EFFECTIVENESS OF COUNSELLING AND GUIDANCE ON PHYSICAL FUNCTIONING AFTER STROKE
A systematic review and meta-analysis of randomized controlled trials

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Syksy 2014

#### ABSTRACT

Effectiveness of counselling and guidance on physical functioning after stroke. A systematic review and meta-analysis of randomized controlled trials, Katja Keränen, FTES011, Master's Thesis on Physiotherapy, University of Jyväskylä, Faculty of Sport and Health Sciences/Department of Health Sciences, Spring 2014, 35 pages, 6 appendices. Tutors: Ari Heinonen and Tuulikki Sjögren

**Background:** In Finland there are total of 25 000 stroke incidents per year. About half of the incident people have neurological injuries in activities of daily living and 40% will need long term rehabilitation. Counselling and guidance are the most used treatment methods in stroke rehabilitation. Evidence of the effects of counselling and guidance is unclear.

**Objective:** To determine the evidence of effectiveness of counselling and guidance for physical functioning after stroke by reviewing the results of randomized controlled trials (RCTs).

**Methods:** A systematic literature search was performed in 1/2007-3/2007 in CINAHL (1982-3/2007), MEDLINE (1950-1/2007) and EMBASE (-2/2007). Two additional searches were completed in Ovid for this systematic review-study, both MEDLINE (7/2008-9/2011) and; also MEDLINE and CINAHL (11/2011-12/2012). The search terms (MeSH) were: strength training, resistance training, aerobic training, motor control, motor learning, counselling, guidance, randomized controlled trial, random allocation, systematic review, stroke, hemiplegia, cerebrovascular disorders, brain ischemia, cerebrovascular accident, brain infarction and adult. In an additional search the more specific terms were stroke, counselling and physical activity. All the randomized controlled studies which met the inclusion criterion were included in the review. The counselling and guidance on patient or on patient and his/her relative or carer was provided by any health professional person or patient's relative or carer. Most of the RCTs included acute stroke patients (0-3 months from the stroke). Meta-analysis was performed for two subgroups of studies: 1) Counselling and 2) Guidance and counselling. The quality assessment of these studies was based on the criteria adapted by Van Tulder.

**Results:** Nine RCTs met inclusion and exclusion criteria in the review. According to the Counselling outcomes, there was found high evidence that "Counselling" outcomes did not improve physical functioning after stroke (p = 0.45). There was moderate evidence which indicates that "Guidance and counselling" did not improve physical functioning after stroke (p = 0.19).

**Conclusion:** "Counselling" or "Guidance and counselling" did not improve physical functioning after stroke. Further studies are needed to determine the definition of counselling and guidance; and to investigate the effect of counselling and guidance without any other treatment simultaneously to develop stroke rehabilitation.

**Keywords:** stroke rehabilitation, counselling, guidance, physical functioning

# TIIVISTELMÄ

Ohjauksen ja neuvonnan vaikuttavuus fyysiseen toiminnallisuuteen aivoverenkiertohäiriön sairastaneilla, Järjestelmällinen kirjallisuuskatsaus, Katja Keränen, FTES011, Pro gradu-tutkielma, Jyväskylän yliopisto, Liikunta- ja terveystieteiden tiedekunta, Terveystieteiden laitos, Kevät 2014, 35 sivua, 6 liitettä. Ohjaajat: Ari Heinonen ja Tuulikki Sjögren

**Tutkimuksen tausta:** Suomessa sairastuu 25 000 ihmistä aivoverenkiertohäiriöön joka vuosi. Noin puolelle sairastuneista jää neurologisia vaurioita päivittäiseen toimintakykyyn ja 40%:a tarvitsee pitkäaikaista kuntoutusta. Ohjaus ja neuvonta ovat yleisimmin käytetyt ohjausmenetelmät aivoverenkiertohäiriön jälkeisessä kuntoutuksessa. Ohjauksen ja neuvonnan tutkimusnäyttö on epäselvää.

**Tutkimuksen tarkoitus:** Tutkia aivoverenkiertohäiriö-kuntoutujien ohjauksen ja neuvonnan vaikuttavuutta fyysiseen toiminnallisuuteen RCT-tutkimusten perusteella.

tehtiin 1/ Menetelmät: Systemaattinen kirjallisuushaku 2007-3/2007 sähköisiin tietokantoihin: CINAHL (1982-3/2007), MEDLINE (1950-1/2007) ja EMBASE (-2/2007). Tätä tutkimusta varten tehtiin kaksi lisähakua Ovid-tietokannassa MEDLINE (7/2008-9/2011) sekä MEDLINE ja CINAHL (11/2011-12/2012). Hakutermit (MeSH) olivat: strength training, resistance training, aerobic training, motor control, motor learning, counselling, guidance, randomized controlled trial, random allocation, systematic review, stroke, hemiplegia, cerebrovascular disorders, brain ischemia, cerebrovascular accident, brain infarction ja adult. Lisähaussa termit tarkensivat hakua: stroke, counselling and physical activity. Ohjausta annettiin potilaalle tai potilaalle ja hänen omaiselleen/avustajalleen terveydenhuollon henkilökunnan tai potilaan omaisen/avustajan toimesta. Suurin osa tutkittavista oli akuutteja potilaita (0-3 kk sairastumisesta). Kaikki sisäänottokriteerit täyttäneet tutkimukset otettiin mukaan. Tutkimusten laadun arviointi perustui Van Tulderin modifioituun luokitteluun. Meta-analyysi tehtiin tutkimuksessa kahdelle alaryhmälle:1) Ohjaus ja 2) Neuvonta ja ohjaus.

**Tulokset:** Tutkimuksen kriteerit täyttivät yhdeksän satunnaistettua kontrolloitua tutkimusta. Tulosten mukaan ei "Ohjaus"-interventiolla (p = 0.45) eikä "Neuvonta ja ohjaus"-interventiolla (p = 0.19) ollut vaikutusta fyysiseen toiminnallisuuteen aivoverenkiertohäiriön sairastaneilla.

**Yhteenveto:** "Ohjaus"- ja "Neuvonta ja ohjaus"-interventioilla ei ole vaikutusta fyysiseen toiminnallisuuteen aivoverenkiertohäiriön sairastaneilla. Lisätutkimuksia tarvitaan ohjauksen ja neuvonnan termien määrittämiseksi sekä pelkän ohjauksen ja neuvonnan vaikuttavuuden arvioimiseksi aivoverenkiertohäiriön sairastaneiden kuntoutuksen kehittämiseksi.

**Asiasanat:** AVH-kuntoutus, ohjaaminen, neuvonta, fyysinen toiminnallisuus

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#### 1 INTRODUCTION

In Finland there are a total of 25 000 stroke incidents per year, that is, 68 individuals have stroke in each day. Brain infarct is the most common stroke type among Finnish people. The prevalence of stroke will increase with the age if prevention will not become more effective. About half of the incident people have neurological injuries in activities of daily living and 40% will need long term rehabilitation (Tarnanen et al. 2011; Aivoverenkiertohäiriöt lukuina 2012). Stroke is the third expensive national disease after psychiatric diseases and dementia in Finland (Kaste et al. 2007, 271). A patient's age and residency modify the admission to rehabilitation services (Tarnanen et al. 2011). Because of the reduced risk factors and health care, ischemic attacks are reduced in Europe and in the Northern America. Ischemic attack patients increase when the population gets older and at the same time stroke incidence increases. About 40 % of the stroke patients need medical rehabilitation and 10 % recover as asymptomatic (Kuikka et al 2001, 279).

Counselling and guidance are the most used treatment methods in stroke rehabilitation. Evidence of the effects of counselling for physical functioning in stroke rehabilitation is unclear because of the mixture concept of the treatment itself. More research about counselling and guidance is needed, in the field of rehabilitation. In this study counselling and guidance are categorized in two different groups according to the type.

The current study is a part of the national project by the Social and Insurance Institution in Finland (KELA) started in 2006. The purpose of systematic review was to investigate the evidence of the effect of "Counselling" and "Guidance and counselling" for physical functioning in people who have suffered stroke. The evidence on the effect of counselling was gathered by meta-analyses, in which interventions were divided into two subgroups: 1) "Counselling" and 2) "Guidance and counselling". In addition, evidence was gathered by the number and quality of randomized controlled trials (RCTs).

#### 2 STROKE

Classification of stroke types is based on pathology; ischaemia or haemorrhage (Stokes 2004, 77; Viitanen 2010,146). Stroke or cerebral vascular accident (CVA) means either local loss of the brain tissue circulation called ischemic stroke (transient ischemic attack/TIA and brain infarct) or a local artery bleed in brains (haemorrhage and subarachnoid haemorrhage) (Kaste et al. 2007, 271; Kuikka et al. 2001, 280; Tarnanen et al. 2011). Haemorrhages can be caused by the obstruction of the carotid artery or vertebral artery in addition to the obstruction or gradual obstruction of the cerebral blood vessels. Blood clots can also cause ischemic attack (Kuikka et al 2001, 280.) Cerebral vascular accident is the malfunction of the brains which can be caused by stroke, brain damage, brain tumour or inflammation (Aivoverenkiertohäiriöt lukuina 2012). About 14 600 individuals are affected with the first brain infarct, 4000 with (TIA) transitory haemorrhage, 2600 individuals with cerebral haemorrhage (ICH) and 1 300 subarachnoid space bleed (SAV) in Finland (Tarnanen et al. Aivoverenkiertohäiriöt lukuina 2012).

## 2.1 Epidemiology

Risk factors to the cerebral attack are atherosclerosis, hypertension, diabetes, lipids in the blood, smoking and rich use of alcohol (Kuikka et al 2001, 280; Stokes 2004, 77; Viitanen 2010,146). Increased risk to have a stroke can be involved with other sicknesses (high blood pressure, diabetes), lifestyle (smoking, obesity, alcohol abuse, low physical activity) or individual attributes (age, sex) (Kuikka et al 2001, 282; Kaste at al. 2007, 282-283; Tarnanen et al. 2011). Two thirds of stroke patients are over 65 years old (Kaste et al. 2007, 273; Viitanen 2010, 146). High age and atherosclerotic system disease can expose to stroke (Korpelainen et al. 2008, 251). The incidence of stroke might double by the year of 2030 in Finland despite of the treatment methods (Kauhanen 2003, 212). Stroke is the third most reason of common death in Finland but mortality rate has decreased half in 20 years (Tarnanen et al. 2011). Stroke is the leading global cause of adult disability (Duffy et al. 2011,

465-466; Harrison et al. 2013, 202-203). About 20% of first-ever stroke patients die within a month. The risk of death decreases after the first month about 6%. Stroke patients are still twice as likely to die of a further stroke or the consequences of the vascular disease than in general (Carr & Shepherd 2010, 251).

## 2.2 Aetiology

A sudden or quite a sudden start with the decrease of conscience, vertigo, nausea and longterm or permanent neurological weakness are the most common symptoms of stroke. Other symptoms are communication problems, visual problems and paralysis. People may have different types of consequences from the cerebral attack because of the personal variety of the vascular wideness (Kuikka et al 2001, 282). Cerebral vascular accidents cause physical ability impairment. The most common impairment is total paralysis, hemiplegia or partly, hemiparesis which is usually more problematic in the upper limb than in lower limb (Kaste et al. 2007, 272, 327; Tarnanen et al. 2011). Hemiplegia is defined as "complete paralysis of the upper and lower limbs on the same side of the body" (Stokes 1998, 79). The excitability of the motor cortex is decreased and cortical representations are reduced after stroke. Functional recovery occurs early following stroke reflects reparative processes in the peri-infarct zone adjacent to the injury for couple of weeks (Carr & Shepherd 2003, 7). Hemiplegia is a symptom of the blood clot in the middle cerebral artery (Kuikka et al. 2001, 282). At acute phase 70-85% of stroke patients have hemiplegia (Korpelainen et al. 2008, 253). Stroke patients' physical, psychological and social abilities can be damaged in different ways. Consequences of the stroke differ individually and they depend on the wideness and location of the damage (Aivoverenkiertohäiriöt lukuina 2012). The cognitive problems vary a lot from the consequence of the side of the attack. Left side attacks cause linguistic problems and apraxia and the right side attacks cause observation and perceiving problems plus left sided neglect (Kuikka et al. 2001, 282).

In the neurological diseases there are often changes in the automatic reflexes or difficulties in voluntary movements. Paralysis is a term which means damage in the motoric nerve pathways, muscles or in the joint between the nerve and muscle causes the weakness of the activity in a muscle or a group of muscles. The weakness in muscle strength appears because of the changes in the tone of muscles, and when the tendon reflexes become faster it is always reason of symptoms of paralysis in the motoric areas of brains and the connections between them. For example right cerebral hemisphere sends an order to the left side of the body and that the reason to talk similarly the brain infarct in right side and the paralysis on the left side. The pyramid tracks which send motoric impulses cross over each other in the brain stem (Kuikka et al 2001, 97-98). Paralysis or weakness (hemiplegia or hemiparesis) of muscles of the limbs, trunk and face on one side of the body is the most common physical consequence of stroke. Recovery after stroke is individual and includes both spontaneous and adaptive recovery processes (Stokes 2004, 83).

#### 3 PHYSICAL AND FAMILY FUNCTIONING CHANGES AFTER STROKE

In this study physical functioning considered essential for maintaining independence and those considered discretionary that are not required for independent living, but may have an impact on quality of life. It means for example increased or developed activities physical activity, stroke information, functions related to indoor and outdoor mobility, some basic activities of daily living, muscle strength, extreme function and coping skills after stroke. This is very wide range of functioning provided by counselling and guidance but they all lead a person to more active and independent life after stroke.

## 3.1 Physical changes after stroke

Motoric damages (the weakness of the muscles, angularity, spastic muscles etc.) are the sum of many different reasons concerning the stroke in cerebrum. Impairments can be neuropsychological deficiency of sense of touch, linguistic impairment (aphasia), voluntary movements (apraxia), neglects, memory problems (amnesia), problems with conceptualization (visuospatial or visuoconstructive problems), lack of symptom cognition (anosognosia), variety of mood, problems with speech (dysarthria) and problems to swallow (dysphagia) (Korpelainen et al. 2008, 253; Aivoverenkiertohäiriöt lukuina 2012). Apraxia appears commonly in ischemic stroke. It means that the impairments in voluntary activities to move even if the motoric and sensorial systems are in order (Kuikka et al. 2001, 100-101). Cognitive disorders are diagnosed in 62-78% of stroke patients (Korpelainen et al. 2008, 254).

Most of the motor recovery is almost completed within 10 weeks post-stroke. The average stroke recovery plateaus are 3 to 6-months after onset (Kuikka et al. 2001, 100-101; Stokes 2004, 84; Kwakkel & Kollen 2013). The recovery is related to one or more of the following reasons: the site and extent of the initial lesion, the age of the patient, the capacity to achieve a motor goal related to functional movement, the capacity of the nervous system to reorganize,

the premorbid status of the patient, and the motivation and attitude of the patient towards recovery (Stokes 2004, 84). The age and scores on scales assessing severity of neurological deficits in the early post-stroke phase are strongly associated also with the final basic activities of daily living outcome after 3-months post-stroke (Kwakkel & Kollen 2013). Cognitive problems and other damages are the most difficult during the first months after stroke but the symptom picture will occur as soon as the temporary changes disappear after few weeks. After one year or more the main aim in rehabilitation is to adapt to the abilities which are left (Kuikka et al. 2001, 37, 282).

Because of the motoric damages, adaptive motor patterns can be seen in the human body. According to Carr and Shepherd (2003, 23) "Adaptive motor patterns after stroke include decreased muscle activity and joint movement leads to adaptive anatomical, mechanical and functional changes in the neuromuscular system. Changes to muscle resulting from weakness and disuse include altered muscle fibre type and length, atrophy and altered metabolism. Functional sequelae are increased stiffness and weakness, decreased endurance and fitness. Increased muscle stiffness is a major contributor to resistance to passive movement and a major cause of disability." The changes in motor patterns decrease physical activity and ability remarkably.

## 3.2 Family changes after stroke

Stroke effects the patient but also his/her relatives and his/her closest people's lives. According to Korpelainen the biggest changes happen in relationships between spouses, health and social activities because of the patient's passivity. Over 1/3 of spouses feel depression and most of them feel external dissatisfaction with their lives (Korpelainen et al. 2008, 256). Carers need education about stroke, counselling, support and access to support agencies (Carr & Shepherd 2010, 265; Stokes 2004, 91). Stroke rehabilitation team should include the person with a stroke and their family members. The patient should be encouraged to be an active participant in rehabilitation. "The focus changes from a medical and sickness

orientation to emphasis on exercise and training planned to regain effective functioning in everyday life" (Carr & Shepherd 2010, 255).

One meaningful part of the rehabilitation is the patient's automatic operation in its entire. The emotional support from the patient's family and their support for the everyday living improve patient's rehabilitation (Kuikka et al 2001, 36). Improved support by health professionals for the carers or family members can guarantee a better support for the patients also. Lack of support for the carers can lead to worse outcomes for the person affected by illness because the carers are often uncertain about their roles and they may have limited understanding about the illness (Reynolds 2005, 163). According to Brereton et al. (2007) systematic review of effectiveness of interventions for adult family carers of people with stroke, and an exploratory examination of the relationship between the conceptual basis of these interventions and their effectiveness. The review showed that some benefits were reported for all interventions but the presence of a conceptual basis for interventions does not appear to influence effectiveness. A longitudinal randomized controlled trial for stroke patients and their families (Kendall et al. 2007) reported declines in functioning in the areas of family roles, activities of daily living, self-care and work productivity in control group. The intervention was a psychosocial skill expansion by an existing self-management program. The groups had reached the similar levels by one year post-stroke.

In the Ellis et al. (2010) review they evaluated the impact of a healthcare worker or volunteer whose multi-dimensional roles have been grouped under the title "stroke liaison worker" for stroke patient. Outcomes did not show a significant overall difference for subjective health status or extended activities of daily living in general but stroke patients with mild to moderate disability benefit from a reduction in death and disability.

In this study family functioning is included in the interventions. Clark et al. (2003) investigated about improving family functioning and psychosocial outcomes for stroke patients and their spouses, and better functional and social outcomes for patients with education and counselling after stroke. The intervention included an information package and three home visits (counselling). The intervention group had better family functioning for both

patients and spouses and a modest benefit in functional status for intervention patients to improve family functioning. In the Andersen et al. (2007 a.) study each home visit consisted of a discussion concerning functional capability including social activity and family functioning. In addition both patients and carers were given information about stroke, stroke rehabilitation, social services benefits and stroke clubs. Andersen et al. (2007 b.) carers were instructed how to assist the patient by using his or her functional skills. Johnston et al. (2007) evaluated the effectiveness of a workbook –based intervention which was designed to change cognition about control, in improving outcomes for the patients and their carers.

## 3.3 Measuring methods

The impressiveness of stroke rehabilitation is measured with many different outcome measures. There are used several combinations of outcome measures in stroke rehabilitation because it is impossible to create only one method. Following six different types of outcome measures are commonly used: activities of daily living (Barthel index) (Wade 1992), neurological deficiencies (i.e. Scandinavian stroke scale), motor functions (Motor assessment scale), IADL activities (Frenchay activity index), depression and psychological loading (General Health Questionnaire) and quality of life (SF-36) (Korpelainen et al. 2008, 268). The validated prediction models using simple algorithms often based on existing outcome scales are used for stratifying stroke patients in trials (Kwakkel & Kollen 2013). There is no ideal stroke outcome measure that would be easy and quick to administer, acceptable to patients and researchers, valid for its chosen purpose, reliable, and response to meaningful clinical change. There are very many different opinions about the most suitable outcome measures after stroke. Three more commonly used functional assessment scales in stroke are: the National Institutes of Health Stroke Scale, the modified Rankin Scale and the Barthel Index (Harrison et al. 2013, 204). According to Stokes (1998, 321) the Barthel Index and Functional Independence Measure (FIM) are generally accepted disability outcome measures and according to Carr and Shepherd (2003, 26) suitable outcome measures of practise needs are: the Barthel Index and the Functional Independence Measure (FIM) for functional outcomes.

#### **4 REHABILITATION AFTER STROKE**

In acute stroke the most important rehabilitation is to prevent additional damages and complications (Kauhanen 2003, 219; Korpelainen et al. 2008, 257). Rehabilitation after a stroke concentrates on minimizing the brain tissue damages and it aims to both fix the hypo function caused by impairment in tissues and minimizes the damage (Kauhanen 2003, 219; Kaste et al. 2007, 327). According to Kwakkel and Kollen (2013) multilevel regression modeling of longitudinal data in stroke survivors, time itself is an independent factor for progress of recovery. In the absence of observational studies without intervention a certain degree of recovery is due to therapeutic intervention. 25% to 74% of the 50 million stroke survivors worldwide require some assistance or are fully dependent on caregivers for activities of daily living (ADL) after their stroke (Kwakkel & Kollen 2013).

The evaluation of the recovery is usually at the beginning, immediate recovery stage (1-3 weeks), 3 months, 6 months, 12 months and 24 months after stroke (Korpelainen et al. 2008, 252). Daily rehabilitation begins first as kinaesthesia treatment and then active treatment. Intensive rehabilitation, 2-3 times per week, continues after the hospital phase at the near clinic. Supportive rehabilitation begins 6-12 months after stroke and the goal is to maintain the achieved results (Kaste et al. 2007, 329). The most remarkable stroke symptoms on the behalf of the rehabilitation are: persistence of the symptoms, lasting time and extensiveness. The effects of these symptoms usually change in person's general patterns and effect on mental endurance and sustainability. Stroke recovery can be divided up in three sections: executive function, ability to concern and communication skills. The biggest changes in recovery can be seen during the first three months. Recovery can be slower with the older people. A stroke patient's rehabilitation depends on the effects of stroke on physical, cognitive and mental ability. A patient's personal goals in rehabilitation and life, compensative abilities, environment and the amount of external help also have a big role in patient's recovery (Korpelainen et al. 2008, 253.)

The sub-acute phase, intensive rehabilitation phase starts after acute phase and endures approximately 3-6 months. At this acute phase the first rehabilitation planning is done at the

hospital. At the end of the intensive phase rehabilitation is done at a clinic from home, as outpatient. The main goal is to transfer functional abilities into everyday life. After one year stroke rehabilitation changes to maintaining when there cannot be seen any big progresses in motoric or cognitive abilities (Korpelainen et al. 2008, 253, 259). The focus of the stroke rehabilitation changes from a medical and sickness orientation to emphasize exercise and functional training planned for the patient's personal needs. Rehabilitation includes training programmes for motor training, visual, cognitive, perceptual, swallowing, communication and continence problems (Carr & Shepherd 2003, 264).

Physiotherapy should be started immediately after the stroke to achieve the best results and continue as daily rehabilitation for the hospital phase (Mälkiä 2003, 366; Kaste et al. 2007, 328; Tarnanen et al. 2011). Physiotherapist evaluates patients' needs for assistive devices. Rehabilitation is quickest during the first few weeks and months. The severity of stroke, age, incontinence, abilities of the paralyzed, upper limb and psychological level are the most effective predictors for the rehabilitation (Kaste et al. 2007, 327-328). Main goals in stroke rehabilitation are to increase strength and skill, endurance, fitness and wellbeing. Persons with motor impairments need to relearn the segmental movement control. It needs the spatial configuration and temporal sequencing of body movements consulting an effective action to gain the goal with minimum energy expenditure (Carr & Shepherd 2010, 15). Rehabilitation should concentrate on optimizing functional recovery using methods of forcing use of the affected limbs in training and exercise, including specific interventions for example treadmill walking and constraint-induced training of the affected upper limb (Carr & Shepherd 2003,7).

In stroke rehabilitation the purpose of the strength training and task practise is to increase individual's ability to perform action in everyday situations and functional ability. Repetition in exercise and skill development facilitates the contraction of the muscles involved and performance in both able-bodied and disabled individuals. Stroke patients have to practise motor actions in different task and environmental contexts to achieve the best result in flexibility (Carr & Shepherd 2003, 20-23 Carr & Shepherd 2010, 15, 258). Muscle strengthening exercises can be done as part of the task-related practice. The aim is to increase ability to generate and time muscle forces appropriately for the task, increase coordination of muscle activations and decrease resistance to movement. Instructions for the patient should be

short and present a clear goal to keep the patient's attention on action. Demonstration can help the patients to understand the goal of the action and the movements to be executed. Observation is a way to learning the temporal and spatial aspects of an action (Carr & Shepherd 2010, 39-43).

Rehabilitation is team work which involves neurologist, nurse, social worker, physiotherapist, occupation therapist, speech therapist and neuropsychologist (Kaste et al. 2007, 328; Korpelainen et al. 2008, 261). The treatment goal is chosen by the patient, therapist and the whole team, including family and health professionals. Therapy goal to be achieved should be meaningful, worthwhile, reasonable challenging and concrete to the individual. These kinds of tasks seem to facilitate action more readily and motivate the individual more than the abstract tasks. (Carr & Shepherd 2003, 18, Guess et al. 2011). After setting physiotherapeutic goals and controlling indications planning, counselling and evaluating and assessing the impressiveness are important (Mälkiä 2003, 353). The important part of the team work includes also patients' family members and carers (Kaste et al. 2007, 327,329; Korpelainen et al. 2008, 262). Illness causes wide changes in patient's functional and physical abilities which effect on family also. Patient, family and relatives need rehabilitation and cultural integration for a long time afterwards to adopt for the situation (Kuikka et al. 2001, 293-294).

In general physiotherapy is a combination of movements and exercise. Therapeutic exercise includes the improvement of body movements, outperforming and relief of the symptoms. Therapeutic exercise and counselling is act in as immediate contact or independent exercise (Mälkiä 2003, 353). The chosen treatment method depends on goals of rehabilitation, the degree of functional limitation experienced and the type and severity of the component skill impairments noted. Multiple treatment methods can be used simultaneously (Guess et al. 2011). Motivation grows when people have possibility to make mistakes during practise. Hands-off therapy where therapist guides patient without manual help and different practise conditions give the opportunity to fail. People do not learn to perform an action unless they have a chance to practise it themselves which can be done increasing semi-supervised or unsupervised practise in rehabilitation. Learning requires an element of trial and error (Carr & Shepherd 2003, 14). The nature of the physiotherapy should include planning strategies for

the patient's possibilities to continue hobbies, past times and leisure interests to increase and maintain the interest to rehabilitation (Stokes 2004, 93).

Physiotherapy is the most used therapy for stroke patients. Because of the many symptoms and hypo functions in stroke accidents stroke patients need also other therapies (Kaste et al. 2007, 327). Other therapies are occupational therapy, speech therapy and neuropsychology if needed (Kuikka et al. 2001, 292). Nature of the therapy intervention can vary at different stages of rehabilitation and it can be provided by several different ways. The most common way is the combined intervention from more than one professional, for example the physiotherapist concentrates on balance and the occupational therapist teaches the components of dressing tasks. The physiotherapist can provide therapy or therapist can give strategies to enable the carer to participate in rehabilitation; or therapy can be organized selfpractise (Stokes 2004, 87). There are many different experimental physiotherapy methods used. These methods include passive movements activating, feedback strengthening, preventing the disturbing movements and returning the reciprocal body image (Korpelainen et al. 2008, 264). There are three different main categories in compensatory or adaptive approaches of physical rehabilitation: developmental (i.e. Bobath and Brunnstrom), biomechanical (strength and endurance) and psychosocial (individual counselling and surrounding adjustment to illness). These methods are used when full recovery is not expected or significant permanent disability is likely (Guess et al. 2011). It has not been established obvious differences between impressiveness in different physiotherapy methods. Better motoric rehabilitation is connected with bigger intensity in physiotherapy (Korpelainen et al. 2008, 264). The most effective part of the rehabilitation is the intensity, not the method used (Kauhanen 2003, 219).

#### 5 COUNSELLING AND GUIDANCE FOR PHYSICAL FUNCTIONING CHANGES

The difference between giving information and giving advice is that advice includes the counsellor's opinion (Burnard 1994, 149). In the beginning of the sickness the need of counselling is the biggest. The aim of the counselling is to prevent the fail form of activity and to practise alternative forms to act in a different way because of the changed abilities to act. The mobility recovers during the first months but it will continue with active rehabilitation and later with active adaption. The counselling about the stroke reasons, mechanisms and consequences are given right after stroke in the groups. Personal active rehabilitation and guidance are given later (Kuikka et al. 2001, 291).

In this study physiotherapeutic "Counselling" and "Guidance and counselling" means counselling which is done by a physiotherapist or another health care person, patient's relative or patient's caregiver after stroke. "Counselling and guidance" means stroke information, physical and psychological education to support both participation and daily activities for a person after stroke. Counselling and guidance is in big role in physiotherapist's daily work but it has not been investigated in stroke patients.

In general listening, helping, empowering and befriending are the central parts of the counselling in the area of health profession. Counselling includes differing mixture of personal qualities, practical skills and interpersonal both verbal and non-verbal behaviours. Counselling on the health profession includes a particular caring aspect. There are many different forms of counselling: supportive, informative, educational and management counselling (Burnard 1994, 6, 10-16). Physiotherapeutic counselling and assist is given to get awareness of patient's own regular physical activity (Korpelainen et al. 2008, 264). The social support can be classified distinguished practical/instrumental support (including information and giving tangible help), emotional support (including empathy and caring) and affirmative support (self-esteem and identify strengthening). Instrumental support includes explanations about the health condition from the patient and self-management advice, an adaptive aid or

advice about entitlement to disablement benefits. Affirmative support means receiving positive feedback from the therapist and successful coping (Reynolds 2005, 146).

According to Hèbert et al. (2012) review most primary care providers of general diseases believe physical activity counselling is important and that they have a role in promoting physical activity among their patients. Providers are uncertain about the effectiveness of counselling, feel uncomfortable providing detailed advice about physical activity and cite lack of time, training and reimbursement as barriers. When researching the studies about ambulatory stroke survivors, the providers are active themselves or if they feel that patient's medical condition would give opportunity to life change they are more likely to counsel their patients about physical activity (Olney et al. 2006).

Emotional support means information about patient's feelings, receiving comfort and being given sufficient time for different feelings and emotions (Reynolds 2005, 146). There are two kinds of categories of counselling: authoritative and facilitative. The first category consists for example informative interventions where the counsellor guides the counselling relationship in a structured way. The facilitative category consist supportive interventions where the counsellor enables the patient to take more control over the relationship (Burnard 1994, 28).

Guidance is one often used technique in therapy where the learner is physically guided through the task to be learned. With physical guidance an individual can be learned a new skill in the same results as any other technique of learning but it has strong transfer effect on later skills (Shumway-Cook & Woollacott 1995, 37). According to Kuikka et al. (2001, 38-40, 290) patient's orientation is support by the guidance for the quality of impairment and cognitive changes.

## **6 THE AIM OF THE STUDY**

The purpose of this systematic review and meta-analysis was to analyse and summarize the available evidence of the effectiveness of "Counselling" and "Guidance and counselling" on physical functioning in health care after stroke. Because of the contradictory outcomes in literature concerning counselling and guidance for physical functioning after stroke, the wide and clear evidence is needed and therefore the meta-analysis was selected as a method for this review. In more detail, the study question of this meta-analysis is: "Are the "Counselling" and "Guidance and counselling" interventions effective methods in improving physical functioning after stroke?"

#### 7 METHODS

The interventions in "Counselling"-group included discussion, information about stroke, mental support, encouragement, self-management and motivating. "Counselling" was based on verbal counselling and discussion, not training. The background was to inform people about stroke, give them support and encourage them to be active. "Guidance and counselling" group included physical training (movement guiding, facilitation), instructions about physical activity and education about stroke. Counselling was more physical and the instructions concerned about the functional and physical activity, and teaching the different and new ways to move and act after stroke. More detailed information about interventions is in appendix 1.

## 7.1 Search strategy and study selection

The original literature search was performed by an information specialist in January to March 2007 in three electronic databases CINAHL (1982 to March 2007), MEDLINE (1950 to January 2007) and EMBASE (to February 2007). The initial literature search was kept wide to guarantee all possible papers concerning stroke rehabilitation.

First additional search was carryout in September 2011 in Ovid. A systematic search was performed in MEDLINE (data from July 2008 to September 2011). Search terms (MeSH) were: strength training, resistance training, aerobic training, motor control, motor learning, counselling, guidance, randomized controlled trial, random allocation, systematic review, stroke, hemiplegia, cerebrovascular disorders, brain ischemia, cerebrovascular accident, brain infarction and adult. The search strategy is in detailed in appendix 2.

A second additional search was carryout in November 2012 in Ovid. The systematic search was made in MEDLINE and CINAHL (data from November 2011 to December 2012).

According to special search terms were concerning stroke, counselling and physical activity. Search terms were entered into each database using either MeSH or keyword headings specific to the requirements of the database. Search strategy is in appendix 3.

The current review includes literature from two above mentioned additional searches. The updated search (year 2012) a number of 48 RCTs were identified for the review. The specific flow chart is in the figure 1. A total of nine randomized controlled trials fulfilled the inclusion criteria (appendix 4). The trials were published during years 2002-2010. Two RCTs (Andersen et al. 2002a., b.; Donaldson et al. 2009a., b.) refers to a trial with two intervention-control pairs which have been referenced separately in the review. The methodological quality of the included RCTs was good; mean 5.9, range 4-7. Three studies (Ertel et al. 2007; Gillham & Endacott 2010; Johnston et al. 2007) out of nine were categorized methodologically as high-quality.

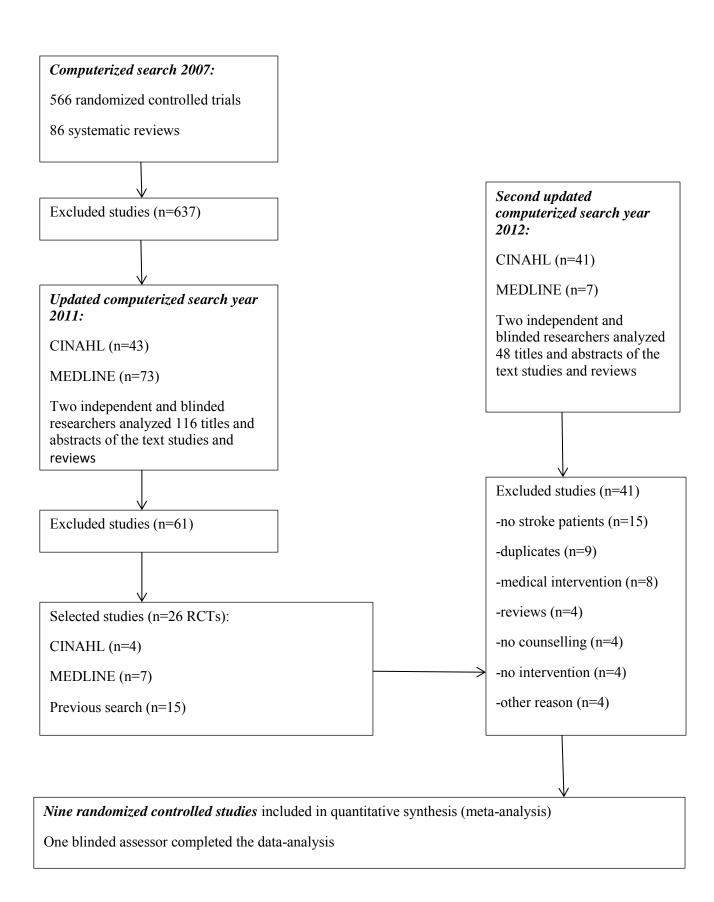


Figure 1. Flow chart of the randomized controlled trials.

In the initial board search (year 2007) three independent assessors screened the titles and abstracts and selected the relevant studies that fulfilled the inclusion criteria. The same method was used in the two additional searches (years 2011 and 2012) made by two independent assessors. After these wide electronic searches the search was limited to counselling and guidance after stroke. This part of the selection was completed by two assessors, who reviewed the relevant titles and abstracts. One assessor screened the remaining full-text articles for their eligibility.

All studies were classified independently by study investigator. There were no limitations for the intervention provider or the type of intervention. Control interventions were required. The specific exclusion ad inclusion criterion is seen in appendix 3. The inclusion criteria were as follow: 1) stroke population in all stages of recovery, 2) physiotherapeutic counselling and guidance provided by any health professional person or patient's relative or carer, 3) randomized and controlled studies, 4) compared intervention to other intervention approach, placebo or no treatment, 5) the intervention and control groups were comparable.

In the second additional search (2012) there was two additional criterions; 6) the effect of counselling and guidance for physical functioning, 7) the effect was measured in the study. Exclusion criteria were: 1) participants that had other diagnosis than stroke or were healthy, 2) medical interventions, 3) no randomized controlled trials, 4) systematic reviews, 5) no intervention in the study, 6) intervention of muscle strength-, aerobic- or motor-control training without counselling and guidance (no counselling and guidance).

The quality assessment of randomized controlled studies was based on the criteria adapted by Van Tulder et al. (2008) (appendix 5). Search, selection and selection method, and synthesis were evaluated by two independent researchers. Qualification of the studies was done by one researcher. The methodological quality of the selected randomized controlled trials was assessed by one researcher according to "Criteria for the methodological quality assessment (A-K) and the operationalization of each criteria"-modified Van Tulder (2008). Quality assessment scale was 11 point scale and each criterion is rated either "yes", "no" or "?"(= do not know). The quality results were categorized according to their quality score in three

phases: low (scores 0-3 points), moderate (scores ≥4 points plus having "yes"-answer for question regarding randomization) and high (scores ≥ 6 points plus having "yes"-answers for questions regarding randomization, treatment allocation, group similarity and drop-out rate plus the amount of participants minimum of 30 persons). The methodological quality of the selected nine studies randomized controlled trials ranged from four to seven points (mean 5.7 points, SD 5.6). Three studies were classified as high-quality (Ertel et al. 2007; Johnston et al. 2007; Gillham & Endacott 2010) and six studies (Andersen et al. 2002a., b.; Clark et al. 2003; Kendall et al. 2006; Donaldson et al. 2009a.,b.) out of nine were categorized for acceptable-quality. The high-quality studies were all in the category "Counselling". More detailed information about qualification in appendix 6.

## 7.2 Data analysis

One independent assessor extracted the data from the RCTs. Documentation was made of patient characteristics, intervention characteristics, control intervention characteristics and outcome measures. The statistical subgroup analyses were made of conventional treatment versus other treatment and conventional treatment and additional treatment versus conventional treatment

The summary statistic, the standardized mean difference (=SMD), was used in analyses because studies have reported outcomes in the different scales. Final values with standard deviation (SD) for intervention and control groups were entered to the Cochrane Collaboration's Review Manager Software (RevMan 5.0.16). It calculated pooled effect estimates for combinations of single RCT effects. In multiple comparisons with two treatment groups (Andersen et al. 2002a., b.; Donaldson et al. 2009a., b.), the numbers of controls were divided among comparisons. When standardized mean difference is used it is necessary to standardize the results of the included studies to a uniform scale before they can be combined, i.e., effects size (Deeks et al. 2008). The random effects model was used for analysis. The overall effect was tested with Z-test, in which a null hypothesis consisted of no difference between intervention group and control group. A P-value below 0.05 was considered

statistically significant. Effect size more than 0.5 represented large effects, 0.3 to 0.5 moderate effects, 0.1 to 0.3 small effects and below 0.1 was considered not meaningful (Cohen 1988). RevMan also tested heterogeneity of trials with Cochran's Q statistic or  $\chi^2$  test and I² statistic. I² statistic describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance). With a value 0 to 40 percent considered not important, 30 to 60 percent represented moderate heterogeneity, 50 to 90 percent indicated 33 substantial heterogeneity and 75 to 100 percent was considerable heterogeneity of intervention effects (Deeks et al. 2008). The standardized mean differences with 95% confidence intervals were reported using RevMan for studies with continuous outcome data, respectively. If a study included more than one intervention group, groups were used as separate studies compared and shared the same control.

"Counselling" and "Guidance and counselling" outcome measures of this study could be linked into category of the World Health Organization's International Classification of Functioning, Disability and Health (ICF). The outcome measures were heterogenic. The interest of this study was to concentrate on physical activity and self-management after stroke. The included outcome measures were chosen because they were able to link to the ICF's categories of "Walking and moving" (d450-469) and "Carrying, moving and handling objects" (d430-d449) in Mobility domain and Self-care domain of "Activities and participation" component. If there were several outcome measures in the same domain, the outcome measures which were made by intervention provider (not self-estimated) were primarily chosen to this study.

#### **8 RESULTS**

## 8.1 Patient characteristics

Total of 899 participants (501 male and 392 female) in the nine randomized controlled studies. The number of the included participants per intervention ranged from 30 to 291. The patients' type of stroke was not informed in three studies (Ertel et al. 2007; Johnston et al. 2007; Gillham & Endacott 2010). Two studies consisted of patients with ischaemic attack and two with infarct. The age was ranged from 66 to 74 years. About two thirds were in the age group of 66-69 years. Six RCTs out of nine (Andersen et al. 2002a., b.; Clark et al. 2003; Ertel et al. 2007; Donaldson et al. 2009a., b.) included acute patients (0-3 months from the stroke), three RCTs (Kendall et al. 2006; Johnston et al. 2007; Gillham & Endacott 2010) did not have information about the stroke timing, and two studies included a control group with acute and subacute (from three to six months after stroke) patients (Andersen et al. 2002a., b.). The study population were outpatients and stroke survivors with their carers (Andersen et al. 2002a., b.; Clark et al. 2003; Kendall et al. 2006; Ertel et al. 2007; Johnston et al. 2007). More information about study characteristics is seen in table 1.

 Table 1. Study characteristics

Study	Participants number Intervention, Control	Age, Mean (SD)	Provider	Disease duration
Andersen et al. 2002	I1:78( 54/24)	I1:70(10) I2: 74(11)	a physician and the instruction by a hospital physiotherapist	I1: 88(76) days I2: 83(74)
Denmark	I2: 77(53/24)	C: 68(12)		C: 98(88.5)
Clark et al. 2003 Australia	68 (35/33)	I patients: 73 (9) I spouse: 71 (7)	a social worker	Days from stroke onset to rehabilitation admission (mean, SD)
		C patients: 71 (9) C spouse:69 (5)		I: 10(4.5) C: 12(3.8)
Donaldson et al. 2009 UK	I1: 15(10/5)	73/73/73	All subjects received conventional physical therapy by the clinical physiotherapists. All extra physical therapy, both conventional physical therapy and functional strength training by the research physiotherapist.	Between 1 week and 3 months after stroke
Ertel et al. 2007 USA	12: 15(10/5) 291 (146/145)	(mean years) I: 69 (11)	a psychologist or social worker	Mean days: 38
		C:70 (11)		SD:14, range 15-115
Gillham & Endacott 2010 UK	52(26/26)	68(68 / 69)	No further information about the provider in the study.	First stroke (no further information in the study)
Johnston et al. 2007 UK	203 (103/100)	69 (13) / 69 (12)	a workbook implementer	When the patient's condition was medically stable and still in hospital or as soon as possible following discharge
Kendall et al. 2006 Australia	100 (58/42)	Mean years (SD) I: 66 (11) C: 66 (10)	Intervention courses were delivered by two trained health professionals	Sustained a stroke in the last few months

# 8.2. Study interventions

The selected nine studies were divided into two groups according to the type of counselling: "Counselling" (n=6) (Andersen et al. 2002a.; Clark et al. 2003; Kendall et al. 2006; Ertel et al. 2007; Johnston et al. 2007; Gillham & Endacott 2010) and "Guidance and counselling" (n=3) (Andersen et al. 2002b.; Donaldson et al. 2009a., b.). "Counselling" group consisted mostly verbal counselling: stroke information, instruction, support and self-management; and "Guidance and counselling" group delivered verbal instruction linked to the physical training: movement guiding, facilitation and functional/physical ability improving. In four studies (Andersen et al. 2002a., b.; Clark et al. 2003 and Gillham & Endacott 2010) out of nine the intervention was provided partly or all at patient's home. Gillham & Endacott (2010) study consisted telephone support and Johnston et al. (2007) included both telephone contacts and home visits. In Kendall et al. (2006) and Donaldson et al. (2009a., b.) studies the interventions were delivered in community settings. More information about interventions is seen in appendix 1.

The duration of the interventions was in the range from five weeks to 24 months. Interventions in two studies (Andersen et al. 2002 a., b.) were provided by physiotherapist and in other two studies (Donaldson et al. 2009 a., b.) they were provided by a clinical physiotherapist and a research physiotherapist. A social worker was the intervention provider in two studies (Clark et al. 2003; Ertel et al. 2007) and in other studies providers were trained health professionals (Kendall et al. 2006) and a workbook implementer (Johnston et al. 2007).

#### 8.3 Outcome measures used in studies

The Barthel Index was framed as primary outcome measure and it was taken as a main outcome for the RevMan-measure of the review. Because of the wide range of the measures only those measures which had outcomes concerning guiding and counselling for functional and/or physical activity were included to the review if the study did not had used the Barthel Index. Only exception was made in measure selection in Ertel et al. (2007) study because of

the lack of main outcome information the alternative measure, The Physical Performance Test (modified from Reuben and Siu), was included. After this selection this review includes following outcome measures: Action Research Arm Test (ARAT), Barthel Index, Exercise frequency, Functional Strength training, (Motor performance in) Functional Quality of Movement Scale, The Physical Performance Test (modified from Reuben and Siu) (Ertel et al. 2007) and the Stroke Specific Quality of Life Scale (SSQOL). The number of outcome measures amount's in included studies were here from 1 to 7 and mean was 3.8 outcome measures. The excluded and included outcome measures per study can be seen in table 2.

**Table 2.** Outcome measures in RCTs

Study	Outcome measures	
	Included outcome measures	Excluded outcome measures in the studies
Andersen et al. 2002	Barthel Index	Functional Quality of Movement, Frenchay Activity Index and Index of Extended Activities of Daily Living
Clark et al. 2003	Barthel Index	Adelaine Activities Profile, SF-36, McMaster Family Assessment Device, Geriatric Depression Scale, Hospital Anxiety and Depression Scale; mastery (perceived and objective measure health): Mastery Scale
Donaldson et al. 2009	Action Research Arm Test	
Ertel et al. 2007	The Physical Performance Test (modified from Reuben and Siu) and some cognitive tests	The Barthel ADL Index (this outcome was not included because of the lack of information!), Instrumental Activities of Daily Living (modified)
Gillham et al. 2010	Self-reported exercise frequency	The primary outcome was "Readiness to change behaviour" measured using a validated stroke specific score based on the transtheoretical model. Secondary outcomes: the Hospital Anxiety and Depression Scale, and self-reported alcohol consumption, smoking behavior and fruit and vegetable consumption.
Johnston et al. 2007	Barthel Index [57]	The main outcome was recovery from disability using a performance measure, with distress and satisfaction as additional outcomes. A self-reported measure assessing 10 activities of daily living; and the Observer Assessed Disability [53] (recovery from disability), a performance measure in which patients perform 18 movements.
Kendall et al. 2006	Stroke Specific Quality of Life scale/physical sub-scales: mobility	The control group reported declines in functioning during the first year following stroke in the areas of family roles, activities of daily living, self-care and work productivity, intervention group not reported.

#### 8.4 Review outcomes

# Counselling

According to the "Counselling" outcomes, high evidence based on three high quality RCTs (Ertel et al. 2007; Johnston et al. 2007; Gillham & Endacott 2010) and three acceptable quality RCTs (Andersen et al. 2002a; Clark et al. 2003; Kendall et al. 2006) indicate that "Counselling" outcomes did not improve physical functioning after stroke (p = 0.45). In figure 2. the outcomes for the standard mean difference can be seen.

## Guidance and counselling

According to three acceptable quality interventions (Andersen et al. 2002b. and Donaldson et al. 2009a., b.) for "Guidance and counselling" outcomes, moderate evidence indicates that "Guidance and counselling" did not improve physical functioning after stroke (p = 0.19, Figure 2). In summary "Counselling" and "Guidance and counselling" did not improve physical functioning after stroke (p = 0.14).

# **Family functioning**

Family functioning was not analysed in this review but it was reported in four studies (Andersen et al. 2002a., b.; Clark et al. 2003 and Johnston et al. 2007). Only Andersen et al. (2002 a.) study had data of "Guidance and counselling" and three other studies "Counselling" was provided.

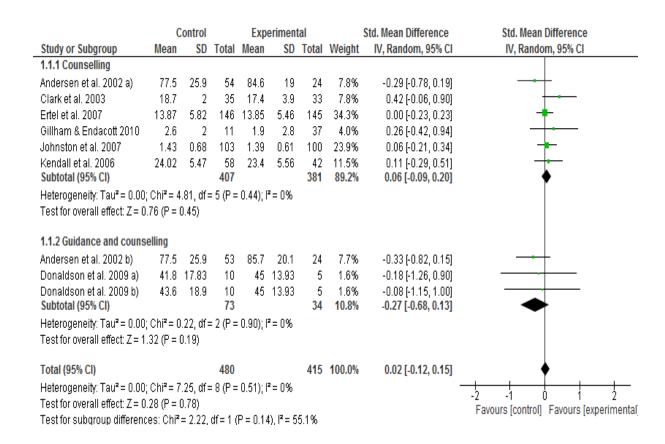


Figure 2. The effectiveness of "Counselling" and "Guidance and counselling" for physical functioning after stroke

## 9 DISCUSSION

There is a limited number of systematic reviews reported about the effectiveness of counselling and guidance on physical functioning after stroke. Therefore, this systematic review and meta-analysis will bring up some recent evidence for stroke population and health care professionals. This review indicates that neither "Counselling" nor "Guidance and counselling" methods did not improve physical functioning after stroke.

Some of the previous reviews about stroke rehabilitation support this finding. In Ellis et al. (2010) review it was found that there was no significant overall difference for subjective health status or extended activities of daily living for patients in impact of a healthcare worker or volunteer. In the other study, there were no statistical differences in functional outcomes between intervention and control groups when evaluating follow-up services for stroke survivors (Andersen et al. 2001). Ertel et al. (2007) found no significant differences on outcomes when evaluating the effectiveness neither of a psychosocial intervention in stroke rehabilitation, nor in the experimental "enhanced secondary prevention" intervention in Gillham & Endacott (2009) study. In spite of counselling the intervention content included the results were parallel.

In the following reviews, in which carers of the stroke patients were included in the intervention there were similar results. According to Smith et al. (2004) there was no improvement in knowledge about stroke and stroke services for stroke patients and carers after an education programme. Also Björkdahl et al. (2007) found that there was no difference between the burdens of care for the carers of stroke patients after "rehabilitation in the home setting". Visser-Meily et al. (2005) review showed that providing specialist services, (psycho)education, counselling and peer support may improve outcomes in carers of patients with stroke. One explanation might be the attitude of the providers for counselling and guidance. According to Hebèrt et al. (2012) most primary care providers are uncertain about the effectiveness of counselling and feel uncomfortable providing detailed advice about physical activity. A workbook-based intervention, including counselling, for stroke patients

showed significantly better disability recovery, allowing for initial levels of disability than in control group which was not provided by additional information (Johnston et al. 2007).

However, there were reviews (Bale & Strand 2007; Sutbeyaz et al. 2010 and Donaldson et al. 2009) which have shown significant positive effects on physical functioning outcomes when using counselling in stroke rehabilitation. Improved outcomes have been found also in the studies Green et al. 2007 and Rodgers et al. 1999 where improving knowledge and information about stroke has been the target of counselling. Olney et al. (2006) found trends to greater improvements in self-reported gains after supervised program and Clark et al. (2003) reported better family functioning for both patients and carers and modest benefit in functional status for intervention patients to improve family functioning. According to Orrow et al. (2012) there was no sufficient evidence to recommend exercise referral schemes over advice or counselling interventions where sedentary, healthy adults were recruited in primary care to increase physical activity levels at 12 months (self-report). Page et al. (2008) found that patients with chronic stroke may achieve impairment reductions and balance gains using a resistance-based, reciprocal upper and lower limb locomotor protocol training. Training treatment in Donaldson et al. (2009) consisted of guided training and the control group was provided a home exercise programme consisting of self-supervised practice with fractionated joint movements of the lower limb. This intervention included "Guidance and counselling" after stroke.

Counselling and guidance as a treatment method is unclear because of the contradictory outcomes. One reason for this unclearness might be the unclear definition of counselling and guidance. There was not any definition in any studies read for this systematic review about the way of counselling or/and guidance which have been provided in interventions. Despite the facts, that most of the studies mentioned counselling or guidance as one of the treatment methods, it was not described in the study. In this study the definition "Counselling" and "Guidance and counselling" was done according to the type of counselling. These definitions might not be the best but they came to prominence from the types of the interventions.

## 9.1. Strengths

This meta-analysis was a comprehensive review of the treatment effects of "Counselling" and "Guidance and counselling" for physical functioning after stroke including seven randomized controlled studies. The purpose of meta-analysis was to provide the best evidence synthesis of the available scientific research in the area. The literature search was systematic and inclusive as the search terms initially represented stroke rehabilitation. Only the studies with randomized control designs were included as they provide the best evidence of the efficiency of the treatment.

Each stage and method in this systematic analysis was well described to minimize errors and to assure the relevance of the study. In the selection phase and quality analysis independent assessor was used to assure that the detection bias was avoided and the conclusions were as objective and reliable as possible. Results of the meta-analysis were reported in detailed and the data outside the statistical analysis was also reported to avoid publication bias.

#### 9.2. Limitations

One limitation of the meta-analysis is that the latest literature search was performed in 2012. This might have some effect on the results since it is highly in likely new high quality studies have been published during last two years. In addition, it could be speculated that in recent studies counselling and guidance are better defined as compared with the previous studies.

The original interventions were short, from five weeks to 24 months and the range was wide. In this meta-analysis the intervention group was mostly men aged 66-69 years, which is the age group with the biggest risk to have stroke. They were mostly outpatients.

Quality analysis of the studies is important because of the weight of the results and their importance. Even though the quality of the original randomized controlled trials were high and acceptable quality there were some deficiencies in most of the studies. The intervention reporting especially counselling and guidance was inadequate. Therefore some valuable data had to be left out from this review. In only half of the studies group similarity was acceptable and in only two studies out of nine study research drop-outs were described properly. The importance of careful and detailed reporting of the study settings and methodological procedures cannot be forgiven in the research article. On the other hand all the studies reported randomization and treatment allocation. In this meta-analysis "Counselling" and "Guidance and counselling" were either very poorly described or there was no description at all in the original articles. This might have effected to outcomes of this review.

#### 9.3 Need for the future studies

First, the term counselling and guidance should be identified and then start researching the possible effects. More of this type of outcome measures and specific counselling methods is needed for clinical work and research.

There are many different ways to handle and look at counselling and guidance as a treatment method which effects on the outcomes. Furthermore, counselling and guidance is the most used treatment method in clinical work done by physiotherapists with people after stroke, as in this meta-analysis most of the intervention providers were physiotherapists. But can we separate counselling and guidance or should we assess them together as one treatment? Is it possible to separate counselling and guidance from training? Can counselling and guidance be measured separately? The consistence of the counselling differed between the original studies very much providing counselling to improve for example exercise frequency (Gillham & Endacott 2010), stroke education (Clark et al. 2003) and arm movement (Donaldson et al. 2009). Can these different methods be compared? How much does the counselling and guidance differ between the consistencies in interventions? The terms should be defined very closely in each study to achieve the best quality and repeatability in the future. This way we

could get more information about the effectiveness of counselling and guidance in stroke patient's treatment.

The Barthel Index was selected for the primary functional outcome measure in this metaanalysis but only three original articles out of seven were included this outcome measure. The
Barthel Index is valid measure of activities of daily living and reliability of standard
assessment is acceptable. (Harrison et al. 2013; Quinn et al. 2011) The sensitivity to change is
limited at extremes of disability, when talking about the range of possible outcomes in minor
or more severe strokes. The Barthel Index is often used in early phase rehabilitation studies.
(Harrison et al. 2013). In this review most of the individuals in interventions were acute
patients, from 0 to three months after stroke, which confirms the validity of the outcome
measure for this meta-analysis. Are there more useful valid outcome measures for measuring
the effectiveness of counselling and guidance? The Barthel Index indicates very widely
individual's physical ability and the grade of independency in daily life which is the most
important aspect after stroke. These outcomes are more useful for daily activities than
walking speed or some other outcomes which are used in stroke rehabilitation as a
measurement. The Barthel Index links best to International Classification of Functioning,
Disability and Health as an outcome measure for the physical functioning after stroke.

Furthermore, the family functioning is a fixed part of the stroke rehabilitation which should be explored more. The family functioning in a part of the counselling and guidance should be automatic in the importance of the carers role in patient's rehabilitation.

Finally, the community demands cost, i.e., efficiency methods of physiotherapy because of economic burden of health care. In addition, evidence based research of counselling and guidance should be done in physiotherapists' clinical work.

### **10 CONCLUSIONS**

This systematic literature review indicated that "Counselling" and "Guidance and counselling" are not effective methods in increasing stroke patients' physical functioning. Counselling and guidance are the main methods to promote physical functioning but it is often performed without guidelines or specific counselling types.

#### **REFERENCES**

Aivoverenkiertohäiriöt lukuina. Aivoliitto.[www-document]4/2011[read11.8.2012] avh\_lukuina2012.pdf

http://www.aivoliitto.fi/aivoverenkiertohairio (avh)/aivoverenkiertohairio

Andersen HE, Eriksen K, Brown A, Schultz-Larsen K, Hysse B. Follow-up services for stroke survivors after hospital discharge- a randomized control study. Clin Rehabil 2002;16:593-603.

Bale M, Strand LI. Does functional strength training of the leg in subacute improve physical performance? A pilot randomized controlled trial. Clin Rehabil 2008; 22:911-921.

Burnard P. Counselling skills for health professionals. Second edition. London. Chapman & Hall. 1994:6,10-16,28,149.

Björkdahl A, Nilsson ÅL, Sunnerhagen KS. Can rehabilitation in the home setting reduce the burden of care for the next-of-kin of stroke victims? J Rehabil Med 2007;39:27-32.

Brereton L, Carroll C, Barnston S. Interventions for adult family carers of people who have had a stroke: a systematic review. Clin Rehabil 2007;21:867-884.

Carr J, Shepherd R. Stroke rehabilitation: guidelines for exercise and training to optimize motor skill. Elsevier Limited. Butterworth-Heinemann. 2003:7,14-15,18,20,23,26,224,264.

Carr J, Shepherd R. Neurological rehabilitation: optimizing motor performance. 2<sup>nd</sup> edition. China. Churchill-Livingstone Elsevier. 2010:21,39,43,45,255,258,265.

Clark M.S, Rubenach S, Winsor A. A randomized controlled trial of an education and counseling intervention for families after stroke. Clin Rehabil 2003;17:703-712.

Donaldson C, Tallis R, Miller S, Sunderland A, Lemon R, Pomeroy V. Effects of Conventional Physical Therapy and Functional Strength Training on Upper Limb Motor Recovery After Stroke: A Randomized Phase II Study. Neurorehab Neural Re 2009;23: 389.

Duffy L, Gajree S, Langhorne P, Stott DJ, Quinn TJ. Reliability (Inter-rater Agreement) of the Barthel Index for Assessment of Stroke Survivors: Systematic Review and Meta-analysis. Stroke 2013;44:465-466.

Ellis G, Mant J, Langhorne P, Dennis M, Winner S. Stroke liaison workers for stroke patients and carers: an individual patient data meta-analysis. Cochrane database of systematic reviews 2010.doi:10.1002/14651858.CD005066.pub2.

Ertel KA, Glymour MM, Glass TA, Berkman LF. Frailty modifies effectiveness of psychosocial intervention in recovery from stroke. Clin Rehabil 2007;21:511-522.

Gillham S, Endacott R. Impact of enhanced secondary prevention on health behaviour in patients following minor stroke and transient ischaemic attack: a randomized controlled trial. Clin Rehabil 2010;24:822-30.

Green T, Haley E, Eliasziw M, Hoyle K. Education in stroke prevention: efficacy of an educational counselling intervention to increase knowledge in stroke survivors. Can J Neurisci Nurs 2007;29:13-20.

Guess E, Debra P, Lane AE. Achieving functional independence. In Braddom RL and Chan L, Harrast MA, Kowalske KJ, Matthews DJ, Ragnarsson KT, Stolp KA (assistant eds). Physical medicine & rehabilitation. 4th ed. Philadelphia. Elsevier Saunders, 2011: 567.

Harrison JK, McArthur KS, Quinn T. Assessment scales in stroke: clinimetric and clinical considerations. Clinical Interventions in Aging.2013;8:202-208.

Hèbert ET, O Caughy MO, Shuval K. Primary care providers perceptions of physical activity counselling in a clinical setting: a systematic review. Br J Sports Med 2012; 46: 625-631.

International classification of functioning, disability and health: ICF. WHO Library Cataloguing-in-Publication Data. Genova 2001.

http://www.disabilitaincifre.it/documenti/ICF 18.pdf

Johnston M, Bonetti D, Joice S, Pollard B, Morrison V, Francis JJ, MacWalter R. Recovery from disability after stroke as a target for a behavioural intervention: Results of a randomized controlled trial. Disabil Rehabil 2007;29:1117-1127.

Kauhanen M-L. Aivoverenkiertohäiriöt. In Alaranta H, Pohjolainen T, Salminen J, Viikari-Juntura E (eds.) Fysiatria. 3rd ed. Jyväskylä: Duodecim. 2003: 212, 219.

Kaste M, Hernesniemi J, Kotila M, Lepäntalo M, Lindsberg P, Palomäki H, Roine RO, Sivenius J. Aivoverenkiertohäiriöt. In Soinila S, Kaste M, Somer H (eds). Neurologia. 2-3<sup>rd</sup> ed. Helsinki: Duodecim, 2007:271-273,282-283,327-329.

Kendall E, Catalano T, Kuipers P, Posner N, Buys N, Charker J. Recovery following stroke: The role of self-management education. Sos Sci Med 2006;64:735-746.

Korpelainen J, Leino E, Sivenius J, Kallanranta T. Aivoverenkiertohäiriöt. In Rissanen P, Kallanranta T, Suikkanen A (eds). Kuntoutus. 2<sup>nd</sup> ed. Helsinki: Duodecim, 2008: 251-254,256-257,259,261-262,264,268.

Kuikka P, Pulliainen V, Hänninen R. "Kliininen neuropsykologia". Porvoo. WSOY. 2001:36-40,97-98,100-101,280,282,290-294.

Kwakkel G, Kollen BJ. Int J Stroke 2013; 8:25-32. doi: <u>10.1111/j.1747-4949.2012.00967.x.</u> <u>Predicting activities after stroke: what is clinically relevant?</u>

Mälkiä E, Sjögren T, Paltamaa J. Liike- ja liikuntahoidot: terapeuttinen harjoittelu ja kuntouttava liikunta fysioterapiassa. In Alaranta H, Pohjolainen T, Salminen J, Viikari-Juntura E (eds.) Fysiatria. 3rd ed. Jyväskylä: Duodecim. 2003:353,366.

Olney SJ, Nymark j, Brouwer B, Culham E, Day A, Heard J, Henderson M, Parvataneni K. A randomized controlled trial of supervised versus unsupervised exercise programs for ambulatory stroke survivors. Stroke 2006;37:476-481.

Orrow G, Kinmonth A-L, Sanderson S, Sutton S. Effectiveness of physical activity promotion based in primary care: systematic review and meta-analysis of randomised controlled trials. BMJ 2012;344:e1389 doi: 10.1136/bmj.e1389.

Page SJ, Levine P, Teepen J, Hartman EC. Resistance-based, reciprocal upper and lower limb locomotor training in chronic stroke: a randomized, controlled crossover study. Clin Rebabil 2008;22:610-617.

Reynolds F. Communication and clinical effectiveness in rehabilitation. Elsevier Limited. China. 2005:145-163.

Rodgers H, Atkinson C, Bond S, Suddes M, Dobson R, Curless R. Randomized controlled trial of a comprehensive stroke education program for patients and caregivers. Stroke 1999;30:2585-2591.

Shumway-Cook A & Woollacott M. Motor control. Theory and practical applications. Lippincott Williams & Williams. USA 1995:37.

Smith J, Forster A, Young J. A randomized trial to evaluate an education programme for patients and carers after stroke. Clin Rehabil 2004;18:726-736.

Stokes M. Neurological physiotherapy. Mosby. International Limited. UK. 1998:79,321.

Stokes M. Physical management in neurological rehabilitation. 2<sup>nd</sup> edition. Elsevier Mosby. UK. 2004:77,81,83,87,91,93.

Sutbeyaz ST, Koseoglu F, Inan L, Coskun O. Respiratory muscle training improves cardiopulmonary function and exercise tolerance in subjects with subacute stroke: a randomized controlled trial. Clin Rehabil 2010; 24:240-250.

Tarnanen K, Lindsberg P, Sairanen T, Vuorela P. Aivoinfarkti. Käypä hoitosuositukset.[www-document]7.1.2011.[read11.8.2012] http://www.kaypahoito.fi/web/kh/suositukset/naytaartikkeli/.../khp00062

Viitanen M. Aivoverenkiertohäiriöt. In Tilvis R, Pitkälä K, Strandberg T, Sulkava R, Viitanen M (ed.). Geriatria. 2<sup>nd</sup> edition. Duodecim. Helsinki. 2010; 146.

Visser-Meily A, Van Heugten C, Post M. Review: counselling and education may improve outcomes in caregivers of patients with stroke. Patient Educ Couns 2005; 56:257-267.

Wade DT. Measurement in neurological rehabilitation. Oxford: Oxford Medical Publications 1992.

Quinn TJ, Langhorne P, Stott DJ. Barthel Index for stroke Trials: Development, properties and application. Stroke 2011; 42:1146, 1150-1151.

### **APPENDICES**

- Appendix 1: Counselling and guidance classification according to intervention
- Appendix 2: Search strategy year 2011
- Appendix 3: Search strategy year 2012
- Appendix 4: Inclusion and exclusion criteria of the studies
- Appendix 5: Criteria for the methodological quality assessment according Van Tulder
- Appendix 6: Methodological quality of randomized controlled studies

# Counselling and guidance classification according to intervention

# Appendix 1/1

Study	Study duration	Intensity of intervention	Type of counselling	Outcomes
"Counselling"				
Andersen et al. 2002 a)	12 weeks	I: Follow-up visits included three, 1 hour home visits (at 2, 6 and 12 weeks after discharge).	I: Follow-up home visits by a physician to improve functional outcome and reduce readmission rate. C: Standard aftercare	No statistically significant differences in functional outcome six months after discharge were demonstrated between the three groups. All measurements showed a tendency towards higher scores indicating better function in both intervention groups compared with the control group.
Clark et al. 2003	5 months	Families were given the information package on rehabilitation discharge. The visits were situated at three weeks, at two months and at five months after discharge.	I: Stroke information package and three visits from a social worker  C: No information, no	At six months the intervention group had better family functioning for both patients and spouses. A modest benefit in functional status for intervention patients was related to improved family functioning.
			counselling	
Ertel et al. 2007	24 months	I: Up to 16 meetings conducted over six months in patient's home, approximately weekly for 12 weeks, followed by triweekly sessions for another 12 weeks. Sessions lasted approximately 1 hour.	I: A psychosocial intervention meetings at patient's home.	No significant differences in outcomes were observed between the intervention and usual care groups when analyzing the total study population.
Gillham & Endacott 2010	2 weeks and 6 weeks after the initial interview	Contacts at two weeks and six weeks after the initial interview.	C: Usual care with standard educational material on stroke recovery. I: Enhanced secondary prevention; telephone support and follow-up to discuss progress.	Statistically significant improvements for change in self-reported exercise were demonstrated to 2-3 times per week in the intervention group compared to 0-1 times per week in the control group.
			C: No further secondary prevention advice.	

Johnston et al. 2007	5 weeks	The group was contacted and visited home within one week of baseline. The second visit was at the following week. The third and fourth contacts were by telephone at weekly intervals. The last home visit was during the fifth week of the intervention period. Duration of interviews was 45-120 minutes.	I: A workbook-based intervention with home visits and telephone contacts.  C: Normal care (no further information in the study)	Appendix 2/1 The intervention group showed significantly better disability recovery, allowing for initial levels of disability, than control group
Kendall et al. 2006	7 weeks	Eight groups were conducted over an 18 months period. The Chronic Disease Self-management course was conducted over 6-week period, for approximately 2 hours each week.	I: Psychosocial skill expansion by an existing self-management program.  C: Standard rehabilitation (no further information in the study)	The study identified a significant impact of the intervention on the quality of family roles, self-care, work productivity and functioning in daily activities.
"Guidance and	counselling"			
Andersen et al. 2002 b)	6 weeks	I: The frequency of visits was determined by the physiotherapist and was adjusted to the patient's needs. Each visit lasted approximately 1 hour.	<ul><li>I: Instructions by a physiotherapist in the patient's home.</li><li>C: Standard aftercare</li></ul>	No statistically significant differences in functional outcome six months after discharge were demonstrated between the three groups. All measurements showed a tendency towards higher scores indicating better function in both intervention groups compared with the control group.
Donaldson et al. 2009 a)  Donaldson et al. 2009 b)	6 weeks	Intervention was provided for up to 1 hour, 4 days a week for 6 weeks (24 hours).	<ul><li>I1: Conventional physical therapy consisting facilitation and movement guiding.</li><li>I2: Conventional physical therapy + functional strength training</li></ul>	The CPT +CPT group's increase was smaller than the increase of the control group in ARAT score.  The CPT + FST group showed the largest increase in ARAT score and this was above the clinically important level.
			C: Conventional therapy using standardized treatment schedule.	

### Appendix 1/2

## Database: Ovid MEDLINE(R) <2007 to September Week 2 2011>

### Search Strategy:

- 1 strength training.mp. (761)
- 2 resistance training.mp. (1932)
- 3 aerobic training.mp. (307)
- 4 motor control.mp. (1676)
- 5 motor learning.mp. (732)
- 6 Counseling/ (4370)
- 7 guidance.mp. (15131)
- 8 1 or 2 or 3 or 4 or 5 or 6 or 7 (24265)
- 9 randomized controlled trial.mp. or Randomized Controlled Trial/ (79622)
- 10 randomized controlled trials.mp. (30532)
- 11 randomised controlled trial.mp. (2880)
- 12 randomised controlled trials.mp. (3354)
- 13 Randomized Controlled Trials as Topic/ (26530)
- 14 randomized clinical trial.mp. (3425)
- 15 randomized clinical trials.mp. (2816)
- 16 randomised clinical trial.mp. (424)
- 17 randomised clinical trials.mp. (511)
- 18 rct.mp. (2564)
- 19 crt.mp. (2607)
- 20 random allocation/ (13607)

### Appendix 2/2

- 21 random\$.mp. (192285)
- 22 systematic review\*.mp. (15896)
- 23 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 (204225)
- 24 stroke.mp. (40345)
- 25 Hemiplegia/ (856)
- 26 Cerebrovascular Disorders/ (2104)
- 27 Brain Ischemia/ (7214)
- 28 cerebrovascular accident\*.mp. (714)
- 29 Brain Infarction/ (1291)
- 30 24 or 25 or 26 or 27 or 28 or 29 (46037)
- 31 8 and 23 and 30 (126)
- limit 31 to (yr="2008 -Current" and ("all adult (19 plus years)" or "young adult (19 to 24 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)") and (english or finnish or german or swedish) and humans) (73)

# Appendix 1/3

Counseling	/ 4602	Advanced
2	guidance.mp.	17173
3	1 or 2	21681
4	randomized controlled trial.mp. or Randomized Controlled Trial/	86776
5	randomized controlled trials.mp.	33432
6	randomised controlled trial.mp.	3378
7	randomised controlled trials.mp.	3896
8	Randomized Controlled Trials as Topic/	28706
9	randomized clinical trial.mp.	3837
10	randomized clinical trials.mp.	3135
11	randomised clinical trial.mp.	512
12	randomised clinical trials.mp.	564
13	rct.mp.	3129
14	crt.mp.	3030
15	Random Allocation/	14437
16	random\$.mp.	209660
17	systematic review*.mp.	19861
18	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17	224538

	Aŗ	opendix 2/3
19	stroke.mp.	44525
20	Hemiplegia/	856
21	Cerebrovascular Disorders/	2262
22	Brain Ischemia/	7943
23	cerebrovascular accident*.mp.	721
24	Brain Infarction/	1332
25	19 or 20 or 21 or 22 or 23 or 24	50407
26	3 and 18 and 25	48
27	limit 26 to (("young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)") and (english or finnish or german or swedish) and humans)	26

## Inclusion and exclusion criteria of the studies

Study	Inclusion Criteria	Exclusion Criteria
Andersen et al. 2002 (outpatients)	Acute stroke (WHO criteria; patients with subarachnoid haemorrhage were not included), discharge planned to own home and impaired motor capacity (SSS at discharge <58, subscore for arm, hand, leg ≤5 or subscore for gait ≤0; or British Medical Research Council Muscle Strength Assessment score ≤4+)	Communication not possible, other disease likely to shorten life dramatically, previously included in this study, participation in other clinical studies and lack of consent to participate in study
Clark et al. 2003 (outpatients)	Confirmed diagnosis of stroke, was discharged home and was coresident with a spouse.	Severe expressive or receptive language problems or very poor command of English, Mini-Mental State Examination score indicated cognitive deficiency, discharged to in-home rehabilitation or residential care, entered residential care subsequent to their discharge.
Donaldson et al. 2009 (no info in the study)	Infarction of the anterior cerebral circulation (diagnosed through neuroimaging) between 1 week and 3 months after stroke; some voluntary muscle activity in the paretic upper limb, scoring 4+/57 on the ARAT but unable to complete the Nine Hole Peg Test (9HPT) in the 50 seconds or less; no obvious unilateral visuospatial neglect on clinical observation of subject's ability to orientate toward objects and people in their environment; able, prior to their stroke, to use the paretic upper limb to lift a cup and drink from it; able to follow a one-stage command; able to participate in routine therapy	No information in the study

### Appendix 2/4

Ertel et al. 2007 No information in the study Globally aphasic or had limited comprehension and expressive aphasia (Boston Aphasia Severity Rating Scale = 0 or 1), (outpatients) extremely socially isolated, residing in a nursing home prior to stroke or discharged to a nursing home, cognitively impaired prior to stroke, living outside metropolitan Boston, only mildly impaired (National Institutes of Health Stroke Severity Index < 3) or very severely impaired (NIH Stroke Severity Index > 8) Gillham & First stroke to eliminate previous knowledge of usual clinic No information in the study Endacott 2010 interventions (outpatients) No information in the study No information in the study Johnston et al. 2007 (outpatients) No information in the study Kendall et al. 2006 Sustained a stroke in the last few months, but had no prior selfreported history of stroke, dementia or psychiatric illness, sufficient (outpatients) expressive/receptive English language skills to take part in interviews and the intervention, as determined by the treating speech pathologist,

> expectation of discharge to their own or a family member's home, and a family member or friend who was willing to participate in the

study with them

### Appendix 1/5

## Methodological quality

Criteria for the methodological quality assessment (A-K) and the operationalization of each criterion

Α	Was the method of randomization adequate?	Yes	No	Don't know
	A random (unpredictable) assignment sequence. Examples of adequate methods are computer generated random number table, use of sealed opaque envelopes, or similar. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.			

"yes" tiukka linja eli hyväksytään, jos on selkeästi mainittu hyväksyttävä satunnaismenetelmä.

Lisäksi ilmaisu "a equal probability" hyväksytään.

"No", jos menetelmä ei ole hyväksytty.

"Don't know", jos toteutus jää epäselväksi tai toteutusta ei ole raportoitu

В	Was the treatment allocation concealed?	Yes	No	Don't know
	Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or the decision about eligibility of the patient.			

"Yes", jos selkeästi mainittu, että ryhmiin jakaminen oli salattu "No", jos maininta, että ei ole toteutunut asianmukaisesti. "Don't know", jos epäselvästi esitetty tai ei ole raportoitu.

С	Were the groups similar at baseline regarding the most important prognostic indicators?	Yes	No	Don't know
	In order to receive a "yes", groups have to be similar at baseline regarding demographic factors (age, setting), duration and severity of the disease, percentage of patients with neurologic symptoms, and value of main outcome measure(s).			

<sup>&</sup>quot;Yes", jos selkeästi mainittu että ryhmät eivät eronneet alkumittauksissa tärkeimpien ennustavien tekijöiden suhteen

Katso teksti ja taulukot. Tilastollinen testaus eroista olisi hyvä olla suoritettuna.

<sup>&</sup>quot;No", ryhmät erosivat alkumittauksissa toisistaan

<sup>&</sup>quot;Don't know", jos epäselvästi esitetty tai ei ole raportoitu.

### Appendix 2/5

D	Was the patient blinded to the intervention?	Yes	No	Don't know
	The reviewer determines if enough information about the blinding is given in order to score a "yes".			

<sup>&</sup>quot;Yes", jos selkeästi mainittu, että potilaat eivät tienneet, mitä terapiaa saivat.

<sup>&</sup>quot;Don't know", jos epäselvästi esitetty tai ei ole raportoitu lainkaan

Е	Was the care provider blinded to the intervention?	Yes	No	Don't know
	The reviewer determines if enough information about the blinding is given in order to score a "yes".			

<sup>&</sup>quot;Yes", jos selkeästi mainittu, että terapeutit eivät tienneet mitä terapiaa antoivat.

<sup>&</sup>quot;Don't know", jos epäselvästi esitetty tai ei ole raportoitu.

F	Was the outcome assessor blinded to the intervention?	Yes	No	Don't know
	The reviewer determines if enough information about the blinding is given in order to score a "yes".			

<sup>&</sup>quot;Yes", jos selkeästi mainittu, että tulosten mittaajat eivät tienneet mihin ryhmään mitattavat kuuluivat.

### Kyselylomakkeet:

- Jos esim. tutkija merkitsee ylös kuntoutujan vastauksen = not blinded -> no
- kuntoutuja palauttaa itsenäisesti täytetyn lomakkeen = voidaan katsoa sokkoutuksen toteutuneen -> yes
- Jos täyttäjästä ei ole tietoa -> don't know.

G	Were the co interventions avoided or similar?	Yes	No	Don't know
	Co interventions should either be avoided in the trial design or similar between the index and control groups.			

<sup>&</sup>quot;Yes", jos selkeästi mainittu, että vältettiin muita samanaikaisia interventioita tai, että ne olivat samanlaiset ryhmien välillä (suunnitelma ja/tai toteutus).

<sup>&</sup>quot;No", jos ei sokkouttettu ("blided")

<sup>&</sup>quot;No", jos ei sokkoutettu ("blinded")

<sup>&</sup>quot;No", jos ei sokkoutettu ("blided")

<sup>&</sup>quot;Don't know", jos epäselvästi esitetty tai ei ole raportoitu

<sup>&</sup>quot;No", jos ei ole otettu huomioon tai muu yhtäaikainen interventio on erilaista

<sup>&</sup>quot;Don't know", jos epäselvästi esitetty tai ei ole raportoitu

### Appendix 3/5

Н	Was the compliance acceptable in all groups?	Yes	No	Don't know
	The reviewer determined if the compliance to the interventions is acceptable, based on the reported intensity, duration, number of frequency of sessions for both the index intervention and control intervention(s).			

<sup>&</sup>quot;Yes", jos suunniteltu toteutuma (%) raportoitu.

<sup>&</sup>quot;Don't know" epäselvästi esitetty tai ei ole raportoitu

I	Was the drop-out rate described and acceptable?	Yes	No	Don't know
	No drop-outs or the number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored. (N.B. these percentages are arbitrary, not supported by literature).			

"Yes" Keskeyttämisen määrä on hyväksyttävä, jos < 20% (short ≤ 6kk) tai < 30% (long > 6 kk). Lisäksi keskeyttämisen syyt oli mainittu.
"No", pudonneita enemmän kuin em. tai keskeyttämisen syitä ei ollut mainittu
"Don't know", jos epäselvästi esitetty tai ei ole raportoitu

(Laske drop-out prosentit, jos raportissa ei ole niin piirrä flow chart -kuvio)

J	Was the timing of outcome assessment in all groups similar?	Yes	No	Don't know	
	Timing of outcome assessment should be identical for all interventions groups and for all important outcome assessments.				

<sup>&</sup>quot;Yes", jos mittaukset tehtiin kaikissa ryhmissä tutkimuksen samassa vaiheessa (sama ajoitus).

(Kts. flow chart –kuvio)

К	Did the analysis include an intention-to treat analysis?	Yes	No	Don't know
	All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and co interventions.			

<sup>&</sup>quot;No" toteumat eivät ole olleet yhdenmukaiset

<sup>&</sup>quot;No", eri ajoitus.

<sup>&</sup>quot;Don't know", jos epäselvästi esitetty tai ei ole raportoitu

### Appendix 4/5

"Yes", selkeästi esitetty, kaikkien satunnaistettujen koehenkilöiden tulokset analysoitiin ja raportoitiin niissä ryhmissä, joihin heidät satunnaistettiin riippumatta siitä toteuttivatko koehenkilöt intervention suunnitellulla tavalla (osallistuminen interventioon ja mittauksiin) tai oliko heillä muita samanaikaisia interventioita. "No", analysointi tapahtui eri ryhmissä kuin mihin satunnaistettiin tai koehenkilöitä poistettiin analyysista interventioon, mittauksiin tai samanaikaisen muun intervention takia.

"Don't know", jos epäselvästi esitetty, esimerkiksi ei voi päätellä koska tuloksissa ei mitään tietoa n-määristä.

(Kiinnitä huomiota mm. tulosten raportoinnissa esitettyihin n-määriin. Onko ristiriitaisuutta? Jääkö epäselvyyksiä?)

#### References

Van Tulder M, Furlan A, Bombardier C, Bouter L, and the Editorial Board of the Cochrane Collaboration Back Review Group. Updated method guidelines for systematic reviews in the Cochrane collaboration back review group. Spine 2003;28(12):1290-1299.

Anttila H, Kärki A, Rautakorpi U-M (ja asiantuntijaryhmä). Lymfaturvotuksen fysioterapia rintasyöpäpotilailla. Vaikuttavuus, käytännöt ja kustannukset. Fiohtan raportti 30/2007. Fiohta, Stakes.

Methodological quality	A	В	С	Е	F	G	Н	I	J	K	L	No of "yes" scores (0-11)
Type of counselling: I	nformatio	n and self	-managem	ent								
Andersen et al. 2002 a)	yes	yes	no	no	no	yes	?	?	yes	?	yes	5 accept able
Clark et al. 2003	yes	yes	yes	?	yes	yes	?	?	no	?	?	5 accept able
Ertel et al. 2007 (earlier publications)	yes	yes	no	?	no	yes	?	yes	yes	yes	yes	7 high
Gillham &Endacott 2010	yes	yes	yes	?	?	no	yes	?	yes	yes	no	6 high
Johnston et al. 2007	yes	yes	yes	no	yes	yes	?	?	no	yes	yes	7 high
Kendall et al. 2006	yes	yes	no	no	no	no	yes	yes	no	no	no	4 accept able

Methodological quality	A	В	С	Е	F	G	Н	I	J	K	L	No of "yes" scores (0-11)
Type of counselling: Movement guiding and facilitation + functional and physical ability												
Andersen et al. 2002 b)	yes	yes	no	no	no	yes	?	?	yes	?	yes	5 accept able
Donaldson et al. 2009 a) +b)	yes	yes	yes	yes	no	?	yes	?	no	yes	?	6 accept able

Note. The methodological quality of the RCTs was rated with criteria and decision rules modified from van Tulder et al. (2003, 26). Grey columns indicate the rating items needed for high-level RCTs with the total number of "yes" answers  $\geq 6$  and the amount of patients  $\geq 30$ . The RCT was rated to acceptable, if number of "yes" answers was  $\geq 4$  containing A, and poor, if number of "yes" answers was 0-3 or  $\geq 4$ , but A was "don't know"=? or if the amount of patients was  $\leq 5$  in the group.

Appendix questions Appendix 3/6

- A= Was the method of randomization adequate?
- B= Was the treatment allocation concealed?
- C= Were the groups similar at baseline regarding the most important prognostic indicators?
- D= Was the patient blinded to the intervention?
- E= Was the care provider blinded to the intervention?
- F= Was the outcome assessor blinded to the intervention?
- G= Were the co interventions avoided or similar?
- H= Was the compliance acceptable in all groups?
- I= Was the drop-out rate described and acceptable?
- J= Was the timing of outcome assessment in all groups similar?
- K= Did the analysis include an intention-to treat analysis?