160900 FIM).

There are few studies on the effect of long-term rehabilitation of stroke survivors. To my knowledge, no previous reports of a multidimensional rehabilitation of elderly patients with a remote stroke have been published. The few studies that have examined the effects and costs of stroke rehabilitation have focused on the period of a few months after hospital discharge (Table 1). A summary of the previous studies would state that no substantial advantages of the rehabilitation interventions have been achieved in terms of functional gains, but there is some evidence for decreased costs due to home-based rehabilitation.

The cost of stroke care is likely to grow in the first decades of the 21st century. The demographic change with a shift to the older age groups will expose an increasing number of people to the risk of stroke. Despite the declining incidence rates observed in Finland during the 10 year period from the early 1980s to the 1990s (Tuomilehto et al. 1996), it has been predicted that we will see a substantial increase in the incidence of stroke (Malmgren et al. 1989) in the coming two decades. In fact, evidence of this phenomenon has already started to emerge (Johansson et al. 2000). Due to the improved survival (Shahar et al. 1995, Sarti et al . 2000), higher prevalence rates can be expected in western countries and hence the financial burden of stroke care is most likely to afflict the health care systems of countries like Finland more than is now appreciated. The scenario of a rapidly growing population of stroke survivors emphasizes the need to develop novel strategies in the field of long-term care for stroke patients.

7. CONCLUSIONS

It is in the interest of patients and caregivers as well as service purchasers to allocate resources to services that have been proved to be effective and resource-efficient. When the effectiveness of stroke rehabilitation is being evaluated one must take account of the temporal aspects of the rehabilitation (acute and long-term) and the multimodal needs of stroke patients, which go far beyond the physical recovery from the illness. The model of long-term rehabilitation examined in the present study comprised elements that have been overlooked in the standard community care, namely the enhancement of social integration of stroke patients and the psychological support of the caregivers. The following findings of the present study are clearly in favour of the feasibility of our model as a supplement to the current stroke care services:

1. There was an improvement in IADL, mood and social behavior of the patients in the intervention group. These are functional abilities that can be considered as essential in pursuing social activities. The intervention had no effect on physical performance or basic ADL.

2. The caregivers' distress assessed with the GHQ-12 was not significantly relieved in the intervention group. However, patient and caregiver satisfaction with the intervention courses and counselling support was overwhelming highlighting the potential usefulness of the intervention in maintaining family function, which has been shown to influence the long-term outcome of the stroke survivor.

3. The attendance to day center and the need for safety phones decreased in the intervention group. The use of other forms of social services did not increase above the standard level. The patients in the intervention group were less frequently admitted to health centers and the number of bed days due to in-patient stay in health centers was smaller in the intervention group.

4. In spite of the resources consumed by the intervention, the overall costs of social and health care services were not higher in the intervention group by the end of the 3-year follow-up.

The multidimensional approach with short annual rehabilitation courses and continuous counselling support by a specialist nurse proved to be as resource-efficient as the standard care and may have supplemental beneficial effects for both the stroke survivor and the caregiver. Future research is recommended to find out whether these results can be generalized to all stroke patients regardless of age and locality. Another key interest for the future studies is whether comparable results can be achieved with less therapy input and fewer resources.

8. SUMMARY

Stroke is a major cause of disablement among elderly people. As the prevalence of stroke is predicted to increase in the near future the impact of chronic disablement will pose a great challenge to the long-term care and rehabilitation of stroke patients. The ultimate goal of stroke rehabilitation is much more than physical recovery of the patient. All the aspects of pre-stroke life styles should be involved in the assessment of rehabilitation outcome. At present, we do not know the best possible approach in the rehabilitation of long-term stroke survivors. It would benefit the patients as well as policymakers and purchasers to provide services that are both effective and resource-efficient.

The aims of the present study were to examine the effects of a multidimensional rehabilitation on the elderly stroke patients' well-being. Furthermore, we wished to study whether the intervention had an effect on the use of social and health care services in the community. Caregiver strain was another object of interest, as previous studies have shown that the caregivers of stroke patients may often experience emotional distress. Finally, our purpose was to compare the costs of the present rehabilitative intervention with the standard care in the community and thereby provide data for the applicability of the intervention within the current health care environment.

The study comprised 117 patients randomised to the intervention group and the control group. Only the patients aged 65 or older with a remote (> 6 months) stroke and living in their homes were included. The intervention involved a short annual course for rehabilitation and continuous counselling support by a specialist nurse. The intervention program was aimed at providing information on stroke, counselling on benefits and services in the community, promoting social activities among the participants, encouraging the establishment of self-directed local exercise groups and providing psychological support for the caregivers. The two groups were comparable in terms of baseline characteristics and functional abilities at study entry. Several functional assessment scales were used to compare the effects between the groups over 3 years of follow-up. The use of social and health care services were also compared and the costs were evaluated.

Physical performance, assessed with the BFM scale, did not improve in either of the two groups during the follow-up period. The gait speed over 10 meters was not significantly better at the end of the follow-up and the distribution of the patients to the FAC was not different between the baseline and 3-year assessments. Abilities in basic ADL measured with the BI were comparable between the groups at each follow-up assessment and no improvement was detected from the baseline scores.

The present study revealed a considerable improvement for the intervention group in the NOSGER scores, which is a behavioral scale of six dimensions. The mean change in the total scores between the baseline and the 3-year assessments was significantly (p=0.003) better in the intervention group than in the control group. The analysis of the different dimensions revealed a favorable effect on IADL, mood, memory and social behavior among the patients in the intervention group. The mood of the patients was more specifically evaluated with the MADRS, which demonstrated a slight improvement for the intervention group in the 3-year period. Summarizing the results of the two assessment scales, the intervention had a beneficial effect on the psychological well-being of the patients and on their abilities to pursue social activities.

The caregivers' emotional distress assessed with the GHQ-12 was not relieved in either of the two groups during the 3-year follow-up. Therefore, further research is warranted to examine the effects of this type of intervention on caregiver strain.

The QoL of the patients and the caregivers was not different between the groups at the end of the follow-up. The vast majority (94,5%) of the patients who completed the study in the intervention group was satisfied with the amount and quality of information involved in the counselling support and 88,9% of the caregivers regarded that they had received adequate attention during the follow-up. Of all the patients who completed the study, 86,9% considered the counselling support for stroke survivors as very important and it should be provided in community care programmes.

The intervention undoubtedly influenced the use of social services and support in the community. In the intervention group, the average amount of visits per case to day center over 3 years was 11,7% higher than before the study while in the control group a 64,8% increase was recorded. Also, the need for home help was greater in the control group, but the difference was attributable to five individuals who consumed three-quarters of the total amount of services. Finally, there was less need for safety phones in the intervention group from the second year on.

The patients in the control group were admitted 67,5% more frequently as in-patients to health centers and the number of accumulated bed days was nearly three times as high in the control group as in the intervention group by the end of the follow-up. The proportion of patients admitted to permanent institutional care during the 3-year follow-up was 9,7% in the intervention group and 18,2% in the control group. Although the intervention courses constituted 39,4% of the total amount of in-patient stays, the total number of bed days per life year in the intervention group did not exceed that recorded in the control group (46,9 vs. 48,4).

When evaluating the costs of stroke care in the two groups, one can conclude that the intervention group was more resource-efficient with regard to community services (61000 FIM/patient vs. 105400 FIM/patient) and in-patient health care (36000 FIM/patient vs. 42100 FIM/patient) but more money was spent in rehabilitation (57400 FIM/patient vs. 10100 FIM/patient). Nevertheless, the overall costs per case for the 3-year follow-up were not higher in the intervention group (158500 FIM vs. 160900 FIM). Taking into account the beneficial effects of the intervention, the cost comparison would support the idea of incorporating the core elements of the present approach into the current stroke care practice in the community.

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APPENDIX I.

Information collected at study entry and at each follow-up assessment

Clinical examination

Onset of stroke / date

Discharge to home / date

Time interval from the onset of stroke to study entry

- ½ - 1 year
- 1 - 2 years
- 2 - 5 years
- > 5 years

Diagnostic examination / date

Clinical examination
CT scan
MRI

Prior stroke / no / yes, number of

Type of lesion

Intracerebral haemorrhage
Atherothrombotic infarction
Embolic infarction
Not defined

Site of lesion

Left hemisphere
Right hemisphere
Cerebellum
Brain stem

Hospital referrals after stroke / days

Kuopio University Hospital
Central hospital
Rehabilitation institute
District hospital
Community hospital

<u>Type of therapies in acute stroke rehabilitation</u> / number of sessions

Physiotherapy
Speech therapy
Occupational therapy
Neuropsychological therapy

<u>Comorbidity</u> / no / yes

Coronary heart disease
Myocardial infarction
Atrial fibrillation / paroxysms
Cardiac insufficiency
Hypertension
Arteriosclerosis obliterans

Asthma
COPD
DM
Complications of DM
Thyroidal dysfunction

Hip arthrosis
Knee arthrosis
Other arthrosis
Fractures
Arthrosis / Fracture prohibits ambulation
Rheumatoid arthritis

TIA
Parkinson´s disease
Other neurological disease

Vascular dementia
Alzheimer´s disease
Mixed dementia

Malignancy cured
Malignancy under treatment

Depression
Other psychiatric symptoms

Urinary tract infection
Gastrointestinal disease
Skin disease
Vertigo
Other diseases or symptoms

Physical performance (NYHA classification I-IV)

Cause of abnormal NYHA score

Complications of stroke / no / yes

Seizures
Skin ulcers
Contractures
Thalamic pain
Thromboembolic problems
Shoulder pain
Sexual dysfunction
Bladder / bowel dysfunction

Medication

Clinical findings

Mood	no depression / mild / moderate / severe
Vision	normal / impaired
Hemianopia	no / left / right / both fields
Hearing	normal / loud voice / deaf
Hemiplegia	no / upper limb / lower limb / equal
Sensation	normal / hypesthesia / dysesthesia
Neglect	no / mild / significant
Apraxia	no / mild / significant
Dysphasia	no / mild / moderate / severe
Dysarthria	no / yes
Communication	speech / gestures / other

Height
Weight
Blood pressure

APPENDIX II.

Information collected by the specialist nurse at each assessment.

1. Patient name /ID
2. Date of birth
3. Age
4. Address
5. Phone number
6. Gender 1=male 2=female
7. Occupation
8. Education
   0 no education
   1 elemetary school
   2 middle grade/professional school
   3 high school
   4 college
   5 university
9. Education time, years

10. Time of assessment
11. Source of information patient/patient and caregiver
12. Marital status
   1 Married
   2 Unmarried
   3 Widowed
   4 Divorced
13. Time since widowed/divorced, years
14. Caregiver
   1 None
   2 Spouse
   3 Child
   4 Other relative
   5 A friend

15 Children, how many?_____
16 frequency of contacts to children
   1 every day
   2 a couple of times a week
   3 once a week
   4 a couple of times a month
   5 once a month
   6 less than once a month
   7 not at all
17 Friends
   0 None
   1 One or a few
   2 Several

18		Frequency of contacts with friends	
		1	every day
		2	a couple of times a week
		3	once a week
		4	a couple of times a month
		5	once a month
		6	less than once a month
		7	not at all
19	Leisure activity		
	0	None	
	1	Housework	
	2	TV, radio	
	3	Reading	
	4	Social activities	
	5	Exercise	
	6	Other activity at home	
	7	Other activity outside home	
20	Accomodation		
	1	Private house	
	2	Condominium	
	3	Residence for the aged	
21	Cohabitant		
	1	Alone	
	2	Spouse	
	3	Child	
	4	Sibling	
	5	Friend	
22	Number of rooms in the residence		
23	Shortcomings in accomodation		
24	Time of dwelling in the same area		
25	Traumatic life events		
	1	Death of a spouse	
	2	Death of a close relative who lived nearby	
	3	Death of a close relative who lived far away	
	4	Acute illness of a close relative	
	5	Other traumatic life events	
26	Home help		no/yes
			visits/year
27	Meals on wheels		no/yes
28	Home nursing		no/yes
			visits/year
29	House-calls at night		no/yes
			visits/year
30	Day center		no/yes
			visits/year
31	Transport service		no/yes
32	Safety phone		no/yes

33 Home adaptations
0 no need
1 required/item
2 provided/item

34 Walking aid
0 none
1 stick
2 roller walker
3 wheel chair

35 Assistive devices for ADL no/yes

36 Pensioner's benefit
0 none
1 level 1
2 level 2
3 level 3

37 Caregiver benefit no/yes

38 Economical status
Poor
Moderate
Good

Factors causing major problem at home
1 No problem
2 Disorientation
3 Restlessness
4 Hallucinations
5 Depression
6 Constipation
7 Memory disturbance
8 Trouble in seeing
9 Trouble in hearing
10 Incontinence
11 Dizziness
12 Dyspnoea
13 Thoracic pain
14 Pain elsewhere
15 Loneliness

39 Patient's opinion, First ______
Second _____
Third _____

40 Caregiver's opinion, First _____
Second _____
Third ____

41 Smoking
0 Not at all
1 1-6 cigarettes/day
2 less than a pack/day
3 more than a pack/day

42 Alcohol
0 Not at all
1 A couple of times a year
2 Once a month
3 Once a week or more frequently

APPENDIX III

Calculation of costs in the year prior to study and over 3 years. (IG=intervention group, CG=control group)

	Before		1st year		2nd year		3rd year		Total for 3 years	
	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG
Community service										
Home help, visits	2523	2909	2841	5863	2353	5664	2430	5434	7624	16961
unit cost/60 min	124	124	125	125	126	126	127	127		
total (1000 FIM)	312,85	360,72	355,13	732,88	296,48	713,66	308,61	690,12	960,21	2136,66
Night call, visits	469	13	469	737	14	1097	365	1100	848,00	2934,00
unit cost/15 min	62	62	62,5	62,5	63	63	63,5	63,5		
total (1000 FIM)	29,08	0,81	29,31	46,06	0,88	69,11	23,18	69,85	53,37	185,02
Home nursing, visits	341	214	252	219	257	167	388	282	897	668
unit cost/45 min	208	208	210	210	211	211	214	214		
total (1000 FIM)	70,93	44,51	52,92	45,99	54,23	35,24	83,03	60,35	190,179	141,575
Day center, visits	372	580	432	720	288	848	240	478	960	2046
unit cost	200	200	211	211	252	252	168	168		
total (1000 FIM)	74,40	116,00	91,15	151,92	72,58	213,70	40,32	80,30	204,05	445,92
Meals on wheels, mo	96	132	102	132	102	126	96	96	300	354
unit cost	1330	1330	1345	1345	1350	1350	1370	1370		
total (1000 fim)	127,68	175,56	137,19	177,54	137,70	170,10	131,52	131,52	406,41	479,16
Transport, months	324	252	366	282	360	294	306	246	1032	822
unit cost/month	950	950	990	990	1035	1035	1080	1080		
total (1000 FIM)	307,8	239,4	362,34	279,18	372,6	304,29	330,48	265,68	1065,42	849,15
Safety phone, months	72	84	66	84	42	96	30	90	138	270
unit cost/month	80	80	85	85	90	90	95	95		
total (1000 FIM)	5,76	6,72	5,61	7,14	3,78	8,64	2,85	8,55	12,24	24,33
Comm. service, total	**899,42**	**942,91**	**1004,34**	**1394,65**	**937,36**	**1445,63**	**896,81**	**1236,52**	**2838,51**	**4076,79**

total/patient	14,51	17,14	18,26	28,46	20,83	37,07	21,87	39,89	60,96	105,42
Outpatient physician										
Private clinic, visits	15	13	14	18	19	4	10	3	43	25
unit cost	350	350	355	355	357	357	362	362		
total (1000 FIM)	5,25	4,55	4,97	6,39	6,78	1,43	3,62	1,09	15,37	8,90
Health center, visits	135	120	133	114	96	98	112	69	341	281
unit cost	150	150	165	165	185	185	200	200		
total (1000 FIM)	20,25	18,00	21,95	18,81	17,76	18,13	22,40	13,80	62,11	50,74
Hospital, visits	60	50	55	43	48	38	54	24	157	105
unit cost	700	700	715	715	780	780	800	800		
total (1000 FIM)	42,00	35,00	39,33	30,75	37,44	29,64	43,20	19,20	119,97	79,59
Physiotherapy										
Clinic, sessions	250	225	354	394	250	154	167	59	771	607
unit cost/45 min	200	200	200	200	200	200	200	200		
total (1000 FIM)	50,00	45,00	70,80	78,80	50,00	30,80	33,40	11,80	154,20	121,40
Home, sessions	250	225	321	297	147	277	185	93	653	667
unit cost/45 min	225	225	225	225	225	225	225	225		
total (1000 FIM)	56,25	50,63	72,23	66,83	33,08	62,33	41,63	20,93	146,925	150,08
Specialist nurse										
total cost			72,50		74,50		78,50		225,50	0
Outpatient, total	**173,75**	**153,18**	**281,77**	**201,57**	**219,56**	**142,32**	**222,75**	**66,81**	**724,07**	**410,70**
total cost/patient	2,80	2,79	5,12	4,11	4,88	3,65	5,43	2,16	15,43	9,92
In-patient stay										
Kuopio univ. hosp., d	155	165	165	90	120	74	127	57	412	221
unit cost	2500	2500	2600	2600	2700	2700	2800	2800		
total (1000 FIM)	387,50	412,50	429,00	234,00	324,00	199,80	355,60	159,60	1108,60	593,40

Harjula hospital, days	75	293	81	303	23	296	29	137	133	736
unit cost	600	600	605	605	590	590	580	580		
total (1000 FIM)	45,00	175,80	49,01	183,32	13,57	174,64	16,82	79,46	79,40	437,42
District hospitals, d	116	62	113,00	18,00	18,00	67,00	44,00	30,00	175,00	115,00
unit cost	1450	1450	1550,00	1550,00	1750,00	1750,00	1850,00	1850,00		
total (1000 FIM)	168,20	89,90	175,15	27,90	31,50	117,25	81,40	55,50	288,05	200,65
Health centers, days	224	313	222	201	112	108	50	287	384	596
unit cost	435	435	450	450	465	465	470	470		
total (1000 FIM)	97,44	136,16	99,90	90,45	52,08	50,22	23,50	134,89	175,48	275,56
Respite care, days	100	200	20	209	39	89	80	60	139	358
unit cost	400	400	410	410	410	410	410	410		
total (1000 FIM)	40,00	80,00	8,20	85,69	15,99	36,49	32,80	24,60	56,99	146,78
In-patient, total	**738,14**	**894,36**	**761,26**	**621,36**	**437,14**	**578,40**	**510,12**	**454,05**	**1708,52**	**1653,81**
total/patient	11,91	16,26	13,84	12,68	9,71	14,83	12,44	14,65	36,00	42,16
Rehab, days	178	152	179	131	49	43	13	13	241	187
unit cost	800	800	1060	800	1400	850	850	850		
total (1000 FIM)	142,40	121,60	189,74	104,80	68,60	36,55	11,05	11,05	269,39	152,40
Courses, days/pat.			550		225		205		980	0
days/caregiver			510		215		190		915	0
unit cost			1010		1100		1100			
total (1000 FIM)			1070,60		484,00		434,50		1989,10	0
Rehab+courses	142,40	121,60	1260,34	104,80	552,60	36,55	445,55	11,05	2258,49	152,40
Inpatient+rehab	**880,54**	**1015,96**	**2021,60**	**726,16**	**989,74**	**614,95**	**955,67**	**465,10**	**3967,01**	**1806,21**
Overall costs	**1953,71**	**2112,04**	**3307,70**	**2322,37**	**2146,66**	**2202,90**	**2075,23**	**1768,43**	**7529,58**	**6293,70**
Costs/patient	31,51	38,40	60,14	47,40	47,70	56,48	50,62	57,05	**158,46**	**160,93**