Professional Assignment Project

Physiotherapeutic treatments compared on muscle tone in patients with chronic CVA
A Systematic Review

Tom Klappert
Sebastian Müller

Amsterdam School of Health Professions (ASHP)
European School of Physiotherapy
Tafelbergweg 51
1105 BD Amsterdam
the Netherlands
Tel. +31 20 595 4200
Fax +31 20 595 4393
E-mail esp@hva.nl

Coach:
Rolf Hoogland
Table of Content

ABSTRACT ............................................................................................................................................3
INTRODUCTION ..................................................................................................................................4
AIM OF THE STUDY ...........................................................................................................................5
MATERIALS AND METHODS ...........................................................................................................5
DATABASES .......................................................................................................................................5
KEYWORDS .......................................................................................................................................5
INCLUSION AND EXCLUSION CRITERIA .......................................................................................6
CRITICAL APPRAISAL ..................................................................................................................6
OUTCOME MEASUREMENTS ........................................................................................................7
EXTERNAL EXPERT ......................................................................................................................7
THE ARTICLES ...............................................................................................................................7
RESULTS ...........................................................................................................................................7
PASSIVE EXERCISES ....................................................................................................................7
ACTIVE EXERCISES .....................................................................................................................8
ELECTROTHERAPY ........................................................................................................................9
DISCUSSION ....................................................................................................................................10
CONCLUSION ..............................................................................................................................13
RECOMMENDATIONS FOR FUTURE STUDIES ........................................................................13
ACKNOWLEDGMENT ....................................................................................................................13
REFERENCES: ...............................................................................................................................13
APPENDIX I ......................................................................................................................................17
THE CRITERIA LIST .......................................................................................................................17
ABSTRACT .......................................................................................................................................17
APPENDIX II ....................................................................................................................................18
THE MANUAL .................................................................................................................................18
Physiotherapeutic treatments compared on muscle tone in patients with chronic Cerebrovascular Accident
A Systematic Review.

Klappert, T. Müller, S.

Abstract

**Background:** Spasticity is one of the cardinal features of an upper motor neuron syndrome. **Design:** Systematic Review **Search Strategy:** The researchers performed a search of the computerised scientific databases available, (including: Pubmed, Embase, Cochrane, Cinahl, PiCarta, GoogleScholar) to identify and gather relevant articles. **Selection Criteria:** All articles then were processed via inclusion and exclusion criteria to determine the relevance of the article. The team had a list of nine articles which met the inclusion criteria; those were read, analysed and graded according to the criteria list conducted by the researchers. **Data selection and analysis:** The selected articles were published between 2002 and 2007 (Mean 2004, 8 / Median 2007). Three of them focused on active exercises, other three on passive exercises and the last three focussed mainly on FES. Four of them were Randomised Controlled Trials and five of them were studies of another kind. **Results:** Four articles have a good quality according to our quality classification and five articles are of moderate quality. Three of those studies showed significant changes from one or more points on the MAS. Other three showed changes of less than one point on the MAS and three of the studies showed no or only neglectable changes on the outcome measurement scale. **Discussion:** Our study and the articles reviewed both encountered, confounding factors: the reliability of the outcome measurement scale (MAS) and the quality of the articles. **Conclusion:** In this study it is visible that all three investigated treatment modalities have a beneficial effect on muscle tone in chronic CVA patients. However there are no significant differences in the outcome between those interventions. Nevertheless there should be future studies which use more reliable outcome measures and have a better general quality.

© 2007 European School of Physiotherapy

Key words: Chronic, CVA, Stroke, Exercise, Functional Electrical Stimulation
Introduction

Stroke is the third leading cause of death in the western world, currently causes five million people to die globally and is expected to cause seven million deaths per year in 2030. (Ten statistical highlights in global health - world health statistics WHO, 2007). But the pathology is much too complex to treat it with one approach, therapists have to split it up into rehabilitation relevant parts. The KNGF Guidelines “Beroerte” (2006) has stated that a patient six month post-stroke can be considered to be in a chronic state. They also have discovered that the improvement in the first six months post-stroke is of a bigger proportion compared to the chronic state and directly related to the time spent on the rehabilitation.

For the time after the first six month (chronic state) there is less evident that more time will also increase the outcome. No matter on which intensity the rehabilitation is carried out though, if the level stays the same throughout the whole rehabilitation process, the size of the treatment effect will be greater in the acute phase.

Spasticity is one of the cardinal features of an upper motor neuron syndrome. (Stokes, 2004) Watkins et al. (2002) state that the prevalence of spasticity at 12 months after stroke was 38%. Another study of Wallesch et al. (1997) has found that spasticity can be found in more than 50 % of all stroke patients.

Spasticity may arise if the inhibitory pathways are interrupted or if there is increased activity in the facilitatory pathways. (Stokes, 2004) It manifests itself in a velocity-dependent increase in resistance to the stretch of a muscle, with exaggerated tendon reflexes (Lance, 1990) and is manifested as an increase in muscle tone. In patients with no functionally useful voluntary limb movement, spasticity can maintain an abnormal resting limb posture which may lead to contracture formation. (Bhakta, 2000) The treatment of contractures is very difficult and will take a lot of time. Next to contractures, spasticity enhances other health problems as stated by Walton (2003): “Spasticity can cause pain”, “can increase the risk of pressure sores” ” reducing self care tasks and functional activities by impacting on mobility”. Therefore it is necessary to find the most appropriate treatment for patients with spasticity.

Francis et al. (2004) states in his review that “there was a clear association between improvement in spasticity and improvement in arm function (p = .0008).”

There are many treatments available, like drugs (Baclofen, Botulinum toxin (BTX)) and surgery (Tendon cut/transfer, Arthrodesis, Osteotomy), but as their effects are not very clear yet, they may be usable for a few cases only and not a modality for us as physiotherapists. For this systematic review we were especially interested in the subject of physiotherapeutic modalities, like exercise (passive or active), splinting and electrotherapy. Concerning the treatment of spasticity, still a lot of doubt exists among the experts, as Bhakta (2000) states for example: “Several approaches are used during rehabilitation, although there is lack of evidence to show which is most effective.” In this project we compare three major different physiotherapeutic treatment interventions specifically on their effect on muscle tone.

Exercise therapy was defined as "physical activity that is usually done regularly with the intention of improving or maintaining physical fitness or health" (MeSH database, 2003)

Passive Exercise as it is defined by Nelson (2007): Movement of the body, usually of the limbs, without effort by the patient. The patient is passive. (Oscillation, Passive
Movements, Massage), Active Exercise in all its meaning as defined by Nelson (2007) is: physical activity done with the intention of improving or maintaining physical fitness or health. (e.g.: Strengthening, PNF, weight bearing)

Functional Electrical Stimulation (FES) has been defined by Nelson (2007) as the application of low-level, computer-controlled electric current to the muscles, including paralyzed muscles, to enhance or produce function.

The term spasticity describes abnormal muscle tone, i.e. resistance to passive muscle stretch which increases with the velocity of the movement. The impairment itself arises from upper motor neuron dysfunction (Francis et al. 2004) in a number of neurological disorders, e.g. stroke.

These definitions and insights are useful for the diagnostics, but are too restrictive in terms of understanding and managing the consequences of spasticity for the patient population of stroke survivors (20-40% mortality) (Ten statistical highlights in global health - world health statistics WHO, 2007). The authors assume that there will be no differences in the outcome, between the interventions in the short term.

**Aim of the Study**

With this Systematic Review we aim to create a broad comparison of passive movement exercise, strengthening, and FES to each other in their short term rehabilitation effect on muscle tone in spastic hemiplegic patients with chronic Cerebrovascular Accident (CVA), visualized by test scores on the Modified Ashworth Scale (MAS), Passive Range of Motion, Active Range of Motion and Torque Resistance.

**Materials and Methods**

**Databases**

The researchers performed a search of the computerised bibliographic databases available (including: Pubmed, Embase, Cochrane, Cinahl, PiCarta, GoogleScholar) to identify relevant articles. The limits on the searches were for full texts, written in English or German language.

**Keywords**

The following keywords were used either alone or in possible combinations while performing database searches:

Pubmed:

Any other Database:
Spasticity, Stroke, Treatment, CVA, Stimulation, Muscle Tone, Therapy, Rehabilitation, Spastic, Exercise

Broad search terms were employed deliberately in order to capture as many papers as possible for later filtering.
Inclusion and exclusion criteria

After the database research, the titles and Abstracts were scanned in order not to miss a relevant article. All articles then were processed via inclusion and exclusion criteria to determine the relevance of the article. (Table 1) The articles in interest discussed stroke in the chronic state (more than 6 month poststroke). The authors excluded all articles which used interventions not directly relevant for physiotherapists, e.g.: BTX, Baclofen and/or Surgery. After applying those criteria fourteen articles remained. Those decreased to a number of nine articles after the authors have added other criteria to specify their research. They defined the treatment modalities which were selected in a different way. The more general treatment electrotherapy has been decreased to FES, only. Further more all studies were excluded which neither discuss Active, Passive or FES treatments. (Figure 1)

Critical appraisal

The team had a list of nine articles which met the inclusion criteria; those were read, analysed and graded according to the criteria list conducted by the researchers.

One of the limitations of past and recent RCT’s is that the majority fails to focus on multiple issues as necessary for spasticity. Another is that frequently chosen outcome measures like the Barthel Index do not posses the required sensibility to draw precise conclusions about the impact on spasticity, a significant improvement in dressing from ‘requiring some help’ to being ‘independent’ would contribute only one point out of 20 to a Barthel score. Collin et al. (1988).

To make sure that the appraisal would deal with those problems in the appropriate way the authors included several points in their criteria list and the article grading form, so process.that a more specific outcome measurement scale and more global and common secondary outcome measures would get more influence on the final product. The grading list consisted of 25 criteria. Different scores (1-4 points) were assigned to each criteria to enable a differential contribution to the maximal score according to the importance of the criteria.

The maximum score of the list was 67 points. Articles which scored between 67-60 points were considered to be of high quality. Articles which scored 59-50 points are of good quality, articles with moderate quality score between 49 – 35 points and articles with a score below 35 are of poor quality and will be excluded. Afterwards the results were administered and compared.

Outcome measurements

In order to have comparable results only a few measurement tools have been accepted by the authors.
The researchers focused on the most common measurement types for spasticity like MAS, Peak Torque resistance, Passive range of motion (PROM) and active range of motion (AROM). (Ada & Patrick, 2005) It has been mainly focused on functional outcome measurements and not on activity measurements as it has been stated by Francis et al. (2004) that "there is a clear link between reduced spasticity and increased function".

**External expert**

We found two different external experts, which are different in their speciality. One of them is an expert in the field of research and the other has a profound knowledge and plenty of experience practicing physiotherapy in the field of neurology and geriatrics. Versions of our work were handed over to the external experts in order to get another view on the topic and guidance for our project.

**The articles**

The nine articles left at the end of the critical appraisal are published between 2002 and 2007 (Mean 2004,8/ Median 2007). Three of them focused on active exercises, three of them focused on passive exercises and three of them focused mainly on FES. Four of them were Randomised Controlled Trials and five of them were studies of other kind.

**Results**

The testing of the quality of the articles brought the following results: Four articles have according to the researchers grading good quality and five articles are of moderate quality. In which the article of Sütbeyaz et al. (2007) got the highest score with a mean of 59 points. (Table 2)

---

**Table 1: The inclusion and exclusion criteria in detail.**

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject population between 18 and 99 years of age</td>
<td>Studies which use robots for the treatment on muscle tone</td>
</tr>
<tr>
<td>Studies which are studying the effect of active exercises, passive exercise, splinting or electrotherapy on the amount of muscle tone.</td>
<td>Articles that do not distinguish clearly between CVA and other CNS disorders in the outcome.</td>
</tr>
<tr>
<td>Subjects are suffering of the consequences of a chronic CVA</td>
<td>Articles written in foreign languages, other than english or german</td>
</tr>
<tr>
<td>Articles, coming from reliable journals from one of the following databases: Pubmed, Cinahl, Embase, PiCarta, Cochrane.</td>
<td>Studies on patients with serious co-morbidities that interfere with the spasticity or treatment.</td>
</tr>
<tr>
<td>The articles should be written in the last 10 years.</td>
<td>Studies that investigate effects of medication or combined medication and interventions.</td>
</tr>
<tr>
<td>All literature must be relevant for the research topic and direct applicable to the target population.</td>
<td>Studies that compare to or work with an operation to reduce muscle tone.</td>
</tr>
<tr>
<td>All studies which are entirely tested on a human population.</td>
<td>Studies which are done on other subjects than humans.</td>
</tr>
<tr>
<td></td>
<td>Articles concerning entirely hemorrhagic CVA’s.</td>
</tr>
</tbody>
</table>
Passive exercises

Selles et al. (2005) found that the passive plantar- and dorsiflexion ROM of the ankle increased with 8.6° on average (p = .001). During active ROM testing Selles et al. (2005) reported contrary findings the mean total standard deviation in directions of plantarflexion and dorsiflexion was 29.7° ± 27.8° at baseline and did not change much, or not at all at follow-up (29.6° ± 30.6°). Next to the ROM, other positive results that have been reported were gains in maximum voluntary contraction of ankle plantar- and dorsiflexion. Additionally, on a scale from 0 (most stiff) to 100 (not stiff at all), the subjective stiffness which was felt by the patients decreased from 35 to 75 (p = .002).

Nuyens et al. (2002) had similar findings as there were no significant differences found between the torque alterations measured during repeated movements in the stroke patients and in the control group.

In the MAS testing in the article of Yeh et al. (2005) all subjects had a mean pre-testing result in MAS of 3(1–3) and post-testing of 3(0–3). Taken a closer look at the individual groups the constant torque group had the highest change in MAS (Pre 3(2–3) and Post 1(0–1)) compared to the other two groups constant angle (2(1–3) / 1(1–3)) and cyclic stretching (2(1–3) / 1(0–3)).

In the active ROM testing Yeh et al. (2005) has changed in all subjects of 9.85 ± 6.14 pre-testing to 16.84 ± 7.02 post-testing, respectively. Divided to all groups: constant torque (9.19 ± 5.18 to 18.29 ± 5.09), constant angle (9.72 ± 6.22 to 16.00 ± 7.54) and cyclic stretching (9.56 ± 5.54 to 14.81 ± 5.99).

Active exercises

Akbari & Karimi (2006) have discovered that the quadriceps tonicity decreased on the MAS only in the experimental group from 1.88±1.05 to 0.82±0.88 (p<.0001), but treatment was not effective in control group (p = .055). The Gastero-soleous tonicity decreased from 3.06±1.43 to 1.65±1.11 (p<0.0001) and 3.23±1.15 to 3±1 (p = .041) in the experimental and control groups measured by the MAS, respectively. Significant reductions after treatment were seen in the experimental group by measuring quadriceps (p = .034) and Gastero-soleous (p = .001) tonicity compared to control group. The Mann-Whitney test also identified a significant difference between the experimental group and the control group with respect to mean difference of quadriceps (p<.0001) and Gastero-soleous (p<.0001) tonicity.

In the pilot study of Mukheerje et al. (2007) the strengthening protocol has shown little decrease in MAS on the wrist joint of the patients from 2.8 to 2.5. Also in the measurement of the torque resistance the change was little (0.7 Nm/deg/s to 0.6 Nm/deg/s)

The protocol of Mirror Therapy done by Sütbeyaz et al. (2007) showed not a lot of decrease in the MAS scores compared pre- and post- treatment (2.6 ± 0.5 to 2.3 ± 0.5) but compared to the follow up (1.8 ± 0.7) after six months. The control group has shown even less decrease in the initial MAS 2.3 ± 0.7 to post-treatment 2.2 ± 0.7 and also at follow up 1.9 ± 0.7.
Table 2: The articles used for the results in detail.

<table>
<thead>
<tr>
<th>Article</th>
<th>Quality</th>
<th>Subjects no.</th>
<th>Type of subjects</th>
<th>Intervention</th>
<th>Length of study</th>
<th>Outcome measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Akbari &amp; Karimi</td>
<td>Good</td>
<td>42</td>
<td>At least 12 month since stroke</td>
<td>Functional, balance and strengthening protocol</td>
<td>12 sessions (4 weeks and 3 times per week) and approximately 3 h per Session.</td>
<td>MAS</td>
</tr>
<tr>
<td>Alon et al.</td>
<td>Moderat e</td>
<td>70 (77)</td>
<td>6 months since stroke / mean 3.3 years since stroke</td>
<td>By the Handmaster system (NESS©) a microprocessor based, functional neuromuscular electrical stimulation system.</td>
<td>5 weeks</td>
<td>MAS</td>
</tr>
<tr>
<td>de Kroon et al.</td>
<td>Good</td>
<td>28 (30)</td>
<td>6 month since unilateral stroke</td>
<td>NESS Handmaster was used to apply the ES.</td>
<td>6 weeks of training period and 6 weeks follow up</td>
<td>MAS and A-ROM</td>
</tr>
<tr>
<td>Mukherjee et al.</td>
<td>Moderat e</td>
<td>7</td>
<td>“chronic stroke”</td>
<td>Strengthening Protocol</td>
<td>6 weeks</td>
<td>MAS and torque</td>
</tr>
<tr>
<td>Nuyens et al.</td>
<td>Moderat e</td>
<td>20</td>
<td>The mean disease duration in the patient group was 19 month(S.D. 12)</td>
<td>Isokinetic apparatus, movements were imposed on the knee in series of 10 repetitions at speeds of 60°/s, 180°/s, and 300°/s.</td>
<td>10 repetitions</td>
<td>MAS and torque</td>
</tr>
<tr>
<td>Hara et al.</td>
<td>Moderat e</td>
<td>20</td>
<td>More than 1 year poststroke</td>
<td>Power-assisted FES system (OG GIKEN Company, Okayama, Japan) is a portable, 2-channel neuromuscular stimulator</td>
<td>Followed for 5 months.</td>
<td>MAS and A-ROM</td>
</tr>
<tr>
<td>Selles et al.</td>
<td>Moderat e</td>
<td>10</td>
<td>Chronic spasticity after stroke</td>
<td>Stretching of the plantar- and dorsiflexors of the ankle 3 times a week for 45 minutes</td>
<td>4 weeks</td>
<td>P-ROM</td>
</tr>
<tr>
<td>Sütbeyaz et al.</td>
<td>Good</td>
<td>40</td>
<td>12 month poststroke</td>
<td>Thirty minutes per day mirror therapy</td>
<td>4 weeks</td>
<td>MAS</td>
</tr>
<tr>
<td>Yeh et al.</td>
<td>Good</td>
<td>47</td>
<td>4 months to 5 years</td>
<td>3 different stretching programs</td>
<td>3 weeks</td>
<td>MAS, P-ROM and torque</td>
</tr>
</tbody>
</table>

**Electrotherapy**

The median change in MAS during treatment and at follow-up was zero for both groups. Statistical analysis showed no difference between the groups. (de Kroon et al. 2004)

The active range of motion of the wrist did not change during the treatment period in either group. However, the active range of motion improved in both groups during follow-up. No difference was found between the two groups. (de Kroon et al. 2004)
Flexors and extensors, start of treatment 1(0–3) and end of treatment 2(0–3). Change from start of treatment to end of treatment (1 to 1) and to end of follow-up 1(0–2). The total change was 0(1 to 1) Extensors only, 1(1–2) 1(1–2) 0(1 to 0) 1(0–2) 0(1 to 1)

Active range of motion of the wrist, mean (SD) measured in degrees Flexors and Extensors, 88.2(27.6) 87.6(34.9) 0.5(19.1) 95.8(33.6) 7.6(11.6) Extensors only, 94.4(26.3) 95.1(24.9) 0.6(16.4) 103.9(18.9) 9.5(15.5)

In the testing of spasticity with the MAS Alon et al. (2003) has shown the following results: Shoulder: Pre-Test Mean 1.27 (S.D.1.13) Post-Test Mean 0.78 (S.D. 0.85) Probability 0.004, Elbow: 2.38 (S.D.1.22), 1.51 (S.D.1.17) 0.0001, Wrist: 1.88(S.D.1.31), 1.10 (1.06) 0.001 , Fingers 1.81 (1.19) 1.08 (1.07) 0.0004 , Thumb 1.28 (1.12), 0.68 (0.96)0.001

Hara et al. (2007) have discovered an apparent downward trend was seen in MAS of finger flexor muscles in the treatment group.

MAS of wrist flexor muscles distributions changed from 3:1, 2:4 before treatment to 2:1, 1:4 after treatment. Spasticity of finger flexor muscles improved 1 grade in MAS for most experimental group patients.

MAS of finger flexor muscles distribution was 2; 2, 1+; 3 for the control group and no control subject displayed an improvement in MAS after 5 months. After participating in the FES home program, subjects in the FES home exercise program group exhibited increased active wrist extension compared to pre- intervention levels. Patients who underwent power-assisted FES showed good improvements in active ROM for wrist and finger extension and shoulder flexion compared to the control group (wrist: F=6.23, p<0.05; MP: F=6.95, p<0.05; shoulder: F=22.1, p<0.001)

**Discussion**

From the present systematic review, it can be seen that most of the interventions presented in the study resulted in a decrease in spasticity, as it has been shown in the results section. The greatest decrease in spasticity measured by the MAS has been reported by Yeh et al. (2005) which achieved a decrease of up to two points on the MAS when they measured right after their stretching session, whereby the constant angle and the constant torque were superior to the cyclic stretching protocol, which only decreased the MAS for one point. These findings are easy to misinterpret and one should bear in mind that these measurements have been taken directly following a 30 minutes stretching session. Since the human tissue is known to adapt to mechanical stress, in order to protect the subject from injuries (Morree, 2003).

Akbari & Karimi (2006) and Hara et al. (2007) reported an improvement of one point on the MAS, which were achieved through FES and a functional approach with focus on balance and strength, respectively. Akbari & Karimi (2006) study was conducted within four weeks with an adequate group of subjects (42) and included a control group which did not improve at all; this and other criteria made him one of our "good quality" articles.
Hara et al. (2007) followed his subjects for five months with the same effect like Akbari & Karimi (2006), with the difference that he only had 20 subjects. The explanation and the illustration of the results were rather unsatisfying and did not give us the opportunity to analyse the exact progress of the subjects during the trial. Hence we could not distinguish whether these improvements occurred more in the early or in the late period or just came gradually.

An in between assessment during the five months would have been helpful to solve this issue.

After his study about the Handmaster system (NESS©) Alon et al. (2003) created an overview of different major joints and their MAS-score, comparing pre- and post-study values. The largest improvements were reported in the elbow and wrist joints followed by finger joint and shoulder joint. This is probably due to the reason that the most of the specific exercises for the Handmaster are involving the elbow and wrist joint. Also in this study the MAS-Score, as well as the improvements were highest for the elbow. Another group who did use the Handmaster as an Intervention was de Kroon et al. (2004). Controversially, they did not find any improvement after 6 weeks.

A rather new area of interest for the rehabilitation of stroke is Mirror Therapy, Sütbeyaz et al. (2007) found a significant improvement for subjects which underwent a 4 weeks lasting Mirror Therapy program when compared to the control group.

This article scored the most points in our grading list, so these results could be used as a solid argument when we request more research in the area of Mirror Therapy. Aspects that could be improved or changed include the time post-stroke (from acute phase on), the duration of the program, so Sütbeyaz et al. (2007) concluded themselves. The organization of a follow up testing would be interesting to see whether the achieved improvements do persist. The problem is though that not much scientific literature exists and that the best settings of Mirror Therapy have not been identified appropriately, yet. (Sütbeyaz et al. 2007)

The outcome measures which have been used in this study as comparison are the most known and widely used quantification of spasticity. The reliability of the MAS can be highly questioned though. Pandyan (1999) has stated that the reliability of the scales is generally better in the upper limb. Clopton's (2005) results demonstrated good interrater reliability (intragrass correlation coefficient [ICC] >0.75) for elbow flexors and hamstrings and poor interrater reliability (ICC <0.50) for other muscles. Intrarater scores were good (ICC >0.75) for hamstrings and moderate (ICC = 0.50 to 0.75) for other muscles. Therefore it can be stated that the results of Alon et al. (2003) can be considered more reliable as other researched articles. Nevertheless there is a need for a better measurement tool, Kumar et al. (2006) concluded in their study that the MAS is not a valid ordinal level measure of resistance to passive movement or spasticity.

Unfortunately the majority of the studies that are conducted use the MAS as tool to measure the differences in spasticity. That forced us to use the MAS also as our outcome measurement tool. Ada & Patrick (2005) stated that “although the Ashworth Scale is currently the most common measure of spasticity used in the clinic, findings provide evidence that the Tardieu Scale is a more valid measurement of spasticity. Therefore, in clinical practice, spasticity after stroke should be measured using the Tardieu Scale.” In a
later study by Patrick & Ada (2006) it was pointed out that “the Tardieu Scale differentiates contracture from spasticity whereas the Ashworth Scale is confounded by it.” Future studies should rather use the Tardieu scale instead of the MAS to distinguish the improvements in spasticity more and make the outcome more valid.

Another important question is if the changes on the outcome measurements were of clinical relevance, as the changes were on the MAS only of maximally two points. The authors were not able to find any researches about the relevance in change on MAS or other outcome measures.

A quick search conducted on PubMed with the keywords spastic, therapy and stroke revealed eight systematic reviews, six of them had BTX in their title, the other two were also including pharmacological agents like Baclofen and similar in their review. It seems there is no rehabilitation of spasticity after stroke without any medicational treatment; this is accredited to the benefits and positive effects resulting from the administration of medication like BTX. Our research team, though made an agreement to exclude any pharmacological treatment in the rehabilitation of spasticity in stroke patients because the administering of those pharmaceutical agents does not belong to typical physiotherapy tasks (for this reason also surgery was excluded as an intervention). Panizza M et al. (2000) reported that the question of whether use of BTX can facilitate the restoration of volitional control of the hand remains unanswered; meaning that even if the spasticity could be treated for a 100% there would still be a need for further physiotherapeutical treatment to enable the patient to function and independence.

Furthermore BTX like the name tells is toxic; it gets produced by the bacterium Clostridium Botulinum which is one of the most poisonous naturally occurring substances and the most toxic protein (Montecucco & Molgó, 2005). Due to this, next to possible beneficial effects there may be several negative side effects for patients taking the medicine. We do not support to take the risks of side effects of Botox in stroke patients until there is a solid clarity of those effects specified in relation to stroke patients. This exclusion alone makes our project special. Considering that many Randomized Controlled Trials or other studies which investigate the issue spasticity in stroke-rehab are sponsored by a certain producer of BTX, it is not surprising that there are plenty of studies working with this kind of intervention. The consequence of excluding pharmalogical treatment was that we could not use a large number of potential articles. Though some of these articles which investigated Botox and similar were also investigating interventions like strengthening or electrotherapy, we excluded them from the pile of our scientific literature to avoid unnecessary confounding factors.

The authors also planned to exclude all articles which used hemorrhagic patients, as ischaemic stroke patients were more in the interest of the researcher. Chae et al. (1997) and Paolucci (2003) stated "if 2 patients at the beginning of rehabilitation had the same basal neurological severity, same basal functional disability, same age, same sex, and same OAI, hemorrhagic patients showed better neurological and functional prognosis compared with ischemic ones". To make sure the outcome measurements were not affected by that. But as the team would have ended up with no articles they have decided not to distinguish between the two forms of CVA. None of the articles excluded either of the CVA types and therefore the results are comparable to each other.
In general, decreasing spasticity in rehabilitation of stroke patients has been questioned. This is because assumptions like, spasticity would be directly related to limitations in function and that reducing spasticity brings an improvement in function, were doubted by some clinicians.

This created a controversy regarding the rationale for treating spasticity, but recent trials confirmed that there would be a relation between spasticity and daily life, like Hesse et al. (1996) who did find a direct relation between reducing spasticity and gain in functional activity. In their meta-analyses Francis et al. (2004) came to the final conclusion that "it is possible to demonstrate that reducing spasticity in the arm is associated with a significant improvement in arm function.

In the contrary Ada et al. (2000) concluded that the cause of activity limitations in spasticity is possibly the underlying weakness and not the spasticity itself.

**Conclusion**

In this study it is visible that all three treatment types have a positive effect on decreasing the muscle tone, but there are no significant differences in the outcome between the interventions. The clinical relevance of the changes can be doubted, though.

**Recommendations for future studies.**

Nevertheless there should be future studies which use more reliable outcome measures and studies of better quality.

**Acknowledgment**

We would like to thank the Hogeschool of Amsterdam to provide us with the possibility to do this study; we especially would like to thank our coach Rolf Hoogland. We would also thank the client for the perfect working relation and all the colleagues which helped us during the process.

**References:**


# Appendix I

*The criteria list*

<table>
<thead>
<tr>
<th>QUALITY OF THE ARTICLE</th>
<th>Abstract</th>
<th>1</th>
<th>The abstract is printed and adequate.</th>
<th>1</th>
<th>Existance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Introduction</td>
<td>2</td>
<td>There is sufficient medical background which logically leads to the research question.</td>
<td>2</td>
<td>Background</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>The research question (PICO) itself and the Hypothesis are stated.</td>
<td>2</td>
<td>Research Question</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methods</td>
<td>4</td>
<td>Eligibility criteria as well as details of the settings and patients are explained.</td>
<td>3</td>
<td>Participants and settings</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>The sample is adequate in size.</td>
<td>3</td>
<td>Participants</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>The subjects are randomly allocated to groups.</td>
<td>2</td>
<td>Procedure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Allocation is concealed.</td>
<td>2</td>
<td>Blinding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>There is blinding of all subjects</td>
<td>2</td>
<td>Blinding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>There is blinding of all therapists.</td>
<td>2</td>
<td>Blinding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>Precise details of the interventions administered are given.</td>
<td>3</td>
<td>Intervention</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>Descriptions of all outcome measurement scales are given.</td>
<td>2</td>
<td>Outcomes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>Spasticity is a primary outcome</td>
<td>4</td>
<td>Outcomes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>To measure the results, appropriate measurement tools are selected.</td>
<td>3</td>
<td>Outcomes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>There is blinding of all assessors.</td>
<td>2</td>
<td>Stat Analysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>The researched groups are similar at baseline regarding the most important prognostic indicators.</td>
<td>3</td>
<td>Stat Analysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Results</td>
<td>16</td>
<td>The presentation of the results is appropriate and includes all outcomes.</td>
<td>2</td>
<td>Outcomes analysis</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>The size of the treatment effect and measures of variability are presented.</td>
<td>4</td>
<td>Outcomes analysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>P-value is clearly stated.</td>
<td>2</td>
<td>Outcomes analysis</td>
<td></td>
</tr>
</tbody>
</table>
The study discusses the generalization (external validity) of the result to other settings and/or patient/client groups.

The conclusions follow the data reported.

The conclusion gives an answer on the research hypothesis.

**CLINICAL SIGNIFICANCE OF THE ARTICLE**

1. The intervention is economically efficient.
2. The intervention is easy to apply.
3. The intervention has no or neglectable side effects.
4. The trial is applicable to the population that the article is interested in.

**Total score:** / 67

**Appendix II**

*The manual*

**Criterion and Reason of QUALITY OF THE ARTICLE**

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It is included in the article and contains a statement of the problem, a description of methods of the study, a report of results and the conclusions drawn from them by the authors.</td>
<td>Structure of the article and getting a first overview what will be presented in the paper.</td>
</tr>
<tr>
<td>2. The author mentions adequate and relevant references related to the study.</td>
<td>To get an impression of the authors to do this study and get information about previous studies in this area.</td>
</tr>
<tr>
<td>3. A research question has to identify the patient population for which the comparison is made, the alternatives being compared, the dependent (outcome) and independent variables (intervention) in a clear way.</td>
<td>It clarifies the purpose of the research and the expectation.</td>
</tr>
<tr>
<td>4. Inclusion and exclusion criteria of participants, setting and the locations’ data should be stated explicitly. Furthermore information on patients and settings should be given</td>
<td>To get an idea of the starting experiment characteristics and to enable the reader to replicate the study on a certain population and setting.</td>
</tr>
</tbody>
</table>
5 It is satisfied if more than ten subjects per group are measured on the outcome the end. ‘Ten’ is determined as the number to generalize the effect into the same population. This item is significant for the external validity.

6 A study is considered to have used random allocation if the report reassures that. Procedures such as flipping a coin are considered random. To ensure that the treatment and control groups are comparable. This is a necessary item for internal validity.

7 The subjects are unaware, to which group each subject would be allocated to. It is satisfied for example, if stated that allocation was done by sealed envelopes or similar. Concealment may affect the size of the treatment effect.

8 The subjects are unable to distinguish between the treatments applied to different groups and unable to discriminate whether they had or had not received the treatment. To ensure non-biased results.

9 Therapists applying the intervention are unable to distinguish between the treatments applied to different groups. To ensure non-biased results.

10 The explanations of all interventions are clearly given. This criterion also includes how they are administered explained in a repeatable way. To ensure validity of the intervention and to increase repeatability.

11 It must fully describe primary and secondary (if used) outcome measurement tools. Non-mechanical measures (e.g. questionnaires, score sheets) must be described in detail. It is necessary to analyse the effects of intervention and compare it to other studies.

12 Spasticity or muscle tone must be taken as (one) primary outcome To increase the topic relevance of the articles.

13 Could be: Modified Tardieu, Tardieu, Modified Ashworth and Ashworth Scale. Or on Functional Measurements, e.g.: FIM and Barthel Index To ensure the validity of the measures and make the comparison to other studies more easy.

14 Assessors performing the outcome measurement do not know which group the subjects have been allocated to. This ensures that the measurement of the outcomes is not influenced by the assessor’s bias.

15 The rater must be satisfied that the group’s outcome would not be expected to differ, due to baseline differences in prognostic variables alone, by a clinically significant amount. Wide inconsistency between groups may be due to insufficient randomisation procedures and may change the results of the trial.

16 The graphs, tables (if used) are clear and well-constructed with explanations. A full identification of all outcomes should be given. This may be statistically described using e.g. the mean value of the outcomes. The reader must be able to clearly see and compare the outcomes. Therefore getting a clear picture of the reliability and validity of the intervention.
The treatment effect should be described as outcome difference between intervention and control groups (e.g. comparing Mean outcomes in each measure between two groups).

In statistical hypothesis testing, the p-value expresses the chance that the alternative hypothesis is rejected. For example, p-value 5% means if the same trial is executed, 5% of experiments would have a larger difference of outcomes between the groups than it is observed in the trial of the article.

It is satisfied when p value of each outcome difference between intervention and control groups are described.

It is satisfied if there is a discussion of external validity, indicating how particular outcomes vary by location, setting, patient population, care provider, etc.

The authors interpret their results cautiously and their conclusions are justified by data. The correlations are correct.

The conclusions are clear and answer the research question.

**CLINICAL SIGNIFICANCE OF THE ARTICLE**

Clinical significance is about the relevance of an intervention for physiotherapists. In some of the four following items, the rating depends on the reviewer's subjective opinion. Further analysis of clinical significance may be done by comparing the result of different articles.

1. Economically efficient is scored if all three of the following criteria’s are met:
   1) duration of applying the intervention
      - should be within 3 months because it is usual treatment duration in the real practice
   2) duration of effect lasting
      - defined by the group as effect lasting for more than 3 months
   3) Economic expenses.
      - is defined by the authors opinion in the article (especially in the introduction and discussion section) and the reviewer's general ideas (e.g. the intervention usually used in physiotherapy practice such as massage, electrotherapy, and exercise are less expensive than using extra facilities and tools which are not normally in the equipment of a practice)

2. The intervention used in the article should be a physiotherapeutic intervention (e.g. massage, electrotherapy, exercise). If it is a new intervention which could be used in the physiotherapy practice for the future or does not belong to the basic PT skills, it should be easy to learn and inexpensive.

   In addition, the value of an intervention would increase if a patient is able to apply it at home.

3. The article describes adverse events or side effects. This criterion is satisfied if the side effects are smaller compared to other interventions applied to the same population.
This item directly relates to the external validity of the article. External validity may be determined if the factors population, place, time and sample size are clearly explained in the article.

The items; 5, 6, 11, 16, 23 in QUARITY OF THE ARTICLE do cover all of the above mentioned factors. Therefore, this item is satisfied if all 5, 6, 11, 23 items are answered with Yes.