Acupuncture and stroke

Bachelor degree in acupuncture

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FOREWORD

The theme for the assignment is acupuncture and stroke. As a nurse and a student of acupuncture I wanted to gain knowledge of a topic that could be applied further in the acupuncture and nursing practice.

Much appreciation to Andrew Byrne for the support and understanding through the whole writing process and I would also like to thank the teachers of Norges Helsehøyskole for making it possible to undertake a Bachelor Degree in Acupuncture.

SUMMARY

Background: 15000 Norwegians are affected by stroke each year, with the direct cost estimated to be 7-8 billion kroner yearly (1). Stroke is prevalent mainly in the elderly, and with an increasing number of elderly people in society the number of stroke patients will also increase (1)(2)(3, p286).
As a professional nurse the author has encountered numerous stroke patients with varying degrees of quality of life hindering patient physical recovery and was therefore interested to what degree acupuncture can improve the quality of life for stroke patients. Symptoms of reduced quality of life can hinder the patient's rehabilitation process (4)
Topic sentence: To what degree can acupuncture improve the quality of life for stroke patients?
Method: The assignment is a literature study based on results from research articles and Traditional Chinese Medicine (TCM) and Western Medicine (WM) theory of stroke. The assignment is based on acupuncture and therefore the TCM theory is emphasized.
Results: NHP 1 improved significantly for patients receiving acupuncture 3-4 times a week from baseline to 6 weeks and 12 months (5, 6), when the treatment was based on syndrome differentiation. NHP 2 also improved at 12 months. NHP 1 improved after treatment twice a week for 10 weeks from baseline to 3, 6 and 12 months, when it was based on TCM theory (7). Results showed no significant improvement between the acupuncture group and control group when acupuncture treatment was standardized (8, 9)
Conclusion: Acupuncture can, to a high degree, improve the quality of life for post stroke patients when the acupuncture treatment is based on TCM theory. All articles included in the assignment are over 10 years old, and it is noted that newer, more detailed research is required.

Table of content

1 Introduction

The aim of this assignment is to investigate to what degree Traditional Chinese Medicine (TCM)- acupuncture can improve quality of life for post stroke patients. TCM and western medicine (WM) literature and research are used to address the research question.

Acupuncture is a part of the treatment for post stroke patients in China (10), however it is not part of the conventional treatment in Norway (11) (1). Stroke is prevalent mainly in the elderly and with an increasing number of elderly people in society the number of stroke patients will also increase.15000 Norwegians are affected by stroke each year, with the direct cost estimated to be 7-8 billion kroner yearly (1).

How the treatment offer for stroke patients is organized has a great implication for the quality of life for each individual patient, as well as reducing the costs for the general society and the health service (1).

1.1 Background

I have encountered many stroke patients in my career as a nurse, all with varying symptoms and degrees of a reduced quality of life. In my experience, a reduced quality of life resulting from stroke is hindering patient physical recovery and I was therefore interested to what degree acupuncture can improve the quality of life for stroke patients. After partaking an internship in a hospital in China, I realized how important acupuncture is in the rehabilitation of post stroke patients. Based on this I wanted to gain more understanding of research and course literature on how it is describing to what degree acupuncture can improve the quality of life for stroke patients.
Chinese Medicine does not distinguish between the psyche and the somatic (12), which is why I am drawn to studying it. An imbalance will always manifest in both the physical and the mental level. The body is the material basis for the mind and the mind is a natural expression of the state of the body (12).

1.2 Clarification of concepts

The assignment is intended for people with a western medicine background and knowledge equivalent to a Bachelor degree in acupuncture.

The first time a long, detailed word appears in the text, an acronym will follow in brackets. An example of this is Traditional Chinese Medicine (TCM). TCM terms will be written with a capital letter, for example; Wind.

Acupuncture is defined as a form of treatment where thin needles are inserted in specific points into the skin and tissue. It has long been used as a treatment form for therapeutic and prophylactic purposes. Acupuncture is based on either Chinese Medical or Western Medical understanding of health and disease (13).

TCM is a relatively new term that has been introduced in an attempt to make Chinese medicine more understandable for researchers in the Western part of the world (14). Syndrome differentiation is applied to determine the TCM diagnosis and acupuncture points chosen according to the individual diagnosis (2, 10, 11, 15, 16).

When performing searches regarding “Quality in life” in dictionaries and “Google” it is clear that there is no standard definition of the term and it can be interpreted differently. In some sources it is defined as personal satisfaction or dissatisfaction with the cultural or intellectual conditions under which one lives (17, 18). The articles for this assignment use the “Nottingham health profile” (NHP) index to quantify quality of life. The NHP reflects the patient's degree of discomfort or distress by measuring “Emotional reactions”, “sleep problems”, “loss of energy”, “pain”, “physical movement”, “social isolation” and “the ability to pursue activities such as work, jobs around the home, social life, home life, sex- life, hobbies and holidays” (5, 6, 7, 8, 9). A definition of the term according to TCM theory was not found in the TCM literature included for the assignment. Quality of life will therefore be defined as in the NHP index.

1.3 Definition and scope of research question

The following research question was chosen for the assignment: To what degree can Traditional Chinese Medicine- acupuncture improve the quality of life for post stroke patients?
Stroke is a complex condition with various symptoms. To narrow down the complexity I have chosen to specify a topic sentence that limits the scope to include only the aspect of quality of life. Thus, I will only present results that are relevant for the research question. Findings from research articles regarding other aspects of stroke, like Motor Assessment Scale and Sunnaas Index of Activity and Daily Living, will therefore be excluded.

Acupuncture is a broad field and incorporate different theories. For this assignment only acupuncture based on Traditional Chinese Medicine (TCM) was included. Articles based solely on electro-acupuncture were excluded. Articles including SHAM treatment in the control group were also excluded.

TCM theory on *how* to treat reduced quality of life for post stroke patients is not emphasized due to the scope of the assignment, for this reason only relevant aspects of syndrome differentiation are included. However, theory will be applied to define “stroke” according to TCM and to access information on treatment procedure and prognosis.

1.5 Assignment format

The assignment is introduced in chapter 1, followed by “Method” in Chapter 2. Choice of method, “Literature-search” and “Method criticisms” is presented in this chapter. Chapter 3 and 4 presents theory and research relevant to the topic sentence. Research requirements for acupuncture treatment are provided in chapter 5. The discussion of findings follows in chapter 6. Finally, the assignment is concluded in chapter 7.

2 Method

The approach taken in writing the assignment was that of a literature study based on course literature and research articles. In structuring the article I have adopted the guidelines outlined by “Norges Helsehøyskole”.
A literature study involves a systematical search for literature, which then is summarized and discussed in accordance with the chosen topic. The purpose of a literature study is to gain knowledge and criticize the articles in order to answer the topic sentence based on relevant literature (19).

2.1 Literature- search

To address the topic a series of literature searches was performed in internationally recognized and quality controlled databases; PubMed, Medline and Cochrane.
The search process was done in the period 02.04.2014-01.03.2015. The original keywords are listed in Appendix 1 and inclusion/exclusion criteria in Table 1. In the middle of the writing process the keyword "depression" was replaced with "quality of life" as there were only a limited number of articles correlating to "acupuncture and depression" matching the research question and inclusion/exclusion criteria. A literature search on "acupuncture and quality of life" resulted in more articles, the choice was then made to change the topic hereafter. Appendix 2 and Table 2 shows keywords and inclusion/exclusion criteria that are relevant for the assignment.

Table 1: Inclusion and exclusion criteria for research on acupuncture and post stroke depression

Inclusion criteria	**Exclusion criteria**
Research on acupuncture treatment for post stroke depression	Pilot studies and study protocols
English language	Other language than English, Norwegian, Swedish and Danish
Randomized Controlled Studies (RCT)	Animal research
Newer research (This criteria was omitted due to limitations of articles)	Research done solely on electro-acupuncture

Table 2 Inclusion and exclusion criteria for research on acupuncture and quality of life for post stroke patients

Inclusion criteria	**Exclusion criteria**
Research on acupuncture treatment for stroke patients, in relation to "quality of life".	Pilot studies and study protocols
English language	Other language than English, Norwegian, Swedish and Danish
Randomized Controlled Studies (RCT)	Animal research
Newer research (This criteria was omitted due to limitations of articles)	Research done solely on electro-acupuncture

The limitation of newer research was extended from 5 to 10 years in the hope of more articles. Unfortunately, it did not result in more articles and the limitation of newer research had to be completely removed. Due to a limited amount of research articles matching the research question and inclusion/exclusion criteria, a search restriction on articles following STRICTA was not possible.
The literature-search resulted in 6 articles matching the research question and inclusion/exclusion criteria. One article was excluded as the author of the article also treated the patients, thus the validation of the results was questionable (20). The remaining 5 articles were included in the assignment. An overview is provided in Appendix 3.

2.2 Method criticism

The databases used in the search process are recommended by "Norges Helsehøyskole", signifying that they are of acceptable quality. Relevant articles may have been overlooked despite thorough searches in several databases. This may be due to a lack of creativity when defining the keywords. A broader search of articles written in Scandinavian languages was not performed, which could have resulted in further articles matching the criteria.
As I do not have a great experience in assignment writing it is possible that emphasis may have been placed on not so relevant subject areas. It is also possible that the inclusion and exclusion criteria omit relevant research. This therefore, could restrict the research material and the basis for evaluation of the topic sentence. Limited experience in research methods, such as probability values and statistics, restricts my ability to check if the results stated in the articles are reliable. However, during the writing process I have tried to gain the necessary skills to discuss the findings. All articles referenced in the assignment are reviewed in full text and was obtained at the "Norges Helsehøyskole" library.

My personal view on acupuncture could have influenced the selection of articles and the results. Contrary to this all the articles that resulted in the literature search was analyzed. The article stating acupuncture does not have a significant effect for stroke patients is evidence of this.

The original goal was to include newer research articles, however, there was not enough articles directly relating to the topic written during the last 10 years. The decision was then made to include articles older than 10 years. This assignment therefore includes research regardless of publishing date. None of the studies included in the assignment are recent, which can limit the validity of the results. However, they met the inclusion/exclusion criteria and were relevant to the topic sentence for this assignment.

The literature research started with post stroke depression and acupuncture. After some time I realized that the articles found on the topic were mainly Chinese or pilot studies and the decision was made to focus on life quality instead of depression. All theory about "depression" had to be excluded and replaced with theory about "quality of life". This proved difficult as the term "quality of life" can be interpreted in many ways and was not clearly defined in TCM, thus delaying the writing process.

A definition of quality of life was not found in course literature or other literature (2, 10, 11, 12, 15, 16, 21, 22). It is possible that relevant books for the topic have been overlooked.

2.3 Presentation of sources

2.3.1 Authors of TCM theory

Giovanni Maciocia has written one of the books that are used in the assignment to illustrate TCM in relation to stroke and acupuncture (21). Giovanni Maciocia is a well-known author within the TCM subject and is a professor at Nanjing University of Chinese Medicine (22). Nigel Ching has studied and practiced acupuncture and Chinese herbal medicine since 1990. He is a well-known teacher at several schools. He is the academic leader and principal teacher at the Nordic Acupuncture education and teaches at international seminars (23). Oscar Heyerdal is a acupuncturist and a specialist in psychiatry. Niels Lystad is an acupuncturist and

a doctor. (11) Gang-Qi Fan and Qi-cai Wang are a professors at the Nanjing University of Chinese Medicine. Gang-Qi Fan has a PhD in acupuncture and has contributed as an advisor for graduates of the cerebrovascular Department at Nanjing Municipal Hospital of TCM in China. This book was recommended by one of the doctors at the Chinese hospital where I undertook an internship (10, p 3-5).

2.3.2 Authors of WM theory

Several authors were also used to illustrate WM theory of stroke. Steinar Hunskår is the editor of the book "Almennmedisin" and he is a professor for the General Practice at the university in Bergen. He has also been head of research program in the Faculty of Medicine at the University of Bergen. Numerous authors contributed to the book and they all have backgrounds in medicine. (3) It is reprehensible that the book was written in 2003, which could result in that information is not updated. However, the book "Acupuncture in neurological conditions" by Val Hopwood and Clare Donnellan was also included in the WM theory. This book is of newer date. Val Hopwod and Clare Donnellan are both a physiotherapist and acupuncturist. Hopwood is a respected researcher and educator in the field of acupuncture, with a special knowledge of stroke. Donnellan is a educator with a specialism of neurological disorders (2) "National Guidelines for treatment and rehabilitation of Stroke" by the "Health Directorate of Norway" was included to provide more statistic and information relevant to the population of Norway. "Health Directorate of Norway" is an advisory for the society. It implements and administers the laws and regulations that are adopted in the health sector. It is a technical branch of the Norwegian Ministry of Health and Care Services. The National guidelines are recommendations of standards in diagnosis, treatment and follow-up care, to ensure high quality and that treatment is standardized. They are developed in conjunction with internationally recognized treatment methods (1).

One articles by MacPherson (2010) was included to evaluate if the research articles are following the "Standard of Reporting Interventions in Controlled Trials of Acupuncture" (STRICTA) guidelines (24). STRICTA suggest what needs to be described in acupuncture studies. (24, 26) and articles following the STRICTA criteria provide a stronger basis for further evaluation of the studies (26). Hugh MacPherson is Senior Researcher in the Department of Health Sciences at The University of York. He has been a practitioner of acupuncture and Chinese herbal medicine since the early 1980's. He founded the Northern College of Acupuncture. Hugh is still working as an acupuncturist and is the Clinical Director at the York Clinic for Integrated Healthcare (25). To evaluate some relevant issues of research on acupuncture an article by Stephen Birch was included (26). Birch has a PhD degree in acupuncture and is a former an associate professor at Norges Helsehøyskole, institute for acupuncture.

2.4 Source criticism

Source criticism is used as a method to evaluate and discuss the certainty of the sources and to give the reader an insight in the relevance and validity of the sources (19).

The assignment is based on RCT articles, which is a method for randomly dividing patients into two equivalent groups. The difference in the outcome is then tested between the group receiving an intervention and the control group (27). Under the literature search articles using other analysis methods were also included, however they were not a sufficient match to the topic sentence and were therefore excluded from the assignment. Because of the focus on RCT articles there is a possibility that newer research and other relative content was

overlooked.

It is noteworthy to mention that two of the articles in the assignment are based on the same research project. One of which presents results after 6 weeks of treatment, while the other presents results as a one-year follow-up. The one-year follow-up study was included to assess any differences between 6 weeks and one year after the treatment. At the end of the writing process it discovered that the article written by Sallstrøm et at (1995) was also published in English one year later (28). Kjendahl et al (..) refers to this articles for a more detailed description of the acupuncture procedure. At the time this was discovered it was too late to further analyze this article.

Some of the information for the assignment was retrieved from Internet sources. The use of Internet as a source must be carefully scrutinized, because it will not provide the same clarity as published literature. One must be critical of who the Internet publisher is, who is responsible for the page and for whom the page is written (29). Based on this, one can question the validity regarding the information found on the Internet. Information found on the Internet page of The Norwegian Health Directorate is, however, considered as a reliable source, as it is the "home page" of a serious organization. The Internet source Store Norske Leksikon is also recognized as a reliable source as it is linked through the "StudentPortal" of Norges Helsehøyskole.

3 Theory

This chapter will present different theories that are necessary to gain further understanding of the assignment.

3.1 Stroke according to TCM

Stroke in TCM theory is defined by the name "Wind-Stroke" (11, 21) and is divided into mild and severe degree (10, 11, 21) In addition to this Hopwood separates the condition into two categories: stroke involving the bowels and stroke involving the vicera. The mild degree affects the meridians and is related to symptoms such as hemiplegia, numbness (mac, hey, gang qi) and slurring of words (10, 21) When the condition penetrates further into the inner organs and meridians it is then defined as severe. Apoplexy, aphasia, loss of consciousness, coma, paralysis and numbness are symptoms of the severe degree. (2, 11, 10, 21) In addition to these symptoms Fan and Wang (2010) also states that stroke is characterized by deviation of eyes and mouth.

External pathogen- wind and underlying conditions that generates wind are all causes of wind stroke. The wind penetrates the meridians and obstructs the free flow of Qi and Blood (11, 21) The term Wind-Stroke covers all forms of stroke diagnosed by Western Medicine (WM) (21). Gang Qi og Qi states that Wind, Fire, Phlegm, Blood stasis and deficiency with Fire-Heat are the primary causes, where the Fire-Heat brings about internal stirring of Liver wind and extravasating of blood, concentrates fluids into Phlegm, and consumes and damages Qi. The interaction between Fire and Wind disturbs the free flow of Qi and Blood (10). Contemporary TCM doctors define stroke as deficiency of upright Qi leading to an internal stirring of Liver-Wind. Imbalances involving the Yin and Yang of the Heart and Liver, Spleen and Kidney are causations of stroke (2).

3.1.1 Treatment procedure and prognosis

Treatment should be given as soon as possible for the best results. (10, 21) The main rule of treatment frequency is that the more acute the condition, the more often it should be treated (11). According to Maciacia (2008) frequency of the treatment should be every day at the start phase and then proceed to every second day. After 1-2 months it is noted that the treatment may have a brief pause of 1-2 weeks with the continuation of treatment resuming after this. According to Fan and Wang (2010) patients with a mild degree of stroke should be treated in an interval with 5 days of treatment and then 2 days break between the intervals. Heyerdal (2013) claims that treatment should be treated daily or even several times a day in the acute stage. A minimum of treatment should be 20 times (11).

Even though modern texts follow patterns in the selection of points, treatment should still always be based on syndrome differentiation, where the point selection is flexible due to the complexity of stroke (2, 10, 21). A general formula for wind stroke is, however, provided by Hopwood (2013) and Fan and Wang (2010) (Table 3). Fan and Wang (2010) select "general points" according to if the stroke is of a mild or severe degree (Table 3).

Table 3 Overview of simple general acupuncture points for post stroke patient

Hopwood (2010)	Gang-Qi og Qi-cai (2010) Mild stroke	Gang-Qi og Qi-cai (2010) Severe stroke
LI 15	LI 15	DU 26
LI 11	LI 11	The twelve Jing points
LI 4	LI 4	PC 8
TE 5	TE 5	ST 40
ST 36	ST 36	
LR 3		LR 3
GB 31	GB 30	
ST 31	ST 41	
LI 10		
SP 10	SP 5	
GB 39	BL 60	
GB 43	GB 34	
GB 20		

Maciocia (2008) divides general treatment into three main categories for stroke patients; attack of internal organs, channels alone and patterns in sequelae stage. Heyerdal (2013) divides general treatment into three groups of points: expel Wind, remove stagnation in the affected meridians and ease the paralysis and improve other malfunctions and symptoms. Neither Maciocia (2008) or Heyerdal (2013) provide a simple acupuncture formula for post stroke patients. However, they make a detailed description of a vast variety of points for the symptoms of the three categories. This description was omitted for the assignment due to the shear amount of points.

The prognosis of "Wind Stroke" is dependent on the TCM diagnosis according to syndrome differentiation, the constitution of the patient and the frequency of the acupuncture treatment. (2, 10, 21). The diagnosis is poor when the condition has penetrated to the inner organs. (10, 21).

3.2 Stroke according to WM

Stroke is defined as a syndrome of rapidly developing neurological dysfunction of vascular origin, which causes focal or global signs of disturbed cerebral function lasting 24 hours or longer. (2, 3, 10, 11, 21).
Thrombosis, embolus and hemorrhage are causations of the damage to the brain tissue, which lead to hemiplegia or some form of hemiparesis (2, 10, 21). Stroke can be caused by ischemia or hemorrhage (10). Prognosis depends on the extensively of the stroke, type of stroke and the patient's general health condition. The prognosis is depended on how quickly a patient is able to get treatment after the onset (3 s 286).

According to the Norwegian Directorate of Health emotional symptoms are of the most neglected problems after stroke and occur in 20-40 % of patients. The emotional symptoms include reduced mood, loss of energy, decreased activity, sleep problems and can decrease the rehabilitation potential. (1) The burden of these symptoms could make it difficult or even prevent the patient benefiting fully from rehabilitation. (1, 10)

General symptoms in neurological conditions are insomnia, fatigue and mood disturbance (2). Prevalence of insomnia is over 50 % in stroke patients. This might be due to a dysfunction in hypothalamus, brainstem and thalamus, which are all involved in maintaining a normal sleep pattern. Acupuncture can increase melatonin at nighttime.
There has been observed increases in serotonin and endorphins with acupuncture treatment, thus linking acupuncture to improvement in mood and energy. Hopwood (2010) also states that acupuncture can be acceptable as an alternative to drug therapy. It will assist the patient compliance with the physical rehabilitation, in addition to the known effect of the acupuncture on the stimulus on the limbic system that can decrease fatigue symptoms, which is prevalence in 72% of post stroke patients. (2)

4 Research

This chapter presents the 5 research articles included in the assignment. Information about the method, participants, aim of the study, inclusion/exclusion criteria and intervention is presented in Appendix 3:Overview of research articles. Information about the practioners and details about the needling is provided in Appendix 4:RCT´s and STRICTA.

4.1 “Acupuncture in the treatment of stroke patients in the subacute stage”

The study was conducted at a hospital in Norway, Sunnaas, and published in the Norwegian Doctors Union in 1993. Approximately 600 stroke patients were hospitalized during 23 months. One third of these patients were undergoing primary rehabilitation, which was an inclusion criteria for the research project. 49 of these patients matched all the inclusion and exclusion criteria and were included in the research and consented after written and verbal information. There were 4 dropouts. The remaining 45 patients were randomized into two groups.
Both groups underwent a customized program of physiotherapy, occupational therapy, vocational therapy and neurological testing. The control group did not get “placebo needling” or any other treatment. The acupuncture group was getting acupuncture 3-4 times a week over 6 weeks. Each patient was diagnosed by interviews, tongue and pulse diagnostics according to course literature of Traditional Chinese Medicine, as well as the point- localization and insertion depth. Electro acupuncture and moxibustion was used when the acupuncturist

considered that it was necessary. Acupuncture doctors from The China Rehabilitation Research Centre, Beijing, provided supervision.
To evaluate the quality of life the NHP was applied. NHP is based on two parts. Part 1 consists of 38 yes or no questions about emotional reactions, sleep, energy, pain, movement and social isolation. Part 2 consists of 7 yes or no questions about work, homelife, social relations, family life, sexual intercourse, hobbies and holidays. The patients answered the questions themselves at the start of the trial and 6 weeks later. 2 patients of the treatment group and one in the control group did not answer the NHP test due to global aphasia.

After 6 weeks of treatment the acupuncture group reported a significant improvement of emotional reactions, sleep, energy, pain and mobility, while the control group did not experience any changes (Table 4). The acupuncture group had a greater improvement of the NHP 1 than the control group. NHP 2 did not reach any significant changes after 6 weeks for any of the groups.

Table 4: Results of NHP 1 from baseline to 6 weeks (5)

Tabell 3 Hjerneslagpasientenes angivelse av livskvalitet ifølge NHP I med seks delskåre, inndelt i akupunktur- og kontrollgruppe. Verdiene er angitt i gjennomsnitt (SD)

	Før	Etter	Signifikans
Følelsesmessige reaksjoner			
Akupunkturgruppen	15,3 (18,6)	5,9 (11,4)	[1](p = 0,02)
Kontrollgruppen	9,6 (11,2)	13,4 (21,4)	
Søvn			
Akupunkturgruppen	28,5 (35,4)	13,3 (17,9)	[2](p = 0,004)
Kontrollgruppen	24,6 (29,4)	36,2 (34,3)	(p = ÷0,02)
Energitap			
Akupunkturgruppen	15,1 (25,8)	5,1 (13,2)	[2](p = 0,006)
Kontrollgruppen	2,4 (7,3)	12,0 (29,9)	
Smerte			
Akupunkturgruppen	19,5 (22,6)	6,9 (10,4)	[1](p = 0,004)
Kontrollgruppen	16,5 (20,3)	13,1 (16,6)	
Mobilitet			
Akupunkturgruppen	71,3 (23,0)	30,8 (27,6)	[1](p = 0,0001)
Kontrollgruppen	60,3 (22,8)	39,6 (30,4)	[1](p = 0,006)
Sosial isolering			
Akupunkturgruppen	9,2 (21,5)	9,8 (23,7)	
Kontrollgruppen	16,8 (20,1)	15,3 (24,1)	

[1] Signifikant endring fra før til etter innen den enkelte gruppe
[2] Signifikant forskjell i endring mellom de to gruppene

The article discusses that the acupuncture group received more attention, which could have influenced the results. At the same time the patients expressed that they thought the needling was unpleasant and several in the control group expressed that they were happy that they did not get needled.
It is concluded that acupuncture can provide a positive effect for post stroke patients in addition to the conventional treatment in a subacute phase. The quality of life was significantly improved in the acupuncture group after 6 weeks.

4.2 "A one year follow-up study on the effects of acupuncture in the treatment of stroke patients in a subacute stage: a randomized, controlled study"

The article is a follow-up study of the previous article and the aim of the study was to determine if the group differences still remained one year after release from the hospital. There were 4 dropouts during the year, leaving 41 of the 45 patients to be examined.

Table 5 shows the scores of NHP 1 at the baseline, after 6 weeks and after 12 months. The scores improved significantly during the whole period for the acupuncture group, while the control group remained almost unchanged. There were significant differences in favor of the acupuncture group regarding emotional reactions, sleeping problems, physical movement and loss of energy. All these items improved significantly in the acupuncture group. A significant worsening of emotional reactions and loss of energy was reported in the control group. There was however, an improvement in mobility for this group. There were no noteworthy differences in social isolation and pain between the control and acupuncture group.
NHP 2 showed no significant differences in the groups after 6 weeks of treatment. One year later however, the acupuncture group significantly improved this score and therefore their ability to pursue activities. The control group remained the same.

Table 5: Results of NHP1 and NHP 2 from baseline to 12 months (6)

Table 4 Life quality (NHP) subscores estimated by the patients' subjective rating

	Baseline	6 weeks	12 months	Significance from baseline to 12 months
Emotions				
Acupuncture (n = 20)	16.8 (18.9) 4.1–21.8	6.14 (11.86) 0.0–8.4	4.20 (8.51) 0.0–4.1	p = 0.002
Control (n = 20)	9.57 (11.16) 0.0–15.1	13.4 (21.4) 0.0–15.5	18.9 (22.8) 0.0–29.5	p = 0.03 (neg)
Significance between groups	NS		p = 0.002	
Sleep				
Acupuncture (n = 20)	31.4 (36.0) 0.0–73.4	14.1 (18.5) 0.0–19.6	5.59 (10.65) 0.0–5.6	p = 0.05
Control (n = 20)	24.6 (29.4) 0.0–38.0	36.2 (34.3) 0.0–60.0	23.2 (28.1) 0.0–39.0	NS
Significance between groups	NS		p = 0.01	
Physical movement				
Acupuncture (n = 20)	69.7 (23.5) 57.0–86.1	26.4 (24.7) 10.2–43.3	14.4 (16.6) 0.0–24.5	$p \leq 0.0001$
Control (n = 20)	60.3 (22.8) 49.2–76.6	39.6 (30.4) 15.9–59.8	33.6 (21.3) 19.4–51.3	p = 0.02
Significance between groups	NS		p = 0.0007	
Social isolation				
Acupuncture (n = 20)	10.1 (22.3) 0.0–5.6	9.61 (24.63) 0.0–0.0	6.67 (14.25) 0.0–0.0	NS
Control (n = 20)	16.8 (20.1) 0.0–42.1	15.3 (24.1) 0.0–24.6	15.5 (24.3) 0.0–25.1	NS
Significance between groups	NS		NS	
Pain				
Acupuncture (n = 20)				
No pain	7 (35%)	13 (65%)	16 (80%)	NS
Some pain	13 (65%)	7 (35%)	4 (20%)	
Control (n = 20)				
No pain	7 (35%)	9 (45%)	10 (50%)	NS
Some pain	13 (65%)	11 (55%)	10 (50%)	
Significance between groups	NS		NS	
Loss of energy				
Acupuncture (n = 20)				
No loss of energy	70%	85%	100%	p = 0.009
Some loss of energy	30%	15%	0%	
Control (n = 20)				
No loss of energy	90%	85%	65%	p = 0.007 (neg)
Some loss of energy	10%	15%	35%	
Significance between groups	NS		p = 0.008	

The authors of the article conclude that acupuncture seems to have a long-term effect on quality of life for post stroke patients, although the mechanism of the effect is debatable.

4.3 "Can sensory stimulation improve the functional outcome in stroke patients?"

The study was conducted in Sweden and published in "The Official Journal of the American Academy of Neurology" in 1993.

78 patients with hemiparesis consented to join the study after written and oral information. CT confirmed the diagnosis of brain infarction in 51 patients. The patients were randomized in two groups with no bias to left or right hemiparesis as the authors' states that with right hemispheric lesions are more difficult to rehabilitate. The control group did not receive other treatment. Acupuncture treatment was provided twice a week for ten weeks.

NHP 1 was applied 3, 6 and 12 months after the onset to determine life quality. The scores of energy, mobility, emotional reaction and social isolation were significantly lower at 3 and 6

months for the acupuncture group (Table 6). This indicates fewer problems. The authors of the article write that the patients of the acupuncture group reported a higher quality of life than the control group.

Table 6: Results of NHP 1 at 3, 6 and 12 months (7)

Table 4. Quality of life (Nottingham Health Profile) 3, 6, and 12 months after stroke onset

	Control months			Acupuncture months					
	3	6	12	3		6		12	
n:	(37)	(36)	(31)	(33)	*p*	(31)	*p*	(26)	*p*
Energy	42.4	50.0	50.0	29.6	(0.025)	31.6	(0.01)	30.4	NS
Mobility	47.9	45.3	49.3	28.0	(0.0007)	25.2	(0.003)	30.0	(0.04)
Emotion	29.2	28.6	27.6	9.2	(0.01)	11.0	(0.003)	9.2	(0.0009)
Social isolation	22.9	24.0	23.8	11.1	(0.03)	11.9	(0.03)	9.2	NS
Pain	13.1	17.0	14.8	7.4	NS	8.1	NS	7.6	NS
Sleep	26.4	24.6	10.3	15.9	NS	11.7	(0.02)	7.6	NS

Mean values. Probability values (*p*) for difference from controls are given within parentheses for the 95% significance level in Mann-Whitney test.

NS Not significant.

The scores of mobility and emotion were also significantly lower for the acupuncture group at the one-year follow- up. The one-year follow-up was based on 10 patients less than the 6 months data since 7 of the patients died and 3 patients did not fill in the survey forms. According to the authors of the article, this explains the lack of significance for social isolation and energy even though the absolute values were unchanged or lower. The number of days in geriatric rehabilitation was 86,5 for the acupuncture group, while the control group had 165,5.
The authors of the article discusses whether the effect is directly related to the acupuncture treatment. Special attention might have speeded up the improvement of the rehabilitation.
The authors of the article conclude that the patients receiving acupuncture recovered faster than the control group and improved their quality of life significantly after 3, 6 and 12 months. Whether the acupuncture is directly responsible for the differences requires further study.

4.4 "Acupuncture and transcutaneous nerve stimulation in stroke rehabilitation" A randomized, controlled trial"

The study was conducted at 7 medical and neurological centers in Sweden and published in "Stroke- American Heart Association" in 2001. 150 acute stroke patients were included after informed consent was obtained, from November 1994 to May 1997. Criteria to participate in the study were according to the World Health Organization criteria for acute cerebrovascular disease. 138 of the patients remained at the 3-month follow-up and 126 at the 12-month follow-up.
The participants were divided into 3 groups:
1. Acupuncture group
2. High intensity frequency TENS and low frequency TENS
3. Subliminal high-frequency transcutaneous electro- stimulation (control group).

The acupuncture group received standardized treatment (Appendix 4).
For group 2, TENS stimulator and adhesive electrodes were placed over areas that corresponded to the points used in the acupuncture group (LI4, LI11, ST 36/GB 34). Only the affected side was stimulated. The amplitude was strong enough to make the muscle contract. Group 3 used the same equipment and electrode placement as in group 2, with high frequency and low frequency stimulation. No skin sensation or visible muscle contractions were noted. The therapists received training before the study to ensure uniformity. Each therapist performed all 3 treatment- modalities. All patients received conventional physiotherapy, occupational therapy and speech therapy if needed. Drug therapy was not pre-specified.

(Table 7) NHP was applied to evaluate the quality of life. NHP 1 items were similar in all groups after 3 and 12 months. The score of energy was more favorable in the acupuncture group, but the result did not reach statistical significance. There were no differences in the groups regarding the NHP 2 items at 3 and 12 months.
During the treatment period the patients in acupuncture group used less benzodiazepines (6%) that the TENS (20%) and control patients (15%).

Table 7: Results of NHP 1 at 3 and 12 months (8)

TABLE 4. Quality-of-Life Domains in the Nottingham Health Profile in Patients Randomized to Acupuncture; High-Intensity, Low-Frequency TENS; and Subliminal Stimulation

	3 mo			12 mo		
Domain	Acupuncture (n=40)	TENS (n=45)	Subliminal (n=41)	Acupuncture (n=34)	TENS (n=41)	Subliminal (n=37)
Emotional reactions	16 (0–39)	8 (0–31)	20 (0–44)	8 (0–39)	16 (0–45)	11 (0–47)
Sleep disturbancies	11 (0–34)	20 (0–34)	23 (11–55)	11 (0–43)	11 (0–34)	23 (0–48)
Lack of energy	24 (0–63)	61 (24–100)	61 (24–100)	24 (0–100)	39 (24–76)	39 (0–100)
Pain	0 (0–19)	8 (0–17)	11 (0–29)	0 (0–22)	9 (0–21)	17 (0–29)
Physical mobility	55 (18–82)	57 (35–82)	68 (38–86)	40 (10–71)	56 (30–86)	67 (35–82)
Social isolation	0 (0–42)	0 (0–27)	24 (0–36)	24 (0–25)	11 (0–25)	24 (0–49)
Total score	27 (16–39)	30 (17–46)	34 (18–50)	28 (8–42)	34 (16–47)	32 (24–47)

Median points (interquartile range). 0–100 point scales with 0 as best and 100 as worst outcome.

The article discusses that the subliminal stimulation could give some sensory input, which could stimulate the brain. This is likely through the placement of electrodes on the skin, which stimulate nerve fibers. According to the authors, adding another control group with no intervention except conventional therapy would provide additional information to future research.

The authors conclude that acupuncture has no beneficial effect of quality of life for post stroke patients when compared to a control group that received subliminal electro stimulation.

4.5 Effects of Acupuncture Treatment on Daily Life Activities and Quality of Life: A Controlled, Prospective, and Randomized Study of Acute Stroke Patients.

The study was conducted at Sahlgrenska University Hospital in 1998. 104 acute stroke patients participated after informed consent. At the one-year follow-up 82 patients still participated. The patients were randomized in 3 treatment groups; deep acupuncture group, superficial acupuncture group and no acupuncture group. The acupuncture treatment was

standardized using ten acupuncture points according to TCM (Appendix 4).

The assessments of NHP were performed after 3 and 12 months. The no acupuncture group scored significantly lower in the item "physical mobility" (P=0.048) compared with the deep acupuncture group after 12 months. This indicates that the no acupuncture group had somewhat fewer mobility problems.

Table 8: Results of NHP 1 at 3 and 12 months (9)

Table 4.
Health-Related Quality of Life by Group as Assessed by NHP at 3 and 12 Months

	Deep Acupuncture (n=30)		Superficial Acupuncture (n=20)		No Acupuncture (n=27)	
	3 mo	12 mo	3 mo	12 mo	3 mo	12 mo
Emotional reactions	19.3	14.8	23.9	12.8	15.8	14.2
Sleep	29.5	23.2	28.3	23.6	25.3	24.0
Lack of energy	34.0	34.6	29.1	36.0	30.4	30.8
Pain	15.8	19.4	13.4	11.8	18.5	16.7
Physical mobility	47.2	53.5	46.1	43.2	39.6	36.0[1]
Social isolation	13.0	15.4	16.6	11.7	10.7	14.6

- Values are mean (ranging from 1 to 100 in each specified dimension); data are longitudinal.

1 P<0.05 versus the corresponding value in the deep acupuncture group. Otherwise, there were no significant changes between the groups.

The authors discusses that this finding can be put down to chance as they describe it as a single observation that favored the group that received no acupuncture treatment. There were no significant differences found between the groups in emotional reactions, sleep, energy, pain, and social isolation (Table 8). The authors state that since there were no baseline values for NHP, they could not present a comparison of change from baseline.

The research articles conclusion is that it does not give support to the previous studies, which has indicated that acupuncture treatment can have a positive effect on quality of life.

5 Discussion

5.1 Quality of life

When one studies the term “Quality in life” it is clear that it does not have a standard definition. It is noteworthy that none of the articles define “quality of life” clearly. However, the NHP index has been applied in all the articles to quantify quality of life. The NHP items; emotional reactions, sleep problems, loss of energy and physical movement are by the Norwegian Directorate of Health defined as “emotional symptoms” and are of the most neglected problems after stroke (1). Hopwood also states that these symptoms are general symptoms in neurological conditions (2)

5.2 To what degree can TCM acupuncture improve the quality of life for post stroke patients?

NHP 1 improved significantly for patients receiving acupuncture 3-4 times a week from baseline to 6 weeks and 12 months (5, 6), when the treatment was based on syndrome differentiation. NHP 2 also improved at 12 months. The control group, which only received conventional treatment, did not experience any changes and even reported worsening of some

items (6). NHP 1 also improved after treatment twice a week for 10 weeks, from baseline to 3, 6 and 12 moths, when it was based on TCM theory (7). Results showed no significant improvement between the acupuncture group and control group when acupuncture treatment was standardized (8, 9)

The quality of life improved significantly for the acupuncture group after 6 weeks, 3, 6 and 12 months (5, 6, 7). The same articles discusses that the acupuncture received attention, which could have an influence on the results. However, Sallstrom et al (1995) discuss that the patients expressed displeasure towards needling and that several in the control group expressed that they were happy that they did not receive acupuncture as a part of their treatment (5). The articles reporting these results however are over 10 years old.
They were included due to lack of newer articles answering the chosen research question and matching the inclusion and exclusion criteria. The assignment would have been more valid if it dealt with more recent research.
STRICTA was not yet implemented when these research articles were written. In Appendix 4 we see that the articles fail to make a fully detailed description of the details of needling. It is crucial that these aspects are described to insure that the research performed on acupuncture is valid (24, 26). By not following STRICTA a further evaluation of the articles is difficult. It was however, discovered that the article written by Sallstrøm et at (1995) also was published in English one year later. A further description of the needling could have been provided in that article and as it was not studied, a conclusion cannot be made whether the articles written by Sallstrøm et al (1995, 1997) are following STRICTA. The three first articles follow all the other STRICTA criteria.

Results showed no significant improvement between the acupuncture group and control group when acupuncture treatment was standardized (8, 9). It is noteworthy that Gosman H. et al. (1998) did not compare changes from baseline, which could result in understatement of the effect of acupuncture. It is also noteworthy that the “control group” for the article written by Johanssen B et al. (2001) did get subliminal stimulation on the same points as the acupuncture group. According to the authors of the article this could stimulate brain, thus influence the results. To gain a more clear understanding of the actual effect of the acupuncture it would be reasonable to compare the results with a control group that did not receive stimuli on acupuncture points. The authors of the article also suggest that this would provide additional information for future research.

Johanssen B et al (2001) and Gosman et al (1998) provide a more detailed description of the needling and thus, following the STRICTA criteria to a higher degree. Articles following the STRICTA criteria provide a stronger basis for further evaluation of the studies (26). However it does not suggest that the studies are adequately performed when considering the application of TCM.

5.3 Treatment and prognosis for wind-stroke

When defining the term TCM it is clear that acupuncture points should be carefully applied according to TCM diagnosis, which is determined by syndrome differentiation for each individual patient (2, 10, 11, 15, 16). In relation to this, it is important to address that the acupuncture group, for the articles that did make a detailed description of the needling, received standardized treatment regardless of TCM diagnosis. This complicates the valuation of the research articles and could result in an incomplete conclusion.
Due to a poor description of the treatment intervention in the study done by Johansson et al (1993) , it is unclear if a standardized treatment was applied. However, it is interesting that the

post stroke patients that received acupuncture according to TCM theory (5, 6, 7) and syndrome differentiation (5, 6) reported better results than the patients that received standardized treatment (8, 9). This correlates to TCM theory that emphasizes that prognosis of "wind stroke" is dependent on the TCM diagnosis according to syndrome differentiation, the constitution of the patient and the frequency of the acupuncture treatment. (2, 10, 11, 21).

None of the articles discuss Syndrome Differentiation according to TCM. Syndrome Differentiation is a crucial tool in the process of determining treatment and selecting acupuncture points according to TCM theory (2, 10, 11, 21). All of the articles, with the exception of Johansson et al (2001), describe that the acupuncture treatment was given according to TCM theory, and all articles describe the reasoning for the treatment provided as required by STRICTA (24).

However, the TCM theory included in the assignment provides a list of acupuncture points in what the authors call a general treatment for stroke. LI 4, LI 11, LI 15, TE 5, ST 36 and LR 3 are common points selected among the authors, while the rest of the acupuncture points listed differ between the authors. Studying the point selection for the two articles that applied standardized treatment we see that LI 4, LI 11 and GV 20 are common. GV 20 is not a standard point according to TCM theory (2, 10), and one can question why this point is chosen as a key point. In addition to these points, Johansson et al (2001) also used the points: ST 36, EX 28:2 and GB 34. It can be seen that LI 4, LI 11 and ST 36 are the only points used in this article that are recommended by TCM theory. Gosman et al (1998) also used the points: ST 38, Ex mob, TE 5. LI 4. These are the only points used in this article that is recommended by TCM theory. A full description of other therapies in addition to the needling is a criteria of STRICTA of which only Salstrom et al (1995, 1997) has followed.

First and foremost, one can question that the articles used standardized acupuncture-points in their research. Secondly it is noteworthy to point out that only 3 of the points used correlate to "the common points" according to TCM theory.

Syndrome differentiation for each symptom of reduced of quality of life (NHP) is not provided in the assignment. As the research question focuses on to what degree acupuncture can improve the *quality of life* for post stroke patients, it would be more valid to discuss treatment of NHP items than general treatment of stroke. As neither the theory or research articles provide more detailed information regarding this term, this proved difficult. Treatment of "quality of life" would be according to syndrome differentiation of each NHP item for each patient, which would encompass a more holistic approach, treating both physical and mental symptoms, which are always interconnected (12). A WM explanation of why acupuncture can improve the energy and mood is due increases in serotonin and endorphin levels. Acupuncture also has shown to have en effect on melatonin levels at nighttime thus improving the item; sleep problems. (2) The general list of standardized points provided by TCM theory, were merely included to discuss the points applied in the research articles.

The post stroke patients that received treatment 3-4 times a week reported better results than the patients that received treatment 2 times a week. This finding correlates with TCM literature that emphasizes prognosis is dependent frequency of treatment (2, 10, 11, 21 Maciocia). Sallstrom et al (1995) provided treatment within 60 days of the onset, while the rest of the articles provided treatment within 10 days after onset. The "best" results were actually reported by the patients who were treated relatively late compared to the other studies. This does not correlate with TCM theory where it is stated that treatment should be given as soon as possible for the best prognosis (10, 21). There are many factors that play a

role regarding the results for the articles and a conclusion cannot be made whether the time of when treatment began can effect the outcome. There is however a agreement between TCM and WM theory that the prognosis of stroke patients relies on early treatment (3 10, 21).

A thorough description of the participating acupuncturists is required in an acupuncture study. (24) Johansson (1993) does not describe the participating acupuncturists. Johanssen et al. (2001) states that the therapists received training that ensured uniformity. This does not fulfill the STRICTA criteria where qualification or professional affiliation, years in acupuncture practice and other relevant experience is required. Salstrom el al (1995), Kjendahl et al. (1997) and Gosman et al (1998) do however describe the qualifications of the therapists, but fail to make a full description according to STRICTA (24). Studying Appendix 4 it is clear that none of the articles follow each criteria of STRICTA.

There seems to be a difference in research method amongst the articles. Studying the Tables 4-8 it seems that some articles looked at comparisons between the acupuncture and control groups, of which the findings were not significant (Table 7 and 8), while the articles that reported significant improvement (5, 6, 7) did not actually compare the significance of the results between the groups, but within the acupuncture group from baseline.

15000 Norwegians are affected by stroke each year and with the increasing number of elderly people in society the number of stroke patients will also increase (1)(2)(3, p286). Symptoms of 'quality of life' are prevalent in 20-40 % of patients (1) and can decrease the rehabilitation potential. Treatment of these symptoms should be an important part of the rehabilitation process. The structuring of the treatment offer for stroke patients has great implications, not only for the quality of life for each individual patient but the overall costs for the general community and the healthcare service (1). The known effect of acupuncture on the stimulus on the limbic system can decrease fatigue symptoms and acupuncture can therefore be of great assistance in physical rehabilitation. (2)

7 Conclusion

Acupuncture can, to a high degree, improve the quality of life for post stroke patients when the acupuncture treatment is based on TCM theory and treatment is given frequently in the sub-acute phase. All articles included in the assignment are over 10 years old, and newer, more detailed research is required. It is clear that when designing acupuncture studies treatment should apply TCM theory and follow STRICTA guidelines, to prevent methodological problems that can result in an under stating of the effect of acupuncture.

TCM theory states that acupuncture treatment should be given every day in the acute phase (11, 21) or within 5 days of treatment, followed by a 2 day break (10). Research should apply TCM theory in relation to treatment frequency which could improve the significans of the results.

It would be interesting to see if further research of quality of life for post stroke patients will incorporate syndrome differentiation according to each of the NHP items, and treat the patients according to the TCM diagnosis. This could lead to a more valid acupuncture treatment. Syndrome differentiation of "quality of life" would enable us to find the "root" of each of the item of the NHP index. The treatment would then be individualized and would encompass a more holistic approach, treating both physical and mental symptoms, which are always interconnected. This could, however, be challenging, as authors of TCM theory do not

share the same opinion in relation to syndrome differentiation and treatment of Wind Stroke. There seems to be an agreement of the WM definition of stroke, which makes it easier to incorporate in research.
The inclusion and exclusion criteria for the articles presented in this assignment are based upon a WM point of view of stroke. It would be interesting to see if results were different if the inclusion/exclusion criteria were based on the degree of "Wind stroke" as this clearly influences the prognosis. This would make it possible to exclude the patients, that according to TCM, have a poor prognosis and the results might have been more valid according to TCM theory.

The assignment has lead to gains in the understanding of stroke, both from a WM and TCM perspective. Greater knowledge of what should be addressed in research and of the STRICTA guidelines will help me in the future analyzing process. Due to the scope of the assignment, TCM theory on *how* to treat reduced quality of life for post stroke patients has not been presented. However, when studying research articles and literature I have gained some knowledge of syndrome differentiation and treatment according to TCM diagnosis.

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Appendix 1: Search process for acupuncture and post stroke depression

	MEDLINE
KEYWORDS	
1. Stroke/	62867
2. Stroke.tw.	154354
3. Brain infarction/ or hypoxia-ischemia, brain/ or cerebral hemorrhage/	34815
4. Cerebral apoplexy.mp.	351
5. Acupuncture/	1263
6. Acupuncture. tw.	15447
7. Acupuncture therapy/	12221
8. Acupuncture therapy.tw.	637
9. depression/	80479
10. Depression.tw.	230030
11. Depressive disorders	59531
12. 1 or 2 or 3 or 4	194962
13. 5 or 6 or 7 or 8	280345
14. 9 or 10 or 11	25
15. 12 and 13 and 14	29
13. Limit 12 to english	16
14. Limit 13 to RCT	2
15. Limit 13 to last 5 years	9
16. Limit 13 to last 10 years	12

Appendix 2: Search process for acupuncture and quality of life

	MEDLINE	PUBMED	COCHRANE	BMJ
KEYWORDS				
1. Stroke/	62867	226691	429	9,688
2. Stroke.tw.	154354	606	0	0
3. Brain infarction/ or hypoxia-ischemia, brain/ or cerebral hemorrhage/	34815	90929	85	0
4. Cerebral apoplexy.mp.	351	1678400	84	7
5. Acupuncture/	1263	22194	133	122
6. Acupuncture. tw.	15447	106	0	0
7. Acupuncture therapy/	12221	19421	96	21819
8. Acupuncture therapy.tw.	637	85	0	0
9. "Quality of life"/	123257	206282	1453	281355
10. 1 or 2 or 3 or 4	194139	1813934	469	9,688
11. 5 or 6 or 7 or 8	18720	22194	133	7
12. 9 and 10 and 11	25	68	2	38
13. Limit 12 to english	16	53	2	38
14. Limit 13 to RCT	10	25	2	0
15. Limit 14 to last 5 years	4	12	2	0
16. Limit 14 to last 10 years		22	2	0

Number of words: 7350

Appendix 3: Overview of included research articles

Author (year)	Sallstrom S., Kjendahl A., Østen P. E., Stanghelle J. K. (1995)	Kjendahl A., Sallstrom, S., Østen P. E., Stanghelle J. K. (1997)	Johansson K, Lindgren I, Widner H., Wiklund I., Johansson B.B **(1993)**	Johansson B.B., Haker E., Arbin M., Britton M., Långstrom G., Terent a., Ursing D., Asplund K. (2001)	Gosman-Hedstrom G; Claesson L; Klingenstierna U; Carlsson J; Olausson B; Frizell M; Fagerberg B; Blomstrand C.(1998)
Design	RCT	RCT	RCT	RCT	RCT
Subjects	45 stroke patients of the originally 49 patients that were included in the study	41 stroke patients of the 45 patients that participated in the previous study	78 stroke patients. At the end of the study 18 of the 78 patients were deceased.	138 of the originally 150 acute stroke patients The mean age were 76 years.	104 acure stroke patients of the originally. 82 patients remained in the one-year follow-up.
Aim	To determine if acupuncture, in addition to the rehabilitation program for stroke patients in a subacute stage, could affect motor function, ability to perform activities of daily living (ADL) and quality of life	To determine if the group differences still remained one year after discharge from the rehabilitation hospital.	To determine if acupuncture could improve or speed up the rehabilitation of stroke patients regarding physical skills, ADL and quality of life.	To study the effects on acupuncture and transcutaneous electrical nerve stimulation on functional outcome and quality of life after stroke compared to a control group that received subliminal electro-stimulation.	To investigate whether electro acupuncture treatment favorably affects stroke patients' ability to perform daily life activities, their health-related quality of life, and their use of health care and social services.
Inclusion criteria	First-time cerebral infarct or hemorrhage, with hemiparesis.	First-time cerebral infarct or hemorrhage, with hemiparesis.	The patient had to be able to cooperate during examination and tests and have a degree of hemiparesis to which they could not walk without support or do ADL activities.	Patients with moderate or severe functional impairment (defined by ADL). Recurring stroke patients were included.	Patients over 40 years with an acute focal ischemic and non-hemorrhagic lesion. and have a degree of hemiparesis to which they could not walk or get dressed without support. The stroke onset had to be less than 1 week before randomization

Exclusion criteria	Infarct or hemorrhage in the brainstem or cerebellum, SAH or with noteworthy symptomatic morbidities	Infarct or hemorrhage in the brainstem or cerebellum, SAH or with noteworthy symptomatic morbidities	Patients who could not manage ADL before the stroke and patients with pacemaker.	Previous neurological, psychiatric, or other disorder making it hard to participate in the study or to make evaluations. Inability to comprehend information about the trial, participation in other studies and failure to obtain informed consent.	Other severe disease requiring hospital or nursing home care, unconsciousness or severe aphasia, prior cerebral lesion with a documented need of care and cardiac pacemaker treatment.
Intervention	The acupuncture treatment began 15-60 days after the onset. The acupuncture group was getting acupuncture 3-4 times a week over 6 weeks, lasting about 30 minutes each time. Acupuncture point-localization and insertion depth according to Traditional Chinese Medicine.	The patients did not receive acupuncture treatment after the 6 first weeks. Two of the patients in the control group did however receive acupuncture therapy on their own initiative.	The treatment started within 10 days after the onset. The patients were treated twice a week for 10 weeks. The control group did not get placebo treatment. Traditional Chinese acupuncture points were used, bilateral. A total of 10 needles were kept in place for 30 minutes each time. Electro stimuli were given on 4 needles.	The treatment started 5 to 10 days after the onset and each session lasted about 30 minutes and was given twice a week for 10 weeks. Standardized treatment.	The treatment started 4 to 10 days after randomization and was given twice a week for 10 weeks. Each session lasted 30 minutes. The acupuncture treatment was standardized using ten acupuncture point according to TCM.

Appendix 4: RCT´s and STRICTA.

	Sallstrom et al	Kjendahl et al	Johansson et al	Johansson et al	Gosman-Hedstrom et al
1. Acupuncture rationale					
a) Style of acupuncture (e.g. Traditional Chinese Medicine, Japanese, Korean, Western medical, Five Element, ear acupuncture, etc)	✓	✓	✓	X	✓
b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate	✓	✓	✓	✓	✓
c) Extent to which treatment was varied	✓	✓	✓	✓	✓
2. Details of needling					
a) Number of needle insertions per subject per session (mean and range where relevant)	X	X	✓	✓	✓
b) Names (or location if no standard name) of points used (uni/bilateral)	X	X	X	✓ **First mode:** LI 4, ST 36, GV 20, Upper limbs; LI 11, LI 4, EX 28:2, lower limbs; ST 36, ST 40 and EX 36:1. **Second mode:** GV20, LI 11, GB 34, upper limb points as in the first mode.	✓ LI 4, LI 11, ST 38, and Ex mob on both the paretic and the nonparetic sides; TE 5 on the nonparetic side; and GV 20 on the scalp.
c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level	X	X	X	X	X
d) Response sought (e.g. de qi or muscle twitch response)	X	X	(✓) Electrical stimuli on 4 of the needles. To such an intensity that a muscle contraction was obtained.	✓ DeQi was induced at all the points except GV 20.	✓ The needles on the nonparetic side were stimulated manually, every 5 minutes, each time until the “de chi” sensation was achieved.
e) Needle stimulation (e.g. manual, electrical) For manual	(✓)	(✓)	(✓)	✓	✓

stimulation, such techniques include lifting, thrusting or rotating the needle to manipulate the de qi sensation.					
f) Needle retention time	✓	✓	✓	✓	✓
g) Needle type (diameter, length, and manufacturer or material)	X	X	X	✓	X
3. Treatment regimen	✓	✓	✓	✓	✓
a) Number of treatment sessions					
b) Frequency and duration of treatment sessions	✓	✓	✓	✓	✓
4. Other components of treatment	✓	✓	X	X	X
a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice)					
b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients	(✓)		X	(✓)	(✓)
5. Practitioner background	(✓) The treatment was given by to physiotherapists with a degree in classic acupuncture.	(✓) The treatment was given by to physiotherapists with a degree in classic acupuncture.	X No description of the participating acupuncturists is provided.	X To ensure uniformity in the treatment procedures between centers the therapists received training	(✓) 4 physiotherapists (PTs) treated the patients and were trained together to give the same information and to use the same techniques.
a) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)					
6. Control or comparator interventions	✓	✓	✓	✓	✓
a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice					

b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above.	✓	✓	✓	✓	✓ The superficial acupuncture group got four short needles (15 mm), 1 in each extremity. The needles were placed superficially just under the skin, where they were left for 30 minutes. The points used were LI 11 bilateral and Ex mob bilateral. No electrical or manual stimulation was applied to the needles.

✓= Følger retningslinjene. X= Følger ikke retningslinjene. (✓)= Følger til en viss grad