Acupuncture during stroke rehabilitation: development of a manual for researching a complex intervention

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Acupuncture during Stroke Rehabilitation: Development of a Manual for Researching a Complex Intervention

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Abstract

BACKGROUND AND AIMS

Evidence on acupuncture during stroke rehabilitation is inconsistent, with methodological problems including inappropriately standardized treatment protocols. This project developed and assessed feasibility of methods to study an individualized acupuncture intervention during acute stroke rehabilitation.

DESIGN AND METHODS

This three-part project aimed to 1) develop a manual for post-stroke acupuncture therapy; 2) determine feasibility of methods for future study and 3) explore stakeholder perceptions of acupuncture's impact. First, a treatment manual was developed. Second, a cohort study used the manual to treat 48 inpatients, who had elected acupuncture treatment (n=25) or usual care only (n=23). Acupuncture was given 3-4 times weekly for 2-4 weeks. Outcomes assessed for feasibility included the Functional Independence Measure (FIM), Modified Rankin Scale of global disability (mRS) and assessments of sleep, swallowing and bowel function (at baseline and discharge, with mRS also at 6-month follow-up). Confidence intervals were compared across mild, moderate and severe subgroups. The third study assessed stakeholder perceptions of acupuncture impact. Acupuncture patients were briefly interviewed, with surveys given to family, rehabilitation therapists, nurses and physicians. Impacts of acupuncture were identified using thematic analysis, and compared quantitatively across severity groups.

RESULTS

Improvement in FIM scores was similar in self-selected cohorts choosing acupuncture (*Mdn*=37.5) and usual care (*Mdn*=35), 95% CI [-6, 6]. FIM

motor domain scores trended higher in the moderate subgroup only. Feasibility criteria were met for the outcomes of 6-month mRS, bowel function, and sleep. Findings of Project 3 included a wide range of perceived benefits, with no negative impact. Benefits included improved upper and lower extremity motor function, walking, relaxation, and pain reduction. Staff reported better mood and participation in physical and occupational therapy. Reported benefits differed across severity subgroups, but proportion of stakeholders perceiving benefit was similar.

CONCLUSIONS

Further research on acupuncture during stroke rehabilitation is feasible, given mutually appropriate intervention, patient population and outcome measures. The widely used FIM appears inappropriate for future study, except possibly for patients in the moderate range of severity. No outcome reached statistical significance in this small non-randomized study. Trends favored the acupuncture group on most secondary outcomes including 6-month mRS, sleep and bowel function. Additional directions for further study include the relationship between cortical damage and acupuncture responsiveness, and possible benefit to the rehabilitation process itself.

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In an early supervision meeting, I expressed diffidence about contacting senior colleagues. Volker said something like: ‘don’t worry, they all got lots of help at your stage, that’s how it works – unless they are really wicked, they will want to pass the favor on’. In the last four years I have encountered a spectacular dearth of wickedness. Many acts of kindness made this project possible, and not half of them will fit in this section.

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Dedication

This thesis is dedicated to two PhD-clinicians:

my father, Robert Citkowitz, whose huge heart and tireless dedication to the least fortunate of patients have been a model all through my professional life,

and his late sister Elena Citkowitz, an evidence-based physician who dismissed acupuncture as a placebo until she read animal studies, at which point she became a passionate advocate. I would not have started this project without her, and I could not have finished it without her distinctive voice in my ear.

Author's Declaration

I declare that all the information contained in this thesis is my own work.

1 CHAPTER 1: INTRODUCTION

1.1 Project Overview

The purpose of this project is to develop and pilot-test a manual for evidence-informed, clinically appropriate acupuncture practice during acute stroke care. The study grows out of a decade's experience giving acupuncture to inpatients with stroke and other neurological conditions at a community hospital in New York City. During this time, both patients and rehabilitation staff reported perceptions of improvement in a wide variety of areas impacted by stroke, including movement, balance, shoulder pain, speech, hiccoughs, sleep, and bowel function.

Acupuncture mechanisms research shows a variety of neurological and systemic effects that suggest multiple pathways of clinical benefit in stroke. A broad spectrum of clinical benefit is also suggested by Chinese clinical literature on acupuncture during stroke, which is plentiful, though rigor of research methods is questionable. Early Western clinical research, emerging in the 1990's, appeared to indicate effect on specific motor outcomes as well as broader 'activities of daily living' (ADL) assessments, which are clinically based indices of patient independence in a variety of functional domains such as walking, eating and dressing. These early results shifted dramatically after 1998, however, when sham acupuncture replaced usual care alone as the most common comparator for research in acupuncture for stroke. Since that time, clinical trials of acupuncture for stroke have been inconsistent in their results, showing no effect or contradictory effects. Systematic reviews are increasingly negative in their conclusions; to date, no clinical trial of acupuncture for stroke has been funded by the National Institutes of Health, though several mechanisms trials were funded.

One reasonable interpretation of the shift in methods and results is that a Type I error was corrected through improved internal validity: failure to control for placebo effect in early research led to findings of clinical effect where there was none. However, the conceptual landscape is shifting around acupuncture efficacy research. The term 'placebo' and its underlying assumptions about the nature of clinical effect are in a process of renegotiation in relation to sham acupuncture, which has robust and reproducible clinical effects that may not be meaningfully separable from the specific effects of acupuncture.

A new look at the research question of acupuncture during stroke recovery and rehabilitation is therefore warranted, and is supported by close examination of study methods used. Placebo control stands as only the clearest example where positivist conventions of clinical research prioritized internal validity over external validity, reducing complexity of the acupuncture clinical encounter, in a way that may have lessened measurable clinical effect. Rather than correct a Type I error by disregarding random noise, researchers may have introduced a Type II error by disregarding meaningful information. I will argue that such error is not only possible but likely in two key areas. First, interventions may not have been adequate to produce clinical effect; and second, outcome measures assessing motor function may not be appropriate for the patient populations included in many of the studies.

Taking a pragmatic approach, this thesis describes the development and implementation of research methods to address the complexities described above, in three linked projects. In a preliminary manualization phase, clinically appropriate acupuncture during stroke rehabilitation was defined and operationalized by a team of experienced acupuncturists, using iterative cycles of planning, implementation and evaluation. Second, a battery of motor and non-motor outcome measures were quantitatively compared in a concurrent cohort study comparing patients electing and declining acupuncture treatment. Third, a stakeholder survey was conducted using thematic analysis to support both qualitative and quantitative exploration of patient experiences of acupuncture's impact, as well as patient family, rehabilitation therapist, and nursing and medical staff perceptions.

Taken together, the projects provide effect sizes and other feasibility data for future, adequately powered investigations. The chapters to follow describe the project's three initiatives in detail.

1.2 Chapter Summary

Chapter 2, Background, discusses the tension between internal and external validity as it relates to study design in researching acupuncture after stroke. It provides relevant background on stroke mechanisms and pathways of care as currently understood in Western medicine. It also describes the evolution of stroke as a clinical entity across two millennia of Chinese medical history, identifying considerable change in theories of causal mechanism, despite substantial continuity of observed clinical features. A review of contemporary research on acupuncture for stroke includes basic research on mechanisms as well as clinical research before and after 1998. The tension between internal and external validity is discussed across four major domains of study design.

In Chapter 3, the methodological choices made for this project and its three initiatives are discussed in terms of the background material presented in Chapter 2. The approaches of manualization, complex interventions research, and participatory action research are introduced as attempts to construct theoretical clarity in the face of clinical or other real-world complexity. The approach taken in this project was to develop a manual for evidence-informed practice in acupuncture for stroke and to pilot it within the Medical Research Council (MRC) framework for research in complex interventions. As discussed and explored in other disciplines, the clinical manual creates a structure within which patients can be equally exposed to a uniform condition of assessment, differential diagnosis and treatment, providing moderate internal validity while optimizing patient care and – crucially – allowing for further exploration of the relationship between treatment and outcome measure in relation to patient population.

Chapter 4 of the thesis describes the manual development process. Literature on manualization is surveyed in Science Studies and several clinical disciplines, notably nursing, psychology and rehabilitation medicine. Foundational work has been done on acupuncture manualization by Dr. Rosa Schnyer, and her advice has informed this project at several junctures. The manual for this study was developed through three cycles of development, implementation and self-evaluation. Version 3 of the manual, which was used in the cohort study described below, consisted of two parts. First was a set of worksheets providing appropriate guidance on assessment and treatment for the majority of patients. Second, for uncommon or refractory cases, the evidence basis was summarized in a packet at the rear of the manual, adapting the format and evidence grades of existing recommendations for development of clinical guidelines. This section was then augmented with cases encountered during the study period. The manual was designed for ongoing clinical use and development after the study.

Chapter 5 of the thesis reports the methods and results of a concurrent cohort study (N=48) assessing feasibility for study of treatment using the manual, comparing outcomes on activities of daily living assessments between acupuncture patients and those receiving usual care alone, and exploring differences in improvement on motor and non-motor outcome measures across mild, moderate and severe impairment subgroups. Results are discussed along with conclusions regarding patient population, intervention and outcome measures for future study. Other implications of this project for study methods are discussed in the whole project's conclusion section in Chapter 7.

Chapter 6 of the thesis reports the methods and findings of a small survey conducted alongside the cohort study. For each patient enrolled in the study, multiple stakeholders in the rehabilitation process were briefly interviewed (patients who received acupuncture) or surveyed (family member, physician, nurse, and physical, occupational, and speech/swallowing therapist). Stakeholders were questioned as to perceived benefit or harm/discomfort resulting from the therapy. The purpose of this approach was to inform interpretation of quantitative results reported in Chapter 5. In particular, because previous research has suggested that severely impaired patients would not show benefit with acupuncture on motor outcomes, it was a question of considerable ethical importance whether such patients experienced any benefits at all that would warrant their inclusion in future trials.

In Chapter 7 I discuss conclusions from Chapters 4, 5 and 6, in the greater contexts of acupuncture research methodology as well as integration of acupuncture into hospital care. I discuss impact and limitations of the project, and propose a program of further research for acupuncture during stroke rehabilitation. I also suggest that the treatment manual, as developed in this preliminary work, can be a useful tool for practicing, researching and teaching East Asian Medicine within Western medical settings without compromising the pluralism that is its most characteristic feature.

1.3 Conventions Regarding Chinese Medical Terminology

Chinese medicine contains a number of technical terms that have no conceptual equivalent in the English language. Chief among these are *qi,* which is discussed in Chapter 2, as well as the more familiar *yin* and *yang*. Following accepted convention, these have been transliterated rather than translated (Wiseman & Ye, 1998). Following the usage of Scheid and others, these terms are italicized only on introduction (Scheid & MacPherson, 2012).

Other terms rooted in lay usage, such as *xin* (heart) and *tan* (phlegm), have grossly recognizable equivalents in English (Wiseman, 2000). A number of authors capitalize such terms to emphasize the non-equivalence (Hicks, 2013; Kaptchuk, 2000; Maciocia, 2008). The Chinese medical Heart many include much of what Western medicine calls ‘mind’. Chinese medical ‘phlegm’ may occlude that mind conceptually, as Western medical phlegm obstructs respiration physically. While acknowledging the need for disambiguation of such terms, some writers choose to minimize distracting capitalizations by clarifying the term when it introduced (de Valois, Young, Robinson, McCourt, & Maher, 2010; Deadman, Al-Khafaji, & Baker, 2007; Farquhar, 1994; Scheid, 2007). I have followed the later convention in this thesis.

Acupuncture point names have been reported using the standardized nomenclature of the World Health Organization (1993). Romanized Chinese names are written in two parts: family name first (usually one pinyin syllable, capitalized) then given names (usually two, which are combined and capitalized as one unit).

2 CHAPTER 2: CLINICAL AND HISTORICAL BACKGROUND

Stroke is a complex illness whose severity and symptoms vary widely, both between patients and over the course of any single patient's recovery. Equally varied are the types of associated patient distress, health care needs and societal burden. The clinical entity of stroke also varies in Chinese medical texts, where it is seen as early as 200 B.C.E., and has retained several primary clinical features despite multiple shifts in the conceptualization of underlying pathomechanisms and treatment approach. Acupuncture for stroke recovery and rehabilitation has been explored in contemporary clinical and mechanisms research, and has shown promise in addressing a number of stroke sequelae. However, clinical research on acupuncture for stroke in the West has slowed considerably after negative results in a series of studies in the late 1990's and early 2000's. On examination of study methods, the later studies have in common higher internal validity than previous trials, with a corresponding loss of external validity. Presently, consensus on acupuncture research methodology is shifting toward greater attention to external validity, particularly in the area of treatment protocol design. Previous research on acupuncture treatments given at LMC reports positive subjective perceptions of effect in a wide variety of stroke sequelae. The question of acupuncture during stroke rehabilitation therefore warrants reopening at this time, but with particular attention to the competing demands of internal and external validity.

Below, sections of this chapter serve to contextualize the question of whether and how acupuncture can be of use during acute stroke rehabilitation. The first section describes the wide range of disease mechanisms and clinical presentations encompassed within the diagnosis of cerebrovascular accident (CVA or stroke) in contemporary biomedicine. The trajectory of post-stroke care from emergent to chronic is described, along with the numerous medical and allied health disciplines of practitioners caring for the patient at each stage. Commonly used assessment instruments are introduced; also discussed is the wide range of conceptual orientations embodied in these instruments and in the training of their assessors. Finally, stroke's prevalence and societal burden of care are discussed.

The second section of the chapter presents the clinical entity of stroke as it is conceptualized and treated across two millennia of Chinese medical history. A brief historical survey identifies five main schools of thought regarding mechanisms of illness in stroke and their associated approaches to assessment and treatment, along with contemporary approaches that integrate historical approaches with Western concepts. Comparable to the 'currents' of thought described in Volker Scheid's work on development of ideas across time in Chinese medical history – but different enough to warrant a separate terminology – these schools of thought have been termed 'illness models' for this project.

A third chapter section presents results of contemporary basic science research on acupuncture mechanisms relevant to a wide variety of stroke sequelae in human and animal stroke models, as well as clinical research in acupuncture for stroke. Three main bodies of clinical research are discussed, which differ considerably in their methods and conclusions: studies published in China, those published in the West prior to 1998, and those published in the West after 1998. Differing study results in all three groups are interpreted in terms of methodological differences and the roles of internal and external validity in study design.

A concluding section summarizes the issues laid out in the preceding sections.

2.1 Physiology, Clinical Management and Societal Burden of Stroke in Contemporary Society

Stroke is the fourth most common cause of death and a leading cause of adult disability in the United States. Approximately 795,000 Americans per year suffer a stroke, with African-Americans and Mexican-Americans at higher risk than non-Hispanic whites (Roger et al., 2011). Stroke incidence increases with age; it also varies with race, sex and geography, as does relative proportion of stroke subtypes[1] (Dyken, 1991; Sacco et al., 1998). Stroke mortality and case-fatality have generally decreased since the 1950's as medical technology has improved. However incidence of new stroke in the United States, which decreased through the 1980's, appears to have stabilized or even increased, likely due to an aging population. The number of stroke survivors and societal burden of care is therefore on the increase, with cost estimates of post-stroke care in the United States ranging widely from 60 million to 230 million dollars per year (Feigin, Lawes, Bennett, Barker-Collo, & Parag, 2009).

Stroke, or cerebral vascular accident (CVA), is a generic term comprising several types of injury due to occlusion and/or rupture of cerebral arteries. Cellular mechanisms of brain injury are relatively similar across stroke types; however symptoms, survival rate, clinical management and long-term prognosis all differ greatly according to the size, location and etiology of the lesion. Below the course of illness and clinical management are briefly described in two sections: stroke recovery, which designates medical stabilization of the patient; and stroke rehabilitation, which designates targeted therapy to restore function.

2.1.1 Stroke Recovery: Disease Course and Clinical Management

Some 87% of strokes are ischemic in nature, resulting when vessels are occluded by embolism or thrombosis. The remaining 13% are due to hemorrhage from ruptured vessels, either intracranially (10%) or in the subarachnoid space (approximately 3%) (Roger et al., 2011). Hemorrhagic stroke is more likely to present at a higher level of baseline severity, which is the single strongest predictor of prognosis (Jorgensen 2004). In a large international review of stroke incidence and case fatality, 30-day mortality for ischemic stroke ranged from 10-30%, versus 35-50% for primary intercerebral hemorrhage (Feigin, Lawes, Bennett, & Anderson, 2003).

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[1] The single most important risk factor for stroke is hypertension. Other well established predisposing factors include: clinical presence of cardiac disease, diabetes mellitus or transient ischemic attacks; cigarette smoking; and alcohol or drug abuse.

During the initial, emergency management phase of stroke, patients present with sudden onset of neurological symptoms: numbness or weakness of face and/or limbs on one side of the body; unconsciousness, confusion, or difficulty understanding or producing language; visual field deficits; dizziness or loss of balance; or 'worst ever' headache. Patients are urgently worked up with CT and/or MRI imaging to determine location and nature of the lesion. Ischemic strokes may be greatly reduced in severity by use of recombinant tissue plasminogen activator (tPA) for hemolysis, which can restore blood flow and greatly reduce the number of cells injured. The therapy is associated with a greatly increased risk of secondary hemorrhage (6.4% in a treatment group versus 0.6% in a placebo group) (Stein et al., 2008) and is therefore not recommended outside the 3-hour time window of maximum possible benefit, and is contraindicated in cases where bleeding is suspected or likely (Lansberg et al., 2007).

For a small area of the brain immediately downstream from the lesion, blood flow is occluded entirely and cell death due to hypoxia occurs within minutes. A larger area, the 'ischemic penumbra', will have reduced blood flow. With reduced supply of respiration-derived adenosine triphosphate (ATP) to power ion transport at the cell membranes, free radicals and arachadonic acid are released while the cell swells with water. This cytotoxic edema begins immediately; it is complicated over the course of hours or days by vasogenic edema, caused by increased permeability of tight endothelial cell junctions in the walls of injured capillaries. In severe cases, swelling from vasogenic edema may compress the brain stem against the foramen magnum, leading to death unless pressure is relieved by craniotomy (Stein et al., 2008).

In the seven to ten days following ischemic stroke, neurological symptoms may improve as cytotoxic edema recedes and the ischemic penumbra is reperfused, allowing for angiogenesis in damaged areas and formation of alternative neural pathways to restore function. Conversely, formation of vasogenic edema and continuing die-off of cells injured by cytotoxic edema may cause worsening of stroke symptoms in this early period, with a poorer prognosis for functional recovery. Clinical management during this time seeks to stabilize cranial blood pressure along with blood sugar and body temperature, which become unstable in severe cases. Blood pressure is elevated in over 60% of patients, even those with no previous history of hypertension. There is poor consensus as to underlying mechanisms or clinical management of this stroke-induced hypertension: persistent hypertension has been proposed as an impediment to reperfusion of the ischemic penumbra – as has lowering of the blood pressure (Qureshi, 2008).

Additional factors complicating early clinical management of stroke include dysphagia, which presents in close to 50% of hospitalized stroke patients and may lead to aspiration pneumonia. Urinary retention and incontinence are prevalent in stroke patients and may lead to urinary tract infection as a result of retention or catheterization. Constipation and fecal incontinence are also prevalent and present meaningful challenges to patient care and well-being. Seizures are more common in hemorrhagic than in ischemic stroke. Alterations in mental status are present in approximately one third of hospitalized stroke patients, and can include aphasia and associated language difficulties; memory deficits; impaired executive function; depression and/or emotional lability; and disordered sleep (Stein et al., 2008).

Planning for discharge to home or to a rehabilitation facility begins as soon as the patient is medically stable, which may be within 48 hours for a mild stroke and a week or more for severe strokes. In the United States, conditions of discharge are categorized as follows:

- Home, with outpatient therapy or home care as needed
- Acute rehabilitation facility[2]

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[2] It should be noted that the same terms are applied differently within the terminology of stroke recovery than in the designation of rehabilitation facilities

- Subacute rehabilitation facility
- Long-term nursing facility

Provided adequate social resources, discharge to home is considered most desirable. Acute rehabilitation facilities (such as Lutheran Medical Center's Neurological and Orthopedic Rehabilitation Unit) provide a condition of high intensity physical, occupational and speech/swallowing therapy; they are intended specifically to prepare patients for discharge to home. For most insurance companies in most cases, admission to such a facility is contingent on a reasonable possibility that the patient may be able to return home after rehabilitation care[3]. Patients considered unlikely to return home are discharged, once medically stable, to less costly subacute rehabilitation or long-term care facilities.

2.1.2 Stroke Rehabilitation: Assessment and Clinical Management of Stroke Sequelae

Inpatient stroke rehabilitation is a complex process in which one or more attending physicians coordinate care by a large interdisciplinary team that includes nurses with specialist training; state-licensed physical, occupational and speech/swallowing therapists; neuropsychiatrists; and social workers. Each of these disciplines brings its own distinct conceptual orientation and associated research methods to bear on the challenge of helping each patient to regain as much function as possible given sharply limited time and resources.

Below is a description of clinical syndromes known as stroke sequelae which commonly present in the rehabilitation setting. These include aphasia and other cognitive impairment; dysphagia (difficulty swallowing);

(which are not specific to stroke). Therefore a patient will likely enter an acute rehabilitation facility during the subacute phase of her stroke recovery.

[3] Reimbursement for continued care is reviewed weekly and remains contingent on documentation of, on the one hand, demonstrable progress towards appropriate functional independence goals, and on the other hand, significant 'barriers to discharge' that are as yet unresolved.

urinary retention or incontinence; constipation or fecal incontinence; motor impairment; sensory impairment; pain; and syndromes of visual or proprioceptive deficit. For each of these post-stroke syndromes, symptoms and their prevalence are described, along with a brief synopsis of the current literature on patient assessment and clinical management, within the relevant discipline of care. This discussion of rehabilitation is prefaced by a brief discussion of key concepts and terms used in discussing rehabilitation.

2.1.2.1 Measurement in Rehabilitation: Impairment, Activity and Participation

Theory and practice of outcome measurement in rehabilitation have been under continual debate since at least the 1960's. From a perceived absence of outcome measures sensitive to clinically meaningful change during rehabilitative therapy, there emerged a spate of publications from clinical research centers describing new scales for measuring patient progress during the rehabilitation period (Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963; Mahoney & Barthel, 1965). These became known as Activities of Daily Living (ADL) indices. Authors in the emerging disciplines of physical and occupational therapy argued that medically oriented neurological or motor function assessments were inadequate to track progress in the work done by physical and occupational therapists to help patients regain function and independence. Several of the new activity-oriented indices were validated and widely adopted for clinical and research, most notably the Maryland Index, later known as the Barthel Index. A subsequent task force of physiotherapists aimed to improve the Barthel Index by modifying the scoring system and adding a cognitive domain, to produce the Functional Independence Measure (FIM) (Keith, Granger, Hamilton, & Sherwin, 1987).

Beginning in the 1980's, a World Health Organization (WHO) task force further clarified the distinction between organic damage and functional capability (Cieza et al., 2004), The WHO's International Classification of Functioning, Disability and Health (ICF) defined three levels of measurement, conceptually distinct but overlapping in practice. These were: the impairment or 'body' level, assessing damage to structure or vegetative function; the disability, activity or 'person' level, assessing capability for independent self-care in one's own environment; and the handicap, participation or 'society' level, assessing level of occupational and recreational participation in community life. As assessments of function at the activity or 'person' level, ADL outcomes are widely considered essential to the rehabilitation process. Indeed, the practice and evidence basis of rehabilitation medicine have grown up in relation to ADL indices: these are considered as the main tools for assessment of the work of rehabilitation, for purposes of quality control and determination of need institutionalization or home care (Salter et al., 2005). The ICF model for levels of measurement[4] (below, Figure 2.1) shows the centrality of the activity or whole-person level of function, as mediating interactions between bodily impairment and societal participation.

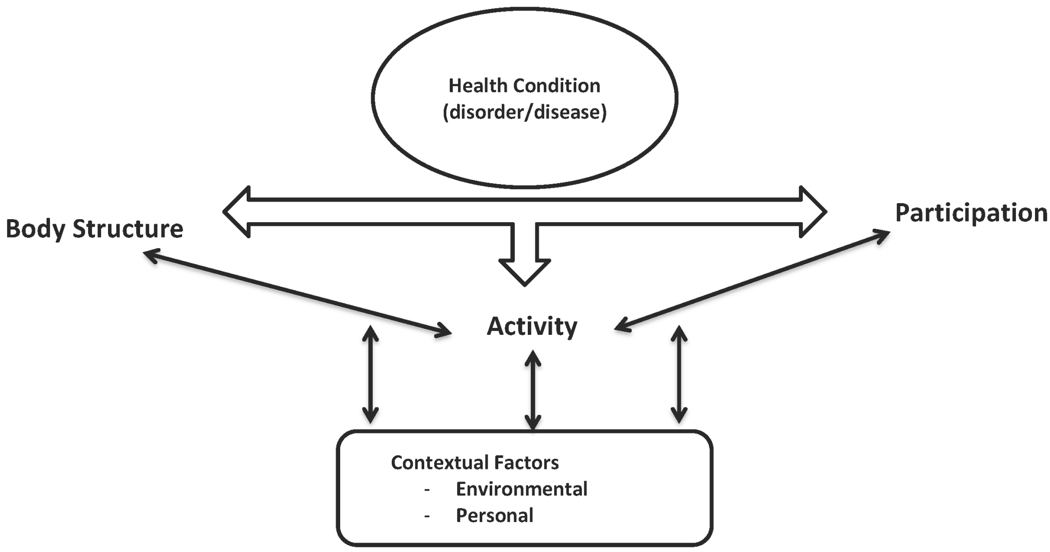

Figure 2.1: ICF Levels of Measurement in Rehabilitation

[4] Adapted from: Towards a common language for functioning, disability and health: the International Classification of Functioning, Disability and Health, http://www.who.int/classifications/icf/icfbeginnersguide.pdf?ua=1, retrieved 5 October 2014

For most patients in acute rehabilitation facilities such as LMC's Rehabilitation Unit, reimbursement for continued care is contingent on appropriate use of ADL assessments. Public and private insurance papers alike require documentation of, on the one hand, significant functional gaps that prevent discharge to home, and on the other hand, progress towards appropriate functional independence goals as assessed using the FIM or similar outcome measure. Patients not making progress under conditions of acute rehabilitation are candidates for transfer to less costly conditions such as subacute rehabilitation, or home with part-time home care.

2.1.2.2 Sensorimotor Impairment of Upper and/or Lower Limb

Weakness or paralysis of one or more limbs is the most common symptom of stroke. Upper limb impairment is slightly more common than lower limb impairment, 77.4% vs 72.4% in one study (Lawrence et al., 2001). Commonly the two present together as hemiplegia (no movement of either limb) or hemiparesis, which ranges from 'dense' (minimal movement) to 'mild' (movement with some weakness). Some 27-30% of patients are estimated to suffer sensory impairment with or without motor impairment. Motor impairment is the main cause of disability after stroke; in over 20% of cases it leaves the patient wheelchair-bound. It can be caused by damage to the motor and sensory areas of the cortex, or by deeper damage to connecting structures such as the basal ganglia (Lawrence et al., 2001).

During rehabilitation, physical and occupational therapists assess volitional and passive range of motion and strength of muscle groups to determine the level of impairment. However, during therapy greater emphasis is placed on restoration of functional activity. Techniques aimed at reducing physical impairment, such as isolated muscle exercise and physical or electrical stimulation, are undertaken only in relation to anticipated functional gain. As the time of discharge approaches and the patient is seen to be nearing her capacity for improvement, the emphasis shifts from restorative to compensatory approaches. Developmentally oriented exercises, intended to stimulate neural regrowth, give way to practice of compensatory strategies and use of assistive devices. Patient progress during this time is generally measured in terms of functional independence, meaning how much assistance the patient requires to perform a given task. Instruments designed for this purpose include the Barthel Index and Functional Independence Measure.

Prognosis for motor recovery after stroke is poorly understood. The largest gains in functional recovery are seen to take place during the first 30 days, and may be due to spontaneous recovery of neurological tissue, as distinct from repair or rerouting of neural pathways in response to therapy. Physical therapy (PT) to encourage rerouting of neural pathways during the acute rehabilitation period is the standard of care in the United States and United Kingdom, but the evidence basis is weak (Stein et al., 2008).

2.1.2.3 Aphasia, Apraxia of Speech and Dysarthria

'Stroke aphasia' is a designation commonly applied to a collection of clinical syndromes that are distinct in their pathomechanisms but often overlap in practice. Within the complex human activity that is verbal communication, Aphasia designates disruption of the initial conceptualization or construction of the linguistic message, and is correlated with poor outcomes in stroke rehabilitation (Laska, Hellblom, Murray, Kahan, & Von Arbin, 2001; Paolucci et al., 1998). Apraxia of speech designates degradation of the complex sensorimotor planning required for speech production. Dysarthria denotes impairment in the physical act of speaking, which includes sensorimotor impairment of orofacial muscles as well as irregularities of respiration and prosody. Clinically these three syndromes are difficult to distinguish, although the distinction can impact treatment and prognosis considerably (Cherney & Small, 2008). The collective term 'disordered speech' will be used to describe all three, with the individual terms used as appropriate.

Disordered speech is estimated to present acutely in 38% of stroke patients (Pedersen, Stig Jørgensen, Nakayama, Raaschou, & Olsen, 1995) and chronically in 30% of the post-ischemic-stroke population. While more than half of aphasic patients are estimated to recover some ability to speak during therapy, complete recovery is rare. Incidence of aphasia increases with age, and for reasons that are not currently understood, is disproportionately correlated with a cardioembolic etiology of stroke (42% of aphasic patients, vs 23% of nonaphasic [*OR* = 2.41, 95% *CI* 1.33 - 4.35]) (Engelter et al., 2006). Disordered speech in general and aphasia in particular can lead to reduced participation in social life with attendant frustration, isolation and depression (Barnes, Dobkin, & Bogousslavsky, 2005).

Therapy for aphasia is administered by state licensed speech and swallowing therapists, and begins with identification of syndromes present – though expert consensus is poor as to the nature and even the utility of such classification. Broadly, aphasia may be described as receptive (impaired ability to comprehend language); expressive (impaired ability to produce language) or global (both are impaired). Within these basic characterizations, eight main syndromes present with distinct etiologies. Accordingly, multiple differing therapeutic approaches have developed, including linguistic approaches (most used for expressive aphasia); melodic intonation therapy (used most with large left-hemisphere lesions, where any hope of recovery is thought to lie in recruiting right-hemisphere function) and functional communication approaches (most useful where speech is present but fluency is impaired) (Cherney & Small, 2008).

Apraxia of speech is a designation more recent than aphasia or dysarthria, with poor consensus on its etiology and a lack of research regarding treatment efficacy. Treatment approaches are generally behavioral, in contrast to treatment approaches for dysarthria which are aimed at strengthening (or reducing spasticity in) muscles that have been affected by the stroke. A 2007 Cochrane report found ‘no evidence of the quality required to support or refute the effectiveness of speech and language therapy interventions for dysarthrias following non-progressive brain damage’ (Xie, Wang, He, & Wu, 2008). However, strengthening of labial, lingual, buccal and pharyngeal muscles is critical to swallowing therapy (see below, section 2.1.2.5) and in care delivered according to the current evidence base the two are conducted by the same therapists (Geeganage, Beavan, Ellender, & Bath, 2012).

2.1.2.4 Cognitive Impairment and Dementia

Acute cognitive impairment has historically been diagnosed in some 45% of patients post stroke, and is associated with poor functional recovery (Hinkle, 2002, 2006). However, it is currently thought that most stroke patients suffer some lasting cognitive impairment, which in strokes of low to moderate initial severity may be mild and isolated to a single cognitive domain, and therefore not diagnosed (Srikanth et al., 2003). Significant impairment in multiple domains of cognitive function, known as dementia, is prevalent in patients with damage to certain 'strategic' areas such as the frontal lobe, paramedian thalamus, and dominant angular gyrus. Additionally, and regardless of initial cognitive impact, stroke patients are at greatly elevated long-term risk for dementia with or without a concurrent diagnosis of Alzheimer's Disease (AD). Some physiological markers are common to post-stroke dementia and AD, and it has been suggested that a distinction between the two diseases may lose relevance in an aging population with increased stroke survival rates. Most clinically useful may be three related spectra denoting relative contribution of vascular and AD etiology; number of cognitive domains impaired; and severity of impairment (Stein et al., 2008).

The main cognitive domains assessed in post-stroke care are: attention, memory, perception (meaning the processing and interpreting of sensory data), language (which is discussed above), praxis (also known as motor planning), and executive function, (meaning the capability to plan, organize and execute tasks) (Legg et al., 2007). At LMC, assessment of cognitive function is conducted at the impairment level[5] by the Neuropsychiatry team and at the functional level by the Speech and Swallowing Therapy (SST) team. Targeted cognitive rehabilitation is generally carried out by the SST team in the areas of language, attention and memory. Therapy for

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[5] See discussion of ICF levels above

disordered perception and motor planning is generally carried out by the Occupational Therapy (OT) team, although overlap with other teams is considerable. The Physical Therapy (PT) team work extensively with motor planning, and executive function is common to all three teams.

Relative to sensorimotor disability, rehabilitation for cognitive disability places less emphasis on remediation of the underlying impairment and more on identification and internalization of useful strategies for functional compensation. Because the learning process itself is impacted by the deficits described above, therapists draw on a repertoire of possible approaches, considered in relation to the patient's individual distribution and severity of impairment (Edmans & Hume, 2010). Core principles of occupational therapy for cognitive function include individualized, task-oriented learning, using SMART[6] goals in which patients contribute to the selection process, with involvement of family or helpers as appropriate, and access to psychological or emotional support for feelings of helplessness, anger or depression that may arise in the process. Also important is a concept of 'errorless learning', in which cues are given as necessary to support correct execution, because it cannot be assumed that stroke patients will learn from mistakes as 'normals' do (Barnes et al., 2005).

Some pharmaceutical therapy is also used to address post-stroke cognitive impairment. Somnolence may be addressed with stimulants, while drugs used in AD such as donepezil, galantamine and memantine are increasingly considered as treatment options. Overall, multidisciplinary care as described above is considered the standard of care, despite a paucity of research demonstrating efficacy of the individual approaches (Stein et al., 2008).

2.1.2.5 Dysphagia

Dysphagia after stroke is commonly documented, though reports of prevalence range widely from 19% to 81% (Martino et al., 2005a). In

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[6] Specific, Measureable, Appropriate, Realistic, Time bounded

addition to aspiration pneumonia it is associated with increased hospital stay, dehydration and malnutrition (Geeganage et al., 2012) which in turn may worsen post-stroke constipation (Harari, Norton, Lockwood, & Swift, 2004). The relation between neural deficit and dysphagia is poorly understood. It was previously thought to occur mainly in brain stem and bilateral infarctions; however recent research suggests that it is present in as many as 25% of left hemisphere lesions and 15% of right hemisphere lesions, and is likely lateralized idiosyncratically at the individual level, rather than following any known predictor (Schroeder, Daniels, McClain, Corey, & Foundas, 2006). Dysphagia is assessed by speech and swallowing therapists clinically at bedside, and through barium swallow or fiber-optic endoscopic assessment (FEES). Both imaging modalities return an 8-point Penetration-Aspiration Scale (PAS). Speech therapists consider this score, together with such clinical factors as dysarthria and abnormal cough or gag reflexes, to generate recommendations for texture alterations in food and thickening of liquids to prevent aspiration. In severe cases, feeding is conducted through a nasogastric tube or a surgically inserted percutaneous endoscopic gastroscopy (PEG) tube (Geeganage et al., 2012).

Treatment of dysphagia by licensed speech and swallowing therapists consists of exercises targeting the specific functional deficits identified on imaging and clinical examination. Oral exercises may strengthen the lingual, labial or buccal muscles, or address sensory deficits causing apraxia. Pharyngeal exercises similarly target motor, sensory and coordination deficits during the complex process of swallowing which includes initial elevation of the hyoid and larynx and closure of the epiglottis; retraction of the tongue base and coordinated constriction of the pharyngeal muscles; and relaxation of the cricopharyngus muscle (Fedorak, Finestone, Little, MacGarvie, & Martino, 2002). A recent Cochrane review suggests that acupuncture as well as behavioral therapy can improve swallowing outcomes, though a link to mortality rate has not been demonstrated (Geeganage et al., 2012; Leppavuori, Pohjasvaara, Vataja, Kaste, & Erkinjuntti, 2002).

2.1.2.6 Disordered Sleep

Disordered sleep, which includes insomnia, somnolence, and disrupted sleep-wake cycle, is known to be common in post-stroke patients, but estimates of prevalence vary widely from 20-40% to 37-56% for insomnia alone. It is correlated with poor rehabilitation outcomes (Hermann & Bassetti, 2009; Leppavuori et al., 2002). Pharmaceutical treatment options are constrained by the risks of polypharmacy, as well as increased risks and side effects of sedatives and hypnotics in the elderly and neurologically impaired (Lenhart & Buysse, 2001a).

Sleep is of critical importance (and is frequently disordered) for patients recovering from any brain injury, as it is during sleep that most extensive repair of neural structures occurs (Stein et al., 2008). Insomnia is also prevalent in the hospital inpatient population generally, but is seldom regarded as an important therapeutic target (Ünsal & Demir, 2012). Nighttime sleep quality and quantity is assessed by the night nursing staff; at LMC a dedicated log is used for this purpose for patients with sleep impairments that are refractory or difficult to quantify. While some fatigue is normal in stroke patients, excessive daytime somnolence may be brought to the attention of the Physiatrist coordinating medical care either by nursing staff or by the physical, occupational and speech therapists. Treatment of post-stroke insomnia is not generally treated differently than in other inpatient populations, other than the above-noted caution. Non-pharmaceutical approaches targeting sleep hygiene are poorly studied and include noise and visitor policies, lights-out times, and distribution of earplugs.

2.1.2.7 Bowel and Bladder Dysfunction

Constipation is recognized as a prevalent post-stroke symptom, affecting 30-60% of primary stroke patients. Poorly studied and often unsatisfactorily treated, it is seen to worsen prognosis for 12-week outcomes (Su et al., 2009). Fecal incontinence after stroke can be primary, or secondary to treatment of constipation (Harari et al., 2004). Bowel function is assessed by the nursing staff and treated pharmaceutically by the medical staff, usually with two stool softeners of differing mechanisms. The nurses have discretion to administer enemas and withhold stool softeners as necessary.

Urinary incontinence affects nearly half of acute stroke patients, although it commonly resolves during the first month. Some 35% of post-stroke patients are catheterized due to complete or partial urinary retention during the rehabilitation period, with a poorer prognosis for functional recovery. Nurses assess urinary function and execute basic bladder training regimes. In patients with retention of urine, the regime may include ultrasound quantification of retained urine. Bladder infection due to catheterization is a common source of post-stroke morbidity, both in the hospital and post discharge. Urinary and fecal incontinence increase risk of bedsores. They are also understood to contribute to depression and other post-stroke emotional disorders, but the relationship has not been formally studied.

2.1.3 Chronic and Long-Term Stroke Care and Societal Burden

As of 2002, there were some 4.4 million stroke survivors, of whom 40% reported moderate disability and an additional 15-30% showed severe disability (American Heart Association, 2005). This number is projected to increase, as crude prevalence of stroke is expected to increase from 3.2 per 1,000 to 4 per 1,000 by 2030 (Heidenreich et al., 2011). Projections suggest that by 2030, an additional 4 million people will have had a stroke, a 21.9% increase in prevalence from 2013 (Go et al., 2013). New technologies such as tissue plasminogen activator (tPA), as well as techniques of aneurysm repair and clot removal via interventional radiology, offer extraordinary improvement in clinical outcome. However, only a minority of patients can benefit from these two techniques: some 3-5% of patients are eligible for tPA (Adeoye, Hornung, Khatri, & Kleindorfer, 2011), while interventional radiology techniques are not widely available and are not useful for small vessel strokes.

Altogether, although there is considerable variation in the degree to which any individual will recover from her stroke, on average 50% will not walk again without assistance, and 95% have reached their maximum recovery by 11 weeks post stroke (Stoier & Olsen, 1995). In the United States, outpatient physical therapy and subacute rehabilitation are not typically withdrawn at this point, or earlier if progress appears to have plateaued. Paretic limbs that do not recover extensor function tend to become spastic as the flexors tighten, often causing considerable pain and further reduced independence unless they are treated with injected botulinum toxin. In patients with dysphagia, malnutrition and aspiration pneumonia are constant concerns.

From the patient's perspective, post-stroke depression affects half of patients post discharge, and is associated with increased morbidity and mortality, and is poorly treated, with dependency in toileting during rehabilitation as the most powerful predictor of depression 2-5 years post stroke (Bergersen, Frøslie, Stibrant Sunnerhagen, & Schanke, 2010; Kouwenhoven, Kirkevold, Engedal, & Kim, 2011). From the perspective of societal burden, a 2011 Danish study estimated costs for stroke in the EU in 2010 at 64 billion Euros (Jørgensen, Nakayama, Raaschou, & Olsen, 1997). With scant evidence for interventions to improve quality of life in chronic stroke, the epidemiological perspective and modeling-based cost effectiveness analysis suggests that even relatively expensive therapies producing only modest benefits during acute rehabilitation may be highly cost-effective in the long run, particularly for younger patients.

Altogether this section has shown that stroke, as a clinical entity in contemporary Western society, is deeply complex in nature, with variation not only between patients and over the course of recovery, but also depending on the professional discipline and associated conceptual perspective from which it is viewed. The next section will survey conceptual perspectives on stroke as they evolved across the history of Chinese medicine

2.2 Stroke in Chinese Medical History

The clinical entity of 'wind stroke', characterized as sudden onset of hemiparesis with or without loss of consciousness, is seen in the Chinese medical literature as early as 200 B.C.E. Across two millennia of practice, wind stroke has endured as a recognizable clinical entity despite multiple shifts in conceptualization of the underlying pathology and treatment approach. A brief historical overview surveys these shifting conceptualizations. Five main disease models are identified, each one of which substantially informs contemporary clinical treatment of stroke. Ephemeral and enduring features of these models are summarized in Table 2.1 and discussed below. Integrative 20th and 21st Century approaches to post-stroke acupuncture – and to biomedical integration itself – are discussed in relation to this complex conceptual landscape.

The purpose of this chapter section is twofold: first, to orient the reader to the range of diagnostic and treatment approaches that are used in constructing this study's treatment manual; and second, to characterize approaches taken to the construction of clinical knowledge – over the course of Chinese medical development and its engagement with biomedicine – that have informed design of this project.

2.2.1 200 B.C.E. – Huang Di Nei Jing

The Huang Di Nei Jing is a seminal clinical text, which is thought to have been compiled from the work of multiple authors across the pre-Imperial Chinese landscape and over the course of centuries. Several of its chapters – notably the Nei Jing Su Wen[7] 5, 42, 45, 62 and Ling Shu 23, 24 – refer to symptoms and mechanisms of sudden collapse and/or hemiplegia as a result of invasion by wind. These chapters are consistently cited in later works as early references to wind stroke.

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[7] The Su Wen or 'simple questions' is the first of two books making up the received text of the Nei Jing; the second is the Ling Shu or 'spiritual pivot'.

The term 'feng' or 'wind' itself has an extensive and complex history over the course of Chinese medicine. Originating in earlier systems of demonic medicine and persisting through to contemporary times, it has undergone multiple shifts of meaning. Broadly speaking, wind in the Nei Jing and other early texts is 'the chief of the hundred diseases', (Unschuld, 2004) a powerful pathogen capable of penetrating weak or situationally vulnerable bodies, and associated with many mysterious symptoms of sudden onset or changeable nature. The human body thrives via the orderly movement of *qi* (translated in different contexts as 'air', 'gas', 'flatus', 'aura', 'breath', 'activity' and 'nature') (Wiseman & Ye, 1998). Superficial degrees of penetration of the body by wind are associated with symptoms of febrile disease. Deeper invasion can lead variously to digestive upset, muscular pain or weakness, and in severe cases, syncope. Over centuries of subsequent history, wind's clinical associations narrowed and stabilized to constitute two clinical areas that are unrelated in biomedicine and reconciled only by some authors and with visible effort in Chinese medical thought[8]. The first of these is exogenous illness, including infectious disease as described in the section to follow, as well as rheumatic pain associated with exposure to the elements. The second is less well defined but can include chaotic neurological function, (tics, tremors, seizures, erratic behavior) as well as any illness characterized by sudden onset or changeability.

Sudden onset hemiparesis and associated clinical syndromes are visible as a clinical entity throughout Chinese medical history, and remain associated with the term 'zhong feng' meaning 'strike by wind' and usually rendered in English as wind stroke. However the membership of wind stroke in either of the above categories of illness due to wind is both changeable and contested across the course of history, as described in the sections to follow. Indeed, persistence of chaotic neurological symptoms

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[8] From a contemporary perspective, a commonality may be seen, of chaos disrupting an orderly signal. Viruses may be thought of as disrupting genetic code, as chaotic electrical impulses disrupt orderly brain waves.

beyond the sudden onset of acute phase CVA (e.g. seizure, hemiballismus) is relatively uncommon, though some authors take the deviated tongue typical of stroke as a wind sign.

Wind stroke is described in Chapter 62 of the Nei Jing Su Wen, as an upward rushing of the qi. The patient's response to treatment is itself considered an indication of prognosis: "If the Qi can be redirected downwards, the patient will live; if not, he will die" (Unschuld, 2004). However, no guidance as to acupuncture or herbal treatment for stroke is given in the Nei Jing.

2.2.2 200 C.E. – Zhang Zhong Jing

Zhang Zhong Jing adapted and systematized concepts of penetration by wind as described in the Nei Jing, and also developed concepts of cold as a pathogen. His model for exogenous disease – still widely in use today – described pathogenic influences of cold and wind disrupting the body function in six stages from superficial to deep. Superficial invasion of wind/cold would manifest with symptoms associated with the common cold including sneezing and chills. Presence of fever, cough, sweat or muscle aches indicated the depth of penetration into the channels and collaterals of the body. These were the large thoroughfares and smaller by-ways through which the qi traveled, and were seen to make up the body's defensive perimeter. Productive cough, digestive or urinary symptoms would indicate breach of the perimeter and invasion of internal organs.

In Zhang's text, sudden onset hemiparesis was described in terms comparable to those he used for infectious disease. Both were modeled penetration of an opportunistic wind 'evil' into a weak channel and organ system. Wind stroke was diagnostically graded by depth of penetration as follows (Wilms, 2014; Zhang, Wiseman, & Wilms, 2013):

- superficial wind strike: deviation (of eyes and mouth)
- feng zhong luo (evil in the collaterals): numbness of the skin

- feng zhong jing (evil in the channels): sudden onset of one-sided weakness with neither loss of consciousness nor internal symptoms
- feng zhong fu (evil in the hollow organs[9]): the patient fails to recognize people
- feng zhong zang (wind striking the solid organs): difficult speech and drooling

2.2.3 Liu Wansu (1120-1200), Zhu Dan Xi (1281-1358), Li Dong Yuan (1180-1251)

After a new publication and revival of the Zhang Zhongjing's work in the Song dynasty, along with an increase in the number of educated scholarly physicians, the Jin-Yuan period was a fertile time of intellectual development in Chinese medicine, also during this time, texts of all kinds were both more plentiful and better preserved than previously. We are thus able to see multiple competing schools of thought as they developed, and began. Authors Liu Wansu, Zhu Danxi and Li Dongyuan actively revising Zhang Zhongjing's ideas on external disease, and they also revised his ideas about stroke. Although there are noteworthy differences in the disease models they present, they all have in common that they rejected the idea of stroke as being caused by exposure to outside wind, providing instead models by which the stroke's 'wind' was stirred up by internal imbalances rooted in weakness of constitution or excess consumption of rich foods. It should be noted that none of these authors rejected the model of exogenous wind as a pathomechanism for infectious disease: they simply argued that it was not the pathomechanism for stroke, providing instead new models of pathogenesis based on behavior or natural endowment (Fruehauf, 1994).

2.2.4 Wang Qing-Ren (1768-1831)

Wang Qingren was a bureaucrat, who in the course of his duties is thought to have performed dissections, not otherwise performed by Chinese

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[9] The bowels and bladder were termed as 'hollow' organs, in contrast to 'solid' viscera such as the heart, liver and kidney

physicians. His text, 'Yi Lin Gai Cuo', 'Correcting Mistakes in the Forest of Medicine' proposed to correct past misconceptions on the basis of his observations. However the text was later criticized for introducing as many medical errors as it corrected, due to limitations of Wang's own understanding as well as the misperceptions of medical science in China at the time (Andrews, 1991). Nevertheless the text was highly influential clinically, introducing concepts of blood stasis and formulas for treating it that are in wide use today .

Wang's model of stroke was that it was always rooted in weakness of qi. Wang conceptualized stroke onset as the moment when a body with a diminishing supply of Qi passed the halfway mark, and the body's Qi was no longer sufficient to service more than one set of channels (ie, half the body). Empty of Qi, these abandoned channels both failed to nourish the flesh and also allowed static blood to accumulate, leading to the weakness, numbness, spasticity and pain characteristic of stroke. This etiological account is likely rooted in Wang's visual observation of the circulatory system after death – empty arteries, full veins – and is given little serious consideration in contemporary clinical reasoning. However, and remarkably, his account of the physical state of affairs following a stroke and the most useful approach to diagnosis and treatment – meaning the functional core of his disease model – proved empirically effective and is widely used today (Neeb, 2007). Wang's herbal formulas include large doses of medicinals that supplement the Qi, with smaller doses of hemolytics and other substances that promote blood circulation. This approach – supplementation of the main channels with dispersion and movement of the collaterals – also underlies the acupuncture treatments of the anterolateral extremities that are today considered as routine in stroke care.

It is interesting to note that Wang Qingren's 'Corrections of Medical Errors' and extensive work on stroke did not include consideration of the brain as the seat of pathology, though they did include the concept of 'brain Qi', and a discussion of neural decussation that is at least partially accurate. Much of his other work concerned the identification of 'blood stasis' as a pathogen, so it seems particularly surprising that his surviving work does not include identification of hemorrhage or blood clotting in the cerebral vasculature as a mechanism of stroke. Explicit integration of that concept into Chinese medicine fell to Zhang Xi-Chun.

2.2.5 Zhang Xi-Chun (1860-1933)

Zhang Xi-Chun was an influential scholar-practitioner working in cosmopolitan Shanghai in the early 20th century. He was well versed in the Chinese medical classics and also acutely aware of scientific medicine's clinical strengths and cultural ascendance. His book of clinical reflections, Yixue Zhong Zhong Can Xi Lu (Chinese at Heart but Open to the West) (Zhang, 1933) stands as a key artifact in the globalization of medical culture. It also develops the fundamental characteristics of clinical reasoning in the prevention and treatment of stroke that remain in place today, based on decades of experience treating a cosmopolitan population in whom he observed a large number of strokes preceded by symptoms of transient ischemic attacks and hypertension.

Zhang's disease model differs from those discussed above in two respects. First, contrary to the common practice of introducing one's model by arguing its superiority to those before, Zhang assumes the basic validity and relevance of nearly all the models previously discussed in this section, also allowing for the possibility that a given patient's stroke might fit one model better than another. Second, Zhang includes in his model the Western concepts of hypertension, and of the brain as the main locus of neurological function and disease. In Zhang's model of stroke, the Nei Jing's 'blood rushing to the head' was sufficiently homologous to the Western diagnosis of hypertension that it could be diagnosed using Chinese pulse diagnosis, along with clinical signs such as dizziness, restlessness, or a sensation of Qi rising in the abdomen. Like Zhu Dan-Xi and Li Dong-Yuan, he conceptualized the stroke's 'wind' element as internally rather than externally generated, but he used elements of Zhang Zhong-Jing's formula Feng Yin Tang which used heavy minerals to descend the Qi and Rhubarb root to open and clear pathogens from the bowels.

Zhang's work was also arguably hypothetico-deductive, in a broadly pragmatic sense. In describing the development of his main formula for stroke prevention, he reports starting with the idea that rising Qi could be redirected downwards with Niu Xi, an herb previously used for pounding headaches and now known to symptomatically lower blood pressure, along with other 'heavy settling' mineral ingredients. However, clinical results with this theoretically based formula were unsatisfactory, with initial lowering of blood pressure followed in many cases by resurgence. He revised his theory to include the classical notion of the liver as having a tough and upwardly mobile quality, and therefore revised the formula with sweet and Qi-spreading herbs to 'soften' the liver, with greatly improved clinical results. The resulting formula, Zhen Gan Xi Feng Tang (Sedate the Liver and Extinguish the Wind Decoction) is in common usage today. However, and importantly, it is taken as one possible avenue of approach (mainly for stroke prevention, and in patients presenting with liver qi 'attacking upwards' due to insufficiency of calming yin) (Zhang, 1933). This 'meta-model' approach – in which Western disease models are considered alongside historically competitive Chinese models with the assumption that any or all may apply to a given case – may constitute Zhang's most influential innovation (Fruehauf, 1999).

2.2.6 Contemporary Clinical Practice

As indicated above, the 'meta-model' approach developed by Zhang has continued through intervening decades. The current disease model for hypertension, hypercholesterolemia, atherosclerosis of cerebral vasculature and a resulting stroke, can be modeled and treated in terms of Chinese pathomechanisms. These can include upward rushing qi, excess phlegm, static blood, or insufficient qi or yin, separately or in combination as they present to the assessing practitioner. This Chinese medical treatment can take place alongside biomedical treatment.

Table 2.1: Clinical Features of Stroke Across Chinese Medical History

		Pathomechanism			Clinical Features				
Text or Author	**Date**	**External Wind**	**Internal Wind**	**Not Wind**	**Graded severity**	**Bladder/ Bowel**	**Insufficiency**	**Excess**	**Treatment Method**
Nei Jing	**200 bce**	External invasion leads to chaotic upward movement of Qi			2 severities: treatable, non-treatable		Initial invasion of wind is due to underlying weakness of form or situational vulnerability		No treatment methods for stroke
Zhang Zhongjing	**200 ce**	External invasion			5 severities: superficial, Luo, Jing, Fu, Zang		Right Qi	Cold Evil	Great wind with vexing heaviness: Hou's Black Powder: warming Yang and Qi tonics with release exterior
							If Heart-Lung Qi is weak, chest fullness and short breath	If Right Qi is strong, itching and papules	Wind Pulling Decoction: cooling with heavy settlers, purgatives,
Liu Wansu	**1120-1200**		Updraft from heart fire				Kidney Yin	Heart fire	Nourish Yin, Descend Qi
Li Dongyuan	**1180-1251**		Sunken Qi creates rising Yin fire				Weak Qi	"Physical form" (ie obesity)	Nourish Qi, transform phlegm
Zhu Danxi	**1281-1358**		Tranformation from phlegm				--	Damp phlegm transforming to heat	Purge, transform phlegm
Ye Tianshi	**1667-1746**		Liver Yang attacking upwards				Kidney/Liver Yin	--	Nourish Yin, descend Qi
Wang Qingren	**1830**	Facial droop		Insufficient Qi unable to fill the channels		Bound dry stool not resolved with purgative medicinals	Qi	--	Nourish Qi and Blood
Zhang Xichun	**1923**		Liver Yang attacking upwards; Phlegm; Yin deficiency	Ischemia or hemorrhage of cerebral blood vessels			Kidney/Liver Yin	Phlegm	Descend Qi, Nourish Yin

Table 2.1: Clinical Features of Stroke Across Chinese Medical History

Acupuncture treatment, little discussed in any of the texts referenced above, emerged as an important modality in the treatment of stroke during the 20th Century, largely as a result of the massive, politically motivated codification of Chinese medical practice undertaken in the 1950's (Taylor, 2004). Within this system of 'Traditional Chinese Medicine,' (TCM) the disease models described above that historically competed for validity were yoked into joint service as 'zheng' – 'syndromes' or 'patterns' of disharmony that could be recognized by pulse, tongue and key clinical signs, and treated accordingly as the internal 'root' of a presenting disorder. In practice, 'bian zheng' or 'differentiation of patterns' occurred secondary to 'bian bing', or 'differentiation of disease', essentially Western diagnosis. Within each bian zheng category, both herbal and acupuncture treatments were provided. Additionally, bian bing allowed for Chinese treatment methods to be applied directly on the basis of Western diagnosis. This was the case particularly in urgent cases such as high fever, or with acupuncture treatments oriented to local physical or channel-oriented effects that were not seen to require extensive bian zheng.

Such was the case with acupuncture for stroke recovery. Wang Qingren's model of empty channels engendering stasis of Blood was translated into a standard acupuncture practice of needling large points on the anterolateral aspect of the affected limbs considered to strongly activate the 'yangming' channels [10]. Also, importantly, by the early 1960's influential practitioners such as Jiao Shunfa had begun experimenting with a new, integrative form of acupuncture performed on the scalp. While some orthodox acupuncture points were located on the scalp, Jiao's scalp acupuncture eschewed traditional points and their associated location methods, instead basing placement of needles on the location of brain structures below. Jiao's primary treatment in stroke was the placement of needles over the motor and/or sensory cortex corresponding to the observed impairment (Jiao,

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[10] The Yangming channels are described in the Huang Di Nei Jing, a seminal acupuncture text, as being most abundant in both Qi and Blood, and therefore optimal for restoring Qi and clearing static blood in paretic limbs

1982, 1997). These two methods used together – anterolateral points on affected extremities with scalp points over the affected motor and sensory areas – became the basic template for post-stroke acupuncture treatment in China for the remainder of the 20th Century, particularly for research. Additional needles could have been added for localized function, such as at the base of the tongue and on the Heart channel for aphasia. However – and importantly – acupuncture treatment seldom addressed the Bian Zheng constitutional issues such as constipation, as concurrent herbal treatment was assumed.

2.3 Acupuncture in Post-Stroke Care: Contemporary Research

This project arose from chart review showing positive clinical outcomes with the use of acupuncture to facilitate acute stroke rehabilitation, at an inpatient Neurology and Rehabilitation unit in Brooklyn, New York, over the last decade. A retrospective chart review of 720 acupuncture treatments conducted in 2003 and 2004 showed stroke patients reporting amelioration of a wide range of symptoms including: motor weakness, pain, hiccoughs, dizziness or vertigo, constipation and insomnia. Patients also reported feeling “relaxed” or “calm” after treatment (Citkovitz et al., 2005). Subsequently, the staff of the Rehabilitation unit (physiatrists; nurses; and physical, occupational and speech therapists) were surveyed for their perceptions of acupuncture effects. A majority reported perceptions that the treatment was helpful to patients, with a variety of apparent symptomatic benefits[11] (Alban, Citkovitz, & Julliard, 2005).

Research on acupuncture mechanisms in humans and animals suggests that acupuncture can both accelerate recovery of function lost due to brain damage (Li & Yang, 2011; Xie, Cui, Zou, & Bai, 2014; Zhang et al., 2014) and also reduce eventual size of the damaged area (Du et al., 2011; Hsiu,

[11] 50% of respondents reported a perception that acupuncture was “usually” helpful to patients; 36% reported “sometimes”. Written-in comments included: “Some [patients] report decreased pain, some report increased range of motion of paralyzed muscles.” “Increased mood, increased energy, increased hope for recovery, increased strength.” “Decrease pain, improved strength”.

Huang, Chen, Hsu, & Hsu, 2011). Studies published in China report improvement in a wide variety of systemic and symptomatic outcome measures with acupuncture (Sze, Wong, Or, Lau, & Woo, 2002). Western clinical research is less positive however; clinical trial results are contradictory and systematic reviews generally equivocal (Ernst & Lee, 2010). At present neither the Chinese-language literature nor the Western peer-reviewed literature on acupuncture during stroke rehabilitation is methodologically or substantively adequate to guide evidence-based clinical practice (Vados, Ferreira, Zhao, Vercelino, & Wang, 2015). The call for larger, more rigorous trials of acupuncture during stroke rehabilitation concludes many trials and reviews, but few clinical trials of acupuncture during stroke rehabilitation have been published in the West over the last few years. Authors surveying the Western literature have identified methodological problems related to the patient population, interventions and outcome measures assessed, all of which may contribute to the apparent discrepancy between mechanisms research and clinical research outcomes (Hopwood & Lewith, 2005; Shiflett, 2007).

2.3.1 Mechanisms Research in Acupuncture for Stroke

The possibility of multiple systemic and symptomatic benefits of acupuncture post stroke is supported by mechanisms research in humans and animals. Several broad categories of effect can be seen, with differing implications for practice and different time frames of optimal effect. These include: neuroprotection from ischemic damage (Feng & Zhang, 2014); increased cerebral blood flow and angiogenesis (Du et al., 2011; Ma & Luo, 2008); and increased neuroplasticity and connectivity of brain structures associated with neural recovery.

Protection of cells from ischemic injury is of most importance during acute onset of stroke and in the 7-10 days following, where cells injured by the stroke continue to die off under conditions of hypoxia, inflammation and cytotoxic insult. These cells are considered to constitute the ‘ischemic penumbra’. Acupuncture appears to shrink the ischemic penumbra, but there is little consensus on underlying mechanisms (Feng & Zhang, 2014).

Candidates include reduced inflammation (Choi et al., 2010; Jeun et al., 2005; Zhang et al., 2007a); increase in cerebral blood flow and increased angiogenesis at the stroke site (Du et al., 2011; Hsieh et al., 2006; Ma & Luo, 2008), as well as accelerated clearance of metabolic waste (Feng & Zhang, 2014; Lee et al., 2010).

A second cluster of related acupuncture effects is of interest during recovery and also throughout the rehabilitation period. These include needling-related activation of brain regions related to the location of injury (Hsiu et al., 2011; Lee et al., 2003) and to cortical reorganization (Bai, Cui, Zou, & Lao, 2013; He et al., 2006; Huang et al., 2012; Wang & Jia, 1996; Zhang et al., 2007b). Kong et al. (2002) demonstrated differential effects between manual and electrical stimulation. Bai et al. (2013) also demonstrated increased connectivity of ipsilesional and contralesional premotor cortex, particularly notable as asymmetrical activation of these structures is characteristic of poor recovery after stroke. In this small study, increase in bidirectional causal influence was correlated with patient-perceived intensity of *de qi* ('arrival of the qi', regarded as a component of needle sensation), which in turn was correlated with improved motor function. Acupuncture is understood to increase connectivity of brain structures during resting state (Dhond, Yeh, Park, Kettner, & Napadow, 2008), and to increase neuroplasticity in a variety of clinical conditions (Liu et al., 2006; Loggia et al., 2012; Pfab et al., 2012). Both effects may be of value in facilitating the extensive neural retraining required during stroke rehabilitation.

Although these findings are promising, their translatability of these findings to clinical practice is not clear. Most of the studies described above use a single point selected from among those typically used in post-stroke care, and stimulated manually or (more commonly) with electroacupuncture. These points include GB-34 (Bai et al., 2013), ST36, GV20 and TE5 (Huang et al., 2012). In some cases, there appears to be a straightforward relationship between the point's traditional use and its apparent biomedical effects. For example, GV20, located at the vertex, is considered to raise qi to the head, and is one of the main points selected for use in studies showing an increase of cranial circulation. In other cases, the apparent relationship is more complex, and the route of translation less clear. For example (Bai et al., 2013) demonstrated that strong de qi stimulation at GB34 was associated with delayed-onset down-regulation of pathologically high activity in the contralesional premotor cortex, which often leads to excessive activation of the healthy side and impedes rehabilitation of the affected side. GB34 is often used in conditions of musculoskeletal over-recruitment, as traditional Chinese texts assign it a function of 'soothing' the sinews. However, neither this study – nor a recent spate of others demonstrating increased neural connectivity with GB34 (Xie et al., 2014; Zhang et al., 2014) – provides evidence to guide its clinical use.

Two of the studies described above (Hsiu et al., 2011; Lee et al., 2003) use standardized protocols typical of the clinical research described in the section to follow. These also may be of limited appropriateness for individual patients.

2.3.2 Clinical Research

Consistent with the picture of multiple overlapping effects, acupuncture studies published in China show strongly positive results on multiple stroke sequelae including: reduced motor function; impaired balance (Liu et al., 2009; Zhao, Liu, & Liu, 2003); disrupted cognition (Lun, Yang, & Fu, 2006); dysphagia (Xie et al., 2008); aphasia (Li & Yang, 2011); insomnia and depression (Wu & Liu, 2008); urinary retention (Yun et al., 2007); and pain of several types (Chen et al., 2000; Yun & Sun, 2010). However, obstacles of convention and epistemology prevent wholesale inclusion of these apparently promising results into the Western evidence basis. 'Clinical research' in Chinese medicine historically includes case discussions and collected impressions of established masters. To date a number of important Chinese language publications take this form, or else compare two forms of acupuncture (Bao, Wang, Zhang, Wang, & Sun, 2008) and are unsuitable for meta-analysis. Those Chinese language clinical trials that do compare acupuncture to a control group are also commonly omitted from meta-analyses due to methodological shortcomings such as poor reporting of control intervention, randomization strategies and allocation concealment (Ernst & Lee, 2010; Wu, Mills, Moher, & Seely, 2010). A paper entitled, “Do certain countries produce only positive results?” (Vickers, Goyal, Harland, & Rees, 1998) suggests that publication bias complicates interpretation of Chinese clinical trials generally. Trials of acupuncture for stroke rehabilitation published in China have therefore not been widely used to inform Western acupuncture research. Some trials conducted in China have been published in Western peer-reviewed journals; those have been selectively included in discussion of the Western literature below.

The Western peer-reviewed literature, like the mechanisms research and Chinese clinical literature, is consistent with the possibility of multiple pathways of action contributing to multiple clinical effects not yet systematically explored. Significant outcomes are reported for lower extremity motor function (Park et al., 2005; Yan & Hui-Chan, 2009). Greater improvement within the acupuncture group is also found on balance assessments, and on some quality of life assessment cognitive assessments (Chou, Chu, & Lin, 2009). Improved sleep with acupuncture is also found, together with changes in heart rate variability suggesting reduced sympathetic nervous activity (Lee et al., 2009). Several trials show improvement on dysphagia with acupuncture, (Akamatsu et al., 2009; Xie et al., 2008). A Cochrane review suggested significantly greater improvement in acupuncture groups, versus usual care only or usual care plus sham treatment ($p<.0001$) (Geeganage et al., 2012).

The measures generally considered most important in assessing clinical benefit during stroke rehabilitation are assessments of independence in Activities of Daily Living (or ADL) (Beninato et al., 2006). Motor and neurological assessments (such as the Fugl-Meyer Assessment and Motricity Index) are considered most sensitive to short-term change, and are generally used in efficacy trials to assess performance of a specific intervention (Cameron & Bohannon, 2000). ADL assessments, by contrast, are designed to assess the patient's ability to function at home; they therefore reflect the combined effect of all the therapeutic interventions the patient has received. In the hospital setting, they are used to determine destination of discharge and level of follow-up care. ADL assessments therefore have a far more direct relationship to the patient's well-being – and the eventual cost to society – than most outcome measures.

Activities of Daily Living were assessed in a series of acupuncture trials in the 1990's in Sweden. Significantly greater improvement in the Barthel ADL index was found in patients treated with acupuncture than those treated with usual care alone, both at the acute stage and the subacute phase, up to 6 months post-stroke (Kjendahl, Sallstrom, Osten, Stanghelle, & Borchgrevink, 1997; Sallstrom, Kjendahl, Osten, Kvalvik Stanghelle, & Borchgrevink, 1996); these differences persisted at 1- and 2-year follow-up. However, no significant between-group differences were found in two different follow-up studies comparing an acupuncture protocol to various placebo controls including mock or 'sham' acupuncture (Gosman-Hedstrom et al., 1998; Johansson et al., 2001). To date, four other trials of acupuncture for acute stroke – all sham-controlled – have found no significant difference in Barthel scores (Hopwood & Lewith, 2005; Johansson et al., 2001; Park et al., 2005; Schuler et al., 2005). This preponderance of negative results in the sham-controlled trials has led some authors to conclude that acupuncture offers no clinical benefit during acute stroke rehabilitation, (Hopwood, Lewith, Prescott, & Campbell, 2008; Kong, Lee, Shin, Song, & Ernst, 2010). Within the last 5 years, little new research has been conducted on acupuncture for stroke rehabilitation in the West, with systematic reviews greatly outnumbering clinical trials. While reviews generally conclude that further study is warranted or necessary, the small number of trials actually conducted may reflect reluctance of researchers and funders alike to address a question where positive clinical outcomes are negatively correlated with high internal validity of trial design (Personal communication, B. Brinkhaus, 18 September 2011). Clinical trials of acupuncture during acute or subacute stroke care, assessing ADL outcomes and published in the West from 1987 to 1998, are summarized in Table 2.2. Trials published between 1999 and 2013 are summarized in Table 2.3.

Table 2.2: Treatment Protocols, Patient Population and Results of Trials of Acupuncture during Acute Stroke Care Published in the West, 1987-1998											
1st Author, Year	**Title**	**Treatment***	**Treatment Course**	**Development Process**	**Outcome Measures**	**Comparator**	**Design**	**Patient Population**	**Time Post Stroke**	**Severity**	**Results**
Naeser, 1992	Real versus sham acupuncture in the treatment of paralysis in acute stroke patients: a CT Scan Lesion Site Study	Fixed protocol: I: LI4, 11, 15; TE5, 9; 3 Ba xie points; ST31, 36; GB34, 39; LV3. C: LI4, 11; ST36; 4-5 needles along scalp motor line; B: ear shenmen. EA 1-2hz at LI11-TE9 or LI4-11 or TE5-BaXie (practitioner's discretion) plus GB34-39 plus scalp needles	20 minutes, 20 treatments over 30 days	3 weeks' protocol development and training with experts in Shanghai hospital	Boston Motor Inventory (study-specific)	Acupuncture at points with high electrical resistance, with sham EA.	RCT N=16	Right-handed with left ischemic stroke	30-90 days	Unknown	NS in small group, but 4 showed improvement in acupuncture group versus 0 in sham group, p<.115.
Johansson, 1993	Can sensory stimulation improve the functional outcome in stroke patients?	Fixed protocol, 2 alternating modes. Mode 1: GV20, nonparetic:LI4, ST36; paretic: LI4,11, BaXie, Ex-mob, ST36, ST40, EX-36:1 plus EA 2Hz ST36-40 and LI4-11. Mode 2: GV20, nonparetic: LI11, GB34; paretic: same upper extremity points; Ex-Mob replaced by GB34 (EA GB34-ST36)	20 minutes, 2 per week for 10 weeks	Unspecified	SSS at 1 and 3 months, mBI at 1, 3 and 12 months, NHP at 3, 6 and 12 months; length of stay (LOS)	Usual care only	RCT N=78	"Severe hemiparesis"	<10 days	Mean mBI=45	**Significant difference in BI (p<.05), Balance and Mobility domains of SSS; NHP, LOS; significantly more living home at 12 months**
Hu, 1993	A randomized controlled trial on the treatment for acute partial ischemic stroke with acupuncture	Semi-standard: scalp motor and speech areas, GB21, LI11, EX-UE-7, GB34 (upper limb); UB60, GB34, LR3, EX-UE-7 (lower limb); also at practitioner discretion: CV23, TE3,6,10,13,15, LI10,15, UB31-34,47,54, ST36,41, BaXie plus EA 10 minutes on scalp needles. 28-30 gauge needles.	30-60 minutes, 3 times per week, 4 weeks	Expert group, no formal consensus process	Scandinavian Stroke Scale (SSS) and Barthel Index (BI) at day 28 and 90.	Usual care only	RCT N=30	Primary ischemic stroke, age 46-78	<3 days	Median SSS=24	**Significantly better SSS improvement day 28 and 90 (p=.020 and p=.009). (Greatest improvement in patients below median at baseline)**
Sallstrom, 1996	Physical therapy, acupuncture in the treatment of stroke patients in the subacute stage	Practitioner discretion....Generally... yang channels of the affected side...[plus] yin point of arm and leg. Supplementary points [addressing] condition and syndrome differentiation. Stimulation of the needles, to tonify or to sedate, were mostly done by hand. If indicated, moxibustion...or electrical stimulation...2-4Hz"	30 minutes 3-4 times per week for 6 weeks	Consensus: acupuncture team	MAS, Sunnaas index of ADL (SADL), NHP, health care social services	Usual care only	RCT N=45	Primary stroke including hemorrhage and aphasia	Median 40 days	Heterogeneous	**Significantly greater improvement on all outcomes: MAS (p=.002); SADL (p=.02); NHP (p=.009)**
Kjendahl, 1997	A one year follow-up study on the effects of acupuncture in the treatment of stroke patients in the subacute stage						Follow-up from above RCT N=41				**Significantly greater improvement on all outcomes: MAS (p=.0002); SADL (p=.0002); NHP (p=.0003)**
Gosman-Hedstrom, 1998	Effects of Acupuncture Treatment on Daily Life Activities and Quality of Life: A Controlled, Prospective, and Randomized Study of Acute Stroke Patients	Deep: 10 fixed points, 30mm needles + estim -> muscle contraction on paretic side. B: LI4/11, ST38, Ex-mob, GV20; I: TE5	2 per week	Unspecified	SSS (motor, orientation, speech); BI (motor-based ADL)	**Arm 2**: Superficial acupuncture: four 15mm needles, LI11, Ex Mob. **Arm 3:** Usual care only	RCT N=104, 3 arms	Acute primary focal ischemic stroke; requiring ADL assistance; no severe aphasia or cognitive impairment; Age 40+,	<7 days	Moderate/Mild (mean mBI 45/100)	No significant differences

Table 2.2: Trials of Acupuncture during Acute Stroke Care Assessing Activities of Daily Living, Published in the West, 1987-1998

Table 2.3: Treatment Protocols, Patient Population and Results of Trials of Acupuncture during Acute Stroke Care Published in the West, 1999-2013

1st Author, Year	Title	Treatment	Treatment Course	Development Process	Outcome Measures	Comparator	Design	Patient Population	Time Post Stroke	Severity	Results
Johansson, 2001	Acupuncture and Transcutaneous Nerve Stimulation in Stroke Rehabilitation	Fixed protocol, 2 alternating modes. Mode 1: GV20, nonparetic:LI4, ST36; paretic: LI4,11, BaXie, Ex-mob, ST36,40, EX-36:1 plus EA 2Hz ST36-40, LI4-11. Mode 2: GV20, nonparetic: LI11, GB34; paretic: same upper extremity points; Ex-Mob replaced by GB34 (EA GB34-ST36)	20 minutes, 20 sessions over 10 weeks	Unspecified	mBI, Rivermead Mobility Index, 9-Hole Peg Test, 10 meters' ambulation time, NHP	**Arm 2**: high intensity TENS **Arm 3**: low intensity TENS	RCT *N*=150, 3 arms	"Moderate or severe impairment".	5-10 days	Moderate to severe' (mean mBI=33/100)	All outcomes NS at 3 months and 1 year. Positive expectations at baseline higher in TENS group than acupuncture (*p*=.031).
Schuler, 2005	Acupuncture treatment of geriatric patients with ischemic stroke	Unspecified	30 minutes, 2 times weekly for 4 weeks (mean 6.2 treatments)	Unspecified	European Stroke Scale, mBI	**Arm 2**: mock TENS **Arm 3**: usual care only	RCT *N*=120, 3 arms	Primary and secondary ischemic stroke, mean 78 years	3-35 days	Heterogeneous (mBI=10-75/100)	No significant differences. Multiple withdrawals and hematomas. One of the acupuncturists was MD with 1 year experience.
Park, 2005	Acupuncture for Subacute Stroke Rehabilitation	Fixed protocol: 4 common points (ST40, CV12, GV20/26) plus 6 points based on Korean sasang typology. Acupuncturist 5 years of experience.	20 minutes, 9-12 sessions in 2 weeks	Unspecified	mBI, National Institutes of Health Stroke Scale, Motricity Index (MI), EuroQoL-5 Dimensional Form and VAS.	Nonpenetrating sham needle at least 1.5cm away from 'real' points	RCT *N*=116, assessor blinded	<4 weeks post stroke, ischemic or hemorrhagic; acupuncture naïve; symptoms expected to persist >2 weeks	<28 days	Mild?	No significant difference, but greater improvement in lower extremity function in more severely impaired patients. Recruitment was closed before required sample size was met.
Hopwood, 2005	Does Acupuncture Help Stroke Patients Become More Independent?	Similar to Hopwood 2008 (pilot study)			Residence at home at 12-month follow-up	Mock TENS	RCT *N*=95	Primary ischemic stroke	Similar to Hopwood 2008		**Among patients living at home before onset, 85.7% of acupuncture group were at home at 12-months (vs 65.6% of controls, *p*=.02)**
Hopwood, 2008	Evaluating the efficacy of acupuncture in defined aspects of stroke recovery	Fixed protocol: LI4,10,15, TE5; GB31,34,39,34; practitioner discretion to add GB20, ST36. EA 2Hz at LI10-TE5, GB31-34 (to elicit slight twitch). Scalp: 4 needles at motor line, EA 100Hz	30 minutes, 3 times per week for 4 weeeks 12 treatments	'Best practice'	BI, MI, mood, NHP, treatment credibility	Mock TENS	RCT *N*=92	Primary ischemic stroke 4-10 days post onset, >25% deficit on MI	4-10 days	heterogeneous	NS at 12 and 52 weeks. MI greater at 3 weeks only (*p*=.0009). NS between severe/mild groups (BI<9 vs. BI=9+)
Zhu, 2013	Acupuncture in Subacute Stroke: No Benefits Detected	10 fixed points: HT1, PC6, LI4, BaXie, ST31, ST32, SP6, SP9, ST36, LV3, plus motor and sensory scalp lines, and additional symptom points at practitioner discretion, eg ST6, ST7, SI18 (facial paralysis); GV15, GB20, jinjin/yuye, CV23 HT5 (dysarthria). Needles inserted 10-15mm at 90-degree angle with de qi and manual stimulation.	5 days per week (body acupuncture only) for first 30 days then 2-3 days per week for 2 months.	Selected by researchers because of proximity to afferent nerve fibers	FMA, BI at baseline and 1, 3, and 6 months	Usual care only	RCT *N*=188	Ischemic or hemorrhagic stroke, age 45-80,	<30 days	heterogeneous	No significant between-group differences however groups differed on FMA at baseline (*d=0.32, MCID=9).* Improvement slightly greater in acupuncture group: 3.14 (95% *CI* = -2.13,8.62)

Table 2.3: Trials of Acupuncture during Acute Stroke Care assessing Activities of Daily Living, Published in the West, 1999-2013

2.3.3 Methodological Considerations

Several methodological problems may contribute to poor study results. Recent research questions the physical inertness of sham acupuncture methods used (Harris et al., 2009) and suggests that their use may limit external validity, increasing risk of false negative findings and reducing effect size, relative to other active or usual care controls. Claudia Witt argues that sham control reduces effect size in acupuncture trials (Witt, 2011) due to nonspecific effects of acupuncture. This argument is consistent with a model of multiple clinical benefits as suggested by previous literature. The studies described above may have failed to elicit clinical acupuncture effects with appropriate treatment. Conversely, they may have failed to statistically identify them with appropriate outcome measures and inclusion/exclusion criteria, at levels of effect size that retain significance when compared to sham controls. Additional methodological issues that may have reduced apparent effect size in previous trials include:

Problematic outcome measures: The Barthel Index has been shown to have a ceiling effect (Kwon, Hartzema, Duncan, & Min-Lai, 2004; Wade & Collin, 1988) which may have affected both Hopwood's (Hopwood et al., 2008) and Park's (Park et al., 2005) results. The Barthel Index has generally been replaced by the FIM (functional independence measure), a lengthier and more complete assessment that in US hospitals has become the standard basis for decision-making regarding the intensity and duration of care that will be covered by public and private insurance. However, the multifactorial nature of the FIM (which assesses independence level across 18 different motor and non-motor activities) reduces the apparent effect size of any single intervention or treatment effect.

Questionable adequacy of acupuncture given: Clinical trials of acupuncture for stroke rehabilitation vary dramatically across multiple parameters of treatment including number and duration of treatments; standardization or flexibility of protocol; and level of practitioner experience. Within trials of acute stroke, highly significant results are found in the study whose acupuncture team travelled to China for 3 weeks' training with experts (Naeser, Alexander, Stiassny-Eder, Lannin, & Bachman, 1994b), while the poorest results among the studies reviewed are in the trial with the least number of acupuncture treatments given, in which practitioners included one with only a year's experience, with reports of multiple hematomas and patient withdrawals due to painful needling (Schuler et al., 2005).

Heterogeneity of patient presentation: Clinical heterogeneity is a fundamental characteristic of the clinical landscape in stroke, well known to complicate research in the area (Kent, Soukup, & Fabian, 2001). Differences in stroke type, circumstances of onset and early care, location and comorbidities greatly differentiate stroke severity as well as experiential impact, both between patients and from early to late in a given patient's recovery process. A biostatistician reviewing the literature on acupuncture for stroke (Shiflett, 2007) argues that heterogeneity of severity alone can account for the difference between significance and non-significance in several trials of motor recovery. Because patients with mild strokes will likely recover motor function regardless of intervention, and patients with severe damage likely will not, it may only be within a 'moderate' group that effects on motor-related outcome measures can be statistically identified.

Poor matching of interventions and outcome measures: The most common type of stroke, ischemia of the Middle Cerebral Artery (MCA), typically results in contralateral hemiparesis that resolves quickly in the leg and slowly or less completely in the arm. Strokes of the Anterior Cerebral Artery may also present with early hemiparesis, but with the reverse pattern of arm and leg recovery. Among acute stroke trials, only one limited the patient population to MCA stroke; that intervention was more strongly focused on arm than on leg motor recovery, and the trial showed strongly significant results both in motor improvements and in post-treatment CT imaging. Other trials generally applied standard protocols intended to improve upper and lower motor function in hemiparesis, regardless of which limb was most affected. When a motor recovery outcome measure such as the Fugl-Meyer Assessment was used, trials to date show conflicting results with two reporting greater recovery in the lower extremity (Alexander 2004, Park 2005) and one reporting greater recovery in the upper extremity (Hsieh 2002). One small trial of acupuncture during acute stroke used an intervention adapted to individual patient presentation (Wayne et al., 2005) and showed significant between-group differences on the Fugl-Meyer assessment (combined upper and lower) as well as differences on FIM scores that approached statistical significance. No sham-controlled trial using standardized arm and leg motor points has reached significance on the FIM or other ADL assessment.

Wayne et al.'s trial used a treatment protocol that included flexibility to address differing patient presentations via a process of manualization developed by Rosa Schnyer and colleagues (Schnyer & Allen, 2002). Schnyer's model addressed the tension inherent in clinical research, between the scientific pressure for standardization to maintain internal validity, and the clinical need for flexibility to provide adequate, externally valid treatment. By operationalizing the entire patient assessment and treatment procedure within a single experimental exposure, Schnyer provided an avenue for delivering acupuncture treatment without abandoning the system of assessments on which such treatment is generally based. Schnyer's manualization process was designed to accommodate the moderate heterogeneity ordinarily encountered when a cohort of patients grouped by Western diagnosis are assessed from a Chinese medicine perspective. Relative to clinical practice, the flexibility in treatment selection is still quite small. However, the process can be extended to address the wide clinical heterogeneity of acute stroke, as well as the multifactorial nature of the FIM assessment (Schnyer, 2011).

Overall, current clinical research to date fails to bear out the promise suggested by mechanisms research in acupuncture for stroke rehabilitation, and is insufficient to guide evidence-based practice. In the

West, clinical trials are decreasing in number, while systematic reviews are increasingly negative in their conclusions. Chinese studies show positive results, though with questionable internal validity. Smaller apparent effects in Western studies may be related to methodological challenges discussed above, for which manualization may be a promising approach.

2.4 Synthesis and Research Questions for this Project

This chapter has argued that stroke as an object of clinical attention is large, complex, difficult to study, and mutable in its conceptualization across the range of contemporary practices that constitute usual care – as well as across two millennia of Chinese medical history. Basic research has identified a large and growing set of changes in cerebral blood flow, neural activation, inflammation and other mechanisms associated with ischemic injury and recovery, reliably elicited by acupuncture in humans, or in animals based on treatment strategies developed in humans. However, clinical research using a narrow repertoire of treatments, standardized between patients and across the course of a patient's recovery, has shown little efficacy. Methodological areas have been identified where reduction of clinical complexity – particularly in the area of diagnosis and treatment – lessened ecological validity, which may have contributed to equivocal results. Most important among these areas is delivery of treatment – in most cases lacking any diagnostic process that would lead to treatment considered clinically appropriate in Chinese medicine. In two studies that described measures taken to provide clinically appropriate acupuncture – one of them including manualization by Dr. Schnyer – strong trends favoring the acupuncture groups were found (Naeser et al., 1994a; Wayne et al., 2005). However these were both pilot studies not powered to reach significance. Protocols piloted in these studies were not used in later trials.

The picture of stroke recovery and rehabilitation that emerges from this review is of acupuncture potentially conferring a range of distinct but related benefits during this complex process, effects which are not easily isolated for study using the positivistic single-factor cause-and-effect model dominant in biomedical research. This project therefore develops and evaluates a manual for provision of acupuncture care during stroke rehabilitation that is informed by current best evidence and provides repeatability for research, training and policy-making purposes, but is also perceived by practitioners as clinically appropriate to the individual patients. This overall purpose drives three research questions. First, what constitutes clinically appropriate acupuncture treatment during stroke rehabilitation, and can it be repeatably operationalized or manualized? Second, which outcome measures are appropriate for use with such manualized treatment? Despite suggested differences in response on motor outcomes, it can still be hypothesized that if each patient is met with individual treatment targeting the full range of motor, cognitive and systemic impairments that constitute post-stroke disability, the result will be whole-group improvement on comprehensive disability measures. Conversely – and finally – if not all patients show improvement even with clinically appropriate treatment, then which patients do, and for which outcomes?

Chapter 3 describes and contextualizes the methods selected for addressing these questions while developing and evaluating the treatment manual. Competing epistemic and methodological approaches to the problem of clinical complexity are briefly surveyed, in terms of their utility to this project. The overall study design is then laid out, with discussion of methods selected to address the project's specific and explanatory aims.

3 CHAPTER 3: RESEARCH METHODOLOGY AND DESIGN DECISIONS

Chapter 2 provided clinical and historical context for this project's aim of developing and pilot-testing a manual for evidence-informed, clinically appropriate acupuncture practice during acute stroke care. It presented in detail two main sources of complexity in that enterprise: the exceptional heterogeneity of clinical presentation post stroke, and the plurality of available models for understanding and addressing those presentations available within the contemporary practice of acupuncture.

In Chapter 3, I review methodologies that have previously engaged the problem of clinical complexity in the study of acupuncture and other disciplines. I then describe how those approaches have informed the conceptual basis and design decisions made for this project.

The first section of the chapter surveys methodologies previously used in the assessment of acupuncture and other complex interventions. The Medical Research Council's guidance on complex interventions (Craig et al., 2008) is identified as a primary model guiding overall study design, while elements of other approaches such as whole systems research and participatory action research additionally inform adaptation of the MRC model to this project's research questions.

A second chapter section describes in detail the project's five objectives and the three-part design that addresses them, using a pragmatic approach to identifying and combining research strategies that best answer the question at hand. Choices of method for each of the objectives are discussed in terms of antecedents described above, and alternatives where they exist.

A concluding section summarizes the conceptual flow of the project's three studies, as shown in Figure 3.1.

Figure 3.1: Conceptual Overview of this Project

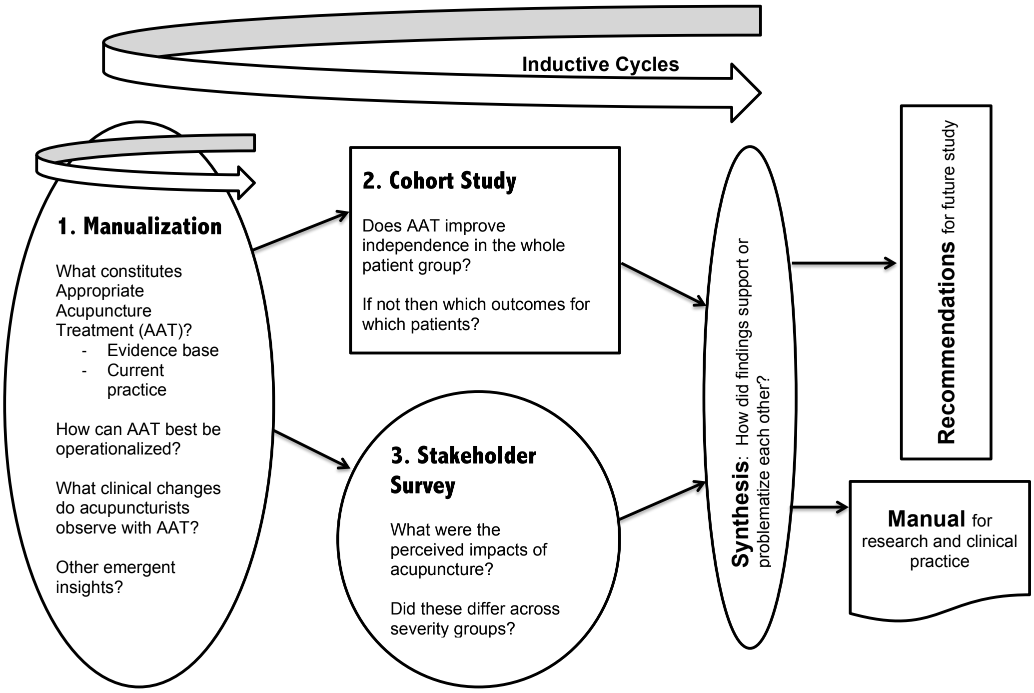

Figure 3.1: Conceptual Overview of this Project

3.1 Research Methodologies previously used to engage clinical complexity

The problem of balancing internal and external validity has been identified as a primary challenge in acupuncture research (MacPherson, Hammerschlag, Lewith, & Schnyer, 2007; Schnyer & Allen, 2002). However, the problem is not unique to acupuncture trials. It is described and addressed in discussions across multiple disciplines of complementary, alternative and integrative health care such as herbal medicine and homeopathy (Lewith, Jonas, & Walach, 2011; Witt & Linde, 2011) as well as complex interventions within conventional health care such as physical therapy and diabetes education (Campbell et al., 2007).

The result of this multidisciplinary engagement with complexity is a broad array of conceptual approaches to the project of clinical knowledge gathering; these are briefly reviewed below. Methodologies whose conceptual frameworks and associated methods have informed the design of this project are summarized. For each approach, the epistemic perspective and key concepts are very briefly introduced in order to discuss acupuncture studies using the approach, along with specific relevance of the approach to this project. Table 3.1 summarizes the discussion.

3.1.1 Qualitative Research

Qualitative methods are applied from a wide variety of epistemic perspectives ranging from social constructionist to critical realist. A core concept shared by those who use qualitative methods is that inquiring into the perceived realities of self and others is a method of choice for understanding human phenomena . Reality is (at least to some degree) locally constructed, and therefore must be approached inductively to be understood. Appropriately 'grounded' theories grow out of the researcher's direct experiential engagement with observed reality, and are revised through iterative re-engagement during the research process (Corbin & Strauss, 1990). To the degree possible, they rely on participants' views of the situation being studied. As seen in the discussion of complex interventions research below (Section 3.1.6), even within a critical realist framework – where objective reality exists but can only be approached by local theoretical understandings – inductive and qualitative approaches are indispensible for preliminary knowledge gathering where the phenomena under study are complex, or available data is mixed or conflicting (Pawson, Greenhalgh, Harvey, & Walshe, 2005). With widespread use across conflicting schools of thought, qualitative methods have been effectively decoupled from their constructivist origins. In health care they now constitute a widely accepted approach for inquiry into human experience. (Patton, 2001).

Table 3.1: Overview of Methodologies Used To Address Clinical Complexity in Acupuncture Research

Epistemic Approach	Method	Strategy for managing clinical complexity	Previous Application in Acupuncture Research: Patient Population	Previous Application in Acupuncture Research: Intervention	Previous Application in Acupuncture Research: Comparator	Previous Application in Acupuncture Research: Outcome	Application in this Project
Constructivist	**Qualitative Research**	Inductive inquiry into diverse lived experiences (versus decuctive statistical pooling)	Insight into characteristics and preferences of acupuncture 'users' (Cassidy 1998)	Acupuncture therapeutic process involves non-needling elements such as conversation during diagnosis and treatment (Paterson 2005 A)		Insight into treatment experience of: cancer survivors (Seers 2009); UTI sufferers (Alraek 2001); chronic pain patients (Paterson 2005 B)	**Study 3 - Outcome, Population**: Exploration of stakeholder perceptions and comparison across severity groups
Constructivist	**Action Research**	Participant researchers bring lived experience to the inquiry process; Cycles of action and evaluation allow dialectic of inductive and deductive methods	Comparison of 'menopause' syndromes with lived experience of women in London (Scheid 2010)	Tracking and ongoing self-assessment of diagnosis and treatment for menopausal women (Scheid, in press)			**Study 1 - Intervention**: Acupuncturists observe their treatment choices, perceptions of effect and patient feedback to develop manual for individualized treatment
Critical Realist (or Pragmatist)	**Mixed Methods**	Combining methods (usually qualitative and quantitative) allows for triangulation	Identifying barriers to acceptability of acupuncture (Hopton 2013)	Exploration of therapeutic properties of acupuncture care beyond needling (MacPherson 2006)		Paterson 2003: for chronic illness, best to assess both qualitative and quantitative outcomes	**Studies 2 and 3 - Outcome, Population:** comparison of quantitative outcome measures and qualitative stakeholder perceptions across severity groups
Critical Realist (or Pragmatist)	**Comparative Effectiveness Research**	Minimizing stepdown of complexity from clinical to research condition	Pragmatic trials with diverse patient populations and non-randomized groups (Witt 2006, Brinkhaus 2008)	Pragmatic trials assessing treatment at the practitioner's discretion (MacPherson 2004; Vickers 2004)	Clnically relevant comparators (usual care or head-to-head) (MacPherson 2004; Brinkhaus 2008)	Patient-centered outcomes (Vickers 2004; MacPherson 2004; Brinkhaus 2008)	**Study 1 - Intervention**: Treatment manual is applicable for both clinical and research use
Critical Realist (or Pragmatist)	**Complex Interventions Research (MRC guidance)**	Cycles of planning, implementation and evaluation allow 'tuning' of population, intervention, outcome and comparator		Standardized yet flexible treatment for depression designed by consensus; not used in published trial (MacPherson 2007)			**Whole project**: Cycles of planning, piloting and evaluation to optimize intervention, outcome measure and patient population
Pragmatist	**Whole systems research**	Model validity: evaluation and treatment is appropriate to the medical system under study, not compromised for internal validity		Ecological validity: intervention performed as in clinical practice (Hammerschlag 2008)		Suggested use of "native" outcome measures (Verhoef 2004)	**Study 2, Intervention, Outcome**: Experimental exposure is the condition of acupuncture evaluation and treatment. Outcome meaures suggested by acupuncturists are included.

Table 3.1: Overview of Methodologies Used To Address Clinical Complexity in Acupuncture Research

Methods of conducting and interpreting qualitative research vary. Both interviews and written questionnaires are used in health care research, while the most common mode of interpretation is thematic analysis (Patton, 2001). In this process, after familiarizing herself with a data set the researcher finds and substantiates meaning by identifying statements as meaningful units and the units into themes (Braun & Clarke, 2006).

Qualitative methods have been used extensively in acupuncture research, both in conjunction with quantitative methods (see Mixed Methods below) and independently. Qualitative research has characterized the content and therapeutic function of acupuncturist-practitioner interactions (Paterson & Dieppe, 2005; Robinson et al., 2012). It has also been used to identify patterns of acupuncture usage (Bishop, Barlow, Coghlan, Lee, & Lewith, 2011). Research using qualitative methods has been influential in characterizing the phenomenon of de qi as an entity to be accounted for in acupuncture research (Kim, Park, Lee, Bang, & Park, 2008; Yuan et al., 2013). However, as a recent opinion paper points out, (Birch, 2015) qualitative exploration of the phenomenon has largely been restricted to the patient's experience, whereas in most traditionally based systems of acupuncture, the practitioner's skilled perception of de qi is more clinically relevant than the patient's. This example illustrates both strengths and weaknesses of qualitative research regarding acupuncture. Initial qualitative work served to reify de qi as a component of acupuncture treatment necessary for adequate acupuncture treatment (White et al., 2008) where previously it did not exist as such. This act of knowledge construction was limited, in that it was conducted according to established norms in which the target of qualitative inquiry in health care is normally the patient, and sensory expertise on the part of the practitioner is normally not an accepted target of research. Altogether though, once qualitative work on patient perceptions in accepted and in place, it is possible to call for exploration of practitioner perceptions, in response to clinical and historical considerations which would not previously have been comprehensible to non-experts.

For this project, where clinical effects of acupuncture during stroke are both complex and poorly understood, qualitative research is integral. Both patient and practitioner viewpoints are important.

3.1.2 Mixed Methods Research

Research combining multiple research methodologies – typically qualitative and quantitative – was first used in the social sciences in the 1950's, but increased in visibility and emerged in health care research in the 1990's following a period of epistemological turbulence. Methodological purists from both post-positivist and constructivist perspectives questioned the legitimacy and feasibility of an approach that combined methods developed within incompatible epistemologies. However, a pragmatic viewpoint emerged which claimed epistemological roots in the work of John Dewey and William James, rejecting claims of incompatibility and holding that in selection of research methods, theoretical assumptions previously associated with methods selected should be subordinate to the research question itself (Tashakkori & Teddlie, 2010).

Morse (2003) distinguishes between multi-method research, in which two or more autonomous projects are conducted together in the course of a single research program, and mixed methods research in which one project provides the primary thrust of the inquiry; one or more secondary projects support the first, and are not expected to stand as autonomous initiatives. Morse suggests an eight-category taxonomy of mixed methods designs, derived from three dichotomies as follows:

- Primary research drive: this may be inductive, implying dominance of qualitative methods for exploratory purposes, or deductive, implying dominance of quantitative methods for hypothesis testing
- Type of secondary method: this may be qualitative or quantitative, and serves to supplement the primary inquiry
- Sequencing: the secondary project(s) may be conducted simultaneously with the primary project, or in sequence (with the

finished product of the first project informing design of subsequent projects)

In acupuncture research, a (secondary, inductive) qualitative inquiry can be embedded within a (primary, deductive) randomized controlled trial to enrich interpretation of quantitative results (Hopton, Thomas, & MacPherson, 2013). Such mixing of methods may bring to light meaningful outcomes that are not included in standard questionnaires or were not anticipated within the initial trial design (Polley 2007). Additional uses of mixed methods in acupuncture trials have included service assessments using qualitative assessments of patient and practitioner satisfaction alongside quantitative pre- and post-treatment assessments (Cheshire, Polley, Peters, & Ridge, 2013), and exploratory research using thematic analysis of qualitative components of a primarily quantitative questionnaire, both to enrich understanding of patient's experience within that study and also to facilitate future interpretation of the questionnaire (Polley, Seers, Cooke, Hoffman, & Paterson, 2007; Seers et al., 2009).

A main strength of the mixed methods approach in health care is 'triangulation,' its ability to provide multiple perspectives on the same intervention: inductive and deductive, subjective and objective, qualitative and quantitative – and simply different (Mason, 2006). This ability to synthesize a pluralistic understanding is useful for acupuncture where systemic or nonspecific effects may be experientially more important to patients than acupuncture efficacy for a given objective outcome measure. An important weakness of the mixed methods approach is the potential for loss of methodological integrity, particularly in the secondary approach. Morse (2003, p. 205) warns that "it can be tempting not to saturate the data", particularly for secondary qualitative work where the sampling strategy is fixed by a primary qualitative inquiry.

For this study, a pragmatic approach allows mixing of three distinct methodologies, as discussed in Section 3.2 below.

3.1.3 Participatory Action Research

Often referred to as simply “Action Research”, this approach was developed in the second half of the twentieth century, across fields as disparate as education, anthropology and political activism. Sharing the basic epistemic assumptions of social constructionism, as a research methodology Action Research further holds that the purpose of knowledge gathering is social or institutional change, and that “human systems [can] only be understood and changed if one [involves] the members of the system in the inquiry process itself.” (Brydon-Miller, Greenwood, & Maguire, 2003).

Action research aims to empower individuals as researchers examining problems and creating positive change in their own daily lives, surfacing previously tacit minority voices. Practitioners therefore explicitly waive positivist claims of objectivity and scientific neutrality, which cannot realistically be maintained while inquiring into one’s own life and work circumstances. Action research study designs are iterative, involving cycles of planning, implementation, and critical self-evaluation. By creating a dialectic between planning and evaluation, these cycles also create an opportunity for dialectic between inductive and deductive methods (Reason & Torbert, 2001).

White and Verhoef (2005) propose incorporating some principles of participatory action research into design of CAM studies. They describe a small focus-group study conducted in this manner with cancer patients. Multiple reported benefits of the study included: spontaneous formation by participants of an ongoing peer support program; new insights on the thematic analysis conducted by the investigators achieved via discussion with the patients; and high follow-up rates likely due to to high personal investment in the study.

Principles of action research were used in a mixed methods study of Chinese medicine for menopausal symptoms (Scheid, Tuffrey, Weijburg, Bovey, & Ward, 2015). In this case the action research was a secondary project within a clinical trial. The participants in the action research process were not patients but the study acupuncturists, who met periodically as they developed treatment protocols based on the patterns of disharmony clinically observed in London women.

For this project, methods drawn from a participatory action research approach empowered the acupuncture team to develop an acupuncture manual for use in clinical research. This allowed for emergence of the practitioner's voice, as distinct from previous researchers, textbook authors or expert consensus panels.

3.1.4 Comparative Effectiveness Research

The research methods described above all explicitly challenge the currently dominant positivist reliance on testing of falsifiable hypotheses as the only valid method of clinical knowledge construction. Comparative effectiveness research (CER) for CAM therapies, by contrast, proposes an alternative strategy for research design without fundamentally challenging the hypothetico-deductive paradigm.

CER researchers contrast CAM therapies to pharmaceuticals never previously used on humans, which must necessarily demonstrate safety and efficacy under conditions of high internal validity to draw the strongest possible statistical conclusion before effectiveness trials are warranted. They argue that where a therapy is already in widespread use, conventional research priorities are inverted: the most pressing public health need is for evaluation of practices as they are currently used, on comparators that are directly relevant to policy decisions. These include usual care alone, or head-to-head with other available modalities of treatment (Fønnebø et al., 2007; Witt, Lao, & Berman, 2012).

Comparative effectiveness research in acupuncture has flourished in the last decade. Several large trials conducted in Germany[12] and England (Thomas et al., 2006) provided sufficient data to influence national policies regarding referral and reimbursement for acupuncture. However, one key issue that remains unresolved in the area of comparative effectiveness research is the acupuncture treatment itself. Pragmatic trials, which "aim to describe the overall benefits of a routine treatment" (Macpherson, 2004) allow for large-scale assessment of acupuncture conducted according to the acupuncturist's discretion for diagnosis and treatment plan. This design has provided an alternative to tightly standardized treatments which may not be clinically appropriate on a per-patient basis (as described above in Section 2.3). However, without any standardization or classification of the treatments used, positive results may not be reliably reproduced in clinical practice or subsequent studies.

A middle ground has emerged in the use of consensus processes such as the Delphi or Nominal Group methods to generate a study protocol (MacPherson & Schroer, 2007) or treatment manual (Schnyer et al., 2005; Wayne et al., 2005). However, as discussed in Chapter 3 below, even consensus of acknowledged experts lacks any process for verification, and may represent a 'consensus of ignorance' (Sherman, Linde, & White, 2007)

This project develops methods for comparative effectiveness research. In particular, it addresses the problem of operationalizing routine care for pragmatic trials.

3.1.5 Whole Systems Research

Whole systems research can be regarded as a subtype of comparative effectiveness research. The experimental exposure in a whole systems trial is not a specific treatment, but a condition of diagnosis and treatment

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[12] (Brinkhaus et al., 2006; Diener et al., 2006; Linde et al., 2005; Melchart et al., 2001; Scharf et al., 2006)

within a selected medical tradition such as Chinese medicine, Ayurveda or naturopathy. Verhoef and Lewith (2005a) further argue for a prioritization of model validity over the rigid conventions of internal validity commonly used in randomized controlled trial (RCT) design. They suggest a flexible mixed methods design combining qualitative and quantitative methods to allow the therapy's native theoretical constructs to guide selection of outcome measures.

Since 2010 the literature on whole systems research has to some degree bifurcated. Complex systems theory has attracted the attention of researchers in homeopathy (Bell, Koithan, & Pincus, 2012; Koithan, Bell, Niemeyer, & Pincus, 2012) and Chinese medicine (Lu, Jia, Xiao, & Lu, 2004) in the development of contemporary scientific models for the effects of older therapies. Meanwhile clinical trials have assessed impacts of Chinese medicine (McCulloch et al., 2011; Ritenbaugh et al., 2008) and Ayurveda (Chopra et al., 2013) prioritizing fidelity to the original model as suggested by Verhoef and Lewith.

This clinically oriented project uses a whole-systems approach as suggested by Verhoef and Lewith, including qualitative evaluation and selection of outcome measures by the acupuncture team on the basis of preliminary self-assessment. Some qualification is required: as discussed in Chapter 2, the term 'system' does not accurately describe the plurality of practices that constitute Chinese medicine[13]. Also, the full range of Chinese medicine techniques was not available to the study's inpatient population. However, the distinctive whole-systems approach of taking a condition of evaluation and treatment as the study's experimental exposure is central to this project.

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[13] This point is argued in greater specificity by Volker Scheid (Scheid, 2002, 2007) and Trina Ward (Ward, 2011a, 2011b)

3.1.6 Complex Interventions Research

Complex interventions research is a designation commonly used for the study of public health and health services, such as health education programs, where tightly controlled delivery and assessment of a single standardized intervention is infeasible. It is associated with realism, a post-positivist stance articulated in clinical research as follows:

> The hallmark of realist inquiry is its distinctive understanding of causality. The successionist model (which underpins clinical trials) holds that causality is established when the cause X is switched on (experiment) and effect Y follows. In contrast, the generative model of causality (which underpins realist enquiry) holds that, to infer a causal outcome (O) between two events (X and Y), one needs to understand the underlying mechanism (M) that connects them and the context (C) in which the relationship occurs. (Wong, Greenhalgh, Westhorp, & Pawson, 2012)

The Medical Research Council's Guidance for Complex Interventions Research (MRC Guidance), was issued in 2000 and revised in 2008 (Campbell et al., 2007; Craig et al., 2008). It has been recognized as both applicable and valuable in designing trials of acupuncture and other CAM modalities (Schroer, Kanaan, MacPherson, & Adamson, 2012; Seers et al., 2009). Five key points are described in a companion paper to the 2008 Guidance, under the heading "What makes an intervention complex?" These points are as follows:

- Number of interacting components within the experimental and control interventions
- Number and difficulty of behaviours required by those delivering or receiving the intervention
- Number of groups or organisational levels targeted by the intervention
- Number and variability of outcomes
- Degree of flexibility or tailoring of the intervention permitted

All but the third of these key points are seen to describe, if not all acupuncture research, then certainly most acupuncture research that would be recognized by practitioners as ecologically valid.

A central message of the MRC Guidance document is that evaluation of complex interventions should be considered as an integral part of their development, suggesting iterative cycles of development, piloting, evaluation and implementation. Also emphasized in the document is the necessity of selecting methods and outcome measures appropriate to the question and intervention being studied, and the plurality of available study designs (including some of the approaches described above).

Jonas and Lewith (2011) cite the MRC Guidance as a model for CAM research, emphasizing the importance of iterative cycles of development and revision of research methods. Paterson and Dieppe (2005) further argue that acupuncture is appropriately viewed as a complex intervention. To date a small number of published trials have explicitly drawn on the MRC Guidance for study design (Huang, Howie, Taylor, & Robinson, 2011; Schroer et al., 2012).

For this project, the MRC Guidance provides a well-developed model that has shown promise for development, piloting and evaluation of acupuncture treatment as a complex intervention. The methodological fit is not perfect, however. The MRC Guidance emphasizes that successful implementation depends in large part on a clear, well-defined theory as to the mechanism of change, even when multiple approaches exist and are complicated by context: "There may be lots of competing or partly overlapping theories, and finding the most appropriate ones will require expertise in the relevant disciplines" (Craig et al., 2008).

As seen in Chapter 2 however, use of a single theory as to the mechanism of change is not consistent with the contemporary clinical practice of acupuncture, nor is it supported by current best evidence, which has identified multiple physiological pathways of effect. The lack of a single, clearly defined mechanism of action is generally agreed to be a central difficulty in acupuncture research (Langevin et al., 2010; MacPherson et al., 2007). This project's negotiation between acupuncture's currently irreducible plurality and the Guidance document's emphasis on a cohesive theory of change is discussed in Chapter 4.

3.1.7 Manualization

Manualization of clinical care is a research method developed during the 1960's, as a strategy for conducting research in psychotherapy that would be accepted as valid within the positivist research conventions dominant in medicine. Several of the research challenges are similar between psychology and acupuncture. Most notable among these is the poor fit between biomedicine's concept of a clearly defined diagnosis and treatment, and a complex clinical encounter in which assessment and treatment emerge from a large number of trained practitioner behaviors that are implemented variably based on interaction with the patient. Manualization as a method in acupuncture research emerged in the 1990's. Early work by Stephen Birch aimed to define 'adequacy' of treatment using structured review of clinical texts (Stux & Birch, 2001). Subsequent work by Schnyer and Allen (2002) proposed specific methods for defining and operationalizing treatment that would accommodate heterogeneity of TCM diagnosis within a group of biomedically defined research subjects.

Manualization is a primary element of this project's design. The method and its use in acupuncture research is described in greater detail in Chapter 4.

3.1.8 Synthesis and Implications for this Project

For this project, the methodologies reviewed above yield three main angles of approach, to the problem of conducting valid outcomes research in the complicated encounter between a heterogeneous patient population and a complex intervention.

3.1.8.1 Individualizing the Intervention

The first approach, common to several of the methodologies described above, is individualization of treatment, meaning use of a study design that allows practitioners flexibility to tailor the intervention to meet the needs of the individual. Most straightforwardly, pragmatic trials used in comparative effectiveness research simply decouple the practical and policy question of clinical impact from the explanatory question of mechanism of action (Macpherson, 2004; Schwartz & Lellouch, 1967). This approach may be optimal for large studies assessing acupuncture under the conditions of its eventual delivery, but in smaller trials under experimental conditions, the problem of representativeness of treatment becomes a serious one. As discussed in Chapter 2, this is particularly the case for stroke where great differences exist between approaches sharing the label 'acupuncture' as well as between study results.

Less straightforward in approach, manualization is a research method used to provide repeatability through operationalization of the assessment and treatment process. As a form of mediation between model validity of the acupuncture intervention and biomedical conventions of internal validity, acupuncture research manuals have historically relied on highly transparent methods for their construction such as structured review of the literature (Stux & Birch, 2001) and formalized methods for expert consensus finding such as the Delphi process (Schnyer & Allen, 2002). Literature review and expert consensus may additionally meet a cultural need in the biomedical community for something resembling a 'best practice', which is the basis of contemporary evidence-based medical care. As discussed below in Chapter 4, manuals used in acupuncture studies to date have also tended to provide relatively little individualization of treatment. For this study, an attempt has been made to define and operationalize appropriate individual acupuncture treatment in a manner that effectively addresses the biomedical imperative for transparency of construction with regard to best available evidence, but also produces a manual that is of immediate practical value in clinical practice.

3.1.8.2 Use of qualitative inquiry to inform selection and interpretation of quantitative outcome measures

As discussed above above, mixing of qualitative and quantitative methods is becoming increasingly common in acupuncture research. The combination may be sequential, so that qualitative understandings inform the selection of quantitative outcome measures, either as part of a single project or within a multi-study research program (Morse, 2003). Conversely, the two methods may be combined concurrently, so that qualitative insights into the data enrich interpretation, allowing researchers to gain some understanding of the treatment's experiential impact, for comparison to that of acupuncture patients outside the trial; and also helping to determine whether impacts included important outcomes that could have been quantitatively assessed but were not (MacPherson et al., 2007). For this study, which aims to understand the relationship of stroke severity and acupuncture benefit, concurrent qualitative inquiry elucidates qualitative differences in perceived impact of acupuncture between patient groups, both separately (to allow comparison) and at a higher level of subtlety than would be possible with quantitative methods alone.

3.1.8.3 Dialogue of inductive and deductive approaches to inform study design

Mixed methods research, participatory action research and complex interventions research all share an explicit principle of allowing inductive and deductive approaches to inform each other in the construction of new knowledge. These approaches may be qualitative and quantitative methods for outcomes assessment, as described in Section 3.1.8.2 above. However in participatory action research and in the MRC's Guidance for research on complex interventions, inductive work can also take the form of stakeholder participation in program design, bringing lived experience of patients, practitioners and other stakeholders directly to the planning of the intervention. This approach increases the utility of deductively based conclusions for implementation and policy development by grounding them in the experience of stakeholders and identifying obstacles to implementation, some of which can be addressed during the study process itself. For this project, cycles of planning, implementation and self-evaluation governed the manualization process, while stakeholder survey informed the assessment process.

3.2 Design Decisions

This chapter section details the application of the MRC Guidance's iterative approach, to the question of acupuncture's utility during acute stroke rehabilitation. The project's aim – manualizing acupuncture treatment during stroke rehabilitation and evaluating feasibility for future study across severity levels – generates five objectives, which are addressed in three linked studies pragmatically combining strategies drawn from the methodologies described above. The conceptual structure of the project is depicted in Figure 3.1.

3.2.1 Methodology and Overall Design for this Project

This project took a pragmatic approach to knowledge construction. Specifically, in order to fully explore Chinese medicine's possible utility when used integratively in an acute rehabilitation setting, three distinct viewpoints were required, and are reflected in the objectives stated below. These are: a pluralistic Chinese medical approach, combining traditional and contemporary theory and practice to optimize patient assessment and treatment; a hypothetico-deductive biomedical approach to evaluation of acupuncture's clinical impact; and an inductive, qualitative approach to understanding positive and negative stakeholder impacts of acupuncture use that would not have been captured by either of the above methods.

Within this project, each of these viewpoints is represented by one of the three studies. This three-study design combines two well-established two-study mixed-method designs. First, as described above in Section 3.1.7 and below in Chapter 4, addition of a preliminary manualization phase to a clinical trial has over the last 50 years been described and refined as a method for bridging the gap between research and clinical practice in psychology, acupuncture, rehabilitation medicine and other complex interventions (Schnyer & Allen, 2002; Westen, 2002). Second, considerable literature exists within and outside of complementary medicine research to suggest that conclusions drawn from clinical trials or other quantitative outcome assessments can be strengthened, and implications for practice more clearly understood, through addition of a concurrent qualitative study (Cheshire et al., 2013; Patton, 2001; Tashakkori & Teddlie, 2010).

The resulting structure of this project was a preliminary manualization phase followed by a cohort study that was conducted simultaneously with a qualitative stakeholder survey. For each of the three studies an appropriate model existed, though in some cases models were combined or revised for this inquiry. Taken together, these three projects follow the MRC Guidance for researching complex interventions described above in Section 3.1.6. Development of the intervention (Study 1, Manualization) was conducted iteratively, allowing it to inform and be informed by subsequent work phases (Study 2, Concurrent Cohort Study; and Study 3, Assessment of Subjective Perceptions). A pragmatic approach allowed each investigation to inform and be informed by the others while proceeding on its own epistemological terms. Design choices specific to these projects, and rationales for these choices, are discussed in Sections 3.2.3-3.2.7 below and in Chapters 4, 5 and 6.

3.2.2 Investigation 1: Development of a Treatment Manual for Acupuncture during Acute Stroke Rehabilitation

3.2.2.1 Aim 1: Development of an acupuncture treatment manual that accommodates individual treatment goals in acute stroke rehabilitation

The main design choice made for this aim was the use of an iterative action research approach in developing the manual, rather than processes for developing expert consensus (such as Delphi or nominal group methods), which have previously been used for construction of acupuncture treatment manuals (Allen et al., 2006; MacPherson & Schroer, 2007; Wayne et al., 2005). I made this decision in relation to the particularities of the study setting. An existing program was already perceived as successful, with substantial continuity of practitioners. Therefore some combination of individual and consensus practice already existed, and was available for observation and further development. An additional constraint of the setting on study design was that because treatment was already available, it was not ethically possible to randomize patients not to receive it, hence the concurrent cohort design. It was also not ethical to ask practitioners to administer treatments they perceived as suboptimal in order to conform to a standardized manual. This was in contrast to funded trials where researchers are obliged to provide scientifically compelling rationales to funding and regulatory institutions for the experimental condition to which they propose to newly expose patients. Therefore the opportunity existed for codification and ongoing iterative development of the intervention under naturalistic conditions. This approach allowed the protocol to be developed maintaining model and ecological validity, using ‘native’ Chinese medical reasoning, as discussed above (Section 3.1.5).

Several secondary choices resulted from use of the action research approach. I considered the use of a formal consensus process in team meetings, but rejected it, again for reasons particular to the circumstances of this study. All of the acupuncturists on the team were senior to me in years of clinical experience (and all but one in age) whereas I was the only team member with training or experience in research, and had the most clinical experience in treating acute stroke. I therefore decided that where formal consensus methods are deployed to reduce intra-group power disparities, within this group equality was better fostered by emphasis of ‘clinical business’ over ‘research business’. I defined consensus for the group as unanimous agreement, with reservations on any team member’s part as sufficient to delay decision until resolved through discussion.

The format of the manual was emergent from the collaborative process. Although I served as an informant based on my review of the manualization and clinical guidance literature, a majority of the manual’s flowsheets were designed and prepared by other team members. Also emergent from the group’s discussion was the key concept that guided the format from

Version 1.0 onward, that the manual should mimic and support the clinical knowledge-seeking behavior of the experienced practitioner. This was accomplished in a two-part structure: first, a repertory of known and trusted strategies to be used in combination for clinical presentations commonly seen; and second, an indexed resource of best available evidence to be consulted for unusual or refractory cases that are outside the practitioner's working knowledge base.

Two final decisions regarding the manualization process are related, and were also made as a conscious decision to make the manual's inquiry process practitioner-driven rather than systematic according to *a priori* standards that might not be clinically useful. The manual was pluralistic in style, juxtaposing historical and modern approaches with the same pragmatic approach taken to mixing methods in the project as a whole. Additionally, after my preliminary review of the historical and contemporary research literature which formed the earliest basis of the manual, further review of the English-language textbook literature by team members (along with a few Chinese sources by myself) was conducted during the course of the study on encountering difficult patients. These literature search results, emergent rather than systematic, were also incorporated into the manual.

The cohort study explored clinical impact of treatments given using the manual as a guide to assessment and treatment planning; however, as discussed above, practitioners were explicitly invited to diverge from treatments suggested by the manual if they perceived them as suboptimal or logistically infeasible, recording what they did instead and providing a rationale for the choice. This design provided an opportunity to assess clinical appropriateness of treatments generated by the manual. A key element in model validity for Chinese medicine is appropriateness of treatment not only to the patient population under study, but to the individual patient. Per-patient perceived appropriateness was therefore used as the key metric assessing success of the manualization procedure.

3.2.3 Investigation 2: Concurrent Cohort Study of Manualized Acupuncture

3.2.3.1 Aim 2: to determine whether patients treated with manualized acupuncture show greater improvement on ADL assessments than those treated with usual care alone

This aim explored the relationship between manualized acupuncture and functional recovery during acute rehabilitation of ischemic stroke. As discussed in Chapter 2, clinical appropriateness of the intervention is a key source of potential Type II error in previous trials: if the intervention has no potential for effectiveness, design decisions regarding patient population and outcome measure are irrelevant. In this methods development context, the question may be framed as, "is variable appropriateness of acupuncture treatment across a severity group a sufficient explanation for previous inconsistent study results?"

As discussed in Chapter 2, ADL assessments are the current standard for assessing functional recovery from stroke. Most commonly used in the United States (and standard at Lutheran Medical Center) is the Functional Independence Measure (FIM). This is a comprehensive instrument that combines functional assessments made by physical, occupational and speech/swallowing therapists as well as nurses in the course of their work with the patient; at LMC it is assessed at baseline and updated weekly until discharge. Reasons for selection of the FIM as primary outcome measure included the dependability of its assessment, and also its central role in the stroke patient's course of treatment. Baseline FIM score and improvement are key indicators used by clinicians and patient care coordinators to determine the patient's length of stay in rehabilitation, destination of discharge (home vs. institution), and level of insurance reimbursement for continuing therapy. The comprehensive, multifactorial nature of the FIM also appeared to be well suited to test the effects of an individualized treatment.

As this was itself a feasibility study, a formal power calculation was not conducted (Arain, Campbell, Cooper, & Lancaster, 2010). Sample size was set at N=48, as representing projected recruitment for a year given inclusion-exclusion criteria.

Inclusion-exclusion criteria were set as widely as possible in order to provide as large and representative as possible a sample, while still isolating degree of damage to corticospinal tracts as the main determinant of severity and course of recovery. For this reason only strokes presenting with contralateral hemiparesis were included, while hemorrhagic strokes (which typically present as more severe at baseline) were excluded (Stein et al., 2008), along with patients who had a history of preexisting stroke (which complicates recovery) (Paolucci et al., 1998); or were not independent at baseline, or suffered additional degenerative disease; or were over 87 years of age. Selection of 87-88 as the cutoff point for this study represents a compromise between external validity in LMC's stroke population, where strokes between the ages of 85 and 90 are commonly seen, and the considerable difference in 3-month mortality between patients aged 75-84 (28.8%) and those aged 85 and over (39.4%). (Nakayama, Jorgensen, Raaschou, & Olsen, 1994)

3.2.3.2 Aim 3: to determine whether apparent effects of acupuncture vary between patients at different severity levels, on ADL and other assessments of cognitive function, depression, sleep and bowel function

This aim explored the secondary question, based on the work of Naeser and Shifflet, whether benefits of acupuncture would differ across severity groups (particularly on motor-dependent outcomes such as the motor domain of the FIM). The original design of this study was to determine severity group membership on the basis of diffusion tensor imaging (DTI), as suggested by Lindenberg et al. (2010). However, anticipated addition of DTI capability to LMC's radiology suite was deferred due to cuts in state funding.

The study was not powered to reach significance on these secondary subgroup questions. However, because the 'moderate' group comprised two quartiles of the group, it contained a sufficiently large sample to make power calculations for future studies.

3.2.4 Investigation 3: Qualitative and Quantitative Exploration of Stakeholder Perceptions of Acupuncture's Impact

3.2.4.1 Aim 4: to assess the subjective perceptions of acupuncture benefit (or harm) among patients and other stakeholders in the rehabilitation process; and determine whether these perceptions differ between severity groups

For this study I chose to gather information on perspectives not only from patients and family members who can speak directly to any experiential impacts of treatment, but also from staff members who are able to report on perceived clinical impacts of acupuncture as well as contextualize their perceptions within their experience of other stroke patients. The concept of the 'stakeholder analysis' derives from early work in the field of evaluation research in the 1960s. Incorporation of multiple client and worker perspectives into the design of the evaluation itself was seen as a way to ensure that the evaluation asked and answered relevant and useful questions. This in turn was seen as the best way to ensure that the work was in fact used (Lawrence & Cook, 1982). I discuss design decisions made for the stakeholder assessment in this project, along with their rationales, in Chapter 6.

3.2.5 Feasibility Assessment

One final objective was to draw together findings of all three studies to assess feasibility for future study. Commonly used criteria for pilot and feasibility assessment (Morin, 2013; Tickle-Degnen, 2013) include:

- Effect size, for calculation of future study sample sizes
- Recruitment, including number of eligible patients and willingness of patients to enroll
- Designing an outcome measure, or assessing characteristics of an existing measure
- Data collection and follow-up rates

- Adherence and compliance

Feasibility studies typically use a small N and a large number of outcome measures to explore logistical challenges to data collection and analysis (Polit & Beck, 2004). Arain (2010) distinguishes between studies that assess feasibility of individual methods at the study site (e.g. adequacy of recruitment and retention) and pilot studies, which assume adequacy of study methods and serve primarily to provide a preliminary indication of effect size on which to base a power calculation. This study was a feasibility study. I calculated effect sizes found in this study as one part of the feasibility assessment process, as described below.

3.2.5.1 Aim 5: to determine feasibility of future study with respect to primary and secondary outcome measures

The following parameters were used to define feasibility:

- Fewer than 25% of patients withdraw from the trial
- Adverse event reports and patient and staff perceptions of harm or discomfort are found to be within acceptable limits
- Acupuncturists perceive the manual as adequately addressing treatment goals 90% of time
- For a given outcome measure, data is complete for least 75% of patients enrolled
- For a given outcome measure, rate of recruitment is sufficient in relation to sample size calculation to allow completion of a trial within 2 years

3.3 Synthesis

Altogether, this chapter has described this project's approach to the problem of conducting research on acupuncture in the complex area of stroke rehabilitation. A pragmatic approach allows construction of a treatment manual that combines best available evidence from biomedical and Chinese medical sources. Approaches to development of the manual and assessment of its clinical impact were drawn pragmatically from a variety of methodologies using qualitative and quantitative approaches.

Methods chosen to address the study's five aims, and rationales for their selection, are presented.

The chapters to follow present the methods, findings and conclusions local to each of the three investigations within the project – development of the manual, evaluation in a concurrent cohort study, and exploration of stakeholder perceptions of acupuncture's impact.

4 CHAPTER 4: THE MANUAL DEVELOPMENT PROCESS

As discussed above in Chapter 3, the first of three studies making up this project was development of a treatment manual for use in the second study. The aims of this study were to define and operationalize clinically appropriate acupuncture treatment during stroke recovery and rehabilitation in a treatment manual, and to evaluate the manual for practitioner adherence. The process was informed by existing literature on manualization in acupuncture and other disciplines, as well as the Medical Research Council's Guidance on developing and evaluating complex interventions.

Section 1 of this chapter introduces manualization as an optimal strategy for this investigation. Section 2 reviews relevant literature on manualization in acupuncture to date, contextualized by an overview of considerations that emerged from a survey of work on manualization within several other disciplines. These include: psychology, science studies, rehabilitation medicine and nursing. Section 3, Key Features of this Manual, develops those considerations into the strategies used for this study. Section 4, Methods: Definition, Operationalization and Evaluation, describes the manual construction process as it unfolded within this project, including several planned cycles of implementation, evaluation and revision. Section 5 presents the results of manualization: the manual in its initial and current form, along with findings on reported practitioner compliance and perceived usability of the manual. Section 6 discusses the work described in this chapter critically, in terms of potential contributions to acupuncture research and practice. Section 7 concludes the chapter by summarizing elements of this project most likely to be of use in future work on stroke, as well as acupuncture research generally.

4.1 Manualization and this Project

A treatment manual can have many physical forms, from a one-page checklist to a collection of looseleaf binders (folders). Functionally defined, a treatment manual serves to operationalize clinical practice. Before the

1990's, manualization was most commonly used for research, but with the rise of evidence-based medicine it has become increasingly common for standard care (Berg, 1998). Increased use of manuals for standardization can be seen as an effect of related developments such as the rise of evidence-based medicine, increased complexity of assessment and treatment options, and increasingly close scrutiny of clinical management by the public and private entities that fund it. These forces are particularly active in critical care and publicly funded settings, where the "flowsheet" – a paper or electronic document visually outlining the sequential steps of differential diagnosis and treatment for common patient presentations – is becoming a new norm (Gawande, 2010; Timmermans & Berg, 2010).

Manuals have been used in acupuncture research to balance standardization and flexibility. Standardized experimental exposure is central to clinical research as it is currently practiced. However in the practice of Chinese medicine, patients with similar presenting complaints, will vary greatly in the individual qualities of their suffering. The pain may be dull or intolerable, the patient strong or weak, hot or cold, etc. Accurate identification and response to these qualities is generally understood to be the defining characteristic of clinically appropriate treatment. As in Western medicine, a symptomatic treatment that is appropriate for one patient can be counterproductive for another, if the underlying pathology is different. For the acupuncture researcher in general, standardization for internal validity and flexibility for external validity appear to be directly opposing imperatives.

In the majority of acupuncture studies published to date, standardization has been prioritized, with patients in the acupuncture group given identical treatment. For this study, the need for flexibility is particularly clear as patients' needs both vary greatly at baseline and also shift during acute recovery and rehabilitation. As discussed in Chapter 2, during the first 7-10 days after a stroke, patients' blood pressure is often too high, or too low; they suffer constipation and urinary retention, or incontinence; somnolence or insomnia; euphoria or depression. Relative to the Western diagnosis of cerebrovascular accident, these symptoms are epiphenomena. In Chinese medicine, they are puzzle pieces whose correct identification and resolution leads to faster and more complete restoration of the whole. During the course of stroke rehabilitation in Western settings, functional restoration moves generally from proximal to distal muscle groups – but with exceptions, and with plateaus that may or may not indicate final limits of improvement. Spasticity begins to appear, in different locations and at different rates for different patients. In clinical practice within the acupuncture program at Lutheran Medical Center (LMC), needles are placed in direct response to these visible and palpable parameters of motor recovery. Studies that standardize treatment protocol in rehabilitation have shown mixed results, perhaps in part because standardized treatment necessarily represents a mix of more appropriate and less appropriate needle placements for any particular patient.

Manualization was an important methodological advance in acupuncture research, in that it raised and addressed the problem of standardized protocols potentially limiting clinical appropriateness of treatment. However, manuals produced to date have in general remained rather on the standardized end of the standardization/individualization spectrum. For this project I and my colleagues in the LMC acupuncture team chose to develop a treatment manual as part of this project because our clinical experience suggested that acupuncture during stroke rehabilitation worked best when deployed in actual response to the patient's individual presentation on a given day. We therefore aimed to operationalize not merely the points needled, but the clinical reasoning by which they were selected. The overarching goal of the manualization process was as much as possible to define and operationalize practice on the basis of clinical experience, rather than *a priori* in relation to conceptual categories.

4.2 A Summary of Considerations Drawn from Relevant Literature

In addition to acupuncture, at least four disciplines of study have developed significant discussions of manualization in theory and practice. Each of these brings a differing perspective. The acupuncture literature tends to focus on the production of the manual itself – specifically, the processes of information gathering and consensus making by which researchers address the problem of determining point selection for patients they have not examined. The psychology literature stands as the oldest and most developed literature on clinical manualization as such, and offers mature insights into the evolving relationship between the manual's form and its purpose. The rehabilitation medicine literature is particularly important to this project for two reasons. First, it already constitutes an important standard of care for stroke patients. Second, in rehabilitation as in acupuncture, each day's session requires the practitioner to address multiple simultaneous treatment goals by selecting judiciously – and in relation to the patient's presentation on that particular day – from a range of possible techniques. Among all the disciplines, the nursing literature is the most direct in its focus on the problem of classifying and quantifying the multitude of qualia that make up effective patient care. Finally, science studies offers the insight that standardization of caregiving work is only one case of a general and global analog-to-digital conversion process that has been underway for decades if not centuries. Such standardization provides unprecedented opportunities for dissemination of clinical knowledge. It also virtually ensures that patients who don't fit well into accepted conceptual models will receive inferior care.

4.2.1 Consideration 1: Flexibility is relative. To date, most acupuncture treatment manuals have been designed for efficacy trials and are therefore on the whole more standardized than flexible.

The concept of the treatment manual is a relatively recent arrival in acupuncture research. Before that time, the norm was a fixed point protocol consisting of one or several points to be needled identically on the intervention group, who were included and excluded via biomedical assessment. In marked contrast with clinical practice, the acupuncturist inserted needles without conducting any Oriental Medical assessment or diagnosis (Stux & Birch, 2001). The paper that proposed use of treatment manuals for acupuncture research (Schnyer & Allen, 2002) argued that, almost universally in complementary and alternative medicine (CAM) systems, disease entities are defined differently than in biomedicine. Therefore, in most cases where a cohort recruited on the basis of biomedical disease or symptom presentation, heterogeneity of CAM disease presentations is inevitable. Treating all these patients with the same treatment will thus be appropriate for some and not for others.

Having articulated an irreducible need for at least some flexibility on the basis of patient assessment, Schnyer et al. in that paper and subsequent research[14] developed methods for providing flexibility without sacrificing standardization. Essentially, the entire 'sterile field' of standardization was stretched to include a tightly operationalized patient assessment and diagnosis process: assessing acupuncturists would conduct the conventional four examinations of Chinese medical intake[15], then interpret the results according to a rubric that divided the intervention group into some 3-5 diagnostically defined subgroups. Members of each group would receive identical treatment, and it was possible to make hypotheses regarding anticipated between-group differences in treatment effect. As such studies were conducted, the researchers monitored the process to assess level of standardization across treatment conditions and subgroups, while assessing acupuncturists met periodically to assess and improve inter-rater reliability.

Overall, this work broke important new ground in demonstrating that standardized point prescriptions are inherently problematic and proposing a workable alternative. However, a marked asymmetry must be noted: the vast majority of methodological innovations introduced in this work serve to ensure standardization, while the flexibility gained amounts to a modest increase in the number of available standardized treatments.

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[14] To date Dr. Schnyer has consulted or collaborated on some 20 acupuncture treatment manualization projects (Schnyer, 2011)
[15] These are: inspection, listening and smelling, inquiry, and palpation

Table 4.1: Overview of Published Studies Using Manualized Acupuncture Protocols						
Year	**1st Author**	**Title**	**Study Design**	**Development Process**	**Point Repertoire**	**Point Selection***
1998	Allen	The efficacy of acupuncture in the treatment of depression in women	RCT** (sham control)	Consensus: expert panel	Fixed	Operationalized
2001	Lombardo	Acupuncture as Treatment for Anxiety and Depression in Persons with Dementia: Results of a Feasibility and Effectiveness Study	RCT (open label)	Consensus: acupuncture team	Fixed	Semi-Operationalized
2005	Wayne	Acupuncture for Upper-Extremity Rehabilitation in Chronic Stroke: A Randomized Sham-Controlled Study	RCT (sham control)	Consensus: expert panel	Fixed	
2008	Schnyer	Development of Protocols for Randomized Sham-Controlled Trials of Complex Treatment Interventions: Japanese Acupuncture for Endometriosis-Related Pelvic Pain	RCT (sham control)	Discussion by expert focus group format, on basis of existing curriculum	Semi-Fixed	Operationalized
2008	Goldman	Experiences of Acupuncturists in a Placebo-Controlled, Randomized Clinical Trial	RCT (sham control)	Consensus: expert panel	Fixed	
2009	Dennehy	The Safety, Acceptability and Effectiveness of Acupuncture as an Adjunctive Treatment for Acute Symptoms in Bipolar Disorder	RCT (open label)	Preexisting manual plus expert advice	Fixed	
2009	Citkovitz	Effects of Acupuncture During Labor and Delivery in a U.S. Hospital Setting: A Case–Control Pilot Study	Case Control	Birch Relevant & Irrelevant Treatment Selection plus on-site experience	Fixed	
2009	Lembo	A Treatment Trial of Acupuncture in IBS Patients	RCT (sham control)	Consensus: expert panel	Fixed	
2010* **	Crew	Randomized, Blinded, Sham-Controlled Trial of Acupuncture for the Management of Aromatase Inhibitor–Associated Joint Symptoms in Women With Early-Stage Breast Cancer	RCT (sham control)	Not reported	Fixed	Semi-Operationalized
2010* **	Manber	Acupuncture for Depression During Pregnancy	RCT (sham control)	Consensus: expert panel	Fixed	Operationalized
2013	MacPherson	Acupuncture and Counselling for Depression in Primary Care: A Randomized Controlled Trial	RCT (pragmatic)	Nominal group: expert panel	No constraints	

* Blank boxes indicate point selection at practitioner discretion; Fully Operationalized = no practitioner discretion; Partially operationalized = some practitioner discretion; blank = full practitioner discretion
**Randomized Controlled Trial
***Where multiple trials have used the same treatment manual, only the most recent is cited

Table 4.1: Overview of Published Studies Using Manualized Acupuncture Protocols

Table 4.1 summarizes past studies using a manual for acupuncture treatment. They have been scored for two main dimensions of flexibility: point repertory (i.e, was the total pool of available points pre-selected by researchers, chosen freely, or semi-structured with some practitioner discretion); and point selection (ie, was per-patient selection of points from the repertory fully operationalized by researchers, was it left entirely to practitioner discretion, or was it semi-operationalized with some guidance to the practitioner informing point selection?).
Under point repertory, nine studies used a fixed point repertory and one used a combination of fixed and practitioner-selected points. For these

studies, choice of points was made almost entirely by researchers. Among these restricted-repertory studies, five left selection entirely to the discretion of the practitioner. Restriction of point repertoire without specific operationalization of the selection process for consistency between practitioners appears more controlled than older trials in which the acupuncture treatment stood as an experimental ‘black box’, but in effect it only reduces the size of the box. This represents a gesture towards standardization, but does not remove differences in practitioner judgment as a confounder.

A meaningful exploration of the historical, cultural and funding-related reasons for the tendency towards prioritization of standardization over flexibility is outside the scope of this thesis. However a reasonable summary might be that there is a prevailing assumption within the research community that, if acupuncture does have a verifiable treatment effect, it is by mechanisms other than (or at least in addition to) those traditionally identified within the medicine (Napadow et al., 2008). From that point of view, it is entirely reasonable to conduct a clinical trial that standardizes the ‘active ingredient’ of point selection and extracts it from the cultural constructs of qi, yin and yang in which it is traditionally discussed, much as berberine or artemisinin have been extracted from Chinese herbs (Hsu, 2006; Lei, 2014). Standardization of the intervention under study is a main determinant of the study’s internal validity: the more heterogeneity of experimental exposure within the active treatment group, the less certainty that any effects observed are solely attributable to such exposure.

In this context, ‘flexibility’ can be defined as the ability of the study design to accommodate the constructs used in Chinese medical assessment, diagnosis and clinical reasoning, on the (also quite reasonable) grounds that they may have clinical importance. Schnyer et al. (2007a) specify ‘ecological validity’ as the fidelity of the experimental exposure to clinical practice, arguing that it is a key component of external validity[16]. A majority of the manuals summarized in the tables above were developed with the participation of Dr. Schnyer, who has argued strenuously for specific operationalization of point selection as a key component of manualization (Schnyer, 2011).

Schroer, MacPherson et al. (2007), (2012) took a different approach in producing a manual for comparative effectiveness research, where external validity is a priority. In preparation for a pragmatic trial, the investigators led highly experienced practitioners in a nominal group process, a technique that brings groups to consensus on approaches to complex problem-solving. Rather than standardize physical components of the intervention (i.e. points needled), the group identified key functional elements of patient active management which require individual variability in implementation to provide ecologically valid, clinically appropriate treatment (MacPherson et al., 2013b). These are condensed and summarized below:

- History taking (including orthodox medical diagnosis) as well as assessment via palpating, observing, smelling and hearing
- Identification of pattern of disharmony within a traditional acupuncture framework
- Implementation of treatment strategy and acupuncture point selection drawing on an appropriate traditional theoretical framework, with per-treatment flexibility based on patient presentation

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[16] This term overlaps with Jonas and Lewith's (2011) usage of 'model validity' (see above, section 3.1.5), largely including it. However as discussed above, fidelity to a single conceptual model may still lack representativeness of a pluralistic clinical practice.

- Practitioner determination of needle length and gauge, depth and duration of insertion, needling technique and de qi or other stimulation based on relevant theoretical considerations
- Practitioner determination of relevant auxiliary interventions and life-style support
- Explanation and discussion with patient of information relevant to diagnosis, treatment, prognosis and expectations for treatment planning, in the context of other treatments given and logistical considerations such as funding
- Eliciting and interpretation of patients' reactions to the acupuncture treatment
- Judgment regarding referrals to medical or other health professionals as needed

Overall, in identifying these points of flexibility found in the clinic the researchers do not assert that all acupuncture research must allow practitioner flexibility on all points. However, they do argue that failure of a study design to account for the per-patient and per-treatment variability of active management processes that inform them in clinical practice can lead to false negative results, either through sub-optimal verum acupuncture treatment that fails to include these acupuncture-specific practitioner behaviors, or through a super-optimal control treatment that incorporates them.

4.2.2 Consideration 2: Classification can be a useful first step towards standardization.

The tension between standardization and flexibility in manualization is by no means unique to the acupuncture research literature. In psychology, the conflict was hotly debated for decades (Najavits et al., 2004). Disciplines that came later to manualization – notably nursing and rehabilitation medicine – tended to accept the opposition of conflicting values and offer perspectives about how to accommodate it in manuals that guide research and practice.

In psychology, the debate raged throughout the 1980s and 1990s: on the one hand, standardization was necessary for internal validity in research and research was necessary for survival of the discipline (Beutler, 1999; Luborsky & DeRubeis, 1984). On the other hand, the flexibility needed to maintain an authentic, living relationship between human beings was central to clinical practice, and research that threatened to micromanage away the essence of what it studied was decried as irrelevant and misguided (Klein, 1997). Through the 1990s, as manualization failed to disappear under the criticism of its opponents, several authors produced considered pieces on how to balance conflicting imperatives to standardization and flexibility. The field appears to have healed its conceptual rift through cathexis and catharsis: the irreconcilable opposition of individualization versus standardization became absorbed in and identified with the more tractable question of specific versus nonspecific treatment effect (McMurran & Duggan, 2005; Westen, 2002). By the late 1990s, there appears to be general agreement to compromise on the principle earlier articulated by Luborsky and DeRubeis (1984) that, underlying any specific style is a set of “common factors” (such as warmth and attentive listening behavior). These are not meaningfully differentiable between different styles of psychotherapy. A psychology treatment manual, therefore, served primarily to specify those elements of a given style deemed unique and functionally important to the therapy under discussion, such as Freudian analysis or cognitive behavioral therapy. The difficulty of standardizing ephemera such as “warmth” and “empathy” became less of an obstacle to manualization because they were no longer its primary targets (Westen, 2002).

A different approach was taken in nursing studies, where there was no easy recourse to a concept of the intervention as active ingredient. Nursing interventions are not merely complex; they exist on a spectrum from relatively standardizable tasks with clear technical requirements (e.g. insertion of intravenous drips) to subtle fleeting moments in which the patient’s healing process may be supported – or not – by verbal or physical interaction with the nurse. Many of these, relating to the patient's emotional state or general comfort level, are passed verbally from shift to shift without being charted. Even those that are charted, relating to nutrition, bowel movements, sore prevention, etc, are conventionally archived separately from the medical record, so as not to clutter it (Bowker & Star, 1999). In the 1980's, a project called the Nursing Intervention Classification or NIC (McCloskey, 1993) was initiated with the understanding that, in an increasingly digital world, tacit or ephemeral activities and skills would be crowded out by ones that were specified in writing.

The developers of the NIC outlined 336 nursing interventions, each comprising a one-page worksheet with a brief definition of the intervention, a list of activities (each activity its own verb phrase); and a short list of background readings. These were sent to nurses working in field sites for feedback, with several cycles of feedback and subsequent revision. Within this consistent format, the worksheets are striking in the variety of their content. The worksheet for "Airway Management" (defined as, "Facilitation of patency of air passages") includes such straightforward and medically oriented items as "Open the airway, using the chin lift or jaw thrust technique, as appropriate", "Position to alleviate dyspnea". By contrast, the "Spiritual Support" worksheet begins with the definition, "Assisting the patient to feel balance and connection with a greater power". While less specific and measureable than "Facilitation of patency of air passages" the worksheet nevertheless brings considerable focus to a domain of nursing activity that would otherwise be highly eclectic in its understanding and expression. Activities listed use verb phrases quite different from those found in the Airway management worksheet ("Be open to", "Listen carefully to," "Express empathy with…", versus "Insert," "Perform," Administer", "Regulate"). However, there is a similar level of clarity and specificity ("Assure patient that nurse will be available to support patient in times of suffering"). Within that specificity, there is also a similar broadness of scope for exercise of individual discretion on the basis of experience. The short sentence "Position to alleviate dyspnea" can be unpacked to show the assumptions that (A) not all patients will find relief in the same position and (B) a beneficial position can be discovered through trial and error based on the nurse's training and experience as well as communication with the patient as to whether dyspnea has indeed been alleviated. Such miniscule exercises of communication and judgment typify nursing work. It is those moments that the NIC attempts to capture as such – rather than, for example, "position the patient on his right side with the head of the bed at a 45 degree angle". Such use of judgment is made explicit in the Spiritual Support worksheet, as in the activity: "Listen carefully to patient's communication, and develop a sense of timing for prayer or spiritual rituals".

The goal of the NIC was to classify such acts of clinical judgment, but not to standardize them. The question is theoretically answerable whether there is a "best" time for prayer or ritual, in that more patients might prefer the morning, or the evening. Practice could theoretically be standardized on the basis of such understanding, in which case the clinical judgment previously exercised by the nurse on the basis of transient and emotionally based cues from the patient, would be made *a priori* by management. In the NIC – as in the identification of acupuncture-specific active management behaviors described in Section 4.2.1 – classification merely acknowledges that such a decision is being made by the care provider. The NIC was undertaken in hopes that documenting the large number of decisions made by the nurses on the basis of training and experience, and the importance of those decisions to patients' experience and outcomes, would allow nursing work to be more accurately modeled in decisions related to training, hiring and budgeting (McCloskey, 1993). However, the NIC's authors expressed a concern similar to that voiced by psychologists opposing manualization: that the act of capturing and assigning functional value to previously ineffable human interactions would create the opportunity for excessive standardization or rigidity (Bowker & Star, 1999).

4.2.3 *Consideration 3: Manualization of complex interventions is never complete; the task is to select which elements will be described in detail.*

In the discipline of rehabilitation medicine, Whyte and Hart (2003) describe the complexity of rehabilitative intervention: multiple treatments applied simultaneously or sequentially, in combinations determined by the patient's presentation on a particular day. They argue that specification and standardization of all of the elements of a rehabilitative intervention – or combination of interventions – would be not merely undesirable but impossible, because of the sheer number of particularities determined by factors as general as the setting and as specific as the patient's learning speed on a given day. Their suggested model is a Russian doll – meaning, a set of nested black boxes. These boxes need not and cannot all be opened for a single experiment, but can be opened selectively in relation to study objectives.

Hart (2009) further suggests that in complex interventions, the concept of 'active ingredient' may need to be broadened to include the act of informed decision-making that takes place when an experienced rehabilitation therapist selects and sequences tasks [17]. For example in stroke rehabilitation, during the first few sessions where walking is attempted, patients are typically weak with uncertain balance, and lean heavily onto the affected side, requiring two therapists for support. However some patients with lesions in the non-dominant hemisphere lose proprioceptive awareness of the affected side. These patients may continue to lean onto

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[17] This pharmaceutically oriented metaphor, which Hart reformulates but does not reject, is of debatable applicability to acupuncture. Schnyer et al. (Schnyer, Birch, & MacPherson, 2007b) suggest that acupuncture interventions lie on a spectrum from simple to complex, with active principles correspondingly easier or more difficult to isolate from the whole of the encounter. Paterson and Dieppe argue that elements of acupuncture treatment 'incidental' to the needling are nevertheless specific and integral to acupuncture treatment. The utility of Hart's overall argument and 'Russian doll' metaphor is that it allows for selective identification and operationalization of key components of a complex intervention, rather than micromanagement of the whole.

that side long after strength is recovered. Reminders to "stand up straight" are of little use because it is exactly the proprioceptive capacity that is damaged. In such a situation, the message may better be conveyed by recruiting a third therapist to walk backwards in advance of the team, with a rolling mirror so that the patient can see that she is leaning. Using the mirror is unwieldy and consumptive of time and effort, and would detract from therapy if it were not specifically serving to facilitate a necessary perceptual shift. Its effective deployment depends on the therapist's accurate assessment that the patient is leaning not due to weakness but due to poor proprioception. Making this assessment generally requires sufficient experience either to recognize the physical characteristics of proprioceptive-deficit-based leaning versus weakness-based leaning, or to make the differentiation based on experience of how long weakness could be expected to persist given the patient's age and history of illness.

A manual used in a study of physical therapy techniques for ambulation in non-dominant-hemisphere strokes might well operationalize in detail the making of this decision by surveying experienced practitioners for the criteria they use in making the decision to try a mirror in the session. Conversely, a less detailed manual for a study with a broader focus – e.g. optimal length of stay in acute rehabilitation after stroke – might either omit the technique, or, in the manner of the NIC described above, list it as one of a menu of options to be selected at the discretion of the therapist, without specifically manualizing the decision.

The metaphor of a sterile field, while not used by Whyte and Hart, is also appropriate here: it would be convenient if the entire hospital could be maintained sterile to prevent nosocomial infection, but as human beings and their secretions naturally teem with microbes, it's simply not possible. Sterile fields are created and maintained where absolutely necessary during surgery; elsewhere, degrees of cleanliness must suffice. Epistemologically, while it would be convenient to work in an experimental field free of confounders, any study of a therapy with a significant experiential component must contend with the high bacterial load of ephemera and ineffables that social creatures carry. The purpose of manualizing complex interventions is not to introduce flexibility. On the contrary, manualization serves to create a clean field of relative quantifiability within the dense primordial ooze of qualia that constitute a complex intervention.

The utility of the ‘Russian Doll’ approach is also clearly illustrated in research on acupuncture for depression by MacPherson et al. (MacPherson et al., 2013b). As described above (Section 4.2.1), the investigators chose to operationalize acupuncture treatment with broad flexibility for practitioner discretion in treatment selection, reflecting the pragmatic study design as well as the wide variety of TCM syndromes found in patients presenting with a Western diagnosis of depression (Macpherson, Elliot, Hopton, Lansdown, & Richmond, 2013a). However, specific protocols for management of patients reporting suicidal thoughts (critically important, and perhaps less familiar to practicing acupuncturists) were tightly operationalized (MacPherson et al., 2013b). This operationalization of an important clinical behavior is distinct from clinical guidance.

4.2.4 Consideration 4: Difficulty of standardization is unequally distributed among patients.

The seminal paper in manualization in psychology (Luborsky & DeRubeis, 1984) cites research indicating significantly better outcomes in patients for whom the manual’s script was followed closely, versus those for whom the therapist departed from the manual. Luborsky offers three possible interpretations for the difference: A, the therapy itself works better when it is conducted exactly as planned by the researchers constructing the manual. B, better therapists are better able to keep the session on track. C, it is easier for any therapist to stay on track with patients who are less ill or less problematic. Clearly, these explanations are not mutually exclusive, but represent three different loci of analysis. (A) looks at factors intrinsic to the manual, regarding therapist and patient differences as noncontributory.

(B) looks at differences between therapists, and (C) looks at differences between patients. Luborsky maintains scientific agnosia on the question, but as a practical matter it seems clear that all three factors may well apply in any given case, and also, that A and B are more likely to come into play if C is the case.

An influential text in Science Studies (Bowker & Star, 1999) looks at medical manualization as one aspect of a general social movement towards standardization and classification that originated with the Industrial Revolution and has accelerated greatly in the digital age. One full section of the book examines the situation of individuals who do not fit clearly into the classification system in use. Chapters on arenas as diverse as apartheid and tuberculosis diagnosis demonstrate with excruciating clarity that where clear divisions are imposed on unclear human experience – as useful as such divisions can be – they inevitably result in problems of inconsistency, arbitrariness and mistreatment for those at the edges of the dividing line.

Certainly in medicine, the effective treatment of illness depends on its accurate diagnosis. Sufferers of disorders that are not easily diagnosed by physical markers – Epstein-Barr syndrome, Lyme disease sequelae, Fibromyalgia, etc – may report medical odysseys previous to receiving a diagnosis of exclusion and appropriate treatment. And, in the absence of a clearly understood physical mechanism, treatment may be lengthy and inadequate to relieve suffering that is quite real, even if not easily categorized. Patients may be difficult to diagnose because of unusual or difficult-to-interpret clinical presentations. They may suffer comorbidities or complications that muddy both diagnosis and treatment. And commonly, there is a component to the patient's suffering that is emotional or psychological and would persist even with optimal physical treatment. Given exposure to a manualized treatment, it can reasonably be anticipated that all three of the 'poor fit' patient types described in this paragraph will not only show less encouraging treatment outcomes but also challenge the classifications and standards attempted within the manual.

4.2.5 Consideration 5: "One size cannot not fit all"; manuals evolve in stages, and provide differing levels of flexibility depending on their intended use.

In the mature phase of the psychology literature, a paper by Caroll and Nuro titled, "One size cannot fit all: a stage model for psychotherapy model development" suggests that "the appropriate roles and content of manuals should evolve with the stage of development of a given treatment". They propose a sequential stage model in which manuals evolve with the level of development of the treatment:

> … from the basic outlines necessary for preliminary evaluation of the treatment in early pilot studies (Stage I) to highly defined guidelines that demark the internal and external boundaries of treatment for efficacy studies (Stage II), and finally to elaborated systems appropriate for use with diverse clinical populations (Stage III) (Carroll & Nuro, 2002)

The authors base their proposal on work done in behavioral therapy, outlining three stages for systematic development of new treatments They provide a substantive and detailed set of outlines, clarifying the purpose, focus, and intended role of the manual at each stage of development.

Responding to Carroll and Nuro's work, Westen (2002) characterizes their guidelines as important for:

> …avoiding (a) overspecifying technique at early stages of manual development, when flexibility is essential to allow further refinement and innovation, and (b) underspecifying planned variability at later stages, when flexibility may be equally essential to applying the treatment to complex and poly-symptomatic cases. (Westen, 2002)

He further suggests that manuals may be expected to vary with the type of patient being treated – with tighter standardization for highly specific symptoms, and greater flexibility for cases involving more general dysfunction.

Tessa Hart, the author of the ‘Russian Doll’ paper, describes the tension between flexibility and standardization in relation to several parameters of research design (see Table 4.2). In addition to Westen’s ‘broad/narrow’ axis described above, she suggests that additional flexibility may be required to accommodate a heterogeneous sample population, as well as longer duration or unpredictability of treatment course. Hart further suggests that, while the intended goal of validation is also a factor – a tightly scripted manual with a high level of fidelity to establish internal validity, a loosely organized toolkit based on treatment principles for external validity – neither purpose can be fully accomplished without detailed algorithms for flexibility in unanticipated situations that may arise in actual implementation. Failure to provide such algorithms, she warns, may constitute “an important source of unplanned treater effects” (Hart, 2012).

In this model, flexibility does not constitute a value in and of itself: more flexibility is not better than less flexibility, except as it is used by researchers to more accurately reproduce clinical decision making in the experimental context. Also useful is the construct proposed by Carroll and Nuro, and further elaborated by other authors: preliminary, exploratory manuals incorporate a large amount of flexibility and evolve through use into less flexible, more tightly defined experimental manuals. After experimental validation in controlled circumstances, the manual then becomes a training document, with a return of flexibility to accommodate heterogeneity of patient presentation and practitioner experience. Also noteworthy is the warning that, even in tightly controlled manuals, provision must be made for unanticipated departure for manual protocol based on patient presentation – because otherwise such departures will be handled differently (and unpredictably) by each practitioner.

Figure 4.2: Low vs. High Manual Flexibility in Relation to Study Design

Study Parameter	LOW FLEXIBILITY	HIGH FLEXIBILITY
Target problem	Narrow; e.g., "working memory"	Broad; e.g., "memory compensations"
Sample population	Relatively homogenous	Relatively heterogeneous
Duration of treatment	Brief, e.g., one or several sessions	Longer, perhaps with an evolving or unpredictable course
Look and feel of manual	Scripts and detailed instructions	Tool kit of techniques linked by underlying theoretical orientation
Validation purpose	Internal validity	External validity

Adapted from: Hart, T. *Treatment definition in experience-based rehabilitation research*. Retrieved 26 October, 2012 http://www.ncrrn.org (Neuro-Cognitive Rehabilitation Research Network)

Table 4.2: Low vs. High Manual Flexibility in Relation to Study Design

Considering the variation in flexibility of treatment manuals depending on their intended use, the term 'manual' should be disambiguated from documents providing structured clinical guidance. Hawe et al. (2004) recommend that manuals for complex interventions research avoid standardizing specific components of the intervention. Instead, "what should be defined as standard are the steps in the change process that the elements are purporting to facilitate or the key functions that they are meant to have" (Hawe et al., 2004, p. 1562). For comparative effectiveness research, ecological validity of the acupuncture intervention may be best achieved by a manual that avoids any specification whatsoever of technical elements of the acupuncture treatment, such as point selection or duration and intensity of needle stimulation. This strategy differs from Schnyer's approach to operationalization, and is exemplified by MacPherson et al. (2013b). Conversely, specific technical guidance may be appropriate for mechanisms and efficacy research, or in situations such as this study where important elements of the intervention under study cannot be expected to have been included in acupuncturists' previous training.

4.2.6 Consideration 6: Clinicians should be involved in early manual development

A 2002 paper entitled, "Manualizing Manual Development," (Westen) begins by describing a central and critical 'gulf' between clinicians and researchers in clinical psychology. His paper uses language similar to that of Dr. Schnyer's paper from the same year, describing manualization as an important method for "bridging the gap" between research and clinical practice. He argues that a central cause of this gap is the implicit assumption, inherited from biomedicine, that the process of treatment development is unidirectional, with knowledge flowing from the researchers to the clinicians, "with some room for feedback toward the end." Westen suggests that this model is appropriate in situations where new understandings in basic science lead to new treatment approaches, but that in most other cases he advocates for a "transactional view, in which the laboratory and the clinic are both seen as resources for hypothesis generation and testing, albeit with different strengths and limitations." He proposes that the initial stages of manual development should involve participation of a focus group of practicing clinicians, sustained over a period or weeks or even months. The group should be encouraged not only to evaluate the research protocol as it develops, but also to explore the core hypotheses and techniques in their own practices and report back. Westen does not explicitly reference either action research or complex interventions research in his discussion. However he describes the cycles of planning, implementation, evaluation and revision characteristic of these two approaches.

In development of protocols used for acupuncture research, unidirectional information flow generally prevails, though not always from researcher to clinician. The system of scalp acupuncture most commonly used for stroke rehabilitation in China involves placement of needles in the superficial tissues directly over the brain region affected, with points selected on the basis of basic science and mechanisms research rather than traditional practice. Conversely, the bulk of research conducted on body acupuncture in China assesses efficacy or effectiveness of clinical protocols already in use. In some cases, these protocols have been developed by well-known practitioners, to whom the researcher is in a subordinate position.

In the United States, Dr. Schnyer (an acupuncturist herself) has participated in the manualization process for some 20 studies in the last two decades. The practice generally involved consensus building. Preliminary point suggestions were solicited from clinicians, developed into a protocol by a clinician-researcher team, then sent back to the clinicians for comment and revision as needed. A feedback loop thus existed between researchers and clinicians, but a limited one in that it included no prospective clinical exploration but only consensus finding on the basis of previous experience.[18]

4.3 Key Features of this Manualization Process

In assimilating the considerations above, it is evident that manualization's greatest challenge is its self-assigned task of "bridging the gap" between research and clinical practice. The struggle to reconcile tidy theoretical models with the ineffable messiness of reality is a central chore of human cognitive development. That struggle becomes acute where there is a procedural need for complex interventions to be used together with pharmaceutical therapy, as is the case with integrative medicine or inpatient care. Contemporary evidence-based medicine is built around the statistical power of the binary, testable hypothesis – which is relatively easy to achieve with pharmaceutical therapy, where the drug is taken or not taken regardless of how skillfully it was given. Complex interventions such as nursing, physical therapy and acupuncture work directly to modulate the patient's physical, mental and emotional experience, so that a single session necessarily comprises multiple acts of assessment, diagnosis, intervention and reassessment. Each of the considerations presented above represents a distinct strategy for 'stepping down' the multiplicity and

[18] Schnyer, personal communication 5/25/12

ineffability of those acts, to render them statistically comprehensible while maintaining as great as possible a fidelity to their original experiential content.

The main question for this phase of the project, then, was: is it possible to develop a treatment manual directly through clinical practice, rather than by consensus *a priori*?

The approach taken in answering this question was for the acupuncture team to begin with the full spectrum of assessment and treatment options available from our own experience, expert advice, and textbook and research literature. From there the team aimed to (A) impose order on a multitude of potentially selectable options through clinically derived categorization, and (B) systematically evaluate our own selection process during the assessment and treatment process, in order to operationalize and streamline those choices to the greatest degree possible without sacrificing clinical validity. Towards this end, the following key features were developed from the considerations above. Table 4.3 summarizes these considerations and key features in relation to the three phases of manual development.

Table 4.3: Conceptual Overview of the Manualization Process

Phase of manualization process	Consideration identified in literature review	Planned feature of this manualization process	Emergent feature of this manualization process
All Phases	Consideration 1. Flexibility has previously been prioritized below standardization	Feature 1. Manualization prioritizes clinical appropriateness as perceived by acupuncturists during practice	
	Consideration 6. Clinicians should be involved in early manual development	Feature 6. Manualization conducted by acupuncturists	
		Feature 3. Manualization included literature review and practice in iterative cycles of development, implementation, evaluation, revision	Phase 2: Selection of three outcome measures for cohort study
Phase 1	Consideration 2. Classification can be a useful first step towards manualization	Feature 2. Work began with observation and classification of clinical process, along with literature review	
	Consideration 3. Manualization is never complete; target behaviors must be selected	Feature 4, Acupuncturists chose to target patient assessment, treatment planning and point selection	
Phase 2	Consideration 5. Manuals evolve in stages, providing different levels of flexibility for different uses	Feature 5. This manual evolves from 'exploratory' towards 'experimental'	
Phase 3	Consideration 4. Difficulty of standardization is unequally distributed among patients		Post hoc: Study patients for whom core manual treatments were not appropriate or did not result in percieved improvement constitute future case series

Table 4.3: Conceptual Overview of the Manualization Process

4.3.1 Feature 1: The manual operationalizes practice directly on the basis of experience, and only to the degree that it remains congruent with perceived clinical appropriateness

This feature was developed directly from Consideration 1, which finds that acupuncture manuals to date have in general prioritized standardization over flexibility. Consideration 1 and Consideration 6 (‘Clinicians should be involved in early manual development’) were guiding principles, to which all other considerations were subordinate.

4.3.2 Feature 2: The manualization process began with classification

This feature was developed from Consideration 2 above (‘Classification can be a useful first step towards standardization’). As was done for the Nursing Interventions Classification described in Section 4.2.1 above, the team created (and further developed) a single tabular format into which treatment approaches (consisting of treatment goals for a given patient presentation, along with their associated treatment methods) from disparate sources could be juxtaposed. Later in the process, these suggestions were sorted by evidence grade (Harbour & Miller, 2001).

4.3.3 Feature 3: Iterative cycles of development, piloting, evaluation and revision allowed a team of experienced acupuncturists to evaluate historical and contemporary clinical and research literature, as it informed their clinical encounters with a given patient population.

This objective responded to Consideration 6 above ('Clinicians should be involved in early manual development') as well as the Medical Research Council's Guidance for research in complex interventions (Craig et al., 2013) discussed in Chapter 2.

4.3.4 Feature 4: During these cycles the acupuncture team identified, operationalized and prioritized those aspects of patient assessment, treatment goal setting, and point selection that were perceived as indispensable to treatment of patients recovering from acute stroke

This objective responded to Consideration 3 above ('Manualization of complex interventions is never complete'). A multitude of behaviors, undertaken by an acupuncturist treating a patient during acute stroke rehabilitation, are potentially identifiable as relevant to treatment outcomes; however, they cannot all be studied simultaneously. As discussed above, Macpherson and Schroer (2007) describe 16 behaviors identified by experienced practitioners as both necessary to acupuncture treatment of patients with depression and also requiring flexible implementation for treatment to be clinically appropriate. As discussed under Consideration 3, it is neither possible nor desirable to closely operationalize all areas of practitioner behavior within a complex intervention. For this study, the acupuncture team decided on two main behaviors as requiring detailed operationalization within a manual for clinically appropriate stroke care. These were the activities of treatment planning and point selection, which are operationalized in detail in the core worksheets of the treatment manual. A number of other areas also required flexible decision-making on the part of practitioner, but were not seen as specific to inpatient stroke care. These areas, such as selection of needle gauge and length in relation to patient body type, were operationalized only to the degree necessary to provide reasonable consistency as well as safety.

4.3.5 Feature 5: The format is an exploratory manual that grows through use towards an experimental manual

This aim was developed from Consideration 5, using Carroll and Nuro's (Carroll & Nuro, 2002) three-stage framework for manualization as an ongoing, multi-project process. Within their framework, 'exploratory' manuals provide structure within which clinicians can explore, develop and define the treatment under consideration, while 'experimental' manuals are mature denotations of a treatment style providing sufficient repeatability to be appropriate for controlled clinical trials. The two-part manual structure described above in Section 4.3.2 allows for development a stable worksheet. Repeatability and perceived clinical appropriateness of this worksheet can be both evaluated and further developed, within a pragmatic trial design that still allows departure to the evidence basis for unusual or refractory cases.

4.3.6 Feature 6: The manual points up unusual or refractory cases, both providing for clinically appropriate treatment outside of ordinary protocols and also pointing towards further research

This objective follows directly from the feature above and was developed from Consideration 4 ('Difficulty of standardization is unequally distributed among patients'). As discussed in Section 4.2.1, it is assumed that refractory cases, and also those falling outside the usual parameters, are poorly served by standard approaches that work well for less unusual cases. A key feature of this manualization process is its two-part structure with a brief worksheet for straightforward cases and a longer index of best available evidence to be consulted for cases not adequately managed with the worksheet. Cases managed using the summary of evidence then remain as case histories to enlarge the available evidence base. This development of this feature is discussed in Section 4.4.

4.4 Methods: Definition, Operationalization and Evaluation of Appropriate Acupuncture Treatment during Stroke Rehabilitation

In this section I describe the three phases of this manual's construction, undertaken by four members of LMC's Acupuncture Team and myself. These overlap considerably with the MRC Guidance's four phases (Development, Feasibility/Piloting, Evaluation, Implementation) and are similarly interpenetrated. The phases below and their associated processes and products are keyed to Figure 4.1, a summary document map of the manualization process, and Figure 4.2, a detailed depiction of the iterative cycles of planning, implementation and evaluation that drove the development process. The development of the manual document itself is described in terms of three main versions (1.0, 2.0, etc.). Intermediate revisions (2.1, 3.2, etc) were generated but are not discussed in this thesis. Final Versions 1, 2 and 3 of the manual are attached as Appendices A, B and C respectively.

Figure 4.1: Document Map of Manualization Process

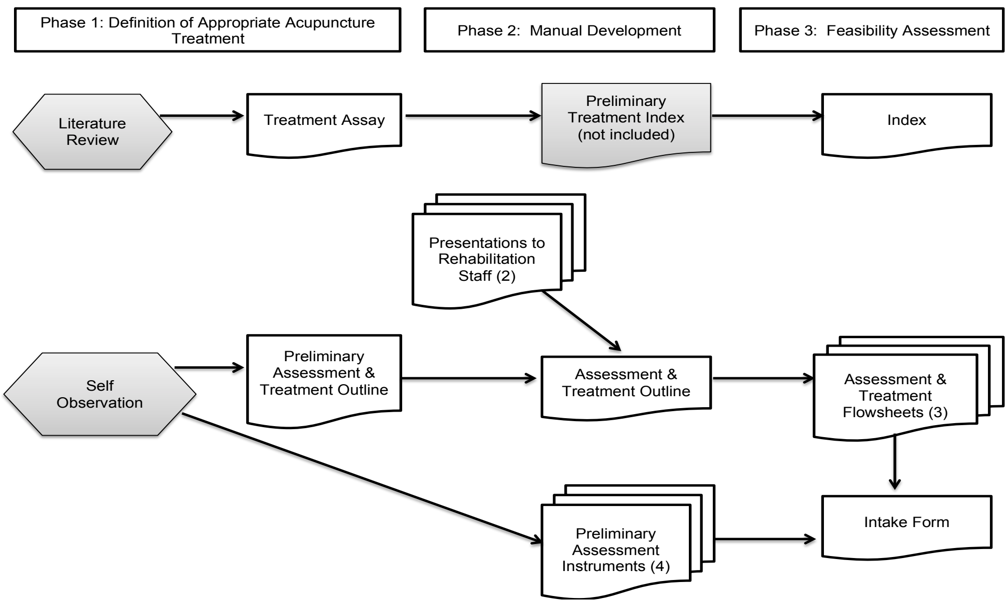

Figure 4.1: Document Map of the Manualization Process

Figure 4.2: Iterative Development of a Manual for Acupuncture Treatment During Acute Stroke Recovery and Rehabilitation

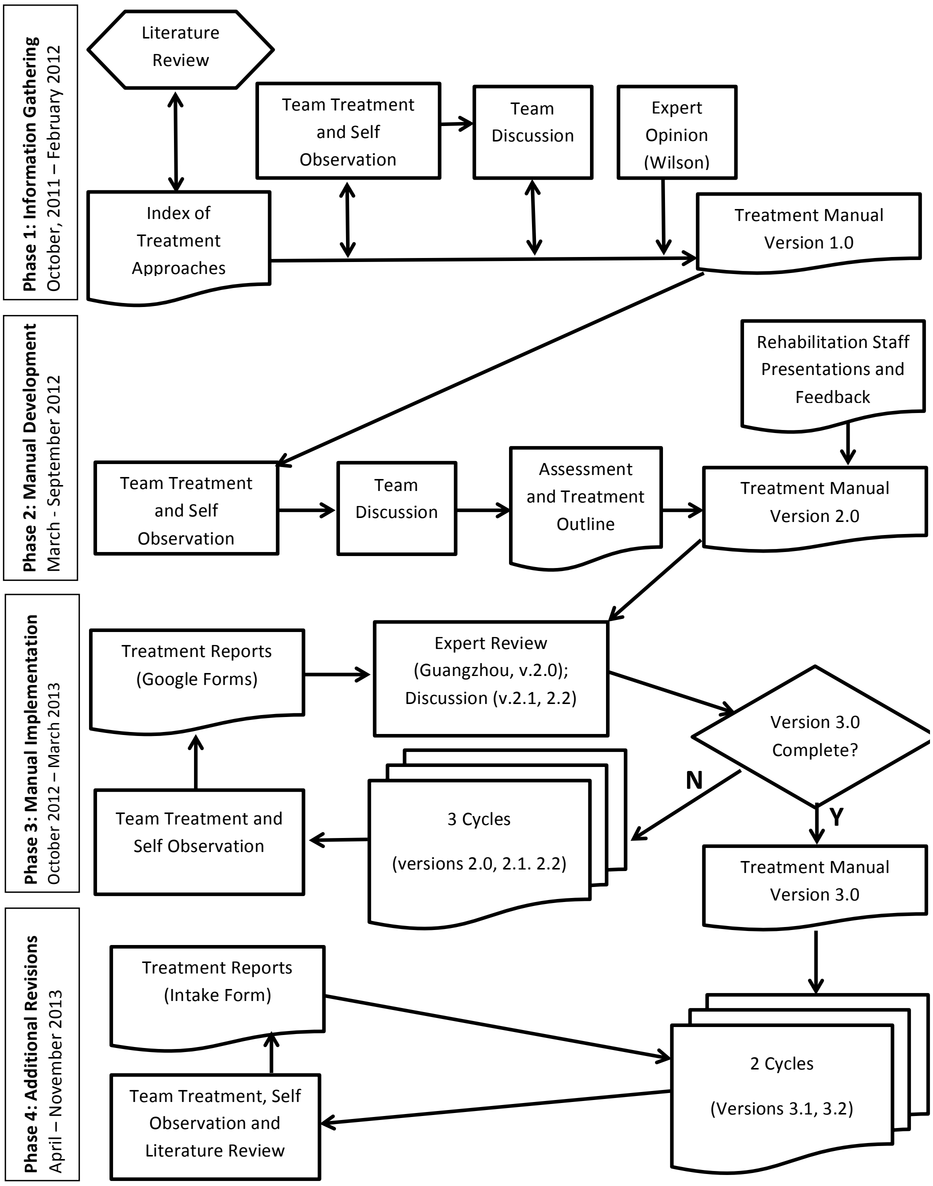

Figure 4.2: Iterative Development of a Manual for Acupuncture Treatment During Acute Stroke Recovery and Rehabilitation

4.4.1 Phase 1: Defining Appropriate Acupuncture Treatment during Stroke Rehabilitation, October 2011 to February 2012

For this study, defining appropriate acupuncture treatment consisted of two quite distinct tasks: preliminary classification of current practice at the research site, and literature review to identify best available evidence. These processes and their intermediate products are described below. The final product of Phase 1 is Version 1 of the manual, which is attached as Appendix A.

4.4.1.1 Literature Review

Several bodies of literature were surveyed for this project. First the clinical literature on Chinese medicine and stroke was surveyed, as available in the English language together with a small number of Chinese texts, as described in Chapter 2. The contemporary clinical and basic research literature on acupuncture and stroke was then reviewed. Included in the review was a current systematic review of literature published in the West, along with 298 Chinese-language studies drawn from a published systematic review (Kong et al., 2010).

4.4.1.2 Treatment Assay

The end product of this review was a “Treatment Assay”, holding stroke-related symptoms and syndromes, along with contemporary and historical methods of addressing them together in one (very large) tabular document. The Assay is seen in Appendix A, Manual Version 1.

4.4.1.3 Team Treatment and Self-Observation

During this time, acupuncture team members assessed and treated patients as we had in the past, without explicit procedural guidelines. In weekly meetings our decision-making process was discussed with the goal of identifying and articulating our underlying algorithms for clinical information-gathering and decision-making. As the Index was constructed it was shared with the team for use and discussion. During this time the team also began drafting instruments for standardized tongue, pulse and abdominal diagnosis. These are discussed below in Section 4.4.2.

4.4.1.4 Team Discussion and Preliminary Outline

After completion of the Index, the team discussed our conclusions regarding approach to assessment and treatment, and summarized them in a one-page text outline. This outline was intended merely to define the elements of what we considered appropriate acupuncture treatment, serving as a structural basis to be used in Phase 2, Manual Development.

4.4.1.5 Expert Advice

Once completed, the Outline was shown to Jane Wilson, a physiotherapist and University of Westminster acupuncture instructor. Highly experienced in stroke care in the context of both disciplines, she provided expert advice during a supervisory visit to London. Ms. Wilson's verbal comments expressed support for the overall structure and advised close attention to operationalization of treatment planning as a key difficulty in acupuncture knowledge transmission generally. These comments were discussed with the group and integrated into the outline.

4.4.1.6 Manual Version 1

The revised Outline and Assay were taken together to constitute Version 1.0 of the manual, which is attached as Appendix A.

4.4.2 Phase 2: Manual Development, February to October 2012

4.4.2.1 Presentation to Rehabilitation Services

In order to refine acupuncture treatment planning and better integrate it with the work of the primary therapists caring for patients, three meetings were held with members of the rehabilitation unit staff. The mode of each meeting was selected by the manager of the service based on her perception of her team's time constraints and preferred mode of information sharing. The Nursing Manager selected a focus group format; notes from the two meetings, taken by the Nursing Manager, are attached as Appendix D. The PT and OT Managers selected a joint in-service presentation with question and answer to follow; this is attached as Appendix E. The SST manager selected one-on-one discussions, as did the unit's three attending physicians (MDs, who direct the patients' care plans, including requesting acupuncture services). These discussions characteristically lasted 4-7 minutes. During the meetings and discussions, plans for the study were shared, along with a summary of the Assay, showing stroke sequelae potentially addressed with acupuncture. Staff members were asked which syndromes they perceived as most important to prioritize from their particular clinical perspectives. They were also asked for clinical and logistical advice on how best to integrate study procedures with existing systems.

4.4.2.2 Team Treatment and Self-Observation; Team Discussion

During this time, acupuncturists treated patients using Manual Version 1. Adherence to manual procedures was not considered a priority: on the contrary practitioners sought to identify instances where their clinical judgment was at odds with what the manual suggested. These instances were discussed in weekly acupuncture team meetings, along with treatments given and perceived degree of clinical effect, and contributed to the manual development process described in the next section.

4.4.2.3 Development of Manual Materials: Index, Outline and Worksheets

At these meetings, team members reorganized the unwieldy tabular Assay into a more user-friendly Treatment Index containing best available evidence (including the clinical literature as 'expert opinion') in paginated form. The Outline was revised and amplified considerably. Where the original outline captured the tacit algorithms for assessment and treatment that team members had surfaced through self-observation, this second version incorporated treatment prioritization as gleaned through discussions with the PT, OT, SST, MD and particularly the Nursing services. During the course of Outline revisions, the team elected to change the format from a text outline to a set of tabular worksheets: one for patient assessment (three pages), and one page each for stroke rehabilitation and stroke recovery phases.

These worksheets operationalized initial evaluation and uncomplicated treatment of patients at all levels of severity seen on LMC's acute rehabilitation unit, with the understanding that the larger, more comprehensive Index was still available for use with unusual or refractory cases. Together, these two documents were taken to constitute Version 2 of the manual.

4.4.2.4 Assessment Instruments and Additional Outcome Measures

As discussed in Section 4.4.1, three preliminary instruments were drafted for operationalizing assessment of tongue, pulse and abdominal diagnosis. The instruments are included within Version 2 of the manual. The protocol for the Cohort study specified that three secondary outcome measures would be developed by the acupuncturists, and it was anticipated that these instruments would be used as those three outcome measures. (This was in keeping with Jonas & Lewith's (2011) recommendation for incorporation of native outcome measures, discussed in Section 3.1). However, once construction of the instruments had served the purpose of developing clear assessment procedures, the team decided that validation of these instruments was of less interest then exploration of the outcomes of bowel function, sleep and swallowing. These were areas identified by nursing staff (in the meeting described above) as central to patient quality of life; they were also areas perceived by acupuncturists as responding strongly to treatment. The operationalized assessment procedures developed by the team were transferred onto a new Intake sheet early in Phase 3, and are seen as part of the Manual Version 3 Patient Assessment Worksheet.

4.4.2.5 Expert Review

In August of 2012, Version 2 of the manual was given for review to two department heads of the Guangdong Hospital of Traditional Chinese Medicine, a 4,000-bed inpatient facility with an active and well-regarded Acupuncture department including an extensive stroke rehabilitation unit. Dr. Xu Zhenghua, director of the Inpatient Acupuncture unit (where stroke patients are taken once medically stable) and Dr. Chen Hongxia, director of the Acute Rehabilitation unit, provided verbal comments on the Outline via Skype, interpreted by LMC acupuncturist Paul Ryan. These comments expressed approval of the overall structure and format, suggesting a few additional points and that less time be spent palpating channels.

4.4.2.6 Manual Version 2

The final product of Phase 2 was Version 2 of the treatment manual, which is attached as Appendix B. Manual Version 2 consisted of an Outline for assessment and treatment, three instruments operationalizing pulse, tongue and abdominal diagnosis, and a preliminary version of the Treatment Index (not attached; see the final Treatment Index in Manual Version 3, Appendix C).

4.4.3 Phase 3: Manual Piloting, November 2012 to November 2013

During the piloting phase, the team kept the Core Worksheets relatively stable, tracking usage of its modules while expanding the Index. Additional developments are described below.

4.4.3.1 Team Case-based Literature review and expansion of the Index

In addition to treatment and self-observation as in the past, the team now began augmenting the Index with the cases they had treated using its guidance. In addition, where team members had consulted literature not previously reviewed for the project, that source was added for the symptom in question, and team members searched for additional material which was added to the appropriate worksheets.

4.4.3.2 Compliance with Manual Protocols

During the piloting period, weekly manual development meetings were consolidated to monthly meetings. In place of weekly group discussion of treatments, written feedback regarding manual compliance was collected from the Intake Worksheet for each treatment.

4.4.3.3 Manual Version 3

The final produce of Phase 3 was Manual Version 3, which is attached as Appendix C. It consists of a Patient Assessment Worksheet; three Core Worksheets for treatment planning; and the Index of Syndromes and Approaches.

4.5 Results

4.5.1 The Treatment Manual

The main result of this first phase of the project is the Stroke Treatment Manual itself. Preliminary, intermediate and final versions of the manual (Versions 1, 2 and 3) are attached as Appendices A, B and C respectively.

4.5.2 Manual Compliance

During the piloting period, 35 of 205 treatments departed from protocol, for an 87% compliance rate. Among the departures, 12 were for refractory cases, where all options within the manual perceived as potentially appropriate had been explored with no satisfactory treatment effect, while only 2 treatments departed from the manual due to perceived inappropriateness of treatment options. Eleven treatments departed from the manual for logistical reasons. These included unavailability of indicated needling sites due to placement of intravenous or percutaneous endoscopic gastrostomy (PEG) tubes, or limb edema. Figure 4.3 summarizes reasons given for departure from the manual.

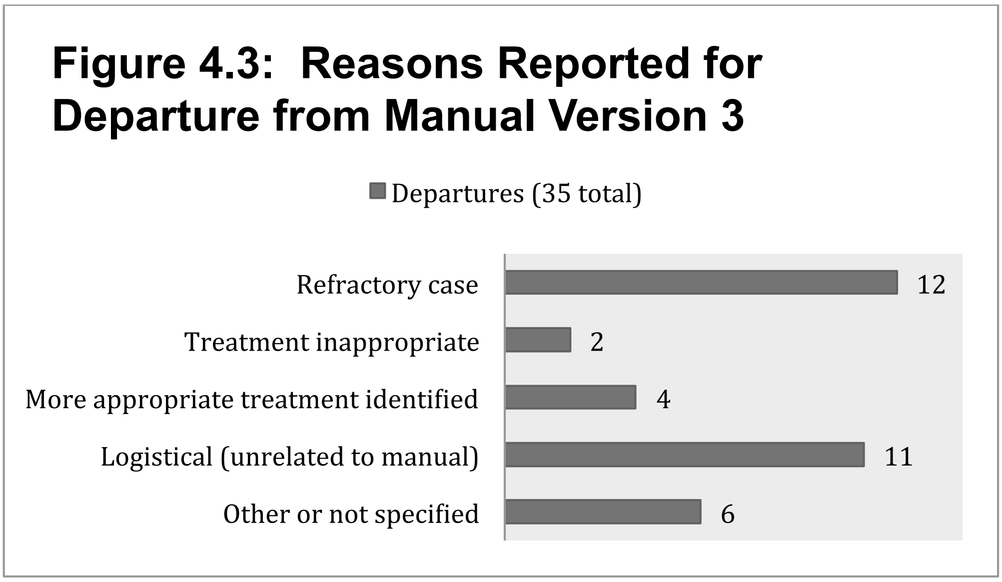

Figure 4.3: Reasons for Departure from Manual Version 3

4.6 Discussion: Findings, Innovations and Potential Impact of the Project

The main question for the manualization phase of this project is answered in the affirmative: it has been possible for the acupuncture team to develop a treatment manual iteratively through clinical practice and self-evaluation in the course of a clinical investigation, rather than *a priori*. As discussed in Chapter 2, this approach shows considerable promise for addressing the methodological difficulties associated with acupuncture research, but has been little utilized for this purpose to date.

In this project, perceived appropriateness of treatments by acupuncturists (reported in Section 4.6 above) was high. Approximately a third of departures from the manual were due to external logistical factors. Another third were refractory cases where manualized options had been perceived as clinically appropriate and applied, but had not resulted in perceived clinical change. This finding, together with positive stakeholder perceptions (described in Chapter 6), suggests that subjectively perceived adequacy of treatments is high for acupuncturists as well as patients and other key participants in the therapeutic process.

In this regard, a novel aspect of this manual's construction is of particular interest: prioritization of treatment goals (Aim 1 Objective 3, Section 4.3.1.3). In meetings with physical therapists and particularly the nurses, the importance of such prioritization was reinforced (notes from this meeting are attached as Appendix D, showing nurses' perception that strategic selection of treatment goals based on chains of causality could increase impact on patient well-being). Physical and Occupational therapists described their own practice of assessing rehabilitation goals from gross to fine, with the understanding that recovery proceeds generally speaking from the trunk to the extremities, with exceptions and with plateaus along the way. Clinical texts on stroke treatment in Chinese medicine similarly assert that until the digestion or 'qi mechanism' is righted, stroke patient's tongues will remain thickly coated and other symptoms will not improve (Jiao, 2006a). Accordingly, the first step towards creating a treatment algorithm was recreating the assessment process of a mature practitioner: gauging the relative urgency and causal centrality of a large number of interrelated 'root' and 'branch' disorders, and prioritizing accordingly. Fundamental elements of recovery such as disordered consciousness and impaired intake and digestion were prioritized high, relative to motor impairment (which itself was prioritized with upper limb after the lower, which is both more important to patient quality of life and also more likely to return). Use of the acupuncture to focus on concerns deemed both most important and also most likely to improve with treatment, may have contributed to the study's exceptionally low rate of withdrawal.

Another novel aspect of this manual's development was the two-part structure: the worksheets containing a treatment algorithm appropriate for most patients, and the Index containing best available evidence for each of the 14 most commonly encountered stroke sequelae not adequately covered within the worksheets. This feature was again intended to mimic the behavior of a mature practitioner who, encountering a new patient, is in most instances scanning for usualness or unusualness in the presentation, while forming and prioritizing treatment goals as described above. Patients who conform to patterns previously seen can be treated as usual; those who do not must be examined further, with recourse to less commonly used treatments or consultation of the evidence base. Between them, the worksheets can be understood as mimicking the mature practitioner's habitual treatment repertoire, and the evidence base (pre-consulted and sorted for easy use). Altogether, this condition can be argued to constitute a reasonably standard experimental exposure, to which patients can be randomized.

In this study, as in a pragmatic trial, practitioners' commitment was to clinically appropriate treatment, rather than standardization. It was therefore possible to track instances of departure from the Core Worksheets – and from the manual altogether (when appropriate treatment options are also not found in the Index or elsewhere in the manual). As discussed above (Section 4.2.4, Consideration 4) such departures likely indicate either a failure of the manual to appropriately categorize an unusual patient, or else a refractory case that does not respond as usual to treatment perceived as appropriate. In either case, these are the cases that (A) reduce effect sizes for the general population and (B) provide opportunities for improving the manual. A manual design that promptly and definitively identified such patients may be useful in moving from a cohort or pragmatic design to a more tightly controlled effectiveness or efficacy study. This manual design can be seen as operationalizing Fonnebø's influential suggestion (Følnnebø et al., 2007) that the 'evidence hierarchy' for commonly used complementary therapies research be reversed, proceeding from clinical practice and effectiveness research towards efficacy research rather than the reverse, as is usual in pharmaceutical research. Using this approach to manualization, it would be possible to make the development of a treatment model a deliverable at the conclusion of some pragmatic trials, particularly for conditions such as stroke where expertise is not widespread and therefore a manual would be seen as a help rather than an unnecessary burden.

The manual developed for this study has been taught to acupuncture students and postgraduates in training programs at Lutheran Medical Center (October, 2012); the Pacific College of Oriental Medicine (March, 2013); and at the University of Westminster (July, 2014). Version 4 of the manual will be in electronic form for use with a tablet. It may be that the capacity of the manual to learn from itself is only fully realized at that point, when a separate data entry step is not required for practitioner's treatment choices at one session to be correlated with pulse, tongue and perceived treatment response data collected at the next session.

4.6.1 Limitations of the Project

This project had several meaningful limitations. First, there was only limited expert review of the manual itself; once in preliminary form and once in intermediate form. Second, as discussed above, review of Chinese language research is limited, and review of Chinese language historical and contemporary clinical sources even more so. Similarly, the literature on manualization across acupuncture and other disciplines was broadly surveyed but not systematically or comprehensively searched. Finally, a formal consensus process was not used. While this decision was made in what I viewed as the best interest of the project for reasons described above, it may limit perceived validity of the process.

4.7 Conclusions

The manual for this study was successful in its goal of standardizing practice while preserving perceived clinical appropriateness of treatments, as shown by high protocol compliance by practitioners. Its development process, over the course of two years and many nested iterative cycles of use and evaluation, could be repeated with greater efficiency for future projects.

Overall, the novelty of this manual's design consists mainly in new juxtapositions of previously existing formats. The prioritized treatment worksheet or flowsheet, though little used in Western acupuncture, is common in biomedical practice, and also in hospital acupuncture departments in China. Similarly, the Index that forms the back end of the manual take roughly the format (if not the rigorous review and consensus processes) of the SIGN guidelines (Scottish Intercollegiate Guideline Network, 2001). The value of combining these two formats is that it mimics the behavior of a mature practitioner – operating from a familiar repertoire of differential diagnosis and treatment algorithms for the majority of patient presentations, with recourse to the evidence base when those algorithms do not provide for clinically adequate treatment. Additional value is added when such cases, on completion, are added to the “bottom” of the evidence base, eventually aggregating to form a case series informing future practice.

The manual in its current form constitutes a flexible but reproducible standard experimental exposure in future effectiveness. It can also be used to teach evidence-informed practice of acupuncture during stroke rehabilitation, allowing practitioners with little previous experience in this complex area to provide clinically appropriate care with relatively little additional training.

5 CHAPTER 5: METHODS, RESULTS AND DISCUSSION OF CONCURRENT COHORT STUDY

5.1 Overview of Cohort Study Design

This concurrent cohort study was designed to assess feasibility of methods for a larger, controlled trial by piloting use of the treatment manual and determining data completeness and effect size for several outcome measures. Inpatients recovering from primary ischemic stroke, who had agreed to receive acupuncture in addition to usual care, were compared to patients who had declined acupuncture treatment and received usual care only. One primary and eight secondary outcome measures were compared between the two groups. Of these, seven were assessed at baseline and discharge, one at baseline and 6-month follow-up, and one at discharge and follow-up.

Acupuncture treatment was conducted by Licensed Acupuncturists with at least ten years of clinical experience, who were previously credentialed and trained in post-stroke care at LMC. Usual care and routine clinical assessments were conducted by members of LMC's Rehabilitation Unit staff including physical, occupational and speech & swallowing therapists, attending physicians, nursing staff and neuropsychologists. Data was collected as described below, from a combination of patient charts and additional assessments. Prior to commencement of this project, an ethics application was submitted to LMC's Institutional Review Board, which approved it on 19 July 2011 (approval is attached as Appendix F); and to the University of Westminster's Research Ethics Sub-Committee which approved it on 2 April 2012 (approval is attached as Appendix G). Appendix H contains the information sheet in simple language and large for patient and family participants. Appendix I contains their informed consent form.

A flowchart of the overall study design is below in Figure 5.1.

Figure 5.1: Study Flow Diagram

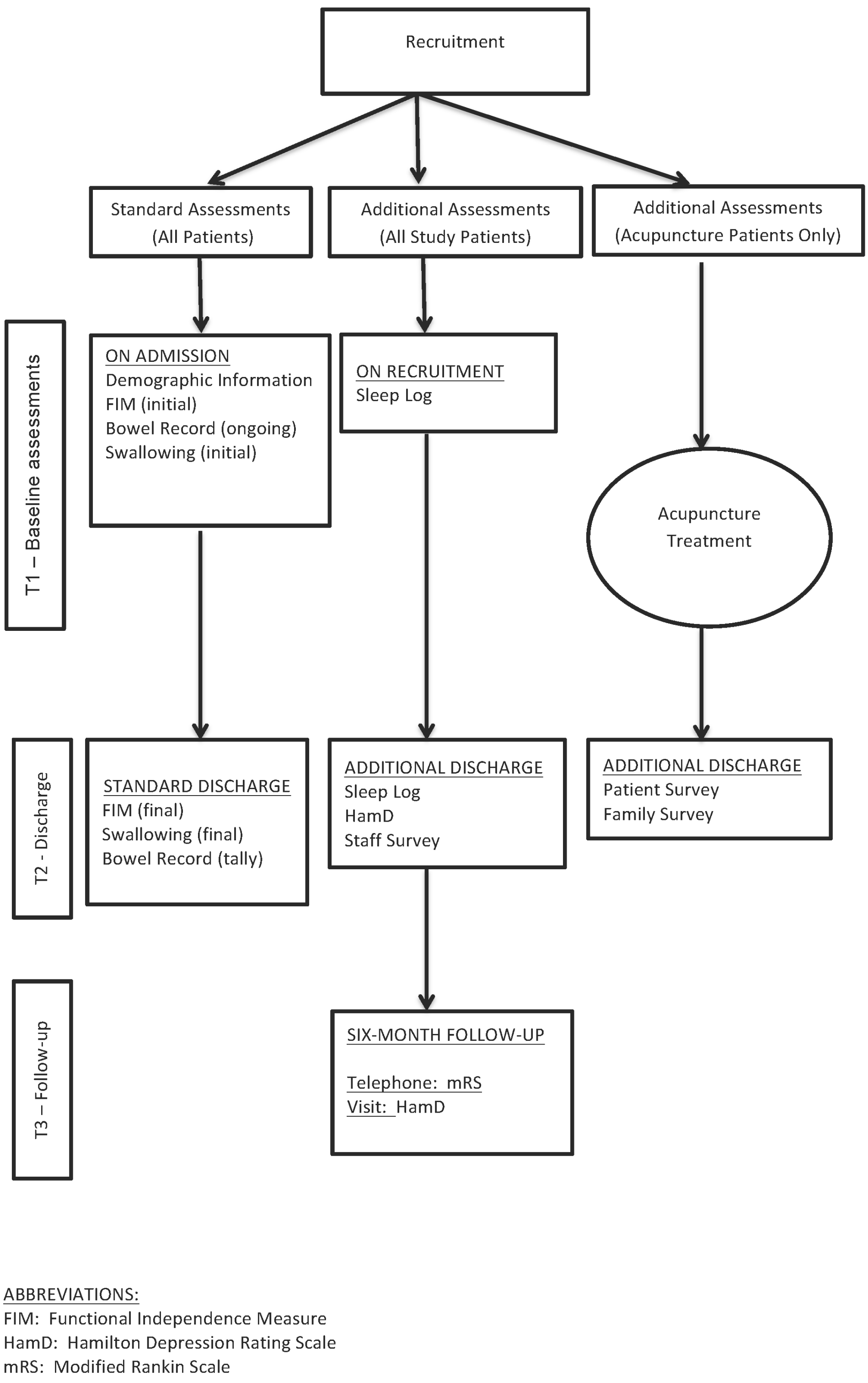

Figure 5.1: Study Flow Diagram

This concurrent cohort study addressed Aims 2, 3 and 5 of the overall project. These were:

2 Determine whether patients treated with manualized acupuncture show greater improvement on ADL assessments than those treated with usual care alone
3 Determine whether apparent effects of acupuncture vary between patients at different severity levels, on ADL and other assessments of cognitive function, depression, sleep and bowel function
5 Determine feasibility of future study with respect to primary and secondary outcome measures, with feasibility defined as:
    a. Fewer than 25% of patients withdraw from the trial
    b. Adverse event reports and patient and staff perceptions of harm or discomfort are found to be within acceptable limits
    c. Acupuncturists perceive the manual as addressing treatment goals 90% of time
    d. For a given outcome measure, data is complete for least 75% of patients enrolled
    e. For a given outcome measure, rate of recruitment is sufficient in relation to sample size calculation to allow completion of a trial within 2 years

5.1.1 Study Participants

Participants were recruited on admission to the Neurology and Neurological and Orthopedic Rehabilitation (NOR) Unit of Lutheran Medical Center (LMC).

5.1.2 Inclusion/exclusion criteria

The following inclusion/exclusion criteria were used to reduce excessive heterogeneity due to differing stroke type or premorbid status, while maintaining sufficient diversity to explore distribution of effects across severity levels.

Inclusion criteria were as follows:

- Primary Ischemic stroke, as assessed by magnetic resonance imaging (MRI) on admission and confirmed by Head of Neurology
- Onset <8 days previous to recruitment
- Contralateral hemiparesis
- Have consented to data collection and interview

Exclusion criteria were as follows:

- Age >87[19]
- Patient was not independent before stroke; Modified Rankin Scale (mRS) >2 as inferred from family or caregiver report
- Diagnosis of carcinoma, Alzheimer's, Parkinson's or other severe degenerative disease
- Pacemaker or other implant preventing use of MRI

5.1.3 Recruitment and Informed Consent

Patients were recruited for the study between November 1, 2012 and November 15, 2013. There were two hiatuses in recruitment to accommodate acupuncturists' schedules, one from 1 December 2012 to 6 January 2013 (5 weeks) and one from 3 to 30 July 2013 (4 weeks) totaling 9 weeks. During that time patients already enrolled in the stroke were treated but new patients were not enrolled.

Potentially eligible patients were identified via examination of hospital daily census reports by the investigator. All patients presenting with a diagnosis of stroke or possible stroke during the recruitment period were screened for

[19] The statistical association between advanced age and poor stroke outcome is well known (Feigenson, McDowell, Meese, McCarthy, & Greenberg, 1977; Nakayama et al., 1994). However, there is poor consensus as to the clinical implications of the association due to difficulty of differentiating concurrent factors such as stroke severity, comorbid dementia and poor compensation abilities independent of neurological damage due to stroke (Bagg, Pombo, & Hopman, 2002). Selection of 87-88 as the cutoff point for this study represents a compromise between external validity in LMC's stroke population (with many patients between 85 and 90) and the considerable difference in 3-month mortality between patients aged 75-84 (28.8%) and those aged 85 and over (39.4%). (Nakayama et al., 1994)

eligibility using the criteria above. Eligibility criteria were assessed in the Electronic Medical Record and confirmed in person by the investigator before study recruitment and signature of informed consent.

Recruitment took place in the patient's hospital room and was conducted by the investigator. First acupuncture was offered to the patient as per standard hospital procedure. Once the patient and/or family members had decided whether or not to receive acupuncture, the investigator then immediately offered participation in the cohort study[20]. The recruitment period ended when the forty-eighth patient was enrolled in the study.

5.1.4 Study Setting

Lutheran Medical Center is an urban community hospital serving a widely diverse population. It is designated as a Primary Stroke Center by the Joint Commission on Accreditation of Healthcare Organizations, and it is the only such center in the borough of Brooklyn. Patient care is delivered in 15 patient rooms with two beds each, and a large multi-purpose rehabilitation gym with dedicated areas for physical therapy, occupational therapy, and strength and endurance training.

5.1.5 Study Size

This feasibility study provided effect sizes for feasibility assessment. Given the heterogeneity of the anticipated patient population, study size was set as large as logistically possible (N=48), given time available (8-12 months) and anticipated rate of recruitment (4-6 patients per month).

5.1.6 Incentives for participation.

No incentives for participation were offered.

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[20] The study compared the cohort of patients electing for acupuncture treatment to the cohort of patients patients declining it. For this reason, all patients were invited to participate.

5.2 Interventions

The intervention in this cohort study was manualized acupuncture treatment, using a treatment manual developed in the course of this project (Chapter 4). Acupuncture treatment was given to patients electing it, as an adjunct therapy alongside usual care. The usual care condition is described immediately below, followed by a more detailed description of the acupuncture intervention.

5.2.1 Control Condition: Usual Care Only

Usual care in the NOR Unit includes one hour each of PT, OT and SST on weekdays, with one hour of one service only on Saturday. Rehabilitative care is delivered by licensed physical, occupational and speech & swallowing therapists at the doctoral and master's degree level, employed by the hospital. Rehabilitative and medical care is coordinated day-to-day by one of the unit's three physiatrists[21]. Treatment goals and discharge planning are coordinated between all of the services described above in weekly team meetings, which an acupuncture team member also attends[22]. Patients typically remain in the unit for two to three weeks after an acute ischemic stroke, but actual length of stay varies from one week to five or more, depending on patient progress and health insurance status.

5.2.2 Intervention: Acupuncture in Addition to Usual Care

Acupuncture care was provided four days per week, with treatment goal setting and execution as described above in Chapter 4. Patients received acupuncture treatment at bedside.

5.2.2.1 Materials

For scalp acupuncture, the practitioners used 'Dr. Zhu Scalp Acupuncture' needles, 36 gauge (0.20mm), 20mm length. They were manufactured in

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[21] In the United States, the term 'Physiatrist' denotes a physician certified by the American Board of Physical Medicine and Rehabilitation.

[22] During the study period, the acupuncture team member attending the weekly meeting was usually though not always one of the team members delivering care as part of the study.

China by Suzhou Medical Appliance Factory (Zhu's Neuro-Acupuncture Center, 2013). They comply with ISO (International Organization for Standardization, Switzerland) standards for quality management, ISO 9001 (ISO, 2014a) and for safety as a medical device, ISO 13488 (ISO, 2014b). They are also certified under the European Commission by the notified body of TÜV SÜD[23], (European Commission, 2014).

For body and auricular acupuncture, the practitioners used 'DBC Spring Ten Acupuncture' needles. They were manufactured in Korea by the DongBang Corporation (Lhasa OMS, 2014). They comply with ISO 9002 standards for quality management, British Q-Mark certification, and 510(k) certification as a medical device (Lhasa OMS, 2014). Practitioners selected from among four sizes of needles based on point depth and patient needle sensitivity: 15mm length 38 gauge (0.18mm); 15mm length 36 gauge (0.20mm); 40mm length 34 gauge (0.22mm); and 50mm length 32 gauge (0.25mm).

For electrical stimulation of acupoints, the practitioners used an 'ITO ES-130', a 3-channel electroacupuncture device manufactured in Japan by ITO Physiotherapy and Rehabilitation. It has a nine-volt power supply, with a maximum output voltage of 30v (+/- 15%) and a variable frequency range of 1-500Hz. It is a type BF, class IIa/MDD medical device (ITO Physiotherapy and Rehabilitation, 2013).

5.2.3 Possible Confounding Variables

Several variables may modify the effects of acupuncture. It was the study's secondary question whether patients would respond differently to acupuncture treatment on motor outcomes depending on severity of damage to corticospinal tracts. Additionally, the hospital's patient population is approximately 15% culturally Chinese. It was anticipated that

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[23] Technischer Überwachungs-Verein Süd, (Technical Inspection Association, South region)

because of acupuncture's greater familiarity to Chinese patients they would be both more inclined to consent to acupuncture treatment and also more likely to anticipate a positive response. Patients with positive expectations are more likely to respond positively to acupuncture than acupuncture-naïve patients (Linde et al., 2007). Time from stroke to first treatment and number of treatments completed may also have modified acupuncture effect. Patient characteristics thought to confound assessment of stroke recovery include age, gender (Appelros, Stegmayr, & Terent, 2010), and premorbid functional level (Bogousslavsky & Pierre, 1992; Kammersgaard et al., 2004; Muir, Weir, Murray, Povey, & Lees, 1996); stroke severity (Appelros, Nydevik, & Viitanen, 2003); aphasia (Laska et al., 2001); impaired consciousness (Chambers, Norris, Shurvell, & Hachinski, 1987; Nys et al., 2005); concordance and neglect syndrome (Paolucci et al., 1998). Concordance occurs when the affected side is the dominant side; neglect occurs when the affected side loses proprioceptive awareness. Occurrence of medical complications and length of stay were also anticipated as confounders of treatment effect.

5.3 Measurements

For this feasibility study, the Functional Independence Measure (FIM) was selected as primary outcome measure. The FIM is a comprehensive, activity-level instrument designed to assess patients from the viewpoint of burden of care and routinely used for that purpose at LMC. Secondary outcome measures for this study included body-level measurements to explore possible effects of acupuncture treatment, with the addition of one activity-level measurement (the Modified Rankin Scale) for follow-up. Table 5.1 summarizes the clinimetric properties of outcome measures selected. Papers cited in the table and not elsewhere in the paper include: (Agrell & Dehlin, 1989a; Dodds, Martin, Stolov, & Deyo, 1993; Gladstone, Danells, & Black, 2002; Godefroy et al., 2011; Naarding, Leentjens, van Kooten, & Verhey, 2002; Toglia, Fitzgerald, O'Dell, Mastrogiovanni, & Lin, 2011).

Table 5.1:	Scoring and Clinimetric Properties of Outcome Measures Assessed in this Study								
	Measure (Sources for clinimetric properties in post-stroke patients)	Scoring	Test Details	Reliability		Validity		Responsiveness	
				Rigor*	Results[1]	Rigor	Results[2]	Rigor	Results[3]
Primary Outcome Measure	**Functional Independence Measure** 1-(Dodds et al., 1993); 2-(Kidd et al.,1995) 3-(Ottenbacher et al., 1996); 4-(Ravaud et al., 1999) 5-(Salter et al., 2013) 6-(Van der Putten et al., 1999)	18 to 126 indicating total dependence to complete independence	18 items in 6 functional areas (self-care, sphincter control, mobility, locomotion, communication and social cognition).	Excellent	Excellent (TR-2,IO-3,IC-1) Adequate (IO-2,IC-4)	Excellent	Excellent (CC-2)	Excellent	Excellent (6) Adequate (5)
Secondary Outcome Measures (Validated)	**Fugl-Meyer upper extremity assessment** 1-(Gladstone et al., 2002); 2-(Salter et al., 2013)	0 to 90 indcating zero function to normal function	30 items scored 0-2 in 7 domains: upper extremity function, wrist, hand, coordination-speed, sensation, passive joint motion, joint pain	Excellent	Excellent (TR, IO)(1,2) Adequate (IC)(2)	Excellent	Excellent (1,2)	Excellent	Excellent (1,2)
	Montral Cognitive Assessment 1-(Godefroy et al., 2011); 2-(Nasreddine et al., 2005); 3-(Toglia et al., 2011)	0 to 30 indicating worst to best cognitive function; normal range =>26 (some debate)	6 tasks in 6 domains: memory, visuospatial ability, executive functioning, attention and concentration, language, and orientation	Poor	Excellent (TR-2); Adequate (IC-2,3)	Adequate	Excellent(1) Adequate(2)	n/a	Insufficient information in Stroke
	Hamilton Depression Rating Scale 1-(Aben et al., 2002); 2-(Agrell & Dehlin, 1989);3-(Naarding et al. 2002)	0 to 54, indicating least to most depressed	17 items scored 0-2 or 0-3. Interpreted as normal (0-6); mild (7-17); moderate (18-24); or severe depression (25-30)	Adequate	Adequate (IC-2)	Excellent	Excellent(3) Adequate(1,2)	n/a	Insufficient information in Stroke
Secondary Outcome Measures (New)	**National Dysphagia Diet Level**	0 to 8 indicating NPO to no dietary restrictions	As assigned based on clinical evaluation by speech therapist, with endoscopic and/or radioscopic assessment as necessary	Not validated					
	Bowel Function index	0 to 5 indicating number of days in last five with (continent) bowel movement	As routinely reported by nurse in hospital chart	Not validated					
	Sleep Log	0 to 10 indicating number of hourly intervals (10pm to 7am) at which patient was observed by nurse to be asleep	As charted by nurse in "sleep log" addendum to patient chart	Not validated					

Rating criteria for rigor adapted from: Salter, K., Jutai, J. W., Teasell, R., Foley, N., Bitensky, J. & Bayley, M. 2005. Issues for selection of outcome measures in stroke rehabilitation: ICF activity. Disability and rehabilitation, 27, 315-40.

Rating criteria for reliability, validity and responsiveness adapted from: Salter, K., Jutai, J., Zettler, L., Moses, M., Foley, N., & Teasell, R. Evidence-Based Review of Stroke Rehabilitation (EBRSR.org)-Outcome Measures in Stroke Rehabilitation, updated October 2013 [retrieved December 12, 2014].

*** Rigor** Excellent = most major forms of testing reported; Adequate = several studies and/or types of testing reported; Poor = minimal information reported (or few studies other than the author's)

1 - Reliability Test-retest (TR) or interobserver (IO) reliability: (ICC or kappa statistics), Excellent: 0.75; Adequate: 0.4 – 0.74; Poor: < 0.40. Internal consistency (IC): Split-half or Cronbach's α statistics, Excellent: 0.80; Adequate: 0.70 – 0.79; Poor < 0.70

2 - Validity Construct/convergent and concurrent correlations (CC): Excellent: 0.60; Adequate: 0.31 - 0.59; Poor: ≤0.30. ROC analysis/area under the curve (AUC): Excellent: 0.90; Adequate: 0.70 – 0.89;

3 - Responsiveness Sensitivity to change: Excellent: Evidence of change in expected direction using methods such as standardized effect sizes; ROC analysis of change scores or relative efficiency; Adequate: Evidence of moderate/less change than expected; conflicting evidence. Poor: Weak evidence based solely on p-values (statistical significance)

Table 5.1: Scoring and Clinimetric Properties of Outcome Measures Assessed in this Study

5.3.1 Primary Outcome Measure: Functional Independence Measure

The FIM is the most widely used ADL assessment in the United States. It forms the basis of the Unified Data System in Medical Rehabilitation (UDS-MR™), the database used by a majority of US rehabilitation facilities (McDowell, 2006). At Lutheran Medical Center, it informs patient assessment, treatment and discharge planning, and remuneration by government and private insurance entities. The FIM is assessed on 18 items in 6 functional areas: self-care, sphincter control, mobility, locomotion, communication and social cognition. Each item is scored using a seven-point scale, ranging from “1” indicating that the patient could perform less than 25% of the task, to “7” indicating that no assistance was required. Total FIM score is a simple sum of item scores, ranging from 18-126. Scores can also be interpreted by separating motor and cognitive domains (13 and 5 items, respectively).

Minimal clinically important differences have been suggested (Beninato et al., 2006) based on assessments of clinical change conducted by physicians after discharge from acute rehabilitation. These are: 22 (total FIM); 17 (motor domain) and 3 (cognitive domain). However it has been argued that smaller differences are perceived as important by patients and caregivers (Granger, Hamilton, Linacre, Heinemann, & Wright, 1993).

The reliability of the FIM has been established, with a 1996 review of 11 studies (Ottenbacher, Hsu, Granger, & Fiedler, 1996) showing a median inter-rater reliability of 0.95, median test-retest reliability of 0.95, and mean equivalence reliability of 0.92 (across versions) for the total FIM. Estimates of Cronbach’s Alpha in stroke patients from more recent studies range from 0.88 to 0.98 (Van der Putten, Hobart, Freeman, & Thompson, 1999).

It is worth noting however, that reliability coefficients of individual items were found to be generally lower in the Cognitive domain than the Motor domain. Strong concurrent validity of the Motor items of the FIM in association with the Barthel Index (BI) was established in 1995 (Kidd et al., 1995), with Spearman's correlation coefficient ranging from 0.74 (admission) to 0.92 (discharge). Construct validity is strong in a stroke population when assessed by comparison with known groups; predictive validity is high for placement after discharge and burden of care (i.e. minutes of help per day required) (Kidd et al., 1995; Salter et al., 2005).

The FIM's responsiveness to change during stroke rehabilitation is high (Van der Putten et al., 1999), with the test showing neither a floor nor a ceiling effect (in contrast with the BI, which has exhibited both). The FIM cognitive domain does show a ceiling effect when used with MS patients. However because stroke patients generally present with greater cognitive impairment, a ceiling effect has not been demonstrated in stroke (Van der Putten et al., 1999). There is some debate as to whether the FIM's seven-point scoring system is in fact more sensitive to clinical change than simpler instruments such as Barthel Index and Modified Rankin Scale (Van der Putten et al., 1999), and whether it is robust across cultures on certain items, notably toileting (Lundgren-Nilsson et al., 2005). The FIM's factor structure has also been questioned, with authors using Rasch analysis to argue that the Motor and Non-Motor domains should be regarded as separate clinical entities (Lundgren Nilsson & Tennant, 2011).

For this study, the main disadvantage of the FIM is that the validity of its cognitive domain has not been specifically evaluated in aphasic patients, who constitute 17% of this study's population. The ceiling effect of the cognitive domain described above may also be of concern in relation to this study's secondary aims of exploring motor and non-motor effect sizes in mild, moderate and severe subgroups.

Overall however, the FIM is regarded as the most comprehensive, reliable and sensitive ADL outcome measure currently available for use in post-stroke rehabilitation (Salter et al., 2005). In addition, it is reliably administered to LMC acute rehabilitation patients.

5.3.2 Secondary Outcome Measures

Four secondary outcome measures used in this study are described below. In addition, four outcome measures returned data for less than 20% of patients and are not described here. These are described in Appendix J. They are: the Hamilton Depression Scale (Ham-D), the Fugl-Meyer Upper Extremity Assessment (FM-UE), the Neurobehavioral Cognitive Exam (Cognistat) and the Montreal Cognitive Assessment (MoCA). Logistical challenges encountered in the administration of these outcome assessments are described in the discussion of feasibility, Section 5.6.7.

5.3.2.1 Hourly Sleep Log

Insomnia in the acute care setting is widely recognized as an obstacle to recovery across medical disciplines. It is a particular concern in post stroke care, where sleep-wake disturbances are estimated to affect 20%-40% of patients (Hermann & Bassetti, 2003). The factors above are further complicated by known disruptive factors common to inpatient care: noise, light, discomfort, anxiety and vitals assessment. Treatment options are constrained by the risks of polypharmacy, as well as increased risks and side effects of sedatives and hypnotics in the elderly and neurologically impaired (Lenhart & Buysse, 2001b).

Few clinical trials in the West have addressed insomnia in the inpatient setting, and previously validated scales for chronic insomnia such as the Insomnia Severity Index or Athens Insomnia Scale are not appropriate for acute situational assessment. The Hospital Anxiety and Depression scale has been assessed as an insomnia measure. However, convergent validity of subjective insomnia report items is known to be poor (McCall, Reboussin, & Cohen, 2000). Emerging actigraphy technology appears reliable and valid for multiple dimensions of sleep quality (Lichstein et al., 2006), but its expense is neither justified nor feasible in this exploratory study. In regular clinical practice at LMC, where sleep is determined to be of concern for a particular patient, nurses fill out an hourly sleep log. The patient is visually observed at hourly intervals and reported as either asleep or awake. This type of sleep log is not widely seen in the research literature, though it has been used in at least one clinical trial in Japan (Manabe et al., 2000). While face validity is apparent, it could be argued that a 24-hour sleep log is more appropriate for stroke patients, where daytime somnolence is also a meaningful form of disordered sleep. However, a 24-hour log is not feasible at LMC.

For this study, our goal was preliminary exploration of any relationship between acupuncture treatment and the complex, multifactorial problem of sleep in acute stroke care, following patient reports of improved sleep after acupuncture treatment. Hourly reports of sleeping and waking were scored ‘1’ and ‘0’ respectively, to yield a score of 0-10. Because the logs greatly increase nursing duties, they were used sparingly: two days at study recruitment, and two more logs were placed on the first day of the third week of admission, or during the week of planned discharge.

5.3.2.2 National Dysphagia Diet Level

Dysphagia after stroke is commonly documented, though reports of prevalence range widely from 19% to 81%. It is associated with pulmonary complications and post-stroke mortality. (Martino et al., 2005b). In order to explore acupuncturists’ perceptions that swallowing improved markedly after treatment in some patients, patients’ dietary levels at baseline and discharge were compared.

Standardized outcome measures for swallowing impairment do exist, notably the Dysphagia Outcome and Severity Scale (O'Neil, Purdy, Falk, & Gallo, 1999), Functional Oral Intake Scale (Crary, Mann, & Groher, 2005) and Penetration-Aspiration Scale (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996). However for this exploratory study the National Dysphagia Diet level (National Dysphagia Diet Task Force. & American Dietetic Association., 2002) was both logistically more feasible and also more in keeping with the project’s orientation to person-level function (as distinct from body-level impairment). Dysphagia diet level is routinely set by LMC’s Speech and Swallowing therapists, taking into account clinical examination findings as well as barium swallow or fiber-optic endoscopy results. The eight-point scale used for this study is a sum of the two scales for solid (four points) and liquid intake (three points[24]). Therefore a score of zero points was given for NPO (no oral intake permitted) and a score of seven points for unrestricted diet and thin liquids.

5.3.2.3 Bowel Function Index

A new measure of bowel function was constructed for this study. The purpose of the new measure was to assess bowel function from a perspective of patient-centered clinical impact rather than functional independence. Recovery of bowel function is seen as central to stroke recovery in Chinese medicine (Jiao, 2006b). As discussed in Section 4.4.2, the bowel function outcome was added in response to acupuncturist perceptions that patients experienced relief of bowel symptoms with treatment.

Disruption of bowel function is common after stroke, with estimates of prevalence as high as 60%. Often unsatisfactorily treated, it is seen to worsen prognosis for 12-week outcomes (Su et al., 2009). Fecal incontinence after stroke can be primary, or secondary to treatment of constipation (Harari, Gurwitz, Avorn, Choodnovskiy, & Minaker, 1994). Both fecal incontinence and constipation are known to diminish quality of life and increase burden of care (Dennison et al., 2005; Rothbarth et al., 2001). A previous study at LMC found that constipation was one of the main themes identified by patients as ‘the most important thing’ for which they wanted help from nursing staff (Cappabianca, Julliard, Raso, & Ruggiero, 2009).

Despite the known clinical and experiential importance of bowel function disruption, on review of the literature for this study no validated instrument

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[24] The liquid intake scale is based on fluid viscosity. The patient’s score designates the thinnest liquid safe for consumption without undue risk of aspiration. They were scored as follows: thin liquids, 3 points; nectar thick, 2 points; honey thick, 1 point. A fourth designation, pudding thick, is not clinically meaningful and was therefore conflated with NPO for 0 points.

for clinical assessment of bowel function for inpatients was identified. Available outpatient instruments have limited applicability to an inpatient population. For example the Rome III guidelines for diagnosis of functional gastrointestinal disorders (Drossman, 2006), widely used in the construction of assessment instruments (McCrea et al., 2008), use a frequency cutoff point of <3 bowel movements per week, losing meaningful distinctions for the inpatient population where 0, 1 and 2 bowel movements with and without mechanical intervention are all clinically distinct possibilities. Finer grained measures in general rely on self-report (Varma et al., 2008), making them infeasible in a population where some patients have moderate to severe cognitive impairment.

The ‘sphincter management’ item of the FIM addresses bowel function from a functional independence perspective (the item is summarized in Appendix T). This approach has the advantage of combining the distinct but co-occurring dysfunctions of constipation and fecal incontinence in one measure[25]. However the item has been criticized as measuring a different construct than the rest of the FIM motor domain, compromising its factor structure (Dallmeijer et al., 2005; Kucukdeveci, Yavuzer, Elhan, Sonel, & Tennant, 2001). Lundgren-Nilsson et al. (2005) found that on this item, the 7-point FIM scale measure only validly distinguished three functional categories.

From a patient-centered perspective, the FIM item shows poor sensitivity to important differences in patient experience. For example, the item would yield an identical score for two very different patients: one having daily bowel movements with the use of one laxative medication, and another patient having one bowel movement per week with four laxatives and self-administered enema. Because neither requires hands-on assistance, both are given a score of 6 indicating ‘modified independence’.

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[25] Fecal incontinence in the inpatient setting is often a side effect of treatment for constipation, but is not reflected in constipation measures.

For the new instrument used in this study, the phenomenon of interest was defined as the ‘normal bowel day’, one in which the patient (1) moved her bowels, (2) at will and (3) without mechanical intervention. The three points of this patient-centered definition reflected the physical and psychological discomforts of constipation, fecal incontinence, and mechanical manipulation respectively. Rather than attempting to separate or weight these interrelated factors, the measure simply calculates the proportion of ‘good bowel days’ experienced over a 5-day period. This new measure is thus continuous rather than ordinal, and evaluates the ICF domain of ‘body’ rather than ‘function’.

5.3.2.4 Modified Rankin Handicap Scale (mRS)

The Rankin Handicap scale is a global measure of post-stroke disability, as is the FIM described above. It predates the FIM, but is still widely used in clinical research for its brevity, reliability, and high content and construct validity (Salter et al., 2005). In January 2015, reporting of mRS at 90-day follow-up became mandatory for designated Comprehensive Stroke Centers (Joint Commission, 2014). The mRS is a gross assessment of disability, originally ranging from 0 (no functional deficits) to 5 (bedridden and unable to engage in self-care). It is currently used in modified form, with a score of 6 added to indicate that the patient is deceased (Farrell, Godwin, Richards, & Warlow, 1991).

Each point on the mRS represents a clinically significant difference, meaning that it may not be sensitive to small treatment effects. Paradoxically however, it has been suggested that the scale is more statistically sensitive to clinical changes perceived as meaningful by patients than finer-grained ADL measurements such as the Barthel Index (Banks & Marotta, 2007b). The mRS has greatest inter-rater reliability when administered by structured interview (Wilson et al., 2005), and a recent study validates use of the structured interview via telephone, with weighted kappa of 0.71 (95% CI 0.59–0.82) (Janssen et al., 2010).

In this study, the mRS is used to assess gross level of disability post discharge. A 2008 post-stroke acupuncture study which found no significant difference in Barthel's Index scores did find more patients living at home (versus dead or institutionalized) on 12-month follow-up, suggesting that acupuncture may possibly confer long-term systemic benefit to which ADL and motor impairment instruments are not sensitive (Hopwood et al., 2008). As discussed above in Chapter 4, this study's treatment protocol is more systemically oriented than that of many previous trials, including Hopwood's. 12-month follow-up is not feasible for this academic project, but 6-month follow-up should indicate whether any theorized systemic effect is measureable with the mRS and should be addressed in future study designs.

The mRS at its lower levels (5, 4, 3) is closely related to the FIM independence levels. These are presented in Appendix U. Kwon et al. (2004) have suggested that statistical conversion of FIM to mRS scores is most reliable for the categories of 5, 4 and '3 or more'. (Patients scoring above 3 are not generally admitted to acute rehabilitation facilities). For this study, mRS at baseline was estimated from the FIM using the principles specified in Appendix U, by a PT manager (Dr. Enza Navarra). Dr. Navarra had no other relationship to the study and was blind to group assignment.

5.3.3 Data Collection and Management

Data was collected by the investigator and research assistants from both paper charts and electronic medical records, as the unit was in transition between the two systems during the study period. Depersonalized data were transferred from raw data collection sheets to master data collection sheets by a research assistant. To ensure accuracy two research assistants performed double data entry, one working from raw sheets and one from master sheets. Paper and electronic documents containing identifying information were stored or disposed of following LMC's document retention policy. Depersonalized electronic data remain available for data sharing by other investigators. Specific measures taken to ensure data quality and security are described below.

5.3.3.1 Patient Assessment

Timing and method of the outcome assessments used in this study is shown in Table 5.2. All but two outcomes were assessed by LMC personnel with data collected from paper charts or electronic medical records (the hospital was in transition between the two systems at the time of the study). The Ham-D and mRS for 6-month follow-up were administered by study research associates.

Table 5.2: Timing and Method of Outcome Assessments

Measure	At Baseline	At Discharge	At 6-month Follow-up	Assessment Method	Assessor(s)	Work Flow	Completeness of Data
Functional Independence Measure	X	X		Criterion-based performance assessment	LMC Physical, Occupational & Speech Therapists; Nurses	Routine	98%
Fugl-Meyer Upper Extremity Assessment (FM-UE)	X	X	X	Scored task completion	LMC Physical Therapist, volunteer	Addition to Routine	0%
Montral Cognitive Assessment (MoCA)	X	X		Scored task completion	LMC Neuropsychology Fellow, volunteer	Alternative to Routine	14%
Cognistat						Expansion of Routine (normally as-needed)	8%
Hamilton Depression Rating Scale (Ham-D)		X	X	Semi-structured interview	Research Associate (D.Psych), volunteer	1 x week	49% (discharge) 4% (6-month)
National Dysphagia Diet Level	X	X		Imaging (barium swallow or endoscopy); clinical assessment	LMC Speech/Swallowing Therapists	Routine	94%
Bowel Function index	X	X		Nursing log: observation or inquiry	LMC Nurse	Routine	94%
Sleep Log	X	X		Nursing log: hourly observation	LMC Nurse	Expansion of Routine (normally as-needed)	79%
Modified Rankin Scale (mRS) (follow-up)	Calculated from FIM score		X	Telephone Interview	Research Associate	3 x week	54%

Table 5.2: Timing and Method of Outcome Assessments

5.3.3.2 Collection of Raw Data

Three methods of data collection were used: extraction from LMC paper charts; extraction from LMC electronic medical records (EMR); and interview by Research Associate. These categories are described separately below.

5.3.3.2.1 Extraction from paper documents

The FIM is routinely assessed at LMC by physical, occupational and speech/swallowing therapists and nursing staff; scores are recorded daily in each service's charting materials and tallied for weekly reassessment in a Team Conference binder. These weekly scores are entered by the Rehabilitation Department's administrator into the Unified Data System™ (UDS™) data management system. On patient discharge, a copy of the system's summary sheet for the patient stay was printed out by a research assistant and stripped of personal information so that it could be used as the raw data collection sheet.

The Bowel Function Index was calculated on its own raw data collection sheet using information collected from the Nursing section of the patient's paper chart. On patient recruitment and in the week prior to discharge, incidence and continence of bowel activity were extracted from the chart and score calculated as described above (section 5.3.2).

The Sleep Log is a preexisting LMC document available for use as needed within the nurse's per-patient paperwork binder. It was placed in the Nursing chart for four nights for each patient in the study. A research assistant retrieved it from the nursing chart, removed identifying information and placed in the study data folder as a raw data collection sheet.

MoCA and Cognistat assessments were performed by Dr. Martha Pham of the hospital's Neuropsychology team. A research assistant photocopied the original score sheet (masking or cutting off identifying information) which then served as the raw data sheet.

5.3.3.2.2 Extraction from Electronic Medical Records

Baseline clinical and demographic information were extracted from the patient's electronic medical record directly into raw data collection sheets by research assistants. Dysphagia diet level at baseline and discharge was also extracted directly from the electronic medical record.

5.3.3.2.3 Assessment by study personnel

The HamD and modified Rankin Scale were assessed by study personnel. For both measurements, the score sheet completed by the practitioner during assessment was stripped of identifying information (if any) and retained as the raw data collection sheet.

5.3.3.3 Data entry

Initial data entry from master data sheets was conducted by two research assistants during the research and data collection period. Double data entry from the raw data collection sheets was performed by a third research assistant after discharge of the last patient. Seven discrepancies were identified and rectified by comparison with the data source (four from paper documents and three from the electronic medical record.

5.3.3.4 Storage and disposition of study data

5.3.3.4.1 Paper records

All paper records relating the study, other than consent forms, are identified only by study ID number and contain no personal information. Consent forms remain secured in a locked file cabinet in the LMC Research Office. As per LMC protocol they are retained for five years, along with all study protocols, amendments and yearly reports; they are then destroyed.

5.3.3.4.2 Electronic data

Depersonalized data remains in an Excel spreadsheet on the hospital's password-protected secure server. All hospital computers have their external drives and USB ports disabled to prevent theft of personal health information. Email from the hospital is closely monitored; unknown recipients of files with attachments are required to register with the hospital's firewall service before delivery is completed. The study ID key linking patient names with study ID numbers was further encrypted for access only by the investigator and was deleted after completion of all study follow-up.

5.3.3.4.3 Retention of de-identified data

De-identified quantitative data remains in an Excel spreadsheet on the hospital's secure server, and in the investigator's personal computer in SPSS Version 21 (originally Statistical Package for the Social Sciences). Depersonalized text data remains in Word and in an account on Dedoose™, an online service for qualitative and mixed methods analysis which is both password protected and encrypted per project. All data is available for sharing for research purposes.

5.3.3.5 Quality Control

Quality control is integral to research at Lutheran Medical Center, where studies are routinely conducted by medical residents and students, and data entry by volunteer research assistants. Specific quality control procedures included the following:

- Data Collection: from paper or electronic source to Master Data Collection Sheet. Three of the first 10 patient records and one of each 10 thereafter, selected at random, were spot-checked by Laura Gabbe MS, L.Ac. (Clinical Research Grants Manager).
- Data Entry: Double data entry was used. One research assistant entered data from the raw data collection sheets while a second assistant entered data from the master data collection sheets.
- Data Analysis. Ms. Citkovitz submitted a printout of analyses run and results obtained to Dr. Indelicato for supervision.
- Data Interpretation. Ms. Citkovitz submitted a preliminary report specifying interpretation of each analysis to Dr. Indelicato and to Kell Julliard, ATR-BC, the hospital's Assistant Vice President for Clinical Research for supervision and further discussion.

5.3.4 Amendments to and Deviations from Planned Study Protocol

5.3.4.1 Study Amendments

The following changes were made to the study protocol in an amendment approved by Lutheran Medical Center's Institutional Review Board on 4 and 16 December 2013, and by the University of Westminster's Ethics Board on 25 March, 2014. The approved amendments are attached as Appendices K and L respectively. Explanatory text from the amendment is reproduced below:

1. Diffusion Tensor Imaging (DTI). LMC's capability to perform DTI has not yet become available as previously envisioned. As an interim surrogate measure to provide Mild, Moderate and Severe groups for analysis, total FIM score at baseline will be divided into top, bottom and the two central quartiles to make 3 unequal groups. Should DTI scores become available, all analyses will be re-run at that time and included in the primary paper or submitted for separate publication as appropriate.
2. Fugl-Meyer Assessment (FMA). The Physical Therapist who originally volunteered to perform the FMA has resigned from LMC and no replacement has been found. For 6-month follow-up purposes, the Modified Rankin Score will be substituted at discharge (calculated from FIM score) and at 6 months (obtained by telephone interview).
3. Montreal Cognitive Assessment (MoCA). The Neuropsychology team had initially agreed to administer the MoCA in place of the Cognistat which is their standard. After two incidents in which confusion over which test to administer led to collection of unusable data, they returned to collecting the Cognistat. Once this amendment is approved, we will retrospectively collect Cognistat data and use it in place of the MoCA for assessment purposes.
4. Feasibility Assessment. To the project's four Aims I have added a fifth, exploring feasibility of future study. It is as follows:
    a. Explore feasibility of future trials with respect to primary and secondary outcome measures, with feasibility defined as:

i. Overall, number of withdrawals from acupuncture treatment and
ii. Number of adverse events or stakeholder perceptions of harm, discomfort or inconvenience
iii. For each outcome measure, completeness of data for each outcome measure and
iv. Rate of recruitment in relation to sample size calculation for future study

5.4 Statistical Methods

5.4.1 Programs Used

All quantitative data management and analysis was conducted by the investigator on SPSS version 21 (IBM-Corporation, 2012). Consultation on statistical methods was provided by Dr. Joseph Indelicato.

5.4.2 Data Cleaning

For each variable used in the study, mean/median, range and frequency tables were printed and examined for erroneous values. Histograms were also examined for each variable. Scatterplots were also run and examined to check for anomalous bivariate values.

5.4.3 Study Population

Basic sociodemographic and clinical characteristics including gender, age, race, ethnicity, and hand dominance in relation to lesion side are summarized in Table 5.3. They are reported as percentages for nominal variables and means with standard deviation for continuous variables. Patient characteristics potentially relevant to prognosis for stroke recovery include age and severity of motor and cognitive impairment at baseline. Additional clinical characteristics thought to be relevant to the course of rehabilitation include, side of lesion in relation to hand dominance, presence of aphasia or neglect syndromes, and body mass index (BMI). Social characteristics thought to affect attitudes toward acupuncture include Chinese ethnicity, age and gender. Finally, characteristics of hospital care potentially affecting course of recovery include use of interpreter and length of stay. These were reported as percentages for nominal variables and means with standard deviation for continuous variables, along with p-value for the difference calculated using Fisher's Exact Test for nominal and ordinal variables and the Mann-Whitney U-test for continuous variables. These data were collected from the patient's EMR by a research assistant at the time of recruitment.

For all outcome measures, median differences at baseline were reported and 95% confidence intervals were calculated using the Mann-Whitney U-test. A non-parametric test was used due to the ordinal data provided by the clinical outcome measures used, and also due to the high likelihood of non-normal distribution in a small sample (Armitage, Berry, & Matthews, 2001).

Additional clinical characteristics thought to be relevant to long-term morbidity and mortality were collected for possible post-hoc use but not included in the primary analysis. These include diagnoses of congestive heart failure, atrial fibrillation, hypercholesterolemia and diabetes mellitus; also use of blood thinning medications in anticipation of any concerns regarding adverse events.

5.4.4 Primary Endpoint: Improvement on Functional Independence Measure

For this aim the change from baseline to discharge was calculated for each patient, and the Mann-Whitney U-test was used to compare change between acupuncture and usual care groups. Group medians and interquartile range at baseline and discharge were reported, along with median change, Cohen's d and 95% confidence interval.

5.4.5 Secondary endpoints: Motor and Non-Motor Outcome Measures by Severity

Aim 3 of this study was to explore possible differences in apparent acupuncture effect, between patients at differing severity levels, on motor- and non-motor-related outcomes measures. The question was addressed whether differences observed comparing acupuncture and usual care alone might be (A) larger in the moderate group than in the mild and severe groups for motor-related outcome measures, and (B) smaller in the mild group than the moderate and severe groups for non-motor-related outcomes. This question was explored in several steps for each relevant outcome measure[26].

First, the file was split into mild, moderate and severe groups for motor and non-motor impairment using the FIM subscales. Two new grouping variables were created based on quartile values for the FIM motor and non-motor domain scores respectively, with “Severe” as the bottom quartile, “Mild” as the top quartile and “Moderate” as the two central quartiles.

Second, for each motor and non-motor outcome measure, change from baseline to discharge was compared between acupuncture and usual care groups using the Mann-Whitney U-test, for the entire cohorts and then within the severity groups described above. Patients with incomplete baseline and follow-up data for given outcome measures were excluded from analysis for that outcome only. Median value and interquartile range of acupuncture and usual care groups were reported for each outcome measure and severity group, along with median difference from baseline to discharge, Cohen’s d and 95% confidence intervals.

Third, Cohen’s d was calculated for all the outcomes reported above. G*Power software (Faul, 2007) was used to divide the mean difference by the pooled standard deviation of the acupuncture and usual care groups.

[26] Motor outcomes include: FIM motor domain; bowel function index; and dysphagia level. Non-motor outcomes include: FIM cognitive domain and sleep log. Non-parametric statistics were used for primary evaluation of outcome measures due to the small size and heterogeneity of the groups; however parametric statistics were also used to calculate and compare sample sizes for future study.

5.4.6 Feasibility Assessment

Aim 5 of this study was: to explore feasibility of future trials with respect to primary and secondary outcome measures, with feasibility defined as:

1. Overall, number of withdrawals from acupuncture treatment and
2. Number of adverse events or stakeholder perceptions of harm, discomfort or inconvenience
3. For each outcome measure, completeness of data for each outcome measure and
4. Rate of recruitment in relation to sample size calculation for future study

The following criteria were used to define feasibility:

1. Withdrawals: fewer than 25%
2. Adverse event reports and patient and staff perceptions of harm or discomfort are found to be within acceptable limits
3. For a given outcome measure, data is complete for at least 75% of patients enrolled
4. For a given outcome measure, rate of recruitment is sufficient in relation to sample size calculation to allow completion of a trial within 2 years

Statistical calculations were not required for item 2. Items 1 and 3 were calculated directly from the number of withdrawals and number of patients providing complete data.

For Item 4, sample size for future study was calculated for each outcome using G*Power software (Faul, 2007) assuming α=0.05, 90% power using the Mann-Whitney U-test. The effect sizes for these calculations were derived by defining a clinically meaningful difference sought (discussed below), which was then divided by the standard deviation for improvement on that outcome measure found in this study population. For the mRS, ½ point was selected as representing the smallest difference likely to be meaningful to patients on a 7-point scale, as suggested by Guyatt et al.

(Guyatt, Juniper, Walter, Griffith, & Goldstein, 1998). For the unscaled sleep log, a change of 12% of mean at baseline (0.8 hours per night) was selected as representing a meaningful change in a rehabilitation outcome, as suggested by Angst et al. (2001). (This calculation was made additionally assuming that patients sleeping 9 or more hours per night should be excluded in future). For the newly constructed bowel function index where baseline was near zero, a change of 1 point on the scale was selected as best representing the original phenomenon of interest, a day of good bowel function.

The second part of item 4 was an estimation of time required complete a study at LMC assuming identical methods and rate of recruitment. For each outcome measure, the projected N was divided by this study's yield of complete data sets per year. Complete data sets were those containing valid data for both initial and final endpoints..

5.4.7 Missing data and loss to follow-up

In keeping with the exploratory nature of a feasibility study, a large number of outcomes were assessed and no measures were taken to estimate missing values (Polit & Beck, 2004). Four outcome measures (the FM-UE, Ham-D, Cognistat and MoCA) are reported in an appendix (Appendix J) rather than the main body of the study because they returned complete data for fewer than 20% of study patients.

5.4.8 Potential Sources of Bias

Multiple sources of potential bias exist in this exploratory cohort study of a complex treatment in a heterogeneous population. They are discussed below along with approaches to mitigation.

5.4.8.1 Selection Bias

As a self-selected cohort, patients consenting to acupuncture treatment must be assumed to differ from patients declining treatment (Chalmers, Celano, Sacks, & Smith, 1983). Differences in physical patient characteristics such as age and severity of illness were addressed during the data screening process. However, it is a limitation of this study that there was no screen at baseline for attitudinal differences or – importantly – previous experience with acupuncture.

5.4.8.2 Performance Bias

In this cohort study no attempt was made to ensure consistency of usual care between treatment groups by blinding therapists and other rehabilitation unit staff to treatment condition. On the contrary, they were asked to report on their perceptions of acupuncture effect, for those patients in whom they were aware that the treatment had been given. As a result, differences in delivery of usual care between acupuncture and non-acupuncture patients cannot be ruled out. However, given the large number of therapists and nurses for each patient and the large number of factors affecting work flow for each therapist, performance bias is of less concern than other sources of bias described above and below.

5.4.8.3 Exclusion Bias

Several sources of potential exclusion bias exist. Patients may be discharged early from the acute rehabilitation unit for medical or financial reasons, resulting in loss to follow-up on some outcome measures. Loss to follow-up at 6 months will also be unequally distributed based on financial and medical factors, and may be greater among more severely affected patients due to poor mobility. There is no reason to anticipate that the above factors will affect one treatment group more than the other, but in this small sample with non-random group allocation distribution may well be asymmetrical.

Additionally, It was expected that without additional compensation for 6-month follow-up, a larger number of acupuncture patients than non-acupuncture patients would be willing to make appointments for reassessment.

5.4.8.4 Combination of Researcher and Practitioner Roles

Considerable debate exists as to whether the integration of clinician and researcher roles is advisable (Yanos et al., 2006), or even possible (Miller et al., 2003). For this unfunded trial it has been necessary, but it is important to examine potential negative impact on the project and possible mitigating strategies.

Advocates of clinician-led research argue that without it clinical research would stagnate: practitioners generate innovative questions rooted in experience of actual problems encountered in health care delivery, and they are able to carry results back from the evidence basis to living practice (Malterud, 2001). However, it is widely agreed that when a clinician researcher combines both roles in a single study, conflict of interest is inevitable. Patients may be intentionally or unintentionally misled: the 'therapeutic misperception' arises when patients fail to understand that scientific advancement, rather than their individual well-being, is the primary goal of the trial (Appelbaum, Roth, Lidz, Benson, & Winslade, 1987). Conversely methodological rigor may suffer, either because of deficiencies in the clinician's research training (Yanos & Ziedonis, 2006), or because of a reciprocal therapeutic misconception on the part of the researcher where study design is compromised in favor of individual patient care (Miller & Brody, 2003).

For this project, use of a concurrent cohort design has greatly reduced the opportunity for the therapeutic misperception and associated problems, relative to a randomized study. Patients have not consented to experimental treatment, but only to data gathering after practitioners have conducted a regularly available hospital service with no scientific agenda superseding that of optimal patient care. Practitioners made use of the clinical manual but were not limited by it. This choice has prioritized clinician beneficence over internal validity, and there has been a corresponding loss of power: no robust statistical conclusions can be drawn about effects of the intervention.

5.5 Results of Concurrent Cohort Study

5.5.1 Baseline Patient Characteristics and Group Equivalence

Forty-eight patients were recruited for the study: 25 elected to receive acupuncture therapy and 23 elected usual care only. Their sociodemograpic and clinical characteristics are reported in Table 5.3.

The patient population was diverse demographically and clinically. Age ranged widely from 42 to 87. Only 50% of study patients were Caucasian, with more patients identifying as nonwhite in the acupuncture group (60% versus 39%). More patients in the acupuncture group identified as racially and ethnically Chinese (24% versus 4%), and more patients in the acupuncture group required use of an interpreter (34% versus 13%). The study included more women than men, although the distribution between groups did not differ greatly with 15 women (60%) in the acupuncture group and 13 (56.5%) in the usual care group. Distribution of lesion side and associated syndromes varied between groups. More patients in the acupuncture group had right-side lesions (52% vs 26%). Five patients in the acupuncture group (20%) presented with neglect syndrome, versus 0 in the usual care group. Five patients in the acupuncture group (20%) were aphasic at baseline, versus one patient (4%) in the usual care group. Dominant hand was also asymmetrically distributed, with all 4 of the left-handed patients in the usual care group (17%). Length of stay was greater in the acupuncture group: mean 24.8 days (SD 9.7) versus 20.6 days (SD 8.1).

Table 5.3 Baseline Sociodemographic and Clinical Characteristics of Patients Enrolled

Characteristic**	All Patients* (N=48)	Acupuncture group (n= 25)	Usual Care group (n= 23)	P-Value (sig. = .05)	Group favored
Age	68.7 (12.3)	68.8 (12.5)	68.4 (12.4)	0.91	
Gender				0.81	
Female	28 (58.3)	15 (60)	13 (56.5)		
Male	20 (41.7)	10 (40)	10 (43.5)		
Use of Interpreter	11 (22.9)	8 (32)	3 (13)	0.17	Usual care
Race				0.26	
Caucasian	24 (50)	10 (40)	14 (60.9)		
Asian Chinese	7 (14.6)	6 (24)	1 (4.3)		
African American	3 (6.3)	2 (8)	1 (4.3)		
Other or Unknown	8 (16.1)	5 (20)	3 (13)		
Ethnicity				0.12	(not clinically significant)
Hispanic	7 (14.6)	3 (12)	4 (17.4)		
Chinese	7 (14.6)	6 (24)	1 (4.3)		
Russian	2 (4.2)	2 (8)	0		
Arabic	1 (2.1)	0	1 (4.3)		
Other or Unknown	31 (64.6)	14 (56)	17 (73.9)		
BMI (N=46, 24:22)	26.8 (6.5)	26.4 (6.5)	27.1 (8.5)	0.58	
Dominant hand					
Right	43 (89.6)	24 (96)	19 (82.6)		
Left	4 (8.3)	0	4 (17.4)	**0.046**	(not clinically significant)
Mixed or unknown	1 (2.1)	1 (4)	0		
Side of Lesion				0.17	(mixed clinical significance)
Right	19 (39.6)	13 (52)	6 (26.1)		
Left	25 (52.1)	11 (44)	14 (60.9)		
Bilateral	4 (8.3)	1 (4)	3 (13)		
Aphasia	6 (12.5)	5	1	0.1	Usual care
Neglect	5 (10.4)	5	0	**0.028**	**Usual care**
Concordance	27 (56.3)	14 (56)	13 (56.5)	0.56	
Days post stroke at recruitment	4.5 (1.7)	4.1 (1.5)	4.8 (1.9)	0.46	
LOS (N=47, 24:23)		24.8 (9.7)	20.6 (8.1)	0.36	

**Scale variables are reported as Mean (SD); dichotomous variables are reported as n (% of N)

*N=48 unless otherwise specified

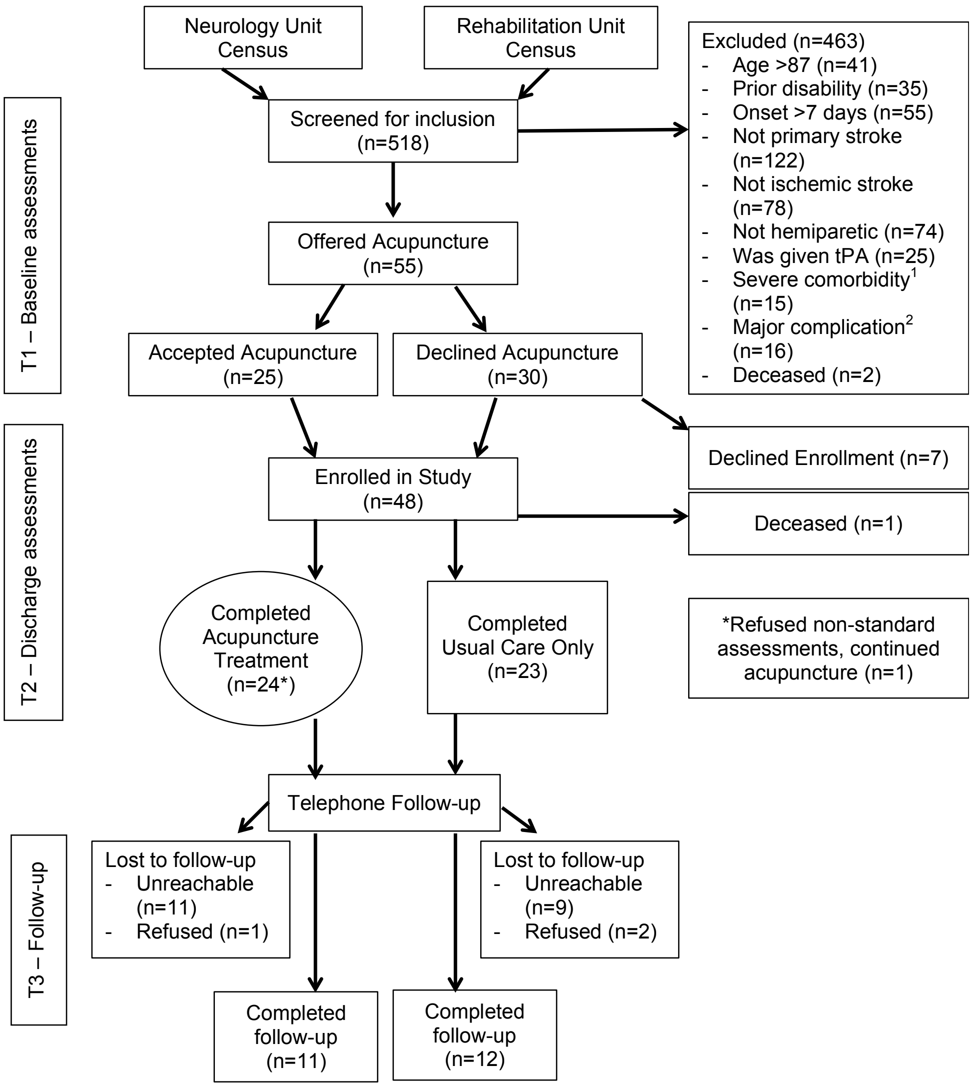
Table 5.3 Baseline Sociodemographic and Clinical Characteristics of Patients Enrolled

5.5.2 Withdrawals and Loss to Follow-Up

Patient recruitment and attrition are summarized in Figure 5.2. One patient in the acupuncture group withdrew from the study. A second patient died after her family had signed the informed consent form but before baseline assessment was conducted.

21 patients were lost to six-month follow-up. Patients were considered lost to follow up after 6 telephone calls placed over a minimum of 30 days' time resulting in either unanswered messages or inability to leave a message (no voicemail, termination of service recording, etc.).

Figure 5.2: Flowchart of Patient Recruitment and Attrition



1. Severe progressive illness including: Carcinoma, COPD, ALS,MS, Parkinson's disease, Alzheimer's disease
2. Any complication requiring readmission to Surgical ICU, Medical ICU or Medicine floor

Figure 5.2: Flowchart of Patient Recruitment and Attrition

5.5.3 Outcomes

5.5.3.1 Primary endpoint: Improvement on Functional Independence Measure

There were no significant differences between acupuncture and usual care groups at baseline or follow-up, nor on amount of improvement. Baseline scores and improvement from baseline to discharge were slightly greater in the acupuncture group, though the interquartile range was lower at baseline. Median improvement in the acupuncture group was 37.5 (interquartile range or *IQR* 28-41.75) versus 35 in the usual care group (*IQR* 32-45). Baseline, discharge and improvement for the two groups are shown in Figure 5.3.

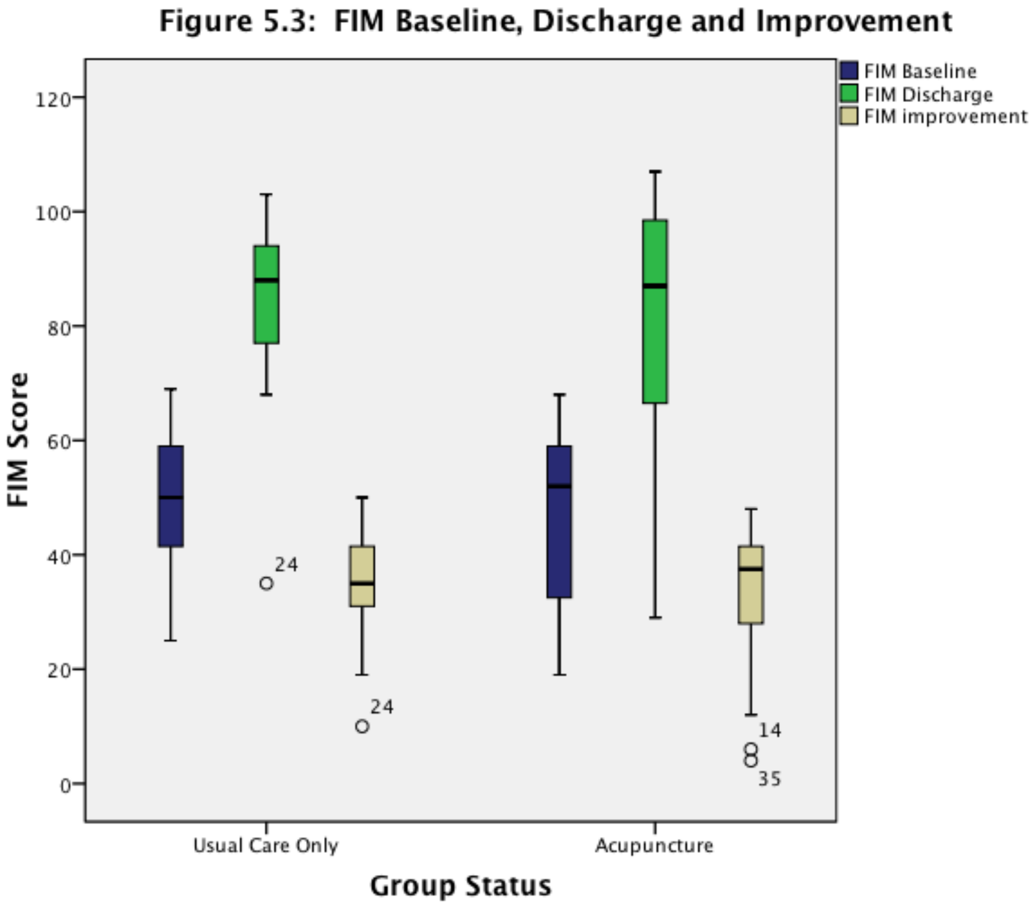


Figure 5.3: FIM Baseline, Discharge, and Improvement

5.5.3.2 *Secondary endpoints: Exploring Motor and Non-Motor Outcome Measures across Severity Groups*

To explore the relationship of stroke severity to motor and non-motor outcomes, Cohen's d was calculated for mild, moderate and severe subgroups. Mild and severe subgroups constituted the top and bottom quartile on the appropriate FIM domain respectively, while the moderate subgroup was the two central quartiles. Treatment-group differences by severity subgroup are shown in Table 5.4. On the FIM motor domain, within the Moderate subgroup, mean gain in the acupuncture group was 37 points (*IQR* = 32.25-40.5), versus 32 (*IQR* = 27-36.5) in the usual care group, Cohen's *d* = 0.66, 95% CI [-10, 1]. Improvement in the dysphagia index was similar across treatment conditions for all severities. For bowel function, improvement trended greater in the acupuncture group across all three severity subgroups, with a median change of 2 points (*IQR* 0-3), versus 0 (*IQR* 0.75-2) in the usual care group (Cohen's *d* = 0.73); 95% CI [-2, 0]. Among subgroups, Cohen's *d* for the Mild subgroup (0.89) was greater than that for the Moderate subgroup (0.55) or Severe subgroup (0.27). No patient scored the top score at baseline. However, nine patients began and ended the study with scores of zero, implying a floor effect.

Within non-motor outcomes, FIM cognitive gain was similar between treatment conditions in all three subgroups. A trend towards greater improvement in sleep in the acupuncture group was greatest in the Mild subgroup, with a median improvement of 1 hour (*IQR* -0.75-1.63) in the acupuncture group and a median <u>decrease</u> in the usual care group of 1 hour (*IQR* -1.5-0) (Cohen's *d* = 1.15); 95% CI [-3, 1].

Table 5.4: Motor and Non-Motor Effect Sizes in Mild, Moderate and Severe Subgroups

		OUTCOME	TOTAL N (%)	USUAL CARE GROUP n (%)	USUAL CARE GROUP Median at Baseline [IQR]	USUAL CARE GROUP Median Change [IQR]	ACUPUNCTURE GROUP n (%)	ACUPUNCTURE GROUP Median at Baseline [IQR]	ACUPUNCTURE GROUP Median Change [IQR]	Difference in Medians	Confidence Interval (95%)	Cohen's *d*	Cohort favored
ALL SEVERITIES		FIM			50 [40-59]	35 [30-42]		52 [30.75-59]	37.5 [28-41.8]	2.50	[-6, 6]	-0.083	acu
		Motor	47 (98)	23 (100)	29 [24-39]	30 [26-34]	24 (96)	28 [18.25-36.75]	30.5 [23.8-38.8]	0.50	[-6, 5]	-0.078	-
		Cognitive			19 [15-21]	5 [3-6]		20 [12.25-22.75]	4.5 [2.25-6.75]	0.50	[-2, 2]	0.017	-
		Sleep	38 (79)	19 (83)	7 [5.5-7.8]	0 [-0.5-1]	19 (79)	7 [6-8]	1 [-0.5-1.5]	1.00	[-0.5, 1.5]	0.54	acu
		Swallowing	45 (94)	21 (91)	6 [4-6]	0.5 [0-1]	24 (96)	4.5 [4-6.75]	0 [0-1]	0.50	[0, 1]	0.042	-
		Bowel Index	45 (94)	22 (96)	1 [0-2]	0 [0.75-2]	23 (92)	0 [0-12.5]	2 [0-3]	2.00	[-2, 0]	0.73	acu
		mRS (disch)	47 (98)	23 (100)	4 [4-5]	3 [2-3]	24 (98)	5[4-5]	3[2-3]	0.00	[0, 0]	0.08	-
		mRS (6 mos)	23 (49)	12 (49)	4 [4-5]	1 [0-2]	11 (46)	5[4-5]	2 [1-2]	1.00	[-2, 0]	0.76	acu
MOTOR	SEVERE	FIM Motor	12 (25)	3 (13)*	15 [15-15]	27 [9-27]	9 (36)	18 [14-19.5]	18 [6.5-35.5]	9	[-22, 30]	-0.24	usu care
		Swallowing	12 (25)	3 (13)*	4 [0-4]	0 [0-0]	9 (36)	4 [0.5-4.5]	0 [0-1]	0.00	[-1, 2]	0.15	-
		Bowel	11 (23)	3 (13)*	0 [0-0]	0 [0-2]	8 (32)	0 [0-0.75]	2 [0.75-3.75]	0.00	[-3, 2]	0.27	-
	MOD.	FIM Motor	22 (46)	12 (52)	26.5 [24-30.5]	32 [27-36.5]	10 (40)	31.5 [25.5-35.3]	37 [32.25-40.5]	5	[-10, 1]	0.66	acu
		Swallowing	20 (42)	10 (43)	5 [3.75-6.25]	0 [-0.25-2]	10 (40)	6 [4.75-7]	.5 [0-1]	0.50	[-1, 1]	-0.076	-
		Bowel	21 (44)	11 (48)	1.5 [0-2]	0 [-1-1]	10 (40)	1 [0.5-2]	1[-0.5-3]	1.00	[-3, 1]	0.28	acu
	MILD	FIM Motor	13 (27)	8 (35)	41 [38.3-47.5]	29.5 [20.8-33.8]	5 (20)	45 [39.5-47.5]	29 [25.5-30.5]	0.5	[-9, 6]	0.04	-
		Swallowing	12 (25)	7 (30)	6 [6-6.75]	1 [0-1]	5 (20)	4 [3.5-7]	0 [0-2]	1.00	[-2, 1]	0.099	-
		Bowel	13 (27)	8 (35)	1 [0-2]	0 [-0.75-1]	5 (20)	0 [0-1]	2 [-0.5-4]	2.00	[-4, 1]	0.89	acu
NON-MOTOR	SEVERE	FIM Cognitive	11 (23)	4 (17)	11.5 [10-13.8]	5.5 [2-9]	7 (28)	9 [5-12]	5 [2-5]	0.50	[-5, 6]	0.10	-
		Sleep	8 (17)	4 (17)	7 [5.88-8.5]	0 [-0.38-0.75]	4 (17)	8.5 [6.75-10.5]	0.25 [-1.25-1.38]	0.25	[-1.5, 1.5]	0.00	-
	MOD.	FIM Cognitive	25 (52)	15 (65)	19 [18-20]	4 [3-6]	10 (40)	20 [18.75-21]	5.5 [3.75-9]	1.50	[-4, 2]	0.15	-
		Sleep	21 (44)	12 (57)	7.5 [5.25-7.75]	0.25 [-0.5-1.38]	9 (36)	7 [5.5-7.75]	1 [0.25-1.18]	0.75	[-2, 0.5]	0.61	acu
	MILD	FIM Cognitive	11 (23)	4 (17)	22 [22-23.5]	3 [0.25-5]	7 (28)	24 [23-27]	3 [2-4]	0.00	[-3, 3]	0.02	-
		Sleep	9 (24)	3 (33)	7 [5.5-7.75]	-1 [-1.5-0]	6 (67)	6.5[6-7]	1 [-0.5-1.63]	2.00	[-3, 1]	1.15	acu

Table 5.4: Motor and Non-Motor Outcome Effect Sizes in Mild, Moderate and Severe Subgroups

5.5.3.3 Feasibility Assessment

For this study feasibility was defined as follows:

1. Fewer than 25% of patients withdraw from the trial
2. Adverse event reports and patient and staff perceptions of harm or discomfort are found to be within acceptable limits
3. For a given outcome measure, data is complete for at least 75% of patients enrolled
4. For a given outcome measure, rate of recruitment is sufficient in relation to sample size calculation to allow completion of a trial within 2 years

Criteria for Points 1 and 2 were met, with only two patients (4%) withdrawing from the study. The first withdrawing patient continued to receive acupuncture and withdrew only from data collection, as she was unwilling to undergo non-essential interviews via translation telephone device. The second suffered a fatal pulmonary embolism after her family had signed informed consent but before baseline evaluation or any study procedures began. This adverse event was not in any way related to the study or its procedures. No other adverse events were reported within the study population. None of the staff or family surveys reported observation of any discomfort or negative effects associated with acupuncture. When asked specifically whether the needles hurt, two patients responded ‘a little’ and the rest of those interviewed responded that they did not.

For Point 3, four measures met the 75% threshold for data completeness. These were the FIM (including motor and cognitive domains); the sleep log, the swallowing assessment and the bowel function index. The mRS on 6-month follow-up yielded only 49% complete data. In addition, four outcome measures yielded few complete data sets and are discussed in Appendix Appendix J. These are the Hamilton Depression Scale (Ham-D), the Fugl-Meyer Upper Extremity Assessment (FM-UE), the Neurobehavioral Cognitive Exam (Cognistat) and the Montreal Cognitive Assessment (MoCA). Logistical challenges encountered in the administration of these outcome assessments are described in the discussion of feasibility, Section 5.6.7.

For Point 4, Table 5.5 shows sample size calculations for all outcome measures that favored the acupuncture group with Cohen's d >0.2. The time was estimated to complete a study assuming similar recruitment rates and completeness of data.

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Table 5.5: Sample Sizes and Estimated Completion Times for Future Study

OUTCOME MEASURE	N (% of 48)	Mean difference found	SD (this study)	Group Favored (d >0.2)	Future Difference sought	Projected N	Estimated Time (years)
FIM	47 (98)	-0.90	10.80				
Motor Domain		-0.78	10.00				
Cognitive Domain		0.054	3.04				
Sleep Log*	33 (69)*	0.83*	1.11*	Acu	0.80	72	1.80
Swallowing	45 (94)	0.05	1.17				
Bowel Index	45 (94)	1.27	1.74	Acu	1 point	138	4.90
mRankin (6-mo)	23 (49)	0.82	1.08	Acu	1/2 point	172	7.37

* Excluding patients sleeping 9 or more hours per night, calculated post hoc

Table 5.5: Sample Sizes and Estimated Completion Times for Future Study

Assuming identical study methods, a fully powered study of the mRS and bowel function were not feasible (taking 7.37 and 4.9 years respectively). A study of the sleep log could be completed in 1.8 years, assuming exclusion of patients sleeping 9 or more hours per night at baseline[27].

5.5.3.4 Additional Findings

As discussed above and in Section 5.5.1, the patients in these non-random, self-selected groups differed at baseline, though these differences did not reach statistical significance on any of the study's outcome measures. mRS scores trended lower at baseline, and FIM Interquartile range was wider and lower in the Acupuncture group, though the median

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[27] As discussed below (Section 5.6.3), failure to exclude hypersomnolent patients was an oversight in the addition of this new outcome measure

was slightly higher: 30.75-59 (*Mdn* = 52), versus 40-59 (*Mdn* = 50) in the usual care group; see figure 5.3. The FIM Motor subscale accounts for most of the difference in IQR between groups, with the acupuncture group skewing lower than the usual care group (see figure 5.5). Conversely the FIM non-motor subscale accounts for much of the variability within the acupuncture group (see figure 5.6). Accordingly in subgroup analysis, acupuncture patients accounted for 9 of 12 (75%) in the 'motor severe' group and 7 of 11 (64%) in both the 'cognitive severe' group and the 'cognitive mild' group.

Median improvement was similar between treatment groups for FIM and both subscales. However, the range of motor improvement was greater in the acupuncture group than the usual care group (46 vs 33) as seen in Figure 5.7.

Figure 5.4: Distribution of FIM Baseline Scores at Baseline

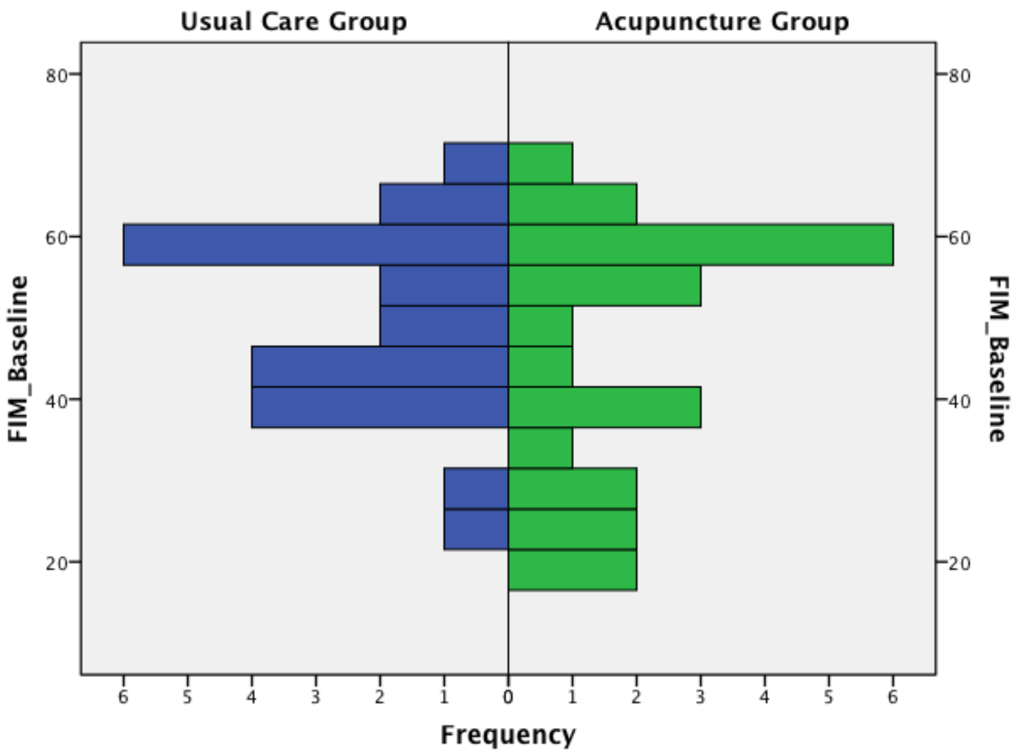

Figure 5.4: Distribution of Total FIM Scores at Baseline

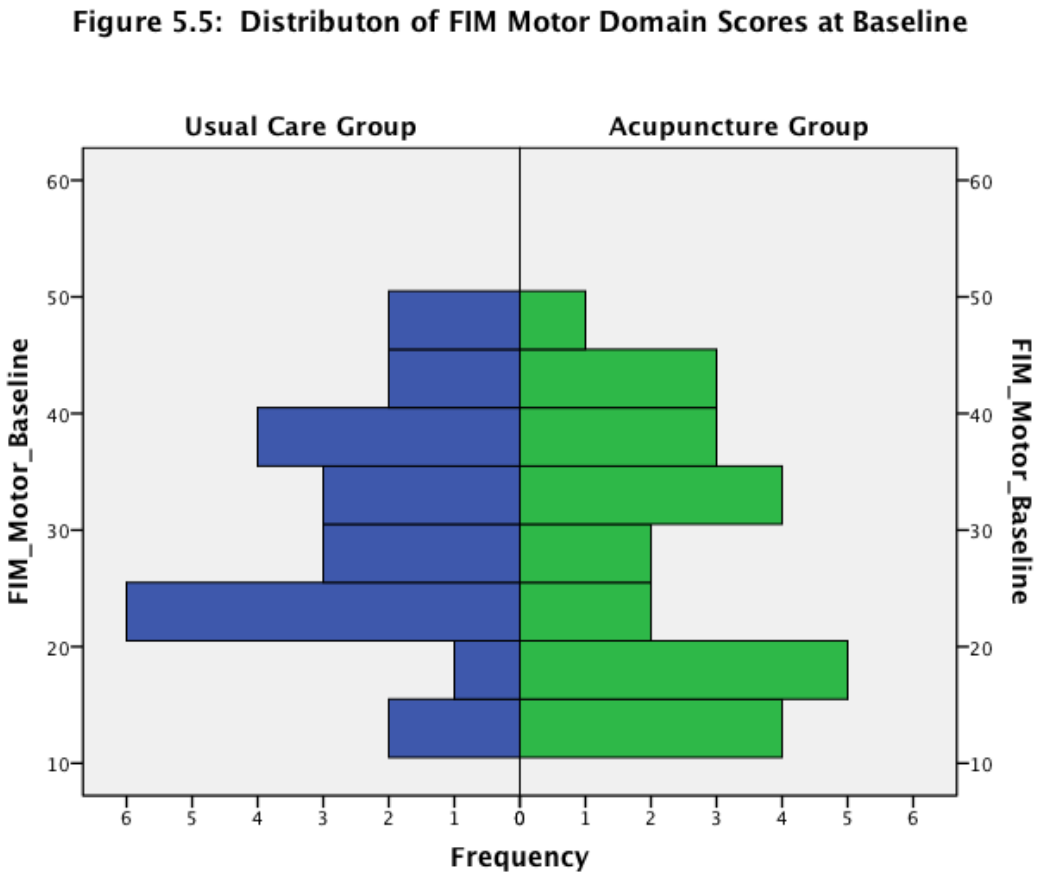

Figure 5.5: Distribution of FIM Motor Domain Scores at Baseline

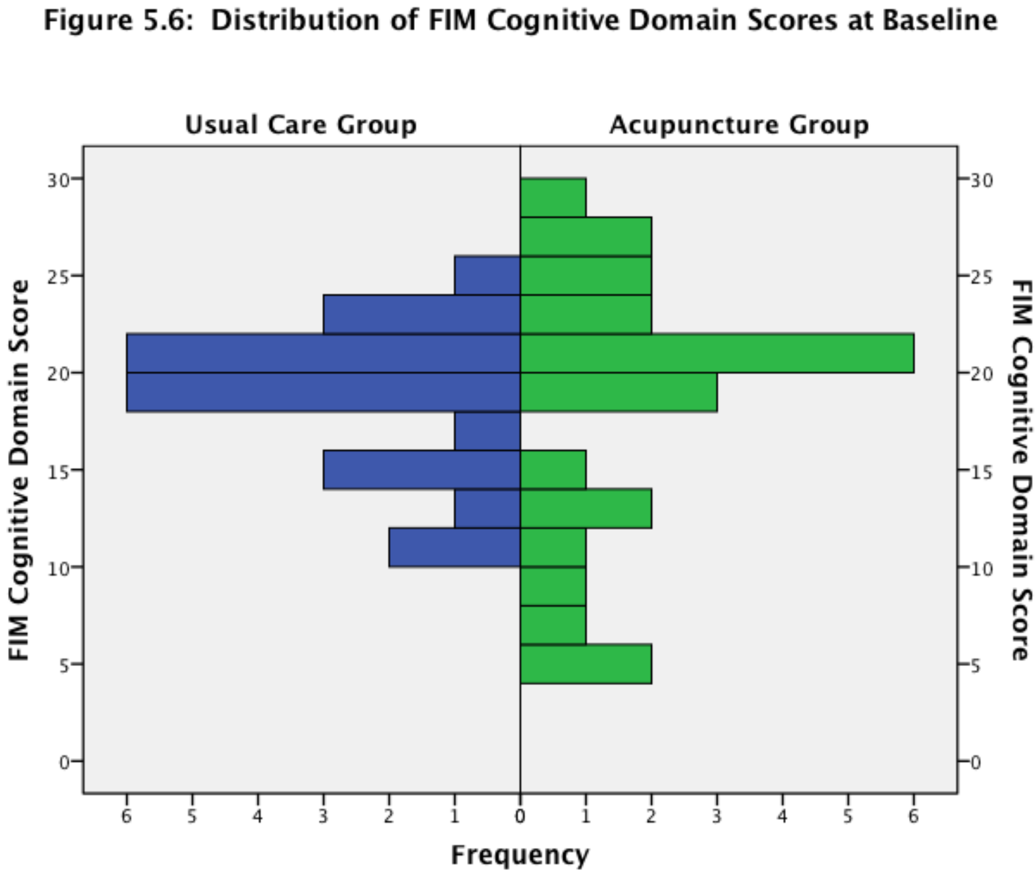

Figure 5.6: Distribution of FIM Cognitive Domain Scores at Baseline

Figure 5.7: Distribution of FIM Motor Domain Improvement

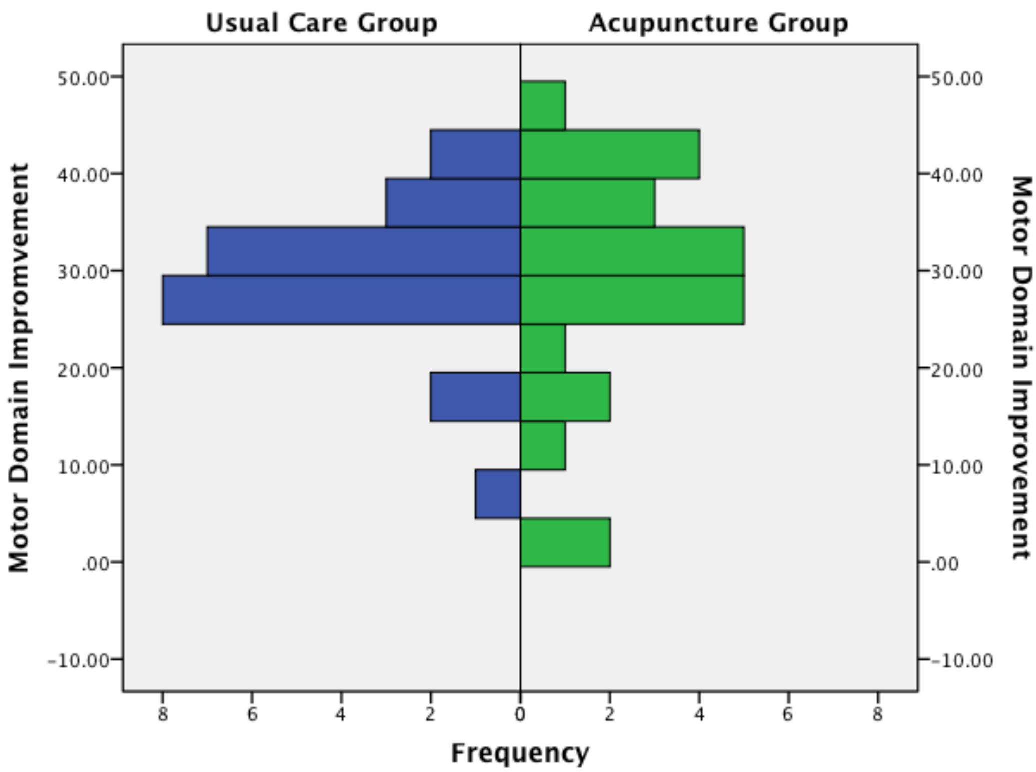

Figure 5.7: Distribution of FIM Motor Domain Improvement

5.6 Discussion of Concurrent Cohort Study Findings

5.6.1 Overview

As discussed in Chapter 2, past trials of acupuncture for stroke have found no significant difference in FIM score between treatment groups. However on examination of study methods, measures taken by researchers to reduce clinical complexity in an inherently heterogeneous study population appear to have increased internal validity at the expense of treatment effect. Sham control for placebo and standardization of acupuncture treatment are methods imported from pharmaceutical trials whose 'goodness of fit' for acupuncture research has been widely questioned (Macpherson, 2004; Scheid & MacPherson, 2012). Additionally, past authors (Naeser et al., 1994a; Shiflett, 2007) have suggested that outcome measures assessing motor function are not appropriate for patients with severe strokes, while inclusion of mildly affected patients will reduce any apparent acupuncture effect as most of these will recover both motor and non-motor capabilities with or without acupuncture.

In this context, this study's first question explored the FIM's appropriateness as an outcome measure across a wide spectrum of severity, when not encumbered by the two methodological issues most widely understood as problematic: standardized point protocols and sham control (Langevin et al., 2011). No firm conclusions can be drawn from this non-randomized study design. However, the similarity of total FIM scores between treatment groups, given individual treatment without sham control does lend support to previous suggestions that the total FIM may not be clinically sensitive to change with acupuncture across a range of stroke severities.

The study's second question addressed the relationship between baseline severity, outcome measures, and apparent effect size. Broadly speaking, it asked the question, 'do differences in effect sizes on motor and non-motor outcome measures support the arguments of Naeser and Shiflett that severity should be considered in research design?' (Naeser et al., 1994a; Shiflett, 2007). While the study was not powered to answer subgroup questions, the moderate severity subgroup did trend towards greater improvement with acupuncture on the FIM motor domain as suggested by both Naeser and Shifflet.

The study's third question, feasibility of future study, was answered in the negative for the primary outcome measure, the total FIM score. However several secondary outcomes – bowel function, sleep and modified Rankin scale – appeared promising for future study..

A new finding of this study is that patients who elect to receive acupuncture treatment may differ at baseline from those who decline it. A median difference of 1 at baseline was found on the modified Rankin scale, which is constructed so that one point represents clinical significance. Additionally, patients electing acupuncture tended to be at the severe end of the motor impairment spectrum – and therefore, as discussed above, less likely to benefit on motor outcomes. They were also more likely to be at the top or bottom end of the cognitive impairment spectrum, versus 'decliners' who were more likely to be in the central quartile. Although these distribution patterns were not statistically significant and cannot be assumed to generalize beyond this study, they do raise an additional question as to what proportion of patients enrolled in past studies were unlikely to show benefit on the motor outcome measures used. At a minimum, these results invite further qualitative exploration of the expectations and actual experience of patients at different severity levels before future quantitative studies are planned.

The study's findings are discussed in further detail below. Within each discussion, results are interpreted in light of past and current research. Implications for future study are discussed along with limitations of this project.

5.6.2 Primary Outcome Measure: Total FIM Score Improvement

Mean FIM gain was similar in both groups. This finding is consistent with several previous study findings, obtained with standardized protocols and sham acupuncture (Alexander et al., 2004; Hsieh, Wang, & Lee, 2007). The finding suggests one of two possibilities: first, acupuncture performed according to this manual produces no meaningful clinical effect; second, an effect was produced but remains obscured by methodological difficulties (other than sham control and point standardization, which were addressed in this question). This second possibility is addressed in the study's second question.

The definitiveness of the finding is limited however, by the cohort study design. In addition to having self-selected by acupuncture preference, the groups differed somewhat at baseline (see Section 5.5.1). Mean motor scores trended lower in the acupuncture group; more patients in the acupuncture group were aphasic at baseline; and more patients in the acupuncture group presented with neglect syndrome at baseline.

Other than self-selection, all of the clinical between-group differences would be expected to result in lower improvement within the acupuncture group than the usual care group. FIM motor score at baseline is understood to be a strong predictor of functional recovery (Duncan et al., 2002). Aphasia is also correlated with worse outcomes in stroke rehabilitation (Laska et al., 2001; Paolucci et al., 1998). Neglect syndrome (in which a patient loses proprioceptive awareness of the impaired side) is considered an unfavorable prognostic factor, “incompatible with an excellent functional prognosis on both ADL and mobility” outcomes (Paolucci et al., 1998). All five of the patients in the study presenting with neglect syndrome were in the acupuncture group.

Figure 5.3 (p. 161) shows both the mean difference at baseline and also a nonsignificant increase in range and variance at discharge, within the acupuncture group only. This increase would be consistent with the simultaneous presence of a treatment effect and one or more effect modifiers.

Any of the baseline differences discussed above could have reduced responsiveness of some patients to acupuncture treatment, producing a wider range within the acupuncture group. Most importantly, patients who have self-selected for any additional treatment may have a more positive attitude and better prognosis than those who have not (Hama et al., 2008b). Hama quantifies ‘insistence on recovery’ as a key positive prognostic factor in stroke, particularly in the elderly. It is also possible that the increase in range and variance is due to higher variability within the acupuncture group itself, or to additional confounders favoring the acupuncture group. As discussed below (Section 5.6.4) in greater detail, baseline FIM cognitive scores in the acupuncture group ranged lower (due largely to the aphasia patients) and also higher than in the usual care group. Additionally, the larger number of Chinese patients in the acupuncture group (24% vs 4.3%) might be expected to have greater familiarity with and more positive expectations from acupuncture treatment.

Expectation effect is understood to modify acupuncture treatment effect (Linde et al., 2007).

Altogether then, this study offers no evidence that use of individualized treatment and a usual care comparator leads to better improvement on total FIM score with acupuncture. However, due to differences at baseline and differences in distribution of improvement, neither does it provide strong evidence for the absence of an effect.

5.6.3 Baseline Severity and Motor vs. Non-motor Outcomes

The original impetus for this project arose from a 1993 study by Naeser et al showing that severe damage to descending corticospinal tracts predicted negative response to acupuncture treatment, while moderate damage successfully predicted improvement with acupuncture even in chronic stroke of up to 8 years' duration. A review article by Shifflet in 2007 reiterated the importance of the result, further suggesting that improvement in mildly impaired patients would be difficult to demonstrate statistically given that rates of recovery are high with or without acupuncture. The question is of considerable relevance to LMC's acupuncture program. With minimal funding and limited personnel, treatment can only be provided to some 10% of patients in the rehabilitation unit. If benefit on motor outcomes can only reasonably be hoped for by moderately impaired patients, and neither motor nor cognitive benefits will be meaningful for mildly impaired patients then some triage of patients requesting acupuncture treatment is in order, along with appropriate management of patient expectations.

The study was not powered for more than exploratory subgroup analysis. Additionally, lower baseline FIM motor scores in the acupuncture group mean that the 'Mild' and 'Severe' subgroups are asymmetrically populated. The motor Mild group contains 3 acupuncture patients and 9 usual care patients, while the motor Severe group has the inverse distribution. The motor Moderate group is both larger (N=23) and also more symmetrical (11 usual care patients, 12 acupuncture patients). Nevertheless, FIM motor scores did trend in the direction anticipated based on Naeser and Shifflet's discussions (see Table 5.4).

Bowel function and dysphagia are also considered motor outcomes and were analysed as well. Bowel function improvement, unexpectedly, was greatest in the mild subgroup. Without overinterpreting a small subgroup finding, it is worth noting that Chinese medicine has historically taken severity of disrupted bowel function as a key prognostic indicator in stroke, and recovery of bowel function as a primary indication of successful treatment.

Dysphagia improvement was similar across severity subgroups, and also between acupuncture and usual care groups. This was an unexpected result as the acupuncture team had selected dysphagia as an outcome based on positive clinical experiences in the early phases of the project. Two authors had reported previous positive results using standardized protocols (Akamatsu et al., 2009; Xie et al., 2008), warranting reexamination of the premise that individualized treatment is preferable to standardized treatment. (See Chapter 4 for a discussion of specific treatment approaches). This result may also help to explain why improvement in constipation was greater among patients with mild strokes, who are likely to have had milder dysphagia if any. Dysphagia and constipation are understood to be closely related, as dehydration and low food intake are prevalent in patients given a dysphagia diet of thickened liquids and pureed food (Harari et al., 2004). Neurogenic constipation may have been less responsive to acupuncture treatment when complicated by this mechanical etiology in the Moderate and Severe groups. As discussed above however, the non-random group allocation asymmetrical population of the Mild and Severe subgroups limits any conclusions drawn about their performance.

Non-motor outcomes did not perform as anticipated, with the Mild group anticipated to show the least comparative improvement. Rather, effect size for the sleep log in the Mild group exceeded the Moderate and Severe groups considerably, while improvement on FIM cognitive scores was similar across severity groups and between treatment conditions (see Table 5.3).

FIM cognitive domain improvement was nearly equivalent in the mild and severe subgroups, both of which were similar to the usual care group while the moderate group improved only slightly more. This is an interesting finding in that the manualized acupuncture used in this study included treatments explicitly targeting cognitive function where most previous protocols did not. It is unfortunate that there were not sufficient MoCA (or Cognistat) scores available to more closely explore cognitive performance. In particular, the MoCA's sensitivity to mild cognitive impairment would have made it a useful supplement to the FIM non-motor domain, which has a known ceiling effect (Ravaud, Delcey, & Yelnik, 1999).

As with bowel function, apparent effect of acupuncture for the sleep log was greatest in the mild subgroup where median gain was 1 hour in the acupuncture group versus a decrease of one hour in the usual care group. Improvement also appeared to be greater in the moderate subgroup (see Table 5.3). Apparent effect was least in the severe subgroup where mean gain of 0.13 hours was equivalent in both groups. It should be noted however that baseline sleep was considerably higher in the acupuncture severe group, median 8.5 hours (*IQR* 6.75-10.5) versus 7 hours (*IQR* 5.88-8.5). Disrupted sleep post stroke can present as insomnia, but can also present as hyper-somnolence or disrupted sleep-wake cycle. Patients with severe stroke are most likely to suffer hyper-somnolence. Of the eight patients in the severe subgroup, four slept more than 9 hours at baseline and three of them were in the acupuncture group. For these patients, 'improvement' constitutes reduction rather than increase of sleeping hours. The sleep log and scoring system used for this study did not take hyper-somnolence into account.

Insomnia is a common but little studied sequel of stroke, affecting some 37-56% of ischemic stroke patients. It is correlated with poor rehabilitation outcomes (Leppavuori et al., 2002). Sleep is of clinical importance (and is frequently disordered) for patients recovering from any brain injury as it is during sleep that most extensive repair of neural structures occurs (Stein et al., 2008). Insomnia is also prevalent in the hospital inpatient population generally (Dogan, Ertekin, & Dogan, 2005). Kim, Lee et al (Kim et al., 2004; Lee et al., 2009) suggest that 3-day retention of intradermal needles at selected acupuncture points can treat post-stroke insomnia by reducing excess nocturnal sympathetic activity. However, retention of intradermal needles was deemed infeasible at LMC due to the possibility of stat MRI imaging which could lead to needle displacement and resulting injury. The question of whether conventional acupuncture can mitigate disordered sleep post stroke is worth investigating further, using improved instrumentation such as 24-hour actigraphy. Also warranting investigation is the question of whether acupuncture can improve sleep in the greater inpatient population.

The specific interest as to whether improvement on motor outcomes would be greatest among clinically defined 'moderates' was based on a physiological argument made twenty years previously. This study's original plan for exploration of the question was to determine mild, moderate and severe subgroups using diffusion tensor imaging (DTI) scans to assess intactness of both motor and associated tracts (Lindenberg et al., 2010). However a delay in availability of DTI capability at the hospital led to the substitution of FIM quartiles for DTI imaging. This substitution has reduced the explanatory capability of the study: although the moderate group showed greater gains as expected, no insight into underlying mechanisms has been gained. Clinical differences in motor and cognitive improvement across baseline severity groups would also have been easier to interpret if the Fugl-Meyer assessment and Montreal Cognitive Assessment had produced usable results. These instruments are designed to measure impairment directly, rather than functional independence as an epiphenomenon of impairment.

5.6.4 Between-Group Differences in Patients Electing versus Declining Acupuncture

Between-group differences at baseline are discussed above in Sections 5.5.1 and 5.6.3.1. Overall, the acupuncture group had lower mean FIM motor scores at baseline and considerably greater variability in the FIM cognitive domain. The larger number of aphasic patients in the acupuncture group discussed in Section 5.5.1 reflects but does not entirely account for a concentration of patients at the high (severe) end of the non-motor severity spectrum in the acupuncture group. Additionally, there is a concentration of patients at the low (mild) end of the spectrum, so that the range and variance of non-motor FIM scores within the acupuncture group is greater at baseline than that of the non-acupuncture group. By contrast, the usual care group shows a concentration of patients in the middle range of severity (see Figures 5.4-5.7). One possible explanation for this (non-significantly) asymmetrical distribution between self-selected treatment groups is the presumed emotional states of the decision-makers: optimism and eagerness to recover at the mild end of the spectrum; caution in the middle associated with moderate cognitive impairment; and eagerness to try anything at the severe end[28].

This finding is specific to a single, non-randomized study in an atypically diverse patient population, as is the downward skew of motor severity in the acupuncture group. Both are noteworthy in interpreting previous randomized trials, however: taken together they suggest that patients who consent to participate in acupuncture trials may be quite differently distributed along motor and non-motor severity spectra than patients who decline participation. Shiflett (2007) argues that patients in the middle range of severity do best with acupuncture, while data for this study suggest that patients in the middle range of severity may be recruited for acupuncture trials at lower rates than patients at the top and bottom ends.

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[28] For aphasic patients, a decision to try the therapy is typically made by family members, though tacit consent is always sought for each needle insertion with readiness to discontinue treatment at any sign of discomfort or distress.

Also notable, though not of apparent clinical significance, is that three (50%) of the study's six aphasic patients were Chinese. It has been asserted that aphasia is less prevalent among Chinese speakers, perhaps because tonal and pictorial elements of the Chinese language are differently lateralized than purely verbal information (Hu, Qiou, & Zhong, 1990). However, that assertion is not supported by this small study. One of the Chinese aphasia patients was 'crossed', having a lesion on the right side (aphasia is normally associated with left-sided lesions), a phenomenon which has previously been reported in Chinese speakers (April & Han, 1980). It could be hypothesized that aphasia is more treatable (or more responsive to acupuncture) in Chinese than English speakers, but the question has not been explored in the English language literature.

5.6.5 Assessment of Bowel Function.

As discussed above (Section 5.3.2.3) a new measure of bowel function was used for this study. Based on nurses' charting, the new measure is less subjective than the FIM assessment. The face validity of the measure is clear, and there was no ceiling effect. However, nine of 46 patients (20%) scored a '0' at discharge, suggesting a floor effect in this mixed severity population. Overall, while results of this cohort study should be interpreted with caution, the median change of 1 in the acupuncture cohort versus 0 in the usual care cohort (95% CI [2-,0]) does suggest that the new measure may be sensitive to improvement with acupuncture therapy and warrants future study.

5.6.6 Modified Rankin Scale

The modified Rankin scale assesses global disability. It is similar to the total FIM in that it encompasses both motor and cognitive functions. However unlike the FIM it assesses capability from the patient's perspective, and globally rather than in terms of individual tasks (Salter et al., 2005). A review of clinical trials using the mRS (Banks & Marotta, 2007a) has suggested that the mRS may be more sensitive than the FIM to treatment effects during acute stroke rehabilitation.

Completeness of follow-up data for the modified Rankin Scale fell below the threshold set for feasibility (49% versus 75%). However, comparison to baseline and discharge scores (which are complete) shows a trend favoring the acupuncture cohort at 6-month follow-up. This is consistent with previous findings by Hopwood & Lewith (2005) that modified Rankin scores were higher in the acupuncture group at 12-month follow-up but not during the treatment period or at discharge. Hopwood suggests the possibility of systemic benefit that does not immediately reflect in ADL scores but improves longer-term wellness. Disability in daily life, as encountered and reported by the patient herself post discharge, is a key metric in understanding the actual impact of stroke rehabilitation interventions both economically and from a patient-centered perspective. Given the increasing number of studies showing no effect of acupuncture on FIM at discharge, mRS on follow-up should be considered as an important outcome measure for future study.

5.6.7 Feasibility for Future Study

As discussed in Section 5.5.3.3, four dimensions of feasibility were assessed for this project: withdrawals, adverse events, completeness of data, and sample size based for future study based on rate of recruitment, completeness of data and variability in this study's population. Additional considerations regarding recruitment and follow-up rates are discussed in section 5.6.6.5.

5.6.7.1 Withdrawals.

Withdrawals were low in this trial, with only one voluntary withdrawal who cited annoyance with the translation process as a reason for withdrawal from further data collection, while electing to continue acupuncture treatment. By contrast, previous studies report withdrawal rates ranging from 10% (Hopwood 2008) to 26% (Schuler et al., 2005), with Schuler et al.

citing low tolerance for acupuncture treatment among stroke patients as the reason for the large number of withdrawals. This study's low rate of discomfort reported by patients may relate to the manual's instruction to practitioners to select needle gauge according to patient sensitivity. The majority of previous studies cited set number and gauge of needles as standard between patients, an approach that may result in excessive 'dosage' for sensitive patients (White et al., 2008). It was the clinical experience of acupuncturists on this team that perceived intensity of de qi sensation as reported by the patient varied quite widely in the stroke population, relative to other inpatient and outpatient populations. It was their opinion that for this population at least, equalization of dosage defined as intensity of de qi sensation required use of larger needles for less sensitive patients and smaller needles for more sensitive patients.

5.6.7.2 Adverse Events

Major adverse events with acupuncture are rare; none have been reported in previous trials of acupuncture during stroke recovery published in English. One patient in the acupuncture group suffered a fatal pulmonary embolism after her family signed informed consent for the treatment, but before she had received her baseline evaluations for the rehabilitation unit. This patient was therefore enrolled in the study but was not treated with acupuncture and does not constitute an acupuncture-related adverse event.

5.6.7.3 Completeness of Outcome Measure Data

Overall a great deal was learned in this project about which measures were <u>not</u> feasible given particularities of place, time and available personnel. All seven outcome measures used in the study are shown in Table 5.2, along with the personnel conducting the assessment. Of the measures originally planned for this study, only four yielded data that was 75% complete or better (FIM, swallowing assessment, bowel function chart and sleep log), while another two became problematic early on and were replaced.

Outcome measures included in the final analysis are described above in Section 5.3; their feasibility for future study at this institution is addressed below in Section 5.6.7. Descriptions and clinimetric properties of outcome measures not included in the final analysis are provided in Appendix N, along with the particular circumstances of their selection and ultimate exclusion.

Here, the challenges to outcomes assessment in this study are examined more generally. The clearest determinant of feasibility for this study was the mode of administration, which is described in Table 5.2. Assessments conducted ordinarily in the course of work flow by LMC staff were in general complete: FIM (98%); bowel function (94%); dysphagia (92%) and sleep (81%). (The sleep logs are ordinary but not routine, and had previously been identified as a potential problem. For this reason the measure was assessed by averaging and comparing two nights each at baseline and discharge, with any singleton values taken as the average. If complete sleep data were defined as four complete sleep logs, only 31 (64%) would meet the criterion. Given the promising data from this study, it seems most reasonable to conduct follow-up research using emerging actigraphy technology rather than adding to nurses' paperwork burden.

Among three assessments originally planned for this study that were conducted outside normal work flow, none yielded 75% usable data. These were: the Montreal Cognitive Assessment (17%), the Ham-D; and the Fugl-Meyer Upper Extremity Assessment (0%). In each case, constraints of available time or changes of personnel resulted in the individual's inability to perform the requisite number of assessments within appropriate time windows. In particular, HamD assessments were incomplete owing largely to the poor fit between the assessor's 4-hour-per-week time window and patients' schedules before and after discharge. Determining when a patient was to be discharged also proved more difficult than expected, with several unanticipated early discharges resulting in incomplete data for outcome assessments not routinely collected by LMC staff in the course of discharge planning.

All follow-up assessments had low return of data, with no compensation offered in this unfunded trial. In addition, difficulty of travel for stroke patients during the unusually harsh winter of 2013-14 made in-person follow-up assessments largely infeasible. The one non-routine assessment that produced more than minimal follow-up data (49%) was the modified Rankin scale. This was conducted by telephone interview by a research assistant who had committed 12 hours per week to the project and was able to make calls at a variety of times of day.

The lessons regarding completeness of outcome measure data for future study are as follows:

- As much as possible, data collected should be part of the hospital's routine work flow
- Non-standard patient assessments to be conducted at baseline before acupuncture treatment should only be conducted by study personnel who can be onsite more than one day per week, preferably 3 or more
- Inpatient assessments not routinely conducted at discharge by LMC personnel should be assessed weekly rather than attempting to coordinate with date of discharge
- Long-term follow-up data are particularly difficult to obtain for stroke patients, who may have difficulty traveling for physical assessments. Possible strategies for managing this difficulty include:
    - Coordination of follow-up assessments with physician visits
    - Home visits for patients not in the hospital's outpatient system
    - Use of outcome measures validated for telephone administration

5.6.7.4 Sample Size for Future Study

Sample size calculations are shown in Table 5.5 above. Three outcomes appear most promising for future study: the mRS (projected N=172); the bowel function index (N=138) and the sleep log (N=72, among patients sleeping less than 9 hours at baseline).

The mRS is increasingly of interest, with 90-day baseline and follow-up scores having been newly set as a required performance measure for designated Comprehensive Stroke Centers (Joint Commission, 2014). Hopwood & Lewith (2005) and Shifflet (2007) suggest collection of longer-term mRS data. As described above (Section 5.6.7.3) long-term follow-up is difficult in the post-stroke population, and completeness of 6-month follow-up data was poor during this study (49%). However, once data collection procedures have been routinized for 90-day follow-up, they can be extended for study participants and may result in more complete mRS long-term follow-up data than was previously available.

The sample sizes projected for future study of sleep and bowel outcome measures are smaller than that for the mRS. Both areas are acknowledged as understudied but important determinants of well-being and prognosis in stroke recovery. However neither of these outcome measures has been validated. They should therefore be studied further as secondary outcomes in a study powered to find differences on the mRS, rather than independently.

5.6.7.5 Additional Considerations regarding Recruitment

As discussed above in Section 5.6.7.4, sample size calculations suggest that the mRS, bowel function index sleep log could be adequately powered at N=172, 138 and 72 respectively. None of these outcomes could be studied at LMC in under two years using recruitment methods used for this study. However, this study's inclusion/exclusion criteria were set relatively narrowly: this was to reduce potential effect modifiers other than stroke severity (see Section 5.2.2). Among the 463 patients excluded to yield the final N=48, more than half of those excluded in this study should be included in studies of sleep and bowel function, and possibly global disability as well. These include patients whose stroke was not ischemic (n=78), and patients who received tPA therapy but still experienced deficits requiring admission to an inpatient rehabilitation facility (n=74). Patients at a similar baseline deficit level with hemorrhagic stroke do not differ greatly in prognosis for recovery although variability is greater than in ischemic stroke (Stein et al., 2008). Patients showing significant deficit after tPA are the unlikely to differ from untreated ischemic stroke patients (Zhu et al., 2014). Additionally, the large proportion of patients excluded because their stroke was not primary (n=122, or 24% of patients screened) suggests that this population is important to include for external validity. Less improvement should be expected on motor function in this population (Edmans & Hume, 2010), meaning that mRS scores (which are related to motor function, particularly at the lower levels) should be analysed and interpreted with attention to this issue.

5.7 Limitations

Four main factors limit strength of any conclusions drawn from this study. These include the self-selected nature of the cohort study, the between-group differences at baseline between the cohorts, the large amount of missing data for some outcome measures, and compromise of the FIM at discharge as an outcome measure by its use in the discharge planning process. These are discussed in detail below.

5.7.1 Self-selected Cohorts

The likelihood of bias due to self-selection of acupuncture and usual-care-only cohorts is discussed in Section 5.4.8.1. Patients consenting to acupuncture treatment should be expected to differ from patients declining treatment (Chalmers et al., 1983; Witt & Linde, 2011). In particular, ‘insistence on recovery’ has been identified as a positive prognostic factor in stroke recovery (Hama et al., 2008a). It must be assumed that patients more determined to recover are more likely to elect acupuncture treatment when offered, which may have contributed to trends favoring the acupuncture cohort.

5.7.2 Differences at Baseline

As discussed in Section 5.5.1, the acupuncture and usual care cohorts differed at baseline. These differences were statistically significant on only two clinical characteristics which favored the usual care group (aphasia and neglect).

5.7.3 Missing Data

As discussed in Sections 5.4.7 and 5.5.3.3, four outcome measures were unusable due to a large volume of missing data. These are found in Appendix J. In particular, as discussed in section 5.4.6.3, 6-month follow-up data on the mRS was only 49% complete. Patients who remained reachable by telephone over that period may disproportionately exclude those with poor outcomes in both cohorts, which may not have been equally distributed between groups.

5.7.4 Use of FIM in Discharge Planning

For this study, the FIM's use by case workers as a consideration in the timing of discharge planning may have led to some equalization of FIM scores at time of discharge, compromising the FIM as an outcome measure. Patients who show very little improvement in the first two weeks may be moved to sub-acute rehabilitation settings sooner, while patients who demonstrate functional independence may be discharged home. Any apparent effect of acupuncture on FIM scores may therefore have been reduced by early discharge of rapidly-improving patients (whose discharge scores would be similar despite unusually fast recovery) or minimally-recovering patients (who could theoretically have recovered more with a longer treatment period).

5.8 Conclusions and implications for future work

The primary question of this feasibility assessment was answered in the negative: total FIM score does not appear to be a feasible outcome measure for assessing effects of acupuncture during stroke rehabilitation. Total FIM scores were similar in acupuncture and usual care cohorts. The comprehensive nature and widespread use of the FIM for baseline, discharge and interim assessment of stroke rehabilitation would appear to make it a promising outcome measure for research of acupuncture used flexibly to address systemic and symptomatic concerns, particularly given the difficulty shown in this study of implementing non-standard assessments during acute stroke rehabilitation. However, no study published in the West to date has demonstrated a treatment effect on the FIM with acupuncture during acute stroke rehabilitation. This cohort study was not designed or powered to support definitive conclusions, but it was designed to explore the appropriateness of the FIM for acupuncture research by using a treatment condition that maximized clinical appropriateness, along with a usual care comparator. The absence of between-group differences in this case does therefore strengthen the argument against using the FIM as a primary outcome measure for future study of acupuncture during stroke rehabilitation.

Also consistent with previous findings (and anticipated in the design of this study) was a trend favoring the acupuncture group on FIM motor scores among patients in the two central quartiles only. The measure was not found to be feasible for future study using current study methods. However the study results do further suggest the importance of the question, whether motor improvement with acupuncture is an appropriate study endpoint for patients at a moderate level of severity only. Future study of this question can best be conducted in small, more tightly controlled trials assessing motor function directly (versus the FIM which assesses independence in motor and cognitive domains).

As a comprehensive outcome measure, the mRS may be more feasible for future study than the total FIM. In this study, trends favored the usual care group on the mRS at baseline and the acupuncture group at discharge and follow-up. Telephone administration of the mRS at 6-month follow-up without patient compensation did not meet feasibility criteria for completeness of data set (49% of patients were reached), so findings must be interpreted with great caution. However, the trend is consistent with previous findings and warrants future study with more robust assessment methods. Recent inclusion of the mRS on 90-day follow-up as a mandatory performance measure for accredited comprehensive stroke care centers suggests that this data will be relatively easier to acquire in future studies.

Two new findings emerged from the manual development process, as acupuncturists inquired into patients' physical wellness and took it as a key parameter of manualized diagnosis and treatment. Insomnia and poor bowel function were identified as commonly occurring obstacles to well-being that were perceived by acupuncturists as responsive to treatments given. Measurements for these outcomes were added and both showed apparent effects appropriate for future study. The instrument used to assess sleep was a simple log based on hourly observation by nursing staff. Although potentially feasible for future use, its reliance on the regularity and accuracy of non-routine staff observations make it less desirable than emerging sleep actigraphy technologies which should be explored. By contrast, the bowel function index developed for this study does appear to be the best available tool for assessment of post-stroke bowel function in the inpatient setting. Unlike the sleep log, data for this instrument is routinely recorded by nurses and can easily be collected from their charts. Future work should include evaluation of this instrument's clinimetric properties, particularly sensitivity to treatment.

Overall, two main and one additional avenues of future inquiry are suggested by this study. They are discussed briefly in the paragraphs to follow, and more fully in Section 7.3 (taking into consideration this study's qualitative findings which are introduced in Chapter 6). First and foremost is the question of which global outcome measure – if any – is appropriate for the assessment of acupuncture's impact on acute stroke rehabilitation. Given the apparent unsuitability of the widely used FIM at discharge, exploration of the mRS on follow-up is a priority with immediate implications for future study in this area. FIM scores at baseline and discharge are routinely assessed at most institutions, and can therefore be used as a secondary measure for comparison with the mRS on follow-up as primary outcome measure.

Second, acupuncture effects on post-stroke impairments in sleep and bowel function should be explored with improved instrumentation. This study should be a pragmatic trial, including non-primary stroke patients and incorporating patient-centered outcome measures, drawing on results of Chapter 6 to be discussed below.

Additionally, clinimetric properties of the bowel function index should be established for use in future studies. The measure may also be of use in the general inpatient population.

6 Chapter 6: SURVEY OF PATIENTS AND OTHER STAKEHOLDERS IN THE REHABILITATION PROCESS

The overarching goal of the third phase of the project was to understand the subjectively perceived clinical impact of acupuncture during acute stroke rehabilitation. It addressed Aim 4 of the project:

> To assess the subjective perceptions of acupuncture benefit (or harm) among patients and other stakeholders in the rehabilitation process; and determine whether these perceptions differ between severity groups.

The study described in this chapter used qualitative and quantitative methods to realize that aim and its multiple objectives, as described below. Several purposes are served by understanding perceptions of acupuncture effect among patients and their families, as well as the rehabilitation staff who care for them, specifically physical, occupational and speech therapists, physicians, and nurses. These purposes include:

- Understanding and describing perceived benefits, which may assist design of future studies by informing the choice of existing outcome measures or development of new ones
- Providing an experiential context for the concurrent cohort study (CCS), which will assist interpretation of clinical outcome assessments, by elucidating:
    - the extent to which treatments are perceived as beneficial by stakeholders in the rehabilitation process, and
    - whether perceived benefits are counterbalanced by any perceived harm or discomfort
- Describing distribution of perceived benefits relative to stroke severity, which may also assist in determining inclusion/exclusion or stratification criteria for future trials

Within this project as a whole, inductive and deductive approaches informed each other through the iterative processes of manual development and feasibility asessment. In this third and final phase of the project, inductive and deductive methods were again combined to describe and quantify subjective stakeholder perceptions of acupuncture's positive and/or negative clinical impact as perceived by patients, their families, and the Rehabilitation Unit staff members caring for them. Quantitatively, positive and negative perceptions were tallied and compared across severity groups. Qualitatively, thematic analysis of brief interview and open-ended survey responses served to identify any effects of acupuncture not adequately assessed by deductively oriented data collection; or other unanticipated dimensions of acupuncture's impact within the acute stroke rehabilitation process[29].

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[29] Broadly speaking, incorporation of a secondary, inductively or subjectively oriented project within a primary quantitative assessment may enrich assessment quantitative outcomes in three main ways, which are not mutually exclusive. Findings of the second project may serve to corroborate or objective findings, adding robustness through triangulation; they may contradict results, suggesting a more nuanced interpretation; or the new data may point in directions previously unanticipated. For this project, all three of

6.1 Research Questions and Study Design

6.1.1 Research Questions and Objectives

In order to meet the study purposes described at the outset of the chapter – understanding and describing stakeholder perceptions of acupuncture benefit and discomfort or harm, and assessing their distribution across severity groups – the following qualitative research questions and quantitative objectives were generated.

Qualitative questions:

- In what ways did the respondents perceive acupuncture as beneficial, or as problematic?
- Did perceived benefits differ meaningfully between patients with mild, moderate, and severe strokes?

Quantitative objectives:

- To determine the proportion of patients, family members and rehabilitation unit staff who perceived acupuncture as (A) beneficial and (B) problematic or painful
- To compare number of stakeholders who perceive acupuncture as beneficial at the top, bottom and two central quartiles of severity
- To compare perceived rate of recovery between acupuncture and non-acupuncture patients, as perceived by rehabilitation unit staff

6.1.2 Methodology

Mason (2006) argues that mixing methods allows the investigator to balance 'macro' and 'micro' views, beginning to account for the web of overlapping contextual associations that shape lived experience of any phenomenon under investigation, even when the phenomenon itself has been clearly delimited. As discussed above in Chapter 2, the phenomenon

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these outcomes occurred, with respect to the pilot study's primary and secondary objective findings, as discussed below.

of ‘ischemic stroke’ designates a multiplicity of physical, cognitive and emotional experiences of impairment and recovery. Where the Concurrent Cohort Study described in Chapter 5 took the ‘macro’ approach to understanding acupuncture’s impact on a group of patients, the stakeholder survey described in this chapter took the ‘micro’ view, using inductive thematic analysis to better understand impact at the individual, experiential level (Braun & Clarke, 2006). Beckner and Harlan, Verhoef and others describe this ‘triangulation’ as a main strength of the mixed methods approach in CAM research (Lewith et al., 2011; Verhoef, Mulkins, & Boon, 2005b).

6.1.3 Overview of Study Design

Patients in the cohort study’s acupuncture group gave brief structured interviews and, where possible, a family member answered a brief written survey containing three closed questions and three open spaces for clarification or additional comment. Additionally, for each patient in either treatment group, rehabilitation staff members answered similarly structured surveys with similar questions for qualitative and quantitative analysis. Staff surveyed included Physical, Occupational and Speech Therapist; physician, and nurse.

6.2 Ethical Considerations

As discussed in Section 5.1, the project was approved by LMC’s Institutional Review Board and the University of Westminster’s Research Ethics Sub-Committee. The informed consent packets for patients and their families covered participation in both the cohort study and also this inquiry. They were described in Section 5.1. A briefer information sheet and informed consent form were given to staff participants in this qualitative inquiry, whose participation was limited to filling out a brief survey. The staff information sheet and informed consent form are attached as Appendices M and N respectively. Both information sheets included a full description of the study and its aims, explained why participants had been chosen, and described the anonymity and confidential handling of all data as well as its secure storage and scheduled destruction. However the patient and family packet was written in simpler language with more explanations of basic concepts. Both packets described the approximate time burden and the nature of participation. Each packet reiterated in two separate paragraphs that that participation was entirely voluntary and could be terminated at any time without consequences. Patients were additionally informed that they did not have to answer all of the questions if they found any of them troublesome. All participants were informed that they would receive a report of study results when they were written up, and were given contact information for the principal investigator for any questions. They were additionally given contact information for the head of LMC's Institutional Review Board, Dr. Claudia Lyon, for any queries or complaints. Participants who could not read English had the informed consent packet read to them by the Investigator, with the assistance of a telephone interpreter service as needed. Participants then signed the informed consent form.

6.3 Procedure

Data collection was conducted during the Concurrent Cohort study period, September 2012 to November 2013. Stakeholders surveyed (or interviewed) included patients who received acupuncture; family members; physical, occupational and speech therapists; nurses; and physicians.

6.3.1 Survey and Interview Design

The surveys and structured interview script for this study consisted of two primary questions for pooled qualitative analysis among all stakeholders, with additional questions for quantitative analysis within and among stakeholder groups. This design aimed to capture the heterogeneity of stroke severity and recovery and Lutheran Medical Center (Alban et al., 2005). The multiple-stakeholder-per-patient design allows for a variety of stakeholder perspectives, and also allows themes to repeat if they are perceived by multiple stakeholders for a small number of patients, or else by a single stakeholder category across multiple patients.

The staff survey form is attached as Appendix O. The family member survey form is attached as Appendix P, and the script for patient interviews is attached as Appendix Q. All surveys and the interview form included a mix of open and closed questions. For all stakeholders, the survey (or interview script) consisted of the two central questions reflecting the study's purposes: did the stakeholder perceive acupuncture as being helpful; and did they perceive acupuncture as being harmful or counterproductive. These closed questions were presented as statements (e.g. 'acupuncture was helpful to this patient') with a five-point scale ranging from 'strongly agree' to 'strongly disagree'; with an additional sixth option of "don't know or can't answer" as described in the paragraph above. For each closed question, an open follow-up question was asked ("In what way?") All stakeholders were additionally asked whether there was anything else they wanted to add.

Introductory questions were specific to stakeholder groups:

- Patients were asked an introductory question ("How was your acupuncture treatment?" with a probe, "how did it feel?") intended to elicit any feelings regarding the acupuncture treatment (in contrast to the core question which solicits their opinion).
- Patient families were asked whether they had seen the acupuncture treatment their family member received, in order to contextualize any response regarding perceived benefit
- Staff members' introductory question asked them to rate the patient's progress relative to their own experience and expectations for progress, using a five-point scale ranging from 'much faster or more complete than expected' to 'much slower or less complete than expected'; with an additional sixth option of "don't know or can't answer" intended to distinguish between genuine expressions of neutrality and situations where the respondent lacked appropriate information or experience to answer the question.

Staff surveys also differed from other stakeholder surveys in that they were to be filled out for usual care as well as acupuncture patients. Staff members were instructed to answer the introductory question for all patients, and the acupuncture questions only for patients they knew to have received acupuncture.

6.3.2 Patient Interviews

A structured interview schedule was used to elicit patients' experience of the acupuncture treatment. Interviews were conducted in the patient's hospital room during the week preceding discharge, by a research assistant. With the permission of the patient interviews were recorded and transcribed. If interpretation was necessary, the hospital's interpretation telephone service was used and the number of the interpreter recorded on the survey. Interviews lasted between three and eight minutes (including interpretation in some cases). In one instance when a translator telephone was not available for a patient about to be discharged, a bilingual nurse read the patient the survey and wrote in an English translation of the patient's reply. The patient interview script is attached as Appendix Q.

6.3.3 Family Surveys

The family survey (Appendix P) was given to the closest family member of each acupuncture patient, where available, during the week preceding discharge. The survey was given by a research assistant to the respondent with instructions for self-completion and return in an opaque envelope (provided along with a pen and clipboard). In one instance when the respondent was not able to read and write English, a translation phone was used as described above, and the respondent wrote answers in her own language (Chinese) which were then translated by a bilingual nurse not otherwise familiar with the study. In two instances, the patient or family member was not able to be reached at the hospital and was contacted by phone as soon as possible post discharge and the survey recorded either via translator phone or ordinary speaker phone.

6.3.4 Physical, Occupational and Speech Therapist surveys

These surveys (Appendix O) were circulated by a research assistant who attended the weekly interdisciplinary rehabilitation team meeting. Folders were circulated containing the blank surveys for recently discharged patients (identified by patient name on a removable sticky note) and an opaque envelope for finished surveys, which were filled out during the meeting. Surveys were prepared for all study patients (both acupuncture and non-acupuncture groups) for all three therapeutic disciplines (physical, occupational, speech). A second sticky note contained the name of the therapist in each discipline who conducted the discharge assessment for the patient. In the instance that the therapist in question was not present at the meeting, a research assistant gave the therapist the survey form, identified with patient name on a removable sticky note which they were instructed to remove, along with an opaque envelope for return of the survey via interoffice mail.

6.3.5 Nurse and Physician Surveys

These were given to nurses and physicians individually by a research assistant (BH, MS) along with an opaque envelope for return via interoffice mail. The surveys were identified with patient name on a removable sticky note, which participants were instructed to remove. Surveys were given to nurses and physicians for all study patients (both acupuncture and non-acupuncture groups).

6.3.6 Sample

All patients receiving acupuncture were invited to be interviewed, and a written survey given to their closest family member if available. Staff members were surveyed for patients in both acupuncture and usual care groups.

In actuality, patient interviews were attempted for 19 of 24 acupuncture patients (excluding one who refused additional data collection and four who were aphasic at discharge). Among these, none refused but only 12 (67%) were completed owing to logistical difficulties described below in Section

6.6. Surveys were attempted for family members of 23 patients (excluding one who had refused additional data collection), succeeding for only 10 of these (43%).

For all patients enrolled in either cohort of the study, five members of the Rehabilitation Unit staff (Physical, Occupational and Speech Therapists; physicians and nurses) were given a survey to complete for each patient. Out of a possible 230 surveys (5 for each of 46 patients) 178 were returned by staff members (77%). Thirty-seven of 178 surveys were returned by physical therapists; 43 by occupational therapists, 32 by speech therapists, 41 by physicians and 25 by nurses. Survey response rates per question for all groups are shown in Table 6.1, and reasons for non-response are discussed in Section 6.6. Sixty-nine staff surveys (42% of 178 staff surveys) included a comment on the rate of recovery, 41 regarding acupuncture patients and 28 regarding patients in the usual care group. Additionally, 23 participants (12% of 200 surveys returned) provided optional comments.

Table 6.1: Survey Response Rate

		Questions Answered			
Respondent Group	Surveys Returned (% of 46)	Rate of Recovery (% of 46)	Perception of Benefit (% of 23)	Perception of Harm (% of 23)	Additional Comments (% of 46)
Patient*	12 (52)*	n/a	12 (52)*	0	5 (21)*
Family*	10 (42)*	n/a	9 (31)*	0	4 (9)*
Physical Therapist	37 (80)	15 (33)	14 (61)	0	3 (7)
Occupational Therapist	43 (93)	23 (50)	17 (74)	0	3 (7)
Speech Therapist	32 (70)	4 (9)	0	0	0
MD	41 (89)	15 (33)	21 (91)	0	6 (13)
Nurse	25 (54)	12 (26)	10 (43)	0	2 (4)

*Only acupuncture patients and their families were surveyed (n=23)

Table 6.1: Survey Response Rate

6.3.7 Interview and Survey Analysis, Qualitative Question 1:

"In what ways did the respondents perceive acupuncture as beneficial or problematic?"

In order to identify, organize and report patterns of perceived benefit within the data, I used the six-part method for thematic analysis proposed by Braun and Clarke (Braun & Clarke, 2006). These steps are described below. Dedoose™ software was used to support the organization, coding and analysis processes.

6.3.7.1 Transcription and familiarization with the data

I transcribed four of the patient interviews and a research assistant transcribed the remaining eight, and entered the written surveys into a spreadsheet for uploading to Dedoose. To familiarize myself with the data and to check accuracy of the uploading process, I checked all the data files in Dedoose against the original written surveys and interview audio files. During this time I began a list of recurring content within the reports, which grew to include some recurring patterns of self-expression.

6.3.7.2 Generating initial codes

Braun and Clarke describe codes as the smallest unit of meaning within the data that can be meaningfully assessed in relation to the phenomenon of interest. They draw a distinction between data-driven'coding in which codes are generated entirely from the data, and theoretically based coding in which the data may be viewed in terms of certain questions, or the researcher may choose to code only a certain portion of the content.

For this study, the theoretically based narrowing described above did take place, but during the data gathering process. Respondents were asked a small number of questions on a specific topic, with little opportunity for expansion or further inquiry. However within this relatively narrow field, to come to a meaningful understanding of acupuncture's impact as perceived by stakeholders rather than researchers, I decided that it was important to code inductively, rather than importing previous theoretical orientations.

This posed a challenge in two ways. First, two theoretical frameworks were clearly at hand for ordering the data: the patient assessment framework that acupuncturists had used in treatment planning, and the WHO's ICF framework for assessing recovery in stroke which guides treatment planning in PT and OT. As a clinician I found it impossible to avoid spontaneous 'emergence from the data' of concepts from of both frameworks – particularly as the rehabilitation therapists themselves frequently used ICF terminology. In each case where such a term emerged, I allowed it to stand in quotation marks if it came from a respondent – for example 'motor function' – but refrained from using it myself, instead coding at the least theoretical level (e.g., 'walking', which later became a sub-theme of function). Second, I began to identify codes that were not directly related to clinical impact of acupuncture, such as personal professions of belief or skepticism regarding acupuncture. I chose to include these initially, though most were laid aside during subsequent rounds of analysis and interpretation. At the end of this process an initial list of codes were generated.

6.3.7.3 Searching for themes:

In this phase, I began to assemble a mind-map of all the codes identified, identifying as many as possible super-categories within which codes could be grouped, and combining or subordinating as many codes as possible in the process to reduce an refine the initial coding list. This second list of codes were then grouped into three themes of perceived benefit (comprising 25 sub-themes), an additional three themes not directly concerning physical benefit, and several codes retained for administrative purposes (not yet assigned to themes, important to report, counter-examples, etc).

6.3.7.4 *Reviewing themes*

For this phase, Braun and Clarke invoke Patton's (1990) evaluative criteria of 'internal homogeneity' and 'external heterogeneity'. These are to be assessed for each theme: do all included items form a coherent pattern, and does that pattern differ meaningfully from the other themes? Then, once themes are found to be sound, they are examined in relation to the data set: do they form a coherent account of the data, and does that account accurately represent the whole of the data collected? At this point in this study, the individual themes were relatively clear and stable with only minor questions remaining. Codes were further refined at this stage (including three additional deletions and additions not reflected in the total count). I then re-read and re-coded all excerpts using the new scheme, which is attached as Appendix T.

6.3.7.5 *Defining and naming themes; Producing the report*

These final two steps of the thematic analysis process necessarily informed each other, and for this project they overlapped considerably in time. At this stage I consulted two other qualitative researchers, and received supervisory guidance. Without changing the coding, I further reduced the number of themes reported.

6.3.8 Survey Analysis, Qualitative Question 2:

Did perceived benefits and harms differ meaningfully between patients with mild, moderate, and severe strokes?

In order to visually capture the distribution of the themes and categories identified in Question 1 across severity groups for further exploration, I reported them in tabular format. Text size was based on prevalence of the theme within the respondent group, as identified using descriptors in Dedoose.

6.3.9 Survey Analysis, Quantitative Questions 1-3

6.3.9.1 Quantitative Objective 1: To determine the proportion of patients, families and staff who perceived acupuncture as (A) beneficial and (B) problematic or painful.

For this analysis, individuals' responses were dichotomized in SPSS within each category of respondent as follows:

- For patients and families, any verbal or written response of “yes” to the question of perceived benefit was coded as ‘1’. Any other response was coded as a ‘2’.
- For staff surveys, on the Likert-type question “acupuncture was helpful to this patient”, any answer of ‘a’ (agree) or ‘b’ (strongly agree) was coded as ‘1’. Any other answer was coded as ‘2’.

6.3.9.2 <u>Quantitative Objective 2</u>

6.3.9.3 : To compare proportion of stakeholders who perceive acupuncture as beneficial at the top, bottom and two central quartiles of severity.

For this objective, chi-square analysis was planned, to compare the number of patients for whom perceived benefit was and was not reported, across the three severity groups. However, only three patients had no reports of benefit from any of the seven stakeholder groups, making the analysis invalid. A continuous variable, “proportion perceiving benefit” was therefore created by tallying the number of reports of benefit per patient (which ranged from 0 to 5) and dividing it by the number of respondents for that patient (which ranged from 2 to 7) to yield a number between 0 and 1 representing the proportion of respondents perceiving benefit for each patient. A Kruskal-Wallis one-way ANOVA was then used to compare the proportion of respondents perceiving benefit across the three severity groups.

6.3.9.4 <u>Quantitative Objective 3</u>: To compare perceived rate of recovery between acupuncture and non-acupuncture patients, as reported by rehabilitation unit staff

For this objective, responses to the questions asking respondents to describe the pace of the patient’s recovery in light of their experience and expectations were pooled for all staff participants. Responses were analysed as an ordinal scale as suggested by Aday & Cornelius (2006). The scale was from fastest perceived recovery (“A, much faster or more complete than expected”, scored as ‘1’) to slowest perceived recovery (“E, much slower or less complete than expected”, scored as ‘5’). The response “F, don’t know or can’t answer” was excluded from analysis (as distinct from the neutral choice, “C, as expected”). Median and interquartile ranges were calculated for the pooled staff responses and compared between acupuncture and usual care groups. Distribution of responses was compared between groups using the Mann-Whitney U-test. Statistical significance was set at the 5% level.

6.4 Qualitative Findings

6.4.1 Qualitative Question 1: Perceptions of Acupuncture as Beneficial or Problematic

Results in this section are ordered and presented around the main themes identified in the analysis: physical changes (improved function; cognitive and experiential benefit); negatives; and ‘helped the rehabilitation process’. Figure 6.1 is a theme map showing the main themes and sub-themes identified. Typical quotations are used to illustrate findings. They are presented with patient identification numbers (used to protect patient anonymity) and the role of the participant (e.g. family member, speech therapist).

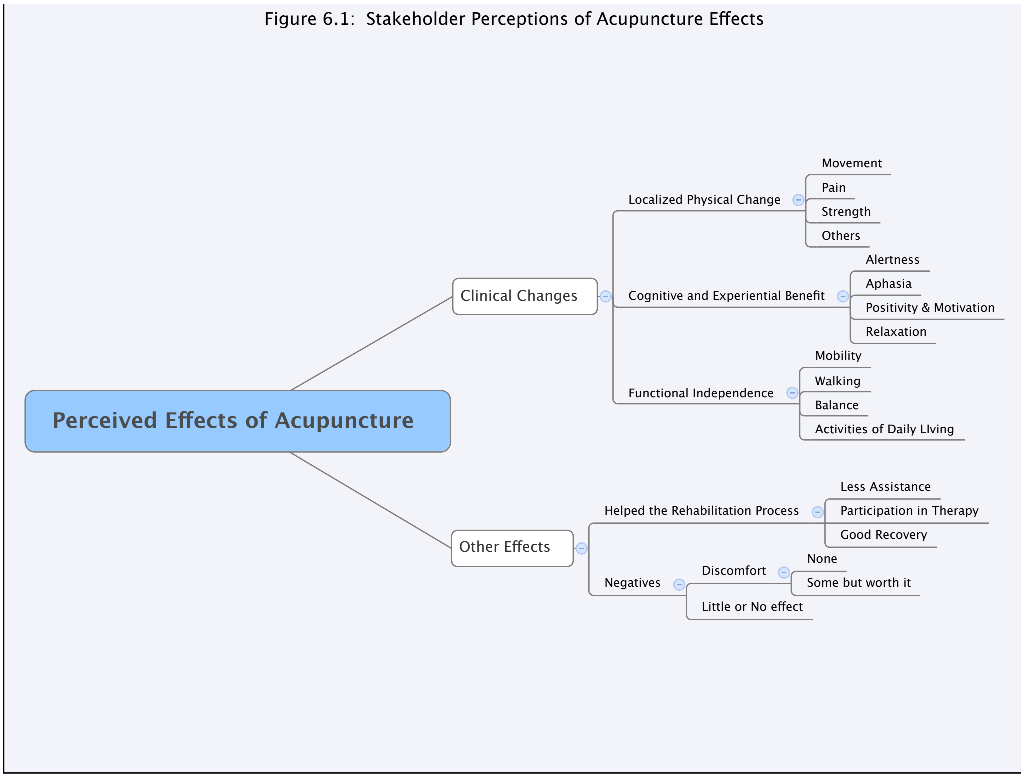

Figure 6.1: Stakeholder Perceptions of Acupuncture Effects

The most striking feature of this data set is the wide variety of benefits attributed to acupuncture by patients and their families, and also by the physicians, physical and occupational therapists and nurses who worked directly with the patients.

6.4.1.1 Physical Changes

Tangible physical change, perceived as a direct result of acupuncture treatment, was widely perceived by patients, families and staff. Location of change ranged across the entire body, including head, spine, trunk and one or both affected extremities.

> *"Increased activation of left lower extremity dorsiflexion." (PT, Patient 12)*

“After her first acupuncture treatment or her second, she was able to move her arm. And then, she was able to move her thumb. And now she tells me she can move her fingers slightly.” (Family member, Patient 6)

Types of change described also varied widely. Most common were improved movement and strength.

"Increased endurance, motivation, balance, mood, and strength." (OT, Patient 41)

"Pt feels stronger after the treatment, mobility to the affected side much better." (Nurse, Patient 20)

"Movement in affected side, especially in upper extremity." (OT, Patient 10)

Within the group of patients reporting improved movement, there was a range from mildly impaired patients experiencing functional return described above and below, to patients with completely flaccid extremities, for whom small movements appeared to have considerable significance.

“…my arm, which was very, it was not alive anymore. It's moving now a bit.” (Patient 6)

“Friday we have acupuncture, I feel, I was say goodbye to woman, and try to press at his hand, my feel its movement. I found it last Friday after acupuncture.” (Patient 47)

Pain relief was widely prevalent among patient and staff perceptions, being reported as commonly as movement. Most common was shoulder pain – a known stroke sequela – but also neck and lower extremity.

“I had needles put into my shoulder. Once it was taken out, my shoulder felt so much better.” (Patient 22)

"Pain relief, patient expectations met." (PT, Patient 39)

"Decreased pain." (PT, Patient 9)

A number of other benefits were less commonly reported including reduced fatigue or increased energy; dizziness and reduced urinary retention.

“Dizzy” (Family member, Patient 10)

“It helped with the neck pain and problems with my head. It seemed to get rid of the pain and the problems with my head.” (Patient 10)

“Voiding became more complete (emptied bladder).” (Nurse, Patient 36)

Notably absent from both patient and staff reports was any discussion of the two outcome measures that were added based on acupuncturist perceptions of benefit – sleep and bowel function – both of which trended better on quantitative outcome measures in the group electing acupuncture than those electing usual care only.

6.4.1.2 Functional Independence

A large number of non-patient stakeholders described gains in function, including performance of activities of daily living (ADL’s), balance, mobility[30] and ability to walk. Patients by contrast discussed function relatively seldom, and only in terms of walking.

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[30] As distinct from simple movement of a body part, ‘functional mobility’ in rehabilitation denotes the level of assistance required in three categories of movement: in bed, transferring to wheelchair, and ambulation. As described

"Before I could not walk, now I can walk." (Patient 36)

"My legs feel lighter, easier to walk." (Patient 4)

Staff members by contrast described benefits in all four areas.

"She was able to do ADL's with an assistive device early." (PT, Patient 19)

"Pushing/decreased trunk balance improved." (PT, Patient 35)

These were often presented in combination.

"Return of strength and patterning of impaired lower/upper extremity." (PT, Patient 46)

"Increased ambulation/increased balance/increased gait sequencing." (PT Patient 12)

Pre-ambulatory mobility itself is a large category which includes level of assistance needed to maneuver in bed (of considerable importance to nurses) and to transfer from bed to wheelchair.

"Before acupuncture he was a complete assist and there was no improvement. After, he was able to lift right arm and ambulate with assistance." (Nurse, Patient 20)

"Increase mobility of the patient." (Nurse, Patient 26)

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above, staff reports specifying 'ambulation' are pooled with patient and family reports of 'walking'.

6.4.1.3 Cognitive and Experiential Shifts

This was a large theme, comprising two sub-themes of cognitive benefit and changes in emotional or bodily experience. Each of these sub-themes itself contains several thinly populated but nevertheless distinct thematic groupings, and there are considerable differences in reporting between staff and patient/family stakeholder categories. The two themes are grouped because in most cases they represent different stakeholder views of the same patient.

Perceptions of cognitive benefit were restricted to staff reports. Groupings within cognitive benefit include purely cognitive dimensions such as alertness, attention and aphasia.

> *"Assist in improved mental state; increased alert for rehab participation." (PT, Patient 25)*

> *"Patient was able to adapt to compensatory strategies and techniques to attend to the R side." (PT, Patient 31)*

> *"Motor and speech/aphasia recovered faster than expected…. [Acupuncture] helped patient's speech and recovery." (MD, Patient 41)*

Staff also reported emotional or attitudinal shifts seen to impact the rehabilitation process, such as motivation and encouragement.

> *"Sudden improvement after slow progress. Increased motivation, increased accuracy, increased motor planning." (OT, Patient 41)*

> *"Assist with UE pain management, motivation." (PT, Patient 22)*

> *"Patient and family were encouraged by acupuncture therapy." (Nurse, Patient 36)*

Several staff members additionally reported improvements in “mood”. Further clarification as to the quality of the mood shift was not provided, and descriptions of the shift remained explicitly contextualized within the patient’s rehabilitation process.

> *“Change in mood; change in functional mobility (increase).” (PT, Patient 37)*

> *“Increased endurance, motivation, balance, mood, and strength.” (OT, Patient 41)*

> *“Acupuncture has helped to improve the patient's motor recovery and mood.” (MD, Patient 26)*

The only emotional shift described by family members was relaxation.

> *“She was very calm and tranquil after her session which is a miracle. For my mother to be calm and tranquil it's miraculous.” (Family member, Patient 6)*

> *“Very helpful - Relaxing, help the nerves.” (Family member, patient 26)*

For their part, patients were slightly more varied in their description of mood changes as such, but relaxation remained a prominent feature of reports.

> *“No pain, a little light/relaxed.” (Patient 4)*

> *“Helped me take my mind off the pain and put me in a better place. Took my mind off all the negative things going on, it did work in a positive way…did feel very relaxing.” (Patient 31)*

6.4.1.4 Negatives

Two questions specifically solicited negative perceptions regarding acupuncture. Each respondent group was queried as to whether in their view acupuncture had caused any problems (patient, family members) or had been counterproductive (staff). In a separate question, patients were asked whether the acupuncture hurt (see the patient interview script, Appendix S). Overall there were strikingly few affirmative responses to this line of negative questioning: none of problems or counter-productiveness, and very few of discomfort. These are presented below, along with a few reports of little or no effect.

6.4.1.4.1 Discomfort

As described below in quantitative findings (Section 6.4.1), patients answering the question 'did the acupuncture hurt' were asked to qualify their answer, whether affirmative or negative. Most patients denied pain.

> *"Felt like nothing. I mean, it didn't hurt or anything." (Patient 16)*

The two patients answering in the affirmative qualified the pain as "a little".

> *"A little bit of pain." (Patient 36)*

Another patient denied pain but reported a non-physical sense of discomfort.

> *"Well, you know, you always have a sensation, I mean you're laying in bed and you've got 25 needles throughout your body, which is a process, but you know, you're always apprehensive about something like that. But she was quite gentle." (Patient 15)*

6.4.1.4.2 Little or no effect

A few reports describe perceptions of no or little effect. It is notable that these responses are all contextualized by the participant in various ways –

personal belief, severity of the case, moderation of expectations – in a manner that countervails the negative content of the statement.

> *"I don't think it hurt, I don't think it helped either. As evidenced by the fact that he's still paralyzed in the joints….I think acupuncture has its validity, unfortunately I just don't think it worked this time." (Family member, Patient 14)*

> *"Didn't have high expectations for this patient based on severity of stroke." (PT, patient 14)*

> *"We installed about 20 needles, so I didn't feel big changing, but small steps I feeling." (Patient 47)*

Some combination of acquiescence bias and social desirability bias could be inferred from the respondents' apparent efforts to speak positively about acupuncture, and is discussed below in sections 6.4 and 6.5.

6.4.1.5 Supporting the Rehabilitation Process

Staff members reported instances in which the therapy process was facilitated by the patient receiving acupuncture. This took several forms. Most prevalent were descriptions of the patient participating more actively in therapy, whether due to pain relief, increased alertness[31], or improvements in mood or motivation.

> *"I believe that the patient was more attentive to his deficits and more focused on restoring function of fine motor skills with the acupuncture treatment." (PT, Patient 31)*

> *"Able to do more therapy because of less pain." (Nurse, Patient 39)*

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[31] As discussed in Chapter 2, patients' cognitive ability to learn and retain new compensatory strategies is a key limiting factor to effectiveness of physical and occupational therapy

"Before acupuncture, patient refused therapy, refused meds. After acupuncture she was more alert, in better spirits, and willing to do therapy and improve." (Nurse, Patient 37)

Also as described in the 'Improved Function' theme above, nurses noted gains in pre-ambulatory mobility which impacted their work.

"Acupuncture definitely helps patient in their early recovery and pain management. Helps with mobility also." (Nurse, Patient 26)

"Went from two person assist to one person assist in 1 week." (Nurse, Patient 16)

Finally, staff describe patients as recovering well with acupuncture, with criteria for good recovery including rapidity of improvement, having started from flaccid (particularly with the upper extremity, where there is less likelihood of motor return), and discharge to home (versus an institution).

"Improved/faster rate of lower extremity and distal upper extremity motor return." (MD, Patient 15)

"Patient presented with 0 degrees active range of motion to left upper extremity, upon discharge had movement in wrist and digits." (OT, Patient 25)

"Patient said acupuncture helped her move her arm that was weak after stroke. Improved fast and went home." (Nurse, Patient 40)

6.4.1.6 Additional Themes Identified

Two additional themes identified were related to acupuncture's impact at the institutional rather than clinical level, and were not included in the primary theme map.

Several patients reported ‘prior ignorance of acupuncture’, indicating their exposure to it through the study was their first.

> *“I heard about acupuncture before, I never knew it would've helped me and I never knew it would work.” (Patient 10)*

> *“I knew nothing about it, during the process they educated me on what was happening.” (Patient 15)*

Multiple staff, patients and family members expressed the desire or opinion that acupuncture should become more freely available.

> *"More stroke patients should have acupuncture therapy on a daily basis" (PT, patient 12)*

> *“Want to do it more.” (Patient 35)*

> *“You know, I wish that I was able to actually get the acupuncture [post-discharge] but I don't think my insurance covers it and I'm not really financially equipped to pay for it. But at some point, once I am, maybe I'll be able to go back to it.” (Patient 22)*

6.4.2 Qualitative Question 2: Differences among Severity Groups

Perceived benefits differed considerably between severity groups. Figure 6.2 shows the most prevalent and important themes for each severity group.

Figure 6.2: Perceived Benefits of Acupuncture Across Severity Groups

	Mild	Moderate	Severe
Main Perceived Benefits	**Pain** *Relaxation*	**Arm movement** **ADL's** Pain	**Reduced assistance** **Arm movement** *Motivation* Participation
Other Perceived Benefits	Arm movement Leg movement	*Relaxation* Alertness Participation	Alertness Aphasia

Key:

Central benefits are reported by a number of respondents equal to or greater than the number of patients in the severity group

Main perceived benefits are reported by a number ≥50% of severity group size

Other perceived benefits are reported by a number ≥25% of severity group size

Oblique type indicates experiential benefits

Figure 6.2: Perceived Benefits of Acupuncture Across Severity Groups

Contrary to prior research using objective outcome measures, these subjective quantitative findings showed a large number of respondents in the severely impaired group reporting benefit. However, these findings must be interpreted with caution given that the acupuncture cohort was self-selected. For the severe group, pre-ambulatory mobility and upper extremity movement were some of the most important perceived benefits. Upper extremity movement was not anticipated as a benefit in this group. However as discussed above, for severely impaired patients the benefit from small volitional movements in the fingers of an otherwise flaccid arm may have been largely experiential – the difference between an injured arm and a lifeless appendage.

Respondents for the moderately impaired group perceived functional improvement more than other groups, particularly of the upper extremity (which is most commonly affected in stroke). This was consistent with the cohort study results. Also important for this group – more so than for the severe group – was pain relief.

Within the mild group, relaxation was most prominent as an experiential shift. Staff also reported improved spirits and increased participation in therapy, both in relation to pain relief and independently. Upper extremity movement was also perceived as a benefit in this group – though for these patients it included wrist extension and fine motor skills. Lower extremity movement was not absent in any group, but was more prominent in this group and included return of ankle dorsiflexion.

Perceptions of cognitive and experiential shifts were seen across all three severity groups.

6.5 Quantitative Findings

6.5.1 Quantitative Objective 1: Proportion of Respondents Perceiving Benefit

Figure 6.3 shows the proportion of respondents reporting that acupuncture had been of benefit to patients, within the seven stakeholder groups. Among the 12 acupuncture patients interviewed, all reported that they had benefitted from their acupuncture treatment. Other groups ranged between 80% and 100% of respondents reporting perceived benefit, with the exception of Speech Therapy, none of whom reported any perception of acupuncture benefit.

No respondent in any group reported acupuncture as harmful or problematic. In a separate question regarding pain or discomfort on needling, two patients (8%) reported that they experienced pain, but additionally qualified the pain as minor. One patient (4%) described a (non-physical) sense of unease during needle insertion[32].

[32] This patient was treated with local needling for facial paralysis

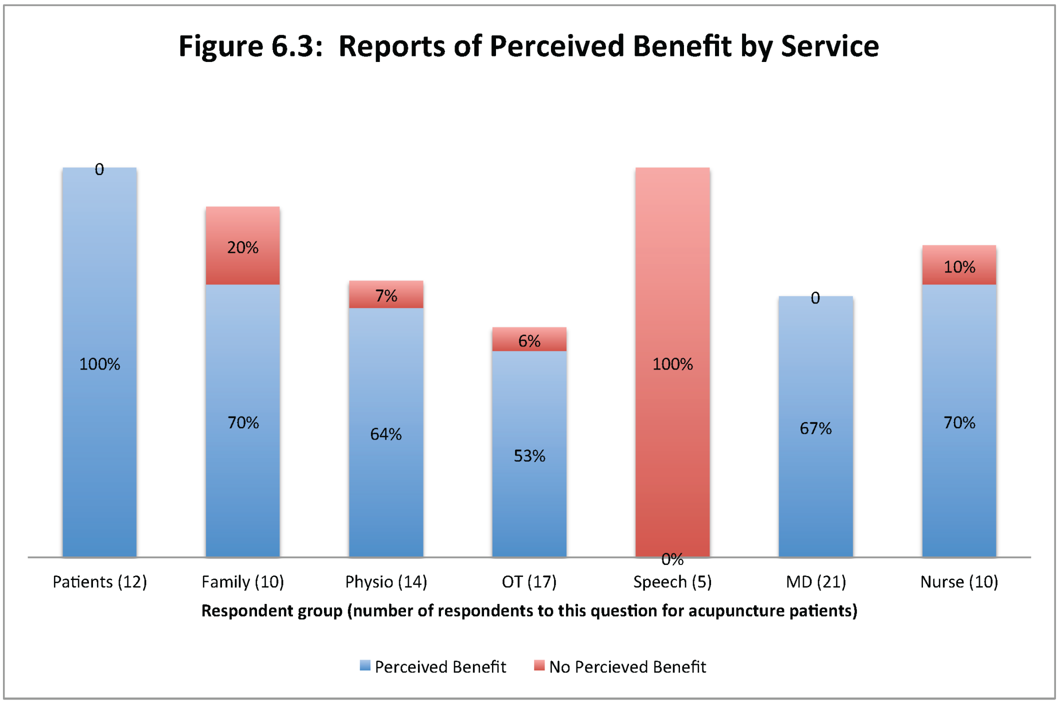

Figure 6.3: Reports of Perceived Benefit vs. No Perceived Benefit

6.5.2 Quantitative Objective 2: Differences among Severity Groups

Among the 21 acupuncture patients for whom at least one stakeholder (among a possible seven) answered the question regarding perceived benefit, only three (14.3%) had no stakeholder reporting benefit. Among those 21 patients overall, the proportion of stakeholders reporting perceived benefit was high (M = 0.82, Mdn = 1, IQR 0.71-1). This ratio was similar across across severity groups, though it did differ across stakeholder groups (see figure 6.3).

6.5.3 Quantitative Objective 3: Rate of Recovery as Perceived by Staff

Staff members were asked to reflect on the patient's progress relative to their expectations based on initial patient presentation and experience with similar patients. Overall 166 (72%) of a possible 230 staff responded to this question; however, 12 of these (5%) had indicated 'not sure or can't answer' and were not included in analysis. Slightly fewer than half (86 or 48%) indicated that they were blind to acupuncture group assignment.

Comparisons between acupuncture and usual care groups for perceived rate of recovery revealed no statistically significant difference between groups (p = 0.384), with a median of 4 and IQR of 4-5 for both groups. However, variance was greater in the acupuncture group (SD = 1.02, versus 0.64 in the usual care group), with 5 responses of 'much faster or more complete than expected', versus 1 in the usual care group and 22 reports of 'much slower or less complete than expected', versus 16 in the usual care group. Figure 6.4 is a population pyramid showing reported rates of recovery compared between the 23 acupuncture patients and 22 usual care patients who had at least one respondent.

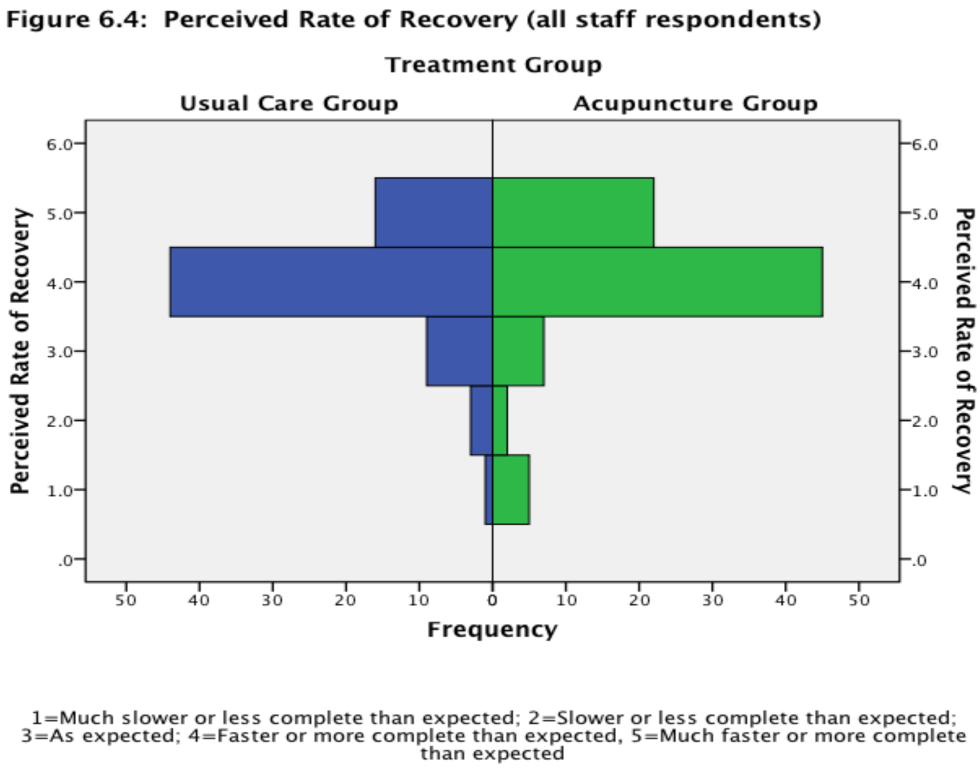

Figure 6.4: Patient Rate of Recovery as Perceived by Staff Respondents

6.6 Discussion of Findings

Overall, answers to this study's research questions were consistent with results of the cohort study, and with the assumptions underlying the project as a whole – chiefly, that clinical impacts of acupuncture during acute stroke rehabilitation are as heterogeneous, multifactorial, and difficult to quantify as the disorder itself. Acupuncture was perceived by most stakeholders as beneficial and by none as problematic, with the few reports of pain or discomfort characterized as mild. Reported benefits differed qualitatively between severity groups – with functional improvement most meaningful for the moderate group – but number of stakeholders perceiving benefit did not differ across groups.

One finding stands in contrast to cohort study results, which is a notable lack of overlap between stakeholder perceived benefits and the three outcome measures selected by acupuncturists for the cohort study: sleep, bowel function and swallowing impairment. This discrepancy deserves particular attention given that outcome measures had been selected in relation to past chart review, staff survey and acupuncturist experience.

For sleep and bowel function, several factors unrelated to acupuncture effect may account for the discrepancy. First, while both outcomes showed greater improvement in the acupuncture group (see Table 5.3), the difference is relative, with absolute levels that are unlikely to have been satisfactory patients in either group. Inpatients are commonly awakened at night by noise and vital signs checks, although the hour is scored as sleep if the patient was asleep when the nurse arrived. Similarly, post-stroke constipation is common and severe. While improvement in bowel function was greater in the acupuncture group, this meant that they had a median of 2 days per 5 with continent bowel movement, (*IQR* = 0-5) versus 1 day per 5 in the usual care group (*IQR* = 0.75-4).

A second explanation for absence of insomnia and constipation in subjective reports is that both are routinely treated with escalating dosage and strength of pharmaceutical agents, so that individual instances of improvement may have been attributed to medication changes, while aggregate differences were seen statistically. Third, the study surveyed day nurses (who would not have observed changes in sleep) rather than night nurses. And finally, patients may have hesitated to volunteer bowel function in response to an open question from the interviewer, who was not previously known to them.

For swallowing function, the most straightforward explanation for a lack of perceived improvement is an actual lack of acupuncture effect, given similarity of acupuncture and usual care outcomes in the cohort study. This finding is surprising not only because the acupuncturists perceived dysphagia as responsive to acupuncture treatment, but also because it is the only stroke symptom for which a Cochrane review suggests possible benefit (Geeganage et al., 2012). Altogether, this finding in a small cohort study with large baseline differences should not be taken as conclusive. Improvement in swallowing may not be apparent to the patient, who is kept on a diet that will not challenge her capabilities. Additionally, as discussed in Section 6.4.1, among the rehabilitation therapists, speech and swallowing therapists returned fewer surveys than the other stakeholder groups and reported less awareness of acupuncture overall.

Several other findings were unanticipated but meaningful for future study. Pain relief appeared more important than anticipated for this patient population, as did relaxation. Staff reports of improvement in motivation and 'mood' were prevalent but not clarified in these brief surveys, and invite further exploration. Also, perceptions of acupuncture as helpful to the rehabilitation process itself were unanticipated.

Findings are discussed in detail below, under four main topics: perceived benefit; qualitative and quantitative differences across severity groups; perceptions of rehabilitation staff in particular; and perceived rate of recovery. Implications for future study are then discussed.

6.6.1 Perceived Benefit

Variety of perceived clinical impact of acupuncture was wide. Among the reported benefits shown in Figure 6.3, nearly all have been studied previously in the stroke population, but with equivocal results in trials of treatment for the symptom alone (Ernst & Lee, 2010). The breadth of perceived benefit by a variety of stakeholders in this trial appears to support the approach taken in this study, of manualizing rather than standardizing treatment, to allow for individual concerns to be addressed.

That said, the relatively small overlap between quantitative outcome measures and the benefits perceived by the different respondent groups – patients and family, staff, and the acupuncturists in the planning phase of the study – begs closer attention. Among the 12 themes of clinical impact reflected in the theme map (figure 6.1), only three were directly addressed by the study outcome measures (mobility, walking, ADL's), and another five indirectly addressed (movement, strength, balance, alertness, aphasia). Conversely, the two outcomes showing greatest between-group difference in the cohort study -- sleep and bowel function, which had been added on the basis of benefits perceived by acupuncturists– were not present in stakeholder reports. Several factors may partially explain the latter absence: these two outcomes in particular have a smaller number of potential respondents – mainly patients and nursing staff. Surveys were filled out by day nurses, who would not have observed changes in sleep, and patients may be more likely to discuss bowel function with acupuncturists (on inquiry during the course of care) than in a structured interview with a research assistant unknown to them. It should be also noted that neither pain nor anxiety (two of the most important outcomes for patients in this study) is widely discussed in the literature on acupuncture for stroke rehabilitation.

Overall, this discrepancy highlights the importance of greater incorporation of stakeholder priorities earlier in study development. This need has been addressed increasingly in recent research, particularly with the establishment in the United States of the Patient-Centered Outcomes Research Institute, a non-profit non-governmental agency which has funded 313 studies since its establishment in 2010 (PCORI).

6.6.1.1 ICF Conceptual Framework

The ICF conceptual framework for stroke rehabilitation has been discussed in Chapter 5, in the context of outcome measure selection. The framework denotes three main levels of recovery from stroke: the body structure or impairment level; the activity or disability level; and the participation or handicap level. This conceptual framework is fundamental in the training of the rehabilitation staff, and is used routinely in their reporting. It is therefore no surprise that staff assessments of benefit fell neatly along the lines of the three levels. Staff reports of improved participation in therapy were particularly interesting because I had chosen not to include participation-level assessments in this feasibility study, viewing them as downstream effects of body- and activity-level improvement more relevant to post-discharge quality of life than to acute rehabilitation. Conversely, the activity and participation levels were almost entirely absent in patient and family reports, which in general either described change at the body level, or else experiential shifts (such as relaxation and feeling more positive). The ICF levels are widely used in the planning and interpretation of research on stroke rehabilitation, and it is clear from staff reports that they are not irrelevant to acupuncture research. However, the divergence of patient and family reports from staff reports in the participation to some degree the function level must be noted.

6.6.1.2 Unpacking pain, relaxation, ‘mood’ and ‘motivation’

Pain relief and relaxation are commonly associated with acupuncture treatment in the ‘worried well’ (MacPherson, Sinclair-Lian, & Thomas, 2006) but pain and anxiety are seldom seen as an outcome for trials of acupuncture in the acute stroke rehabilitation population (Ernst & Lee, 2010; Pilkington, Kirkwood, Rampes, Cummings, & Richardson, 2007). The promising results with insomnia shown in the cohort study may be related to these qualitative reports of improvements in pain levels and relaxation. Consequently, scales measuring these outcomes should be considered for future study.

A disadvantage of the brief survey and structured interview formats used in this study is that they did not allow for clarification of terms. For example, some of the reports of pain relief are clearly associated with local musculoskeletal dysfunction, directly or indirectly related to the stroke. In many other cases a location is not given, and it is not clear whether the respondent is indicating another instance of musculoskeletal pain, or central or peripheral nerve pain secondary to the stroke.

Similarly, the terms ‘relaxation’ and ‘mood’ are much in need of clarification, particularly as the first is used exclusively by patients and families, and second almost exclusively by staff. What phenomena they are describing, and to what degree they overlap, is not knowable from this study. Generalized anxiety disorder is a known stroke sequela occurring in some 21% of post-stroke patients, and has been found to be nearly as common as depression (occurring in 22.8%). Both are correlated with greater cognitive impairment, particularly in the 12.3% of patients in whom they co-occurred in one observational study (Barker-Collo, 2007). If acupuncture were found to assist in loosening the grip of either or both syndromes, the clinical implications would be considerable. However, ‘relaxation’ may not imply cessation of anxiety, any more than ‘improved mood’ necessarily invokes depression. This is clearly an area for further exploration. Staff descriptions of increased ‘motivation’ during therapy may be associated with underlying mood, but warrant specific study. This can be a brief survey question.

6.6.2 Differences across severity groups

As discussed throughout this thesis, previous research has led to hypotheses that severely impaired patients will not show benefit from acupuncture treatment on quantitative motor assessments, and therefore should not be included in such studies. The qualitative and quantitative findings on stakeholder perceptions discussed in this chapter do not contradict those suggestions – on the contrary, they support them, as do the results of this project’s cohort studies. However, this chapter’s findings suggest that severely afflicted patients do derive benefit from acupuncture treatment. Examples include Nurses' reports of improved pre-ambulatory mobility and willingness to participate in therapy, and patients' reports of the large experiential impact of even a small degree of motor return in an otherwise flaccid upper extremity.

6.6.3 Staff perceptions: enthusiastically (but not unanimously) positive

A meaningful and unexpected result emerging from staff reports is that they perceived acupuncture as beneficial to the rehabilitation process itself, over and above clinical benefit to the patient. Perceived benefits included pre-ambulatory mobility (meaning fewer staff members needed to assist with bed-based tasks such as toileting, as well as physical therapy); also improvements in alertness and motivation (as well as decreased pain) leading to more focused and productive therapy sessions.

Perceptions of acupuncture have not always been enthusiastic among LMC staff. A previous survey (Alban et al., 2005) had showed that staff on LMC's rehabilitation unit regarded acupuncture as helpful to patients, though not strongly so. A study conducted at LMC's Labor and Delivery unit found 17% of nurses reporting that the acupuncture process had 'sometimes' interfered with their work (Citkovitz et al., 2009). Reports from this study also were not unanimously positive. Notable in Figure 6.3 is the absence of perceived benefit by the speech/swallowing therapists (SST), along with a relative scarcity of SST staff indicating they were aware that the patient had received acupuncture, and a low level of survey response for SST staff overall. These low numbers do not indicate an absolute lack of acceptance by the service: the 70% survey completion rate for SST therapists is only slightly lower than the staff rate overall (77%). A few respondents did indicate perceptions of faster than average progress, and there were no reports of negative perceptions. However, the discrepancy between the SST's relative neutrality and the other services' enthusiasm does warrant examination.

Apparent similarity of improvement rates in the acupuncture and usual care cohorts offers a straightforward explanation for the lack of perceived benefit by SST staff, but does not account for the related but distinct phenomena of low awareness and survey response level[33]. Two additional sets of factors may contextualize these. First, the SST team was less familiar with the acupuncture service and research project than the PT and OT teams. As discussed in Section 4.4.2.1, a formal introduction to this study was given to PT and OT staff as part of their in-service education (see Appendix E), while SST staff were given a briefer verbal introduction. PT and OT teams also increased familiarity with acupuncture procedures as some treatments were conducted in the Rehabilitation gym, concurrently with PT/OT training and visible to other PT/OT staff (but not SST staff, who see patients at bedside). Additionally, the SST team is similar to the nursing team in having greater patient turnover. As with the nursing team, in a number of cases surveys went unfilled because no single team member was identified as a primary therapist.

A second factor with a potentially differential effect on PT/OT and SST perceptions of acupuncture is work flow. While schedules for all three services were set each morning, the SST schedule was expected to flex in response to unavoidable daily events (patient indisposition, medical procedures, etc.). It was therefore not an uncommon occurrence that an SST session, once having been rescheduled, was then additionally delayed because the patient was undergoing acupuncture therapy. This type of delay due to interim scheduling shifts occurred more with SST than with PT or OT sessions. Although the matter was discussed with the SST team leader and rehabilitation manager, the issue was deemed as unavoidable within the system in use at the time, and not so commonly occurring or deeply problematic as to warrant systemic change. Although relations remained cordial, it must be assumed that the inconvenience

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[33] For example, one aphasic patient was identified by both SST and MD respondents as improving “faster or more completely than expected”; for this patient the MD listed acupuncture as a perceived benefit of acupuncture treatment while the SST did not.

associated with the conduct of the study contributed to the SST staff's unenthusiastic participation in it. From this experience, formal introduction to all services and early identification and resolution of work flow difficulties can be identified as important elements of institutional feasibility.

Altogether though, staff and patient reports alike were largely positive, and included calls for greater availability of the service as described in Section 6.4.1.6, Additional Themes Identified. These findings should be interpreted with caution given the self-selected treatment cohorts. However, the positive stakeholder responses do suggest that the intervention is well accepted by staff and patients, and strengthen the cohort study's conclusion that acupuncture during stroke rehabilitation is feasible.

6.6.4 Perceived rate of recovery

The rate or completeness of patients' recovery, as rated by staff who were largely blind to treatment group, did not differ significantly between groups. However, variability was greater in the acupuncture group with more patients reported as recovering 'much slower' or 'much faster' than expected. This finding is consistent with greater variability in FIM improvement in the acupuncture group, seen in Figure 5.4 and discussed in Section 5.6.4.

6.7 Limitations

Limitations to this project included missing surveys increasing the possibility that respondents are not entirely representative of the sample as a whole, particularly for quantitative assessments. Also limiting the strength of findings from this inquiry was the small but heterogeneous sample, the brevity of the survey and the difficulty of the structured interview format for stroke patients at varying degrees of cognitive impairment.

Missing surveys were chief among the limitations to this project. While some of the staff respondent categories were quite complete, several were not. Speech Therapists and Nurses rotate their staff more than other services, leading to more situations where no single staff member feels they know the case well enough to respond to the survey. Only half of acupuncture patients were successfully interviewed: among 24 acupuncture patients completing acupuncture treatment, 1 refused any non-standard data collection, 5 were aphasic and an additional 8 required the use of a translation telephone with limited availability. 13 interviews were obtained but one was lost due to inadvertent erasure before transcription. Family surveys were also difficult to obtain, with linguistic challenges complicated by the difficulty of scheduling during the week before discharge – often quite a busy one for family members. Altogether, logistical barriers were sufficient to explain the missing surveys and there is no indication that the potential respondents not reached differed meaningfully in their perceptions from the ones surveyed.

While the main themes were saturated, the wide diversity of patient presentations and experiences mean that a number of perceived benefits were reported only once or twice in the relatively small sample. Also, the data was relatively thin: the surveys had been kept brief in order to maximize completeness by minimizing the time burden. The decision to keep the patient interview script nearly identical to the survey appeared necessary in light of the analytic scheme. However, it contributed to the thin quality of the data.

6.8 Implications for future research

Logistical and other implications for improving future studies on the basis of lessons learned include:

- Exploring the use of other outcome measures for pain, mood and relaxation for future study
- Administration of family surveys and patient interviews, if used, well before discharge to increase likelihood of simultaneous availability of personnel and translation phones
- Strategies for inquiring more deeply into the predominantly positive response, including:

    - Freer patient and rehabilitation staff interviews (semi-structured or topic list)
    - Specific questions for patients and staff on motivation
    - Specific questions for staff on positive or negative impacts of acupuncture on work flow
- Early identification and (mutually satisfactory) resolution of work flow problems
    - A run-in period is essential to identify logistical challenges that may arise in scheduling and work flow
    - Prior to the run-in period, thorough introduction of the study to all affected services is necessary. If possible, services should be actively engaged in research design and methods development

6.9 Conclusions

Altogether this inquiry has performed as anticipated within the context of the project as a whole. Inductive exploration of stakeholder perceptions served to contextualize these and prior quantitative results, showing that benefit with acupuncture is perceived by staff across all three WHO ICF domains, but that perceived benefits differ across severity groups. These findings warrant further exploration with deeper qualitative inquiry as well as coordinated mixed methods approaches.

In general, findings reinforced the main conclusions of the cohort study. Motor benefit was experienced most strongly by those in the Moderate subgroup, and patients in the Mild subgroup reported fewer benefits in general. However, the finding that pain is an important treatment outcome for patients in the Mild and Moderate groups is a new one. Along with reports of post-treatment relaxation, this may partially account for the cohort study's finding of reduced insomnia particularly in the Mild subgroup.

Also notable was the preponderance of perceived benefit in the Severe group. Reports of improved pre-ambulatory mobility reducing the burden of care for nursing and other rehabilitation staff are new and warrant further study, along with reports of improved cognition, motivation and participation in therapy.

Lower survey participation and a lack of perceived benefit by speech and swallowing therapists, relative to other staff, point to the importance of early feasibility piloting. Scheduling conflicts between the SST and acupuncture services were identified during the study period but were not systemically addressed.

Overall however, the degree to which acupuncture was perceived by staff as beneficial to the stroke rehabilitation process, over and above clinical outcomes, is an important new finding that warrants further exploration. Shifts in mood and motivation, described by stakeholders without further clarification, may relate to findings in this and previous projects of improved functional status on post-treatment follow-up. Further qualitative and mixed methods exploration of these potentially related questions is also warranted.

7 Chapter 7: Summary Discussion and Conclusion

7.1 Summary Discussion and Synthesis of Study Findings

The manualization, concurrent cohort and survey phases of this study were described in Chapters 4, 5 and 6 respectively. Those chapters discussed the results, conclusions and process evaluation of the current study design as conducted at Lutheran Medical Center. The final product of the study is a set of recommendations for future study of acupuncture during stroke rehabilitation, which has largely been set aside in the West over the course of the last decade. This study has demonstrated that such research is feasible, given appropriate choices of patient, intervention, control and outcome measure. Specific contributions of each project are discussed and synthesized below, then summarized in terms of their implications for patient population, intervention, control and outcome measure selection for future study.

7.1.1 Development of a Manual for Individualized Acupuncture Treatment during Stroke Rehabilitation

Manual development for this study diverged from previous work on manualization by Schnyer, MacPherson and others. As suggested by the MRC Guidance for research in complex interventions, iterative cycles of practice and self-evaluation were used to develop a manual that balanced concerns of repeatability and external validity. Stroke rehabilitation in particular challenged past models for development of treatment protocols in acupuncture research. The extraordinary heterogeneity of the condition limited the utility of Schnyer's approach of identifying a small repertoire of diagnostic and treatment protocols via Delphi or other consensus method. Conversely the maximally flexible approach used by MacPherson and others, specifying practitioner behavior without explicit clinical guidance, was not easily applicable in this case because of stroke's relative difficulty and low level of familiarity for most practitioners. For this condition, a middle road consisted of a brief structured clinical guidance document to be followed where applicable, supported by a summary of available clinical and research literature for reference in difficult and refractory cases. Development of the document took a year prior to the cohort study, continued through the year of the cohort study, and is expected to continue indefinitely on the basis of new research and ongoing use.

The format for the document, and the process of its development, may be of use for future studies where repeatability and flexibility are perceived to be in conflict, and where the majority of practitioners cannot be expected to be sufficiently familiar with the condition under study. This study found the development process to be successful in that practitioners complied well with final versions of the manual, but not early ones. Perceived clinical adequacy of manualized treatments increased over time, as did perceived usability of the document itself.

The manual development period was also useful to the study process as a whole in several ways. Three study outcome measures emerged from the manual development process. Such emergence had been planned for, but took place differently than anticipated: rather than use ‘native’ outcome measures, the team opted to use biomedical assessments for symptoms that they perceived as highly responsive to acupuncture. Among the ‘new’ outcome measures, two were indeed promising for future study (sleep and bowel function) while the third (swallowing) was not.

The process was time-consuming, and likely unnecessary for the majority of conditions studied for acupuncture therapy effectiveness. However an abbreviated version of the process should be considered for any study using a treatment protocol (standardized or not) that has not previously been piloted. Benefits of the process found in this study included identification of logistical and clinical difficulties with the protocol, and emergence of new outcome measures. Logistical difficulties encountered during the study period could additionally have been identified and addressed during this period, including difficulty with data collection which impacted completeness of study data, and a scheduling conflict with the speech and swallowing service which may have impacted its subsequent participation in the study.

7.1.2 Concurrent Cohort Study

While this cohort study did not randomize patients to treatment conditions and was not powered for hypothesis testing, its findings are nevertheless useful in guiding future study design. No difference between treatment groups was found on the FIM, supporting previous authors' suggestions that the outcome measure may not be appropriate for assessing clinical change with acupuncture during stroke rehabilitation. As anticipated however, FIM motor domain scores trended higher among the central two quartiles for severity, supporting suggestions that outcomes research related to motor function may only find clinical benefit for patients at a moderate range of severity. This suggestion is consistent with recent conclusions of multiple researchers who suggest that benefits of tPA and other interventions in acute stroke are most consistently found at the moderate ranges of severity (Shuaib et al., 2013).

In this light, baseline differences between patients who accepted and declined acupuncture therapy were noteworthy. Patients accepting acupuncture trended more severe on motor impairment at baseline, while cognitive impairment had more patients at the mild and severe end of the spectrum relative to the middle. Only seen as a result of this study's non-randomized design, this entirely unanticipated finding suggests that the subset of patients consenting for acupuncture research in the past may have overrepresented patients unlikely to show benefit.

Trends favoring the acupuncture group were found for three outcome measures: the mRS, a sleep log, and a newly constructed measure assessing bowel function from a patient-centered perspective. Four criteria for feasibility of future study were set, and met to varying degrees. Withdrawals were extremely low, and there were no adverse events related to acupuncture treatment. The sleep log and bowel function index had >75% completeness of data sets. The mRS did not, but has recently been designated for mandatory reporting by the Stroke Center's accrediting agency, meaning that data can be expected to be more complete in future. A final criterion for feasibility was the projected completion of a study in less than years using this study's methods. While none of the measures assessed met that criterion, all three of the measures discussed above remain promising for future study with revised methods.

7.1.3 Survey of Patients and Other Stakeholders

Alongside the cohort study's exploration of objective motor and non-motor outcomes across severity groups, a survey examined subjective reports of acupuncture's impact as experienced within and across the same groups. In contrast to cohort study results, there were perceptions of acupuncture benefit across all three severity groups. In particular, small changes in motor function were meaningful to severely impaired patients (e.g. small movements in an otherwise flaccid arm) and to staff (changes from two-person to one-person assistance in bed mobility).

Overall, acupuncture was well accepted by patients and their families, and by all staff groups except the speech and swallowing therapists (who, as discussed above, may have experienced acupuncturists as interfering with their work flow). Staff, patient and family perceptions of improved mood, motivation and participation in therapy are meaningful and should be further explored.

7.1.4 Extension of previous work.

Several previous authors' conclusions were strengthened by this study. As discussed in Chapter 5, study results were consistent with Naeser's (1994a) and Shiflett's (2007) arguments that benefit with acupuncture on motor outcomes (including the FIM, which largely assesses motor function) would be seen mainly in patients at a moderate level of severity.

Hopwood & Lewith's (2005) finding of better global disability scores (mRS) in the acupuncture group at 12-months post discharge (despite equivalent FIM scores at discharge) was previously unexplained, with emergent systemic benefit of acupuncture suggested as a possible cause. This study also found a difference on mRS at follow-up, with no difference on FIM at discharge. Benefits on sleep and constipation, as well as perceived impact on patient mood and the rehabilitation process itself, contextualize and strengthen Hopwood's suggestion that changes with acupuncture during the rehabilitation period may positively alter the patient's health trajectory post-discharge. This finding is consistent with Schnyer et al.'s suggestion that "acupuncture's greatest impact on clinical outcomes may hinge upon how it modifies the trajectory of illness, rather than on how it changes short-term, narrowly defined biomedical outcomes." (Schnyer et al., 2007a, p. 158)

7.1.5 New Findings

Several results of this project had not previously been seen. As discussed in Chapter 4, the manualization process drew on previous guidelines and models but was novel in its two-part structure allowing for ongoing development through use. Findings of apparent effect on sleep and bowel function were new to the Western literature, and are of interest for inpatient populations beyond stroke. Impact of acupuncture during stroke rehabilitation as perceived by patients and other stakeholders is a new research question. As discussed in Chapter 6, distribution of perceived benefits combined with cohort study results further substantiates an emerging picture of acupuncture in stroke rehabilitation as inherently personalized, with a wide variety of potentially appropriate treatment goals meeting the heterogeneous impacts of the disease itself. Reports of improvement in mood and motivation, as well as increased participation in rehabilitation therapy, have not been seen previously.

7.1.6 Synthesis of Findings

Taken all together, findings of this study suggest that, despite a decade of predominantly negative trial and review conclusions, further study of acupuncture during stroke rehabilitation is both warranted and feasible, given appropriate methods. In particular, the FIM is not recommended as a primary outcome measure; the mRS on post-discharge follow-up appears to be a more appropriate measure of acupuncture's global impact on recovery.

Motor and independence outcomes are not specifically supported by this study, but the trend towards greater improvement on the FIM motor domain, among moderately impaired patients only, supports Shifflet's suggestion that research on acupuncture for motor outcomes exclude mildly and severely impaired patients (Shiflett, 2007). Current research on outcomes of pharmaceutical interventions during acute stroke care have reached similar conclusions (Shuaib et al., 2013).

That recommendation is both supported and counterbalanced by this study's survey findings. Reports of perceived acupuncture benefit in motor-related areas such as walking were indeed most prevalent among moderately impaired patients. However other benefits including pain relief, relaxation and improved mood and participation in therapy were reported across the severity spectrum. Reports of motor improvement were also not absent among severe patients, and in some cases were of considerable experiential impact to patients and staff. For this reason, it is strongly recommended that patient-centered outcomes be evaluated among the widest possible group of patients. In particular, patients suffering second and subsequent strokes are typically excluded from clinical outcomes research as existing damage greatly complicates acute stroke recovery. Such patients constituted 24% of those screened out during recruitment, but represent a large and growing population whose needs should not be ignored.

Further recommendations regarding patient population, intervention, comparator and outcome measures are outlined below. Also outlined are recommendations for a run-in period, particularly important for sites where acupuncture has not previously been in use. Mutual accommodation of study methods to existing routines is indispensable, as is a period of familiarization for acupuncturists new to the treatment manual, and hospital staff unfamiliar with acupuncture.

7.1.6.1 Recommendations for Research in Acupuncture during Acute Stroke Rehabilitation

<u>Patient Population</u>

1. **Patients at mild and severe levels of stroke severity may be inappropriate for studies of motor and ADL outcomes.** The National Institutes of Health Stroke Scale (NIHSS) is most commonly used for evaluating stroke severity at baseline. A moderate range is usually defined as being from 7-8 to 15-16 (with 28 being the most severe) (Shuaib et al., 2013).
2. **A wider range of patients should be included in studies of patient-centered outcomes.** In particular, non-primary stroke patients constituted 24% of patients screened for this study, but were excluded as deficits from a primary stroke confound evaluations of motor recovery. (See “O” below for suggested patient-centered outcomes).

<u>Intervention</u>

3. **Use a treatment manual to balance repeatability and flexibility.** Patient presentations during acute stroke rehabilitation are complex and varied, as are assessment and treatment approaches within acupuncture therapy. A treatment manual provides consistency of approach while allowing the flexibility to provide clinically appropriate treatments.
4. **Run-in the manual.** In this study, manual development preceded the clinical study and stakeholder survey. For future trials, particularly at new sites, a manual run-in would also provide an opportunity to gather data on stakeholder impact and site feasibility at a time when such feedback could still be used to revise study methods. (See below under Environment for specifics).

<u>Comparator</u>

5. **Avoid a sham acupuncture comparator.** This study was not powered to draw statistical conclusions. However the widespread perception of benefit and moderate trends favoring acupuncture in this study are consistent with arguments of Witt (2011), Lewith et al. (2011) and others that sham control may lead to Type II error by separating small but meaningful specific and nonspecific effects of acupuncture. Comparative effectiveness research designs that incorporate nonspecific effects are therefore preferable for studying the impact of acupuncture on acute stroke rehabilitation, both of which constitute complex interventions. Sham control may be appropriate for explanatory trials investigating single specific effects of fixed needling protocols during early acute care, or post rehabilitation.

<u>Outcome Measures</u>

6. The **FIM does not appear to be an appropriate primary outcome measure for acupuncture during acute stroke rehabilitation**.

However, it may be useful as a secondary outcome measure to contextualize other outcomes.

7. The **mRS on 90-day follow-up** should be considered as a promising primary outcome measure as it is now mandatory reporting for many stroke centers
8. **Patient-centered and quality-of-life oriented outcomes should be studied.** Pain relief, relaxation, sleep and bowel function are meaningful outcomes for patients regardless of prognosis. Additionally their possible relationship to participation in therapy and post-discharge wellness warrant further exploration. Outcomes identified as promising in this study include:
   a. **Bowel function**
   b. **Sleep**
   c. **Motivation to participate in therapy**
   d. **Mood** (Anxiety, Depression, Well-being, alertness)
9. **'Extracurricular' outcome measures should be used sparingly.** Patients in acute rehabilitation are tightly scheduled and regularly evaluated using FIM, mRS and other outcome measures. Appointments for additional evaluations are difficult to make and keep; they may also challenge patients' energy or attentional capacity. This study does suggest new and additional outcome measures; however the number should be kept small and attention should be paid to making best possible use of routinely collected data.

Run-in, Relationships and Revision of Study Methods. In addition to the conventional dimensions of study design discussed above, much of the knowledge gathered by this study related to specific determinants of study feasibility at the procedural and interpersonal level. The following are areas where a manual run-in period was of use in this study, or could be of use in future studies. This run-in is particularly important to provide an opportunity for revision of study methods early in the project, if thorough feasibility testing has not been conducted at the institution in question.

10. Acceptability of acupuncture to patients, family members and rehabilitation unit staff should be carefully assessed (see #3c below)
    a. In-depth interviewing of stakeholders could be conducted at this time, or surveys for mixed-method work could be validated
11. Comfort of treating acupuncturists with the manual increased with use, as did compliance and perceived appropriateness of treatments.
    a. New outcome measures were added on the basis of practitioner experience and patient feedback
12. Rehabilitation staff members gained familiarity with the project through solicitation of their advice on study methods. Their advice was indispensable and should be solicited in at least the following areas:
    a. Selection of and design of new outcome measures
    b. Methods of data collection

c. Potential problems with work flow – early identification and resolution of such problems could avoid difficulties such as were encountered in this study with one rehabilitation service
d. Other perceived positive or negative impacts of acupuncture not previously identified

13. Data collection methods should be pilot-tested for practicality and completeness of data sets

7.2 Limitations of the Project

Limitations of this project's three studies have mainly been discussed in their associated chapters; chief among them is the provisional nature of any conclusions drawn from comparison of self-selected cohorts that differ at baseline. A more global limitation is the size and complexity of the research design; for each of the project's three studies, methods should have been stronger had the work stood as an independent project. For the manual, review of the historical Chinese literature on stroke addressed only the most major texts. For the concurrent cohort study, several planned outcome measures were abandoned due to personnel changes or logistical challenges which might have been worked around given more time. The resulting outcomes were weaker for not including discrete measures of cognitive and motor impairment (as distinct from function). For the assessment of subjective perceptions the data set was relatively thin, and less complete than it might have been given a longer survey development period and more time spent optimizing logistics of interview and survey administration.

Another global limitation of the project is my multiple roles in it. In the manualization project, I was simultaneously facilitator of the iterative development process, the main researcher providing background information, and a treatment team member, although the potential for power imbalance was mitigated by the longer clinical experience of all other participants. Of greater potential concern is cross-contamination of researcher and practitioner roles after running and interpreting two interim analyses in the cohort study, and while conducting thematic analysis of stakeholder perceptions. Within the cohort study, the potential would have been for me to change my treatment on the basis of early results; however, none of these results was sufficiently definitive to suggest decisive change in any direction. By contrast, there is no doubt that my thematic analysis was influenced by my clinical experience – both during the study and in the decade preceding. I discuss this influence more thoroughly in Chapter 6, but conclude that transparency in reporting of my dual role and the analysis process itself provide sufficient protection against readers being led to unjustified conclusions.

7.3 Future Work

Looking towards future work, a top priority is establishing whether the post-discharge mRS – rather than the FIM – is an appropriate measure for capturing any global impact of acupuncture on stroke rehabilitation outcomes. New requirements of 90-day follow-up mRS for many institutions provide an excellent opportunity to explore this question.

Outcomes of sleep and bowel function were also promising for future study, and may contribute to a model of acupuncture as conferring systemic benefit which is more apparent on follow-up than at discharge. Each is also important in its own right: as discussed in previous chapters, both function equally as predictors of prognosis for recovery and risk factors for future stroke. Both are also of considerable experiential importance to patients during the already difficult period of stroke rehabilitation.

Additional patient-centered outcomes were suggested by this study's qualitative inquiry and should be assessed in future. These include experiential impact of pain relief, as well as reports of relaxation and improved mood and motivation. In particular, staff perceptions of improved patient participation in therapy should be qualitatively and quantitatively explored.

This study does not support use of the FIM as a primary outcome measure in stroke rehabilitation, nor does it support inclusion of mildly or severely impaired patients in assessments of acupuncture for motor or functional independence outcomes.

7.4 Conclusion

Drawing on MRC Guidance for iterative development of research methods in complex interventions, this project demonstrated their feasibility for future study in an area of acupuncture research that has long been regarded as problematic. Innovations in structure of the treatment manual provide a template for evidence-informed practice that is suitable for both research and clinical use. Cohort study results are consistent with previous hypotheses that use of motor outcomes for acupuncture research is inappropriate in patients with mild and severe stroke. However stakeholder perceptions of acupuncture impact – and objective assessments of global disability, bowel function and sleep (in those suffering insomnia) – suggest that benefits of acupuncture are experienced by patients across the severity spectrum, and are measureable given attention to mutual appropriateness of acupuncture intervention, outcome measures and patient population.

Appendix A: Manual Version 1

LMC Manual for Acupuncture during Stroke Rehabilitation
Version 1, October 2011

	Elements of Stroke Syndrome	WM lit	Old CM lit	Mod CM	Nurses
1	Ischemia	X		X	
2	Local Hypoxia	X		X	
3	Hyperglutemia	X		X	
4	Cell death	X		X	
5	Disrupted signal	X		X	
7	Depression	X	31	X	X
8	Aphasia/Dysarthria	X	X	X	X
9	Dysphagia	X	X	X	X
11	Upper limb	X	31		
12	Lower limb	X	31		
13	Pain (eg subluxation)	X	31		X
14	Hypersensitivity	X			X
15	Urinary incontinence	X	32		X
16	Urinary retention	X	34		X
17	Bowel incontinence	X	32		X
18	Constipation	X	34		X
19	Bedsores	X			
20	Poor appetite		31		X
21	Thirst		34		X
22	Fatigue, low motivation		32		X
23	Disorientation		30		X
24	Insomnia				X
25	Lowered independence				X
26	Frustration		31		X
27	Altered sense of body			X	
28	Damp heat (greasy tongue)			X	
29	Wind			X	
30	Phlegm			X	
31	Qi Xue Xu Yu			X	
32	Qi xu			X	
33	Blocked channels			X	
34	Blocked Qi mechanism			X	

Key

x	Object of clinical concern; target of therapy
(red)	Primary pathomechanisms - highest impact on downstream effects
(yellow)	Additional areas of high clinical impact

STROKE TREATMENT MANUAL

Preliminary Outline of Acupuncturists Procedures

1. Chart: preliminary needs assessment
    a. Patient age, sex, comorbidities, significant history, meds
    b. Stroke type, location, size, time and circumstances of onset
    c. Rehab goals as per therapists
    d. Preliminary constitutional picture – above plus BMI? Hypertension? Diabetes? Cholesterol? Depression? Substance abuse?
2. Bedside constitutional assessment:
    a. Observation and Palpation: tongue, pulse, abdomen, plus observe form/shen/vitality
    b. Stroke symptom inventory
        i. Differential diagnosis as needed
        ii. Assess patient priorities
    c. Inquiry: heat/cold, sweat, head/body pain, taxation/sleep, nutrition, menses/birth, family support/stress
    d. Additional information – note what questions asked and why?
3. Treatment planning: identify priorities within categories below, then combine into single prioritized plan with 2-5 treatment goals per week.
    a. Most centrally causal (ie constitution, constipation/appetite/energy)
    b. Highest QOL priority to patient (also check with nurse)
    c. Highest Rehab priority to PT/OT/Speech
4. Treatment methods:
    a. First 10 days
        i. Du points to stimulate Qi/Blood flow to head (unless uncontrolled hypertension in which case treat that)
    b. Ear seeds at ipsilateral lesion location
    c. Constitutional treatment with Balance method to regulate the center, circulate fluids/blood
    d. Scalp for motor rehabilitation:
        i. Jiao system when motor <u>or</u> sensory impairment
        ii. Zhu system when both
        iii. Estim (2hz) scalp area plus affected limb
    e. Treatments from Assay (below) as appropriate by presenting syndrome

		Pat's sources	Zhu atlas	Hopwood book	Pei-Xin book	Rationales	Modern OM Research
1	Ischemia				"Awaken the brain and open the orifices, course the channels and free collaterals" p39 PC6 Du26 SP6 H1 Lu5 B40	p6 lift thrust drain	
2	Local Hypoxia					then Du26 sparrow peck	
3	Hyperglutemia					all others lift thrust drainage method	
4	Cell death					P6 is luo of pc collateral; with Du26 this opens/awakens. SP6 fosters yin subdues yang. Ht1/Lu5/B40 courses/frees	
5	Disrupted signal						
6	Depression	Deadman: H5, Liv5; Deadman: Melancholy P4, Lu3, Sp5	p3: head and face area; upper jiao area			Deadman: does he give a rationale?	Mode 1: Du20, LI4/ST36U; LI4/11 EX28:2, "mobility point:, ST36/40, EX36:1; Estim LI4/11, ST36/40 low freq. Mode 2: Du20, LI11, GB34U; same UE; LE minus mobility/ST36, plus GB34. De qi every needle except Du20, restim every 10 minutes for 30 mins.
7	Aphasia/Dysarthria			deviation of the tongue and aphasia shenmen R24 D15 H5; loss of voice p111 LI17	Regulate spirit open orifices: GB20 Du 20/23 yintang supplement, jinjin yuye bleed, UB10 R23 drain	Pei-xin p41: B10 benefits marrow and supplements brain; jinjin yuye, R23 promote movement of tongue	
8	Dysphagia						
9	Motor impairment					From Hopwood: Body points: "best practice" Essentials of Chinese Acu; scalp points Jiao's book 1997	PT's with training. LI4/10/15, SJ5, GB31/34/38/43, optional GB20 ST36; 4 scalp needles upper/lower ends plus junctions. Estim 2Hz body points (see TENS), 100Hz first/last scalp.
10	Upper limb	Deadman: Atrophy - Sj10, Contraction-St32, LI15, Si4, No raise - Lu5/6, Li13/14/15/16, St12, Si2/9, Sj2/13, Gb20/22/29, Liv13 Paralysis -Li10, P3, Sj5,Sj8/14, Weak Li14, Si10	p6: upper limb area	p111 Extensors (Yang aspect): GB21 LI15/11 TH5, GB10 Baxie (&LI17); p111 Flexors (yin aspect): LU10 PC8 H8 Baxie	p41: chourse channels free collaterals GB20 H1 Lu5 LI4 baxie SJ5 LI11/15 p39: XNKQ above plus: clenched fingers p39 add LI4; inability to extend/stretch add LI11	Pei-xin: needle LI4 towards LI3, drain lift thrust; drain baxie with lifting, thrusting and rotation; drain SJ5 with lifting thrusting; supplement GB20 with roattion drain H1 Lu5 with lifting thrusting.	Du20 GB20 LI15/11/4, GB31/34, ST36 affected side. E-Stim LI4-11 and GB31-34, variable output up to 10mA, alternating 3/15Hz. 20min.
11	Lower limb		p6: lower limb area	p111 Yang: GB30/31/34, ST31 B36 Bafeng; p111 Yin SP10/6, Lv2, Ki3 Bafeng; Sp9 if edema	SP6 B40 GB31/34 drain with lifting/thrusting; UB30 manipulate until electrical sensation reaches toes UB60 drain with rotation		ST40, R12, D20/26 plus Dx: Korean 4 groups (B66 LI11 H3/4, GB34/44; Lu8 Sp3 H8/9, K3/7; ST36 Li15/11, H7.8, SI5; Sp1/2 H8/9 Liv1 Rn4)
12	Functional independence						Refs 1, 7-9, 12, 19 (Sze, Wong, Johansson, Gosman-Hedstrom); taiwanese TCM text
13	Pain (eg subluxation)		p6: shoulder area (or other local areas)	subluxation p111 eyes of shoulder SI11 LI11 SJ9 baxie	SI15/14 needle subcutaneously, drain with rotation; ST38 drain with lifting, thrusting, rotating; Du26 pecking; drain LI15 jianneiling jianwailing SI9 with lifting/thrusting.		
14	Hypersensitivity						

15	Urinary incontinence	Qi def: Lu7,UB13/23/53, Du 12/20, Sp def: Ub20,St36, R12, Ki yang def: Ub23/28,Du4,K7, R4, Yin def: R4,K3, Sp6, Liv Fire: Liv2,Ht7,yin tang, Sp6 **(PC 1/12- Principles CM)** Lu5,St22, Sp6/9/11, Ht5,/7/8, Ub23/26/27/28/32/39/40, Ki3/6/11, Gb34/41, Liv1/2/3/8/9/10, R1/2/4 (**Deadman)**	p4: lower jiao area				
16	Urinary retention	Lu Heat:Lu5,7,R3, LI11, Ht Heat: H8,Si2,R3,Ub28, Ki2 Mid/low Damp heat: R3/12, UB20/22/28, Sp6/9,R3, Central Qi def: Du20, R6/12, Ub20/28, Sp6, R3, Stag of Essence: Sp6/10,Ub17, Liv5,R6, St 29 Ki yang def: Ub23/28, du4,R4 **(PC 1/12- Principles CM)**	p4: lower jiao area				
17	Bowel incontinence		p4: middle jiao area				
18	Constipation	Heat:Li4/11,Sj6, St28/29/444, Sp14,15 Liv Qi Stag: R6/10,Gb34, 4 gates, Sp15, Def: St36, Sp6/15, R4,Ub21/23/25, K3/6/7 Cold: R6/8, K8, Ub23/25/26 (**PC 1/12 - Principles CM)** St22/25/37/40/41/44, Sp2/3/5/13/15/16, Ub25/26/27/28/32/33/34 /39/51/56/57, Ki1/4/6/7/14/15/16/17/18/Sj5/6, Gb27/34, Liv1//2/3/13, R6 **(Deadman)**	p4: middle jiao area				
19	Bedsores						
20	Poor appetite	Ub20/21 **(Deadman)**	(p4: middle jiao area)	appetite/constipation/difficult urination p111 R4/12, ST25/36		Zhu: Not stated but implied by "for diseases and symptoms of the LV, GB, SP, ST"	
21	Thirst	Lu7,St44,Sp20,SI2,Gb25,Liv2,R23,UB40,LI11, Du26 **(PC- 1/12 - Deadman)**					
22	Fatigue, low motivation	*Def:(LU)*: Lu9, St36, R6/12/17, Ub13/43, Du12,Sp6 *(SP)* Sp3,St36, R12, Ub17/20/21, St44, Du20 *(HT)* 5/6/7, P6/7, Ub15, R4/6/14/15, Du14, K3/6 *(Ki Yang def)* K3/7,R4, Ub20/23, Sp6 *(Blood def)*H7,P6,R4/14/15, Ub17/18/20, St36,Sp6, Liv8 *(Liv yin def)*R4, Liv8,Sp6,St36 *(Ki yin)*K3/6, Lu7, R4,Ub23/52 *Excess:* *(Liv Qi Stag)* Gb34, Liv3/13/14, P6, Sj6 *(Liv Yang Rise/Fire/Wind)* Liv2/3/8, Sp6, Ki3, R4,P7, Ht7, Du16, GB20, Si3,Ub62 *(Phlegm)* R12,St36,Ub20,St8, Du20, Lu5 *(Damp)* Sp6/9, Ub22, R9, Lu7, Li4/11, Ub20, R12 **(PC- 1/12- Principles CM)**	p4: middle jiao area				

23	Disorientation	Ht7,Ub8/15, K20, Gb2,Du11/20, R14, Lu3 **(Pc-Deadman)**					
24	Insomnia	*<u>Def</u>: (Blood):* St36, Sp6, H7, R14, Ub15, Yin Tang *(Yin):* Ht7, Ub15, R14, Sp6, St36, R4 *(HT/KI x harm):* Ht 6 red, All reinfoc: Ht7, P7, R4/15, Sp6, K3/6, Ub15/23/44/52 *(Ht/Gb Def):* Ht7, GB40 *(Liv yin def):*¯Liv8, R4, Sp6, K3/6, Ub15/23/44/52 *<u>Excess</u>: (Liv Fire)* Red. Liv2/3, Gb12/13/15/20/44, Sp6, Ub18, Du 24, Ub1/4/7/62, K6 *(Ht Fire):* Ht 7/8, Sp6,Li11, R15, Du 19 Ub15/44 *(Phlegm Heat):*St40, R9/12,Ub20, Sp6/9, Li11, St8,Gb12,St45, Sp1 *(Residual Heat in Diaphragm) :* Lu10, H8, Ub17, St40, Li11, Sp6, R15 **(PC- 1/12 Principles CM)**					
25	Helplessness						
26	Frustration	Ht7 **(for insulting people) - Deadman**	p4: middle jiao area				
27	Altered sense of body	*(Oppressive sensation of):* K6 **Deadman**					
28	Damp heat (greasy tongue)	St40 (**Deadman)**					
29	Wind	Du16,P7, Ub11/12/13/4567, Li6, Lu10,M-LE-34,LI 15 *(Windstroke)* LI 10/15, St36, Ub15/23/40, P6/8/9, GB2/13/15/21/40, Liv2, Du16/20, R4, Si Shen Cong, Shixuan, Ub62, P5 **(Deadman)**			**Deviation of mouth/eyes: GB20 taiyang ST4/7 LI4;** Benefit marrow supplement brain course/regulate sinew vessels; supplement GB20 to benefit marrow supplement brain. Taiyang towards ST6. Drain ST6/7. Drain LI4 on unaffected side to fortify spleen transform dampness, course sinew channels		
30	Phlegm						
31	Qi Xue Xu Yu						
32	Qi xu						
33	Blocked channels						
34	Blocked Qi mechanism				Organ stroke block pattern: open blocked orifices PC6 Du26/16 shi xuan.	rationales/tecniques p39	
	Dizziness/vertigo		p4 Vertex, perineum, foot area; p7 Auricle-temporal area; p8 Occipital-temporal area, Occipital area			Zhu: "Sinks liver yang, raises yang qi"	
	UTI		p7 lower abdomen area			Zhu: "acute diseases of lower burner"	
	Headaches, mouth deviation, tics		p7 frontal-temporal area			Zhu: "lies on ST and GB channel"	
				* add syndromes p110			
				facial paralysis p111 qianzheng ST2/4, R24			
				general trunk weakness and asymmetry p111 GB20 bailao UB23/25			
				pathogenic wind GB20/12, SJ17			

	eyelids not closing				circle eyelids, 1 needle per 0.1 cun	
	club foot				KD9 UB60 ST41 GB40	
					*add electro-acupuncture, scalp	
					auricular: adrenal, heart, liver, brainstem, subcortex.	
					*Tui na: pushing grasping rolling pulling scrubbing, rotating foulage. GB20/21, LI10/11/15, SJ10, GB30/34, UB40/57. Face back limbs primarily on affected side.	

Appendix B: Manual Version 2

ACUPUNCTURE DURING STROKE RECOVERY AND REHABILITATION

TREATMENT MANUAL, VERSION 2

MARCH 2012

LUTHERAN MEDICAL CENTER
ACUPUNCTURE TEAM

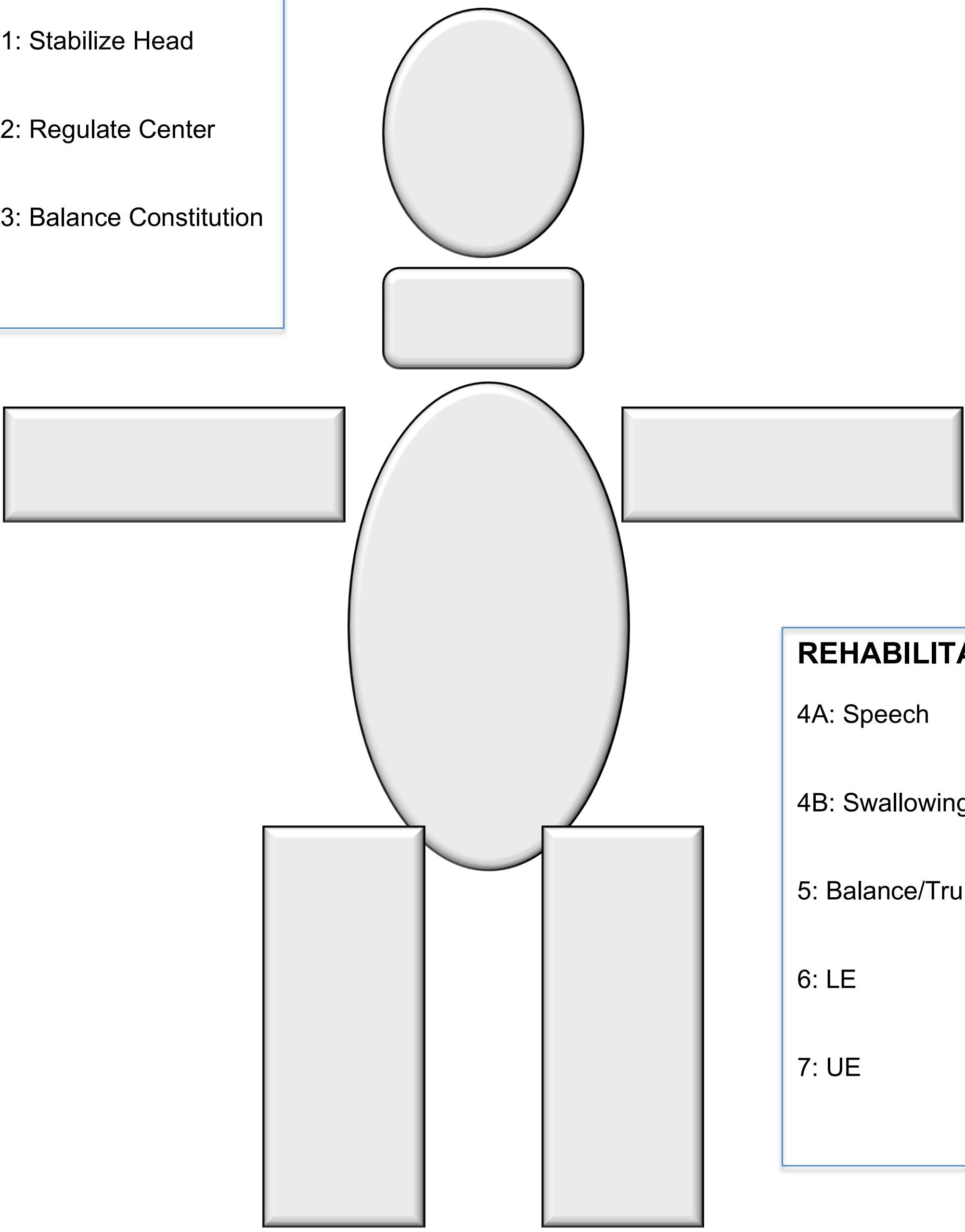
Patient ________________________ Treatment # _____ Date________________

RECOVERY

1: Stabilize Head

2: Regulate Center

3: Balance Constitution



REHABILITATION

4A: Speech

4B: Swallowing

5: Balance/Trunk Stability

6: LE

7: UE

Needles:_____ Time:_______ # Needles out:_____ Time:______ Initials:________

STROKE RECOVERY: Day 2 until admission to Rehabilitation Unit

Continue these treatments until Day 10. If no treatment effect after 2 treatments (improvement in spirit, pulse/tongue; change in BM/urination, blood pressure) then reevaluate diagnosis.

1. **Stabilize Qi/Blood flow to the head**. Check last 2 BP readings, and take blood pressure before and after. (If patient is on continuous monitor, use 4-hour intervals).
    a. If **systolic >160**: GB20, Liv3->Kid1, Sp6, PC6, Du20, si shen cong
    b. Otherwise: Du20, Yintang, Du16(in&out, no manipulation), PC6 SP6
2. **Regulate the center**. Palpate dan tian, assess whether patient is strong/weak, hot/cold. Start with abdominal tui na (round rubbing) to restart Qi Ji.
    a. If **constipation**: LI4, ST37, SP15
        i. If **phlegm/heat** (thick colored tongue fur): +LI11, ST44
        ii. If **Qi stagnation** (tight pulse, purplish tongue, firm dan tian): + Liv3, SJ6, GB34
        iii. If **cold** (palpation, pulse rate): + warming therapy on Ren4/Du4
        iv. If **weak patient** (soft dan tian, poor vitality): + Ren4/12
    b. If **urinary retention**: Ren3/5/9, Du23, Kid7
        i. If infection: UB67, Liv5, GB34, UB23 (3 needles, chicken foot)
    c. If **diarrhea**: LI4, ST25, Ren 23 (Zhu's Lower Jiao point)
        i. If cold (palpation, pulse rate): + warming therapy on Ren4/Du4
        ii. If weak (soft dan tian, poor vitality): + abdominal tui na
    d. If **urinary incontinence**: Du20, Kid7, Ren4
        i. If cold (palpation, pulse rate): + warming therapy on Ren4/Du4
3. **Address constitutional problems**. Additional needles as determined by differential diagnosis. Do not exceed 12 needles per treatment in weak patients.
    a. **Blood stasis** (distended sublingual veins; spider veins; stasis macules on tongue or limbs): + SP10
    b. **Phlegm** (slippery pulse, obesity, visible phlegm-drool): ST40, PC5
    c. **Full heat** (heat effusion with strong dan tian; forceful rapid pulse): LI4/11, ST44
    d. **Damp heat** (with putrid odor, greasy thick coat colored yellow or dark): GB34, Liver 2/3
    e. **Qi stagnation** (wiry pulse, purplish tongue, firm dan tian): + Liv3, SJ6, GB34
    f. **Qi xu** (scalloped/pale tongue, poor appetite, soft or weak pulse): abdominal tui na, warming therapy on Ren4/Du4, Ren12
    g. **Yang xu** (soft abdomen, slow pulse rate, weak right Chi pulse): + warming therapy on Ren4/Du4; KD3
    h. **Yin xu** (emaciated appearance, soft abdomen, heat signs): Ren4, KD6 or 2(if KD fire)
    i. **Shaoyang signs** (half tongue coat; alternating hot/cold; dry throat/dizzy head/bitter taste): GB34, SJ5/6
4. **Treat the Spirit**
    a. If **wind signs** (seizures, shaking, twitching): St2(downward, no manipulation)
    b. If spirit is **clouded**: +Du26(in&out, pecking till eyes water); SP6, PC5, si shen cong
    c. If spirit is **scattered**: PC8, Kid1 (affected side only); Ren4/6

STROKE REHABILITATION: On Admission to Rehabilitation Unit

For each category, start with master points below then refine treatment by assessing xu/shi, blockage and flow in the channels specified. For extremities, follow or adapt sequential channel treatments based on patient's presentation and course of recovery.

Continue treatments on previous page if weakness, disruption of Qi mechanism or constitutional problems persist. In strong patients, aim to treat before PT/OT; in weak patients, treat after.

1. Swallowing: GB12/20, SJ17, Lu7, Kid6, lower 1/5 of motor line, sensory if needed
    a. Assess channels: Ren, GB, TH, Chong, Lu, ST, KD
2. Speech: Ht5, lower 1/5 of motor and sensory line
    a. Assess channels: HT, KD, Ren, Chong, Lu
3. Balance and trunk stability: Balance points; Du20; treat central Qi (above)
    a. Assess xu/shi in 8 extra channels especially Du, Chong/Dai
4. Lower Extremity: Upper 1/5 of motor line, sensory if deficit; SP6
    a. UB: UB40; GB30, UB53/58/59
    b. ST: ST31/36/41
    c. GB/Liv: GB40->Kid6; Liv3
5. Upper Extremity: Second 2/5 of motor line, sensory if deficit; Lu5, Ht1
    a. LI: LI4/11/15
    b. LU: Lu2/3/5/9/10
    c. TH: TH14/10/5/6
    d. PC: PC4/3/1
    e. HT: HT1/5
    f. SI: SI 11/19/9/8.5/6/5/4

Needle Technique:

1. Unless otherwise specified, supplement if pulse is weak and/or dan tian is soft, drain if pulse is strong and dan tian is firm.

Differential Diagnosis:

1. Liver signs
2. Kidney signs

Tongue Diagnosis Form

Patient ID #:	Date:		Assessor:	

Variable	Pathological Characteristic	Severity			Location			
Form	Small (short, thin or narrow)	1	2	3	Front	Middle	Side R/L	Back
	Enlarged – whole or part	1	2	3	Front	Middle	Side R/L	Back
	Scalloped or indented[i]	1	2	3	Front	Middle	Side R/L	Back
	Sunken Area	1	2	3	Front	Middle	Side R/L	Back
	Deviated or asymmetrical	1	2	3	Front	Middle	Side R/L	Back
		1	2	3	Front	Middle	Side R/L	Back
Bearing	Stiff	1	2	3	Front	Middle	Side R/L	Back
	Flaccid	1	2	3	Front	Middle	Side R/L	Back
	Curling	1	2	3	Front	Middle	Side R/L	Back
	Contracture	1	2	3	Front	Middle	Side R/L	Back
		1	2	3	Front	Middle	Side R/L	Back
Color	Pale	1	2	3	Front	Middle	Side R/L	Back
	Red	1	2	3	Front	Middle	Side R/L	Back
	Red spots (raised or flat)	1	2	3	Front	Middle	Side R/L	Back
	Bluish (or purple)	1	2	3	Front	Middle	Side R/L	Back
	Additional ____________	1	2	3	Front	Middle	Side R/L	Back
Cracks:	Severity Index[ii] 4	1	2	3	Front	Middle	Side R/L	Back
Coating	Thick	1	2	3	Front	Middle	Side R/L	Back
	Too thin	1	2	3	Front	Middle	Side R/L	Back
	Peeled (whole or part)	1	2	3	Front	Middle	Side R/L	Back
	Without root	1	2	3	Front	Middle	Side R/L	Back
	Dry	1	2	3	Front	Middle	Side R/L	Back
	Wet	1	2	3	Front	Middle	Side R/L	Back
	Greasy/Sticky/Tofu	1	2	3	Front	Middle	Side R/L	Back
	Apparent food influence	1	2	3	Front	Middle	Side R/L	Back
Coat Color	Bright white	1	2	3	Front	Middle	Side R/L	Back
	Dirty White or Grey	1	2	3	Front	Middle	Side R/L	Back
	Yellow	1	2	3	Front	Middle	Side R/L	Back
	Green, Brown, Black, etc	1	2	3	Front	Middle	Side R/L	Back
Sublingual Veins	Darkness	1	2	3	Front	Middle	Side R/L	Back
	Thickness	1	2	3	Front	Middle	Side R/L	Back
	Asymmetry	1	2	3	Front	Middle	Side R/L	Back
Other	Brown spots[iii]	1	2	3	Front	Middle	Side R/L	Back
		1	2	3	Front	Middle	Side R/L	Back
		1	2	3	Front	Middle	Side R/L	Back
		1	2	3	Front	Middle	Side R/L	Back
		1	2	3	Front	Middle	Side R/L	Back

PULSE WORKSHEET

1. Enter Patient ID, Date, Time and your initials.
2. Enter Pulse Rate.
3. Enter 8 parameter Pulse qualities.
4. Use the arrows and equal sign to distinguish between qualities on either side. Only use the 28 pulse qualities listed if there are abnormalities that stand out and are not covered by the 8 parameters.

Patient ID:	Date: Time::	L.Ac. Initials:

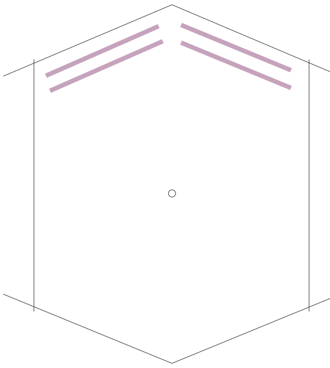
Yin	8 Parameters							Yang
Slow	3	2	1	0	1	2	3	**Fast**
Deep	3	2	1	0	1	2	3	**Superficial**
Narrow	3	2	1	0	1	2	3	**Wide**
Forceless	3	2	1	0	1	2	3	**Forceful**

Rate: ________BPM

	Left	<=>	Right
Cun			
Guan			
Chi			

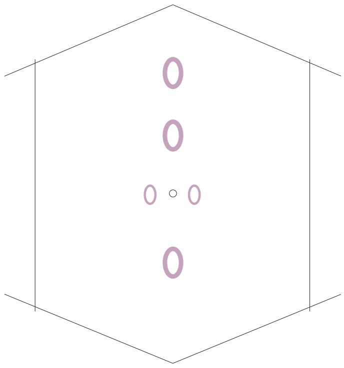
PULSE QUALITIES			
Rhythm	1) Bound	*jie mai*	Slow, irregularly interrupted
	2) Intermittent	*dai mai*	Interrupted at regular intervals
	3) Hasty	*cu mai*	Rapid, irregularly interrupted
	4) Choppy/Rough	*se mai*	Knife lightly scraping bamboo
Rate	5) Rapid	*shuo mai*	More than 80 beats per minute
	6) Slow	*chi mai*	Less than 60 beats per minute
	7) Racing	*ji mai*	More than 95 beats per minute???
	8) Moderate	*huan mai*	70 beats per minute
Force	9) Excess	*shi mai*	Forceful at all three positions
	10) Deficient	*xu mai*	Forceless at all 3 positions and weak with pressure
	11) Floating	*fu mai*	Hits your fingers with light pressure
Depth	12) Empty	*san mai*	Floating, large, and forceless; can be pushed through
	13) Soft /soggy	*ru mai*	Thin but pressure goes right through it
	14) Drum-skin	*ge mai*	String-like but empty in the middle
	15) Hollow	*kou mai*	Floating and empty in the middle
	16) Scattered	*dong mai*	Rapid, short and slippery
	17) Surging	*hong mai*	Extremely large, billowing like waves and arriving with a great force
	18) Sinking	*chen mai*	Not felt under light pressure and only felt under heavy pressure
	19) Hidden	*fu mai*	Considerable pressure needs to be applied to even feel it
	20) Faint	*wei mai*	Extremely fine, and feels like on the verge of expiry
Shape	21) Long	*chang mai*	Can be felt beyond the cun and chi position
	22) Short	*duan mai*	Felt only at the guan position
	23) Thready	*xi mai*	Like a fine but distinct thread
	24) Slippery	*hua mai*	Pearls rolling in a dish
	25) Wiry	*xian mai*	String like a musical instrument
	26) Tight	*jin mai*	String-like and forceful
	27) Weak	*ruo mai*	A deep pulse without force
	28) Full	*lao mai*	Forceful and feels tied to the bone

Draft 2/22/12



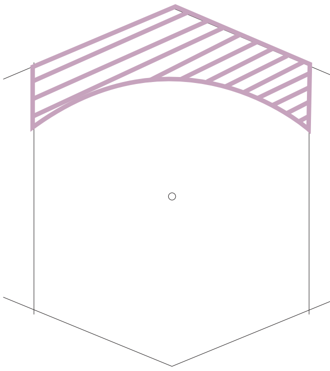
hypochondriac tightness
(objective)

1-3 lines for severity

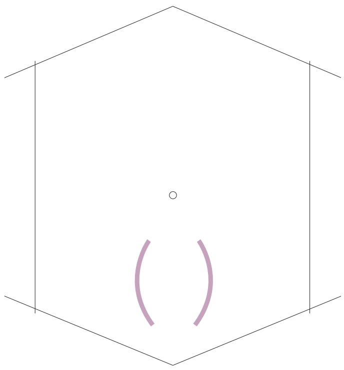


pulsations

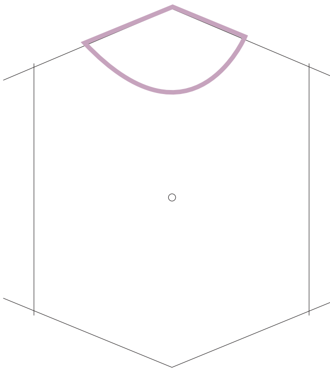
peri-umbilical or CV



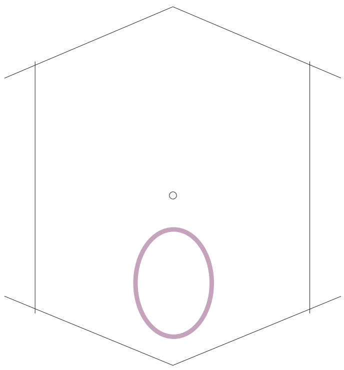
hypochondriac tightness
(objective + subjective)



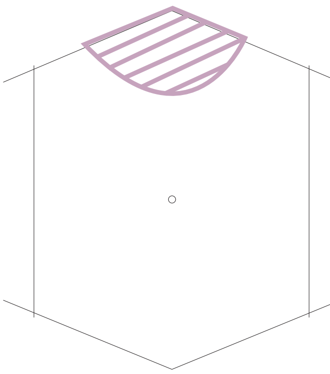
low abdomen empty



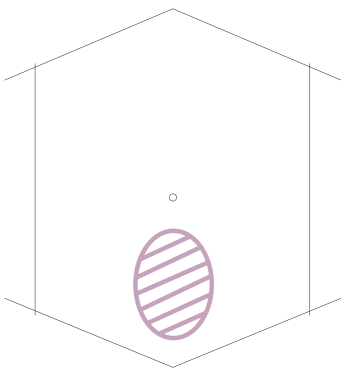
epigastric tightness
(objective)



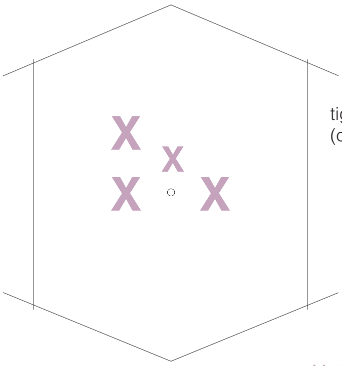
low abdomen tightness
(objective)



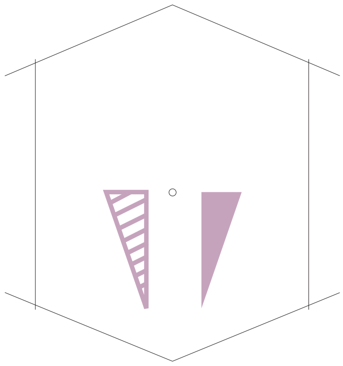
epigastric tightness
(objective + subjective)



low abdomen tightness
(objective + subjective)



tight obstruction / mass
(objective)

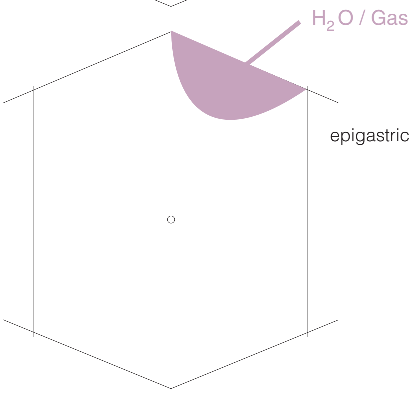


oketsu (blood stagnation)

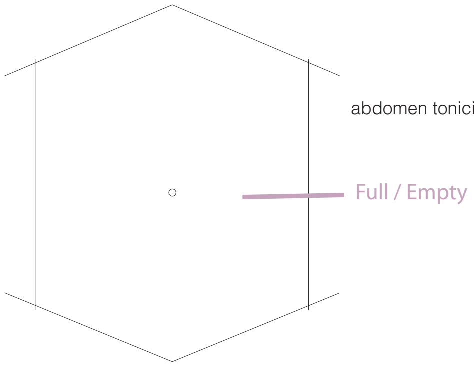
(L) St 25 - St 27 area

immune (Lu / LI)

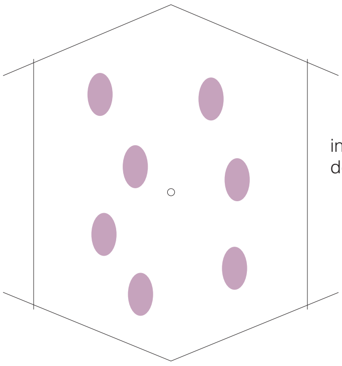
(R) St 25 - St 27 area



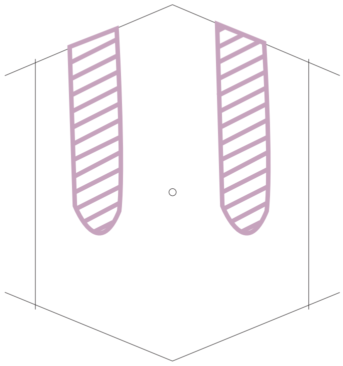
epigastric splash



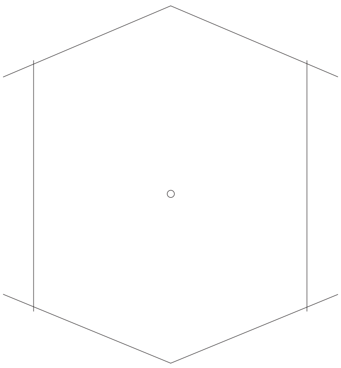
abdomen tonicity

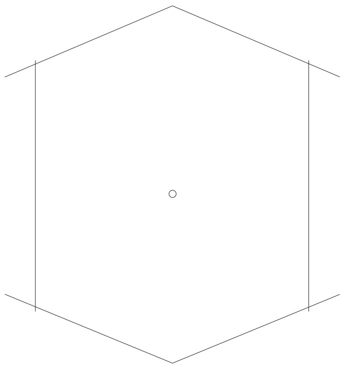


inside emergency
deficient tenderness



inside emergency
rectus tightness





Appendix C: Manual Version 3

TREATMENT MANUAL
FOR
ACUPUNCTURE DURING STROKE RECOVERY AND REHABILITATION

VERSION 3: SEPTEMBER 2012

Introduction

Acute post-stroke care is one of the most rewarding areas for acupuncture treatment, but it is also one of the most challenging. Challenges include the severity of the illness, the large number of Western interventions under way, the great variation in patients' diagnoses and treatment needs, and the fact that those needs change greatly over the course of the 2-4 weeks that patients typically remain in the Neurology and Acute Rehabilitation units.

For all of these reasons, use of this manual is not recommended without the 2- or 3-day training programs in its use offered through Lutheran Medical Center and other educational institutions.

This manual covers treatment of patients who have suffered ischemic stroke. At the onset of this condition, blood flow is blocked by occlusion of one or more vessels, and the directly affected cells die of en masse, forming an "ischemic core." Over the following 7-10 days, cells downstream from the blockage continue to struggle with hypoxia and buildup of metabolic waste, even as the rest of the brain begins to heal and make new connections. During this time of stroke recovery, hospital care focuses on medically stabilizing the patient and controlling blood pressure -- which is typically high and labile – without lowering it so much that cranial circulation drops. During stroke rehabilitation, the patient works with rehabilitation therapists in Speech/Swallowing, Physical Therapy and Occupational Therapy. Each of these areas represents an important dimension of the patient's well-being and what will become their new life. Depending on the size and location of the stroke, and the patient's age, health status and emotional makeup, the patient's journey through these stages will vary greatly from person to person, and may overlap.

Over the last 9 years at this institution, LMC's acupuncture team has found acupuncture to be beneficial in helping the patient to progress – in different ways for different patients, and to varying degrees for reasons that are not always apparent. The goal of this manual, therefore, is not to lay down a specific "best practice" point prescription which can only have general applicability. Instead, we hope to create a template for clinical assessment and decision-making that will allow acupuncturists to draw on skills of individualized diagnosis and treatment developed in other settings, for accurate and effective use in the complex clinical picture described above. The manual does contain recommended point selections for specific clinical presentations. However its emphasis is on determining which treatment principles to apply when, by sequentially addressing general treatment goals and prioritizing them relative to the patient's needs as a whole. All of the guidelines given in this manual are suggestions.

The manual is structured as follows:

When using the manual in routine care, experienced acupuncturists who have been trained in use of the manual and developed some practical familiarity with the manual's approach are encouraged to incorporate point combinations from their own practice, if they believe such substitution will better serve a particular patient's recovery. They are then encouraged to email us with the case history and results! In this way, the manual will continue to grow based on clinical experience among the community of practitioners who have chosen to pursue this challenging but highly rewarding area of practice.

- The Lutheran Medical Center Acupuncture Team, September 2012
  Patricia Cassidy, Claudia Citkovitz, Sally Rappeport, Paul Ryan, Maryanne Travaglione
  Email us at: CCitkovitz@LMCMC.COM

Overview of the Manual

Three core worksheets guide the patient encounter, as follows:

The **ASSESSMENT AND TREATMENT PLANNING (ATP) WORKSHEET** looks and functions much like an ordinary paper chart used in clinical practice. Its first page streamlines the traditional clinical exam, focusing on key clinical signs and symptoms that guide the choices made in the flowsheets described below, and holding all that information in one place to guide treatment planning. The second page of the worksheet guides constitutional assessment, showing 8 major syndromes (and three subgroups) commonly seen in stroke recovery patients at LMC.

The **RECOVERY WORKSHEET** introduces the primary priorities of stroke recovery:

1. Stabilize Qi/Blood flow to the head: this is integrative care, in which we use our concept of Qi flow to support the MD's treatment goal of maintaining stable and somewhat elevated blood pressure to ensure optimum blood circulation – and, particularly in the first 7-10 days, clearance of metabolic waste. Treatment approaches here also cover absent, clouded or agitated spirits, or remaining symptoms of wind (relatively few in ischemic stroke).
2. Regulate the Center: this is a key component of the manual's approach. Our experience is that stroke in Chinese medicine is characterized by massive disruption of Central Qi flow, and that to be effective, treatment must focus on restoration of digestive function and fluid metabolism.
3. Balance the Constitution: restoration of appropriate upward and downward movement in the center relies on an understanding of the current state of yin, yang, Qi, Blood and fluids. Key diagnostic signs and symptoms for commonly seen patterns of disharmony in ischemic stroke are shown on the second page of the ATP worksheet described above, along with suggested treatment approaches.

These first three problems may present together or separately; they can and should be addressed together in treatment planning for the first 7-10 days following stroke. One or more of these problems may persist long past the first week of recovery, in which case recovery treatments can be combined with the rehabilitation treatments described below.

The **REHABILITATION WORKSHEET** can be used after 10 days post stroke, or earlier if the patient is progressing well. It is structured more loosely than the Recovery worksheet, but continues the overall progression of treatment priorities as seen below.

Treatment priorities for rehabilitation are:

4. Speech and Swallowing: because of their devastating effect on the patient's morale and quality of life, these deficits should be addressed aggressively until resolved.

5. Balance and Trunk Stability: these problems most commonly presents in strokes that are deeper in the brain or more severe, and can be assessed and treated as a continuing problem of central Qi, often using extraordinary meridians as well as contemporary scalp and auricular approaches.
6. Lower Extremity Motor Recovery: In the most common type of ischemic stroke, the lower extremity typically recovers sooner and more completely than the upper. For this reason, it is useful to promote lower motor recovery as soon as possible (given higher priorities above). Standing and walking provide a deeply meaningful boost to the patient's morale, and facilitate faster recovery by circulating Qi and Blood. Recovery in general moves from distal to proximal muscle groups, starting with the hamstring and gluteals. In milder strokes, recovery of dorsiflexion can mean the difference between wearing or not wearing a foot brace for life, and may also be worth focusing on towards discharge.
7. Upper extremity motor recovery: Once lower extremity recovery is under way, it is useful to switch to upper extremity recovery as soon as possible to give the best chance of upper extremity return – with always the possibility of returning to the lower extremity if progress stalls.

Inevitably, there will be situations where a patient either does not respond to the first-line treatments on the two core flowsheets, or initially presents in a way that is not adequately addressed by the assessments and treatments shown. (Lack of response is defined as three successive treatments with no improvement in either the problem or the associated OM signs/symptoms). The **INDEX OF STROKE SYNDROMES** contains what we think of as the 'best available evidence' for what may help in treating stroke. This is a combination of: excerpts from textbooks that the team has found helpful; several kinds of research literature; and advice gleaned from classes with a few experts like Shi Xue-Min and Zu Ming-Qing. The team thought of this structure as a way to reproduce the usual 'research' process of an experienced clinician: treat what you see, using the approaches that usually work for you; then if that doesn't help (or if the case is outside your experience base) go to your bookshelf, then the internet, then call or email trusted colleagues for assistance.

Taken together, the 3 core worksheets of the manual plus the Index are intended to guide the majority of treatments. There will always be difficult cases for which you are encouraged to (A) look for research or texts that have come out subsequent to this manual; (B) email us with questions; and (C) begin to rely on your own clinical experience, which will extend the principles learned in successful treatments to understanding what's needed in more difficult cases.

Essential Features

There are a number of self-contained systems for treatment of acupuncture after stroke, constructed by long-time practitioners with decades of experience such as Zhu Mingqing, Jiao Shunfa and Shi Xuemin. This manual is not one of them – for many reasons, including the authors' lesser degree of experience. We have all been practicing acupuncture for over 10 years but less than 20, and only one of us has been treating stroke patients for that long. Rather than provide a single authoritative set of points or protocols, this manual aims to guide practitioners in identifying what is most important clinically, and selecting judiciously from among a range of available treatment options. Four key principles are essential to the manual's clinical and procedural approach.

First of all, this manual is eclectic (some may prefer to say pluralistic, or integrative, though there are important distinctions in how those terms apply). We do not set out a single biochemical or energetic "model" of how the treatments work. Instead, we try to provide a step-by-step practical framework for choosing and applying the plentitude of biochemical and energetic models available in clinical research and Chinese medicine texts. Several of these models are described in more detail in this introduction to the manual, including Balance methods and auricular acupressure. Others appear only briefly in the Index of Stroke Syndromes, as they apply to a given complaint.

A second defining feature of post-stroke care as defined in this manual is its emphasis on restoring normal upbearing and downbearing. This applies equally to the biomedical concept of cranial circulation (particularly in the first 7-10 days) and to the Chinese concept of 'qi mechanism'. Stroke often presents with constipation and urinary retention, or conversely with incontinence. Within this manual, rectifying the qi dynamic is an important root treatment that in most cases should be addressed at each treatment until it is resolved.

A third and very useful principle of motor recovery is to regard the affected limb as deficient of Qi in its primary meridians, and full of static blood (combined with some proportion of phlegm) in the luo. Treatment thus aims to fill and 'light up' the large meridians, particularly Yangming, Taiyang and Taiyin; while pushing through stagnation in the flesh. Palpation of affected channels should aim to identify areas of deficiency to supplement and areas of excess to move.

One final principle useful in pulling all these treatment priorities together is that treatment planning on any given day requires the practitioner to adapt her theory to several layers of practical considerations. The overall treatment plan is medically driven from head and center to lower and upper extremities, with a priority on rebalancing the qi mechanism as well as sleep, speech and swallowing. But the patient may have different priorities: for example, having <u>some</u> movement in a paretic upper limb may be of great psychological importance. Or, acupuncture's most useful contribution on a given day may be to facilitate the work of the primary rehabilitation therapists. (For instance, addressing nausea, headache or shoulder pain so that Occupational Therapy can progress). If there is an opportunity to communicate before and after with the physician, nurse, or physical, occupational or speech therapist, it is always best to do so. (Even if this communication is to say, "I am having a hard time with this case, what are your treatment goals, and is there anything unusual about it from your point of view?").

Safety Considerations

Medical escalation and the urgent need for vigilance

Patients who have recently suffered a stroke are at elevated risk for recurrence, or for conversion of ischemic to hemorrhagic stroke. **Before and after the session, assess the patient's responsiveness to touch and verbal stimuli, as well as speech quality and, smile**. These should be grossly equivalent to or better than previous assessments. If there is a downward change, immediately notify the Registered Nurse (RN) who will either be aware of the change (e.g. due to change in medication) or will continue escalation to medical personnel. Make sure you or other trusted personnel are at the patient's bedside throughout needle retention, and observe any changes in status such as involuntary movement or sudden unresponsiveness (versus drifting off to sleep). At LMC, **any pain of 8/10 or greater must also be reported to the RN**.

Clean needle technique at the bedside

Clean needle technique (CNT) is important for any patient, but particularly so for these elderly and vulnerable patients in the hospital environment where presence of blood-borne pathogens and drug-resistant bacteria must be assumed at all times. The Council of Colleges' CNT manual, 6th edition, should be followed.

Cautions and contraindications

Seizures

Seizures with acupuncture treatment are rare, but have been reported. Patients are more prone to seizures post stroke, although in most cases these are small focal seizures that present as brief periods of unresponsiveness. **It is important both to check the medical record and to ask the patient whether they have any history of seizure activity before or since the stroke**. If yes, confirm that the patient understands the small but real risk of another seizure. Treat patient in supine position in bed, and alert the nurse to the situation, making sure that she is available to help secure the patient and call the Rapid Response team if necessary. Make sure you or other LMC personnel are at the patient's bedside throughout needle retention, and observe any changes in status such as involuntary movement or sudden unresponsiveness (versus drifting off to sleep).

Limb precautions and pacemakers

Treatment procedures must be modified for patients with limb precautions and those who have pacemakers. **Do not insert needles into any limb that is edematous or marked with a limb precaution band**. If the limb precaution is due to removal of lymph nodes, also avoid needling that quadrant of the torso. **Patients with pacemakers must not receive electrical stimulation** but can be treated with acupuncture.

Bruising and bleeding

Do not needle patients within 48 hours of acute anticoagulation therapy (tPA etc). After ischemic stroke nearly all patients receive prophylactic anticoagulation therapy such as Lovenox, Coumadin or Plavix and aspirin. **Anticoagulation therapy is not contraindication for acupuncture**. However bruising or bleeding for these patients may be greater than for typical outpatients. Scalp and ear points in particular should always be pressed for **90 seconds** after removal; other points should be pressed for **10 seconds**, and an **additional 90 seconds if there is bleeding**. Pressure should always be applied with **cotton swabs** rather than cotton balls, as these provide greater pressure and more protection from blood-borne pathogens.

Cardiac conditions

Past history of atrial fibrillation, myocardial infarction, any other heart surgery (stent placement, CABG graft, etc), angina or **any cardiac condition is a contraindication for use of electrical stimulation**.

Acupuncture "Dosage" - needle selection, stimulation and retention

Needle Selection

As a default, the team uses 34 gauge neeldes (1" and 1.5" as appropriate). We also carry 32 gauge needles for robust patients and 38 gauge needles for vacuous or needle sensitive patients. Additionally, for scalp acupuncture we prefer Dr. Zhu's specialized scalp acupuncture needles (36 gauge, 0.8")[1], though 0.5" auricular needles can be used.

Needle sensitivity in stroke

Stroke patients in general are less needle sensitive than the outpatient population. This manifests in two ways:

1. Even without diagnosed sensory impairment, stroke patients often have very little needle sensation on the affected side. They may also suffer hemineglect, in which the affected side occupies little if any perceptual space despite unimpaired

[1] http://www.scalpacupuncture.org/products/needles-2/

sensation. In either case this reduced needle sensitivity allows the treating acupuncturist to use large needles with strong stimulation to restore flow. However, **care should be taken to recheck sensitivity at the beginning of each treatment**, as normal sensitivity often returns within 3-5 treatments. Also, **if these patients have motor function they must be supervised closely during needle retention, as they will tend to move the limb incautiously**.

2. In general, the team has found patients with phlegm or congested fluids to have very low needle sensitivity, to the degree that larger needles and more stimulation may be required to have a treatment effect. By contrast, patients with vacuity of blood or yin are often more needle sensitive and require smaller needles with less stimulation.

A small proportion of patients suffer increased sensation on the affected side. Particularly with damage to the thalamus, central post-stroke pain (CPSP) may occur and **can be exacerbated with ipsilateral needling**. See the Syndrome Index for more information on CPSP.

Retention of needles

In general, the team's experience has been that hospitalized acute stroke patients fare better with short needle retention and frequent restimulation, rather than longer retention as in clinical practice. Default 'settings' for needle retention should be as follows:

- patients with slack dan tian, visible emaciation or other signs of significant vacuity: after insertion of last needle, retain for approximately 16-18 minutes, restimulating twice.
- Patients with resilient dan tian, robust appearing form: retain for approximately 23-25 minutes.
- All others: retain for approximately 20-22 minutes.

Treatment approaches used in this manual

An important feature of this manual is that it allows the practitioner to select and combine treatment approaches drawn from a variety of sources. These are briefly described below, for the purpose of operationalizing the selection process and application in the context of the manual. These descriptions will serve as a reminder for acupuncturists who have taken the training, but **they do not replace training in use of the manual, nor are they equivalent to training in other systems.**

TCM body and scalp acupuncture – Shanghai system

Unless otherwise specified, body and scalp acupuncture are to be practiced using point locations, depths and attention to *de qi* as described in the Shanghai text, Fundamentals of Chinese Medicine (Wiseman et al., 1996).

For scalp acupuncture, this manual mainly uses the Motor and Sensory lines, which are based on the Western anatomical concept of somatotopic representation of the body on the surface of the brain. Also used are the Balance points, which are in the area of the cerebellum. For scalp acupuncture, this system should be used as directed in the Rehabilitation Worksheet, and also in the following instances:

1. When the patient presents with motor impairment or sensory impairment only. (If both are affected, use the Zhu system below). In this instance, **the Shanghai location of the motor or sensory lines should be used, but needle selection and stimulation should be as for the Zhu system described below**.
2. With electrical stimulation for severe cases: when there has been no motor return in the upper and/or lower extremity (i.e. dense paresis) and at least two previous treatments using Zhu style needling have been tolerated without excessive needle sensitivity **and the patient has no history of seizure activity or cardiac condition**
    a. Upper extremity: place scalp needles at the top and bottom of the 3rd fifth of the motor line (forearm and hand). Connect these with one lead. Place needles at TE9 (or nearby ashi trigger point where tapping elicits a twitch response) and at LI4 and Ba Xie (perpendicular insertion with knuckles held bent at a 90 degree angle, 1-1.5 cun depth). Connect TE9 and LI4 with a second lead and start stimulation at 2hz continuous frequency, raising amplitude to the maximum level that is genuinely comfortable for the patient. A twitch response of the forefinger or (ideally) wrist extensors should be elicited. At this point, start stimulation on the second lead until the stimulus is perceptible but mild for the patient. Continue stimulation for 20 minutes, moving the lead from LI4 to the closest Ba Xie point after 5 minutes, and continuing to move it laterally at 5-minute intervals.
    b. Lower extremity: place scalp needles at the top and bottom of the 1st fifth of the motor line (lower extremity). Connect these with one lead. Needle perpendicularly to 1 cun at ST36 and ST38 (located directly on the belly of the tibialis anterior muscle). Connect them with a second lead and start stimulation at 2hz continuous frequency, raising amplitude to the maximum level that is genuinely comfortable for the patient. A twitch response of the tibialis anterior should be elicited. If there is no movement and the patient's maximum comfort level has been reached, recheck location. At this point, start stimulation on the second lead until the stimulus is perceptible but mild for the patient. Continue stimulation for 20 minutes.

3. With long needle threading for severe cases: when there has been no motor return in the upper and/or lower extremity (i.e. dense paresis) and at least two previous treatments using Zhu style needling (see below) have been tolerated without excessive needle sensitivity and the patient either is not eligible for electrical stimulation or has not responded to three such treatments. **Previous history of seizure activity is a contraindication for this treatment.**
    a. Using a 30 gauge 1" or 1.5" needle as appropriate, thread the lower or upper extremity area as described in the Shanghai text, from superior to inferior.
4. With electrical stimulation for distal extremity motor return: use the electrical stimulation procedure described above for the following situations:
    a. Physical or occupational therapist reports slow return of dorsiflexion or wrist extension
    b. Patient (or therapist) reports poor fine motor control of upper extremity

Zhu's Scalp Acupuncture

This is an alternative system of scalp acupuncture developed by Mingqing Zhu, an early graduate of the Shanghai school. It has some similarities to the Shanghai system, but is conceived as a yin/yang microsystem representing the body holographically on the surface of the scalp.

Another key difference between Zhu and Shanghai style acupuncture is the type and depth of needle. The Zhu system uses **small needles: 0.8" x 36 gauge** is a common size, used for scalp acupuncture at LMC and recommended for use with this manual. However, auricular needles (0.5" x 36 gauge) can be substituted. Rather than threading a large area on the scalp, the Zhu system uses multiple needles following the same line with little space between them. Needle stimulation is another difference between Zhu and Shanghai styles. Where the Shanghai system uses rapid twirling, the Zhu system calls for rapid low amplitude thrusts to supplement (80-120 per minute). For draining, the movement (and Qi intention) is reversed. For scalp needling within this manual, this is the default style except as described above.

Xing Nao Kai Qiao

Shi Xuemin's well known 'xing nao kai qiao' (awaken the brain, open the orifices) method is based on the treatment principle of restoring the flow of Qi to the head using yin channels (principally SP6 and PC6) as well as Du Channel points (16, 20, and pecking stimulation at Du26). Several of his treatment approaches are used in the Recovery Worksheet, as well as several treatment approaches that appear both in Dr. Shi's texts and and the 1601 compilation, the Zhen Jiu Da Cheng (Great Compendium of Acupuncture and Moxibustion) (Yang, 1987). One of our team members (CC) attended a training with Dr. Shi and was introduced to his specialized needling technique. This is a light, rapid twirling (120/minute) with very small amplitude and periodic light flicking to enliven the channel; the technique is supported by standing meditation practice. This manual does not assume that practitioners have the ability to perform this technique. The point combinations shown have been used with supplementing, moving or even technique as they are described in the manual.

Balance Methods

All of the acupuncturists participating in this manualization process used some type of meridian balancing method in our inpatient and outpatient practices. The best known of these is Richard Tan's method as described in his book, "Acupuncture 1, 2, 3" (Tan, 2007) and in the training program for this manual. Commonly used to circulate Qi in pain patients, the method mainly consists of devising a 'balanced' treatment where yin and yang surfaces of the four extremities are needled in alternating fashion, as when master points for Du and Ren or yin qiao and yang qiao vessels are needled. It has been the experience of three team members (PC, CC, SR) that use of this yin/yang alternating strategy on appropriate points can also circulate the fluids and Blood with positive effects in internal medicine. This strategy is used as a default for point selection throughout the manual, both for suggested point combinations and for use where the practitioner is selectively combining strategies. Specific guidance on implementation is provided below:

1. Where there is pain, use a balance method preferentially. As described in Acupuncture 1, 2, 3, identify ashi points at homologous (e.g. contralateral wrist for wrist pain) analogous (e.g. ipsilateral ankle for wrist pain) or opposite points (e.g. ipsilateral or contralateral shoulder or hip for wrist pain) on related channels. This order (i.e. direct to indirect) should be followed in palpating for ashi points. The order of related channels, located on the Intake Worksheet, should also be followed. When a balance treatment is used for pain, retain the needles an extra 10 minutes, restimulating every 10 minutes. Supplement this treatment with retained ear seeds, ipsilateral at tender points corresponding to the painful area, plus Shenmen and Zero. Counsel the patient to press the seeds rhythmically for 90 seconds when awakened by pain, and every 4 hours or more often if desired.
2. Contraindications: Balance type treatments are **contraindicated** in the following situations
    a. Dizziness or agitation
    b. Vomiting or severe nausea
    c. Extreme debility
    d. Signs of wind stirring (tics, tremors; deviated tongue is not a contraindication)
    c. Auricular

Auricular Acupressure

Supplement treatment with ear seeds on the following ear points. These should be actual seeds, usually *vaccaria* seeds (*wang bu liu xing zi*). **Metal beads, magnets and ear tacks must be avoided as they can cause injury in the event of emergent MRI imaging**. Replace weekly and alternate ipsilesional and contralesional placement:

- Find the site of the lesion on Oleson's auricular microsystem where the brain maps onto the ear (Oleson, 2003, pp. 240-241)
- Add the following points as appropriate
    - Large Intestine (constipation or diarrhea/incontinence)
    - Liver (if wiry pulse)
    - Lung (bilateral if audible phlegm rale or diagnosis of pneumonia)
    - Shenmen (if anxiety)
    - Location of any pain, plus Shenmen and Zero (instruct patient to stimulate every 4 hours, plus on retiring and whenever pain is bothersome)
    - Occiput – for dizziness/vertigo, pontine strokes
    - Heart (if aphasia)

Using the Patient Intake and Assessment Worksheet

Preliminary information gathering from medical record: Page 1 (top)

Working from the patient medical record, gather as much information about the case as possible, using the tick boxes at the top of the Worksheet as a guide to key information, and noting anything else of interest in the blank space at the bottom right. This should include:

1. Patient age, sex, comorbidities, significant history, meds
2. Stroke type, location, size, time and circumstances of onset
3. Rehab goals as per therapists
4. Preliminary constitutional picture – above plus Body mass index? Hypertension? Diabetes? Cholesterol? Depression? Substance abuse?
5. Preliminary treatment goals, as stated in the Interdisciplinary Patient Evaluation or the initial notes of the rehabilitation physician and physical, occupational and speech therapists. Also note on any specialist consultations that have been made and their findings: neurology, cardiology, internal medicine, etc.

Bedside examination: Page 1 (middle/bottom)

This is guided by the Page 1 of the Assessment Worksheet, which is very crowded in an attempt to collect a large amount of data in a form that can someday be analyzed by computer. To save space, we use numbers 1, 2 and 3 as a way around the modifiers 'slightly' and 'very'. A 'very slow' pulse can be notated by circling 'slow' and '3'; 'slightly slow' is '1' and 'slow' would be '2'. The order and nature of information requested serves two purposes: first, it provides the key diagnostic indicators used on Page 3 of the Worksheet. Second, it should inform your own understanding of how the Qi mechanism is disrupted in stroke, to help in understanding and treating those patients who either do not respond to manualized treatments or did not fit its diagnostic criteria to begin with.

1. Pulse: note beats per minute (bpm) as well as any qualities that you notice (the blank at the top right of the box is for one dominant quality that you notice without trying; the space at the bottom is for anything you'd like to add on consideration.
    a. Please note that in stroke patients, the seemingly disparate qualities of 'slippery' and 'wiry' often present together. Appearing together they can be considered as a single dominant quality suggesting the presence of phlegm
    b. The "eight parameters" of pulse. Practitioner interpretations of the 28 pulse qualities can vary greatly, and in treating complex cases at the hospital we have frequently found them more confusing than helpful. The 'pulse basics' of rate, level, size and force can be easier to hold on to, and clearer in their implications for diagnosis. It's a good habit to assess them in this order as well: you need to locate the pulse in order to count it, then while you are counting the pulse you can think about its size and force.
    c. Left> <Right: This is a cryptic way of asking whether one side is more forceful than the other. It is common for the affected side pulse to be weaker, but sometimes it is more forceful. The team has not yet arrived at any brilliant insight into the meaning of this reversal.
    d. Pulse grid: in this box, you can chart any pulses that deviate greatly from the 'eight parameters' picture given above. For example, it is not uncommon for the left Chi position to be nearly absent from a pulse that is otherwise forceful. It is not necessary to chart minor positional variations. Also, it is assumed unless otherwise specified that the chi pulse is slightly deeper and less forceful than the guan and cun, that the cun pulse is slightly more superficial, and that the left guan is slightly more wiry than the right, which is slightly more slippery. (In stroke patients this is commonly reversed, or the right guan is very vacuous, or the right chi is very slippery; these are all examples of what you might indicate in the box or under 'other qualities/notes').
2. Tongue: This box uses the same system of 1-3 to replace 'slightly' and 'very.' Simply circle and grade all qualities that apply; there is space below for specific notes, e.g. "peeled spot at L side"
    a. Sublingual veins (SLV): these are commonly dark and distended in stroke indicating blood stasis, with distention on the affected side increasing over time as the condition becomes chronic. It may be difficult for stroke patients to show the underside of their tongues, due to tongue stiffness and/or dentures. Two attempts is enough.
    b. Tongue coat: A very thick coat is extremely common, in keeping with the impaired Qi transformation of the condition. Reduction in this coat with treatment is also common – but if you see a change do check as to whether the tongue has also been cleaned by the speech therapist. Also, sudden appearance of a green color does not indicate new onset illness but only that the patient has had a swallowing test.
3. Abdominal Palpation: This examination is central to our understanding of the patient's basic weakness or robustness, and the function of the central Qi. Distention indicates blockage, while tone ranges from too tight to too slack. Overall

temperature helps clarify the severity of yin and yang xu, while hot and cold spots can indicate stomach cold or stasis generatingheat. Indicate locations of tightness tenderness under "ashi@" (e.g. right ribside indicating Liver Qi), as well as hot and cold spots.

   a. Dan Tian: the state of the Dan Tian in particular (as distinct from the whole abdomen) is a key indicator of Kidney vitality, as seen in the Assessment sheet. A vital, springy quality is considered normal. A slack quality at Ren 4-6, or excessive tightness/tenderness at the level of ST30-Ren2 (a 'bow tie') indicate vacuity. Cold indicates yang xu.

4. Temperature: The three lines of this box indicate overall body sensation, upper extremity, and lower extremity. Simply circle all that apply, and score 1-3 as appropriate.
   a. For Objective/Subjective, inquire whether the patient is 'always hot, always cold or just normal'. (If hot or cold, ask whether this has changed since the stroke, obtain a 1-3 qualifier, and note in the margin.
   b. Upper extremity: RUE indicates right and LUE indicates left; select a temperature and circle both if bilateral, scoring 1-3 as appropriate
   c. Lower extremity: as for upper extremity.
5. Sweating: indicate temperature and time
6. Gastrointestinal (GI) and urinary symptoms: Inquire about these closely. Lack of appetite (LOA) is common, as is constipation.
   a. Urinary retention is also common, though the patient is not the best reporter of this problem: check the nursing notes.
   b. Nocturia is common; inquire how many times per night and whether it disturbs sleep
   c. Color – the patient may not know, but a catheter bag is often present
2. Stroke symptom inventory
   a. Differential diagnosis as needed
   b. Assess patient priorities
   c.
3. Pain: Headache, shoulder and neck pain are common after stroke. Inquire as to all sources of discomfort and obtain 1-10 scores. **Any pain score over 8/10 must be reported to the nurse** caring for the patient, though likely s/he is already aware.
4. Observation:
   a. Form is robust, thin, heavy (or obese); flesh tone may additionally be firm or slack
   b. Bearing is upright, stiff or slack, or in some cases crooked.
   c. Color is pale, red, grey, blue, yellow or qing, scored 1-3
   d. Shen is dull, clouded, scattered, agitated, scored 1-3. It is assessed mainly but not exclusively through eye contact. 'Dull' indicates lethargy or poor responsiveness; 'clouded' indicates a patient who maintains eye contact and appears to be emotionally present, but has cognitive confusion or difficulty speaking. 'Scattered' indicates a sense that the patient is not emotionally present or able to maintain eye contact, though there may be transient moments of connection.

Constitutional Assessment Worksheet (page 2)

This page of the worksheet should be largely self-explanatory. It links the signs and symptoms gathered on page one to the treatment planning on page 3. For each of the syndromes listed, key clinical signs encountered in post-stroke care are listed. It is to be expected that patients will show signs of at least two and often three or four syndromes. For that reason, the points listed under Points/Strategy do not constitute recommended stand-alone prescriptions. Rather, they are to be combined or incorporated into the Recovery and Research treatment priorities identified on the worksheets described below. There will be considerable overlap, particularly between recovery treatments and constitutional treatments. For newer practitioners, or for use of the manual in a research context where tighter standardization is required, the points/strategies are listed in approximate order of importance and can be considered for integration in that order. Instructions for constructing the treatment are given below under treatment planning.

Treatment Planning (page 3)

The bulk of the treatment planning within this treatment manual is accomplished via stepwise progress through the Recovery and Rehabilitation worksheets (see below). The treatment recommendations from those worksheets are combined on the ATP worksheet. **The summary of this process below will serve as a reminder for acupuncturists who have been trained in use of the manual, but is not a substitute for such training.**

1. Identify the first two Treatment Goals from the Treatment Goals bar at the top of Page 1 of ATP Worksheet
2. Identify the primary constitutional disharmony to be addressed (this will be the one with the most clinical signs pointing to it).
3. Copy the suggested treatment approaches for each of these treatment priorities onto the Treatment Planning section of the ATP Worksheet, at the bottom of page 3. Cross out redundant points.
4. Write the resulting point prescription on the stick figure, Balance method style (see above). Start with yang points on the affected arm first and alternate per treatment (the first few treatments may have only head and torso points).
5. Double check the treatment: in general you need one or two arm points and two or three leg points, for a maximum of 14 needles, 9 in weak or needle sensitive patients.
    a. If not then what can you add from additional recommended points or secondary diagnoses
    b. If balance is contraindicated (e.g. for dizziness, see above) treat bilaterally. This may require letting go of the second treatment goal.
    c. For mild cases, you can move on to rehabilitation goals as soon as either the center or the constitution improves.

Using the Recovery and Rehabiliation Worksheets

The Recovery worksheet governs treatment during the first 10 post stroke. Its priority is first regulating upbearing and downbearing in the head and center, and then addressing any root and branch constitutional disharmonies that present. Once some of this recovery work is done, it becomes possible to incorporate rehabilitation priorities into the treatment, again in a stepwise fashion from the acutely distressing difficulties of aphasia and dysphagia, to balance and trunk stability, and finally to lower and upper extremities.

The first treatment

As shown in the worksheet, the primary treatment priority for the first 10 days is bringing Qi and Blood to the head to nourish injured cells and carry away metabolic waste. In addition, because many stroke patients are new to acupuncture, the treatment should begin with SP6 and Du20, as non-challenging points that will allow the practitioner to assess the patient's needle sensitivity. If three needles is enough (as occasionally happens) then the three needles will still constitute a clinically appropriate intervention.

Refractory cases

For severe strokes, the first 10 days of treatments will likely be restricted to head, center and constitution. It is also not unusual for recovery of GI and urinary function to remain impaired well into the rehabilitation period and beyond. After the initial 10-day recovery period, once the same combination of treatment priorities has been used for three treatments with no perceived clinical effect, the practitioner should consult the Index.

The Index of Stroke Syndromes:

The Index contains everything that the acupuncture team found in searching their libraries and the internet during the manual construction and study period. It constitutes the 'best available evidence' to date. It is the team's plan in future to augment this evidence with cases from our own records – as well as those of other practitioners using the manual.

Finishing the treatment

At the conclusion of the treatment, the following items are important:

1. Reassess level of responsiveness. It should be similar or better than at the commencement of the treatment. If it is not, or if there is any question at all, ask the nurse for a second opinion. There is no harm in this extra vigilance.
2. Reassess the pulse. Particularly if you have used electrical stimulation, be on the alert for reduction in strength of pulse or irregularity of rhythm. If the force of the pulse is reduced (even if it was pathologically forceful before) **ask the nurse to take a blood pressure reading and compare to the patient's two previous readings** in the medical record.

3. If pain or discomfort was reported at the beginning of the session, ask for a post-treatment level and record both.

Oleson, T. (2003). *Auriculotherapy manual : Chinese and Western systems of ear acupuncture* (3rd ed.). Edinburgh: Churchill Livingstone.

Tan, R. (2007). *Acupuncture 1, 2, 3*. San Diego.

Wiseman, N., Ellis, A., & Zmiewski, P. (1996). *Fundamentals of Chinese medicine* (Vol. 127): Paradigm publications Brookline, Massachusetts.

Yang, J. (1987). Great Compendium of Acupuncture and Moxibustion (Zhen Jiu Da Cheng). *People's Health Publishing, Beijing, China*.

ID #_____ Treatment #: _____ **Limb**? ☐ Yes ☐ No **Seizure**? ☐ Yes ☐ No **Pacemaker**? ☐ Yes ☐ No

Preliminary Information Gathering:

PMH: ☐Smoking History ☐Diabetes ☐Hypertension ☐Cholesterol ☐ A-fib ☐Sickle Cell Trait ☐OCP/Estrogen
☐ Migraines ☐Vertigo/Tinnitus ☐TIA ☐Surgery/hardware ______________________ ☐Other ________________________

HPI: ☐Type ☐Location ☐Side ☐Size of stroke ☐Time Date & Circumstance of onset ☐Old stroke?
☐Hospitalization course ☐Intubation ☐Pneumonia ☐UTI ☐H/T ☐Fever ☐Procedures (esp. tPA, PEG)

Treatment Goals (circle all that apply, or add "Other" in Notes):

1. Stabilize Head	**1. Day 1-10 or first tx** **2. Spirit Clouded** **2. Spirit Scattered** **3.Agitation, Insomnia**	**2. Regulate Center**	**1. Constipation** **2. Diarrhea or Fecal incont.** **3. Urinary incontinence** **4. Urinary retention**	**3. Balance Constitution**	**1. Deficiency** * Yang/ Qi * Yin/ Blood **2. Stagnation** * Qi * Blood **3. Accumulation** * Water * Phlegm * Heat	**4a. Speech**	**1. Aphasia** (Can't find words) **2. Dysarthria** (Physical Diff.)	**4b. Swallowing**	**5. Balance & Trunk Stability**	**6. Lower Extremity**	**1. No Return** **2. Weakness** **3. Stasis**	**7. Upper Extremity**	**1. No Return** **2. Weakness** **3. Stasis** **4. Pain**

Bedside examination:

Pulse: ____ bpm Quality: ____________

Deep	**3 2 1 0 1 2 3**	**Sup.**
Slow	**3 2 1 0 1 2 3**	**Fast**
Narrow	**3 2 1 0 1 2 3**	**Wide**
Forceless	**3 2 1 0 1 2 3**	**Forceful**

	Left >		**< Right**	
Cun	**Shi 3 2 1**	**Xu 1 2 3**	**Shi 3 2 1**	**Xu 1 2 3**
Guan	**Shi 3 2 1**	**Xu 1 2 3**	**Shi 3 2 1**	**Xu 1 2 3**
Chi	**Shi 3 2 1**	**Xu 1 2 3**	**Shi 3 2 1**	**Xu 1 2 3**

-------- Other Qualities/Notes -------

Tongue (circle & grade 1-3)

Body: Sm < WNL < Lg Scalloped Deviated R/L Pale - Red - Blue **Cracks:** Horizontal Vertical	**Coat:** WNL – Thick Peeled – Dry Wet – Tofu **Coat Color:** White – Grey Yellow – Black Other: ________ Tip:

SLV: R > < L ☐ **Dark** ☐ **Thick** ☐ **WNL**

Notes:

Palpation:

Abdomen: **Distention? 1 2 3**

Tone: (taut) 3 2 1 0 1 2 3**(slack)**

Temp: (hot) 3 2 1 0 1 2 3 **(cold)**

Ashi @: __________________________

Masses @: ________________________

Hot/Cold@: ______________________

DanTian: Vital Slack 'Bow tie'

Other_____________________________

Temperature:

Cold/Hot	Objective	Subjective
Cold/Hot	RUE	LUE
Cold/Hot	RLE	LLE

Pain? 1-10 scale

Observation:
Form Bearing Color Shen

Sweating:

Cold	Hot	Day
Cold	Hot	Night

Location: _____________________

Notes:

GI:

LOA	Nausea	Heartburn
Incont.	Const.	Vomiting

Urination:

Incontinence	Retention	Nocturia

x/Night, color_______________________

Insomnia:

Premorbid	1 2 3
Current	1 2 3

Disturbed – Reason: _______________________

CONSTITUTIONAL ASSESSMENT WORKSHEET

#	Pattern	Key Clinical Signs (should see at least 2)	Points/Strategy	Stimulation
1	Qi Xu	Scalloped tongue, pulse is slack or lacks force, rapid pulse with no heat signs; soft/spongy abdominal flesh; weakness/fatigue, orthostatic hypotension	LI10/ST36/SP3/ Lu9; CV6/12	Sup
2	Blood xu	Pale tongue; dry flaky skin; pulse volume is small (vessel is thin or narrow); tight sinews; blood loss , anemia or sickle cell trait	LI10/ST36/SP10 /Lu9; Liv8, SP6	Sup
3	Yin xu	Small, red, dry, peeled or cracked tongue; empty heat (in 5 hearts, worse w/fatigue or with KD signs below); tight rectus; rapid pulse with small volume (vessel is thin or narrow)	Kid6/SP6, R4 (B)	Sup
4	Yang xu	cold belly or subjectively cold (patient or assessor); diarrhea or incontinence with slow pulse; pale puffy tongue; pitting edema	Warm ming men/Dan Tian; Kid3/7 (B)	Sup
4a	Kidney Qi xu	Nocturia, urinary frequency or incontinence; soft dan tian or "bow tie"; age over 70	CV4, Kid 7 (B)	Sup
5	Qi zhi	Pulse has tense or wiry quality; tight or tender hypochondrium	LI4/GB34/Liv3/ PC6	Drain or even
6	Xue yu	Distended/dark or many branches on sublingual veins; tongue bluish or with macules; stasis macules or spider veins on legs; choppy pulse quality	Liv3, SP10, GB34, LI4, PC6	Drain or even
7	Accumulation of Yin (Water)	Edema; soft puffy flesh; swollen tongue; watery fluid in lungs; congestive heart failure; cold signs or absence of heat signs	Warm ming men/Dan Tian; Kid7/R9, SP9, SP6(KD aspect)	Bilateral, Sup KD; SP9 drain or even
7a	Accumulation of Yin (Phlegm)	Thick tongue coat; overweight or obese; audible phlegm rale; cough with sputum; cognitive or sensory impairment	LI4/TH10, ST36/40, SP3/8 Lu7/PC5	Drain or even (sup SP3)
8	Accumulation of Yang (Full Heat)	Yellow rooted tongue moss; red tongue large or normal size; rapid pulse with large volume	LI4/11, ST40/44, SP5, Lu5	Drain or even
8a	Accumulation of Yin & Yang (Damp Heat)	Body odor; thick yellow tongue coat; body discharge (vaginal, pus, weeping sores); cloudy dark urine; feverishness in afternoon (with other signs); bitter taste in mouth	LI4/11, GB34/ST44; SP5/9, Lu5/7	Drain or even

Treatment Planning:

Balance Method

LU	SP	UB	LI	UB	LR
LI	ST	LR	LU	KI	ST
ST	LI	PC	SP	PC	LI
SP	LU	SI	ST	SJ	HT
HT	KI	GB	SI	GB	SP
SI	UB	SP	HT	LR	UB
UB	SI	LU	KI	LU	SI
KI	HT	SJ	UB	LI	PC
PC	LR	ST	SJ	ST	KI
SJ	GB	KI	PC	SP	GB
GB	SJ	HT	LR	HT	SJ
LR	PC	LI	GB	SI	LU

ZHU/ SHANGHAI Scalp:

______ Zhu Arm

______ Zhu Leg

______ Zhu Hip

______ Zhu Shoulder

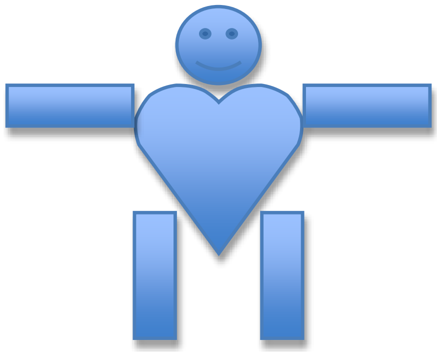
Zhu Other:

Sh. Motor: 1 2 3 4 5

Sh. Sensory: 1 2 3 4 5

Balance:

Other:



Needles In: #______ Time _______ Needles Out: #______ Time _______ Any issues?___________________________________

Tx given: ____

TxPriority 1: ____

TxPriority 2: ____

Constitution or TxPriority 3: ____

☐Recovery Flowsheet ☐Rehab Flowsheet ☐Constitutional Flowsheet ☐Index ☐Other_______________________________

Source/Rationale for Other: ____

____

Response (& timing): ____

____

Response to previous Tx: ____

____

Follow-Up after Tx: ____

____

Additional Notes:

STROKE RECOVERY WORKSHEET

1.	***STABILIZE QI/BLOOD FLOW TO HEAD* - *ALL PATIENTS, FIRST 10 DAYS***	Normal BP		Du 20, Yin tang, Du16 (in/out; de qi no manipulation), SP6 & PC6 (bilateral
		Systolic > 160		GB 20, Lv3>>Ki1, Sp 6, Du 20, Si shen cong (even, bilateral)
1a.	***STABILIZE QI/BLOOD FLOW TO HEAD* -** *Additional concerns*	**Wind** (seizures, shaking twitching)		St2 downward, no manipulation; GB20/31 (even)
		Clouded		Du26 peck; P5,SSC(drain) Sp6(even)
		Scattered		P8/K1(affected side only), R4/6 (even)
		Agitation (tx above plus)		SSC/YT(even), ear seeds ESM, Amygdala, M. cerebral
		Insomnia		Bilateral: An Mian, Liv3->Kid1 plus constitutional tx; ear seeds ESM
2.	***REGULATE THE CENTER*** Begin with tuina (round rubbing) to restart the Qi mechanism *Needling technique: supplement, drain or even technique as specified. "(Pt)" indicates that the points should be drained if the patient is generally replete, supplement if vacuous, or even if not clearly one or the other.* *Alternate needling sides, with all head needles bilateral and body needles partitioned by upper/lower yin/yang. Start with hand yang on affected side on Day 1 and alternate.*	**Constipation**	General	LI4, St 37/25 (Pt); if no result add estim ST25/27
			Phlegm-heat+	LI11, St40, SP15 (drain)
			Liver Qi +	Sp15, TH6, GB34 (drain) Liv3 (Pt)
			Cold +	Warming therapy on Ren 4 + Du4
			Weak+	R4/12 (sup)
		Urinary Retention	General	R3/5/9 drain, Kid7/Ht5 (sup)
			If infection+	UB67, Lv5, GB34, Du23x3 (drain)
		Diarrhea	General	LI4, ST25, Kid3, Du20/20.5 (sup)
			Cold+	Warming therapy on R4/Du4
		Urinary incontinence	General	Du20, Kid7, R4 (sup)
			Cold+	Warming therapy on R4/ Du4
4.	***TREATMENT WORKSHEET*** *Use this space to put together your treatment – write in points from each section as appropriate, then cross out any that are redundant. Use the space below to plan a treatment with 1-3 points on each limb, using Balance method unless bilateral needling is indicated.*	**1. Stabilize the head**		
		1a. Spirit issues and/or Wind		
		2. Regulate the Center		
		3. Constitutional treatment (primary)		
		5. Secondary Constitutional tx.		
		6. Other (write rationale below)		

STROKE REHABILITATION WORKSHEET

Look and palpate for Qi xu stagnation in the channels and blood stasis in the Luo. **DO NOT NEEDLE ALL THE POINTS SUGGESTED**: use as a guide for palpation, for each channel draining the 3 most excess points (on yang channels on robust patients only) or supplementing the 2 most deficient for weak patients. In general, follow the order of points suggested, tracing the path of recovery from proximal to distal.

4a	**SPEECH**	**Aphasia (can't think of the words)**	Rn23 Du24 Ht5 Ht7		
		Dysarthria (physical difficulty)	During therapy	Ren23, Du24, Lower 1/5 of motor and sensory line	
			Body points	Ht5, Ki2, jinjin/yuye, assess Ht/ Ki/ Ren	
4b	**SWALLOWING**		During therapy	Lower 1/5 of motor line, sensory if needed	
			Body points	GB12, GB20, SJ17, Lu7, K2, palpate Ren/GB/SJ/Chong/Lu/St/K (if tight in neck, check distal wrist/ankle points to release)	
5	**BALANCE & TRUNK STABILITY**		During therapy	Balance points, Du20, treat central qi (see Recovery worksheet)	
			Body points	Du 20, see recovery worksheet, assess 8 extras	
6	**LOWER EXTREMITY**		During therapy	Upper 1/5 of motor line, sensory if deficit	
			Key body points	GB30 UB40 SP6 (supp if weak; if strong drain at Shi Xuemin location)	
			Palpate channels	UB	UB53, UB40, UB58, UB59
				ST	ST31, ST36, ST 41
				GB/LV	GB30, GB34, LV8, GB40>>K6, LV3
7	**UPPER EXTREMITY**		If shoulder pain:	Contralateral St38, Dr. Zhu shoulder area; SI6, Si10, jian qian, also drain excess and supp def as described below	
			During therapy	Second 2/5 of motor line, sensory if deficit	
			Key body points	Ht1, Lu5, (for pain SI10, jian qian)	
			Palpate channels	LI	LI14, LI11, LI4
				LU	Lu2, Lu3, Lu5, Lu9, Lu10
				SJ	SJ14, SJ10, SJ6, SJ5
				PC	PC1, PC3, PC4
				SI	SI11, SI10, SI9, trigger point on triceps below SI9, SI6, SI5, SI4

APHASIA/DYSARTHRIA

Brief medical background:
"One of the most devastating conditions after stroke is aphasia, a disturbance in language function, which affects about 27% of all stroke patients. About half of the initially affected patients still suffer from aphasia one year after stroke. Apart from the emotional burden associated with aphasia, language dysfunction in the post-acute or chronic phase after a stroke is a major reason for failure of vocational rehabilitation. Impaired communication ability commonly represents an obstacle to vocational and professional reintegration, thus incurring health care costs and losing potential contributors to the 'social contract'." (Baumgaertner et al., 2013)

Evidence basis: Overall Grade = B

NHS Grade	Citation *Book Title*	Treatment Approach *Study Design, Population*	Study Results *Notes*
		POST STROKE	
1-	(Luo et al., 2008)	'Tiao Shen Fu Yin': Sishencong, GB14, DU24, RN23, UB15, 44, DU11, HT4 *RCT (N=60); Broca's aphasia*	(+)
1-	(L. Wang et al., 2011)	Constitutional treatment plus: Jinjin, Yuye, Speech function scalp area, RN23 *RCT (N=120) vs usual care alone*	(+)
1-	(Xu et al., 2010)	RN23, Jinjin, Yuye, GB12, 20, SJ17 *RCT (N=61) – DYSARTHRIA*	(+)
1-	(H. M. Zhang, 2007)	'Cluster needling' - threading parallel lines 1 & 2 cun outside DU20-21, DU21-22, plus usual care *RCT (N=56) – APHEMIA*	(+)
1-	(G. Li & Yang, 2011)	Electrical stimulation at SJ8 *RCT (N=21)*	(+) 'Significant' change in signal activation of speech centers
4+	(X.-M. Shi, 2006, pp. 667-668)	Xing nao kai qiao: Du 16 (in & out); Du20; Du26 (peck until eyes water); PC6 SP6	

4+	(Flaws, 2010, p. 112) *The Treatment of Modern Western Diseases with Chinese Medicine*	Presentation: Drool flows by itself. Tongue is mostly wry & deviated. Tongue fur is thin and slimy, pulse slippery and moderate. Treatment Principle: Break phlegm and disinhibit orifices; quicken blood transform stasis. Acupoints: Du20/16, LI4 Sp6, Rn23, Ht5, Du15.	
4+	(P.-X. Huang & Liu, 2008, p. 48)	B10 benefits marrow and supplements brain; Jinjin Yuye, R23 promote movement of tongue	
4+	*(Hopwood & Donnellan, 2010, pp. 112-113)	Deviation of the tongue and aphasia: Ear Shenmen; R24; D15; HT5 Loss of voice: PC11, LI17	
4	V. Scheid *(personal communication, October 10, 2011)	Important to differentiate aphasia (shen, HT organ, constitutional treatment) vs dysarthria (stiff tongue, HT channel, channel-based treatment)	

CONSTIPATION

<u>Brief medical background:</u>
"Constipation occurs frequently in the elderly with a prevalence as high as 28%. Its prevalence among stroke patients is even higher, ranging from 30% to 60%. Such large difference in the results can be attributed to the adoption of different time points, use of different diagnostic criteria for constipation, and the enrollment of patients with different characteristics." (Su et al., 2009)

<u>Evidence Basis:</u> Overall Grade = B

NHS Grade	**Citation** ***Book Title***	**Treatment Approach** ***Study Design, Population***	**Study Results** ***Notes***
		ACUTE STROKE	
1-	(Xiao et al., 2011)	Acupoints: LU11, LI1, ST40, ST25, SJ6, plus others. *RCT (N=160) – Phlegm-heat syndrome only*	(+) Best results with acupuncture plus herbal therapy
		GENERAL POPULATION	
1-	(C. W. Wang et al., 2010)	ST25 deep needling with electrical stimulation *RCT (N=95) – FUNCTIONAL CONSTIPATION*	(+)
1-	(Z. L. Zhang et al., 2007)	Electroacupuncture at SJ6 for cases of Qi stagnation or deficiency *RCT (*N=35)*	(+)
2	(Ding et al., 2009)	Acupuncture and moxibustion on two alternating groups of acupoints. Group one: ST25, SP15, SP15, RN6, RN4, ST36, ST37. Group two: BL25, UB23, UB31-34; Sishencong. *RCT (N=30)*	(+)
2	(L. J. Wang & Wang, 2011)	Alternating point sets: Set 1: Tianshu (ST 25), Daheng (SP 15), Qihai (CV 6), Guanyuan (CV 4), Zusanli (ST 36), Shangjuxu (ST 37) and Sanyinjiao (SP 6). Set 2: Zhongliao (BL 33), Xialiao (BL 34), Dachangshu (BL 25), Shenshu (BL 23) and Pishu (BL 20). All treatments: Qihai (CV 6), Zusanli (ST 36), Dachangshu (UB 25) and Pishu (UB 20) *RCT (N=100, Acupuncture vs Acu & Moxa)*	(+) Acupuncture & Moxa better than acupuncture alone

4+	(X.-M. Shi, 2006, p. 669)	ST40 bilateral 1 cun reducing, twirling 1 minute ST28/29, Waishuidao (EX-CA4)/Waiguilai (EX-CA5) oblique 1.5-2 cun medial/inferior reducing (with exhale) 1 minute; retain 20 minutes. "Most of the patients will move the bowels 1 hour after the acupuncture session, and the bowel movements will be normal after one consecutive week of acupuncture treatments"	
4+	(X. M. Shi, 2011)	ST36/40 for constipation of any etiology.	
4+	(Deadman et al., 2007)	ST: 22/25/37/40/41/44 SP: 2/3/5/13/15/16 UB: 25/26/27/28/32/33/34/39/51/56/57 KI: 1/4/6/7/14/15/16/17/18 TE: 5/6, Gb27/34, Liv1//2/3/13, CV: 6	
4+	(Maciocia, 2008)	Heat: Li4/11, Sj6, St28/29/444, Sp14/15 Liv Qi Stagnation: R6/10, GB34, 4 gates, Sp15 Deficiency: St36, Sp6/15, R4, UB21/23/25, K3/6/7 Cold: R6/8, KI8, Ub23/25/26	

DYSPHAGIA

Brief Medical Background:

"(Dysphagia) is one of the causes of morbidity following a cerebrovascular accident. The evaluation of swallowing disorders and their rehabilitative modalities are evolving topics. The benefit to the patient, in terms of improvement in quality of life, cannot be underestimated. Many studies have attempted to assess the utility and efficacy of the various methods used to tackle the problem. As with many other neurological disorders, stroke often leads to an impairment of the swallowing mechanism. There is a proven high incidence of aspiration with the potential to cause pneumonia. This is a significant factor causing mortality in stroke. Hence, care needs to be taken by the treating stroke team to prevent this complication.

The initial management of dysphagia in stroke often consists of the insertion of a naso-gastric tube (NGT). This is followed by bedside assessment of the return of normal swallowing process, and decision for NGT removal. While this suffices in most cases, occasionally there exists a doubt about aspiration." (Radhakrishnan et al., 2013)

Evidence Basis: Overall Grade = B-

NHS Grade	Citation, *Book Title*	Treatment Approach / *Study Design - population*	Study Results / Notes
		CHRONIC STROKE	
1-	(Akamatsu et al., 2009)	Electrical stimulation to ST36 and KD3 to decrease latency time in swallowing reflex *RCT (N=12)*	+
		GENERAL STROKE	
1-	(Z. Huang et al., 2010)	Acupuncture (GB20, LI18, forehead needles, plus others) vs electrical stimulation vs rehabilitation *RCT (N=97)*	(+)
1-	(Jing et al., 2007)	Shallow needling of RN23 vs deep needling of RN23 vs multiple deep needles at RN23 *RCT (N=111)*	(+) Deep needling better than shallow; multiple deep needles better than single
1-	(M. Li et al., 2009)	Comparison of two different groups of acupuncture points: five-needle-in-nape (DU15, UB10, Zhiqiang) vs RN23, HT5, KD6 *RCT (n=60)*	(+) FNN versus other group
4+	(X.-M. Shi, 2006, p. 671)	GB20 2.5-3 cun towards larynx 'by vibrating slowly', then reinforcing with high frequency/small amplitude. Then TH17/GB12, same technique	

4+	(Flaws, 2010, p. 112)	For deviated mouth, ST4, Rn24 Du26.	
4+	(X. M. Shi, 2011)	GB20/12, SJ17	Cf Great Compendium

DYSPHORIA

(Depression, Anxiety, Frustration, Low Motivation; see also FATIGUE)

Brief medical background:

"Post stroke depression (PSD) is a common complication of stroke that negatively interferes with outcome of stroke patients. Patients with PSD has [sic] more functional disability, poorer rehabilitation outcomes, reduced quality of life and increased mortality. According to previous published data, mainly from developed countries, PSD has a high prevalence among stroke patients, ranging from 20 to 50%. The report also indicate that depression persists 3–6 months after stroke." (W.-N. Zhang et al., 2013)

"Apathy and depression are important neuropsychiatric symptoms that can occur after a stroke and may be the core symptoms in some stroke patients. It has been reported that in the acute phase of a stroke, 15.2-71% of patients demonstrate apathy. Three to six months after a stroke the incidence of apathy has been reported to be 26.7% versus 5.4% in controls. Cognitive dysfunction has been found to be related to apathy; however, some patients with moderate to severe dementia do not show apathy so cognitive dysfunction per se does not produce apathy. Some patients with post-stroke depression develop apathy; however, apathy should probably be regarded as different from depression and it requires distinct prognostic and therapeutic strategies. For example, it has been found that in patients with a stroke, crying and sadness were associated with a subjective feeling of depression whereas apathy was not. The situation may be more complex, however, as a relationship between depression and apathy could develop over time. A recent study found that 3 months after a stroke there was no significant overlap between apathy and depression, but one year later there was a significant overlap." (Yang et al., 2013)

Evidence Basis: Overall Grade = B

NHS Grade	Author, Year (or Text)	Approach	Results/Notes
POST-STROKE			
1-	Chou, 2009	Cognitve impairment and QOL: electroacupuncture at PC6 and HT7 *RCT (n=38)*	+
1-	(He & Shen, 2007)	PC6, DU26, DU20, YT, plus SP6 affected side for depression *RCT (n=256)*	(+) CF xing nao kai qiao
1-	(Dong et al., 2007)	'Point-through-point' electroacupuncture for depression *RCT (n=108)*	(+)
1-	(H. J. Li et al., 2011)	DU20, Yintang, Sishencong, LV3 *RCT (n=43) verum vs fluoxetine + minimal needling non-acupoints*	(+)

1-	(S. K. Liu et al., 2006)	Sishencong, Anmian, PC6, HT7, ST36, SP6, LV3, KD6, UB62 *RCT (n=560) acupuncture versus Prozac 20mg*	(+)
1-	(Nie et al., 2011)	Acupuncture (with moxa) at RN12, LV13, ST36, SP9, UB20, and UB21 *RCT (n=63) acupuncture vs fluoxetine 20mg*	(+)
1-	(J. P. Wu, 2010)	Sishencong, DU20, DU24, plus pattern differentiation *RCT (n=300) vs fluoxetine 20mg*	(+)
1-	(P. Wu & Liu, 2008)	Anxiety: electroacupuncture at DU20, DU24, YT, DU26, LI4, LV3, HT7, PC6 *Control trial (n=67) verum vs alprazolam for anxiety*	(non-inferior)
1-	(Guo et al., 2009)	Depression, cognition and quality of life with Ling Gui Ba Fa (stems and branches) acupuncture *RCT (N=80 men only), acupuncture vs Sertraline*	(+)
GENERAL POPULATION			
4+	(X. M. Shi, 2011)	Liv3 LI4 for dysphoria, also hyperlipidemia. SP6 Rn4 PC6 yintang Du20. Technique: peck yintang (will leave these in to prevent suicide); supplement SP6.	
4+	*(Deadman et al., 2007) *A Manual of Acupuncture*	H5, Liv5; Melancholy P4, Lu3, Sp5	
4	(Zhu & Siu, 2007, p. 3) *Color Atlas of Zhu's Scalp Acupuncture*	Head and face area; Upper jiao area	

FATIGUE

Brief medical background:

"Fatigue is a common and distressing consequence of stroke. Its aetiology is poorly understood. Fatigue starts early after stroke and is more common in patients with minor stroke than transient ischaemic attack, indicating that the stroke lesion itself may contribute to its development. Some studies have reported an association between post-stroke fatigue (PSF) and stroke lesion location…The presence of brain changes associated with ageing [atrophy and white matter lesions (WML)] may also contribute to the development of fatigue.…Significant fatigue has been reported in over 50% of patients on admission, 59% of patients at 10 days and 92.3% of patients (95% confidence intervals 78.3-100) at 1 month after stroke. This early period is a critical one for starting rehabilitation, and if fatigue delays rehabilitation it may worsen prognosis." (Kutlubaev et al., 2013)

Evidence Basis: Overall Grade = D (no studies of acupuncture for fatigue in stroke)

NHS Grade	Author, Year (or Text)	Approach	Results/Notes
4+	(Maciocia, 2008)	*Def:* *(LU)*: Lu9, St36, R6/12/17, Ub13/43, Du12,Sp6 *(SP)* Sp3,St36, R12, Ub17/20/21, St44, Du20 *(HT)* 5/6/7, P6/7, Ub15, R4/6/14/15, Du14, K3/6 *(Ki Yang def)* K3/7,R4, Ub20/23, Sp6 *(Blood def)*H7,P6,R4/14/15, Ub17/18/20, St36,Sp6, Liv8 *(Liv yin def)*R4, Liv8,Sp6,St36 *(Ki yin)*K3/6, Lu7, R4,Ub23/52 *Excess:* *(Liv Qi Stag)* Gb34, Liv3/13/14, P6, Sj6 *(Liv Yang Rise/Fire/Wind)* Liv2/3/8, Sp6, Ki3, R4,P7, Ht7, Du16, GB20, Si3,Ub62 *(Phlegm)* R12,St36,Ub20,St8, Du20, Lu5 *(Damp)* Sp6/9, Ub22, R9, Lu7, Li4/11, Ub20, R12	
4	(Zhu & Siu, 2007, p. 4)	Middle jiao area	

Additional Approaches **INCONTINENCE (FECAL)**

Brief medical background:

"Bowel dysfunction is a common and distressing condition after stroke, but there are virtually no intervention studies in this important clinical area. Fecal incontinence (FI) affects ≥ 56% of individuals acutely after stroke, 11% at 3 months, and ≥ 22% at 12 months. Constipation is recognized as a serious problem in clinical practice, affecting 60% of those in stroke rehabilitation wards. FI may develop months after acute stroke and can be transient, consistent with constipation overflow as a possible cause" (Harari et al., 2004).

Recent research has used electrical stimulation of sacral and tibial nerves (at Kid7) for fecal as well as urinary incontinence.

Evidence Basis: (Overall grade is B including tibial nerve stimulation, otherwise D)

NHS Grade	Citation, *Book Title*	Treatment Approach *Study Design, Population*	Study Results / Notes
1+	(Thomas et al., 2013)	Electrical stimulation of tibial nerve (percutaneous and transcutaneous) *Review (13 studies, N=273)*	+ Studies were heterogeneous and quality was variable
1	(George et al., 2013)	30 minutes of percutaneous electrical stimulation of tibial nerve (ie e-stim at KD7) *RCT (N+30)*	+
1	(Booth et al., 2013)	30 minutes of percutaneous electrical stimulation of tibial nerve (ie e-stim at KD7) *RCT (N=30)*	(+) Significant in urinary incontinence, strong trend in FI (p=0.1)
3	Scaglia M, 2009	Acupuncture at UB32/35 *Pre/post (N=30)*	+
4	*(Wiseman et al., 1996, p. 196)	Kidney Yang xu: periodic discharge of slimy stool; physical cold, fear of cold, reduced eating, frequent voidings of clear urine; pale enlarged tongue with white fur; pulse sunken and fine. UB23/20, ST36, Liv13, ST25, Moxa Du4/R4/R12 Vacuity fall: involuntary passing of stool without awareness; dull shen; Qi xu including poor	

		appetite, palpitations, SOB, low voice, bright white complexion; swollen scalloped pale tongue; sunken fine forceless pulse. GV20/1, UB25/57, SP6, CV6 (supplementing needle and moxa)	
4	*(O'Connor & Bensky)	Raise the yang Qi and activate the area: Du1/20, UB57; UB30 Ear: distal segment of rectum; subcortex	

INCONTINENCE (URINARY)

Brief background:
Urinary incontinence (UI) is common among stroke survivors and is associated with higher levels of mortality, disability, and discharge to institutional care than in continent survivors. In previously continent stroke survivors at 1 week, UI was found in 35% in one study . Higher rates have been found at the time of maximum stroke severity [4] and in older people. These rates have been shown to decline to as low as 19% by 6 months although half of those who were incontinent at presentation died during that time. Being younger, having a lacunar stroke and greater functional independence are associated with an increased likelihood of regaining continence. Other factors that influence continence in stroke include cognitive impairment, the ability to communicate, mobility and conscious level. (Wilson et al., 2008)

Evidence Basis: Overall Grade = B-

NHS Grade	Author, Year (or Text)	Approach	Results/Notes
1-	(H. L. Liu & Wang, 2006)	RCT (n=82) moxibustion with ginger and salt at CV8	(+)
4+	(X.-M. Shi, 2006, pp. 669-670)	CV3 perpendicular 1-1.5 cun reinforcing 1 minute SP6 perpendicularly 2.5-3 cun reinforcing 1 minute, then reducing 1 minute	Same treatment for retention and incontinence
4+	(Zhu & Siu, 2007, p. 4)	Lower jiao area	
4+	(Deadman et al., 2007)	Lu5,St22, Sp6/9/11, Ht5,/7/8, Ub23/26/27/28/32/39/40, Ki3/6/11, Gb34/41, Liv1/2/3/8/9/10, R1/2/4	
4+	(Maciocia, 2008)	Qi def: Lu7,UB13/23/53, Du 12/20 Sp def: Ub20,St36, R12 Ki yang def: Ub23/28,Du4,K7, R4 Yin def: R4,K3, Sp6 Liv Fire: Liv2,Ht7,yin tang, Sp6	

INSOMNIA

Brief medical background:
"In addition to physical and cognitive impairment, the occurrence of sleep disorders is an important aspect that needs to be considered in the clinical approach to patients with stroke. The rehabilitation process, for example, which occurs from the initial stage following the stroke, is continuous and prolonged in many cases, and may be compromised if patients experience poor sleep quality or sleep disturbances, mainly because sleep is a function that interferes significantly in the learning and memory consolidation processes. Studies on patients with stroke show the occurrence of disturbed sleep, the main disorder being obstructive sleep apnea syndrome, which occurs in 60% to 90% of patients. Complaints of insomnia and excessive daytime somnolence are also found in this clinical population. Campos et al. (2005) showed various episodes of dozing at different times and poor sleep quality in chronic stage stroke patients." (Rocha et al., 2013)

Evidence Basis: Overall Grade = D (more studies to come)

NHS Grade	Author, Year (or Text)	Approach	Results/Notes
4+	*(Maciocia, 2008)	Deficiency: *(Blood):* St36, Sp6, H7, R14, Ub15, Yin Tang *(Yin):* Ht7, Ub15, R14, Sp6, St36, R4 *(HT/KI disharm):* Ht 6 red, All reinforc: Ht7, P7, R4/15, Sp6, K3/6, Ub15/23/44/52 *(Ht/Gb Def):* Ht7, GB40 *(Liv yin def):*^Liv8, R4, Sp6, K3/6, Ub15/23/44/52 Excess: *(Liv Fire)* Red. Liv2/3, Gb12/13/15/20/44, Sp6, Ub18, Du 24, Ub1/4/7/62, K6 *(Ht Fire):* Ht 7/8, Sp6,Li11, R15, Du 19 Ub15/44 *(Phlegm Heat):*St40, R9/12,Ub20, Sp6/9, Li11, St8,Gb12,St45, Sp1 *(Residual Heat in Diaphragm) :* Lu10, H8, Ub17, St40, Li11, Sp6, R15	

MOTOR IMPAIRMENT – HEMIPARESIS, HEMIPLEGIA

Brief medical background:
"Following a stroke, patients frequently suffer severe disability and marked limitations in activities of daily living. Postural instability is one of the major deficits following a stroke, with associated increased risk of fall; a consequence of this problem is reduced mobility, increased disability and even mortality. Stroke subjects who retain the ability to stand show delayed and disrupted equilibrium reactions, exaggerated postural sway in both sagittal and frontal planes, reduced weight-bearing on the paretic limb and increased risk of falling. The clinical and social impact of postural instability has produced a great deal of research in this field that allowed the development of several functional tests and laboratory methods (posturography) to explore the extent of balance dysfunction." (Sawacha et al., 2013)

Evidence Basis: Overall Grade = D

NHS Grade	Author, Year (or Text)	Approach	Results/Notes
4+	(Flaws, 2010, pp. 111-112)	Boost qi transform stasis, extinguish wind and free flow of channels/vessels. Du20/16 (drain), LI4, SP6 (sup). In mild cases, there is numbness; in severe cases, no sensitivity. Body and limbs are paralyzed and weak. Tongue purple dark, fur white slimy. Pulse slippery, moderate, forceless. "According to Ling Shu, fengfu/bai hui govern flow if Qi and blood in sea of marrow. When drained, they transform stasis, extinguish wind, transform phlegm in the head. Supplementing LI4 boosts Qi, SP6 nourishes blood; together they harmonize yin/yang, free the luo."	
4+	(Jarrett, 2003, p. 41)	Course channels free collaterals GB20 H1 Lu5 LI4 baxie SJ5 LI11/15 p39: XNKQ above plus: clenched fingers p39 add LI4; inability to extend/stretch add LI11; Pei-xin: needle LI4 towards LI3, drain lift thrust; drain baxie with lifting, thrusting and rotation; drain SJ5 with lifting thrusting; supplement GB20 with rotation drain H1 Lu5 with lifting thrusting.	

MOTOR IMPARIMENT – LOWER EXTREMITY

Brief medical background:
The ability to walk at the speeds and distances needed for home and community ambulation is an especially important and readily measured outcome after hemiplegic stroke and spinal cord injury (SCI). Six months after stroke, patients with persistent hemiparesis walk approximately one third as fast and only 40% the distance of age-matched healthy persons. (Dobkin et al., 2004)

Evidence Basis: Overall Grade = C

NHS Grade	Author, Year (or Text)	Approach	Results/Notes
1-	(G. Liu et al., 2010)	Electroacupuncture at UB20, 23, 24, 25, and individual points, to evaluate effect on gait biomechanics *RCT (n=21) vs usual care alone*	(+) NS for Fugl-Meyer and BI, significant for 'single-foot supporting phase'
4+	(X. M. Shi, 2011)	ST30. UB40 is main point; also SP6b - behind tibia to waken the luo, move local blood stasis Weak vastus medialis weak: surrounding needles. Tibia - tendinomuscular merdian. GB34/39 plus ashi for pretibial myoatrophy. SP6b & GB40=>K6 for strephenopodia (spastic ankle eversion)	
4+	(X.-M. Shi, 2006, p. 670)	Strephenopodia and Foot drop: needle GB40 3 cun perpendicular through to KD6, even method	
4+	(Flaws, 2010)	4-6 points from: ST31/32/36/41; GB30/31/34/39. Contraction of knee, UB40 Liv8. Swelling/numbness of toes, Ba feng. Leg/foot twist to inside, SP4/6, KD3/6. If to outside, GB39/40, UB60/62. If foot bends downward, ST41/37, GB40, Liv4.	
4+	(Jarrett, 2003)	SP6 B40 GB31/34 drain with lifting/thrusting; UB30 manipulate until electrical sensation reaches toes UB60 drain with rotation. Club foot: KD9 UB60 ST41 GB40	
4+	(Hopwood & Donnellan, 2010, p. 111)	Yang: GB30/31/34, ST31 B36 Bafeng; Yin SP10/6, Lv2, Ki3 Bafeng; Sp9 if edema	
4+	(Zhu & Siu, 2007, p. 6)	Lower limb area	
4	(Y. Zhang, 2004)	Effect of needling technique used at UB54	Direction of needling affects efficacy of point - needle along the channel for lower limb flaccidity

MOTOR IMPAIRMENT – UPPER EXTREMITY

Brief medical background:

"Recovery of upper extremity movement and function is a major concern facing individuals who have upper extremity paresis after stroke. Of the 80% of patients experiencing acute paresis of the upper extremity after stroke, only approximately one-third achieve full functional recovery. Predicting functional recovery for these patients is highly important to provide focused, cost-effective rehabilitation. Although there are several good models for predicting mortality, life satisfaction, discharge destination, or likelihood of independent function, only a few models have tried to predict recovery of upper extremity function specifically.… We have recently found that the simple measure of active range of motion (AROM) can account for 82% of the variance in upper extremity function in people with hemiparesis <1 month after stroke." (Beebe & Lang, 2009)

Evidence Basis: Overall Grade = B

NHS Grade	Author, Year (or Text)	Approach	Results/Notes
1-	(Cheng et al., 2011)	Acupuncture at TH3 and TH5 plus usual rehab *RCT (n=60), vs usual rehab alone*	(+)
1-	(Shang et al., 2008)	LI15, SJ14 *RCT (n=120), acupuncture alone vs usual rehab alone vs both*	(+)
3	(L. C. Wang et al., 2008)	Hand spasm: PC6, lifting/thrusting/twirling (or rapidly twirling) five minutes, twice per day plus usual rehab *RCT (n=172) 5 arms randomized to different treatments, no placebo control*	(+)
4+	(Deadman et al., 2007)	Atrophy - TH10 Contraction-St32, LI15, Si4 No AROM - Lu5/6, LI13/14/15/16, St12, SI2/9, TE2/13, GB20/22/29 Liv13 Paralysis -Li10, P3, Sj5,Sj8/14 Weak - Li14, Si10	
4+	(Flaws, 2010)	3-5 points from: LI15/14/11/10, TH5. For contraction: PC5/6, Lu5. Difficult flexion of wrist: TH4. Thumb: LI5. Swelling or numbness of fingers: Ba xie.	
4+	(X. M. Shi, 2011)	LI11 Ht1 Lu5 LI4. 3 yin channels = ulnar, radial, median nerves.	
4+	(Zhu & Siu, 2007, p. 6)	Upper limb area	

4+	(Hopwood & Donnellan, 2010, p. 111)	Extensors (Yang aspect): GB21 LI15/11 TH5, GB10 Baxie (&LI17); p111 Flexors (yin aspect): LU10 PC8 H8 Baxie	
4+	(X.-M. Shi, 2006, p. 670)	Frozen shoulder: LI15 + 2 cun either side, 1.5-2 cun obliquely towards the articular cavity with reducing method, retain 20 minutes. Cupping/bleeding on painful points, up to 2-3ml per day.	

PAIN

Brief medical background:

"Central post-stroke pain (CPSP) is a neuropathic pain syndrome that can occur after a cerebrovascular accident. This syndrome is characterised by pain and sensory abnormalities in the body parts that correspond to the brain territory that has been injured by the cerebrovascular lesion. The presence of sensory loss and signs of hypersensitivity in the painful area in patients with CPSP might indicate the dual combination of deafferentation and the subsequent development of neuronal hyperexcitability. The exact prevalence of CPSP is not known, partly owing to the difficulty in distinguishing this syndrome from other pain types that can occur after stroke (such as shoulder pain, painful spasticity, persistent headache, and other musculoskeletal pain conditions)." (Klit et al., 2009)

"Glenohumeral subluxation (GHS) is a frequent complication in patients with post-stroke hemiplegia: it is reported to be present in 17–66% of patients with hemiplegia following stroke. GHS usually develops immediately after stroke when flaccid paralysis prevents normal muscle response and stabilizing mechanisms to loading. Although emphasis has been placed on the reduction of GHS and several studies were aimed at the treatment of the hemiplegic GHS, its role among post-stroke complications is still controversial. Some investigators found an increased incidence of sympathetic reflex dystrophy in the upper limb associated with GHS and others found a correlation between GHS and rotator cuff injury. Some investigations reported dysfunction of brachial plexus and other peripheral nerves in patients with GHS, but other studies have not found evidence of that. Moreover, the relation between GHS and shoulder or arm pain is still debated." (Paci et al., 2005)

Evidence Basis: Overall Grade = C

NHS Grade	Author, Year (or Text)	Approach	Results/Notes
		POST-STROKE THALAMIC PAIN	
2-	(Jiang et al., 1999)	Electroacupuncture at Huatuojiaji points *Case control (n=60) vs carbamazepine*	noninferior
4+	(Oleson, 2013)	Thalamus, Brain, Master Cerebral, Zero, Shenmen	
		POST-STROKE SHOULDER PAIN	
2	* (Lu et al., 2010)	Electroacupuncture at LI15, SJ14, SI9 plus individual points plus rehabilitation, versus rehabilitation alone *Case control (n=60)*	(+)
4+	(X. M. Shi, 2011)	GB34/SP9, SI14/15, supplement or disperse according to palpation and strength of patient	
4+	(Zhu & Siu, 2007, p. 6)	Shoulder area	
4+	(Hopwood & Donnellan, 2010, p. 111)	Subluxation: eyes of shoulder, SI11, LI11, SJ9, ba xie	

URINARY RETENTION

Brief medical background:
Fifty-one consecutive patients with recent unilateral, ischemic, hemispheric stroke admitted to a neurorehabilitation unit were studied prospectively to determine the causes of post-stroke urinary retention. Elevated post-void residual urine volumes (PVR) were correlated with position of voiding (in bed or on commode), presence of incontinence, infarct location, and functional status. Urodynamic studies and cystoscopy were performed on all patients with elevated PVR. Twenty-two patients (43 percent) had elevated PVR. Urinary retention was associated with large infarcts, urinary incontinence, and functional disability ($p<0.05$), but not with age, sex, side of stroke, time from stroke to study entry, or position of voiding. Urodynamic studies revealed bladder outlet obstruction in 32 percent, bladder hyporeflexia in 27 percent, and combined bladder outlet obstruction and bladder hyporeflexia in 5 percent. Of eight patients in whom urodynamic studies and cystoscopy did not reveal an obvious cause for urinary retention (bladder hyperreflexia in 27 percent, normal study in 9 percent), seven were either aphasic or demented. We conclude that there are multiple causes of urinary retention following acute stroke. In cognitively impaired or aphasic patients, PVR may not provide an accurate indicator of urinary retention. (Gelber et al., 1994)

Evidence Basis: Overall Grade = B-

NHS Grade	Author, Year (or Text)	Approach	Results/Notes
1-	(Yun et al., 2007)	RCT (n=39) moxibustion RN3, 4, 6	(+)
4+	(X.-M. Shi, 2006, pp. 669-670)	CV3 perpendicular 1-1.5 cun reinforcing 1 minute SP6 perpendicularly 2.5-3 cun reinforcing 1 minute, then reducing 1 minute	Same treatment for retention and incontinence
4+	(Hicks, 2013)	Lu Heat:Lu5,7,R3, LI11 Ht Heat: H8,Si2,R3,Ub28, Ki2 Mid/low Damp heat: R3/12, UB20/22/28, Sp6/9,R3, Central Qi def: Du20, R6/12, Ub20/28, Sp6, R3 Stag of Essence: Sp6/10,Ub17, Liv5,R6, St 29 Ki yang def: Ub23/28, du4,R4	
4+	(X. M. Shi, 2011)	UB54, towards perineum. For Cystitis, Rn4/SP6.	
4+	(Zhu & Siu, 2007, p. 4)	Retention: Lower jiao area UTI: add lower abdomen area	

WIND

Brief medical background:

Deviated eyes: "The spontaneous horizontal deviation of the eyes is a striking symptom in acute stroke. Correspondingly, its evaluation is part of different clinical stroke scales, including the National Institutes of Health Stroke Scale, the European Stroke Scale, or the Scandinavian Stroke Scale." (Berger et al., 2006) "Conjugate eye deviation, sustained shift in horizontal gaze toward the affected hemisphere, is a well-recognized finding in acute stroke. Several supranuclear lesions, such as in the cortical frontal eye fields or in the brainstem paramedian pontine reticular formation, can cause conjugate eye deviation." (Simon et al., 2003)

Facial and tongue deviation: "Bilateral strokes involving the pyramidal tract may produce supranuclear or pseudobulbar palsy without significant somatic motor dysfunction. However, recent reports have shown that unilateral lesions may cause supranuclear dysarthria with or without lower facial paresis, without signficant motor weakness. These case reports have been described under various headings, including isolated facial palsy, supranuclear facial palsy, pure dysarthria, and isolated dysarthria.[10]" (Kim, 1994)

Evidence Basis: Overall Grade = D

NHS Grade	Author, Year (or Text)	Approach	Results/Notes
4+	(Deadman et al., 2007)	Du16,P7, Ub11/12/13/4567, Li6, Lu10,M-LE-34,LI 15 *(Windstroke)* LI 10/15, St36, Ub15/23/40, P6/8/9, GB2/13/15/21/40, Liv2, Du16/20, R4, Si Shen Cong, Shixuan, Ub62, P5	
4+	(Jarrett, 2003)	Deviation of mouth/eyes: GB20 taiyang ST4/7 LI4; Benefit marrow supplement brain course/regulate sinew vessels; supplement GB20 to benefit marrow supplement brain. Taiyang towards ST6. Drain ST6/7. Drain LI4 on unaffected side to fortify spleen transform dampness, course sinew channels	
4+	(X. M. Shi, 2011)	ST2 for wind: needle downward to go deeper. For epilepsy (incl caused by hemorrhage): R12, ST2, SI3, B62, Du1, Yintang. Technique: Lift/thrust, don't turn. SI3, use the crease. UB62, just tap in. Rationale: ST2 moves Qi/Blood in Yangming, also use to move blood/remove stasis (ST36 is overused).	
4+	(Hopwood & Donnellan, 2010)	Pathogenic wind GB20/12, SJ17	

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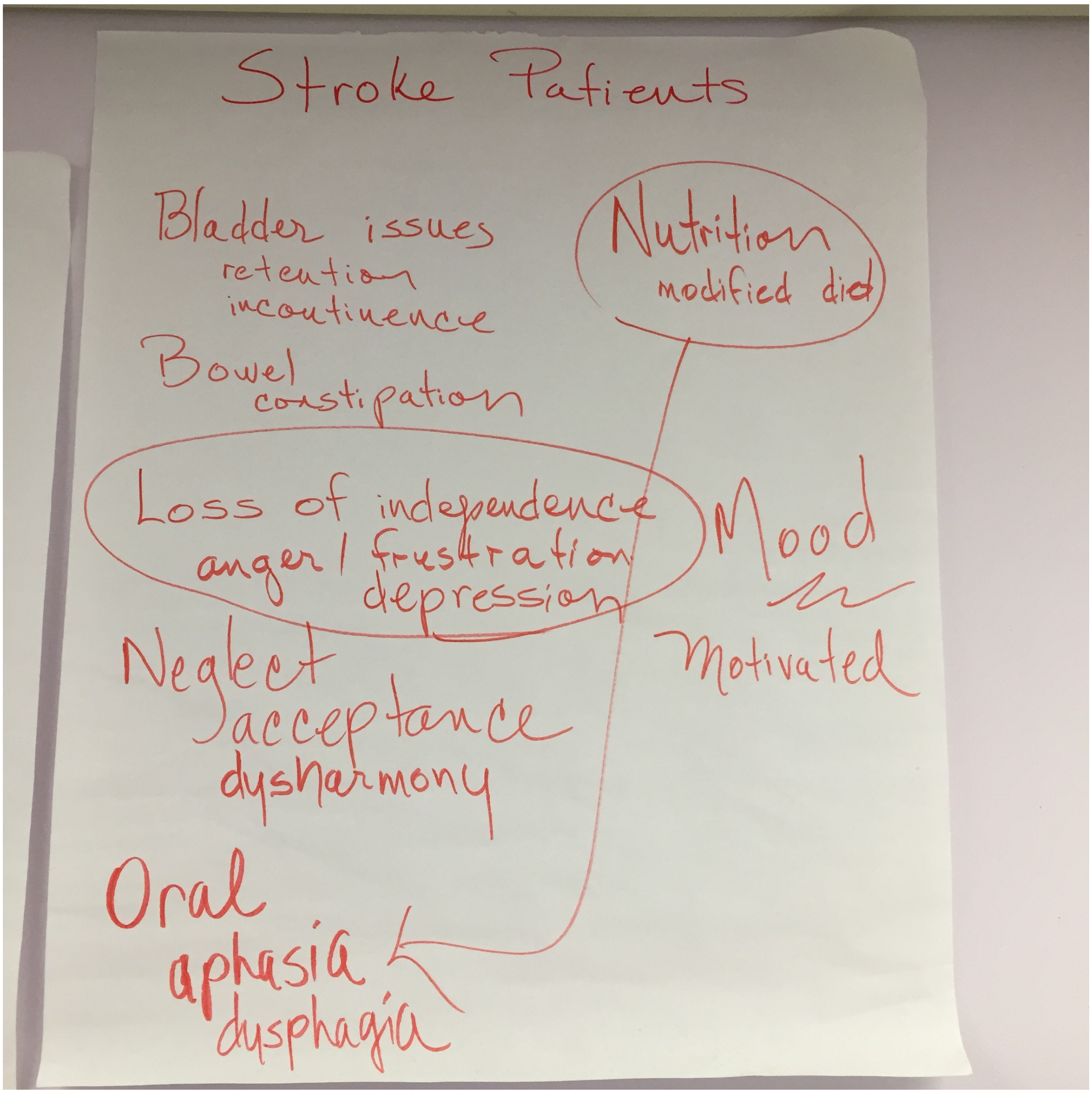
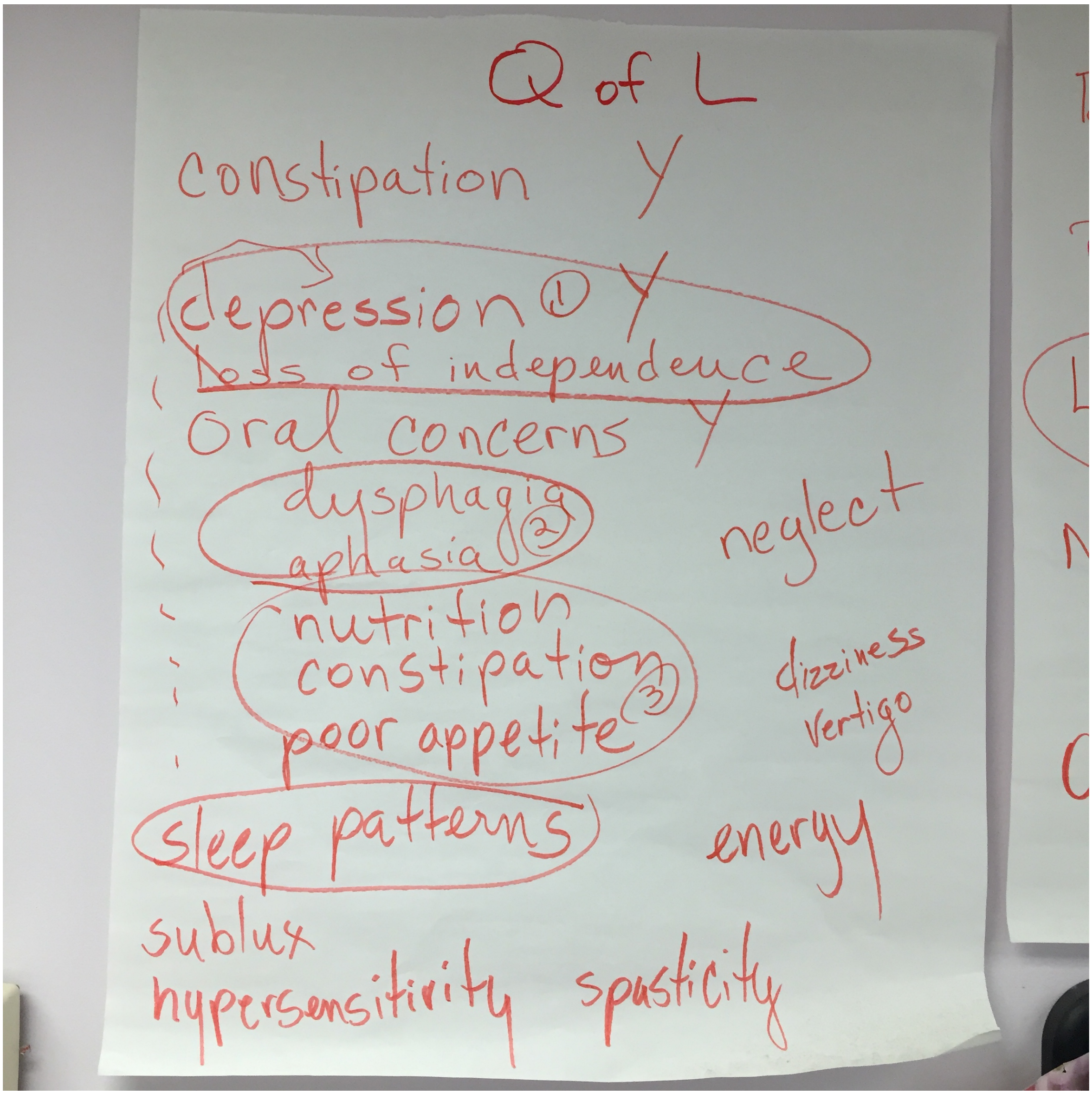
Appendix D: Notes from Nursing Staff Meetings



Meeting 1: March 7, 2012 - Day Shift



Meeting 2: March 9, 2012 - Night Shift

Appendix E: Presentation to Physical and Occupational Therapists

Acupuncture during Stroke Rehabilitation: Which Patients Benefit?

Development of a mixed methods study.

Claudia Citkovitz, MS, L.Ac.
Acupuncture Preceptor, Lutheran Medical Center
MPhil/PhD candidate, University of Westminster, London

Overview:

- Background:
  - What is Acupuncture?
  - Acupuncture and Research at LMC
- This Project:
  - Literature Review
  - Defining the Question
  - Refining the Intervention
  - Treatment and Data Collection
  - Data Analysis, Writing and Publication

What is Acupuncture?

- Insertion of sterile, disposable, filiform needles
- Solid body, not hollow
- Typically 28-36 gauge (.12-.35 mm)
- 1/4 size of 21 gauge hypodermic needle
- Typically 6-15 needles per treatment
- Needles usually (but not always) retained 15-45 minutes

Local Needling: What's her Chief Complaint?

Local/Adjacent Needling

"Balance Method"

Acupuncture techniques used in stroke rehabilitation

- Body acupuncture – patient supine, 4 to10 needles retained 15-25 minutes, 34 gauge, 1"; may use mild electrical stimulation.
  - Local, distal and "balance" strategies
  - Patients usually find the treatment relaxing, often sleep
  - Various treatment goals: stimulate affected limb; relax antagonists; fatigue, constipation, insomnia, mood; other symptoms eg intractable hiccups
- Scalp acupuncture – in rehabilitation, very small needles retained on injured side, over target area:
  - Motor (UE, LE, head), sensory, balance, vision, speech, swallowing

Scalp Acupuncture: MingQing Zhu

Acupuncture at LMC: Education Programs

- Started in June 2003 – Jill Blakeway then Claudia C.
  - NOR, L&D, Oncology
- Mercy College (2003-4); Touro College (2004-7)
  - Master's Degree Acupuncture students
  - 2-3 days/week, 4-8 hrs/day; 212 stroke patients
  - NOR referral ad hoc by Dr. Kornfeld, PT's, OT's
    - Plateau; dysphagia; balance; wrist extension; patient interest
- After Touro College, less Masters' level teaching:
  - DOM (equivalent of DPT); focus on L&D, research
- 2006 L&D study – fewer C-sections – presented, published
  - Led to more involvement @ L&D, less @ NOR

NOR Acupuncture Research

- 2004, Dr. Azhar initiated study with Dr. Cui (N=6)
  - Assessed FIM, LOS; did not reach significance
- 2005, Chart review for Research Fair: 190 NOR patients reported improvement with:
  - Stroke sequelae including: balance, dizziness, visual acuity, dysphagia, aphasia, limb weakness, dropped foot, fatigue, headache
  - Associated symptoms including: anxiety, depression, cough, shoulder pain, urinary retention, constipation, (diarrhea), persistent hiccups
- 2005-6 survey of NOR staff as "expert witnesses", presented at national conference
  - All 22 full-time NOR staff surveyed; perceptions shifted more positive from working with acupuncture program ($p=0.04$)
  - Written comments observed positive effects on: pain, mood, energy, strength, ROM, hope for recovery.

This Project

- PhD Program at University of Westminster, London
  - Emphasis on chronic disease, public health problems
    - Strong on qualitative research
  - Conduct research here, 2 months/year in London
    - 3½ years – completion June 2014
- Key concept in a PhD is the "contribution to knowledge"
  - The question asked must be both important and unanswered
- LMC research values (Julliard, Citkovitz, McDaniel):
  - Scientific method applied to acupuncture, not just RCT's
  - Compare to standard care, use staff as "expert witnesses"
  - Actual clinical questions derived from problems encountered
    - Which patients should we refer for acupuncture treatment?

Literature Review – Mechanisms:

- Animal mechanism studies look great!
  - Reduction of cerebral edema; increase in cerebral blood flow
  - Faster glutamate clearance and increased angiogenesis at the ischemic boundary; activation of motor area
  - Reduction of ischemic volume at 24 hours
  - (Animals are not prone to placebo effects)
- Mechanism studies in humans also look very promising
  - Increase in cerebral blood flow; decreased vascular resistance on stroke side
  - Activation of limbic system; changes in gene expression
  - Some chronic stroke/aphasia patients treated with acupuncture (no therapy) improved speech, increased O2 in Wernicke's area

Literature Review – RCT's:

- Chinese literature shows remarkable results – as always!
  - Hemiplegia, gait analysis, upper extremity function, dysphagia, aphasia, depression, pain, spasticity, etc.
  - No blinding, poor outcome measures – and better technique?
- Western "well designed" trials are very few and inconclusive:
  - Living status @ 12 months – changing result (Hopwood 2005 vs. Hopwood 2008)
  - Spasticity – several trials showing lack of effect
- Western reviews and meta-analyses are mixed but generally negative

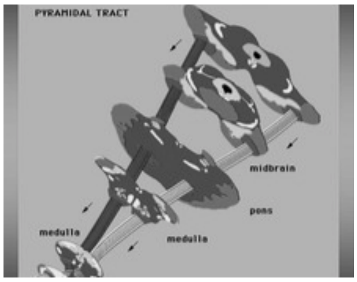
Why the inconsistency?

- Chinese start earlier and technique is better – note response to documentary, "9,000 needles"
- "Window of opportunity" for shrinking penumbra?
- "Responders" vs "Nonresponders"
  - Kaptchuk et al: as with any treatment, some respond more than others; related to placebo effect?
  - This was our experience here: widely differing responses to similar treatments
- Sam Shiflett, 2007 – multiple overlapping factors
  - Won't reach significance at low, high end of spectrum
  - Different treatment styles and outcome measures!

An old hypothesis that was ignored for years….

- Margaret Naeser, 1993, 1994
  - <50% damage to descending corticospinal tracts (DCT) "predicted" response to acupuncture, even >10 years
  - At the time, could only be measured on post hoc CT
- DTI (diffusion tensor imaging) can show damage to DCT in real time
  - Other therapies (eg PT) have shown reduced effectiveness with greater damage to DCT
- LMC is getting DTI capability in October 2011

Descending Corticospinal Tracts



Diffusion Tensor Imaging

Defining the Question

- Start with real problem: "Who should we refer for acupuncture treatment?"
  - Current clinical use; future NIH grant proposal
- Based on Naeser's hypothesis: "Should we exclude patients with severe damage to DCT?"
  - What about the other apparent benefits previous LMC patients experienced?
  - Naeser's results should only apply to <u>motor</u> outcomes
- Use qualitative and "expert witness" approach as a safety net – to identify possible non-motor benefits

“Which patients experience which benefits?”

- Naeser’s Boston Stroke Scale – motor improvement
  - 7 simple tests
- NIHSS
- FIM – look motor and non-motor separately
- HamD or Beck depression scales
- Subjective perceptions by patient and/or family
- Observations (subjective and objective) by NOR staff
  - 6-question survey per patient

Phase 1: Refining the Intervention

- October 17 – December 16, 2012: recruit and treat patients with fully individualized treatment
  - Patient response, PT/OT/Speech Therapy input as to procedures, timing, apparent benefit/impact
  - Medical staff, nursing opinions
  - Acupuncturists are self-evaluating treatments and perceived effectiveness
- January – June 2012: acupuncturists create provisional treatment manual
- If any new insights are gained or problems identified, this is the time I will submit a revision of study methods!

Phase 2: Treatment and Data Collection

- July – December 2012: recruit and treat 30 patients with ischemic MCA stroke
  - On admission: DTI (blinded); NIHSS; FIM; Boston Motor Inventory (BoMI)
  - After first and last acupuncture treatment, patient questions (conducted by speech therapist?)
  - Before discharge:
    - NIHSS, FIM, BoMI, Beck/HamD; patient/family survey
    - Primary PT, OT, Speech, MD, nurse: 6 question survey
- 6 month follow-up: NIHSS, FIM, BoMI, Beck/HamD

Phase 3: Quantitative Data Analysis

- Find out who had what % of intact DCT
- Scatterplot - for measures of motor and non-motor function (NIHSS, FIM, BoMI, Beck/HamD):
  - Scatterplot: % damage is on X-axis (left to right), score is on Y-axis (bottom to top)
  - Motor-related and non-motor should be differently distributed, with motor dots lower at the left (less intact DCT) side of the cluster
    - If so, can do ROC (receiver operating characteristic) curve analysis – does % intact predict response?
- Compare patients to matched controls as appropriate

Phase 3: Qualitative Data Analysis

- Did patient/family and NOR staff perceptions match the quantitative data and motor/non-motor curves?
- Were there subjectively perceived benefits that did not show up in quantitative data? Did these match?
- Were there problems or concerns? (Hopefully we found these in Phase 1, but still want to ask)
- Were there patients who did not appear to benefit from the acupuncture but still liked it?
  - Ultimately, who should be referred for treatment?

Writing and Publication: 2013-14

- As soon as data are in (and possibly earlier) it’s time to start publishing as many good papers as possible
- LMC’s rules on this are clear: whoever does writing work is an author.
- In our 2006 study, nursing staff independently wrote and published a paper about nurse perceptions of acupuncture.
- This project has many subtopics and will probably generate more as it goes – contact me!

Appendix F: LMC Ethics Approval

IRB-14

LUTHERAN MEDICAL CENTER
Institutional Review Board

EXPEDITED REVIEWER FORM

PROTOCOL TITLE: Integrating acupuncture into routine post-stroke care: Which patients experience benefit?

PROTOCOL NUMBER: 270

AUTHORS: Claudia Citkovitz, MS, L. Ac, Salman Azhar, MD, Laura Gabbe, MS, L.Ac

REVIEW REQUESTED BY: Claudia Lyon, DO

DATE SUBMITTED: July 18, 2011

COMMITTEE MEMBER REVIEW / DISPOSITION

IRB MEMBER: **Dr. Claudia Lyon**

COMMENTS: ______________________

____

____

CATEGORY OF EXEMPTION:

__ Drug or device meeting conditions
__ Approved collection of blood samples
__ Noninvasive biological specimens
__ Routine noninvasive clinical procedures
__ Data collected for nonresearch purposes
__ Voice, video, digital, or image recordings
✓ Survey or behavior research
__ Retrospective chart review

DISPOSITION: ✓ Approved ____ Not Approved and Referred to Full IRB

____Pending modification / further information
(See above "Comments")

____This project does not require IRB approval or continuing review.

If approved, please check time period for continuing review:

☑ 1 year ☐ 7 months ☐ 3 months ☐ Other: ______________

Signature: C. Lyon DO

Date: 7 / 19 / 11

7/18/2011, t:\irb\forms\irb-14a_expedited reviewer form 3 merge master.doc

LUTHERAN MEDICAL CENTER HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD (IRB)
APPROVAL DISPOSITION FORM

Principal Investigator: Claudia Citkovitz, MS, L. Ac
Other Pertinent Investigators: Salman Azhar, MD, Laura Gabbe, MS, L.Ac

The Institutional Review Board (IRB) made a decision on your research protocol entitled:
"Integrating acupuncture into routine post-stroke care: Which patients experience benefit?"

☐ At the IRB meeting on ___________ ☐ Through expedited review
☐ After reviewing subsequent revision ☐ Continuing review

Protocol #: 270 **Time period for continuing review:** Not yet determined

Next review date:

Disposition: ✓ Approved ____ Not Approved ____ Reapproved

____ Request modification / additional information

____ IRB approval not required

____ HIPAA waiver of informed consent was granted or is not needed.

Comments:

IRB requirements for all approved protocols:

In carrying out this study, the investigators agree to the following:
1. To accept responsibility for the scientific and ethical conduct of this research study;
2. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form, except when needed to eliminate hazard to the patient;
3. To use consent forms date-stamped by the IRB only during the period in which it is valid to enroll subjects;
4. To promptly report in writing to the IRB any severe/adverse medical events pertaining to this project, any unanticipated problems regarding risks to subjects or others, and any changes in the protocol or consent form;
5. To keep copies of the informed consent of all LMC patients enrolled in the protocol in the patient's chart and the principal investigator's file.
6. To fully complete the continuing review form sent from the IRB and return it promptly to the IRB.

7/19/11
(Date)

C. Lyon
Claudia Lyon, DO, Chair, IRB

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June 20, 2011

To whom it may concern:

Claudia Citkovitz has initiated submission of the proposal for a cohort study, "Integration of Acupuncture into Post-Stroke Care: a preliminary, mixed methods inquiry" to Lutheran Medical Center's Institutional Review Board for Ethics review. I understand that this submission is undertaken as part of a research PhD with the University of Westminster's department of Life Sciences.

Pending acceptance, the Hospital agrees to host this research in its entirety. Strictly speaking, Ms. Citkovitz' research will consist only of additional information gathering from patients treated according to the hospital's existing policies and procedures for acupuncture treatment. Facilities used for these treatments ordinarily include patient rooms as well as the Rehabilitation Unit inpatient and outpatient treatment spaces. Acupuncturists performing the treatments are credentialed by the hospital, with a full review of each file every two years and malpractice insurance information kept up to date on an ongoing basis. Acupuncture needles are purchased by the hospital.

Ms. Citkovitz will also be supported by the clinical research department for data collection and storage, including the use of hospital secure server and locked file drawers. Medical students may assist in the collection of data, which will include patient demographics and clinical data, radiological imaging examinations and progress notes. Rehabilitation unit staff has agreed to fill out surveys and assist with the oral administration of surveys to patients and family members as necessary. The hospital will provide computer support and the use of SPSS software with which to conduct data analysis. Various research and medical staff including Dr. Salman Azhar, Julie Pearson MPH and myself will be available to assist with data interpretation.

Should Ms. Citkovitz' application not be accepted on the basis of the current submission, Ms. Pearson and I will make ourselves available to guide the resubmission process including any necessary revisions or additional paperwork.

The hospital regards Ms. Citkovitz' research activities as a unique and valuable contribution to our patient care and educational programs. I can be contacted at the address below or at kjulliard@lmcmc.com should any further questions arise in connection with this innovative research work.

Sincerely,

Kell Julliard

Kell Julliard
Assistant Vice President, Clinical Research

Clinical Research Office
Lutheran Medical Center, 5802 3rd Ave, Room 357, Brooklyn, NY 11220
Telephone (718) 630-6332 • Fax (718) 759-5807 • E-mail kjulliard@lmcmc.com

Lutheran Medical Center™

150 55th Street
Brooklyn, NY 11220-2574
Telephone: 718.630.7000

June 20, 2011

To Whom it may concern,

The following acupuncture providers are credentialed at Lutheran Medical Center as Allied Health Staff. Their malpractice insurance records are on file, as follows:

Claudia Citkovitz: expires 8/31/11
Maryanne Travaglione: expires 10/21/11
Patricia Cassidy: expires 5/05/12
Sally Rappeport: expires 6/01/12
Tzivya Kraus: expires 1/19/12
Nieve Shere: expires 8/24 /11

Should you require any other information please feel free to contact me at mhirschhorn@lmcmc.com

Sincerely,

Mark Hirschhorn
AVP, Professional Affairs

Appendix G: Westminster Ethics Approval

UNIVERSITY OF
WESTMINSTER

PRIVATE AND CONFIDENTIAL
Claudia Citkovitz
135 Corson Avenue
Staten Island
NY
10301

13 April 2012

Dear Claudia

Ethics App. No. 11_12_07
Claudia Citkovitz: School of Life Sciences
Mode: MPhil/PhD
Supervisor: Volker Scheid

Proposal title: Integration of acupuncture into Post-Stroke Care: which patients experience which benefits? A preliminary, mixed-methods inquiry.

I am writing to inform you that your application and your response to conditions set were considered by the Research Ethics Sub Committee at its meeting of 2 April 2012. The proposal was **approved**.

Please carry out the following and have this approved by your Supervisor:

- Please include a section on the 'right to withdraw' for the participant and their data (data; the right to withdraw up to a certain point) on the Participant Information Sheets.

If your protocol changes significantly in the meantime, please contact me immediately, in case of further ethical requirements.

Yours sincerely

Huzma Kelly
Secretary, Research Ethics sub Committee

cc. Dr. John Colwell (Chair, Research Ethics sub Committee)
Professor Volker Scheid (Supervisor)
Mike Fisher (Research Degrees Manager)
Professor Taj Keshavarz (School Research Ethics Advisor)

Academic Services Department
101 New Cavendish Street
Cavendish House, University of Westminster
London, W1W 6XH
T: +44 (0) 20 7911 5051
E: H.Kelly01@westminster.ac.uk
westminster.ac.uk/research

I am advised by the Committee to remind you of the following points:

1. Your responsibility to notify the Research Ethics sub Committee immediately of any information received by you, or of which you become aware, which would cast doubt upon, or alter, any information contained in the original application, or a later amendment, submitted to the Research Ethics sub Committee and/or which would raise questions about the safety and/or continued conduct of the research.
2. The need to comply with the Data Protection Act 1998
3. The need to comply, throughout the conduct of the study, with good research practice standards
4. The need to refer proposed amendments to the protocol to the Research Ethics sub Committee for further review and to obtain Research Ethics sub Committee approval thereto prior to implementation (except only in cases of emergency when the welfare of the subject is paramount).
5. You are authorised to present this University of Westminster Ethics Committee letter of approval to outside bodies, e.g. NHS Research Ethics Committees, in support of any application for further research clearance.
6. The requirement to furnish the Research Ethics sub Committee with details of the conclusion and outcome of the project, and to inform the Research Ethics sub Committee should the research be discontinued. The Committee would prefer a concise summary of the conclusion and outcome of the project, which would fit no more than one side of A4 paper, please.
7. The desirability of including full details of the consent form in an appendix to your research, and of addressing specifically ethical issues in your methodological discussion.

Appendix H: Patient and Family Participant Information Sheet

Patient Information sheet

July, 2012

Acupuncture during Acute Stroke Rehabilitation: which patients experience which benefits?

Hello, my name is Claudia Citkovitz. I prepared this information sheet in order to tell you what this study is about so you can decide if you want to be in the study.

What is the purpose of the study?

The hospital has been offering acupuncture to patients recovering from stroke for nine years now, and some patients have told us they like it and think it helps. We want to get more specific information about which patients find it helpful and in what ways.

Why have I been chosen?

You recently had a stroke for the first time, in the area of the brain that we are interested in studying.

Do I have to be in the study?

No. It is up to you to decide whether or not you want to be in the study. If you decide to be in the study, you will be asked to sign a 'consent form'. *If you decide to take part, you are still free to stop at any time without giving a reason*. No questions will be asked if you stop. No matter if you decide to be in the study, or decide not to be in the study, or start and then change your mind, the rest of your care will be the same.

Who benefits from this study?

You may benefit slightly by receiving an extra session with the physical therapist as they evaluate you.

Other patients in the future may also benefit, because when the hospital knows more about which patients benefit the most from acupuncture, it can make better decisions about which patients to offer it to.

What will I have to do if I decide to be in the study?

First you will be given the 'consent form'. You only sign this form if you agree to take part in the study. You will be given a copy of the consent form to keep.

You will be asked to commit to taking part in the *whole* of the evaluation process. This involves the following:

- Doing some extra exercises with the physical therapist while they check your progress.

- Answering some questions about yourself, how you feel, and how you liked the acupuncture. These will be asked by different staff members during your hospital stay.

- Coming in to see us 6 months after you leave the hospital. At that time you will do a few more exercises so we can see how you are doing.

What type of questions will I be asked.
None of the questions are of a sensitive nature. We want to know how the acupuncture treatment felt, and if you thought it was helpful to you or not. We also want to know how you are feeling in your body and also your mood.

How long will it take to answer the questions?
Different people take different amounts of time, but for most people it will be three different visits of about 20 minutes each.

Do I have to answer all the questions?
We would prefer that all questions were answered but if you feel unhappy about answering any of the questions then you can leave them out. Remember if you want to stop and come out of the study at any point you are free to do so at any time without any effect to your normal hospital care.

Will my doctor see the forms that I have filled in?
No. All of your answers are private and confidential. They will only be read by the researchers.

What will happen after I answer the questions?
The researchers will analyse all the forms that have been filled in, and compare them to the other tests that have been done on you. The forms will be locked up in a safe place in my office in the hospital. All of the forms will be given a code. The data will then be entered onto a computer under each code so that none of the data on the computer will contain information that could identify you.

I will then look at all the data, together with Dr. Azhar (the head of the Stroke Center) and the Clinical Research office of this hospital. But, all identifying details will be removed, so it will not be possible to identify you when we discuss the data.

How will we use the study data?

All data use is strictly within the rules that the government makes for safe handling of patient information. Once all the analysis is complete, I will write up several reports that will be used for educational purposes. I will also send them out to be published, but there will be no identifying information at all in any of these reports.

Will I get to know the results of the study?

When all the data has been analysed and written up, all patients that took part in the study will receive a report, letting them know what the final results were.

Contact for further information & complaints

We hope that this information sheet about the study has told you what you need to know before deciding whether or not to take part. If you have any questions at all about the project or wish to make a complaint please call me at 718-630-7056 or email me at ccitkovitz@lmcmc.com.

Notes:

- This study has been approved by the University of Westminster Ethics Committee and the Lutheran Medical Center Institutional Review Board.
- If I cannot answer your queries or complaints, please contact the head of the Institutional Review Board, Ms. Claudia Lyon, at 718-630-6332, or email her at CLyon@lmcmc.com

Appendix I: Patient and Family Participant Informed Consent Form

Informed Consent Form for Patients

Project: *Integrating Acupuncture into routine Stroke Rehabilitation: which patients experience which benefits?*

I agree to take part in the above evaluation. I have had the project explained to me, and I have read the explanatory sheet “Patient Information Sheet”, which I may keep for my records. I understand that agreeing to take part means that I am willing to:

1. Answer questions during my hospital stay
2. Give permission for my family to fill in a paper survey during my hospital stay (but they can say no if they want to)
3. Do some extra exercises with the physical therapist so they can see how I am doing during my hospital stay

Data Protection
I understand that any information I provide is confidential, that any data disclosed will be used solely for the purpose of this evaluation and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party. Only Claudia Citkovitz and the Clinical Research Office will have access to this information.

No identifiable personal data will be published. The identifiable data will not be shared with any other organization.

I understand that the information I provide will be held and processed for the following purpose:

- to help the Lutheran Medical Center determine the benefit of providing acupuncture treatments for patients recovering from stroke
- to be used in educational reports, conference reports and/or publications related to this study

I agree to Lutheran Medical Center and University of Westminster keeping and processing this information about me from the evaluation. I understand that this information will be used only for the purpose set out in the explanatory sheet “Participant Information Sheet” and my consent is conditional on the University complying with its duties and obligations under the Data Protection Act 1998.

Withdrawal From Study
I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without any questions being asked, and without my healthcare at Lutheran Medical Center being affected in any way.

Name: ....

Signature: ………..……

Date: ……………………..…………………….........................…

Appendix J: Outcome Measures Returning Little Usable Data

For each of the four outcome measures below, a brief description includes original rationale for its use and its clinimetric properties. Method of data collection and completeness of data is shown in Table 5.1A. Logistical difficulties associated with usage leading to incompleteness of data are discussed in Section 5.6.7.3.

1. Hamilton Depression Scale (Ham-D)

Depression is prevalent after stroke, with estimates ranging from 5% to 54% of patients during acute care (Kouwenhoven et al., 2011). While mechanisms of association remain unknown and are assumed to be multifactorial, relationships between post-stroke depression and long-term disability and mortality are well established, and appear to be particularly concerning for patients who have not recovered by 3 months post stroke (Ayerbe, Ayis, Rudd, Heuschmann, & Wolfe, 2011). While evidence regarding acupuncture in the treatment of depression has been inconclusive, a 2010 Cochrane review (Smith, Hay, & MacPherson, 2010) identified a subgroup of patients showing improvement in depression as a comorbidity; also a large recent trial (MacPherson, Thorpe, Thomas, & Geddes, 2004) found statistically significant reduction in depression at 3 and 12 months with acupuncture treatment versus usual care alone. No study of acupuncture for post-stroke depression has been identified in the Western acupuncture literature.

The Ham-D was used to screen for depression at discharge and 6-month follow-up, in order to determine whether any association existed between acupuncture treatment during acute rehabilitation and persistence of symptoms after discharge. The Ham-D is commonly used for depression screening, and shows high reliability (Cronbach’s Alpha = 0.81), good discriminant, external and concurrent validity in geriatric stroke populations (Aben, Verhey, Lousberg, Lodder, & Honig, 2002; Agrell & Dehlin, 1989b). Responsiveness of the measure to clinical change has been criticized (Bagby, Ryder, Schuller, & Marshall, 2004; Faries et al., 2000). The test was administered by a licensed Psychologist on a volunteer basis (Deborah Barbiere, PhD).

The Ham-D consists of 17 items, eight scored 0-4 and nine scored 0-2 for a total of 50 points. It is interpreted as: normal (0-6); mild (8-13); moderate (14-18); severe (19-22) or very severe (23 or above) depression.

For this study, use of the Ham-D was to screen for depression at discharge and 6-month follow-up, in order to determine possible association between acupuncture treatment during acute rehabilitation and persistence of symptoms after discharge. The Ham-D is commonly used for depression screening, and shows high reliability (Cronbach's Alpha = 0.81) and good discriminant, external and concurrent validity in geriatric stroke populations (Aben et al., 2002).

2. Fugl-Meyer Upper Extremity Assessment

While the motor domain of the FIM assesses the patient's ability to perform coordinated activities, it is not considered sensitive to the underlying impairment and recovery of motor function. Motor impairment is the most prevalent symptom of acute stroke, and acupuncture has shown promise in addressing motor impairment (Naeser et al., 1994a).

The Fugl-Meyer upper extremity test was selected to assess the degree of upper extremity motor recovery. While study screening criteria included hemiparesis (ie, weakness of both upper and lower extremities), the upper extremity test alone was selected because the upper extremity is more commonly affected in stroke (Lawrence et al., 2001).

Specifically designed to assess post-stroke motor recovery, the Fugl-Meyer Upper Extremity assessment (FM-UE) assesses motor function, sensory function, and joint range of motion and pain. 45 items are scored on a 3-point ordinal scale based on the patient's ability to perform a motor or sensory task. 0 indicates no ability to perform and 2 indicates full performance, for a total score from 0 to 90. The assessment is based in generally agreed-upon, observable stages of motor recovery and has been used as the gold standard in validation studies of other measures. Reliability and validity in an acute stroke rehabilitation population are well documented generally (Teasell & Kalra, 2004); see table 5.1B. Recent papers have suggested modification to the number and order of items to increase construct validity and hierarchical properties (Velozo & Woodbury, 2011b; Woodbury et al., 2007). The test was administered by a physical therapist employed by Lutheran Medical Center (Christopher Chan, D.P.T.). For the purposes of this non-funded study, the main disadvantage of the FM-UE is that it is not routinely administered at LMC, nor is it validated for administration by anyone other than a trained Physical or Occupational therapist. For future studies, it may be possible to train acupuncturists or research assistants in the abbreviated form of the assessment proposed by Velozo et al (Velozo & Woodbury, 2011a).

3. Montreal Cognitive Assessment (MoCA)

Cognitive impairment is a common symptom of stroke, presenting in some 44% of patients during acute rehabilitation (Lawrence et al., 2001). It is associated with poor functional recovery (Hinkle, 2002). While contemporary Chinese approaches to acupuncture during stroke rehabilitation emphasize cognitive recovery as a treatment goal, the question of whether acupuncture reduces cognitive impairment in stroke remains unexplored in the Western clinical literature.

The Monteal Cognitive Assessment is a screening tool designed to identify mild cognitive impairment not captured by other instruments used for cognitive screening. It consists of six unequally weighted domains with several tasks each (memory, visuospatial ability, executive functioning, attention and concentration, language, and orientation), yielding a total score of 30. While the original validation study (Nasreddine et al., 2005) placed the cut-off point for impairment at 26 or below, subsequent authors have suggested a cut-off point of 24 (Godefroy et al., 2011) or even 21 (Dong et al., 2012).

Because of its ability to distinguish even mild degrees of impairment, the MoCA was initially selected to assess improvement in cognitive function (from baseline to discharge). The MoCA was administered by LMC's Neuropsychology team of Dr. Ross Gourvitz and Dr. Martha Pham, in place of the hospital's standard cognitive screen, the Cognistat (see below).

4. Neurobehavioral Cognitive Status Examination (Cognistat)

The Cognistat is a clinical instrument designed to assess cognitive impairment in inpatients. It was constructed to fill the gap between global cognitive assessments, which are relatively quick to administer but provide no insight as to the area of impairment, and lengthier neuropsychological batteries. Its 'screen and metric' approach uses a screening question for each of seven cognitive domains; if the screen is failed then additional testing is provided. Rather than a raw score, the instrument returns assessments of function (normal; mild, moderate or severe impairment) in ten domains, based on comparison to age-related norms. Its validity is not well-studied in stroke populations (Nøkleby et al., 2008). However it is the standard for admission and discharge assessment of inpatients in Lutheran Medical Center's Neurology and Rehabilitation departments.

While the clinical strength of the Cognistat is its ability to distinguish types of cognitive impairment, its qualitative, multifactorial approach is problematic for research purposes. A simplified quantitative reporting scheme has been evaluated in an acute post stroke population. This is to calculate the number of unimpaired domains based on recommended age-related norms, yielding a scale of 1-10 with 10 indicating normal function. Relative to standard neuropsychological testing, with 8 versus 9 used as the cutoff point for diagnosis of impairment, sensitivity was 81% (CI 68-93) and specificity was 67% (CI 22-96) (Nøkleby et al., 2008). In this study, the domain score was intended for use in this manner. It was administered by Dr. Martha Pham, a member of the hospital's Neuropsychology team.

Appendix K: Amendments to Study Protocol (LMC Approval)

IRB-15

LUTHERAN MEDICAL CENTER HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD (IRB)
APPROVAL DISPOSITION FORM

Principal Investigator: Claudia Citkovitz, MS, L. Ac
Other Pertinent Investigators: Salman Azhar, MD, Laura Gabbe, MS, L.Ac

The Institutional Review Board (IRB) made a decision on your research protocol entitled:
"Integrating acupuncture into routine post-stroke care: Which patients experience benefit?"

☐ At the IRB meeting on ___________ ☐ Through expedited review
☐ After reviewing subsequent revision ☐ Continuing review

Protocol #: 270 **Time period for continuing review:** 1 year

Next review date:

Disposition: ____ Approved ____ Not Approved ____ Reapproved

____ Request modification / additional information

____ IRB approval not required

____ HIPAA waiver of informed consent was granted or is not needed.

Comments: The PI would like to update the IRB with the following modifications

1. **Diffusion Tensor Imaging (DTI).** LMC's capability to perform DTI has not yet become available as previously envisioned. As an interim surrogate measure to provide Mild, Moderate and Severe groups for analysis, total FIM score at baseline will be divided into top, bottom and the two central quartiles to make 3 unequal groups. Should DTI scores become available, all analyses will be re-run at that time and included in the primary paper or submitted for separate publication as appropriate.
2. **Fugl-Meyer Assessment (FMA).** The Physical Therapist who originally volunteered to perform the FMA has resigned from LMC and no replacement has been found. The Modified Rankin Score will be substituted at discharge (calculated from FIM score) and at 6 months (obtained by telephone interview).
3. **Montreal Cognitive Assessment (MoCA).** The Neuropsychology team had initially agreed to administer the MoCA in place of the Cognistat which is their standard. After two incidents in which confusion over which test to administer led to collection of unusable data, they returned to collecting the Cognistat. Once this amendment is approved, we will retrospectively collect Cognistat data and use it in place of the MoCA for assessment purposes.

IRB requirements for all approved protocols:

In carrying out this study, the investigators agree to the following:

1. To accept responsibility for the scientific and ethical conduct of this research study;
2. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form, except when needed to eliminate hazard to the patient;
3. To use consent forms date-stamped by the IRB only during the period in which it is valid to enroll subjects;
4. To promptly report in writing to the IRB any severe/adverse medical events pertaining to this project, any unanticipated problems regarding risks to subjects or others, and any changes in the protocol or consent form;
5. To keep copies of the informed consent of all LMC patients enrolled in the protocol in the patient's chart and the principal investigator's file.
6. To fully complete the continuing review form sent from the IRB and return it promptly to the IRB.

12/4/13 C. Lyon DO

(Date) Claudia Lyon, DO, Chair, IRB

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IRB-15

LUTHERAN MEDICAL CENTER HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD (IRB)
APPROVAL DISPOSITION FORM

Principal Investigator: Claudia Citkovitz, MS, L. Ac
Other Pertinent Investigators: Salman Azhar, MD, Laura Gabbe, MS, L.Ac

The Institutional Review Board (IRB) made a decision on your research protocol entitled:
"Integrating acupuncture into routine post-stroke care: Which patients experience benefit?"

☐ At the IRB meeting on ___________ ☑ Through expedited review
☐ After reviewing subsequent revision ☐ Continuing review

Protocol #: 270 **Time period for continuing review:** 1 year

Next review date:

Disposition: ✓ Approved ___ Not Approved ___ Reapproved

___ Request modification / additional information

___ IRB approval not required

___ HIPAA waiver of informed consent was granted or is not needed.

Comments: The Principal investigator would like to add an addition aim to her study.
Feasibility Assessment. To the project's four Aims I have added a fifth, exploring feasibility of future study. It is as follows:
Explore feasibility of future trials with respect to primary and secondary outcome measures, with feasibility defined as:

a. Overall, number of withdrawals from acupuncture treatment and
b. Number of adverse events or stakeholder perceptions of harm, discomfort or inconvenience
c. For each outcome measure, completeness of data for each outcome measure and
d. Rate of recruitment in relation to sample size calculation for future study

IRB requirements for all approved protocols:

In carrying out this study, the investigators agree to the following:
1. To accept responsibility for the scientific and ethical conduct of this research study;
2. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form, except when needed to eliminate hazard to the patient;
3. To use consent forms date-stamped by the IRB only during the period in which it is valid to enroll subjects;
4. To promptly report in writing to the IRB any severe/adverse medical events pertaining to this project, any unanticipated problems regarding risks to subjects or others, and any changes in the protocol or consent form;
5. To keep copies of the informed consent of all LMC patients enrolled in the protocol in the patient's chart and the principal investigator's file.
6. To fully complete the continuing review form sent from the IRB and return it promptly to the IRB.

12/16/13
(Date)

C. Lyon
Claudia Lyon, DO, Chair, IRB

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Appendix L: Amendments to Study Protocol

(Westminster Approval)

UNIVERSITY OF WESTMINSTER

APP. NO. 11-12-07_Amend: Claudia Citkovitz
UREC 25 March 2014

PRIVATE AND CONFIDENTIAL
Claudia Citkovitz
c/o Faculty of Science & Technology
115 New Cavendish Street
London

27 March 2014

Dear Claudia

App. No.:	**11-12-07_Amend**
Name:	**Claudia Citkovitz**
Faculty:	**Science and Technology**
Mode:	**MPhil/PhD (ERDS)**
Supervisor:	**Volker Scheid**

Project Title: **Integration of Acupuncture into post-stroke care: which patients experience which benefits? A preliminary, mixed-methods inquiry: Amendment - Confirmation of Institutional Review Board decisions**

I am writing to you following submission of the revised Lutheran Medical Center Health System Institutional Review Board (IRB) approvals dated 4 January 2013 and 16 December 2013 relating to protocol 270. I can confirm these were noted by the University Research Ethics Committee.

If your protocol should change again, please contact me immediately, in case of further ethical review is required.

Yours sincerely

Dr Bob Odle
Acting Secretary, University Research Ethics Committee

cc. Chair, University Research Ethics Committee
Chair, Faculty Research Ethics Committee (for information)
Supervisor
Graduate School Registry

Academic Registrar's Department
Quality and Standards Office
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I am advised by the Committee to remind you of the following points:

1. Your responsibility to notify the University Research Ethics Committee immediately of any information received by you, or of which you become aware, which would cast doubt upon, or alter, any information contained in the original application, or a later amendment, submitted to the University Research Ethics Committee and/or which would raise questions about the safety and/or continued conduct of the research.
2. The need to comply with the Data Protection Act 1998
3. The need to comply, throughout the conduct of the study, with good research practice standards
4. The need to refer proposed amendments to the protocol to the University Research Ethics Committee for further review and to obtain University Research Ethics Committee approval thereto prior to implementation (except only in cases of emergency when the welfare of the subject is paramount).
5. You are authorised to present this University of Westminster Ethics Committee letter of approval to outside bodies, e.g. National Research Ethics Committees, in support of any application for further research clearance.
6. The requirement to furnish the University Research Ethics Committee with details of the conclusion and outcome of the project, and to inform the University Research Ethics Committee should the research be discontinued. The Committee would prefer a concise summary of the conclusion and outcome of the project, which would fit no more than one side of A4 paper, please.
7. The desirability of including full details of the consent form in an appendix to your research, and of addressing specifically ethical issues in your methodological discussion.

Appendix M: Staff Participant Information Sheet

Participant Information sheet, July 2012

Acupuncture during Acute Stroke Rehabilitation: which patients experience which benefits?
You are being invited to participate in a research project regarding acupuncture during stroke rehabilitation. The goal of this project is to look at the relationship between degree of damage to descending corticospinal tracts and recovery with acupuncture added to regular rehabilitation therapy. It is an observational study, meaning that we are collecting additional data from patients who have chosen to be treated with acupuncture, rather than studying the acupuncture treatment itself.

If you choose to participate in the study, we will ask you to fill out a brief survey (6 questions) for each patient you work with who is also being treated with acupuncture. We plan to look at 24 patient and 24 controls over a period of 6-10 months.

What are the aims of the study?
We aim to determine whether patients with moderate to severe stroke (NIHSS 13-22) do better on standard outcome measures when they've had acupuncture, and also whether the severity of a patient's stroke affects how they respond to acupuncture treatment.

Why have I been chosen?
Our plan is to collect data from the primary physical, occupational and speech therapist for each study patient, as well as the primary day and night nurse and the admitting neurologist.

Do I have to be in the study?
No. It is up to you to decide whether or not you want to be in the study. If you decide to be in the study, you will be asked to sign a consent form. *If you decide to take part, you are still free to stop at any time without giving a reason*. No questions will be asked if you stop.

Who benefits from this study?
Future patients may benefit, because it is hoped that this study will improve our understanding of which patients are more likely to benefit from acupuncture and should be referred.

What will I have to do if I decide to be in the study?
Around the time of the patient's discharge, you will receive an anonymous survey to fill out and return to Claudia Citkovitz in the envelope provided, asking your opinion about the patient's progress. You don't need to keep track of anything else.

How long will it take to answer the questions?
We estimate less than 7 minutes per survey.

Do I have to answer all the questions?

Participant Information Sheet, Page 1 of 2

We would prefer that all questions were answered but if you feel unhappy about answering any of the questions then you can leave them out.

Will the acupuncturists see the forms that I have filled in?
No. All of your answers are private and confidential. They will only be read by the researcher entering and analysing the data, and they will not contain your name.

How will we use the study data?
We will mainly use your observations of patient responses in the part of the study where we look at whether the severity of the stroke determines response to acupuncture. It may be that there are benefits of acupuncture that are not being captured by the standard outcome measures we have chosen. We feel that truly the most sensitive measure of improvement in a patient's condition may be the expert opinion of the rehabilitation unit staff who treat them day in day out, and we would like to make use of that expertise in determining which patients have benefited from acupuncture therapy.

Contact for further information & complaints

We hope that this information sheet about the study has told you what you need to know before deciding whether or not to take part. If you have any questions at all about the project or wish to make a complaint please call Claudia Citkovitz at 718-630-7056 or email me at ccitkovitz@lmcmc.com.

Notes:
- This study has been approved by the University of Westminster Ethics Committee and the Lutheran Medical Center Institutional Review Board.
- If I cannot answer your queries or complaints, please contact the head of the Institutional Review Board, Ms. Claudia Lyon, at 718-630-6332, or email her at CLyon@lmcmc.com

Appendix N: Staff Participant Informed Consent Form

Informed Consent Form for Participants

Project: *Acupuncture during Acute Stroke Rehabilitation: which patients experience which benefits?*

I agree to take part in the above evaluation. I have had the project explained to me, and I have read the explanatory "Participant Information Sheet", which I may keep for my records. I understand that agreeing to take part means that I am willing to:

1. Answer one 6-question survey for each patient treated with acupuncture for whom I am the primary Physical, Occupational or Speech Therapist, Day/Night Nurse, or Neurologist.

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without any questions being asked.

Name: ....

Signature: ………..……

Date: ……………………..…………………….........................….

Appendix O: Staff Survey Form

Stroke Study: Acupuncture during Stroke Recovery **Study ID #: ___________**
RDCF 26: Staff Perception Survey (PS) **Data Collector Initial:_________**

Rehab Staff Role: PT OT SPEECH MD NURSE ACUPUNCTURIST

1. Relative to my experience and expectations, this patient's progress has been:

   a. Much faster or more complete than expected
   b. Somewhat faster or more complete than expected
   c. As expected
   d. Slower or less complete than expected
   e. Much slower or less complete than expected
   f. Not sure or can't answer

2. If faster or slower than expected, how so, or in what way(s)?

3. "Acupuncture has been helpful to this patient."
   a. Strongly agree
   b. Agree
   c. Neutral or don't know
   d. Disagree
   e. Strongly disagree
   f. Not sure or can't answer

4. If you feel acupuncture has been helpful, how so, in what way(s)?

5. "Acupuncture has been counterproductive for this patient."
   a. Strongly agree
   b. Agree
   c. Neutral or don't know
   d. Disagree
   e. Strongly disagree
   f. Not sure or can't answer

6. If you feel acupuncture has been counterproductive, in what way(s)?

7. Additional Comments (use other side if you would like):

Instructions: Please enter patient's study number and circle your answer.
To be completed by: PT, OT, Speech Therapist, Neurologist, Day Nurse, and Treating Acupuncturist.

Appendix P: Family Survey

Acupuncture in Stroke Rehabilitation | **Study ID #: ____________**
RDCF 25: Family Perception Survey (PF) | **Data Collector Initials: ______**

1. **Your Relationship to the Patient?**

Husband/Wife   *Sister/Brother*   *Son/Daughter*   *Other* ____________________

2. **Did you see any of the acupuncture treatments your family member received?**

   YES   *NO*   *NOT SURE*

3. **Did you feel the acupuncture treatment was helpful to your family member in any way?**

   YES   *NO*   *NOT SURE*

4. **If so, how was it helpful, in what ways?**

5. **Did you feel the acupuncture treatment caused any problems?**

   YES   *NO*   *NOT SURE*

6. **If yes, how so, what problems?**

7. **Is there anything else you'd like to tell us about the acupuncture?**
   Use the other side if you would like.

Instructions: Please circle or write in your answers.

Appendix Q: Patient Interview Script

Stroke Study: Acupuncture during Stroke Recovery **Study ID #: ___________________**
Script for Patient Perception Interview

"I understand you've been having acupuncture treatments, is that correct? I'm going to ask a few questions about those treatments, if you don't mind."

1. "How was your acupuncture treatment?"
    a. (If little response, re-prompt with, "do you remember the acupuncture?" or "how did it feel?" as appropriate).

2. "Did the acupuncture hurt?"
    a. If yes, "a lot, a little, or medium?"
    b. If not, "how did it feel?"

3. "Do you think it helped you?"
    a. If yes, "what did it help with, how was it helpful to you?"
    b. If no, "do you think it had any effect at all?"

4. "Do you think it caused any problems?"
    a. If yes, "what problems?

5. "Is there anything else you want to say about the acupuncture?" (Is there anything else you thing I might want to know?)

Instructions: Please enter patient's study number and write in answer

Appendix R: Coding Scheme for Stakeholder Surveys

PERCEIVED BENEFITS

1. Localizable physical changes
    a. Improvements
        i. Movement
        ii. Pain
        iii. Strength
        iv. Other: sensation, urination, dizziness
    b. Locations
        i. Upper extremity
            1. Shoulder pain
            2. Wrist extension
            3. Hand movement
        ii. Lower (including Dorsiflextion)
        iii. Head & neck
2. Functional independence
    a. Balance
    b. Mobility
    c. Ambulation
3. Cognitive and Emotional Shifts
    a. Alertness
    b. Aphasia
    c. Positivity and motivation
    d. Relaxation

NEGATIVES

1. None
2. Some but worth it
3. Little or No effect

OTHER THEMES

1. About my Subjectivity
    a. I'm a believer
    b. Active Bracketing
        i. Clear benefit in this case
        ii. Scientific neutrality
        iii. Prior ignorance
    c. If you can't say something nice…
2. Helped Rehabilitation Process
    a. Participation in therapy
    b. Good recovery
        i. Speed
        ii. Started flaccid
        iii. Went home
    c. Less assistance required
3. Availability of Acupuncture

Appendix S: Dissemination of Findings

Podium Presentations

“Acupuncture during Acute Stroke Rehabilitation: Development and Pilot-Testing of a Manual for Researching a Complex Intervention”. Podium presentation, University of Westminster Postgraduate Research Fair. April, 2013.

Poster Presentations

“Acupuncture during Acute Stroke Rehabilitation: Development and Pilot-Testing of a Manual for Researching a Complex Intervention”. Poster presentation, Lutheran Medical Center Research Fair. April, 2014

“Mind the Gap: Developing clinically valid treatment manuals for acupuncture trials”. Poster presentation, Conference of the Society for Acupuncture Research, Ann Arbor, Michegan. April, 2013.

“Development of an Instrument for Tongue Diagnosis in Chinese Medicine”. Poster presentation, University of Westminster Postgraduate Research Fair, April 2012.

Seminars

“Is 'Evidence-Based Acupuncture' an Oxymoron? Constructing clinical knowledge across a cultural divide”. Seminar presentation at EastMedicine summer conference, July 2014

“Promoting Cerebral Wellness”. Presentation at Westminster Summer School, July 2014.

“Researching Acupuncture during Acute Stroke Rehabilitation: Balancing clinical complexity and theoretical clarity”. Seminar at University of Westminster, London. February, 2014

Acupuncture during Acute Stroke Rehabilitation. NCCAOM-approved didactic program, Level I, New York, NY (Pacific College of Oriental Medicine). March, 2014.

Acupuncture during stroke rehabilitation: focus on shoulder subluxation. In-service presentation to Physical and Occupational Therapy Department, Lutheran Medical Center. June, 2014.

Acupuncture during Acute Stroke Rehabilitation: NCCAOM-approved didactic program, Level I, New York, NY (LMC). March, 2014.

On the Front Lines of Biomedicine: Development of a Manual for Individualized, Acupuncture Treatment during Acute Stroke Rehabilitation. Seminar presentation at EastMedicine summer conference, July 2014

Appendix T: FIM Sphincter Control Item

Below are the 7-point scoring categories for the FIM sphincter control item as summarized in the LMC nursing guidelines.

1. Total Assistance: Patient performs less than 25% of bowel management tasks in past 3 days. Helper provides all the effort, sets up, cleans after accidents, changes an absorbent pad or performs digital stimulation, or administers an enema.
2. Maximal Assistance: Patient performs 25-49% of bowel management tasks in the past 3 days.
3. Moderate Assistance: The patient performs 50-74% of bowel management tasks in the past 3 days. The patient requires moderate assistance to maintain a satisfactory excretory pattern by using suppositories, enemas, or an external device.
4. Minimal Contact Assistance: Patient performs 75% or more of bowel management tasks in last 3 days. The patient requires moderate assistance to maintain a satisfactory excretory pattern by using suppositories, enemas, or an external device. If needed, a helper inserts a suppository but does NOT provide any digital stimulation.
5. Supervision or Setup: The patient has required supervision (standing by, cueing or coaxing) or setup of equipment necessary for the individual to maintain either a satisfactory excretory pattern or an ostomy device at any time during the past 3 days.
6. Modified Independence: The patient requires a bedpan, bedside commode, digital stimulation or stool softeners, suppositories, laxatives (other than natural laxatives like prunes) on a regular basis; alternately the patient uses other medications for control.
7. Complete Independence: The patient controls bowels completely and intentionally without equipment or devices, and does not have any bowel accidents.

Appendix U: Relationship between mRS and FIM Scoring for mRS Levels 3-5

Appendix U: Relationship of mRS and FIM Scoring for mRS Levels 3-5				
mRS Grade	**mRS Description**	**FIM Items**	**FIM Level and description**	**Notes**
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention	Bed to chair transfer; Sphincter management	1, Total assistance (patient can perform less than 25% of the task or requires more than one person to assist)	If the two do not agree, bed to chair transfer is taken as primary
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance	FIM Motor Domain (all items)	2, Maximal Assistance (patient can perform 25% to 49% of taks) 3, Moderate Assistance (patient can perform 50% to 74% of task)	Selected if patient does meet specific criteria for 5 or 3
3	Moderate disability; requiring some help, but able to walk without assistance	Locomotion (ambulatory only)	4, Minimal Contact Assistance (patient can perform 75% or more of task)	

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Glossary

ADL	Activities of Daily Living
ATP	Adenosine tri-phosphate
BI	Barthel Index
CAM	Complementary and Alternative Medicine
CI	Confidence Interval
Cognistat	Neurobehavioral Cognitive Status Exam
Corticospinal Tract	Originating chiefly from the motor cortex and descending to the to the contralateral spinal cord, it mediates all voluntary movement
CT	Computerized Tomography
de qi	"Causing the acupuncture needle to elicit the sensations associated with the presence of qi at or near the insertion site"[34]
DTI	Diffusion Tensor Imaging. Specialized use of magnetic resonance imaging to map intactness of neuronal tracts by tracking direction of fastest water diffusion (Conturo et al., 1999)
EMR	Electronic Medical Record
FIM™	Originally 'Functional Independence Measure'
Four Examinations	In a Chinese medical assessment, Inspection, Listening and Smelling, Inquiry and Palpation[30]
FM-UE	Fugl-Meyer Upper Extremity Assessment
HamD	Hamilton Depression Scale
Hemiparesis	Impaired motor function or weakness on the right or left side of the body
Hemiplegia	Paralysis of the right or left side of the body
ICF	International Classification of Functioning and Health (Cieza et al., 2004)

[34] (Wiseman & Ye, 1998, p. 419)

ISO	International Organization for Standardization, Switzerland (http://www.iso.org/iso/home.html)
LMC	Lutheran Medical Center (http://www.lutheranhealthcare.org/Main/Home.aspx)
mBI	Modified Barthel Index
MoCA	Montreal Cognitive Assessment
MRI	Magnetic Resonance Imaging
MRC	Medical Research Council
mRS	Modified Rankin Scale
NIHSS	National Institutes of Health Stroke Severity Scale
NOR	Neurological and Orthopedic Rehabilitation Unit
NPO	nil per os, i.e. no oral intake
OT	Occupational Therapy, Occupational Therapist
PEG	Percutaneous Endoscopic Gastroscopy
Prosody	Perceptually classified qualities of rate, phrase length, and appropriateness of pacing and stress (Cherney & Small, 2008),
PT	Physical Therapy, Physical Therapist
Pyrimidal tracts	See Corticospinal Tracts
qi	"Air, gas, vapor, flatus….any of various dynamic phenomena of the body that are described in terms of: activity…warming, defense…transformation…containment…strength…anger"[30]
RCT	Randomized Controlled Trial
ROM	Range of Motion
SIGN	Scottish Intercollegiate Guidelines Network
SPSS™	Originally 'Statistical Package for the Social Sciences'
SST	Speech and Swallowing Therapy, Speech and Swallowing Therapist
tPA	Tissue Plasminogen Activator
UDS™	Unified Data System
WHO	World Health Organization

wind	"The nature of wind as an evil and its clinical manifestations are similar to those of the meteorological phenomenon from which it derives its name….its clinical manifestations as an evil have the following characteristics: Rapid onset and swift changes….Convulsions, tremor, shaking of the head, dizziness, and wandering pain and itching….Facial paralysis and hemiplegia."[30]
yin	"The dark, female, receptive principle that stands in complementary opposition to yang"[30]
yang	"The bright, male, active principle that stands in complementary opposition to yin" [30]