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The effect of Functional Electrical Stimulation compared to conventional therapy for the functional recovery of the upper extremity in chronic stroke patients, a systematic literature review.

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Preface

I think we all know some people who have suffered a stroke. Some people get along quicker than others. The ones that do not recover very quickly can be left with problems during everyday life. Especially functional activities like undressing, combing their hair, holding a pen or opening a bottle can be very difficult.

Nowadays, the treatment approach for neurological patients varies greatly, depending on the kind of therapy chosen and the symptoms encountered by the therapists. A very interesting approach is the functional, task oriented way. A therapy that reasons following this approach is Functional Electrical Stimulation. It tries to help these patients and get them back to doing the usual things that many of us take for granted.

That is why over the past few months, I have taken a closer look into the effect of Functional Electrical Stimulation by comparing it to other types of therapy used for stroke patients.

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Abstract

Background: Worldwide, fifteen million people suffer from a stroke every year. Approximately 55% of stroke survivors have a non-functional upper extremity following initial therapy, consisting of physical therapy and occupational therapy. Functional Electrical Stimulation is a treatment modality geared towards functional improvement of the upper extremity after stroke.

Objective: To find out if Functional Electrical stimulation is more effective for improving functional recovery of the upper extremity of chronic stroke patients compared to conventional therapy.

Method: Based on inclusion and exclusion criteria, relevant articles were searched in various databases. The selected articles were assessed on methodological quality using the PEDro scale and the data was extracted. Consequently, a best evidence synthesis was applied to gain more insight into the level of evidence.

Results: Three articles of “moderate” and one of “good” methodological quality were found. Two separate best evidence syntheses were applied. The best evidence synthesis showed moderate evidence that FES significantly improves functional recovery of the upper extremity compared to conventional physiotherapy. It also showed moderate evidence that FES significantly improves active range of motion compared to conventional therapy.

Conclusion: FES is an effective and, most importantly, a functional treatment modality that can be used to improve the functional recovery of the upper extremity for chronic stroke patients. FES has shown to be more effective than conventional therapy.

Keywords: Functional Electrical Stimulation, Chronic, Stroke, Upper Extremity

Table of contents

Introduction

Worldwide, fifteen million people suffer from a stroke every year. Stroke is the second leading cause of death in people above 60 years of age, and the fifth leading cause of death in people aged 15 to 59 years old.[1] Out of the 50 million worldwide stroke survivors, 25% to 74% need assistance or are fully reliable on caregivers to carry out activities of daily living (ADL).[2] Approximately 50% and 70% of these stroke survivors become functionally independent, but 15 to 30% are left with permanent disabilities.[3] Patients that are left with disability more than 6 months after onset are classified as chronic stroke patients, according to the KNGF.[4]

With regards to achieving functional independence to carry out these ADL activities, the upper extremity can cause problems for hemiplegic stroke patients.[3, 5-7] The majority of stroke patients have reported that the impaired arm function is a major problem for them.[7] A study investigating the top 10 priorities of stroke survivors, caregivers, and health professionals relating to life after stroke showed arm and hand function to be the 4th most important goal.[8] With regards to range of motion and strength, partial recovery of upper limb function is obtained in about 30% of the stroke survivors.[6] However, these patients are still not able to carry out ADL with their affected upper extremity.[6] This affects their functional independence and consequently increases the burden of care.[6] Approximately 55% of stroke survivors have a non-functional upper extremity following initial therapy. This initial therapy often consists of conventional physical therapy and occupational therapy.[6]

Conventional therapy consists of various interventions geared towards improving the functional recovery of the upper limb and thus trying to increase the quality of life of stroke patients.[9, 10] Some examples of these interventions are sensory-motor training, cardiovascular fitness programs, mobility and mobility related activity programs, biofeedback therapy, exercise therapy and occupational therapy.[9, 11] Knutson et al.[11] state that routine occupational therapy has limited effects concerning restoration of independent use of the impaired upper limb.[11] Due to this fact stroke survivors do not regain hand function on the affected side.[11] Next to these conventional interventions, Functional Electrical Stimulation (FES) has been used by physical therapists for the functional recovery of the patient's upper extremity [6, 10, 12]

The principle of FES is to provide electrical stimulation by placing electrodes on or near the innervating nerve fibers.[13] The aim of this process is to provide functional recovery.[13] The incorporation of functional movements in combination with electrical stimulation is what makes FES unique compared to other electrical stimulation methods like Neuromuscular Electrical Stimulation (NMES). NMES namely does not incorporate functional movements together with electrical stimulation.[14] An example of a functional, task-oriented movement in combination with FES is the attempt to reach out and grasp an object, move it to a new location, and release the object.[15] This way, the patient involves all joints of the upper extremity and will relearn to use

the affected extremity in a functional way.[15]

The advantage of FES is that it can be used in several clinical settings which are not only limited to hospitals or rehabilitation centres.[6] FES can also be used in outpatient and home based settings. An advantage of FES is, is that it is applicable to stroke patients in the acute, subacute as well as the chronic stage of stroke recovery.[10, 15] Because FES has already shown to be a powerful method for restoring upper extremity function of acute and subacute stroke patients,[15, 16] this review focuses solely on the effects of FES on chronic stroke patients.

This review aims to answer the following research question: Is FES more effective compared to conventional therapy for improving functional recovery of the upper limb in chronic stroke patients?

Methods

Inclusion criteria

Before the start of this systematic literature review, in- and exclusion criteria for the selection of relevant studies were set. In order to do this, the following aspects of studies were taken into account: study design, participants, type of intervention, control intervention, outcome measures and language of the study. A summary of the in- and exclusion criteria is provided in (table 1).

Table 1: Inclusion and exclusion criteria

Inclusion criteria	• Study design: Randomized Controlled Trials or Controlled Clinical Trials • Participants: patients that had been diagnosed with hemiplegic stroke in the chronic stage at any age (>6 months post-stroke) • Intervention: Functional Electrical Stimulation on functional recovery of the upper extremity • Control intervention: studies that use conventional therapy using a task oriented approach similar to the experiment group for the upper extremity • Outcome measures: disability/ability (activities of daily living) or functional status: active range of motion, arm strength, grip function • Language: studies published in the English language
Exclusion criteria	• Studies reported only in the abstract form • Studies investigating the effect of Neuromuscular Electro Stimulation, EMG-triggered electrical stimulation, TENS or intramuscular electrical stimulation • Studies that apply FES on lower limbs or trunk besides the upper limb at the same time • Studies that include patients with shoulder subluxation
** EMG-triggered = Electromyographically triggered, TENS = Transcutaneous Electrical Nerve Stimulation, FES = Functional Electrical Stimulation*	

Study design

Only Randomized Controlled Trials (RCTs) or Controlled Clinical Trials (CCTs) were included. Only full-text articles were included in this systematic literature review. Articles reported only in the abstract form were therefore excluded.

Participants

The subjects included in the selected studies should fulfil the following criteria: the subjects had to be clinically diagnosed with a stroke or cerebrovascular accident in the chronic stage (> six

months post stroke).[4] The subjects included in the studies needed to be 18 years or older.

Intervention

Studies were eligible for further screening if they used FES as the intervention. Studies using EMG-triggered electrical stimulation, TENS or NeuroMuscular Electrical Stimulation were excluded. The control intervention had to be a conventional therapy form, using a task-oriented approach for the upper extremity, as listed in the Dutch guideline for stroke treatment by the KNGF.[4]

Outcome measures

Because this review focused on functional status or functional recovery of the affected upper extremity, these are the main outcome measures. Tests like the Wolf-Motor-Function-Test (WMFT) and Fugl-Meyer Assessment (FMA), amongst others, assess the ability to use the affected upper extremity in a functional way. The FMA is shown to be a moderately reliable measure to assess impairment in patients during rehabilitation after stroke.[17] The WMFT has a high test-retest reliability, internal consistency and interrater reliability.[18] The test has good stability and it is a supported test in research and clinical settings when used for chronic stroke patients.[18] Next to these tests, active range of motion, muscle strength and grip function of the upper extremity are frequently used outcome measures for the functional use of the hemiplegic arm.

Language

Solely articles written in the English language were included. Studies in any other language were excluded from this review.

Search Strategy

PubMed (January 1996 – March 2013), PEDro (1999 – March 2013), Cochrane (1994 - March 2013) and ScienceDirect (1999 - March 2013) were searched to find relevant studies. Relevant studies investigated the effect of FES on functional recovery of the upper extremity in chronic stroke patients. The keywords mentioned in (table 2) were used to search titles and abstracts of relevant articles. The Boolean operators and/or were used to combine the search terms during this search method. Furthermore, a specific search of the reference lists of all the included articles was performed to identify more relevant articles.

Table 2. Keywords for literature search

Intervention	Outcome	Participants
Functional electrical stimulation	Upper extremity	Chronic stroke
Functional electrical therapy	Upper limb	Chronic hemiplegia
	Functional recovery	Stroke
		Hemiplegia

The following search string was used for the search in Pubmed: Functional electrical stimulation [OR] functional electrical therapy [AND] upper limb [AND] chronic stroke. The search string was rebuilt for additional searches in Pubmed and the other databases. More detailed information about the search procedure in the various databases can be found in (appendix I).

Data selection

The articles were selected based on the recommendations by van Tulder et al.[19] During the first step, the identified articles were scanned on title. If the titles indicated that the selected articles could be included, the abstracts were screened to find out if they contained relevant information. These selected abstracts were read and a selection was made by applying the inclusion and exclusion criteria.

On base of the abstracts, the full text articles likely to fit the systematic literature review were selected. The in- and exclusion criteria were applied on the full text articles. The articles that were estimated to fit the review were read more thoroughly and assessed on content and methodological quality.

Assessment of Methodological Quality

The methodological quality of the selected articles (RCTs and CCTs) was examined by the author with use of the PEDro scale. The PEDro scale is an evidence-based tool that is often used to assess the internal validity of articles.[20] The PEDro scale included 11 criteria that were scored as 'positive' or 'negative'. The criteria that make up the PEDro scale consist of: eligibility criteria, random allocation; concealed allocation; baseline similarity; blinding of participants, therapists and assessors; measures of key outcomes from more than 85% of participants; intention to treat analysis; between-group statistical comparisons; point measures and measures of variability. By scoring these criteria, the author was able to assign a PEDro-score to each selected article. However, the PEDro score was scored on 10 out of 11 criteria. The first

criterion, “eligibility criteria”, was not included in the final PEDro-score, because it related to the external validity of articles. In case of doubt about they quality of an article, both the second and third reviewers (J. Kainz, K. Olsen) were asked to evaluate the article and decide about the quality as a secondary quality assessment. Based on their PEDro-score, the articles were qualified as “very good (9-10), good (6-8), moderate (4-5) or low (0-3) methodological quality”.[4] The levels of methodological quality are presented in (table 3).

Table 3: Levels of methodological quality based on PEDro score[4]

PEDro score	Methodological quality
9-10 points	“Very good”
6-8 points	“Good”
4-5 points	“Moderate”
0-3 points	“Low”

Data extraction

The author of this paper then performed the data extraction. Data was extracted and presented in an extraction table with the use of the Cochrane Collaboration data extraction form.[19] This data extraction form consists of:

- The study characteristics, including number of participating subjects, in- and exclusion criteria, types of interventions, frequency of interventions, duration of interventions and risk of bias assessment.
- The patient characteristics: age, sex and diagnosis (type of stroke, severity, mean onset and duration).
- The data of measuring functional improvement (disability/ability (activities of daily living) or functional status: active range of motion, arm strength, grip function).

Best Evidence Synthesis

A best evidence synthesis was performed on the recommendations of van Tulder et al.[19] Taking the methodological quality of the studies into account. The synthesis was done to come to an overall finding of the level of evidence. The included articles were classified as strong evidence, moderate evidence, limited evidence, indicative findings or no or insufficient evidence. The levels of evidence according to van Tulder et al.[19] are shown in (table 4). A p value of < 0.05 was considered to be statistically significant.

Table 4: Levels of evidence according to van Tulder et al.[19]

Strong evidence	Consistent findings in at least 2 high quality RCT's*
Moderate evidence	Consistent, statistically significant findings in at least one high quality RCT and at least one low quality RCT or high quality CCT*
Limited evidence	Consistent findings in in at least one high quality RCT or at least two high quality CCT's*
Indicative findings	Consistent findings in at least one high quality CCT or one low quality RCT*
No evidence	In cases of results eligible studies that do not meet the criteria for one of the above stated levels of evidence, or in case of conflicting results among RCT's and CCT's, or in case of no eligible studies
** If the proportion of studies that show evidence is < 50% of the total number of studies within the same category of methodological quality and study design (RCT's and CCT's), no evidence is stated.*	

Results

The initial search results from the databases mentioned in the method section resulted in 440 articles. After screening of the titles, 394 articles were excluded based on the title. This means that 46 abstracts were checked using the inclusion and exclusion criteria. Out of these abstracts, 18 full-text articles were retrieved and screened manually. Out of these 18 articles, 14 articles were excluded because of the following reasons: study design (n=4)[10, 11, 21, 22], type of intervention (n=2)[23, 24] or because the participants were not in chronic stage of stroke (n=1)[25]. The included articles were also found double in various databases, so therefore duplicates of the selected articles were removed (n=8). Thus four articles were included in this study (Chan et al.[26] Tarkka et al.[27], Hara et al.[28] and Hara et al.[29]). A flowchart of the literature search can be found in (figure 1).

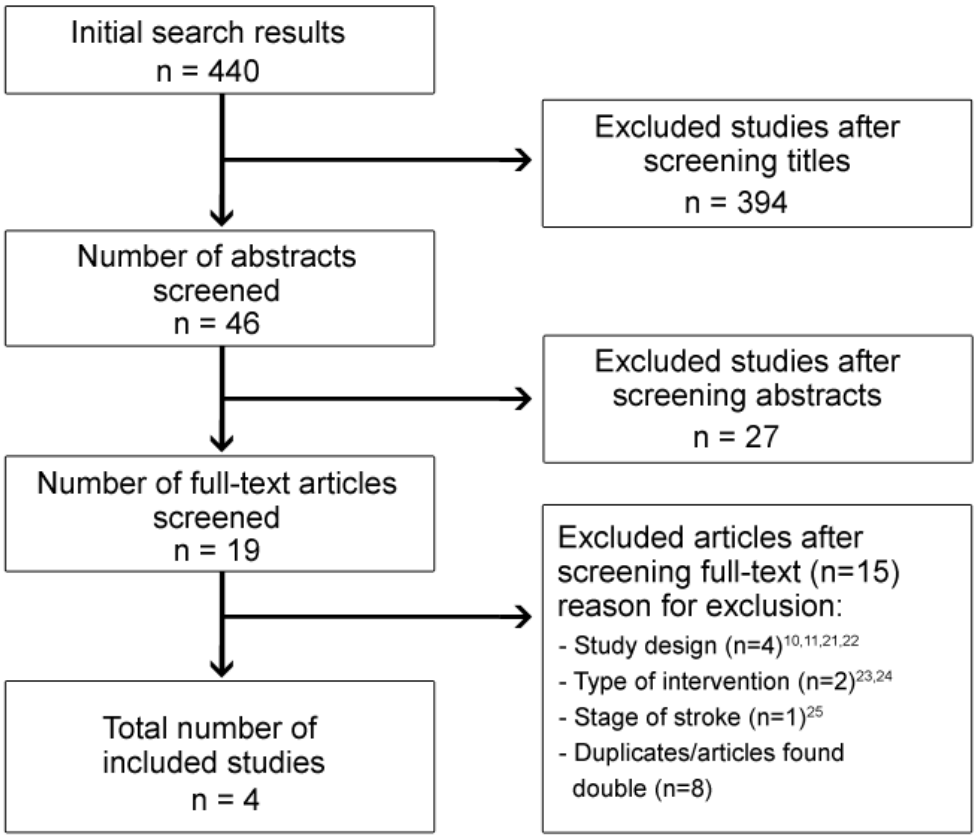

Figure 1: Flowchart of literature search.

Assessment of methodological quality:

Four randomized controlled trials were included in this study. The methodological quality was determined using (table 3) from the method section of this review. One article was scored as a "high quality RCT" (7/10).[26] The remaining 3 articles were of moderate methodological quality

(5/10; 4/10 and 4/10).[27-29] Detailed information regarding the application of the PEDro-scale to assess the methodological quality can be found in (appendix II). On a number of occasions, both the second and third reviewers (J. Kainz, K. Olsen) were asked to evaluate the article and decide about the quality as a secondary quality assessment. This has happened because there was discussion or disagreement about some criteria of the PEDro scale for two articles.[28, 29] Articles that were rated as 'good' or 'very good' methodological quality were considered as high quality RCT's for the best evidence synthesis.

Data extraction

The included studies were all designed as an RCT. All of the selected studies included participants in the chronic stage of stroke (>6 months after onset).[4] The age of the participants ranged from 24 to 77 years. Furthermore, the severity of impairment of the affected upper extremity and hand was assessed at baseline through Stroke Impairment Assessment Set (SIAS)[28, 29], Fugl Meyer Assessment[26] and Wolf Motor Function Test.[27] The main characteristics of the studies are presented in (table 5). More detailed information about the study characteristics of each study can be found in (appendix III).

Table 5: Main study characteristics

Author	Participants	Intervention	Duration	Outcome Measures
Chan et al.[26]	- 20 subjects - mean age: 45.5 years - mean time after onset: E: 18.1, C: 12.1 months	**E:** Stretching/ passive mobilization + FES + occupational therapy **C:** stretching/ passive mobilization + placebo FES + occupational therapy	15 training sessions	- Fugl-Meyer Assessment - FTHUE - Active ROM wrist extension
Tarkka et al.[27]	- 20 subjects - mean age: 53.0 years - mean time after onset: 2.4 years	**E:** Hand + arm exercises + FES. **Con:** Voluntary movement exercises and passive manual stretching	2x/day 5x/week 2 weeks	- Wolf Motor Function Test
Hara et al.[28]	- 16 subjects - mean age: E: 57.6 C: 61.5 years - mean time after onset: E: 16, C: 13 months	**E:** - passive ROM + stretching exercises - bilateral movement training, moving and releasing training + FES. **C:** same procedure without FES	- 1 or 2x /week - 4 months	- Active ROM for wrist; MP; PIP extension - 10 cup moving test - 9 hole peg test

Hara et al.[29]	- 22 subjects, - mean age E: 56.0, C: 60.5 years - mean time after onset: 13 months (E + C)	**E:** Specific affected limb + grasping, moving, releasing exercises + ADL training with FES device. **C:** same procedure without FES + rehabilitation sessions: wrist & finger ext. + shoulder flexion.	- 30 min - 5x/ week - 5 months	- Active ROM wrist + finger extension + shoulder flexion - 10 cup moving test - 9 hole peg test
**E=experiment group, C=control group, FTHUE=Functional Test for Hemiplegic Upper Extremity, Active ROM=Active range of motion, MP=metacarpophalangeal joint, PIP=proximal interphalangeal joint*				

Reported effects of the intervention

Functional outcome measures

Chan et al.[26] found no statistical difference between the 2 groups on the Fugl Meyer Assessment (FMA) and Functional Test for Hemiplegic Upper Extremity (FTHUE) at baseline.[26] After the intervention they found that the FES group showed a statistically significant higher post-treatment score in the FMA of motor function of the upper extremity (p = .039) as well as the FTHUE (p = .001).[26] In a study done by Tarkka et al.[27] the FES group significantly improved after intervention (p<0.01) and continued to improve at follow-up (p <0.02) on the Wolf Motor Function Test, a behavioural voluntary motor function test. Tarkka et al.[27] reported a non-significant tendency towards improvement in the control group.[27] However, Tarkka et al.[27] did not state a statistical between group difference, and did not provide statistics nor p values for these findings.[27] Hara et al.[28, 29] found in two studies that all of the experimental group patients had improved hand performance in the 10CMT (p < 0.01;) and the 9-hole peg test (p < 0.01), whereas the control patients maintained the same level of performance in both test sessions.[28, 29]

Active Range of Motion

Besides the functional outcome measures, the FES group showed a statistically significant larger active range of motion of wrist extension (p = .020) compared to the control group in the study done by Chan et al.[26] In the study done by Hara et al.[29] the experiment group showed good improvements in active ROM for wrist and finger extension and shoulder flexion compared to the control group (wrist extension; p <0.05; MP extension; p <0.05; shoulder flexion; p <0.001). Another study by Hara et al.[28] showed similar findings. In this study, the active ROM of wrist extension (p < 0.01) MP extension (p < 0.01) and IP extension (p < 0.05) increased significantly.[28]

Best Evidence Synthesis

A best evidence synthesis (BES) was performed following the recommendations of van Tulder et al.[19] The BES was performed for functional outcome and active range of motion separately. The BES is based on the levels of evidence that were presented in the method section of this review. The BES of the included studies is presented in (table 6).

Table 6. Best Evidence Synthesis[19] on functional outcome and active range of motion

Study	Methodological quality	Functional recovery	Active ROM
Chan et al.[26]	"High"	*Fugl-Meyer Assessment* **(p=0.039)*** *FTHUE* **(p=0.001)***	Wrist extension **(p=0.020*)**
Hara et al.[28]	"Moderate"	*10 cup moving test* **(p<0.01)*** *9 hole peg test* **(p<0.01)***	Wrist; MP; PIP ext. **(p <0.01*; p <0.01*; p<0.05*)**
Hara et al.[29]	"Moderate"	*10 cup moving test* **(p<0.01)*** *9 hole peg test* **(p <0.01)***	Wrist, finger ext. and shoulder flex. **(p <0.05*; p <0.05*; p <0.001*)**
**p-value < 0.05, considered as a statistically significant difference.*			

A best evidence synthesis was applied on all the included studies. Because the outcome measures of the studies consisted of functional recovery and active ROM, two separate best evidence synthesis were applied. Because of the fact that Tarkka et al.[27] did not state any p values for the between group comparison, this study was excluded from the BES.

Effectiveness of FES on functional recovery

Three RCT's[26, 28, 29] were included in the BES, one high quality RCT[26] and two RCT's of moderate quality.[28, 29] All of the studies showed significant improvements. Based on the BES by van Tulder et al.[19] there is moderate evidence that FES is a significantly effective intervention to improve functional recovery of the upper extremity in chronic stroke patients compared to conventional therapy.

Effectiveness of FES on active range of motion

Three RCT's[26, 28, 29] were included in the BES, one high quality RCT[26] and two RCT's of moderate quality.[28, 29] All of the studies showed significant improvements. Based on the BES by van Tulder et al.[19] there is also moderate evidence that FES is a significantly effective intervention to improve active range of motion of the upper extremity in chronic stroke patients compared to conventional therapy.

Discussion

The goal of this study was to investigate if FES is a more effective intervention than conventional therapy for the functional recovery of the upper extremity in chronic stroke patients. The database search of the existing literature resulted in the inclusion of four studies for this systematic literature review. All of the studies used FES as an intervention and conventional therapy aimed at functional recovery as a control intervention. Because this review used two different outcome measures, two separate analyses were made.

Effect of FES on functional recovery

Four studies[26-29] compared FES to conventional therapy for the functional recovery of the upper extremity. They all stated significant improvement of the experiment group compared to the control group, except the study of Tarkka et al.[27]. This study did not provide specific information about the between group comparison and was therefore excluded from the BES. However, Tarkka et al.[27] reported significant improvements in the experiment group and a non-significant tendency towards improvement for the control group.[27] Not all of these studies used similar tests to assess functional improvement. Two studies[28, 29] used the 10CMT and the 9HPT, one study[27] used the WMFT and the last study[26] used the FMA for upper extremity and the FTHUE. Despite the fact that different outcome measures were used, the goals of all these outcome measures were to assess functional improvement of the affected upper extremity. The FMA is shown to be a moderately reliable measure to assess impairment in patients during rehabilitation after stroke.[17] The WMFT is a supported test in research and clinical settings when used for chronic stroke patients.[18] Next to these two tests, the FTHUE has also proved to be a be a valid and reliable test for the assessment of the integrated function of the upper extremity of an adult hemi paretic patient, according to Wilson et al.[30] The 9HPT showed excellent test-retest reliability.[31] However, a study investigating the test-retest reproducibility and smallest real difference (SRD) of the 9HPT gave the following advice concerning the test.[31] They advised that clinicians using the 9HPT as an outcome measure may want to use the SRDs as a reference point.[31] The importance of the SRD and the link with the clinical relevance of studies will be described later in this review. Unfortunately, information about the validity and/or reliability of the 10CMT could not be found.

Effect of FES on active range of motion

The effect on active range of motion was measured in three studies.[27-29] All three studies reported significant improvements in the extension of the wrist of the experiment groups compared to the control groups.[26, 28, 29] The study by Hara et al.[28] also measured MP and PIP extension, while another study by Hara et al.[29] measured finger extension and shoulder flexion. These measurements also stated significant improvements in active ROM of these joints in the

experiment groups compared to the control groups.

Interventions

FES was used as an intervention method in all of these studies. Two studies also used gentle stretching and passive mobilizations before the FES treatment.[26, 28] The other study by Hara et al.[29] used active ROM exercises besides the FES treatment, but it was not specified when this was done, because the study investigated a home based FES program. Because the other three studies used supervised training sessions in an outpatient setting, there is a possibility that the results can be biased, since the study by Hara et al.[29] used an unsupervised home-based training program. Furthermore, Chan et al.[26] used additional therapy for the experiment group. Subjects in their study were assigned to conventional occupational therapy for 60 minutes after each FES session. This therapy focused on the functional use of the upper extremity in activities of daily living. The study done by Tarkka et al.[27] applied solely FES as the intervention for the experiment group.

One factor that could possibly contribute to the significant improvement in Hara's study was identified.[28] This study used a phenol motor point block (injection) to relieve spasticity of the flexor digitorum sublimis and flexor pollicis longus. This injection was used for the experiment group, but not for the control group. This was done because the severe spasticity of the upper limb could limit the arm to be used for FES training. A review[32] about the use of phenol or other toxins for reducing spasticity in stroke patients implies that phenol or alcohol may be used to reduce spasticity and improve passive ROM.[32] However, this statement is based on uncontrolled studies.[32] One RCT[33] comparing phenol to Botulinum-Toxin-A states that it is of no doubt that treatment with phenol is an effective way of alleviating spasticity.[33] The same article states that physiotherapy rather than the toxin will maintain long-term benefits and recommends that a multidisciplinary approach should be used for the treatment of spasticity.[33] Hara et al.[28] also describes the effect of the phenol block on the results of their intervention. They conclude that it is impossible to detect whether muscle tone balance is enhanced by a phenol block or is mediated solely through the use of the new FES therapy.[28] These findings reduce the strength of the findings, because the significant improvements cannot be attributed to the FES therapy alone.

Control interventions

The control group received the exact same intervention as the experiment group in the study by Chan et al.[26] The only difference was that instead of FES they received placebo FES while carrying out functional tasks. In the two studies conducted by Hara et al.[28, 29] the control group also received the exact same interventions as the experiment group but instead of FES they performed functional tasks. In one of those studies by Hara et al.[29] the control group even

received additional supervised rehabilitation sessions that focused on wrist, elbow and shoulder movement recovery. In the study by Tarkka et al.[27] the control group received voluntary movement exercises and grasping exercises focusing on the hand and arm with the addition of passive manual stretching. The significant differences between the FES and control groups in these studies can be attributed to the FES intervention, because both groups received the same interventions.

Treatment time, frequency and duration

The study done by Chan et al.[26] was a very condensed study that consisted of fifteen sessions that lasted for ninety minutes.[26] Frequency of the sessions was not mentioned in the study. The study done by Tarkka et al.[27] was also a very condensed study with two treatment sessions of 30 minutes for ten days.[27] Contrary to these two study designs, Hara et al has done two studies of a longer duration.[28, 29] One study[29] used a FES-program of 60 minutes with 5 sessions a week for five months with a total number of 150 sessions. The other study[28] used one or two treatment sessions of 40 minutes a week that lasted for four months with a total of 26 sessions.

As mentioned before, the sessions (except the study by Tarkka et al.[27]) did not only consist of FES therapy. The actual time that the FES was applied varied within these studies. The studies used 20, 30, 40 and 60 minutes of FES per session. In the study by Chan et al.[26] the subjects received a total of 300 minutes of FES. In the other studies this total time was 600 min[27], 1040 min[28] and 9000 minutes.[29]

Despite these differences in study designs, all three studies[26, 28, 29] included in the BES showed significant improvements in functional recovery tests. With regards to functional recovery, there were no big differences in significance of those improvements. The study by Chan et al.[26] reported p values of 0.039 and 0.001.[26] Both studies by Hara et al. stated p values of <0.01 for all the results of their functional tests.[28, 29] Based on these findings, there is a tendency to state that the actual time, duration or frequency of treatment is not of very high importance for the amount of improvement regarding functional recovery. Even though Tarkka et al.[27] did not provide p values for the between group comparison, the study showed significant improvements for the FES group (<0.01 post intervention and <0.02 at six month follow up).[27]

The studies that measured active ROM of the wrist all reported significant improvements for the FES group compared to the control group. However, in these studies some improvements were more significant then others. The study by Hara et al.[29] showed a large increase of over 25º in active range of motion of wrist extension. This improvement was not stated in statistics, but it was derived from a table in the study. Therefore an accurate number could not be extracted, so the improvement could have been even larger. As mentioned before, this study used FES session of 60 minutes with a frequency of 5 sessions a week. The studies by Chan et al.[26] and

Hara et al.[28] also showed significant between group differences, with increases of 13.5º and 20.7º in favor of the FES groups, respectively. So in this case, the larger improvement of active ROM of wrist extension may be caused because the study done by Hara et al.[29] uses a higher session frequency, a longer duration per session and a longer treatment period.

Methodological Quality of the studies

Despite the fact that all of the studies show significant results, it is very important to consider the methodological quality of the included studies. Three out of four studies were of moderate methodological quality.[27-29] Only one study was classified as high methodological quality.[26] The amount of high quality RCTs was very low, which decreases the strength of this review. The PEDro scale was used to assess the internal validity of the included studies.[20] One factor that is not considered within the methodological quality assessment using the PEDro scale is the sample size. All of the included studies used a relatively small sample size. Three studies[26, 27, 29] used a sample size of 20 subjects, while one study used 14 subjects.[28] Initially, 78 subjects were included from the four studies, but 4 subjects dropped out. In total, 74 subjects completed the study of who 38 received FES and 36 control interventions. Despite the low sample size, the low dropout rate adds strength to this review. Contradictory to the low dropout rate is the fact that only the study by Chan et al.[25] scores positive on the intention to treat criterion of the PEDro scale. All the other studies were not clear in their design regarding intention to treat.

Clinical relevance

The clinical relevance of the results was assessed by using the smallest detectable change (SDC) and minimal clinical important difference (MCID) of the various outcome measures. The SDC is another term used for the Smallest Real Difference (SRD) in the article by Chen et al.[31] The SDC or SRD and MCID values could only be found for the FMA[34], WMFT[35] and 9-hole peg test.[31] Unfortunately, statistics of the differences between baseline and post intervention measures were only provided in the study of Chan et al.[26] All of the other included studies only stated p-values of these differences and therefore had to be excluded for analysis of clinical relevance. Because of this reason, the study by Chan et al.[26] was the only study that could be used to analyse the clinical relevance. The SDC value of the FMA was found to be 5.7 points according to Wagner et al.[34] Unfortunately, the MCID value could not be found. The study by Chan et al.[26] showed a change of 7.7 points in the experiment group, meaning the change is clinical relevant and cannot be attributed to variability of the measurement tool. The between group difference in this study was found to be 5.6 points.[34] Because of the fact that the between group comparison is the main comparison that is used within this review, it can be concluded that the difference between the experiment and control group for the FMA is not clinically relevant.

Strengths and weaknesses of the studies

The strength of this study is that it is an up to date review of the literature written on the application of FES on chronic stroke patients. As far as is known, this study appears to be the first review written on the application of FES on just chronic stroke patients. Three other reviews on FES were found, but all three included patients in the acute or sub-acute stage as well as the chronic stage.[16, 20, 36] The use of the PEDro scale for the assessment of methodological quality was considered a good point of this study, since the inexperienced researcher was able to use the tool in an appropriate manner and got good insight in the methodological quality of the studies.

The weakness of this study is that an inexperienced researcher carried out the search procedure and data selection. Due to this reason, it is possible that some articles were missed during these processes. Furthermore, the data selection and extraction processes were performed individually. It would have been more reliable if two researchers had performed this in cooperation. Due to the limited time this was unfortunately not possible. One other important factor that needs to be considered is that in three[27-29] studies, only p-values were stated to illustrate the significance of the results of FES on functional recovery. Statistics providing the baseline measurement and post intervention measurement plus between group differences were not provided in these studies. This fact makes the results of these studies weaker, since the amount of change cannot be seen and compared to support the stated results. The author of this paper can only rely on the p-values of these studies. The low sample size of all of the included studies can be seen as another weakness of this study.

Implications for future research

More research is needed to investigate the effect of FES on functional recovery of the upper extremity in chronic stroke patients. The focus of future research should ideally be on treatment frequency, length of the treatment sessions and duration of the treatment period. Furthermore, it is recommended that more participants are involved in future RCTs to add more strength to the findings. If all of these parameters are investigated, and optimal treatment protocol for the use of FES can be designed for practice.

Implications for practice

FES is a therapy that can be applied on a variety of patient groups that experience a lack of functional recovery of the upper extremity following stroke. The sex and age of the participants does not play an important role with regards to eligibility for FES treatment. FES can be applied in a private practice, hospital or in a home-based setting. The only instrument that needs to be purchased for the application of FES is the FES-device. The selection of which device is

purchased depends mainly on the type of setting. As seen in the study by Hara et al.[29] a home based FES device is different compared to a FES device used in a private practice or hospital setting. The FES training itself must be functional and task oriented. Since there is no clear standard about the frequency of a session, it can be advised that a patient would benefit the most from a FES stimulation program that is applied approximately 5 times a week.[29] If this is not feasible or not possible time wise, it can be advised to combine FES sessions (once or twice a week) in private practice with home-based FES. The duration of these sessions can last from 30 minutes up to 60 minutes. FES offers a treatment modality that is effective, functional, easy to apply and use by patients and health professionals. Furthermore FES is applicable to the majority of stroke patients with functional upper extremity problems. Therefore, the use of FES as part of the treatment for chronic stroke patients can be recommended to health care professionals.

Conclusion

The findings of this systematic review show moderate evidence that FES significantly improves functional recovery of the upper extremity of chronic stroke patients compared to conventional therapy. It also shows that there is moderate evidence regarding the significant improvement of active range of motion compared to conventional therapy. FES is an effective and, most importantly, a functional treatment modality that can be used to improve the functional recovery of the upper extremity for chronic stroke patients. This systematic review shows that FES is more effective than conventional therapy for the functional recovery of the upper extremity.

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** References formatted according to the 2012 Fontys Writer's Guide.*

^ Official Journal abbreviations retrieved via Pubmed if necessary.

Appendices

Appendix I

Literature search details

Database	Keywords	Initial results	Abstracts screened	Full-text articles screened	Nr of excluded articles after screening full-text + reason for exclusion	Nr of included articles
Pubmed	Functional electrical stimulation [OR] functional electrical therapy [AND] upper limb [AND] chronic stroke	79	16	8	4 articles excluded: - type of intervention (n=1) - study design; no RCT or CCT (n=3)	4
	Functional electrical stimulation [OR] functional electrical therapy [AND] upper limb [AND] chronic hemiplegia	20	8	2	2 articles excluded: - study design; no RCT or CCT (n=1) - duplicate of article found in earlier search (n=1)	0
PEDro	Functional electrical stimulation OR functional electrical therapy	109	6	3	3 articles excluded: - duplicates of articles found in earlier search (n=3)	0
Science Direct	Functional electrical stimulation [AND] stroke	100	5	1	1 article excluded: - type of intervention; FES on other body parts as well as upper limb (n=1)	0
Cochrane	Functional electrical stimulation [AND] stroke	132	11	5	5 articles excluded: - stage of stroke; subjects not in chronic recovery stage (n=1) - same article but with different title (n=1) - duplicates of articles found in earlier searches (n=3)	0
Total		**440**	**46**	**19**	**15**	**4**

Appendix II

PEDro scores of the included articles

Criteria	Chan et al.[26]	Tarkka et al.[27]	Hara et al.[28]	Hara et al.[29]
Elegibility criteria	Yes	Yes	Yes	Yes
Random allocation	Yes	Yes	Yes	Yes
Concealed allocation	No	Yes	No	No
Baseline measures	Yes	Yes	Yes	Yes
Blinding of subjects	No	No	No	No
Blinding of therapists	No	No	No	No
Blinding of assessors	Yes	No	No	No
Adequate follow-up	Yes	No	Yes	Yes
Intention to treat	Yes	No	No	No
Between-group comparisons	Yes	Yes	Yes	Yes
Point & variability measures	Yes	Yes	No	No
Total PEDro score	7/10	5/10	4/10	4/10

Appendix III

Data extraction forms of the included studies

Study characteristics Chan et al.[26]	*Intervention:* - 10 minutes stretching/ passive mobilization activities - 20 minutes functional electrical stimulation with muscle movement - 60 minutes conventional occupational therapy training *Control intervention:* - 10 minutes stretching/ passive mobilization activities - 20 minutes placebo electrical stimulation (sensation only) - 60 minutes conventional occupational therapy training	*Duration/frequency:* 15 training sessions, no specifications on duration in days or weeks.
Subject characteristics	*Inclusion criteria:* - No skin allergy to electric stimulation/electrodes - score of “0” in the finger mass extension sub item of the FMA - able to follow simple commands - 6 weeks after onset of stroke - first episode of stroke - Glasgow Coma Scale = 15/15 *Exclusion criteria:* - severe dysphasia (either expressive or comprehensive) with inadequate communication - any additional medical or psychological condition affecting their ability to comply with the study protocol - history of other neurological diseases and psychiatric disorder, including alcoholism and substance abuse.	*Experiment group:* - group number: 10 subjects - mean age: 46 years ± 17 years - 5 male, 5 female - right hemiplegic stroke: n=4, left hemiplegic stroke: n=6 - mean time after onset: 18.1 months - education level (years of education): 10.8 ± 4.2 - Mini Mental State Exam score: 27.3 ± 2.8 *Control group:* - group total: 10 - mean age: 45 ± 16 - 6 male, 4 female - right hemiplegic stroke: n=5, left hemiplegic stroke: n=5 - mean time after onset: 12.1 months - education level (years of education): 9.7 ± 3.6 - Mini Mental State Exam score: 27.4 ± 1.5
Outcome measures	*Functional recovery:* - Fugl-Meyer-Assessment upper extremity: (p = 0.039) - Functional test for Hemiparetic upper extremity (p = 0.03)	*Active range of motion:* Wrist extension: (p = 0.027)

Study characteristics Tarkka et al.[27]	*Intervention:* - Hand and arm exercises combined with functional electrical stimulation by a 4-channel programmed FET device. - Tasks included: lifting a hairbrush or small bottle from on place to another. *Control intervention:* - Voluntary movement exercises concentrated on the upper extremity - Passive manual stretching performed by the therapist (if excessive spasticity occurred during the training session)	*Duration/frequency:* - 2 treatment sessions/day, - 5 days/week - 2 week-period
Subject characteristics	*Inclusion criteria:* - >6 months from cerebral infarction or hemorrhage - Severe functional deficits in the affected upper limb - No major cognitive problems - No severe aphasia - No cardiac pace-maker - No epilepsy *Exclusion criteria:* - none	*Experiment and control group:* - 13 male, 7 female - 10 with cerebral infarction, 10 with cerebral hemmorhage - mean age: 53 years ± 6 years - mean time after onset of stroke: 2.4 years
Outcome measures	*Functional recovery:* - Wolf Motor Function Test: ($p < 0.01$) follow-up ($p < 0.02$)	

Study characteristics Hara et al.[28]	*Intervention:* - general passive range of motion activity with the hemiparetic arm. - gentle stretching exercises of the finger and wrist flexors. - bilateral movement training simultaneously involving mirror movements of the unimpaired wrist and fingers on initiation of attempts to extend the impaired wrist and fingers with FES - Cup grasping; moving and releasing training assisted by the power-assisted FES. - Box grasping, rotation, and releasing. *Control intervention:* - The control group followed the same procedure as the experimental group except that they did not receive the neuromuscular electrical stimulation.	*Duration/frequency:* - 40 minutes per session - 1 or 2x/week - Total period of 4 months
Subject characteristics	*Inclusion criteria:* - The diagnosis of no more than two strokes on the same side of the brain - Upper-extremity impairment Stroke Impairment Assessment Set (SAIS) scores ranging from 0 to 5 for the upper extremity and finger paresis 1a-c or 2 - The absence of other neurological deficits except hemiparesis - The ability to understand and follow directions during the prescreening and pretesting *Exclusion criteria:* - none	*Experiment group:* - group total: 8 - 7 male, 1 female - 57.6 years (range: 43–77 years) - mean onset after stroke: 16 months (range: 12–34 months) - left hemisphere stroke: n=4, right hemisphere stroke: n=4 *Control group:* - group total: 6 - 4 male, 2 female - mean age, 61.5 years - mean onset after stroke, 13 months
Outcome measures	*Functional recovery:* - 10 cup moving test: ($p < 0.01$) - 9 hole peg test ($p < 0.01$)	*Active range of motion:* Wrist extension: $p < 0.01$; Metacarpophalangeal joint extension: $p < 0.01$; Proximal interphalangeal joint extension: $p < 0.05$;

Study characteristics Hara et al.[29]	*Intervention:* Specific affected limb exercises in the home exercise program: - Supination/pronation exercises; flexion and extension of individual fingers; wrist extension and flexion exercises in group A, - Elbow flexion and extension exercises; and shoulder adduction and abduction exercises in group B. - reaching, grasping, moving (e.g., pulling, rotating) and releasing an object on a desk using the hemiplegic upper extremity. - ADL activity training (washing, drying dishes and folding clothes) using a power-assisted FES device. *Control intervention:* - The control group followed the same procedure as the FES without FES. The hemiplegic limb was moved through a ROM and stretched, subjects tried to voluntarily lift the wrist and extend the fingers with ADL exercises. - Attempting to extend the impaired wrists and fingers or flex the shoulder voluntarily during supervised rehabilitation sessions once a week. Sessions lasted for approximately 40 minutes. Occupational therapists were directed toward patient goals and focused on their particular impairments and disabilities.	*Duration/frequency:* - 30-60 minutes/session (duration of a session gradually increased to a max of 1 h/session) - 5 days/week. - total period of 5 months
Subject characteristics	*Inclusion criteria:* - The diagnosis of >2 strokes on the same side of the brain; - Upper extremity impairment Stroke Impairment Assessment Set (SIAS) scores ranging from 0 – 5 for proximal upper extremity and finger paresis. - Absence of neurological deficits other than hemiplegia; - Cognitive function abilities sufficient to understand and follow directions during prescreening and pretesting; - Passive range of motion (ROM) in the affected wrist of extension to 45º from neutral, and in the affected shoulder joint of flexion to 140º, as measured by goniometry.	*Experiment group:* - group total: 10 - 8 male, 2 female - mean age: 56.0 years (range, 24 – 77 years) - mean onset after stroke: 13 months (range: 12 – 16 months) - upper limb hemiplegia on dominant side: n=8

	Exclusion criteria: - Inability of FES to open the impaired hand or flex the shoulder or intolerance of FES by the subject - No voluntary movements of the wrist, finger or shoulder - Serious cognitive deficit (Mini-Mental State Exam. score <20), visual hemi neglect or severe depression - Other serious medical conditions - Pacemaker or other implanted stimulator - Excessive pain in the affected upper limb, wrist or shoulder	*Control group:* - group total: 10 - 6 male, 4 female - mean age: 60.5 years - mean onset after stroke: 13 months
Outcome measures	*Functional recovery:* - 10 cup moving test: ($p < 0.01$) - 9 hole peg test ($p < 0.01$)	*Active range of motion:* Wrist extension: $p<0.05$; metacarpophalangeal joint extension: $p<0.05$; shoulder flexion: $p<0.001$

Appendix IV

Project Plan assessment form

B4 Assessment form project plan

Name: Hanb Haberts Student no: 2140127

Date: 25-4-2013

Title: "The effect of FES - - - - a SR"

General

- The project plan is according to format yes / no
- Spelling and language are correct yes / no

Problem description and problem definition (introduction)

- The problem description is sufficiently clearly formulated yes / no
- The problem description reflects social and paramedical relevance yes / no
- A concrete and relevant research question (or questions) can be formulated based on the problem definition, including possible sub questions yes / no

Objective

The objective is:

- Sufficiently clearly and concretely formulated yes / no
- Relevant for a selected target group within the (paramedical) professional practice yes / no
- Practically feasible yes / no
- Achievable within the set time yes / no

Project product

The project product:

- Is in line with the problem definition, research question and objective yes / no
- Is usable for the selected target group yes / no
- Is in line with the client's wishes yes / no
- The product requirements are accurately described yes / no

Activities/method

Sufficient insight is given into the type of activities and types of sources for the performance of the research and the realization of the product yes / no

Time schedule

- The time schedule gives a global phasing and time investment for the project as a whole and for the coming weeks an increasingly detailed schedule yes / no
- Important moments are recorded in the table (typographically noticeable) (e.g. contact moments, handing-in moments) yes / no
- The time schedule gives a global task division of the planned activities yes / no

Estimated costs

Clear insight is given in:

- The costs to be expected concerning money and hours — yes / no
- The division of these costs (project leader, student, programme) — yes / no

Literature

- Used and planned literature is specific and mentioned to a sufficient extent — yes / no
- Relevant and recent literature is referred to — yes / no
- Literature references, in the text and in the literature list, are made according to the Writer's Guide (Wouters 2012) — yes / no

Comments:

Be consistent in your reference list
There are some discrepancies like pedro 76 and a BE
say something about articles with more than 1 author
(exclusion are buying). Be in the ~~research~~ final report
more detailed about the exact search strategy.

All points under B3.1 up to and including B3.8 must be answered with a 'yes' in order to receive a GO for the project. The supervisor discusses with the student which points need adjustment.

GENERAL:	**GO**

Name assessor: Date + Signature

Jago Jansen 25-1-2013

Zackerick Wonderaam 25-1-2013