Acupuncture for the management of low back pain

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A thesis submitted for the degree of

Doctor of Philosophy

At the University of Otago, Dunedin,

New Zealand

20 September, 2016

Abstract

Background: Low back pain is an extremely common health problem, and is associated with significant economic and social impact. Acupuncture is one of the most frequently sought complementary and alternative medicine modalities for treating low back pain. This thesis investigated the effectiveness of acupuncture in the management of low back pain, with a focus on one aspect of dosage, i.e. number of treatment sessions.

Methods: This thesis took a systematic, step-wise, pragmatic approach to address the research question. The United Kingdom Medical Research Council guidelines for developing and evaluating complex interventions provided the framework for the thesis development. Emphasis was placed on the development and feasibility phases of the research process. In the development phase, an overview of systematic reviews was conducted to evaluate evidence for the effectiveness of acupuncture for low back pain; and a review of the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines was performed to explore strategies to improve on the reporting quality of acupuncture research. In the feasibility phase, a randomized controlled feasibility trial was conducted to test the feasibility for conducting a fully powered randomized controlled trial investigating the optimal number of sessions of acupuncture (4, 7 or 10 sessions) used as an adjunct to usual care, for the management of chronic low back pain in adults.

Results: Evidence from the overview of systematic reviews suggested that acupuncture is an effective treatment option for patients with chronic low back pain. When compared with no treatment, or used as an adjunct to conventional care, acupuncture provided significant clinical

benefits including pain relief and functional improvement at short-term follow-up. In order to improve clinical effectiveness of acupuncture, future research may evaluate the dose response of acupuncture (e.g. number of treatment sessions) in this area. It was demonstrated that STRICTA is a valid reporting guideline based on robust methodology and scientific content. However specific implementation strategies are needed for improvement in the efficacy of the STRICTA, which may serve to promote the reporting quality and reliability of acupuncture research including: updating the STRICTA checklist; improving the STRICTA reporting efficiency; implementing the 'Instructions to authors' for journals consistently; establishing STRICTA research centres globally; and expanding the STRICTA website. Results from the feasibility study supported the feasibility of carrying out a definitive randomized controlled trial comparing outcomes from different session numbers of acupuncture for the management of chronic low back pain. 45 participants were recruited within 10 weeks (recruitment rate of 43.7%), and agreed to be randomized. Acupuncture was demonstrated to be acceptable among participants, and high retention rates (86.7%, 86.7%, 100% for the 4, 7, 10 sessions groups, respectively) were recorded. Over 80% of participants indicated that they were 'very satisfied' and/or 'extremely satisfied' with acupuncture. Participant follow-up rates were 88.9% at discharge (Q1) and at six weeks post randomization (Q2), and 84.4% at 12 weeks post randomization (Q3).

Conclusions: The current thesis has provided evidence to add to the scientific basis underpinning the therapeutic value of acupuncture for LBP. From the overview of systematic reviews, acupuncture, either used in isolation or as an adjunct to conventional therapy, has been demonstrated as an effective clinical option for patients with chronic LBP. The need for improvements in the external validity of acupuncture research has been highlighted by the findings of the overview; potential options to improve on such reporting have been discussed

surrounding the specific strategies for improving the efficacy of the STRICTA guidelines. There is currently limited evidence available regarding the dose dependence of acupuncture for chronic LBP based on the number of sessions. Collectively, results from the feasibility study supported the decision to proceed to a full-scale randomized controlled trial to definitively test the dose response effects of acupuncture, and investigate the optimal number of sessions of acupuncture for the management of chronic low back pain. Findings may assist with the development of future clinical guidelines regarding the dosage of acupuncture treatment in routine practice, a point of clinical relevance to clinicians, researchers, and policy makers.

Acknowledgements

I would like to express my sincerest gratitude to my supervisors Professor David Baxter, Dr Margot Skinner, and Professor Suzanne McDonough for the extensive knowledge, insightful ideas, patient guidance, and great support that they have provided me during my PhD study process. I feel very honored to be their student, and I would like to follow their footsteps as they have demonstrated highly impressive professionalism and scientific rigor.

Thank you to the administration and technical staff (Dr Marina Moss, Ms Donna Keen, Ms Jennifer Ramsay, and Mr Chris Hay) in the School of Physiotherapy for their kind help and support when I conducted my clinical trial. Thank you to Dr Andrew Gray for his suggestions and assistance with statistical analysis of the trial.

I am grateful to Mr David Jackson for his assistance with my conference poster design and output, in addition to generous encouragement in my daily life.

I thank Ms Karen Taylor for her huge support with my clinical acupuncture work as well as supervision for my PhD clinical trial.

Thank you to the staff at the School of Physiotherapy Clinic (including Mr Stuart Horton, Ms Lesley Inglis, Mr Greg Usherwood, Ms Evelyn Tulloch, and Ms Zoe Cook) for the positive support on clinic orientation, acupuncture registration and daily clinical work.

I thank Ms Trish Leishman, Mr Jundong Wang, Dr Ines Becker, and Mr Masashi Aoyagi for their kind help with the reviews.

I am extremely grateful to Ms Angela Gisselman, Ms Priya Kannan, and Mr Leon Mabire for their intellectual advice, powerful support, numerous encouragement, and a priceless international friendship.

Thank you to all the study participants in my clinical trial for the time and valuable suggestions.

Finally, I would like to give a special thanks to my husband Mr Haoyu Xiong who is my constant companion in New Zealand, and my family members based in China. You are my power sources, and your great support and care have helped me succeed to completion of my PhD.

Outputs of work conducted during the thesis

Full-text publications:

Liu, L., Skinner, M. A., McDonough, S. M., & Baxter, G. D. (2016). Traditional Chinese Medicine acupuncture and myofascial trigger needling: The same stimulation points? *Complementary Therapies in Medicine, 26*, 28-32.

Liu, L., Skinner, M. A., McDonough, S. M., Taylor, K. G. M., & Baxter, G. D. (2016). Does the dose of Traditional Chinese Medicine acupuncture in addition to usual care affect outcomes for adults with chronic low back pain? Protocol for a randomized controlled feasibility study. *Physical Therapy Reviews*, 1-8.

Liu, L., Skinner, M., McDonough, S. M., Kannan, P., & Baxter, G. D. (2015). STRICTA: Is it time to do more? *BMC Complementary and Alternative Medicine, 15*, 190.

Liu, L., Skinner, M., McDonough, S., Mabire, L., & Baxter, G. D. (2015). Acupuncture for low back pain: An overview of systematic reviews. *Evidence-Based Complementary and Alternative Medicine, 2015*, 18.

Conference presentations:

Liu, L., Skinner, M., McDonough, S. M., Kannan, P., & Baxter, G. D. (2015). Developing STRICTA to improve the quality of reporting on acupuncture. *International Scientific Acupuncture and Meridian Symposium (iSAMS): Integrated Medicine: Integrating Science, Practice, and Research, Dunedin, New Zealand.*

- Oral presentation

Liu, L., Skinner, M. A., McDonough, S. M., Taylor, K. G. M., & Baxter, G. D. (2015). Dose of Traditional Chinese Medicine acupuncture for chronic low back pain: A randomized controlled feasibility study. *International Scientific Acupuncture and Meridian Symposium (iSAMS): Integrated Medicine: Integrating Science, Practice, and Research, Dunedin, New Zealand.*

- Poster presentation/AMS Poster Award

Liu, L., Skinner, M., McDonough, S. M., Kannan, P., & Baxter, G. D. (2014). Concerns about STRICTA guidelines. *Centre for Health, Activity and, Rehabilitation Research (CHARR) Graduate Research Student Conference, Dunedin, New Zealand.*

- Oral presentation

Liu, L., Skinner, M., McDonough, S., Mabire, L., & Baxter, G. D. (2014). Acupuncture for low back pain: What do systematic reviews say?. *Health Sciences Research Forum - Learning Different Research Languages, Dunedin, New Zealand.*

- Poster presentation

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List of abbreviations

AG	Andrew Gray
AMSTAR	Assessment of Multiple Systematic Reviews
BMI	body mass index
CAM	complementary and alternative medicine
CI	confidence interval
CONSORT	Consolidated Standards for Reporting Trials
DALYs	disability-adjusted life year
EQUATOR	Enhancing the Quality and Transparency of Health Research
GDB	George David Baxter
JW	Jundong Wang
LBP	low back pain
LL	Lizhou Liu
LM	Leon Mabire
M	million
MCID	minimal clinically important difference
MCS	mental component summary
MD	mean difference
MM	Marina Moss
MRC	Medical Research Council
MTrP	myofascial trigger point
NETSCC	National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NSAIDs	non-steroidal anti-inflammatory drugs
PCS	physical component summary
PK	Priya Kannan
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomized controlled trial
RDQ	Roland-Morris Disability Questionnaire
RR	relative ratio
SD	standard deviation
SF-12	Short-Form 12
SMD	standardized mean difference
STARD	Standards for Reporting of Diagnostic Accuracy
STRICTA	Standards for Reporting Interventions in Clinical Trials of Acupuncture
STRICTA	Standards for Reporting Interventions in Controlled Trials of Acupuncture
TCM	Traditional Chinese Medicine

TENS	transcutaneous electrical nerve stimulation
TIDieR	Template for Intervention Description and Replication
UK	United Kingdom
US	United States
VAS	Visual Analogue Scale
WHO	World Health Organization
WMD	weighted mean difference
5-HT	5-hydroxytryptamine

1 Introduction

The main focus of this thesis was to investigate the effectiveness of acupuncture for the treatment of low back pain (LBP), particularly in terms of dosage dependence – number of treatment sessions. This introduction chapter provides the background and context for the role of acupuncture in the management of LBP. It begins with a brief discussion of LBP classification, followed by an overview of LBP epidemiology, its economic impact and current treatment options for nonspecific LBP in clinical practice. Next, acupuncture for LBP is introduced with a description of acupuncture classification, an overview of the mechanisms of action, and clinical use worldwide. The current scientific research environment of acupuncture is presented, along with an outline of the research plan for this thesis. Finally, a research framework for developing the thesis is introduced, and an overview of the structure of the thesis described.

1.1 Low back pain

1.1.1 Background

LBP is defined as 'pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without leg pain' (quoted from p. S171) (van Tulder *et al*., 2006). LBP is an extremely common health problem, and is associated with significant economic and social impacts (Hoy *et al*., 2014; Hoy *et al*., 2010).

A large number of environmental and personal factors influence the onset and duration of LBP (Hoy, Brooks, Blyth, & Buchbinder, 2010). Evidence from cohort studies has indicated that the peak incidence of LBP occurs in the third decade of life (Kopec, Sayre, & Esdaile, 2004; Waxman, Tennant, & Helliwell, 2000); the overall prevalence of LBP increases with age

until 60 to 65 years, after which there is a gradual decline in prevalence (Hoy *et al*., 2010). Epidemiology studies have found that the risk of developing LBP is higher amongst women, those who are obese and physically inactive, and individuals with low education level (Dionne *et al*., 2001; Holth, Werpen, Zwart, & Hagen, 2008; Hoy *et al*., 2010; Shiri *et al*., 2013; Vogt, Lauerman, Chirumbole, & Kuller, 2002; Webb *et al*., 2003). Other commonly reported risk factors include psychosocial personal factors (e.g. stress, distress, anxiety, depression, and cognitive dysfunction), psychosocial workplace factors (e.g. job dissatisfaction, poor work relations, and low level of social support at workplace), and occupational factors such as heavy physical work, frequent bending, twisting, lifting, repetitive work, static postures, and whole-body vibration (Carroll, Cassidy, & Cote, 2004; Currie & Wang, 2005; Hoogendoorn, van Poppel, Bongers, Koes, & Bouter, 2000; Hoy *et al*., 2010; Linton, 2001; Rubin, 2007).

LBP has a substantial impact on individuals and societies. Physical consequences of LBP include pain, functional limitations, and participation restrictions (Hoy *et al*., 2010). Apart from these, people with LBP suffer from a series of psychosocial co-morbidities, with depression and anxiety most commonly reported (Kayhan, Albayrak Gezer, Kayhan, Kitis, & Golen, 2016). There is no consistent and conclusive evidence regarding the association between LBP and mortality (Delitto *et al*., 2012).

1.1.2 Categorization

According to clinical course, LBP is categorized into four subgroups: acute LBP refers to an episode of LBP persisting for less than 6 weeks; sub-acute LBP as an episode persisting between 6 and 12 weeks; chronic LBP as an episode persisting over 12 weeks (Savigny *et al*., 2009; van Tulder *et al*., 2006); and recurrent LBP as a new episode after a 30-day remission period, which persists over 24 hours with a minimum pain intensity at 2/10 units on the

numerical rating scale or a disability level at 5/24 units on the Roland-Morris Disability Questionnaire (RDQ) (Stanton, Latimer, Maher, & Hancock, 2009). While acute LBP is usually regarded as self-limited and generally resolves within six weeks (a recovery rate at 90%), in a minority of instances, approximately 2% - 7% of patients develop chronic pain, which imposes a heavy burden to healthcare systems and business (Koes, van Tulder, Ostelo, Kim Burton, & Waddell, 2001; van Tulder *et al*., 2006; Waddell & Burton, 2001).

Current literature does not support a definitive cause for triggering an episode of LBP (Delitto *et al*., 2012). LBP may arise from numerous anatomical structures, including muscles, bones, ligaments, fascia, joints, intervertebral discs, nerves, and blood vessels (Delitto *et al*., 2012; Deyo & Weinstein, 2001; Savigny *et al*., 2009). According to etiology, LBP is classified as specific LBP and nonspecific LBP (Violante, Mattioli, & Bonfiglioli, 2015). Nonspecific LBP is described as LBP not attributed to any recognizable, pathoanatomic causes (e.g. fracture, infection, tumor, neoplasm, osteoporosis, ankylosing spondylitis, inflammatory process, radicular syndrome or cauda equina syndrome) (Savigny *et al*., 2009; van Tulder *et al*., 2006). In over 85% of LBP, the causes are unclear, resulting in nonspecific LBP being a common primary complaint in clinical practice (Deyo & Weinstein, 2001; Kent & Keating, 2005; van Tulder *et al*., 2006).

1.1.3 Global incidence, prevalence and recurrence

Estimates of the one-year incidence of LBP (first-ever episode) range from 6.3% to 15.4% of population globally, and the annual incidence of any episode LBP (i.e. first-ever and/or recurrent) ranges from 1.5% to 36% (Hoy *et al*., 2010). However, since the epidemiological studies did not include recurrent episodes of LBP within a given period, the incidence rate may be underestimated (Hoy *et al*., 2010).

The point prevalence of LBP is estimated at 18.1% (ranging from 1% to 58.1%), with a one-year prevalence estimated at up to 38.1% (ranging from 0.8% to 82.5%) (Hoy *et al*., 2010). With growing evidence of high prevalence in developing countries (Hoy, Toole, Morgan, & Morgan, 2003; Jin, Sorock, & Courtney, 2004; Louw, Morris, & Grimmer-Somers, 2007), LBP is no longer regarded as a disorder confined to high-income nations but is a major health problem globally (Hoy *et al*., 2010). The prevalence of chronic LBP has increased over the last two decades (Freburger *et al*., 2009): mean prevalence for chronic LBP is estimated at 19.4% globally (Hoy *et al*., 2010).

Studies suggest that LBP is typically recurrent; rates of recurrence range from 24% - 80% within a 12-month period, which disproportionately contribute to the burden of LBP (Hoy *et al*., 2010; Stanton *et al*., 2009). Previous episodes of LBP is a predictive factor for recurrence within the next one year (odds ratio= 1.8 - 2.0) (Stanton *et al*., 2008); people who experience activity disability over one day are more likely to have a recurrent episode of LBP (Elders & Burdorf, 2004; Hestbaek, Leboeuf-Yde, & Manniche, 2003; Pengel, Herbert, Maher, & Refshauge, 2003).

1.1.4 Economic and disease burden

LBP is considered to be one of the most costly clinical musculoskeletal conditions globally. The economic burden of LBP is enormous, which includes direct costs such as healthcare services and medications, and indirect expenditure including lost productivity, lower income, and employee retraining (Hoy *et al*., 2010). In the United States (US), it was estimated that the total costs attributable to LBP range from $84.1 billion to $624.8 billion per year, with work disability or absenteeism responsible for 85.5% of this annual cost (Dagenais, Caro, & Haldeman, 2008). In New Zealand, it was estimated that LBP costs the Accident Compensation Corporation alone over NZ$430 million (M) per annum (June 2016) for the

direct expenditure (compared with NZ$312M/annum in June 2012) ("ACC Statistics,"); total costs are significantly higher given this figure did not include costs to Ministry of Health or private providers, nor wider societal costs.

The latest World Health Organization (WHO) global burden of disease study indicated that out of the 291 conditions studied, LBP ranks the highest in terms of disability (measured in years lived with disability), and the sixth in terms of overall burden (measured in disability-adjusted life years (DALYs)) (Hoy *et al*., 2014). In 2015, LBP makes up a 2.43% of the total DALYs ("Global Health Data Exchange- GBD Results Tool,"). The global burden of LBP in 2010 was estimated to be 83M DALYs (95% confidence interval (CI): 56.6M to 111.9M), which was nearly 1.5 times of that in 1990 (58.2M, 95%CI: 39.9M to 78.1M) (Hoy *et al*., 2014). DALYs were higher in men (44.2M, 95%CI: 30.3M to 60.1M) than women (38.9M, 95%CI: 26.5M to 52.9M), and peaked between 35 and 50 years of age (Hoy *et al*., 2014).

1.1.5 Treatment options for nonspecific LBP

Current consensus for the management of nonspecific LBP is aimed at improving symptoms (e.g. pain, disability and distress), and preventing recurrence and chronicity (Delitto *et al*., 2012; van Tulder *et al*., 2006). While staying physically active is the best treatment option for acute LBP (Savigny *et al*., 2009), a multimodal, combination treatment approach is suggested for patients with chronic LBP (Dale & Stacey, 2016). Recommendations for nonspecific LBP management include a multidisciplinary approach that may consist of nine therapeutic options (Figure 1.1) (Keller, Hayden, Bombardier, & van Tulder, 2007; Savigny *et al*., 2009).

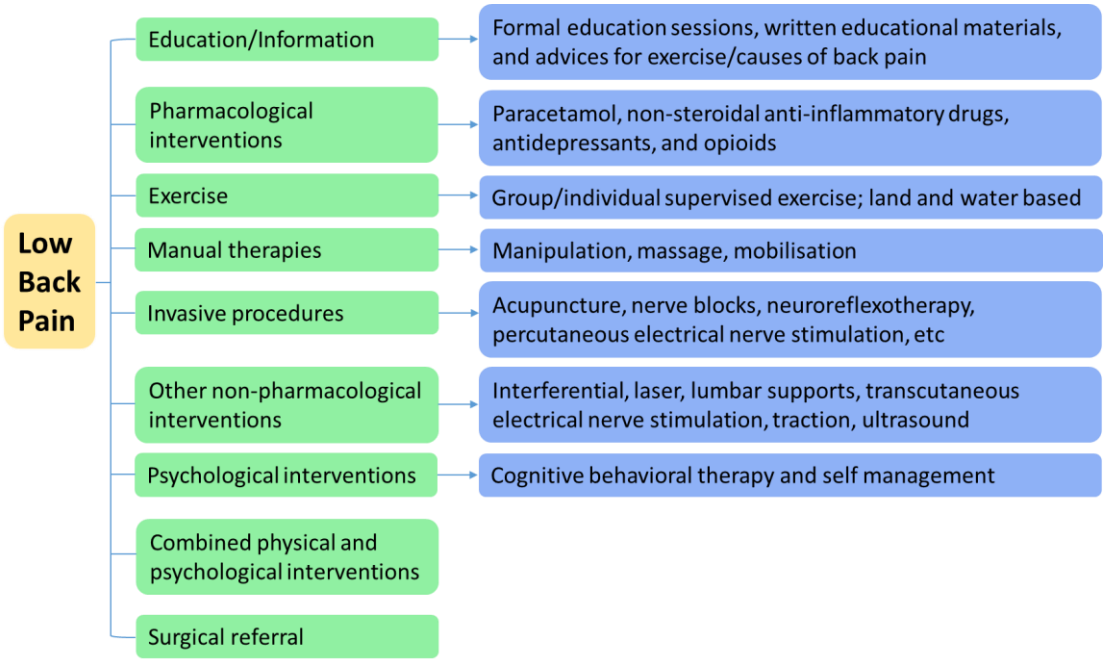

Figure 1.1. Treatment options for nonspecific low back pain in clinical practice (adapted from Keller *et al*, 2007 and Savigny *et al*, 2009)

Although numerous randomized controlled trials (RCTs) have investigated the effectiveness of various interventions for chronic LBP, conflicting findings have been reported, and consequently, no interventions is universally endorsed in clinical practice (Beland, 2016; Chang, Holt, Sklar, & Groessl, 2016; Chou *et al*., 2007; Furlan *et al*., 2005a; Hutchinson, Ball, Andrews, & Jones, 2012; Shen, Samartzis, & Andersson, 2006). The range of cost-effective options for management of chronic LBP, outside the common pharmacological approaches such as non-steroidal anti-inflammatory drugs (NSAIDs), is becoming an important area of interest for researchers. One such option, acupuncture, may represent one component of a multimodal approach to the effective management of chronic LBP.

1.2 Acupuncture in the context of complementary and alternative medicine (CAM)

Acupuncture is defined as 'the insertion of a solid needle into any part of the human body for disease prevention, therapy or maintenance of health' (quoted from p. 28) (Savigny *et*

al., 2009). It was first documented in 100 BCE (White & Ernst, 2004), and is considered a powerful therapeutic modality of CAM. Over the 2500 years of development, a wealth of anecdotal evidence has accumulated about the practice of acupuncture, and demonstrates potential effectiveness in a wide range of diseases. In 2003, the WHO released a report regarding the effectiveness of acupuncture; the therapeutic effects of acupuncture have been well supported by controlled clinical trials for 28 diseases and disorders including LBP (World Health Organization, 2002). During the last two decades, systematic reviews carried out by the Cochrane Collaboration have further highlighted the positive benefits of acupuncture for a variety of conditions, including chronic LBP (Table 1.1).

Table 1.1. Efficacy of acupuncture according to WHO Report (2003) and Cochrane reviews

	Conditions for which efficacy of acupuncture has been demonstrated
WHO report (World Health Organization, 2002)	Adverse reactions to radiotherapy and/or chemotherapy; allergic rhinitis (including hay fever); biliary colic; depression (including depressive neurosis and depression following stroke); dysentery, acute bacillary; dysmenorrhoea, primary; epigastralgia, acute (in peptic ulcer, acute and chronic gastritis, and gastrospasm); facial pain (including craniomandibular disorders); headache; hypertension, essential/primary; induction of labour; knee pain; leukopenia; LBP; malposition of fetus, correction of; morning sickness; nausea and vomiting; neck pain; pain in dentistry (including dental pain and temporomandibular dysfunction); periarthritis of shoulder; postoperative pain; renal colic; rheumatoid arthritis; sciatica; sprain; stroke; tennis elbow
Cochrane reviews	Chronic LBP (Furlan *et al*., 2005b); chemotherapy-induced nausea or vomiting (Ezzo *et al*., 2006); irritable bowel syndrome (Manheimer *et al*., 2012); migraines (Linde *et al*., 2009); neck disorder (Trinh, Graham, Irnich, Cameron, & Forget, 2016); osteoarthritis (Manheimer *et al*., 2010); postoperative nausea and vomiting (Lee, Chan, & Fan, 2015); tension-type headaches (Linde *et al*., 2016)

Nevertheless, over the past quarter of a century, with an increasing number of scientific studies conducted on acupuncture from diverse research bodies, there have been conflicting evidence regarding the effectiveness of acupuncture, for example, in the management of LBP. Given this, thorough investigations, such as overviews of systematic reviews, are required to present a comprehensive evaluation of the therapeutic value of acupuncture.

1.2.1 Classification of acupuncture

With the wide dissemination of traditional acupuncture from China to other Asian countries and the Western world, a variety of styles of acupuncture have been developed over the centuries. However, there is no uniform classification framework for the diverse styles of acupuncture treatment; two commonly used classification criteria are described according to the needling site (i.e. body and micro acupuncture) and/or stimulation techniques (Liang, 2006). Table 1.2 presents the main styles of acupuncture that are currently used in clinical practice worldwide (Furlan *et al*., 2005a; Liang, 2006).

Table 1.2. Main styles of acupuncture applied in clinical practice

Classification criteria	Acupuncture styles	
Needling sites	Body acupuncture	Traditional Chinese Medicine acupuncture; Myofascial trigger point needling; Japanese meridian therapy; Korean constitutional acupuncture; French energetic acupuncture; Lemington 5 element acupuncture
	Micro acupuncture	Scalp acupuncture; auricular acupuncture; hand acupuncture; abdominal acupuncture; foot acupuncture
Stimulation techniques	Manual acupuncture; electro-acupuncture; warm-acupuncture; fire needle acupuncture; laser acupuncture; injection acupuncture	

While these various acupuncture approaches have their roots in Traditional Chinese Medicine (TCM) acupuncture, all involve a certain degree of adaption from classical acupuncture (Filshie, White, & Cummings, 2016; Furlan *et al*., 2005a). Due to limited research which has involved a direct comparison of any two forms of acupuncture (i.e. direct 'head to head comparison'), the evidence for the optimal style of acupuncture treatment is not clear.

In routine practice of LBP, TCM acupuncture and myofascial trigger point (MTrP) needling have been demonstrated to be the most two commonly applied acupuncture styles used by

physician acupuncturists and licensed acupuncturists (i.e. usually nonphysician) (Kalauokalani, Cherkin, & Sherman, 2005). MTrP needling approaches reject the traditional based explanations of meridians and the concepts of acupoints, and provide mechanistic underpinnings from contemporary scientific-based medicine including anatomy, physiology, and pathology. While it seems that MTrP needling has developed medical frameworks (e.g. terminology, theoretical constructs, and philosophies) that are different from TCM acupuncture, further investigation has demonstrated a significant correspondence in the stimulation sites of TCM acupuncture and MTrP needling (see Chapter 6, section 6.4.3). This correspondence enhances contemporary understanding of the mechanism of action of acupuncture, and may serve to facilitate increased integration of acupuncture into clinical management.

1.2.2 Mechanisms of action on acupuncture analgesia

1.2.2.1 Mechanisms based on traditional (TCM) theory

In TCM, pain is usually a sign of a particular disease or physiological malfunction. Mechanistic explanations of acupuncture analgesia based upon traditional (TCM) theory involve a number of philosophic concepts, including Yin and Yang forces, qi, blood, and meridian (Table 1.3) which do not correlate easily with Western medicine. Although a large number of studies have been conducted to explore the correlated anatomical and physiological basis for these oriental philosophy concepts, consensus has not been reached (Ahn *et al*., 2008; Bai *et al*., 2011; Li *et al*., 2008; Lo, 2002; Longhurst, 2010; Ma *et al*., 2003; Zhang, & Louise, 2009). In TCM acupuncture, a disorder arises from stagnation of qi and/or blood along meridians, and an imbalance between Yin and Yang forces within the body (Liang, 2006). An appropriate prescription (needling and stimulation) of acupoints (e.g. primary channel acupoints, extra acupoints, and Ah-shi points) is believed to stimulate

meridians, release stagnation, correct balance in the body, and consequently, restore health (Liang, 2006).

Table 1.3. Definitions of five philosophical concepts in TCM acupuncture theory (World Health Organization, 2007)

Philosophical concepts	Definition
Yin	In Chinese philosophy, the feminine, latent and passive principle (characterized by dark, cold, wetness, passivity, disintegration, etc.) of the two opposing cosmic forces into which creative energy divides and whose fusion in physical matter brings the phenomenal world into being
Yang	In Chinese philosophy, the masculine, active and positive principle (characterized by light, warmth, dryness, activity, etc.) of the two opposing cosmic forces into which creative energy divides and whose fusion in physical matter brings the phenomenal world into being
Qi	The basic element that constitutes the cosmos and, through its movements, changes and transformations, produces everything in the world, including the human body and life activities. In the field of medicine, qi refers both to the refined nutritive substance that flows within the human body as well as to its functional activities
Blood	The red fluid circulating through the blood vessels, and nourishing and moistening the whole body
Meridian	A system of conduits through which qi and blood circulate, connecting the bowels, viscera, extremities, superficial organs and tissues, making the body an organic whole, the same as channels and networks

When needles have been placed successfully, the patient is supposed to experience a sensation known as *De qi*. *De qi* is described as a sensation of soreness, numbness, distention, heaviness, warmth, or electrical tingling at the area of needle insertion that may radiate along the corresponding meridians; simultaneously, the physician also experiences tenseness around the needle (Liang, 2006; World Health Organization, 2007). TCM acupuncturists always emphasize this needling feeling in clinical practice, and extensive research has highlighted the significance of *De qi* for acupuncture analgesia (Haker & Lundeberg, 1990; Hui *et al*., 2005; Tian *et al*., 2014).

1.2.2.2 Mechanisms based on contemporary medicine research

Over the past four decades, investigations on the mechanisms of acupuncture analgesia have been widely carried out to establish physiologically and anatomically based explanations in support of its effectiveness (Chou, Kao, & Lin, 2012; Lin & Chen, 2008; Lin & Chen, 2011). However, results of experiments are controversial; to date, no consensus has been reached regarding the exact mechanisms of pain relief from acupuncture (Chang, 2013; Chou *et al*., 2012; Lin & Chen, 2008; Wang, Kain, & White, 2008).

Evidence on the mechanisms of acupuncture analgesia have been mainly based upon investigations involving electro-acupuncture (Lin & Chen, 2008). Amongst the various theories, the endorphins theory is probably the most commonly accepted (Chang, 2013; Chou *et al*., 2012; Lin & Chen, 2008; Lin & Chen, 2011). A number of reviews have demonstrated the role of endogenous opiates, such as β-endorphin, enkephalin, endomorphin and dynorphin, on central antinociception, in the analgesia effects of acupuncture (Chang, 2013; Chou *et al*., 2012; Lin & Chen, 2008; Rapson & Banner, 2008; Zhao, 2008) (Figure 1.2). The secretion of endogenous opiates by electro-acupuncture is frequency dependent and mediated by different opioid receptor subtypes (Chang, 2013; Lin & Chen, 2008; Zhao, 2008). While low frequency electro-acupuncture (2 Hz) stimulates the production of β-endorphin, enkephalin, and endomorphin through the μ- and δ-opioid receptors, high frequency electro-acupuncture (100 Hz) stimulates the release of dynorphin via the κ-opioid receptor (Han, 2003; Han *et al*., 1999; Huang, Wang, Chang, & Han, 2000).

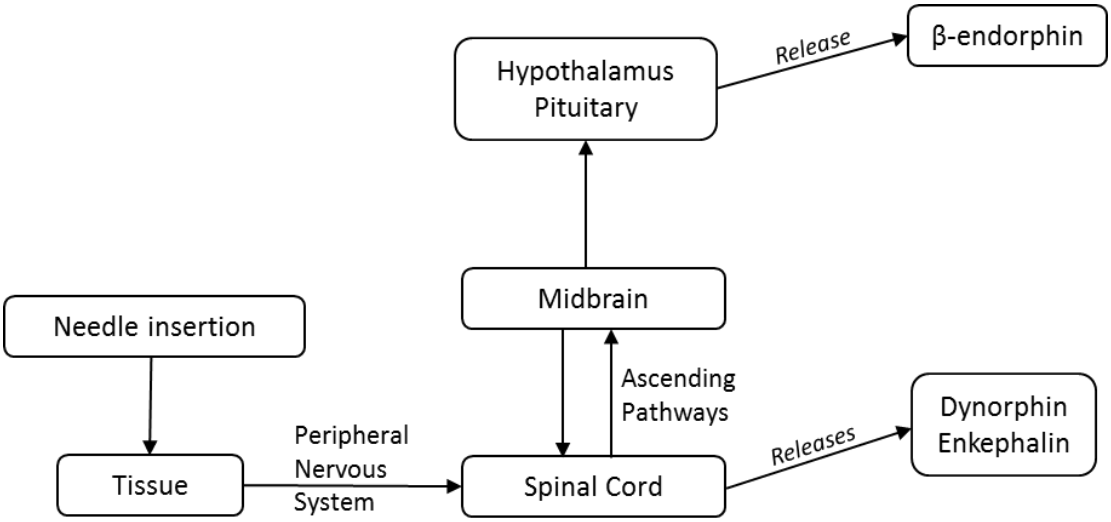

Figure 1.2. Endorphin theory of acupuncture analgesia (adapted from Rapson and Banner, 2008)

In addition to endogenous opioids, other important pain relieving mechanisms include serotonin (5-hydroxytryptamine (5-HT)) release and the related descending pain inhibitory pathway through inhibitory interneurons (enkephalinergic interneurons) in the spinal cord (Cabyoglu, Ergene, & Tan, 2006; Lin & Chen, 2008; Liu, Zhu, & Zhang, 1986; Tang, Qu, & Huo, 2009). It has been found that electro-acupuncture analgesia is enhanced by agonists of 5-HT1a and 5-HT3 receptors at either low or high frequency, and antagonists of 5-HT2 receptors at high frequency level (100 Hz) (Chang, Tsai, Yu, Yi, & Lin, 2004). As the 5-HT2 receptor is also an excitatory receptor in the cortex and hippocampus, both the descending pain inhibitory pathway and the cortex may be involved in the analgesic effects of high frequency electro-acupuncture (Lin & Chen, 2008). In parallel with effects upon serotoninergic systems, inhibitory interneurons at spinal cord level may reduce the expression of receptors to excitatory amino acids which are associated with nociception, thus may result in an anti-hyperalgesic effect (Lin & Chen, 2008; Yan, Wu, Yin, & Ma, 2011).

There is also evidence that acupuncture impacts immune modulation through the hypothalamus-pituitary-adrenal axis (Chiu *et al*., 2003; Lao *et al*., 2004; Lee *et al*., 2004; Son

et al., 2002). Moreover, the anti-inflammatory reflex of acupuncture through the autonomic nervous system is hypothesized to be another potential mechanism of acupuncture analgesia (Lin & Chen, 2008; Lin & Chen, 2011). More research is required to elucidate the definite mechanisms underlying the analgesic action of acupuncture.

1.2.3 Usage and provision of acupuncture

Acupuncture is one of the most frequently sought CAM modalities worldwide. While being heavily practiced in Asia, acupuncture is gaining increasing acceptance and utilization in English-speaking countries for disease treatment and health promotion. In the United Kingdom (UK), it is estimated that a total of 4 million acupuncture treatments were administrated in 2009 (Hopton, Curnoe, Kanaan, & MacPherson, 2012). A national telephone survey in 2005 indicated that Australian adults made 10.2 million visits to acupuncture practitioners over a 12-month period, with back pain being the primary health condition for the use of acupuncture (Xue *et al*., 2008). In the US, approximately 3.1 million (1.6%) adults used acupuncture in a year; further, back pain was reported as the most common complaint for which individuals sought acupuncture (Austin, Ramamonjiarivelo, Qu, & Ellis-Griffith, 2015). Limited data on acupuncture usage in New Zealand are available; the most recent official report from the Ministerial Advisory Committee on Complementary and Alternative Health estimated that approximately 2.6% of New Zealand adult population used acupuncture during a 12-month period in year 2002/03 (Ministerial Advisory Committee on Complementary and Alternative Health, 2004).

The worldwide usage of acupuncture has been challenged by some contemporary physicians based upon mechanisms of action derived from traditional theory, and the lack of evidence of effectiveness beyond non-specific or placebo effects (Ahn *et al*., 2008; Colquhoun & Novella, 2013; Mann, 2000; McGeeney, 2015). Nevertheless, with an increasing body of

evidence from systematic reviews and RCTs, acupuncture has been integrated into several best practice recommendations for LBP. Since April 2006, the *German Federal Committee of Physicians and Health Insurers* has decided to include acupuncture treatment in routine reimbursement within the German healthcare system for patients with chronic LBP (Brinkhaus & Streng, 2006). One year later, the joint clinical practice guidelines from the *American College of Physicians and the American Pain Society* has recommended acupuncture as a non-pharmacologic treatment option for chronic LBP (Chou *et al*., 2007). Additionally, in May 2009, the *National Institute for Health and Clinical Excellence (NICE)* in the UK has recommended the use of acupuncture (up to 10 sessions over a period up to 12 weeks) in the early management of LBP (Savigny *et al*., 2009). In the updated NICE guidelines (published in November 2016), acupuncture is no longer recommended because evidence shows that it is no better than sham treatment (National Guideline Centre, 2016). However, it is argued by researchers that these recommendations were not robust (Cummings, 2016a, 2016b; Lai, 2016). Dr Cumming reviewed the meta-analysis that compared acupuncture with sham acupuncture for pain severity within 4 months, and found that there were analytical errors in the key meta-analysis as incorrect data were entered (Cummings, 2016a, 2016b). In addition, Dr Lai indicated that the updated NICE recommendations were based upon post hoc analysis (undue emphasis on the efficacy of acupuncture over clinical effectiveness and cost-effectiveness) that was selectively applied to the evidence for acupuncture alone (Lai, 2016). With ongoing debates further research would indeed be warranted prior to the next review of the NICE guidelines in 2018.

1.3 Acupuncture in the research environment

1.3.1 Internal and external validity of clinical research

Internal and external validity are two crucial components of controlled clinical trials.

Internal validity refers to the reliability or accuracy of the results (Godwin *et al*., 2003). Researchers seek to maximize the internal validity of clinical trials by rigorous control of all variables other than the intervention (Godwin *et al*., 2003). Accordingly, trials are carefully designed and well conducted to minimize possibility of bias. On the other side, relevance of the study results depends on the external validity- whether the results can be generalized to a definable group of patients in particular clinical settings (Godwin *et al*., 2003; Rothwell, 2005). External validity is affected by several issues including setting of the trial, selection of patients, characteristics of randomized patients, differences between the trial protocol and routine practice, outcome measures and follow-up, and adverse effects of treatment (Rothwell, 2005).

Whereas a great deal of methodology research has provided guidance on the design and performance of trials, external validity of clinical research has been rarely considered (Eldridge, Ashby, Bennett, Wakelin, & Feder, 2008; Purepong, Jitvimonrat, Sitthipornvorakul, Eksakulkla, & Janwantanakul, 2012; Rothwell, 2005). Poor external validity causes concerns amongst clinicians, leading to low acceptance of research results in clinical practice; this may explain the widespread underuse in routine practice of treatment interventions that are reported as effective in trials and systematic reviews, and that are recommended in guidelines (Rothwell, 2005).

It is not practical that the results from RCTs and systematic reviews could be applicable to all patients or in all clinical settings, but to be clinically useful they should at least be designed and reported in a way that allows clinicians and patients to make reasonable judgement. This thesis emphasized both the internal validity and the external validity of systematic reviews and clinical trials. Details were reported in Chapters 2, 3 and 4.

1.3.2 Components of acupuncture treatment

In the context of clinical research, acupuncture is a complex intervention. Clinical practice of acupuncture mainly involves five aspects consisting of various components (Figure 1.3) (Luo, Xu, & Liu, 2015). Clinical trials of acupuncture, accordingly, should clearly articulate these components to allow for an objective and reliable evaluation, and replication as appropriate.

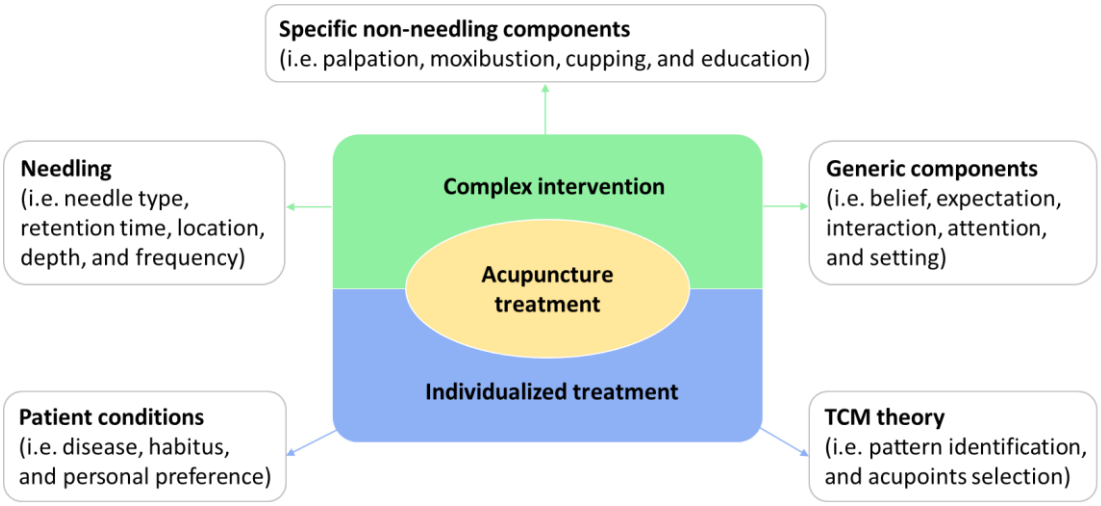

Figure 1.3. Components of acupuncture treatment (reused with permission from the corresponding author) (Luo *et al*., 2015)

1.3.3 Problems in current acupuncture research

Due to the essential features of acupuncture, clinical acupuncture research presents various methodological and practical problems. A prominent challenge is the inappropriate evaluation of individual acupuncture components rather than considering acupuncture as a complex and comprehensive intervention (Hawe, Shiell, & Riley, 2004; Luo *et al*., 2015; Nahin & Straus, 2001). Additionally, low external validity (reporting quality) of acupuncture interventions impedes critical analysis of the data and further research replication; this has become an issue of concern and has been raised by a number of researchers (Miao, 2010; Purepong *et al*., 2012; Walji & Boon, 2006). Previous research has shown that dosage is as important for the effectiveness of acupuncture interventions as it is for pharmacological agents (Ezzo *et al*., 2000). However, research into the use of acupuncture for LBP has largely ignored dose dependency (White *et al*., 2008). Furthermore, sham and/or placebo controls

implemented in acupuncture trials are often problematic (not fully inert from a physiological perspective), and may lead to underestimation of the efficacy of acupuncture (Kaptchuk, Chen, & Song, 2010; Luo *et al*., 2015; Paterson & Dieppe, 2005).

1.3.4 Priorities of acupuncture research

Considering the problems above, scientific evaluations that include a rigorous research methodology are required in the field of acupuncture. Such evaluations should be developed in accordance with the UK Medical Research Council (MRC) guidance for developing and evaluating complex interventions (Craig *et al*., 2008). A key question in evaluating acupuncture (as a complex intervention) is its effectiveness in routine practice, for the treatment of medical conditions where there is inconsistent evidence, such as LBP (Craig *et al*., 2008; Luo *et al*., 2015). Associated with this, two key areas of research priority include strategies to improve external validity of acupuncture intervention components, and establishment of optimal acupuncture treatment dosage for each medical condition.

1.4 Developing the research questions

Given the chronic episodic nature and high recurrence rate of LBP, more effective and comprehensive treatment options are needed to optimize current management. Although two clinical guidelines have recommended the use of acupuncture in the management of LBP (Chou *et al*., 2007; Savigny *et al*., 2009), a more consistent approach for integration of acupuncture into mainstream health care of LBP relies on more rigorous investigations on effectiveness of acupuncture. To improve applicability of these findings, external validity of research requires greater attention. Few clinical trials have evaluated the dose dependence of acupuncture for chronic LBP in terms of the number of treatment sessions, and reported conflicting conclusions; further research is needed to investigate the optimal number of sessions of acupuncture for the management of chronic LBP.

The main purpose of this thesis was to address these research gaps, in the context of the methodological problems and priorities in the current acupuncture research area. Accordingly, the work described in the following chapters investigated three research questions:

1) Is acupuncture an effective treatment intervention in the management of LBP?
2) How to improve the external validity of acupuncture studies by improving the efficacy of the specific acupuncture reporting guidelines - Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA)?
3) Is it feasible to conduct a RCT to investigate the optimal number of TCM acupuncture treatment sessions for patients with chronic LBP?

1.5 Research framework and structure of the thesis

This thesis has been developed following the MRC guidelines for developing and evaluating complex interventions which involved a dynamic progress comprising four definitive phrases (Figure 1.4) (Craig *et al*., 2008).

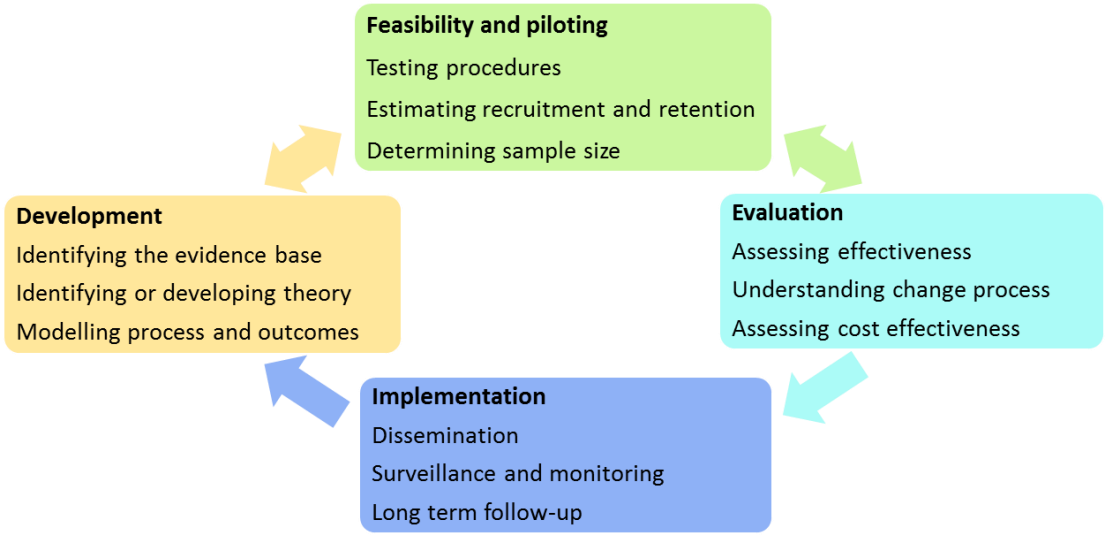

Figure 1.4. Research process of the Medical Research Council guidance for developing and evaluating complex interventions (reused with permission from the corresponding author) (Craig *et al*., 2008)

As suggested by the MRC guidelines, emphasis was placed on the development and feasibility phases of the research process (Craig *et al*., 2008). In order to address the research questions, a systematic, step-wise, and pragmatic approach was applied in this thesis. This approach involved a linear model of evaluation process, including a comprehensive evaluation of the evidence for the effectiveness of acupuncture for LBP (Chapter 2), a review of strategies to improve on the external validity of acupuncture research (by improving the efficacy of the STRICTA guidelines) (Chapter 3), and a preliminary test of the feasibility of conducting a fully powered RCT investigating the optimal number of sessions of acupuncture to be used as an adjunct to usual care for adults with chronic LBP (Chapters 4 and 5). Finally, the thesis concluded with a general discussion of findings from the thesis studies, and implications for future research regarding acupuncture for the treatment of chronic LBP (Chapter 6). Accordingly, the research structure of this thesis is displayed in Figure 1.5.

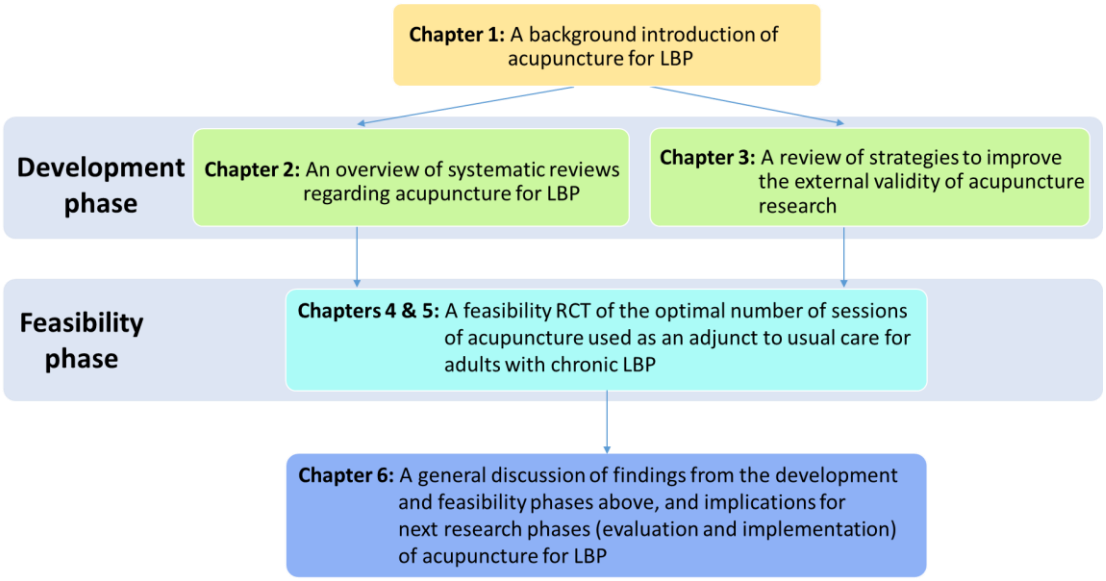

Figure 1.5. Thesis structure
Abbreviations: LBP, low back pain; RCT, randomized controlled trial.

2 Effectiveness of acupuncture for low back pain: An overview of systematic reviews

2.1 Introduction

As described in Chapter 1, low back pain (LBP) is associated with significant economic and social impacts (Hoy *et al*., 2014; Hoy *et al*., 2010). Although a considerable variety of conservative therapy alternatives are available for the treatment of LBP, no single modality appears to be superior (Furlan *et al*., 2005b; Shen *et al*., 2006). Patients are often dissatisfied with conventional medical approaches, and turn to complementary and alternative medicine (CAM) to manage their symptoms (Grazio & Balen, 2011; Sherman *et al*., 2004); among such treatments, acupuncture is one of the most popular options (Santaguida *et al*., 2009).

Despite an increasing interest in acupuncture from the public as well as health professions (Sherman *et al*., 2004; Thomas, Coleman, & Nicholl, 2003), to date the effectiveness of acupuncture for LBP is not without dispute: over the past quarter of a century, numerous systematic reviews have investigated the effectiveness of acupuncture in the management of LBP, but conclusions are sometimes contradictory, and often limited by the quantity and quality of the included studies. In the past decade, three clinical practice guidelines have been published with inconsistent conclusions regarding the recommendations for acupuncture in the treatment of chronic LBP (Airaksinen *et al*., 2006; Chou *et al*., 2007; Savigny *et al*., 2009); this has led to confusion for clinicians when making evidence-based clinical decisions concerning acupuncture. Given this, an overview of evidence provided by the reviews would overcome the limitations of the single systematic review, allowing a systematic assessment of the strength of the current evidence, and comprehensive analysis of the results of existing systematic reviews.

This chapter reports an overview of systematic reviews evaluating the effectiveness of acupuncture for LBP. This is the first phase of a coherent investigation on the role of acupuncture in the management of LBP, which was conducted to establish the evidence base for subsequent research. The aim of this overview was to summarize and critically appraise the evidence of relevant systematic reviews, and to present a comprehensive evaluation of the therapeutic value of acupuncture for LBP.

2.2 Methods

2.2.1 Search strategy

A comprehensive computer-aided literature search was undertaken in the following databases from their inception until February 2014: Medline, EMBASE, AMED, CINAHL, Cochrane Library, and two Chinese databases, the China National Knowledge Infrastructure and the Wan Fang Database that include 'grey literature', such as dissertations and conference reports. Search terms used were (systematic review OR meta-analysis) AND (acupuncture OR acupuncture therapy OR acupuncture points OR needle OR electro-acupuncture OR auricular-acupuncture OR warm-acupuncture OR dry needling OR trigger-point therapy OR moxibustion) AND (low back pain OR back pain OR backache OR lumbago OR sciatica OR dorsalgia) with slight modifications for individual searches in each database. Boolean operators were used and the search was limited to adult participants. Reference lists of all papers retrieved were manually scanned to identify further articles missed by electronic searching. No language restrictions were applied, provided there was an abstract available in English or Chinese. Appendix 1 presents the search strategy.

2.2.2 Selection criteria

Three reviewers (Lizhou Liu (LL) and Leon Mabire (LM) for English database; LL and Jundong Wang (JW) for Chinese database) independently screened for potential articles and resolved disagreements by discussion. Where necessary, full papers were obtained for final decision. 'Systematic review' was defined methodologically as reviews with a systematic analysis, either meta-analysis or best-evidence synthesis.

Articles were included if they were systematic reviews of randomized controlled trials (RCTs) that evaluated the effectiveness of acupuncture compared to controls for nonspecific LBP (defined as LBP not attributed to recognizable, known specific pathology including infection, tumor, osteoporosis, ankylosing spondylitis, fracture, inflammatory process, radicular syndrome or cauda equina syndrome) (van Tulder *et al*., 2006), using at least one of the following outcome measures: pain relief, functional improvement, overall improvement, or effectiveness rate (frequently used in Chinese articles as the ratio of 'cured and improved' to the total number of the group). Systematic reviews assessing needle acupuncture were considered irrespective of intervention styles. Acupuncture was described as a treatment procedure involving one or more needles penetrating into the skin without an injection (Manheimer, White, Berman, Forys, & Ernst, 2005). The modes of acupuncture were not restricted: Traditional Chinese Medicine (TCM) acupuncture that adhered to energetic philosophical theory, or Western medical acupuncture (e.g. dry needling) based on contemporary scientific principles were both eligible. However, articles relating to techniques similar to acupuncture but without needle insertion (e.g. laser acupuncture, acupressure, acupoint embedding, and auricular seeds) were excluded.

Systematic reviews were eligible that included control groups treated with sham acupuncture, no treatment/waiting list, conventional therapy, or sham therapy/placebo (e.g.

sham laser or sham transcutaneous electrical nerve stimulation (TENS)). Only systematic reviews in which the effectiveness of acupuncture could be isolated were included: i.e. systematic reviews that tested effects of acupuncture alone over control comparators, or evaluated acupuncture as an adjunct to other therapy and compared to the other therapy alone.

The following were excluded: (1) review comments, overviews of evidence, guidelines, editorials; (2) systematic reviews that included trials other than RCTs; (3) systematic reviews without formal analysis contained in the methods; (4) systematic reviews with no control comparisons, where only different forms of acupuncture were compared; (5) systematic reviews that only evaluated the cost-effectiveness of acupuncture; (6) systematic reviews that assessed the combined effects of acupuncture with other treatments over control interventions; and/or (7) systematic reviews where a series of conservative therapies or musculoskeletal conditions were investigated, but there were no separate data available for effectiveness of acupuncture for LBP.

2.2.3 Data extraction

Data from articles written in English were extracted independently by two reviewers (LL and LM) using a standardized spreadsheet designed to record descriptive characteristics, methodological quality of primary studies, acupuncture style and adequacy (assessment on acupuncture appropriateness by experts' judgment or comparison with textbooks and/or literature resources), data analysis approaches, main results, and conclusions. Articles written in Chinese were extracted independently by LL and JW in the same manner. When retrieving articles published in other languages, translations of essential details were obtained for data extraction; differences during this process were settled by discussion with reference to the original papers.

The methodological qualities of the original (RCT) studies were then extracted, and quality levels recorded as 'low' or 'high', based on the judgments made by the authors of the respective systematic reviews. As recommended, for systematic reviews using the Jadad scale (Jadad *et al*., 1996), a score of two points or less (out of a maximum of five) represented poor quality; for systematic reviews using the PEDro scale (Maher, Sherrington, Herbert, Moseley, & Elkins, 2003), three points (out of a maximum of ten) was considered the cut-off for low quality (Ferreira, Ferreira, Latimer, Herbert, & Maher, 2002; Machado, Kamper, Herbert, Maher, & McAuley, 2008); for systematic reviews which used criteria list from the Method Guidelines for Systematic Reviews in the Cochrane Back Review Group (Furlan, Pennick, Bombardier, & van Tulder, 2009; van Tulder, Assendelft, Koes, & Bouter, 1997; van Tulder, Furlan, Bombardier, & Bouter, 2003), low quality was defined as a score less than 5/10, 6/11 and 6/12 for the versions of 1997, 2003, or 2009, respectively; two systematic reviews used additional requirements to judge the quality, the related information was extracted: one review (Lee *et al*., 2013) emphasized the necessity of adequate randomization and/or allocation concealment of RCTs to be of high quality, and another review (Yuan, Purepong, *et al*., 2008) weighted the importance of low drop out at follow-up, between group statistical tests, and adequate power. When no clear judgment was available from the authors, two reviewers (LL and LM) made determinations in accordance with the guidelines for each scale; the included RCTs were judged as 'low' quality if over 50% of these were of high risk.

The external validity of included systematic reviews was assessed, using the Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) (MacPherson *et al*., 2010b), a recommendation for reporting related characteristics of acupuncture trials. Furthermore, in order to identify whether the adequacy of acupuncture

was considered in the analysis and the conclusions of the reviews, assessments concerning acupuncture adequacy in individual systematic reviews were extracted.

2.2.4 Quality assessment

Quality assessment of systematic reviews was performed using the Assessment of Multiple Systematic Reviews (AMSTAR) criteria, a validated instrument with good construct validity and reliability (Shea *et al*., 2007). It comprised 11 items, scored as 'Yes', 'No', 'Cannot answer', or 'Not applicable' on a checklist. Before the assessment started, each topic of AMSTAR was intensively discussed to achieve homogeneity in the following procedure. Two reviewers (LL and LM) independently rated the methodological quality, scored one point for item assigned 'Yes', and then calculated the overall score of each systematic review. The kappa statistic was used to measure the agreement level between the two reviewers; kappa index less than 0.4 reflected poor agreement, 0.4 to 0.75 fair agreement, and over 0.75 excellent agreement (Fleiss, 1971). Again, consensus was reached by discussion between two reviewers and an independent decision was obtained from a third author (George David Baxter (GDB)) if necessary. A review was considered as low quality if the total score was 4 or lower, moderate quality if the score was between 5 and 7, and high quality if the score was 8 or higher (Graham *et al*., 2013). The classification of quality was used to grade the strength of the evidence in conclusions.

2.2.5 Data synthesis

As outcomes of systematic reviews (effects of acupuncture) were likely to be affected by factors such as chronicity, the range of control groups, and the follow-up time-points used, *a priori,* systematic reviews were assigned to predefined subgroups according to the following criteria:

1) LBP chronicity: acute/sub-acute LBP: < 3 months; chronic LBP: ≥ 3 months (van Tulder *et al*., 2006);
2) control comparisons: sham acupuncture involving non-penetration or superficial insertion of needles; sham therapy which was physiologically inert; no treatment or waiting list; conventional therapy including usual care or any active treatment other than acupuncture; and acupuncture added to conventional therapy compared to the conventional therapy alone;
3) outcome measures: primary outcome: pain relief and functional improvement, and secondary outcome: overall improvement or effectiveness rate;
4) time-points: short-term follow-up: < 3 months after randomization; intermediate follow-up: ≥ 3 months and < 1 year; long-term follow-up: ≥ 1 year (van Tulder *et al*., 2003).

Outcomes of subgroup comparisons were summarized and appraised. A narrative synthesis of the evidence was presented to generate final conclusions, taking into account methodological quality, and the total numbers of systematic reviews that reported consistent results (effectiveness or non-effectiveness). The overall conclusion was determined by the majority (> 50%) of systematic reviews that reported consistent outcomes. Outcomes from systematic reviews with higher quality were assigned larger impact weights (i.e. when equal numbers of systematic reviews reported conflicting results, the systematic reviews of higher quality decided the final conclusion).

2.2.6 Sensitivity analysis

A sensitivity analysis was conducted by excluding systematic reviews of low quality, and then repeating the aforementioned analysis.

2.2.7 Clinical relevance

In order to identify whether any observed differences between acupuncture and control groups were clinically relevant, the pooled effect magnitudes of the meta-analyses were recorded.

For systematic reviews which used the same outcome instruments, an anchor-based approach using mean difference (MD) in pain intensity and functional disability was used to address clinical relevance. The minimal clinically important difference (MCID) for pain relief was defined as 15/100 for the Visual Analogue Scale (VAS), 2/10 for the Numerical Rating Scale (Ostelo *et al*., 2008); for functional improvement these were defined as 5 points for the Roland-Morris Disability Questionnaire (RDQ), 10 points for the Oswestry Disability Index, and 20 points for the Quebec Back Pain Disability Questionnaire (Ostelo *et al*., 2008).

For systematic reviews that used different scales, distribution-based methods were used to operationalize clinical relevance: i.e. weighted mean difference (WMD) or standardized mean difference (SMD) for continuous outcomes, and odds ratio or relative ratio (RR) for dichotomous outcomes. Findings were determined to be clinically relevant based on the effect size only, and the degree was specified in accordance with the 2009 Updated Guidelines for Systematic Reviews in the Cochrane Back Review Group (Furlan *et al*., 2009): (1) small: WMD< 10% of the VAS scale; SMD< 0.5; RR< 1.25; (2) medium: WMD≥ 10% and ≤ 20% of the VAS scale; SMD≥ 0.5 and < 0.8; RR≥ 1.25 and ≤ 2.0; (3) large: WMD> 20% of the VAS scale; SMD≥ 0.8; RR> 2.0.

2.3 Results

2.3.1 Systematic review selection

The search strategy resulted in the identification of 1044 records; after excluding duplicates, 796 publications were manually screened by titles and abstracts, and 70 papers were eligible for further consideration. On the basis of review of full-text articles, 50 papers were excluded and 20 met the inclusion criteria. After discussion, four reviews were subsequently removed due to: one was a Cochrane review update (van Tulder, Cherkin, Berman, Lao, & Koes, 2000), three represented the same reviews reported as journal articles (Furlan *et al*., 2005a; Furlan *et al*., 2010; van Tulder, Cherkin, Berman, Lao, & Koes, 1999). Thus a total of 16 systematic reviews were finally included in this overview (Figure 2.1). Appendix 2 presents the excluded papers after full-text article review.

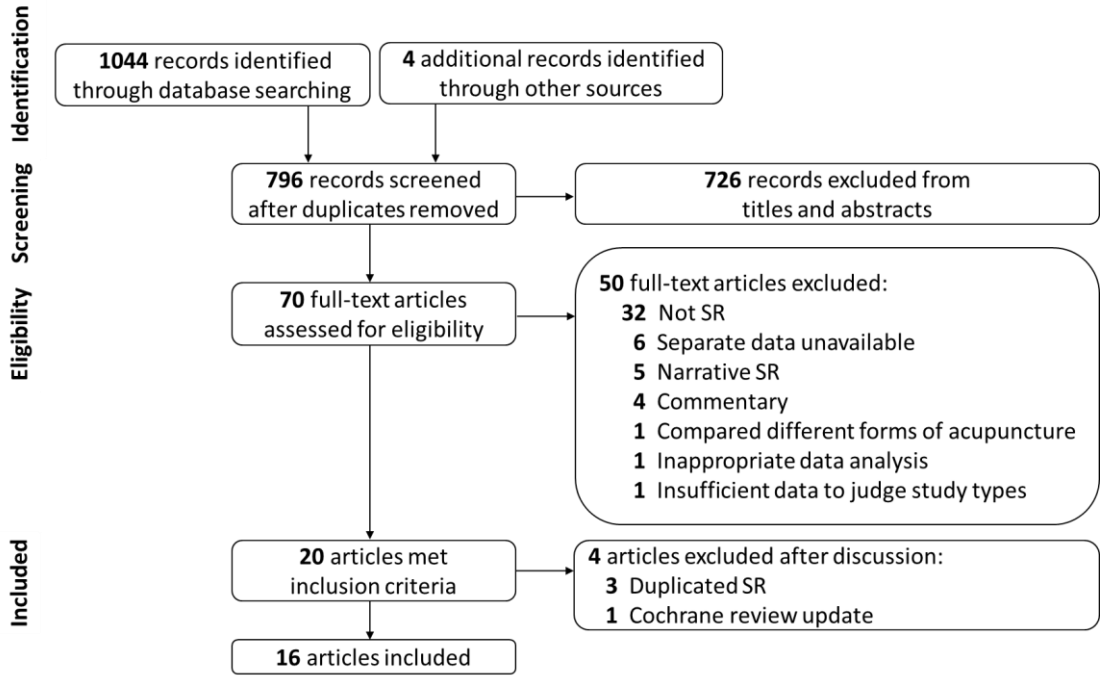

Figure 2.1. Overview of systematic reviews: Flow diagram of literature search
Abbreviation: SR, systematic review.

2.3.2 Systematic review characteristics

The main characteristics of systematic reviews are displayed in Table 2.1. Thirteen systematic reviews performed meta-analyses (Ernst & White, 1998; Furlan *et al*., 2012; Keller

et al., 2007; Lam, Galvin, & Curry, 2013; Lee *et al*., 2013; Li, Zhan, Gao, Chen, & Shi, 2010; Li *et al*., 2008; Machado, Kamper, Herbert, Maher, & McAuley, 2009; Manheimer *et al*., 2005; Rubinstein *et al*., 2010; Wu, Li, He, & Wen, 2013; Xu *et al*., 2013; Zhu, Origasa, & Wang, 2002), one conducted best-evidence syntheses (Ammendolia, Furlan, Imamura, Irvin, & van Tulder, 2008), and a further two used both quantitative and qualitative analyses (Furlan *et al*., 2005b; Yuan *et al*., 2008), one of which based conclusions on the qualitative analysis only (Yuan *et al*., 2008). The included systematic reviews were published between 1998 and 2013; twelve were published in English, three in Chinese, and one in Japanese. The number of RCTs included in the systematic reviews varied widely, ranging from 5 to 35 studies; original studies were (repeatedly) identified in the sixteen systematic reviews. Five systematic reviews were on chronic LBP (Ammendolia *et al*., 2008; Lam *et al*., 2013; Machado *et al*., 2009; Rubinstein *et al*., 2010; Xu *et al*., 2013), one on acute LBP (Lee *et al*., 2013), eight included a mixed group of participants with acute, sub-acute, and chronic LBP (Ernst & White, 1998; Furlan *et al*., 2005b; Furlan *et al*., 2012; Keller *et al*., 2007; Manheimer *et al*., 2005; Wu *et al*., 2013; Yuan *et al*., 2008; Zhu *et al*., 2002), and the remaining two did not specify chronicity (Li *et al*., 2010; Li *et al*., 2008). In regard to the cause of LBP, seven systematic reviews only included RCTs of nonspecific LBP (Furlan *et al*., 2005b; Keller *et al*., 2007; Lam *et al*., 2013; Lee *et al*., 2013; Machado *et al*., 2009; Rubinstein *et al*., 2010; Yuan *et al*., 2008), three systematic reviews in Chinese focused exclusively on RCTs of lumbar intervertebral disc herniation (LIDH) (Li *et al*., 2010; Li *et al*., 2008; Wu *et al*., 2013), one involved RCTs of both specific and nonspecific LBP (Furlan *et al*., 2012), and the remaining five did not clearly state the type of LBP (Ammendolia *et al*., 2008; Ernst & White, 1998; Manheimer *et al*., 2005; Xu *et al*., 2013; Zhu *et al*., 2002).

Table 2.1. Overview of systematic reviews: Characteristics of systematic reviews

Authors (Date)/ Country	Condition	No. of RCTs (patients) included	Quality of original studies Scale/ Level	Acu style of SR	Acu adequacy assessment of original studies	Quality of SR	Data analysis methods	Reported results			Authors conclusions / Comments (Notes)
								Comparisons	Pain relieve	Function improve	
Lee *et al* (2013)/ Korea	Acute NSLBP	11 (1139)	2009 CBRGC and additional criteria (5/11) Low	TCM, Western	Judged by two experts about two questions	6	Meta-analysis	1) Sham acu 2) Medications	+ #	= NR	Acupuncture may be more effective than medication for symptom improvement or relieve pain better than sham acupuncture in acute NSLBP. / Included Asian database. Strict criteria of being high quality studies. Emphasized the impact of language restriction and Chinese studies. (Overall Improve (+) compared to medications)
Lam *et al* (2013)/ Ireland	Chronic NSLBP	32 (5931)	Cochrane risk of bias tool (7/32) Low	TCM	NR	6	Meta-analysis	1) Sham acu 2) No treatment 3) plus usual care 4) Medications 5) TENS	+ + + + =	= + + + NR	Acupuncture may have a favorable effect on pain and function on chronic NSLBP. / High heterogeneity of included studies. Confused subgroups. Clear definition of clinical significance.
Wu *et al* (2013)/ China	LIDH	6 (540)	Cochrane risk of bias tool (NR) Low	TCM	NR	5	Meta-analysis	Various controls (oral medications, traction, medication injection or transfusion)	=	NR	Acupuncture is effective and safe for LIDH. / Article in Chinese. Restricted publication status. No subgroup comparison provided. Quality of evidence evaluated by GRADE. (Non-effectiveness rate (-))
Xu *et al* (2013)/ China	Chronic LBP	13 (2678)	2003 CBRGC (12/13) High◎	NR	NR	5	Meta-analysis	1) No treatment 2) Conventional therapy 3) Sham acu	+ + =	+ + =	Acupuncture is an effective treatment for chronic LBP, but may due to nonspecific effects. / Excluded Asian database other than Chinese. No key studies characteristics provided. (No treatment group included blank treatment comparison)
Furlan *et al* (2012)/ Canada	LBP	33 (NR)	2009 CBRGC (NR) NR	NR	NR	5	Meta-analysis	*For acute/ sub-acute NSLBP:* 1) Sham acu *For chronic NSLBP:* 1) Sham therapy 2) No treatment 3) Medications 4) Manipulation 5) Usual care	 = + + = - +	 = = + = NR +	Same as reported results. / Not specific to acupuncture. No studies characteristics provided. Quality of evidence evaluated by GRADE.

Li *et al* (2010)/ China	LIDH	5 (718)	Jadad (2/5) Low	TCM (Electro)	NR	5	Meta-analysis	Various controls (oral medications or physiotherapy)	+	NR	Electro-acupuncture is effective and safe for LIDH. / Article in Chinese. Restricted publication status. No subgroup comparison provided. Poor quality of meta-analysis (repeatedly pooled the same study in one analysis). (Effective rate (+))
Rubinstein *et al* (2010)/ Netherland	Chronic NSLBP	20 (5590)	2003 CBRGC (8/20) Low	TCM	NR	5	Meta-analysis	1) Sham therapy 2) No treatment 3) plus conventional therapy 4) Usual care	+ + + +	+ + + +	Acupuncture provides short-term clinically relevant effects when compared with no treatment or added to other therapy. / Not specific to acupuncture. No studies characteristics provided. No heterogeneity present. Quality of evidence evaluated by GRADE.
Machado *et al* (2009)/ Australia	NSLBP	4 (149)	PEDro (4/4) High◎	NR	NR	3	Meta-analysis	Placebo controls	=	NR	Acupuncture is not more effective than placebo. / Not specific to acupuncture. No studies characteristics provided. No heterogeneity present.
Ammendolia *et al* (2008)/ Canada	Chronic LBP	19 (5001)	2003 CBRGC (10/19) Low	TCM, Western	NR	4	Best-evidence synthesis	1) Waiting list 2) plus conventional therapy 3) Conventional therapy 4) Sham therapy	+ + = #	+ + = =	Same as reported results. / Lack rigorous format of SR.
Yuan *et al* (2008)/ UK	NSLBP	23 (6359)	2003 CBRGC and additional criteria (6/23) Low◎	TCM, Western	Compared to textbooks, surveys and primary reviews	4	Meta-analysis, best-evidence synthesis	1) No treatment 2) plus conventional therapy 3) Sham acu 4) Conventional therapy	+ + = #	+ + = #	Acupuncture versus no treatment, and as an adjunct to conventional care, should be advocated in the European guidelines for chronic LBP. / Excluded non-English articles. No heterogeneity present. No overall effect size of pooled studies provided. Strict criteria of being high quality studies. Clear definition of clinical significance.
Li *et al* (2008)/ China	LIDH	5 (547)	Jüni (NR) High	TCM (Electro)	NR	7	Meta-analysis	Various controls (oral medications or physiotherapy)	+	+	Electro-acupuncture is effective and safe for LIDH. / Article in Chinese. No subgroup comparison provided.
Keller *et al* (2007)/ Norway	NSLBP	7 (528)	2003 CBRGC and Jadad (NR) High	NR	NR	2	Meta-analysis	Various controls (sham therapy or no treatment)	+	NR	Acupuncture has a modest effect for chronic LBP. / Not specific to acupuncture. No subgroup comparison provided.
Manheimer *et al* (2005)/ USA	LBP	33 (2300)	1997 CBRGC and Jadad (12/33, 17/33) Low	TCM, Western	NR	8	Meta-analysis	*For acute LBP:* *For chronic LBP:* 1) Sham acu 2) No treatment 3) Conventional therapy 4) Manipulation	⊥ + + ⊥ -	⊥ = + ⊥ -	Acupuncture effectively relieves chronic low back pain. No evidence suggests acupuncture is more effective than other active therapies. / Excluded Chinese database. Restricted publication status. Clear definition of clinical significance.

Furlan *et al* (2005)/ Canada	NSLBP	35 (2861)	2003 CBRGC (14/35) Low	TCM, Western	Judged by three experienced acupuncturists based on four questions	9	Meta-analysis, best-evidence synthesis	*For acute NSLBP:* *For chronic NSLBP:* 1) Sham therapy 2) No treatment 3) plus conventional therapy 4) Conventional therapy	⊥ + + + =	⊥ = + + =	No firm conclusions for acute LBP. For chronic LBP, acupuncture is more effective than no treatment or sham treatment. Acupuncture is not more effective than other conventional treatments. Acupuncture and dry needling may be useful adjuncts to other therapies. / Included Asian database. High heterogeneity of included studies. Subjective assessment of clinical relevance.
Zhu *et al* (2002)/ China	LBP	9 (426)	NR	TCM	NR	2	Meta-analysis	Various controls (sham acu, TENS, medications or physiotherapy)	+	NR	Acupuncture might be effective for LBP. / Article in Japanese. Included Japanese database. No subgroup comparison provided.
Ernst and White (1998)/ UK	Back pain	12 (472)	Jadad (10/12) High	TCM, Western	Judged by six experienced acupuncturists	8	Meta-analysis	Various controls (sham acu, no treatment, TENS *et al*)	NR	NR	Acupuncture is superior to various control interventions, but insufficient evidence to judge whether it is superior to placebo. / No subgroup comparison provided. (Symptoms Improve (+))

Abbreviations: RCT, randomized controlled trial; SR, systematic review; LBP, low back pain; NSLBP, nonspecific low back pain; LIDH, lumbar intervertebral disc herniation; CBRGC, Cochrane Back Review Group Criteria; TCM, Traditional Chinese Medicine; Acu, acupuncture; TENS, transcutaneous electrical nerve stimulation; GRADE, Grading of Recommendations Assessment, Development and Evaluation; NR, not reported.

◎: judged by reviewers; #: conflicting evidence; ⊥: insufficient evidence.

+: more effective than; =: no difference found or not more effective than; -: less effective than.

2.3.3 Acupuncture details

The majority of systematic reviews (n= 12/16) indicated the types of acupuncture assessed: six investigated TCM acupuncture as the exclusive intervention (Lam *et al*., 2013; Li *et al*., 2010; Li *et al*., 2008; Rubinstein *et al*., 2010; Wu *et al*., 2013; Zhu *et al*., 2002), and six focused on both TCM and Western medical acupuncture (Ammendolia *et al*., 2008; Ernst & White, 1998; Furlan *et al*., 2005b; Lee *et al*., 2013; Manheimer *et al*., 2005; Yuan *et al*., 2008). However, the reporting of acupuncture trials was of poor quality: only one systematic review clearly presented the extracted details of acupuncture in accordance with the STRICTA guidelines (Lee *et al*., 2013). Assessment of the adequacy of acupuncture treatment was rarely considered in the systematic reviews: only four (25%) provided explicit criteria for judging whether acupuncture intervention was adequate or not (Ernst & White, 1998; Furlan *et al*., 2005b; Lee *et al*., 2013; Yuan *et al*., 2008).

2.3.4 Methodological quality

The quality assessment scales of the original studies varied across the included systematic reviews; nine used the criteria list from the Method Guidelines for Systematic Reviews in the Cochrane Back Review Group (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Furlan *et al*., 2012; Keller *et al*., 2007; Lee *et al*., 2013; Manheimer *et al*., 2005; Rubinstein *et al*., 2010; Xu *et al*., 2013; Yuan *et al*., 2008), three adopted the modified Jadad scale (Ernst & White, 1998; Li *et al*., 2010; Manheimer *et al*., 2005), two selected the Cochrane risk of bias tool (Lam *et al*., 2013; Wu *et al*., 2013), and the remaining two employed the PEDro scale and the assessment model used by Jüni (Juni, Altman, & Egger, 2001), respectively (Li *et al*., 2008; Machado *et al*., 2009). However, the different quality assessment scales (applied in the included 16 systematic reviews) resulted in consistent assessment outcomes of the original studies- overall, the quality of RCTs was relatively low: of the 15 systematic reviews that provided quality assessment, nine were considered to include limited quality of RCTs by

primary authors, and by the two reviewers (LL and LM) (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Lam *et al*., 2013; Lee *et al*., 2013; Li *et al*., 2010; Manheimer *et al*., 2005; Rubinstein *et al*., 2010; Wu *et al*., 2013; Yuan *et al*., 2008).

Agreement of the two reviewers for quality assessment of systematic reviews using AMSTAR was regarded as excellent (kappa index was 0.797) for independent reviews. After discussion the reviewers reached consensus giving a kappa index of 1. Table 2.2 provides an overview of the assessment results. The overall scores ranged from 2 to 9 (out of a maximum of 11); three systematic reviews were considered as high quality (Ernst & White, 1998; Furlan *et al*., 2005b; Manheimer *et al*., 2005), eight as moderate quality (Furlan *et al*., 2012; Lam *et al*., 2013; Lee *et al*., 2013; Li *et al*., 2010; Li *et al*., 2008; Rubinstein *et al*., 2010; Wu *et al*., 2013; Xu *et al*., 2013), and five as low quality (Ammendolia *et al*., 2008; Keller *et al*., 2007; Machado *et al*., 2009; Yuan *et al*., 2008; Zhu *et al*., 2002). The number of reviews satisfying the criteria for individual items varied widely: four items were satisfied by over 75% of the systematic reviews, namely Item 2, duplicate processes of study selection and data extraction (n= 13); Item 3, comprehensive literature search strategy (n= 12); Item 7, scientific quality assessment of the included studies (n= 15); and Item 9, appropriate methods of meta-analysis (n= 13). In contrast, three items accounted for the major methodological limitations: Item 11, the interest conflict statement, was not met by any of the systematic reviews but one, which indicated source of funding for the review as well as for the included studies; Item 1, *a priori* design requirement, and Item 5, presenting a list of excluded studies in addition to included studies, were rarely reported (in two systematic reviews).

Table 2.2. Overview of systematic reviews: Methodological quality assessment of systematic reviews

Authors (Date)	1	2	3	4	5	6	7	8	9	10	11	Total
Lee *et al* (2013)	N	N	Y	Y	N	Y	Y	CA	Y	Y	N	6
Lam *et al* (2013)	N	Y	Y	N	N	Y	Y	Y	Y	N	N	6
Wu *et al* (2013)	N	Y	N	N	N	Y	Y	Y	Y	N	N	5
Xu *et al* (2013)	N	Y	Y	N	N	N	Y	N	Y	Y	N	5
Furlan *et al* (2012)	N	Y	Y	N	N	N	Y	N	Y	Y	N	5
Li *et al* (2010)	N	Y	Y	N	N	N	Y	Y	Y	N	N	5
Rubinstein *et al* (2010)	N	Y	N	N	N	N	Y	Y	Y	Y	N	5
Machado *et al* (2009)	N	Y	Y	N	N	N	Y	N	N	N	N	3
Ammendolia *et al* (2008)	Y	N	Y	N	N	Y	Y	N	NA	NA	N	4
Yuan *et al* (2008)	N	Y	Y	N	N	Y	Y	N	N	N	N	4
Li *et al* (2008)	N	Y	Y	Y	N	N	Y	Y	Y	Y	N	7
Keller *et al* (2007)	N	CA	N	N	N	N	Y	N	Y	N	N	2
Manheimer *et al* (2005)	N	Y	Y	Y	N	Y	Y	Y	Y	Y	N	8
Furlan *et al* (2005)	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	9
Zhu *et al* (2002)	N	Y	N	N	N	N	N	NA	Y	N	N	2
Ernst and White (1998)	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	8
Score	2	13	12	4	2	8	15	7	13	7	1	Mean = 5.25

Abbreviations: Y, yes; N, no; CA, can't answer; NA, not applicable.

1. Was an 'a priori' design provided?

2. Was there duplicate study selection and data extraction?

3. Was a comprehensive literature search performed?

4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?

5. Was a list of studies (included and excluded) provided?

6. Were the characteristics of the included studies provided?

7. Was the scientific quality of the included studies assessed and documented?

8. Was the scientific quality of the included studies used appropriately in formulating conclusions?

9. Were the methods used to combine the findings of studies appropriate?

10. Was the likelihood of publication bias assessed?

11. Was the conflict of interest stated?

2.3.5 Outcomes

Because of the inconsistent definition of follow-up time-points in individual systematic reviews, only short-term (< 3 months) comparisons could be assessed. The duration of 'short-term' was in the range from 6 weeks (Keller *et al*., 2007; Manheimer *et al*., 2005) to 3

months (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Furlan *et al*., 2012; Yuan *et al*., 2008). Subgroup analyses were conducted as planned, except for the comparison between acupuncture and conventional therapy due to high heterogeneity: while some systematic reviews mixed various conventional treatments as one control arm, some considered different interventions as independent control groups, thus pooling data for conventional therapy was impossible. For secondary outcomes, data were sparse and insufficient for drawing conclusions. Ultimately, comparisons of four control groups for pain and functional outcomes at short-term follow-up were made. Table 2.3 and Table 2.4 present the pooled effects for the related outcomes.

Table 2.3. Overview of systematic reviews: Summary of meta-analyses reported positive results – *pain relief*

Comparator	Authors (Date)	No. of RCTs (patients) pooled	Outcome measured time-points	Effect estimate (MD, SMD, WMD) 95% Confidence Interval
Sham acupuncture	Lam *et al* (2013)	4 (287)	Immediately	(VAS) MD= -16.76 (95%CI: -33.33 to -0.19)
	Manheimer *et al* (2005)	4 (343)	< 6 weeks	SMD= -0.58 (95%CI: -0.80 to -0.36)
Sham therapy	Furlan *et al* (2012)	10 (1727)	Immediately	(VAS: 1-10) WMD= -0.59 (95%CI: -0.93 to -0.25)
	Rubinstein *et al* (2010)	4 (918)	< 1 months	WMD= -5.88 (95%CI: -11.20 to -0.55)
		4 (1076)	< 3 months	WMD= -7.27 (95%CI: -12.66 to -1.89)
	Furlan *et al* (2005)	4 (314)	Immediately	WMD= -10.21 (95%CI: -14.99 to -5.44)
		2 (138)	< 3 months	WMD= -17.79 (95%CI: -25.50 to -10.07)
No treatment	Lam *et al* (2013)	4 (2911)	Immediately	SMD= -0.72 (95%CI: -0.94 to -0.49)
	Xu *et al* (2013)	5 (NR)	> 1 month	SMD= -0.64 (95%CI: -1.13 to -0.14)
	Furlan *et al* (2012)	3 (2684)	< 3 months	(VAS: 1-10) WMD= -1.19 (95%CI: -2.17 to -0.21)
	Rubinstein *et al* (2010)	1 (214)	< 3 months	WMD= -24.10 (95%CI: -31.52 to -16.68)
	Manheimer *et al* (2005)	8 (586)	< 6 weeks	SMD= -0.69 (95%CI: -0.98 to -0.40)
	Furlan *et al* (2005)	2 (90)	< 3 months	SMD= -0.73 (95%CI: -1.19 to -0.28)
Plus conventional therapy	Lam *et al* (2013)	4 (269)	Immediately	(VAS) MD= -13.99 (95%CI: -20.48 to -7.50)
	Rubinstein *et al* (2010)	2 (99)	< 1 months	WMD= -9.80 (95%CI: -14.93 to -4.67)
		3 (185)	< 3 months	WMD= -16.91 (95%CI: -25.18 to -8.64)
	Furlan *et al* (2005)	4 (289)	Immediately	SMD= -0.76 (95%CI: -1.02 to -0.50)
		3 (182)	< 3 months	SMD= -1.10 (95%CI: -1.62 to -0.58)

Abbreviations: RCT, randomized controlled trial; VAS, Visual Analogue Scale; MD, mean difference; WMD, weighted mean difference; SMD, standardized mean difference; CI, confidence interval; NR, not reported.

Table 2.4. Overview of systematic reviews: Summary of meta-analyses reported positive results – *functional improvement*

Comparator	Authors (Date)	No. of RCTs (patients) pooled	Outcome measured time-points	Effect estimate (MD, SMD) 95% Confidence Interval
Sham therapy	Rubinstein *et al* (2010)	1 (745)	< 1 month	SMD= -0.18 (95%CI: -0.32 to -0.04)
		3 (1044)	< 3 months	SMD= -0.28 (95%CI: -0.41 to-0.16)
No treatment	Lam *et al* (2013)	3 (451)	Immediately	SMD= -0.94 (95%CI: -1.41 to -0.47)
	Xu *et al* (2013)	4 (NR)	> 1 month	SMD= -0.58 (95%CI: -0.82 to -0.34)
	Furlan *et al* (2012)	1 (NR)	Immediately	MD= -8.20 (95%CI: -12.0 to -4.40)
	Rubinstein *et al* (2010)	1 (214)	< 3 months	SMD= -0.61 (95%CI: -0.90 to -0.33)
	Manheimer *et al* (2005)	6 (NR)	< 6 weeks	SMD= -0.62 (95%CI: -0.95 to -0.30)
	Furlan *et al* (2005)	2 (90)	< 3 months	SMD= -0.63 (95%CI: -1.08 to -0.19)
Plus conventional therapy	Lam *et al* (2013)	3 (144)	Immediately	SMD= -0.87 (95%CI: -1.61 to -0.14)
	Rubinstein *et al* (2010)	2 (99)	< 1 months	SMD= -1.04 (95%CI: -1.46 to -0.61)
		4 (2824)	< 3 months	SMD= -0.66 (95%CI: -0.74 to -0.58)
	Furlan *et al* (2005)	3 (173)	Immediately	SMD= -0.95 (95%CI: -1.27 to -0.63)
		3 (173)	< 3 months	SMD= -0.95 (95%CI: -1.37 to -0.54)

Abbreviations: RCT, randomized controlled trial; MD, mean difference; SMD, standardized mean difference; CI, confidence interval, NR, not reported.

2.3.5.1 Acute/sub-acute LBP

There were two systematic reviews with meta-analyses, which provided sufficient data for comparison (Furlan *et al*., 2012; Lee *et al*., 2013).

2.3.5.1.1 Acupuncture versus sham acupuncture

In the two systematic reviews, sham acupuncture meant mimicked non-penetration on the same acupoints used for genuine acupuncture.

Pain relief. The two systematic reviews produced conflicting conclusions. Furlan and colleagues performed one meta-analysis (moderate quality) with two RCTs (one for acute LBP and one for sub-acute LBP) which indicated that the effectiveness of acupuncture did not differ from sham acupuncture for post-treatment pain intensity (Furlan *et al*., 2012). In contrast, another systematic review of moderate quality based on two RCTs of low risk of bias (one was common to both systematic reviews) found that there was a statistically - but not clinically relevant - difference immediately post-intervention between a single session of acupuncture and sham acupuncture for individuals with acute LBP (MD= -9.38, 95% confidence interval (CI): -17.00 to -1.76; P= 0.02; I^2= 27%) (Lee *et al*., 2013).

Functional improvement. Two systematic reviews of moderate quality both yielded a negative result that suggested similar benefits from real and sham acupuncture needling. Furlan *et al* reported that results for acupuncture and sham acupuncture were not significantly different at 3 months follow-up (Furlan *et al*., 2012). Similarly, Lee *et al* using three studies of low risk of bias found no significant difference between real and sham acupuncture for either acute LBP (2 studies, 100 participants) or sub-acute LBP (1 study, 48 participants) (Lee *et al*., 2013).

2.3.5.2 Chronic LBP

2.3.5.2.1 Acupuncture versus sham acupuncture

There was wide variation in the definition of sham acupuncture, including: (1) mimicked non-penetration on identical acupoints used for verum procedure (Manheimer *et al*., 2005; Xu *et al*., 2013); (2) superficial insertion outside acupoints without stimulation (Lam *et al*.,

2013; Manheimer *et al*., 2005; Xu *et al*., 2013; Yuan *et al*., 2008); and (3) 2% lidocaine injection at non-acupoints plus superficial insertion without stimulation (Yuan *et al*., 2008).

Pain relief. Four systematic reviews reported contradictory outcomes (Lam *et al*., 2013; Manheimer *et al*., 2005; Xu *et al*., 2013; Yuan *et al*., 2008), but those that supported real acupuncture were of higher quality overall, with more careful consideration of pooling of data. Two systematic reviews (one high quality and one moderate quality) found statistically significant effects of authentic acupuncture in relieving pain compared with sham (Lam *et al*., 2013; Manheimer *et al*., 2005), while another two (one moderate quality and one low quality) showed equivalent outcomes (Xu *et al*., 2013; Yuan *et al*., 2008). Of the two systematic reviews that found data in favor of acupuncture, a moderate clinically relevant effect size was observed at the end of treatment (Manheimer *et al*., 2005).

Functional improvement. The four eligible systematic reviews consistently found no evidence supporting the effectiveness of acupuncture over sham acupuncture (Lam *et al*., 2013; Manheimer *et al*., 2005; Xu *et al*., 2013; Yuan *et al*., 2008).

2.3.5.2.2 Acupuncture versus sham therapy

Sham therapy groups included either a combination of sham acupuncture and sham TENS (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Rubinstein *et al*., 2010) or a mix of sham interventions (Furlan *et al*., 2012).

Pain relief. While five systematic reviews reported contradictory results (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Furlan *et al*., 2012; Machado *et al*., 2009; Rubinstein *et al*., 2010), the three of higher quality suggested that individuals who received acupuncture experienced lower levels of pain than their counterparts who received sham treatments. One systematic

review with best-evidence synthesis (low quality) failed to demonstrate the positive benefits of acupuncture over sham interventions (Ammendolia *et al*., 2008); in contrast, three of the four systematic reviews with meta-analysis (one high quality and two moderate quality) revealed that acupuncture compared to sham therapies led to significantly lower pain intensity at short-term follow-up (Furlan *et al*., 2005b; Furlan *et al*., 2012; Rubinstein *et al*., 2010). Effect sizes were small to moderate; WMD ranged from -5.88 (95%CI, -11.20 to -0.55) at 1 month (Rubinstein *et al*., 2010) to -17.79 (95%CI, -25.50 to -10.07) at 3 months (Furlan *et al*., 2005b).

Functional improvement. Relatively clear consensus emerged among the four systematic reviews that acupuncture did not significantly differ from sham therapy in reducing disability (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Furlan *et al*., 2012; Rubinstein *et al*., 2010). While the evidence of three systematic reviews (one high quality, one moderate quality, and one low quality) seemed to be negative (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Furlan *et al*., 2012), one systematic review of moderate quality using meta-analysis demonstrated that subjects receiving acupuncture had significantly fewer functional limitations, but the effect size was small (Rubinstein *et al*., 2010).

2.3.5.2.3 Acupuncture versus no treatment

There was disagreement in the description of 'no treatment' among the included systematic reviews. While seven systematic reviews defined no treatment as waiting list control (i.e. no care while waiting for acupuncture) (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Furlan *et al*., 2012; Lam *et al*., 2013; Manheimer *et al*., 2005; Rubinstein *et al*., 2010; Yuan *et al*., 2008), one systematic review included waiting list control as well as another form of treatment comparison, which assessed the effects of adding acupuncture to other therapies compared with other therapies alone (Xu *et al*., 2013). As there was a significant difference

between the two categories of 'no treatment' (acupuncture versus a waiting list control, and acupuncture plus other therapy versus other therapy), the latter was not included for analysis.

Pain relief and functional improvement. All seven systematic reviews (two high quality, three moderate quality, and two low quality) indicated that acupuncture was superior both in reducing pain and improving function for chronic LBP (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Furlan *et al*., 2012; Lam *et al*., 2013; Manheimer *et al*., 2005; Rubinstein *et al*., 2010; Yuan *et al*., 2008). Moreover, the overall effect sizes were medium to large for both outcome measures.

2.3.5.2.4 Acupuncture in addition to conventional therapy versus conventional therapy alone

Conventional therapy consisted of usual care (Lam *et al*., 2013) or other treatments such as physiotherapy, medications, or exercises (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Rubinstein *et al*., 2010; Yuan *et al*., 2008).

Pain relief and functional improvement. All five systematic reviews (one high quality, two moderate quality, and two low quality) consistently supported acupuncture as an adjunct to conventional care in the treatment of LBP (Ammendolia *et al*., 2008; Furlan *et al*., 2005b; Lam *et al*., 2013; Rubinstein *et al*., 2010; Yuan *et al*., 2008). For measures of pain, two of the three systematic reviews that provided pooled effects demonstrated the differences in effect were medium to large (Furlan *et al*., 2005b; Rubinstein *et al*., 2010), and the remaining one reported statistically but not clinically significant (15/100 for VAS as MCID for pain) effects (MD= -13.99, 95%CI: -20.48 to -7.50; P< 0.000; I^2= 34%) (Lam *et al*., 2013). For

measures of function, three systematic reviews showed large effect sizes (Furlan *et al*., 2005b; Lam *et al*., 2013; Rubinstein *et al*., 2010).

2.3.6 Sensitivity analysis

The results of sensitivity analysis are given in Table 2.5. As planned, after excluding five systematic reviews of low quality, eleven systematic reviews were subsequently included for analysis (Ernst & White, 1998; Furlan *et al*., 2005b; Furlan *et al*., 2012; Lam *et al*., 2013; Lee *et al*., 2013; Li *et al*., 2010; Li *et al*., 2008; Manheimer *et al*., 2005; Rubinstein *et al*., 2010; Wu *et al*., 2013; Xu *et al*., 2013). The current conclusions regarding the effectiveness of acupuncture compared with no treatment, and acupuncture in addition to other conventional therapies for chronic LBP did not change with the exclusion of two systematic reviews (Ammendolia *et al*., 2008; Yuan *et al*., 2008). Conclusions regarding the effectiveness of acupuncture compared with sham therapy for pain intensity with the two reviews excluded would be consistently positive, in that acupuncture has a more favorable effect. Furthermore, the conclusions regarding the effectiveness of acupuncture compared with sham acupuncture would point to stronger evidence that real acupuncture is more efficacious than sham for self-reported pain, as the majority of systematic reviews were in favor of true acupuncture.

Table 2.5. Overview of systematic reviews: Sensitivity analysis*

Condition	Comparisons	Systematic reviews (n)		Systematic reviews in favor of acupuncture (n)	
		Pain relieve	Functional improvement	Pain relieve	Functional improvement
Acute LBP	Sham acupuncture	2	2	1	0
Chronic LBP	Sham acupuncture	3	3	2	0
	Sham therapy	3	3	3	1
	No treatment	5	5	5	5
	plus conventional therapy	3	3	3	3

Abbreviations: LBP, low back pain.

*** Sensitivity analysis was performed by excluding systematic reviews of low quality in analysis.**

2.4 Discussion

2.4.1 Statement of main findings

This overview aimed to critically evaluate the evidence concerning the effectiveness of acupuncture in the treatment of LBP from systematic reviews, and to provide a rigorous and objective summary from the best credible evidence. Overall the analysis suggested that: (1) for acute LBP, there is inconsistent evidence that acupuncture has a more favorable effect than sham acupuncture in relieving pain, but consistent evidence that acupuncture does not significantly differ from sham acupuncture in improving function; (2) for chronic LBP, consistent evidence found that acupuncture provides short-term clinically relevant benefits on pain relief and functional improvement when compared with no treatment or when acupuncture is added to another conventional intervention; (3) for chronic LBP, it seems that genuine (real) acupuncture produces a clinically significant reduction in pain when compared to sham acupuncture and sham therapy at short-term follow-up, but no impact on functional limitation.

2.4.2 Internal validity of the included systematic reviews

Methodological quality assessment of the included systematic reviews revealed there are common areas for improvement. Of the sixteen systematic reviews assessed, only three met the preset 'high quality' level (≥ 8/11 on the AMSTAR checklist). Given that systematic reviews are not equally reliable due to variable quality, and the ones with insufficient quality are likely to have biased findings (Moher, Tetzlaff, Tricco, Sampson, & Altman, 2007), it seemed reasonable to place a greater weighting on systematic reviews of higher quality in drawing conclusions. Furthermore, in order to address the impact of low quality systematic reviews on the overall conclusions, a sensitivity analysis was conducted by excluding all the systematic reviews of low quality (≤ 4/11 on the AMSTAR checklist); under these conditions, conclusions concerning the effectiveness of acupuncture for LBP pointed to stronger evidence showing that acupuncture is an effective treatment for patients with LBP.

As AMSTAR provides for qualitative rather than quantitative assessments, there is no consensus on the definition of quality levels. One of the challenges with using AMSTAR in this way is that the interpretation depends on the total score, and there is no weighting of individual items. However the selected cutoff point was the one employed in the overviews of reviews conducted by the International Collaboration on Neck working group that evaluated evidence for the management for neck pain (Graham *et al*., 2013; Gross *et al*., 2013); and is consistent with that from the UK National Institute for Health Research (NIHR): the systematic review of the highest quality (Furlan *et al*., 2005b) in the overview was considered to have a very low risk of bias according to the National Institute for Health and Clinical Excellence (NICE) guidelines (Savigny *et al*., 2009). For other reviews, the use of AMSTAR produced a low quality rating e.g. Yuan *et al* (Yuan *et al*., 2008), whereas in a separate review of systematic reviews (Ernst, Lee, & Choi, 2011) this review was rated as good (the higher possible rating) using a different rating scale. Some of these differences can

be explained by AMSTAR including 'new' items considered potential sources of bias (language and publication bias, not included in older scales); or differences between raters in how questions on both scales are interpreted. Authors of each systematic review were not contacted to determine whether certain methodological items were completed (and perhaps not reported), and given the relative newness of the AMSTAR scale and journal space limitations for the published reviews, this could have altered the scores for some of the systematic reviews.

2.4.3 External validity of the included systematic reviews

Overall, the external validity of the included systematic reviews was limited: only one systematic review (Lee *et al*., 2013) reported the characteristics of interventions on the basis of STRICTA (MacPherson *et al*., 2010b), and the remaining showed considerable heterogeneity in terms of data presentation. While it may be argued that the poor reporting of acupuncture intervention could simply be explained by space limitations for systematic reviews which may already be quite lengthy, the lack of endorsement of the STRICTA reporting guidelines may be an additional explanation for the suboptimal external validity: currently few journals have endorsed the STRICTA guidelines and even fewer have made these mandatory requirements for publication (Hopewell, Altman, Moher, & Schulz, 2008).

As an official extension of the Consolidated Standards of Reporting Trials (CONSORT), STRICTA is mainly designed for clinical trials to improve the completeness of intervention reporting, however it is also useful for authors of systematic reviews (Prady & MacPherson, 2007). Systematic reviews that include complete detail on the STRICTA items could furnish researchers with a reasonable and transparent interpretation for clinical heterogeneity, and provide health professionals with greater confidence when using the related evidence in their routine practice. Furthermore, it may also facilitate the development of criteria for

assessing the adequacy of acupuncture where there is little agreement (MacPherson *et al*., 2002a); indeed, this might be the very reason for the limited acupuncture adequacy assessment conducted in the included systematic reviews (4/16). Investigators undertaking future systematic reviews and trial studies are strongly encouraged to apply and adhere to the STRICTA guidelines, and hence enhance the scientific quality of acupuncture research. In order to address this issue further, the next chapter explores the STRICTA guidelines from various aspects, and presents a critical review on strategies for improving the efficacy of the STRICTA.

2.4.4 Strengths of this overview

Efforts have been made to minimize the risk of bias in every step of this overview. Firstly, for literature identification, systematic, comprehensive, and independent search strategies were used over a wide range of English and Chinese electronic databases, without restriction of language and year of publication. Secondly, for quality assessment, two independent reviewers (LL and LM) with diverse academic backgrounds were engaged. LL and LM have participated in Cochrane training for systematic reviews. In this overview, they used the AMSTAR checklist with added quantitative rating criteria to assess validity of the included systematic reviews, and the interrater agreement was excellent. Thirdly, for data synthesis, subgroup analysis (stratified by LBP chronicity, control comparisons, and outcome measures) was performed to address the influence of heterogeneity. Fourthly, for conclusion generation, results from systematic reviews with formal analysis methodology were synthesized to guarantee reliability of the conclusions, and sensitivity analysis was performed to test scientific robustness. Finally, for evidence applicability, outcomes of clinical (as well as statistical) relevance were considered to increase clinical applicability.

2.4.5 Implications for practice and research

For acute LBP, no firm conclusions regarding the effectiveness of acupuncture could be made on the basis of only two systematic reviews, and thus there is a need for future research to make more definitive recommendations. For chronic LBP, consistent evidence showed that acupuncture is more effective for pain relief and functional improvement at short-term follow-ups when compared to no treatment, or when used with other conventional therapies; these results had medium to large clinical effects. According to these findings, it is encouraging to note that acupuncture - either used in isolation or as an adjunct to other interventions - has been demonstrated as an effective clinical option for patients with chronic LBP, and should be advocated in routine clinical practice. Considering the intractable nature of LBP, more effective, comprehensive treatment options, which might include acupuncture, are needed to optimize current management (Xu *et al*., 2013).

Evidence from the overview of systematic reviews suggested that acupuncture is an effective treatment option for patients with chronic low back pain. This included TCM acupuncture and Western medical acupuncture as a whole. As the original type of acupuncture that is still widely used in routine practice, effectiveness of TCM acupuncture should be clarified by future research. In order to improve clinical effectiveness of TCM acupuncture, future research may evaluate the dose response of acupuncture (e.g. number of treatment sessions) in this area. There is a need for future higher quality RCTs and systematic reviews which strictly adhere to relevant guidelines and particularly STRICTA guidelines to improve both internal and external validity. Furthermore, as empirical evidence has indicated that the response of acupuncture is associated with an adequate dose of stimulation (Sjölund, 2005), as for pharmaceutical therapy (Ernst & White, 1998; Ezzo *et al*., 2001), future systematic reviews should assess the adequacy of acupuncture treatment, and consider the results in their conclusions as identified in some of the included reviews (Ernst

& White, 1998; Furlan *et al*., 2005b; Lee *et al*., 2013; Yuan *et al*., 2008). Future systematic reviews should also grade the strength of evidence by adopting accepted instruments such as the Grading of Recommendations Assessment, Development and Evaluation (Guyatt *et al*., 2008) to enable rigorous recommendations to evidence-users. From the available outcomes of the included systematic reviews, some subgroups could not be analyzed; therefore, more research is needed to focus on areas where there is little evidence, for example: acupuncture for acute LBP, acupuncture for other outcome measures besides pain and function, acupuncture in long-term follow-up, and acupuncture compared to conventional therapy.

2.5 Conclusions

The current chapter explored the evidence base of the effectiveness of acupuncture in the management of LBP. Based on seven systematic reviews (two high quality, three moderate quality, and two low quality), acupuncture was more clinically effective in pain relief and functional improvement than no treatment at short-term follow-up. Based on five systematic reviews (one high quality, two moderate quality, and two low quality), acupuncture as an adjunct to conventional therapy provided short-term clinically relevant improvements in pain and functional measures for the treatment of chronic low back pain.

As demonstrated in this chapter, the external validity of acupuncture research is poor. This mirrors the extensive central weakness in research involving acupuncture – the reporting quality is poor, and the applicability of the findings is limited (Kim, Kang, Lee, & Lee, 2014; Purepong, Jitvimonrat, Sitthipornvorakul, Eksakulkla, & Janwantanakul, 2012). Inadequate description of acupuncture intervention impedes results interpretation and further investigation of the essential characteristics of acupuncture for its effectiveness. A progressive step toward addressing this issue is improving the impact of the specific

acupuncture reporting guidelines - the STRICTA guidelines. Accordingly, the next chapter presents a comprehensive evaluation of STRICTA, and highlights potential strategies which may impact positively on the utilization of STRICTA, and ultimately on the quality of reporting on acupuncture research outcomes.

3 A critical evaluation of the development procedure, validity, endorsement, and citation of the STRICTA guidelines

3.1 Introduction

The need for better quality reporting on acupuncture interventions is evident from difficulties associated with result interpretation and research replications (MacPherson *et al*., 2002a). Findings from Chapter 2 provided evidence suggesting the poor reporting of acupuncture details in systematic reviews of low back pain (LBP). These findings were consistent with previous research that demonstrated the suboptimal description of acupuncture components in other clinical diseases, including cancer pain, diabetic peripheral neuropathy, and neck disorders (Chen *et al*., 2012; Chu, Guo, Brian, & Chen, 2014; Lu, Liao, Zeng, & He, 2013).

To investigate a potential way forward to improve on the reporting of acupuncture, improvement in the efficacy of the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines is called for. Prior to implementing any specific strategies, it is reasonable to conduct a systematic evaluation of STRICTA. This chapter therefore sets out a critical review exploring STRICTA from four different aspects (development procedure, validity assessment, endorsement and adherence, and citation situation). The findings inform recommendations for potential approaches for further development of STRICTA, which will consequently positively influence the quality of reporting on acupuncture research.

3.2 Methods and Results

3.2.1 Development of STRICTA

In July 2001, a consensus group of international experts worked on the development of a recommendation entitled *Standards for Reporting Interventions in Controlled Trials of Acupuncture* (STRICTA) to address reporting issues of controlled trials using acupuncture. The experts comprised academic researchers and experienced acupuncturists, as well as editors of five key complementary and alternative medicine (CAM) journals (*Acupuncture in Medicine, Clinical Acupuncture and Oriental Medicine, Complementary Therapies in Medicine*, *Journal of Alternative and Complementary Medicine*, and *Medical Acupuncture*). The STRICTA guidelines were subsequently published in late 2001 and early 2002 (MacPherson *et al*., 2001, 2002a, 2002b, 2002c, 2002d). Acting as an extension of the Consolidated Standards for Reporting Trials (CONSORT) statement (Moher, Schulz, & Altman, 2001), STRICTA were divided into six categories with 19 sub-items to address the specific needs of adequately describing acupuncture interventions: acupuncture rationale, needling details, treatment regimen, co-interventions, practitioner background, and control interventions. It was anticipated by the development team that the full reporting of these items would enhance accurate analysis and interpretation, and ease replication of acupuncture research. To broaden their use internationally the guidelines were subsequently translated into Chinese, Japanese, and Korean.

As with any such standard, the STRICTA guidelines need timely, ongoing review and updating. Six years after the original release of STRICTA, a survey was published to assess the utility of STRICTA among acupuncture trial authors and systematic reviewers (Prady & MacPherson, 2007). This survey recommended STRICTA to be revised to reduce the ambiguity of items. One year later, Prady *et al* explored the possible impact of STRICTA on the reporting of acupuncture interventions. They conducted systematic reviews with before-

and-after approaches to examine whether more STRICTA items were fulfilled in randomized controlled trials (RCTs) over time. Their findings showed that the publication of STRICTA did not have the anticipated impact in the description of acupuncture trials and the reporting quality remained poor (Prady, Richmond, Morton, & MacPherson, 2008). The revision process was initiated in 2008 and involved a collaboration of the STRICTA Group, the CONSORT Group, the Chinese Cochrane Centre, and a range of professionals with specific expertise, including acupuncturists, physicians, academic personnel, and journal editorial board members (MacPherson & Altman, 2009).

Through a multi-staged procedure of expert consultation, consensus workshops, draft editing, and finalization, the revised STRICTA guidelines were agreed upon, and the final document was co-published in 2010 by six medical journals (*Acupuncture in Medicine*, *Australian Journal of Acupuncture and Chinese Medicine*, *Journal of Alternative and Complementary Medicine*, *Journal of Evidence-Based Medicine*, *Medical Acupuncture*, and *PLoS Medicine*) (MacPherson *et al*., 2010a, 2010b, 2010c, 2010d, 2010e, 2010f). As a standalone checklist STRICTA 2010 became an official extension to CONSORT containing six categories with 17 sub-items. In order to minimize misunderstanding and ambiguity, specific explanations were added for each sub-item, and examples of 'good reporting' were included. The updated STRICTA were applicable to a broad range of clinical research, including RCTs (same as STRICTA 2002), uncontrolled studies, and case reports. Furthermore, the standards were also translated into a fourth language, Russian.

3.2.2 Validity of STRICTA

Any reporting guidelines should meet minimum standards for validity including a robust methodology and scientifically validated content (content validity). A large number of reporting guidelines have been developed during the past decade (Simera, Moher, Hoey,

Schulz, & Altman, 2010); however, the quality of these is not always clear: one systematic review evaluated eighty-one reporting guidelines, and noted problems with development, based upon questionable methodologies (Moher, Schulz, Simera, & Altman, 2010). The development approach has not been independently analyzed for STRICTA, as a reporting guidelines. To address this issue, two frameworks suggested by the Enhancing the Quality and Transparency of Health Research (EQUATOR) network ("EQUATOR Network,") were used: (1) *Guidance for Developers of Health Research Reporting Guidelines* (Moher *et al*., 2010) which provided prospective reporting guidelines developers with widely accepted methodologies during the development procedure, and (2) the *Template for Intervention Description and Replication (TIDieR)* (Hoffmann *et al*., 2014), which recommended the minimal essential items for describing an intervention. It was hypothesized that the two frameworks could provide a quantitative assessment for the STRICTA guidelines (2010), on the robustness of the guidelines development process as well as the content integrity.

The STRICTA guidelines 2010 (MacPherson *et al*., 2010f) were used as the primary assessment material for the current review; in addition, the reference list and the official website of STRICTA ("STandards for Reporting Interventions in Controlled Trials of Acupuncture,") were scanned to identify further articles and/or information concerning its development process. As this was an initial evaluation, original authors of the guidelines were not contacted to determine whether missing items were completed and were available but not reported. The two frameworks (Hoffmann *et al*., 2014; Moher *et al*., 2010) were converted into two validity assessment checklists. Items were closely aligned with the original recommendations, and the answers could be simply given as ‘Yes’ or ‘No’. Prior to assessment, each topic on the checklists was intensively discussed to achieve consensus on interpretation; two reviewers (Lizhou Liu (LL) and Priya Kannan (PK)) then independently rated the validity of the STRICTA. The inter-rater reliability was calculated using the kappa

statistic; disagreements were resolved by discussion, and an independent decision was obtained from a third author (George David Baxter (GDB)) when disagreement persisted.

Four relevant papers (MacPherson & Altman, 2009; MacPherson *et al*., 2010f; Prady & MacPherson, 2007; Prady *et al*., 2008) plus the STRICTA website were identified and served as primary source for assessment. Agreement of the reviewers for the two checklists was regarded as excellent for independent reviews, with a kappa index of 0.785 for the development process and 0.873 for the content integrity. After discussion the reviewers reached consensus giving a kappa index of 1. Table 3.1 and Table 3.2 present the assessment results. For the two checklists, the STRICTA guidelines (2010) satisfied over half of the items (11/18 for the guidelines development process, and 8/12 for the content integrity). While the STRICTA group publicized details regarding the development procedures for the initial steps, the post-meeting and the post-publication activities, details on the transparency of the pre-meeting activities and the face-to-face consensus meeting were mostly not disclosed. As for the content validity of the STRICTA 2010, four missing items revealed room for improvement, namely Item 6: delivery modes description; Item 10: intervention modifications explanation; Item 11: planned intervention fidelity assessment; and Item 12: actual results.

Table 3.1. Validity assessment of the STRICTA 2010 on reporting guidelines development process*

Step	Item No.	Item	Satisfaction of STRICTA 2010
Initial steps	1	Identify the need for a guideline	Yes
	2	Review the literature	Yes
	3	Obtain funding for the guideline initiative	Yes
Pre-meeting activities	4	Identify participants	Yes
	5	Conduct a Delphi exercise	No
	6	Generate a list of items for consideration at the face-to-face meeting	No
	7	Prepare for the face-to-face meeting	No
Face-to-face consensus meeting itself	8	Present and discuss results of pre-meeting activities and relevant evidence	No
Post-meeting activities	9	Develop the guidance statement	Yes
	10	Develop an explanatory document (E&E)	Yes
	11	Develop a publication strategy	Yes
Post-publication activities	12	Seek and deal with feedback and criticism	Yes
	13	Encourage guideline endorsement	Yes
	14	Support adherence to the guideline	No
	15	Evaluate the impact of the reporting guidance	No
	16	Develop Web site	Yes
	17	Translate guideline	Yes
	18	Update guideline	No

Abbreviations: STRICTA, Standards for Reporting Interventions in Clinical Trials of Acupuncture; E&E, explanation and elaboration.

*** Structured according to the EQUATOR *Guidance for Developers of Health Research Reporting Guidelines* (Moher *et al*., 2010).**

Table 3.2. Validity assessment of the STRICTA 2010 on content integrity※

Item No.	Item	Satisfaction of STRICTA 2010
1	Brief name Provide the name or a phrase that describes the intervention	Yes
2	Why Describe any rationale, theory, or goal of the elements essential to the intervention	Yes
3	What (materials) Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)	Yes
4	What (procedures) Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities	Yes
5	Who provided For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given	Yes
6	How Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	No
7	Where Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features	Yes
8	When and how much Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose	Yes
9	Tailoring If the intervention was planned to be personalized, titrated or adapted, then describe what, why, when, and how	Yes
10[a]	Modifications If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)	No
11	How well (planned) If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them	No
12[a]	How well (actual) If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	No

Abbreviation: STRICTA, Standards for Reporting Interventions in Clinical Trials of Acupuncture.
※Structured according to the *Template for Intervention Description and Replication (TIDieR)* (Hoffmann *et al*., 2014).
[a] Not applicable to a protocol.

3.2.3 Endorsement and adherence to STRICTA

In accordance with the official website of the STRICTA Guidelines, nine international medical journals endorse the STRICTA (2010), including seven CAM specialties and two general medicine journals ("STRICTA Participating Journals,"). In order to investigate adherence to STRICTA, '*Instructions to authors*' on the websites of those journals were scanned, and relevant information was extracted. In addition, in order to examine the awareness of reporting guidelines of those journals, where there was mention of other research reporting guidelines and/or the EQUATOR network was also extracted.

Of the nine journals, six mentioned STRICTA in the online version of '*Instructions to authors*' (Table 3.3). However, the majority of journals (n= 5) did not make it an explicit requirement to use STRICTA for potential manuscripts. Only one journal, *Medical Acupuncture*, enforced strict use of the checklist as a compulsory requirement for article submission. It elaborated on the need to adhere to STRICTA throughout the process of manuscript preparation, including appropriate sequencing of the STRICTA items to follow, and the six STRICTA categories required in the methodology section. In regard to referencing, the majority of journals (n= 5) referred to the current STRICTA website, but one referred to a URL currently inaccessible. Two journals included the full STRICTA (2010) guidelines (one of which was via the STRICTA website). The EQUATOR network was referenced by only two of the endorsing journals, and other relevant reporting guidelines (e.g. CONSORT, Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), and Standards for Reporting of Diagnostic Accuracy (STARD)) were also recommended for use by six journals.

Table 3.3. 'Instructions to authors' of journals that endorsed STRICTA

Journal	Mention of STRICTA	Specific requirement of STRICTA (quote)	STRICTA website link	Appropriate reference	Mention of EQUATOR	Other reporting guidelines
Acupuncture in Medicine	Yes	*All acupuncture treatment should be described according to the current STRICTA recommendations*	No[2]	Yes	Yes	CONSORT, PRISMA, MOOSE, STROBE, STARD, SQUIRE
Australian Journal of Acupuncture and Chinese Medicine	Yes	*The reporting of acupuncture treatment needs to follow STRICTA guidelines*	Yes[3]	NR	No	CONSORT, QUOROM
Deutsche Zeitschrift für Akupunktur[1]	Yes	*For better reporting of acupuncture trial interventions, please adhere to STRICTA*	Yes	NR	No	No
Journal of Alternative and Complementary Medicine	Yes	*For controlled trials of acupuncture, use our preferred reporting criteria based on the STRICTA guidelines*	Yes	No[4]	No	CONSORT
Journal of Integrative Medicine	No	NR	No	NR	No	CONSORT, PRISMA
Journal of Evidence-Based Medicine	Yes	*All acupuncture treatment should be described according to the current STRICTA recommendations*	Yes	Yes	No	CONSORT, PRISMA
Korean Journal of Acupuncture	No	NR	No	NR	No	No
Medical Acupuncture	Yes	*All papers must adhere to the new STRICTA 2010 requirements*	Yes	NR	No	No
PLoS Medicine	No	NR	No	NR	Yes	CONSORT, PRISMA, STARD, STROBE, MIBBI, MIAME, ARRIVE

[1] German Journal of Acupuncture and Related Techniques; [2] but provides hyperlink to the STRICTA checklist; [3] but provides an inaccessible URL; [4] inappropriate title
Abbreviations: NA, not reported; STRICTA, Standards for Reporting Interventions in Clinical Trials of Acupuncture; EQUATOR, Enhancing the Quality and Transparency of Health Research; CONSORT, Consolidated Standards of Reporting Trials; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; MOOSE, Meta-analysis of Observational Studies in Epidemiology; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology; STARD, Standards for Reporting of Diagnostic Accuracy; SQUIRE, Standards for Quality Improvement Reporting Excellence; QUOROM, Quality of Reporting of Meta-analyses; MIAME, Minimum Information About a Microarray Experiment; MIBBI, Minimum Information for Biological and Biomedical Investigations; ARRIVE, Animal Research: Reporting In Vivo Experiments.

The availability of reporting guidelines by itself is not sufficient to drive improvements in the completeness of reporting: journal practices clearly have a major role to play (Altman, Simera, Hoey, Moher, & Schulz, 2008; Simera *et al*., 2010). However, the extent to which journals endorse and adhere to reporting guidelines seems to vary widely (McLeroy, Northridge, Balcazar, Greenberg, & Landers, 2012). The most well-known reporting guidelines, CONSORT, has been adopted by 585 biomedical journals, and empirical evidence supports the view that the implementation of CONSORT has been associated with improved reporting of randomized trials (Plint *et al*., 2006; Prady *et al*., 2008). This has been achieved over an extensive period of nearly two decades (CONSORT was initially introduced in 1996). Given such timescales in the uptake of reporting guidelines by journals, sufficient time should be allowed prior to assessing the level of awareness of any new guidelines such as STRICTA (Kim *et al.*, 2014). There might be intrinsic challenges for STRICTA to obtain a degree of support comparable to CONSORT, as it is a 'specialty-specific' reporting guidelines not applicable for all journals; this notwithstanding, it follows that more stringent enforcement of STRICTA within the endorsed journals is more likely to yield the benefits for which it was intended.

3.2.4 Citation of STRICTA

As fifteen years have elapsed since STRICTA was first published, it is timely to examine the utilization and potential impacts of STRICTA.

Although it is possible to measure the impact of STRICTA in numerous ways, perhaps the most logical (if novel) approach is examination of citations for STRICTA. Furthermore a broad search of the literature has shown that previous reviews of STRICTA have been limited to English-language papers (and papers published in English) (Prady *et al*., 2008). Therefore, it was worthwhile to conduct a comprehensive evaluation of the application of STRICTA in

relevant articles in three publication languages - English, Chinese, and Japanese. The latter two are considered representative of the main acupuncture research in Asian countries.

Citations for STRICTA 2002 and STRICTA 2010 were searched from 2002 up to May 2016. Cited Reference Search and/or Citation Tracker (slight differences in different databases) were used for two English databases (Web of Science and Scopus), one Chinese database (China National Knowledge Infrastructure) and one Japanese database (Japan Science and Technology Information Aggregator, Electronic). For literature in English, full titles of publications were used as search terms. Due to potential limitations on the dissemination of the English STRICTA in non-English speaking countries, the key word and/or the topic of 'STRICTA' were used as additional search terms in both Chinese and Japanese databases. Two standardized spreadsheets were used to record the basic characteristics of articles regarding the publication year, study type, and the journal type (general medical non-CAM journals, specialty medical non-CAM journals, CAM journals with STRICTA endorsement, and CAM journals without STRICTA endorsement) (Prady *et al*., 2008).The annual STRICTA citation counts were calculated, including those relating exclusively to RCTs and related studies (e.g. protocols) for which STRICTA was initially designed. Line plots were set up to investigate the possible changes in citations over time. Linear regression (the Spearman's rank correlation) was used to identify the potential predictors of citation counts, i.e. the language of publication, and the year of publication.

The search strategy resulted in the identification of 567 articles that cited STRICTA 2002 and 491 that cited STRICTA 2010, and a further 118 articles in Chinese and 11 in Japanese that mentioned STRICTA as either a key word or topic. After excluding duplicates and those outside of the study limitations, a total of 657 papers were eligible for inclusion. The main characteristics of the articles are displayed in Appendixes 3 and 4.

Overall citation counts increased over time. For the STRICTA guidelines 2002, the two English databases demonstrated growing citation numbers until the revised STRICTA guidelines were published in 2010: it grew steadily from two citations in 2002 to 40 citations in 2008, but plateaued over the next two years (Figure 3.1). In the context of citations in RCTs, this similarly increased with some oscillation from 2005 (three years after the initial introduction); however, the counts were low (maximum of 11 citations in 2009) (Figure 3.2). For the STRICTA guidelines 2010, continuing citation was found for both RCTs and papers of other study types published in English (Figures 3.3 and 3.4). By contrast, in the Chinese literature there were fewer citations. Although there were small increases (with some small variation), few authors referred to the STRICTA guidelines in their publications: until May 2016, STRICTA 2002 was cited in total only 24 times and the STRICTA 2010 33 times; only eight such RCTs have cited STRICTA over the past fifteen years. For citation in Japanese articles, STRICTA 2002 and STRICTA 2010 were barely cited: seven articles cited the STRICTA guidelines 2002 (published in the years 2002, 2005, 2008, 2010, 2013 and 2014, respectively), and only one RCT article (2012) cited the revised STRICTA 2010. Results of linear regression suggested that the date of publication (due to incomplete data in 2016, analysis was limited to the end of 2015) was a significant predictor of increasing citation counts for STRICTA guidelines 2010 in English literature (R^2= 0.831).

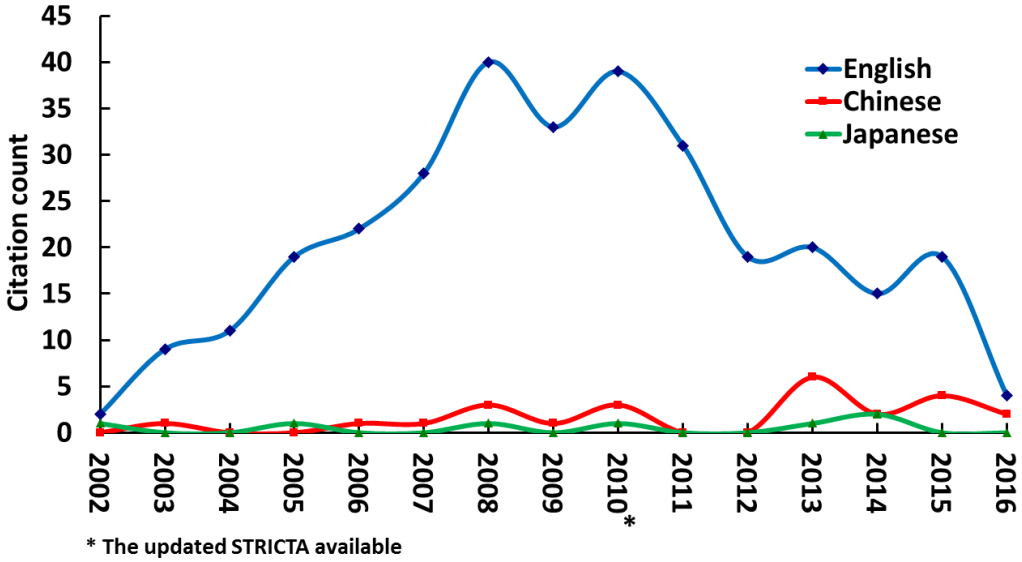

Figure 3.1. Citation of STRICTA 2002 in all studies
Abbreviation: Standards for Reporting Interventions in Controlled Trials of Acupuncture.

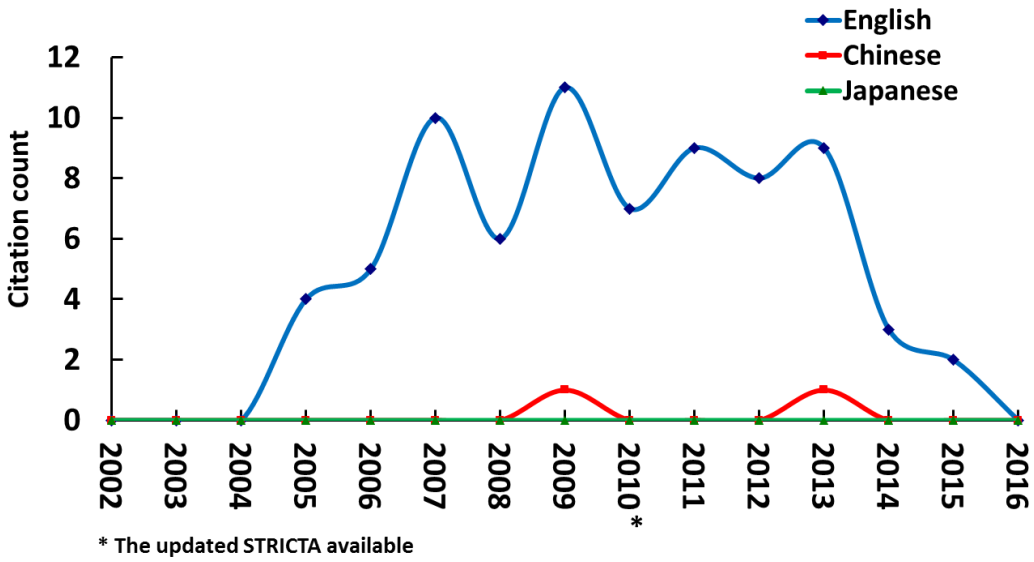

Figure 3.2. Citation of STRICTA 2002 in RCTs
Abbreviation: Standards for Reporting Interventions in Controlled Trials of Acupuncture.

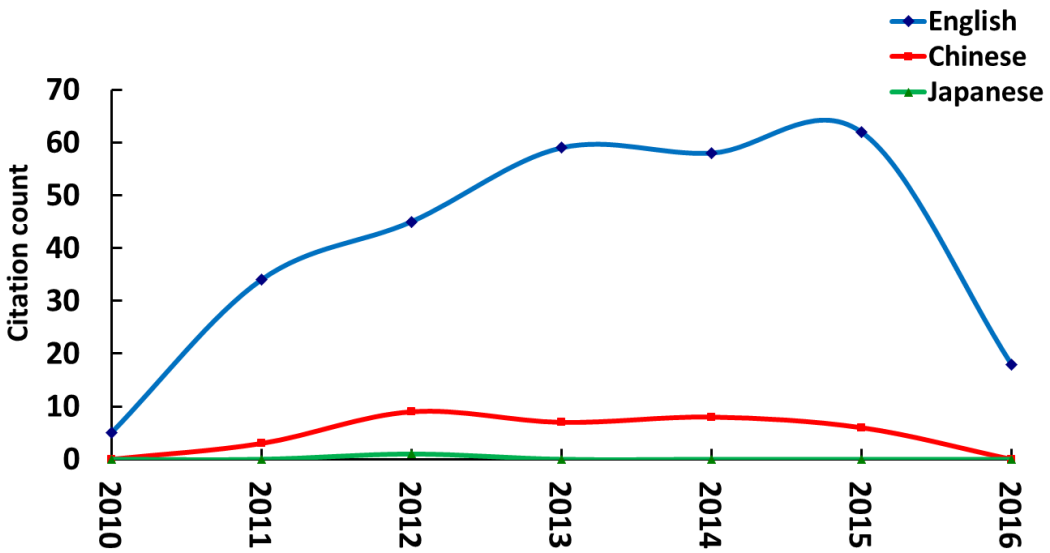

Figure 3.3. Citation of STRICTA 2010 in all studies
Abbreviation: Standards for Reporting Interventions in Clinical Trials of Acupuncture.

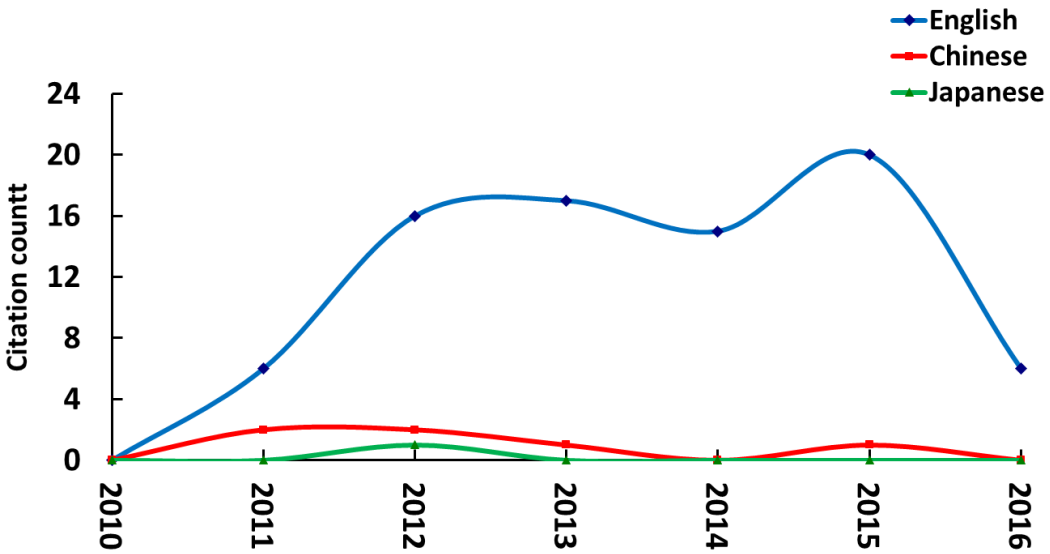

Figure 3.4. Citation of STRICTA 2010 in RCTs
Abbreviation: Standards for Reporting Interventions in Clinical Trials of Acupuncture.

With regard to journal of publication, authors citing STRICTA 2002 preferred publishing the articles in non-CAM specialty medical journals in the English language, whilst those published in Chinese and Japanese languages were in the CAM journals without STRICTA endorsement (Figure 3.5). In contrast, for STRICTA 2010, the most frequently cited were

those published in the CAM journals without STRICTA endorsement for both English and Chinese languages (Figure 3.6).

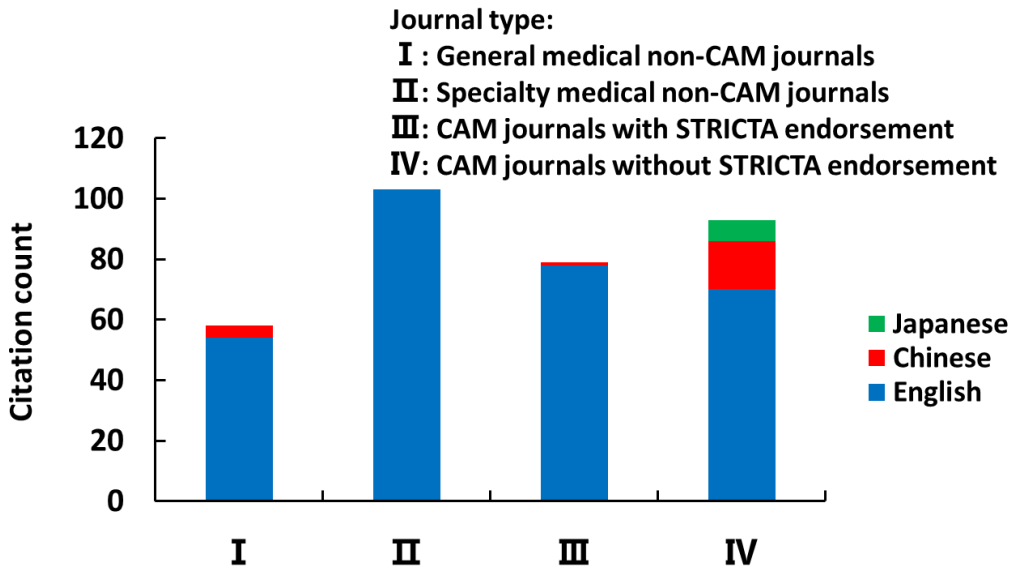

Figure 3.5. Journal of publication for articles citing STRICTA 2002
Abbreviation: Standards for Reporting Interventions in Controlled Trials of Acupuncture.

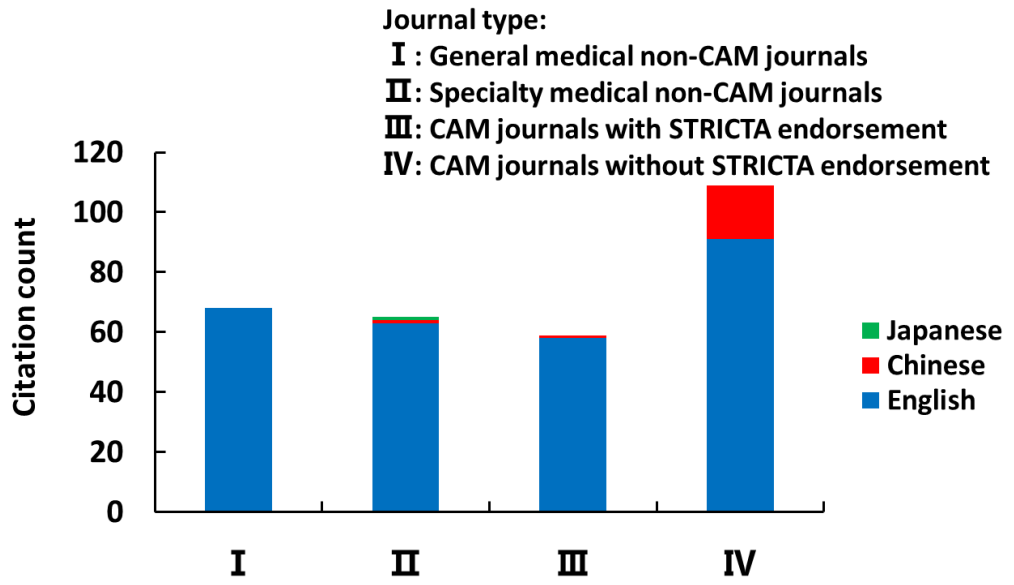

Figure 3.6. Journal of publication for articles citing STRICTA 2010
Abbreviation: Standards for Reporting Interventions in Clinical Trials of Acupuncture.

3.2.5 Implications for STRICTA

Since the first systematic review which examined the impact of STRICTA on the reporting quality of acupuncture trials (Prady *et al*., 2008), subsequent evaluations have drawn similar

conclusions: it appears that STRICTA (2002 and 2010) has not improved the quality of reporting to the degree anticipated, thus descriptions of the acupuncture specific aspects of publications remain suboptimal (Chen *et al*., 2012; Chu *et al*., 2014; Lu *et al*., 2013). Although a small increase (17%) in reporting quality was revealed by another review using a combined CONSORT and STRICTA assessment instrument (Hammerschlag *et al*., 2011), the reporting of practitioner background (e.g. training, experience and expertise) is extremely poor, and there continues to be a need for improvement in reporting on the details of acupuncture trials (Hammerschlag *et al*., 2011; Prady *et al*., 2008). Besides potential lack of awareness of the guidelines based on the limited numbers found in the database searches (Prady *et al*., 2008), it is possible that dissemination of the STRICTA guidelines was a limiting factor in itself, though it is acknowledged that the means of dissemination are clearly outlined on the web site.

In regard to potential for improvements with respect to the dissemination and use of STRICTA (2010) the following concepts could be considered. Firstly, it may be beneficial to update the STRICTA checklist. As an official extension of the CONSORT statement 2010 (item 5), the content integrity of the STRICTA guidelines may be improved by embedding all the items suggested by the TIDieR guidelines (which specify a minimum set of items to describe an intervention) in the checklist. For the STRICTA to remain credible it may be helpful to collaborate with the TIDieR group, and to refer to the other relevant reporting guidelines in the EQUATOR network. The revision process might also benefit from solicitation of a wider range of expert opinions. It was argued by Chinese scholars that several Traditional Chinese Medicine (TCM) characteristics of acupuncture (e.g. syndrome differentiations, treatment opportunities, and disease stages) have not been clearly articulated in STRICTA (Liu *et al*., 2013). Furthermore, it is also suggested that items concerning the standards and precision of acupoint localizations, the angle and direction of needle insertion, and the acupuncture

experiences of participants are included in any future revision of STRICTA (Bian & Chang, 2011; Dorsher, 2009; Liu *et al*., 2013). Moreover, it is suggested the updated STRICTA checklist be standardized with the current format and any modifications or additions clearly highlighted.

A second strategy may be to improve the efficiency of reporting by using a flowchart. As print journals have limitations on manuscript length, full reporting of all intervention details within one primary paper is almost impossible, especially when the study protocols or relevant papers have not been previously published. Although hosting the specific components in relevant websites may seem to be a rational solution, there are inherent risks such as resourcing, and responsibility for maintaining the website. Such problems were revealed in a recent review which evaluated the description of non-pharmacological interventions in randomized trials (Hoffmann, Erueti, & Glasziou, 2013). A more fruitful approach might be to provide a graphical representation instead of text descriptions of the details of the interventions. This might be based on a flowchart with squares and circles which represent the objects and activities of each treatment arms in specific columns; below the flowchart, a legend could provide brief instructions of each components, including forms, contents, functions, and details of the intervention providers (Perera, Heneghan, & Yudkin, 2007). Such an approach may clarify the majority of components (except for the rationale of interventions) required by the STRICTA checklist. In addition, it may have advantages and encourage the more rigorous use of guidelines including: providing a better description of the interventions, decreasing manuscript word count, promoting an easier understanding of the trial structures, and helping with the design and conduct of acupuncture research at the early stage (Narahari, Ryan, Aggithaya, Bose, & Prasanna, 2008).

Thirdly, there is potential for journals that endorse STRICTA to be more consistent with their requirements for authors to adhere to the guidelines. The benefits of reporting in accordance with the guidelines, and in publications that use the guidelines was reinforced by Hopewell *et al* (Hopewell *et al*., 2008) in their review of the CONSORT statement. Likewise for STRICTA, more consistent enforcement of adherence to the guidelines is advocated. There continues to be a need for complete descriptions in clinical trials of acupuncture. Thus it may be advantageous for the STRICTA group to develop an official statement with a clear message relating to adherence requirements. One possible way forward would be to request authors to comply with reporting on specific details and submit a completed STRICTA checklist as a requirement for consideration for publication (Hopewell *et al*., 2008; Mills, Wu, Gagnier, Heels-Ansdell, & Montori, 2005). This may be assisted in the future by using web-based technologies that allow automated text identification for essential elements (Shamseer, Galipeau, Turner, & Moher, 2013). It is suggested that the statement is included in the published '*Instructions to authors*' for the relevant journal. In addition, an appropriate reference to the STRICTA guidelines and an accessible URL of the STRICTA web site, included as part of author support resources, would also be expected to be provided by the journal. As it is argued by some that reviewers and editors unfamiliar with STRICTA may be responsible for the missing details relating to acupuncture in the final publications (Prady & MacPherson, 2007), health related journals would need to ensure their editorial staff enforce adherence to STRICTA, and incorporate the checklist into the peer-review and editorial processes. In addition, journals may consider providing editorials to encourage use, the positive impacts of which have been demonstrated by the greater degree of CONSORT implementation (Mills *et al*., 2005; Mills, Wu, Gagnier, & Devereaux, 2005).

Although STRICTA is designed mainly for clinical trials, it may also be usefully applied to systematic reviews. The reporting quality of RCTs has been shown to be better than that of

systematic reviews (Glasziou, Meats, Heneghan, & Shepperd, 2008), and for Cochrane reviews of acupuncture, the reporting of treatment details has been noted to be inadequate (Kim *et al*., 2014). As few reviews recommend appropriate treatment regimen(s) to be used in routine practice, practitioners in such cases are unable to use the related evidence to inform their treatments (Glasziou *et al*., 2008). Thus, it may be beneficial for journals to widen the use of STRICTA to acupuncture reviews, which would improve the applicability and utilization of review results in future research and clinical practice.

Fourthly, as there is evidence of a lack of consistency of endorsement among journals not published in the English language, it may be beneficial to implement a strategy where the STRICTA are more strictly endorsed in non-English speaking countries. Findings of this critical review showed growing levels of uptakes of STRICTA in the English literature, but the citations of STRICTA in Asian articles, such as Chinese and Japanese, appeared inconsistent and remain low. It seems that other strategies besides simply providing STRICTA translations are worthy of consideration. As there is a large amount of acupuncture research undertaken in non-English-speaking countries, for example in China, Japan, Korea, and Germany, it may be feasible to develop a global network of STRICTA research centers. Possible missions of these centers would be to organize regular education and training workshops or seminars (including webinars) which concentrate on the efficient use of the STRICTA guidelines and good research reporting practices, seek users' feedback, handle criticism from relevant stakeholders, and maximize endorsements and adherence to STRICTA in local journals.

Fifthly, consideration could be given to updating and expanding the STRICTA website. Findings showed that details on key elements of the development procedure of the STRICTA guidelines, such as the pre-meeting activities and the face-to-face consensus meeting, is not publicly available (or is hard to locate). This finding concurred with the previous systematic

review by Moher *et al* in which the authors noted the problems of non-transparent processes for the development of, and reporting on, guidelines (Moher *et al*., 2011). It may be possible to provide relevant data on development of STRICTA on the web site, and append this address in articles on the guidelines. Beyond this, related papers that have evaluated the reporting quality of the acupuncture studies could be included on the web site, to inform the impact of STRICTA, and to help to maintain it. It is expected that such evaluations could be undertaken collaboratively by different research parties including authors, editors, publishers and funders. This may reduce the risk of bias in self-evaluations, and also provide a better opportunity for broader support (Simera, Altman, Moher, Schulz, & Hoey, 2008). It may also be useful to include a 'News' section on the website concerning any new issues related to the guidelines such as plans for updates, and perhaps the STRICTA centers, if possible.

Finally, it is recommended to provide the linkage to the EQUATOR network ("EQUATOR Network,"), a repository for good reporting guidelines for health research, on the STRICTA web site. This will improve the general standards of reporting of research within the field of acupuncture.

3.3 Discussion

A complete description of complex interventions is challenging (Hoffmann *et al*., 2014); the process of treatment such as specific regimens and description of the necessary materials, are often missing from such descriptions (Glasziou *et al*., 2008). Problems with inadequate reporting have led to the creation of several reporting guidelines, including STRICTA and those in other areas such as homeopathy, yoga, and moxibustion (Cheng *et al*., 2013; Dean, Coulter, Fisher, Jobst, & Walach, 2007; Sherman, 2012). Although it is encouraging to note that the development of these reporting guidelines may be one valuable step towards the

enhancement of reporting quality and research reliability, it is only a first step. Given the low utilization, and consequently the limited impact, of these guidelines, specific implementation strategies are necessary to remedy this situation.

The reporting quality of the interventions in clinical trials of acupuncture will only be improved by wide dissemination and strict adherence to the STRICTA guidelines. Beyond the current implementation measures such as co-publications and translations into other languages, more effort is needed to disseminate and promote the more widespread use of STRICTA. All stakeholders (i.e. researchers, journal publishers, funding organizations, policy regulators) should take a shared responsibility to collaborate to implement STRICTA to a greater extent. This will, in turn, ensure the quality of reports of acupuncture studies is improved, thus assisting the potential for research results to be efficiently translated into clinical practice. As there is a lack of funding for developing reporting guidelines (Simera *et al*., 2008), health research funding organizations are appealed to emphasize the importance of STRICTA, and ensure dedicated funding to support its revision and maintenance on a routine basis in future. Such support is believed to influence reporting quality and, therefore, the subsequent impact, of future acupuncture research.

It may be argued by some that if the reporting guidelines themselves are deficient, this would undermine their impact on improvement in scientific quality and thus the benefits to clinical practice. However, it may also be argued that improvements in the reporting guidelines are based on their wide utilization and exposure to critical appraisal. Continual improvement in the quality of reporting related to particular treatment interventions will also benefit clinical practice and drive research further forward.

As yet there are no formal tools to assess the validity of the reporting guidelines; the *Guidance for Developers of Health Research Reporting Guidelines* (Moher *et al*., 2010) and the *TIDieR* (Hoffmann *et al*., 2014) are designed to inform the development of reporting guidelines. In this review, the original format of the *TIDieR* was used, and the 18 primary items of the *Guidance for Developers of Health Research Reporting Guidelines* were kept. The two validity checklists are helpful but do have limitations, as some items are optional and there are no weighting criteria of individual items. Hence, in order to reduce bias, more researchers are called for to participate in the evaluation, provide critical appraisements, and help with the optimization of the STRICTA guidelines.

3.4 Conclusion

The current chapter aimed to identify and discuss potential approaches to enhance the reporting quality of acupuncture research by improving the efficacy of the STRICTA guidelines. Findings of the systematic evaluation of STRICTA concluded that STRICTA is valid reporting guidelines based on robust methodology and scientific content. However, specific implementation strategies are needed for further development of STRICTA, including: updating the STRICTA checklist; improving the STRICTA reporting efficiency; implementing the 'Instructions to authors' for journals consistently; establishing global STRICTA research centers; and expanding the STRICTA website. Such strategies may serve to improve the STRICTA utilization and impact positively on the quality of reporting on acupuncture research outcomes.

This chapter, together with the previous chapter (Chapter 2) completes the development phase of this thesis. The next phase in the research process is feasibility testing (see Chapter 1, Figure 1.4) (Craig *et al*., 2008). Findings from Chapter 2 supported the use of acupuncture for patients with chronic LBP, and encouraged investigation of the essential characteristics

of acupuncture for its effectiveness. Few clinical trials have evaluated the dose dependence of acupuncture for chronic LBP based on the number of sessions, and reported conflicting conclusions. In order to address this, the following two chapters (Chapters 4 and 5) describe a randomized controlled feasibility study investigating the optimal number of treatment sessions of acupuncture in addition to usual care for patients with chronic LBP. To ensure a high external validity, details of acupuncture intervention are described in adherence to the STRICTA guidelines (MacPherson *et al.*, 2010b). Outcomes of this feasibility study will inform the decision to conduct a full-scale trial to definitively test the dose dependence of acupuncture.

4 Dose of Traditional Chinese Medicine acupuncture in addition to usual care for adults with chronic low back pain: Introduction and method of a randomized controlled feasibility study

4.1 Introduction

A feasibility study involves preliminary work on a concept carried out prior to developing a fully powered definitive trial. These are used to test the rationale for and method proposed for use in the main study (e.g. recruitment process, randomization willingness, intervention acceptance, retention rate, outcome measure reliability, and follow-up rate) (Arain, Campbell, Cooper, & Lancaster, 2010). As clinical trials are usually costly and time consuming, in recent years there has been an increasing emphasis on the importance of conducting feasibility studies (Whitehead, Sully, & Campbell, 2014). This chapter and the chapter that follows describe a randomized controlled feasibility study established to explore the feasibility of the study method. The concept involved randomization to assign adults with chronic low back pain (LBP) to receive different numbers of sessions of Traditional Chinese Medicine (TCM) acupuncture in addition to usual care.

As demonstrated in an overview of systematic reviews in Chapter 2, acupuncture provides short-term clinically relevant benefits for pain relief and functional improvement for chronic LBP. However, existing literature does not differentiate the styles of acupuncture – the term 'acupuncture' suggests a number of different acupuncture styles including TCM, Western, Japanese, Korean, and French. TCM acupuncture is the most widely accepted and used

acupuncture style in routine practice. In order to determine the effectiveness of TCM acupuncture, future research is needed in this area.

To date there exists no credible and accepted guidelines on optimal TCM acupuncture treatment protocols (an elaborate description of the procedures and schedule for a course of acupuncture). As a consequence, treatment regimens are arbitrarily selected on the basis of opinion or clinical experience but not the evidence base. The conclusion of the overview of systematic reviews (Chapter 2) suggested further research is required to explore the essential characteristics of acupuncture for its effectiveness, and to determine the potential relevance of such characteristics in relation to the effectiveness of acupuncture for LBP. Previous research has shown that dosage is as important for the effectiveness of non-pharmacological interventions as it is for pharmacological agents. This is not limited to the application of acupuncture (Ezzo *et al*., 2000) as it has also been demonstrated in reviews of other forms of physiotherapeutic treatments such as laser therapy (Tumilty *et al*., 2010), and transcutaneous electrical nerve stimulation (TENS) (Bjordal, Johnson, & Ljunggreen, 2003). TCM acupuncture has, for the most part, skipped over the necessary earlier stages of research in which the dosage dependency is thoroughly exemplified (White *et al*., 2008); therefore suggesting that further exploration of dose-response relationship of TCM acupuncture treatment might be a research area worthy of further exploration and which may add an important contribution to clinical guidance.

The few randomized controlled trials (RCTs) that have investigated the dose dependency of TCM acupuncture for chronic LBP have tended to focus on the role of the frequency of sessions (Yuan *et al*., 2009), and the intensity of stimulation (Thomas & Lundberg, 1994). A pilot RCT that examined the effects of different session numbers of TCM acupuncture on clinical outcomes in patients with chronic LBP found that 10 sessions of acupuncture lead to

lower pain intensity than 5 sessions (Ceccherelli, Gagliardi, Barbagli, & Caravello, 2003). The findings were inconsistent with a previous study that demonstrated the benefits of acupuncture in health status tailed off after seven treatment sessions (MacPherson & Fitter, 1998), and also with the secondary findings of a pilot RCT comparing frequency of TCM acupuncture treatments, which indicated that four sessions were as effective as 10 sessions (Yuan *et al*., 2009). A recent Individual Patient Meta-analysis of 17,922 patients with chronic pain (back and neck pain, headache, shoulder pain, and osteoarthritis) demonstrated that better pain outcomes were associated with more treatment sessions when comparing acupuncture to non-acupuncture controls, including waiting list and usual care (MacPherson *et al*., 2013). However, the evidence for an optimal number of TCM acupuncture treatment sessions for chronic LBP was not clear, and it could not be assumed that outcomes would be the same as for chronic pain in other body regions as benefits of TCM acupuncture may be condition specific.

To relieve pain and maintain the effectiveness of acupuncture in clinical practice, successive sessions of acupuncture treatments are necessary (Gao *et al*., 2014). According to previous studies, a minimum of six sessions of TCM acupuncture is optimal for chronic LBP (Molsberger, Zhou, Arndt, & Teske, 2008; Sherman, Hogeboom, & Cherkin, 2001), and six to ten treatment sessions is the number generally reported by textbooks and clinical studies as well as in clinical practice (Yuan, Kerr, Park, Liu, & McDonough, 2008). The paucity of high quality evidence to support the cumulative effects of repeated TCM acupuncture interventions together with the effect of each treatment suggests the outcomes need further investigation.

Thus far, several experimental studies have shown that successive courses of TCM acupuncture (with electrical stimulation) induced a cumulative analgesic effect in chronic

neuropathic pain in rats (Gao *et al*., 2013; Gao *et al*., 2014; Liu *et al*., 2010). Findings from this cumulative effect suggested 4-5 sessions of TCM acupuncture was optimal when presented a time-dependent manner (Gao *et al*., 2014). As yet no clinical studies have explored the accumulative effects of TCM acupuncture in adults. To address this gap, it was necessary to conduct a RCT to evaluate the outcomes from 4, 7, and 10 sessions of TCM acupuncture applied in addition to usual care in the treatment of chronic LBP in adults. These three session numbers were decided upon previous research where conflicting results were reported. Moreover, an equal increment of the treatment sessions (3 'additional' sessions, ranging from 4 to 10) facilitated an exploration of the accumulative effects of acupuncture. In order to undertake a fully powered definitive RCT, a parallel three arm feasibility study described below was the first step. The specific objectives were as follows:

1) To investigate the recruitment process and retention rate.
2) To assess the follow-up rates and level of missing data for outcome measures.
3) To determine the appropriateness of the outcome measures.
4) To monitor adverse effects and participant satisfaction of TCM acupuncture.
5) To estimate the sample size required to power a full-scale trial.

4.2 Methods

4.2.1 Study design

This was a pragmatic parallel three-armed randomized controlled feasibility study with three-month follow-up. Participants received usual care plus either 4 sessions, 7 sessions, or 10 sessions of TCM acupuncture based on randomized group allocation (see this chapter, section 4.2.5). A flow chart of the study is represented in Figure 4.1. The study was reported in accordance with the *Consolidated Standards of Reporting Trials* (CONSORT) statement for trials of non-pharmacologic treatments (Boutron, Moher, Altman, Schulz, & Ravaud, 2008), and details of acupuncture intervention were described in adherence to the *Standards for*

Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines (MacPherson *et al*., 2010b); details about these were discussed in Chapter 3. This feasibility study was conducted at the Centre for Health, Activity & Rehabilitation Research, School of Physiotherapy, University of Otago. The research centre includes dedicated clinical research suites which have hosted a variety of small-large clinical research projects, including large Health Research Council-funded trials. Ethical approval (Northern B Health and Disability Ethics Committee, 15/NTB/54, refer to Appendix 5), Māori consultation (Ngāi Tahu Research Consultation Committee, refer to Appendix 6) and research locality authorization (University of Otago, refer to Appendix 7) for the trial were completed before participants were recruited. This trial was registered with the Australia New Zealand Clinical Trials Registry (ACTRN12615000534583, refer to Appendix 8).

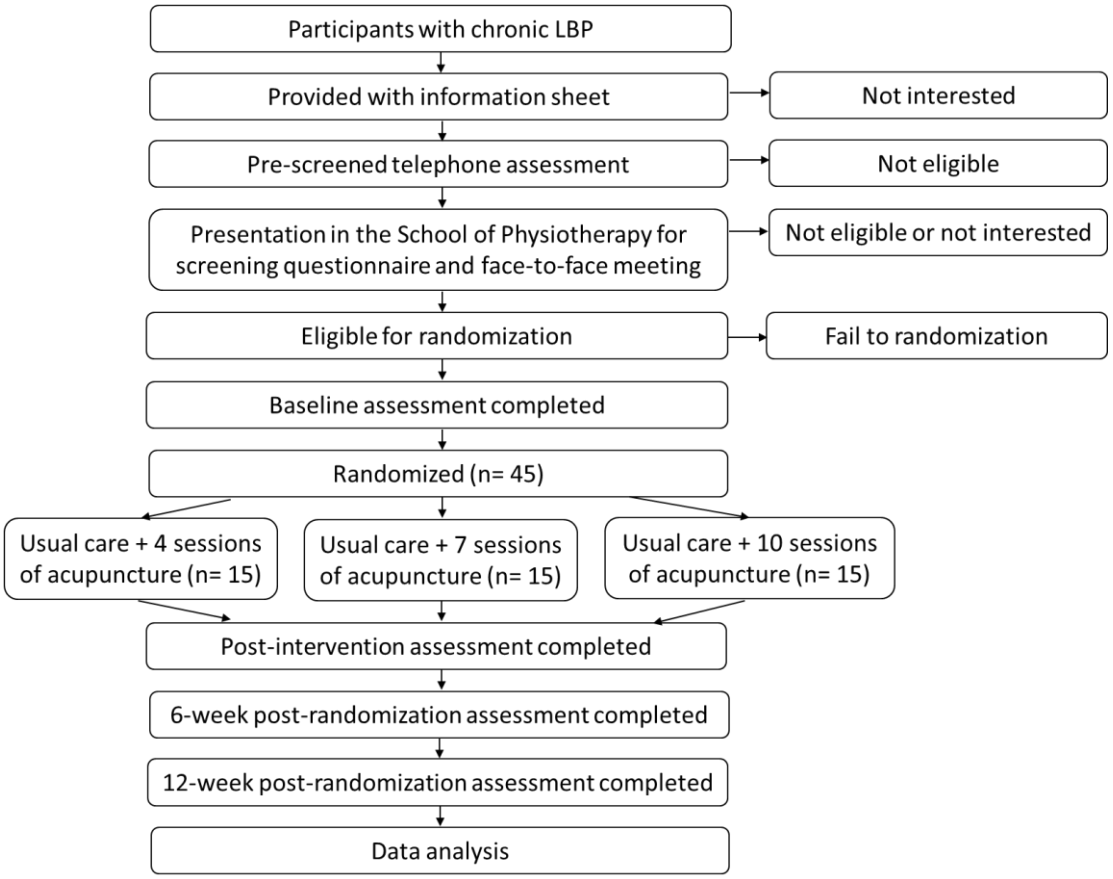

Figure 4.1. Feasibility study: Flow chart of the study protocol
Abbreviation: LBP, low back pain.

4.2.2 Sample size

As this study was a preliminary study to inform the feasibility of a main RCT, no sample size calculation was carried out. Considering the time limitation (over a 24-week period), a sample size of 30 participants was considered appropriate and achievable in accordance with a previous study (Yuan *et al*., 2009). In consultation with a study biostatistician (Andrew Gray (AG)), the potential for withdrawal or incomplete data may be 30%. Thus, 45 participants were recruited for this study, and randomized equally to three intervention arms. This targeted sample size was considered sufficient for evaluating the feasibility of the study method and estimating effect size for changes in secondary outcomes.

4.2.3 Eligibility of participants

Inclusion and exclusion criteria were established, based upon previous research published on acupuncture for chronic LBP (Cherkin *et al*., 2009; Meng *et al*., 2003; Yuan *et al*., 2009). Participants were eligible if they: (1) were 18 years or older; (2) had a history of LBP of more than 3 months in the lumbosacral region (below the 12th costal margin and above the inferior gluteal folds) with or without radiating leg pain (Airaksinen *et al*., 2006); and (3) reported a score of greater than 4 on the Roland-Morris Disability Questionnaire (RDQ) at randomization (Little *et al*., 2008; UK BEAM Trial Team, 2004).

Exclusion criteria included: (1) history of any known serious spinal disorders, including malignancy, neoplasm, infection, congenital spinal deformity, spinal fracture, inflammatory arthritis, spondylolisthesis, ankylosing spondylitis, cauda equina syndrome; (2) history of spinal surgery or currently wait-listed for spinal surgery; (3) previous attendance at a specialised pain clinic or use of morphine (or similar) for LBP in the past 1 year; (4) unresolved litigation or compensation claim; (5) severe psychological disorders or dementia; (6) use of acupuncture for LBP in the past 1 year (Cherkin *et al*., 2009; Hinman *et al*., 2014);

(7) prolonged use of steroids or current use of anti-coagulant medication; (8) any bleeding disorders; (9) fear of needles; (10) history of any systematic medical conditions precluding participation in this trial (e.g. cardiovascular, liver or kidney diseases, deep vein thrombosis, and epilepsy); (11) postpartum, pregnancy or intended pregnancy; (12) unable to communicate in English or Mandarin.

4.2.4 Recruitment process and participant identification

Recruitment of participants was carried out from the beginning of June 2015 for a 24-week period. Participants were recruited from the community in Dunedin, through posting flyers about the study (Appendix 9) around the University of Otago campus, community centres, waiting rooms in medical centres, and in the University's School of Physiotherapy Clinics, as well as advertisements in University staff newsletters and social networking sites as appropriate. The recruitment target was 2 participants per week.

Interested participants were asked to contact the Clinical Research Administrator (Marina Moss (MM)) at the research centre for further information. They were provided with an information sheet (Appendix 10) regarding the study procedure, and consent to be contacted by MM several days later to confirm participation intention. If still interested, they were pre-screened for eligibility by MM via a telephone assessment using the eligibility criteria stated in the information sheet (Appendix 10). If eligible, participants then made the first appointment for a visit to the School of Physiotherapy. At this appointment, the participant met face-to-face with the primary researcher (Lizhou Liu (LL)), and was asked to complete a further screening questionnaire (Appendix 11) to clarify final eligibility for participation. Cross checking by using the questionnaire ensured that the participant did not meet any of the exclusion criteria, checked via the telephone by MM. The rationale of the treatment and any questions from participants were explained in detail by LL before written

informed consent (Appendix 12) was obtained. A full case history of participants (including participants' presenting complaint and complaint history) was taken by LL, and used for guiding acupuncture treatment (e.g. needling sites, and needles numbers). Baseline data were collected prior to randomization.

4.2.5 Randomization

Participants were randomized on a 1:1:1 basis to receive usual care plus either 4 sessions (n= 15), 7 sessions (n= 15), or 10 sessions (n= 15) of TCM acupuncture in the first appointment at the School of Physiotherapy. Prior to participant enrolment, MM prepared a computer-generated random allocation sequence. Allocation was concealed from LL, who determined eligibility of participants for entry in the trial. Eligible participants were randomized into one of the three groups by choosing a sequentially numbered, sealed, opaque envelope.

4.2.6 Blinding

Blinding of the participants and acupuncturist was not possible due to the nature of the intervention. The only blinded personnel in the trial was the Research Assistant (Priya Kannan (PK)), who was independent of the research team and carried out outcome measure data collection at discharge (2 weeks, 3.5 weeks, or 5 weeks after the initial treatment), and at 6 weeks and 12 weeks post randomization. Data entry was conducted by PK after data collection was completed. To ensure blinding of researchers during the process of data analyses, participant ID number and group code (Group A, B, C) were used to remove participant identification.

4.2.7 Interventions

4.2.7.1 Usual care

All participants were advised to continue usual care for chronic LBP during the intervention period. This could include any self-management or pragmatic management (medications, or non-pharmacological therapy e.g. manual therapy) as directed by any health practitioner (e.g. general practitioner, physiotherapist, chiropractor, or osteopath). Data on usual care treatments received by participants were collected at baseline.

4.2.7.2 TCM acupuncture

In addition to usual care as described above, participants received either 4 sessions, 7 sessions, or 10 sessions of TCM acupuncture at the School of Physiotherapy Clinic. Participants were informed of the three groups of acupuncture interventions in the study before treatment started. Treatment was performed by a Chinese-trained acupuncturist (LL) who is registered with the New Zealand Acupuncture Standards Authority and at the time had four year's clinical experience (including internship work) in using acupuncture to treat patients.

The treatment protocol was semi-standardized (fixed needle formula plus flexible points) and followed the Meridian Theory of TCM. The semi-standardized treatment permitted a degree of standardization for the purpose of an RCT. Suggested acupoints were determined on the basis of historical context (Liang, 2006; Lin & Hsu, 2014; Norris, 2001; Shi, 1998), published literature (Cherkin *et al*., 2008; Meng *et al*., 2003; Molsberger *et al*., 2008; Sherman *et al*., 2001; Yuan *et al*., 2008), and the consensus of the research group (by discussion) that included three experienced acupuncturists working at the School of Physiotherapy Clinic. Each participant was treated with a combination of local and distant points, including BL 23 (Shenshu) and BL 25 (Dachangshu), which were needled bilaterally,

low back Ah-shi points, BL 40 (Weizhong), and KI 3 (Taixi) (Table 4.1). Additionally, up to four supplementary acupoints for possible concomitant buttock or leg pain were allowed, which might include BL 36 (Chengfu), BL37 (Yinmen), BL 54 (Zhibian), GB 30 (Huantiao), GB 31 (Fengshi), BL 57 (Chengshan), and/or BL 60 (Kunlun) (Table 4.1).

Table 4.1. Feasibility trial: Range of Traditional Chinese Medicine acupoints used

Acupoints	Location (Pacific., 2008)
BL 23 (Shenshu)*	In the lumbar region, at the same level as the inferior border of the spinous process of the second lumbar vertebra (L2), 1.5 B-cun lateral to the posterior median line
BL 25 (Dachangshu)*	In the lumbar region, at the same level as the inferior border of the spinous process of the fourth lumbar vertebra (L4), 1.5 B-cun lateral to the posterior median line
Low back Ah-shi points	Any tender point in the area below the 12th costal margin and above the inferior gluteal folds (as assessed by acupuncturist)
BL 40 (Weizhong)	On the posterior aspect of the knee, at the midpoint of the popliteal crease
KI 3 (Taixi)	On the posteromedial aspect of the ankle, in the depression between the prominence of the medial malleolus and the calcaneal tendon
BL 36 (Chengfu)	In the buttock region, at the midpoint of the gluteal fold
BL 37 (Yinmen)	On the posterior aspect of the thigh, between the biceps femoris and the semitendinosus muscles, 6 B-cun inferior to the gluteal fold
BL 54 (Zhibian)	In the buttock region, at the same level as the fourth posterior sacral foramen, 3 B-cun lateral to the median sacral crest
GB 30 (Huantiao)	In the buttock region, at the junction of the lateral one third and medial two thirds of the line connecting the prominence of the greater trochanter with the sacral hiatus
GB 31 (Fengshi)	On the lateral aspect of the thigh, in the depression posterior to the iliotibial band where the tip of the middle finger rests, when standing up with the arms hanging alongside the thigh
BL 57 (Chengshan)	On the posterior aspect of the leg, at the connecting point of the calcaneal tendon with the two muscle bellies of the gastrocnemius muscle
BL 60 (Kunlun)	On the posterolateral aspect of the ankle, in the depression between the prominence of the lateral malleolus and the calcaneal tendon

*** Acupoints that were needled bilaterally.**

Treatments were performed twice weekly. Acupuncture was administered with the participant in a prone position on a treatment couch. Sterile filiform, single-use needles (0.25mm x 40mm, 0.30mm x 50mm, and 0.30mm x 75mm, Hwato brand, Suzhou, China) were used to penetrate the skin. The depth of insertion varied slightly, depending on the point location, the participant's age, and response to the needles (shallower insertion for acupoints on lower extremity, aged participants, and quick needling responders, vice versa), but was generally between 1cm and 3cm. Selected acupoints were stimulated manually by gentle rotation of the needles with lift and thrust until the participant achieved a *De qi* sensation, and then every 5 minutes to ensure *De qi* was still present. A maximum of 10 needles was inserted per session and left in place for approximately 20 minutes (between insertion of the last needle and cessation of treatment) (Yuan *et al*., 2008). LL was present throughout the treatment, and monitored the participant's response to acupuncture. Needles were disposed of in a bedside sharps container at the end of treatment. Moxibustion and other interventions (e.g. cupping, scraping, and bloodletting) were excluded from this trial. All costs relevant to the treatment (e.g. acupuncturist consultation, treatment materials and administration) were covered by the funding support (School of Physiotherapy PhD research funding). No monetary reimbursements or incentives to participants were provided.

A treatment log (Appendix 13) for each participant was completed by LL after each acupuncture session. It included date of attendance of the participant, acupoint prescription, and specific notes including any particular details of needling, participant's adherence to the treatment, any adverse effects observed or reported by participant from the previous and/or current session, or reasons for participant withdrawal from treatment. In order to optimize attendance rate of acupuncture interventions, LL reminded participants of the next treatment time at the end of each study visit. The research group met every two

weeks throughout the trial to discuss any treatment-related issues and ensured consensus with the current therapy.

4.2.8 Outcome measures

4.2.8.1 Primary outcomes

The primary outcome measures included the feasibility of the recruitment approaches, participant retention rate, and completion of the outcome measures specific to the trial. Specific items were as follows (Pincus *et al*., 2013):

1) Feasibility of the recruitment process
    i. Number of participants showing interest in joining the trial
    ii. Number of participants completing telephone screening
    iii. Number of participants eligible after completing screening questionnaire
    iv. Number of participants willing to be randomized into the trial from amongst those eligible
    v. Reasons for non-participation and ineligibility
2) Participant retention rate
    i. Number of sessions attended
    ii. Reasons for non-attendance or withdrawal from treatment
    iii. Adherence to treatment protocol (treatment compliance)
3) Feasibility of the measurement tools
    i. Difficulty in questionnaire completion (at all time-points)
    ii. Time taken to complete questionnaires (at all time-points)
    iii. Number of missing items
    iv. Follow-up rates

4.2.8.2 Secondary outcomes

Five recommended core domains of patient-based outcome measures (Bombardier, 2000) were assessed by questionnaires (Appendix 14):

1) Back specific function: The RDQ was used to measure the functional limitations experienced by participants, and the higher the score the more severe the impairment. The RDQ consists of 24 items, each addresses the individual's activity limitations due to LBP (e.g. walking, standing, sitting, bending over, lying down, and other daily activities) (Roland & Morris, 1983). The RDQ is a validated instrument with good construct validity and reliability; besides its simple and quick application, RDQ is suggested to be more sensitive to functional limitations than other assessment tools such as Oswestry Disability Index, in LBP patients with mild to moderate levels of disability (Roland & Fairbank, 2000).
2) Pain: the intensity of pain was measured by the standard 100-mm Visual Analogue Scale (VAS), where *0* represented 'no pain' and *100* was the 'worst pain ever'. VAS as a measurement for pain is widely used in the clinical setting, and has been demonstrated as being reliable, sensitive, and reproducible for expressing pain severity (Scott & Huskisson, 1976). Since the impact of pain may differ widely among participants, it is recommended that the bothersomeness of pain is also assessed (Bombardier, 2000; Schaufele & Boden, 2003). Participants were asked to rate how bothersome their LBP was over the past week on a 0 to 10-cm scale where *0* indicated 'not at all bothersome' and *10* 'extremely bothersome' (Cherkin *et al*., 2008). This measurement has established validity (Cho *et al*., 2013; Patrick *et al*., 1995).
3) Generic health status: the Short-Form 12 (SF-12) is a self-administered questionnaire used to assess the participant's health status and quality of life, with higher scores indicating a better level of functioning. The SF-12 was developed with the aim of reducing respondent burden of the full version of Short-Form 36 while retaining

comparable validity and reliability (Ware, Kosinski, & Keller, 1996), and has been recommended for use in research of spinal disorders (Bombardier, 2000).

4) Activity disability: restriction of activity due to LBP was measured with a questionnaire of three separate questions taken from the United States National Health Interview Survey about the number of days spent in bed, lost from work or school, or cut down on usual activity during the past week (Ries, 1986). A similar method has been used in a previous RCT evaluating the format of acupuncture (individualized or standardized) for patients with chronic LBP (Cherkin *et al*., 2008).
5) Patient satisfaction: since there was no single measure clearly recommended within the literature (Bombardier, 2000), a general assessment of satisfaction which has been widely employed in LBP research was used (Cerrada, Weinberg, Sherman, & Saper, 2014; Rigoard *et al*., 2013). The simple question, *'All things considered, how satisfied are you with the care you received?'* is rated on an eight-point rating scale (1= extremely satisfied, 2= very satisfied, 3= somewhat satisfied, 4= mixed (approximately equal satisfaction and dissatisfaction), 5= somewhat dissatisfied, 6= very dissatisfied, 7= extremely dissatisfied, 8= not sure/no opinion) (Hudak & Wright, 2000). In addition, an open-ended question regarding participants' comments on acupuncture treatment was obtained and used for a qualitative analysis; this was collected once, at discharge.

Current pain intensity was collected pre and post each acupuncture session to evaluate the analgesic effect of each treatment and the cumulative effects of previous treatments. As the overall treatment duration varied amongst the three groups (i.e. 2 weeks, 3.5 weeks or 5 weeks), in order to examine the effectiveness of different treatment sessions of acupuncture at the same time point, post randomization measurement was employed. All data except for item 5, patient satisfaction, were collected at four time-points: baseline (Q0), completion of intervention (Q1), as well as 6 weeks (Q2) and 12 weeks post randomization (Q3). Primary

endpoint was set at 12 weeks post randomization. Table 4.2 summarizes the time points for data collection.

After the last treatment session participants were provided with three stamped and addressed envelopes to return completed questionnaires to the independent Research Assistant (PK). Due dates for completing questionnaires were written on the upper-right corner of the first page of each questionnaire. LL underlined the due dates for each participant and informed them of further reminder procedures prior to participants being discharged. A reminder email was sent out by LL on the due date of each questionnaire, with a repeat email after 1 week if the questionnaire was not returned. A subsequent reminder was sent out by MM if the questionnaire was not returned within two weeks, and participants were contacted via phone and/or email twice in successive two weeks. *A priori*, it was decided that participants had dropped out after four unsuccessful attempts to contact. Figure 4.2 details the reminder process for the trial.

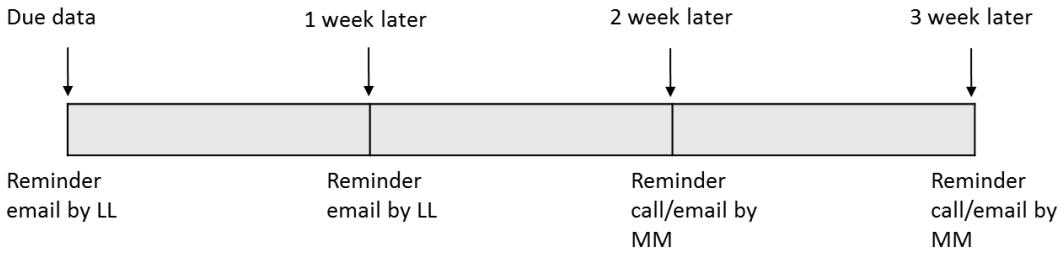

Figure 4.2. Feasibility study: Reminder process for follow-up questionnaires
Abbreviations: LL, Lizhou Liu; MM, Marina Moss.

Table 4.2. Feasibility trial: Time points at which measures and data were collected

Measure	Recruiting process	Baseline (Q0)	During intervention	At discharge (Q1)	6 weeks post randomization (Q2)	12 weeks post randomization (Q3)
Number of participants showing interest to join the trial	X					
Number of participants completing telephone screening	X					
Number of participants eligible after completing screening questionnaire	X					
Number of participants willing to be randomized into the trial from amongst those eligible	X					
Reasons for non-participation and ineligibility	X					
Demographic data		X				
Number of sessions attended			X			
Reasons for non-attendance or early withdraw			X			
Adherence to treatment protocol			X			
Difficulty in questionnaire completion		X		X	X	X
Time taken to complete questionnaires		X		X	X	X
Number of missing items		X		X	X	X
Follow-up rates				X	X	X
Back specific function		X		X	X	X
Pain intensity		X	X	X	X	X
Pain bothersomeness		X		X	X	X
Generic health status		X		X	X	X
Activity disability		X		X	X	X
Patient satisfaction				X		
Adverse reactions			X			

4.2.9 Adverse reactions

An adverse reaction was described as any undesired harmful sign, or symptom resulting from acupuncture, which could reasonably be related to the procedure. The severity of adverse reaction was rated as mild (those resolved within 24 hours and required no treatments), moderate (those lasted more than 24 hours or resolved by non-prescription medication) or serious (those required medical therapy) (Chung, Yeung, Kwok, & Yu, 2014).

Participants were asked about any adverse reaction experienced from the previous session at each subsequent visit and 1 week after the final acupuncture needling session. Detailed information about any adverse reaction was recorded on an adverse reaction form (Appendix 15), and the participant was examined by LL to determine the most appropriate course of action. Further consultation with a research supervisor was undertaken if deemed necessary after discussion with Karen Taylor (Director of Clinics and Acupuncturist, School of Physiotherapy Clinic).

The trial was terminated in a case where any unanticipated serious adverse event happened (e.g. life-threatening events or death, hospitalization, or persistent or significant disability or incapacity as a result of receiving acupuncture) (Cherkin *et al*., 2008). However such an event is extremely unlikely, as acupuncture is considered a low risk intervention (Park, Lee, Choi, Kim, & Choi, 2010).

4.2.10 Data analyses

Data analyses were conducted by LL and the trial biostatistician (AG) at the end of the study, when all data collection, entry and validation were completed. Data was blinded to LL and AG by using participant ID number and group code (Group A, B, C). The analysis was descriptive in nature and provided estimates of key trial elements to determine whether to

proceed a larger definitive RCT. Demographic data and primary outcomes were classified as continuous or categorical, and appropriate descriptive statistics and percentages were calculated. The feasibility of recruitment strategy was measured by summarizing overall contact counts, recruitment rate (recruited/screened), and randomization rate (randomized/recruited). The retention rate was assessed by analysis of treatment withdrawal counts and participant treatment adherence level which was revealed in the treatment log. The feasibility of a measurement tool was evaluated by summarizing any difficulty with questionnaire completion and the time taken; the amount of missing data (for individual item); and participants' follow-up rate (participants who completed and returned questionnaires/recruited) at all time-points.

Secondary outcomes were analyzed using SPSS (version 22.0) on a modified intention-to-treat basis excluding participants who had no post-randomization data (E9 Expert Working Group, 1999). A complete case analysis was conducted using listwise deletion as the main analysis. In order to investigate the robustness of results in the presence of incomplete data, a sensitivity analysis was undertaken using imputation analysis whereby missing values were filled in with imputed values that were 30% worse than the last observation values. There are no universally applicable approaches for dealing with missing data, and imputing by last observation carried forward was not valid under any assumptions (Bell, Fiero, Horton, & Hsu, 2014; Shih, 2002; White, Horton, Carpenter, & Pocock, 2011). In consultation with the trial biostatistician (AG), the sensitivity analysis using values 30% worse relative to last observation was considered to present less risk of bias, and was valid for examining the effects of missing outcome data on results of the main analysis. Since this was a feasibility study, tests for significance were not performed. Descriptive statistics were applied, and focused on confidence interval (CI) estimation. Data were reported as mean ± standard deviation, together with 95%CIs. Differences from baseline to each interim and the primary

endpoint (12 weeks post randomization) were calculated by subtracting the mean at baseline from that at the relevant time-points, and descriptively compared between groups for the primary endpoint.

In addition, sample size calculation for a fully powered trial was completed using the minimal clinically important difference (MCID) of 2.5 points on the RDQ scale (Roland & Fairbank, 2000; Yuan *et al*., 2009) or 20 mm (of 100 mm) on the VAS (Ostelo & de Vet, 2005), at a two-sided alpha of 0.05 and power of 80%, using the standard deviation and correlations between repeated measure estimated as part of the feasibility study.

4.2.11 *A priori* criteria for feasibility and acceptability

The following *a priori* criteria were established to inform whether to proceed to a fully powered trial, and to highlight particular areas where further modification was required for the future trial.

Criteria for feasibility of the recruitment process were set at a 20% recruitment rate over a 24-week recruitment period. The retention rate was set at 80% of participants completing the allocated acupuncture visits; this took into account participant adherence to treatment protocol that was reported by the acupuncturist (LL) in accordance with the treatment log. To proceed a larger trial, at least 80% of participants should be followed post randomization (percentage of withdrawals and drop-outs at all time-points should not exceed 20%) (Furlan *et al*., 2009).

5 Dose of Traditional Chinese Medicine acupuncture in addition to usual care for adults with chronic low back pain: Results and discussion of a randomized controlled feasibility study

5.1 Introduction

On the basis of rationale and methods discussed in the previous chapter (Chapter 4), this chapter presents the results and discussion relating to the randomized controlled feasibility study. The primary aim of this study was to examine the feasibility of the study method, which involved randomization to assign adults with chronic low back pain (LBP) to different numbers of sessions of Traditional Chinese Medicine (TCM) acupuncture in addition to usual care. The secondary aim was to estimate the sample size for a fully powered randomized controlled trial (RCT).

This chapter has been written in accordance with the *Consolidated Standards of Reporting Trials* (CONSORT) statement for trials of non-pharmacologic treatments (Boutron *et al*., 2008), and details of acupuncture intervention are described in adherence to the *Standards for Reporting Interventions in Clinical Trials of Acupuncture* (STRICTA) guidelines in Chapter 4 (see section 4.2.7.2).

5.2 Results

5.2.1 Demographics

Forty-five participants were recruited from the Dunedin community by the end of the study. Participant baseline demographics are displayed in Table 5.1. As this was a feasibility study, tests for significance were not performed.

Table 5.1. Feasibility trial: Baseline characteristics of 45 participants

Variables	4-sessions (n= 15)	7-sessions (n= 15)	10-sessions (n= 15)
Female sex, No. (%)	9 (60%)	9 (60%)	11 (73.3%)
Age, mean (SD), y	30.0 (13.7)	37.1 (15.2)	30.8 (14.9)
Height, mean (SD), cm	170.5 (7.2)	169.9 (7.5)	173.4 (9.9)
Weight, mean (SD), kg	69.8 (12.9)	78.1 (16.0)	81.8 (14.8)
BMI, mean (SD), kg/m	23.9 (3.3)	27.0 (5.2)	27.4 (5.5)
Smoker, No.	0	1	1
Ethnicity New Zealand European, No. (%)	9 (60%)	8 (53.3%)	10 (66.7%)
Employed, No. (%)[a]	11 (73.3%)	10 (66.7%)	3 (20%)
LBP duration, mean (SD), y	4.14 (4.4)	9.26 (12.5)	3.69 (5.1)
LBP with leg pain, No. (%)	7 (46.7%)	7 (46.7%)	9 (60%)
Previous LBP, No. (%)	7 (46.7%)	11 (73.3%)	10 (66.7%)
Health professional consultation, No.[b]			
General practitioner	5	3	6
Physiotherapist	5	5	5
Chiropractor	3	0	1
Osteopath	1	1	0
Image test findings associated with LBP, No.[c]	6	6	4
NSAIDs use, No.[d]	3	2	6
Positive impression of acupuncture, No. (%)	11 (73.3%)	11 (73.3%)	7 (46.7%)
Acupuncture treatment history, No.[e]	2	3	0

Abbreviations: SD, standard deviation; LBP, low back pain; NSAIDs, non-steroidal anti-inflammatory drugs.

[a] Defined as full-time and/or part-time employment.

[b] Defined as health professional consultation for LBP over previous one year.

[c] Defined as participants' self-reported findings of image tests that might be relevant to back pain (e.g. scoliosis, stenosis).

[d] Defined as NSAIDs use over previous one week for LBP.

[e] Defined as acupuncture treatment history for conditions except for LBP.

Participants were mainly female (64.4%), and non-smokers (96.6%). New Zealand Europeans composed the majority of participants (60%), followed by Maori (8.9%) and Chinese (8.9%). Participants' age ranged from 18 to 69 years; the mean age of participants in the 7-session group (37 years) was slightly higher than those in the other two groups (30 years). Twenty-two participants were classified as overweight (body mass index (BMI) ≥ 25 kg/cm^2), and eight as obese (BMI≥ 30 kg/cm^2). Duration of back pain symptoms ranged from 4 months to 45 years, and over 60% of participants indicated that this was not the first episode of LBP.

Twenty-three participants had leg pain along with LBP, but no one reported pain below the knee. When compared to the 4-session group and the 7-session group, fewer participants in the 10-session group were working (full-time or part-time) at baseline.

Twenty-six participants consulted healthcare professionals for LBP within the previous year, eight of whom sought care from two or more medical practitioners. Nearly one third of participants underwent an imaging for LBP (i.e. magnetic resonance imaging and/or computed tomography), and self-reported the test findings (e.g. scoliosis, stenosis) that might be relevant to their back pain symptoms. Non-steroidal anti-inflammatory drugs (NSAIDs) were the most commonly used medication among participants; the use of NSAIDs was higher in 10-session group participants than the other two groups. Five participants had previous experience of using acupuncture (three for conditions other than LBP, and two for LBP, however, treatment occurred more than one year ago), but nearly 65% of all participants showed expectation of acupuncture helpfulness.

5.2.2 Primary outcomes

5.2.2.1 Feasibility of the recruitment process

The recruitment process is displayed in Figure 5.1. Between June 2015 and August 2015 131 people showed interest in participating in the trial and were provided with the trial information sheet: 103 (78.6%) underwent telephone screening, 50 (48.5%) of whom were subsequently excluded. The main reasons for ineligibility after telephone screening were previous use of acupuncture, history of spinal surgery, and previous use of morphine (or codeine) (Table 5.2). Eight people were excluded after completing screening questionnaires mainly because of low pain intensity (a score of 3 or less on the Roland-Morris Disability Questionnaire (RDQ)) when presenting. Forty-five participants (100% of the targeted sample

size of this study) satisfied the inclusion criteria and consented for randomization (15 in each intervention group).

Table 5.2. Feasibility trial: Reasons for ineligibility after telephone screening (n= 42)

No. of participants	Reasons for ineligibility
11	Previous use of acupuncture for LBP in the past 1 year
8	History of spinal surgery or currently wait-listed for spinal surgery
8	Previous use of morphine or codeine for LBP in the past 1 year
5	Not suffering from LBP currently
6	Diagnosed with other spinal disorders
2	Severe psychological disorders*
3	Current use of anti-coagulant medication
3	Diagnosed with a systematic medical condition precluding participation
2	Pregnancy or intended pregnancy
1	Prolonged use of steroids

Abbreviation: LBP, low back pain.

***Diagnoses were self-reported by participants, including schizophrenia and major depression.**

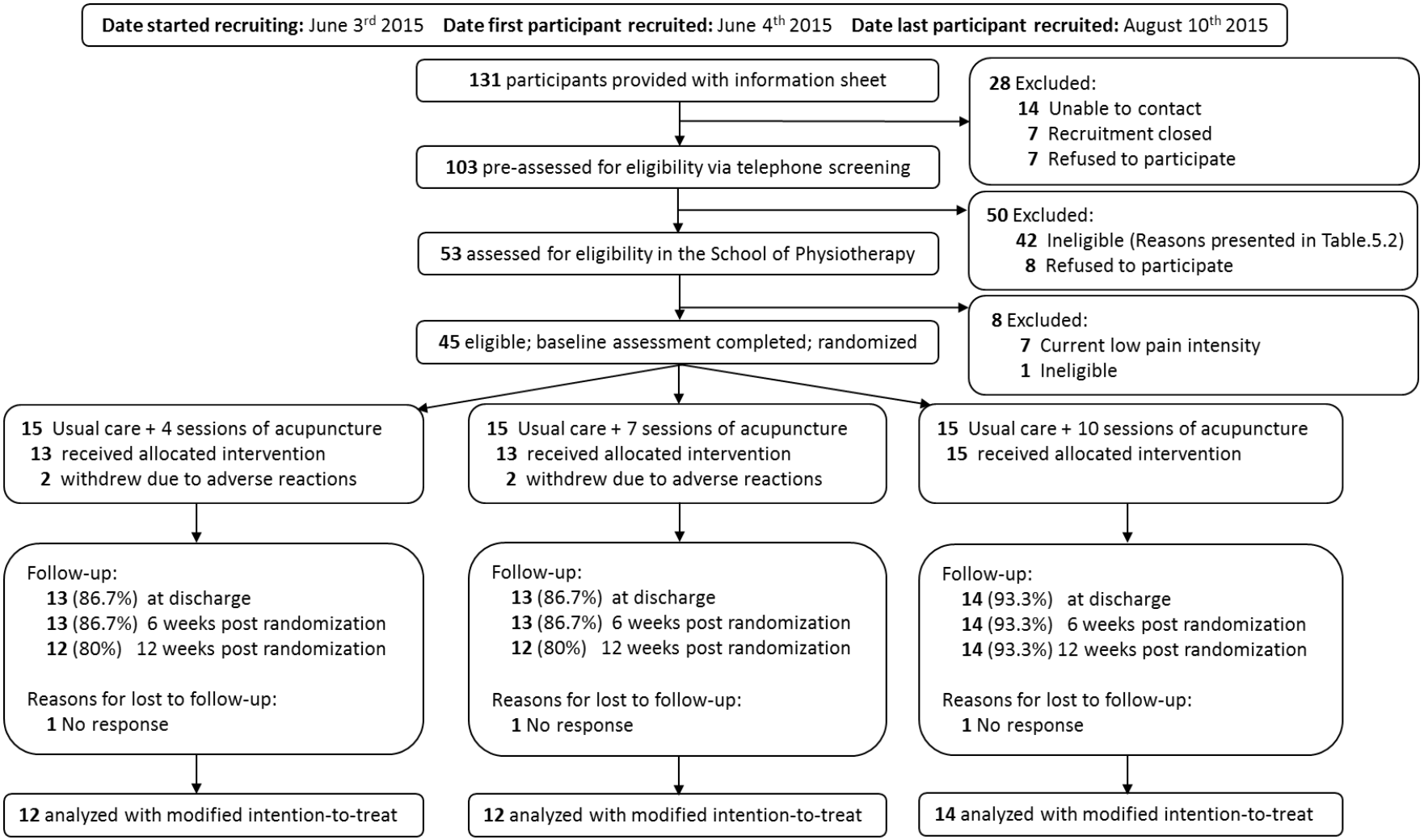

Figure 5.1. Feasibility trial: Participant flow diagram

The study recruitment strategy was demonstrated to be feasible: recruitment rate was 43.7%. Overall, five participants were recruited each week over a 10-week recruitment period (Table 5.3). Recruitment started on June 3rd 2015 via posting study flyers around the University of Otago Dunedin campus, community centres, waiting rooms in medical centres, and in the University's School of Physiotherapy Clinics. Sixteen participants were recruited in the first two weeks via these flyers. In order to boost recruitment rate, the study flyer was posted on the Facebook page (Otago Flatting Goods ("Facebook- Otago Flatting Goods,")) on June 14th 2015, and resulted in a high recruitment number the following week. Four participants were recruited in the final three weeks after circulating the study flyer in the University staff newsletters. The average duration between participant first contact and recruitment was five days (range 0 to 21 days). The mean duration between recruitment and baseline assessment (the first visit) was nine days (range 0 to 31 days).

Table 5.3. Feasibility trial: Participant recruitment during the 10-week recruitment period

Week	Date	No. of participants contacted	No. of participants recruited
1	June 3-9, 2015	25	7
2	June 10-16	64	9
3	June 17-23	8	14
4	June 24-30	2	6
5	July 1-7	2	3
6	July 8-14	5	0
7	July 15-21	1	2
8	July 22-28	8	1
9	July 29- August 4	5	1
10	August 5-10, 2015	11	2

5.2.2.2 Participant retention rate

Participant retention rate met the *a priori* level: 87% of participants in the 4-session and the 7-session groups, and all participants (100%) in the 10-session group, completed the pre-specified treatment sessions and complied adequately with the treatment protocol as described in Chapter 4 (see section 4.2.7.2). Of these, four participants (one in 4-session

group, one in 7-session group, and two in 10-session group) changed their attendance date because of temporary emergency, ill health, or forgetting treatment appointments. The Clinical Research Administrator (Marina Moss (MM)) rearranged alternative treatment visits for these participants, and ensured the same treatment frequency (twice weekly) for each participant.

Four female participants (two in the 4-session group and two in 7-session group) withdrew from the study because of adverse reactions after treatment. Of these, the two participants in the 4-session group withdrew in the first session after the insertion of two needles due to needle-site pain, thus no longer complied with the treatment protocol. One participant in the 7-session group discontinued acupuncture treatment after insertion of two needles in the second session because of needle-site pain; another declined subsequent treatments after the first session because of aggravation of back pain in the evening. Details of these adverse reactions are described in section of 5.2.5 in this chapter.

Acupuncture treatment was delivered within 30 minutes in each session. On average 6-10 needles were inserted for each participant per session. The mean number of insertions per session was eight for the 4-session group, nine for the 7-session group, and nine for the 10-session group. Apart from the standardized set of acupoints that was needled for each participant (BL 23, BL 25, low back Ah-shi points, BL 40 and KI 3), other acupoints that were used most frequently (used on more than 50% of the participants) were BL 54, GB 30, and BL 60.

5.2.2.3 Feasibility of the measurement tools

Participant follow-up rate exceeded the *a priori* feasibility level of 80% at all four time-points (Figure 5.1). All participants completed the baseline questionnaire (Q0). Baseline data were

collected prior to randomization during the participant's first visit to the School of Physiotherapy. The aforementioned four participants who discontinued acupuncture treatment did not provide any follow-up questionnaires. Forty participants (88.9%) completed questionnaires at discharge (Q1) and six weeks post randomization (Q2), and 38 (84.4%) at 12 weeks post randomization (Q3). Although strict reminder procedures (see Chapter 4, section 4.2.8.2) were adhered to for the questionnaires, three participants (one in each group) were unable to be contacted and were thus considered as dropouts.

Thirty participants indicated that the questionnaires were easy to complete at baseline. With subsequent use, an increasing number of participants reported the ease of questionnaire completion (Table 5.4). Participants were asked to report the time taken to complete each questionnaires; the mean time taken to complete questionnaires was 3, 5.9, 4.7, and 4.2 minutes for Q0, Q1, Q2 and Q3, respectively (Table 5.5). There were no missing data in the completed questionnaires.

Table 5.4. Feasibility trial: Ease of completing questionnaires at all time-points

Intervention group		Q0	Q1	Q2	Q3
4-session group					
No. of participants indicated	somewhat easy	5	4	4	5
questionnaires	very easy	4	5	4	4
7-session group					
No. of participants indicated	somewhat easy	4	4	3	3
questionnaires	very easy	5	5	5	6
10-session group					
No. of participants indicated	somewhat easy	5	3	4	4
questionnaires	very easy	7	8	8	8
% of participants indicated questionnaires easy* to complete		66.7%	72.5%	70%	78.9%

Q0, at baseline; Q1, at discharge; Q2, 6 weeks post randomization; Q3, 12 weeks post randomization.
*** Defined as somewhat easy and very easy.**

Table 5.5. Feasibility trial: Time taken to complete questionnaires at all time-points (minutes)

Intervention group	Q0 Mean (SD)	Q1 Mean (SD)	Q2 Mean (SD)	Q3 Mean (SD)
4-session group	2.8 (0.8)	5.4 (2.1)	4.2 (2.1)	3.8 (1.2)
7-session group	3.2 (0.8)	6.9 (3.8)	4.8 (2.2)	4.6 (2.2)
10-session group	3.1 (1.0)	5.5 (2.6)	5.0 (3.5)	4.3 (2.6)
Overall	3.0 (0.8)	5.9 (2.9)	4.7 (2.7)	4.2 (2.1)

Abbreviation: SD, standard deviation.

Q0, at baseline; Q1, at discharge; Q2, 6 weeks post randomization; Q3, 12 weeks post randomization.

5.2.3 Secondary outcomes

Data analyses were conducted in accordance with the modified intention-to-treat approach as described in Chapter 4 (see section 4.2.10). Thus, five participants (four withdrawals in the 4-session group and 7-session group, and one dropout in the 10-session group) were excluded from analyses due to lack of data post randomization. Primary analysis (complete case analysis) included thirty-eight participants with complete data for observed variables. Descriptive statistics for secondary outcome measures are reported in Table 5.6. The mean differences (and 95% confidence intervals (CIs)) of secondary outcome measures from baseline to each interim period are presented in Table 5.7. P values were not calculated as this was a feasibility study.

Table 5.6. Feasibility trial: Mean (standard deviation) scores on secondary outcome measures over time for 38 participants

Outcome measures	Baseline (Q0)			At discharge (Q1)			6 weeks post randomization (Q2)			12 weeks post randomization (Q3)		
	4-sessions (n= 12)	7-sessions (n= 12)	10-sessions (n= 14)	4-sessions (n= 12)	7-sessions (n= 12)	10-sessions (n= 14)	4-sessions (n= 12)	7-sessions (n= 12)	10-sessions (n= 14)	4-sessions (n= 12)	7-sessions (n= 12)	10-sessions (n= 14)
RDQ[a]	6.0 (2.0)	7.3 (2.7)	8.5 (4.4)	2.6 (1.5)	2.8 (1.8)	3.5 (2.3)	3.4 (2.4)	4.5 (3.8)	3.4 (2.2)	2.8 (2.2)	3.8 (4.0)	2.6 (2.4)
Pain intensity[b]	49.3 (24.1)	43.0 (22.9)	54.4 (15.8)	28.3 (16.5)	15.6 (14.5)	18.1 (10.1)	17.8 (15.2)	21.8 (19.9)	19.9 (15.2)	19.6 (19.1)	18.8 (20.7)	24.8 (20.8)
Pain bothersomeness[c]	5.1 (2.1)	4.6 (2.3)	6.1 (2.0)	3.0 (1.9)	1.3 (1.1)	1.8 (1.4)	2.2 (2.0)	2.3 (2.2)	2.4 (1.8)	2.1 (1.8)	2.0 (2.2)	2.9 (2.2)
SF-12 PCS[d]	45.5 (6.9)	44.9 (8.5)	37.1 (5.5)	49.3 (7.6)	49.6 (5.5)	44.4 (8.1)	50.1 (7.9)	48.2 (10.0)	47.1 (9.0)	49.9 (7.1)	47.0 (9.6)	50.0 (8.7)
SF-12 MCS[d]	41.7 (10.4)	46.6 (10.8)	46.3 (9.9)	43.3 (9.6)	48.3 (4.4)	54.2 (7.7)	43.3 (12.0)	50.6 (9.2)	52.0 (9.4)	43.4 (11.3)	48.5 (7.8)	49.2 (9.9)
Activity disability[e]	0.9 (1.2)	1.0 (1.5)	3.3 (3.5)	0.3 (0.9)	0.1 (0.3)	0.9 (1.3)	0.8 (1.6)	0.6 (1.5)	1.0 (1.2)	0.3 (0.6)	0.9 (2.1)	1.3 (2.1)

Abbreviations: RDQ, Roland-Morris Disability Questionnaire; SF-12, Short-Form 12; PCS, physical component summary; MCS, mental component summary.

[a] Ranged 0-24; higher scores indicated more severe impairment.

[b] Visual Analogue Scale, ranged 0-100mm; higher scores indicated worse pain intensity.

[c] Visual Analogue Scale, ranged 0-10cm; higher scores indicated worse pain impact.

[d] Ranged 0-100; higher scores indicated better health.

[e] Activity restriction days; higher scores indicated worse activity restriction.

Table 5.7. Feasibility trial: Mean differences on secondary outcome measures over time using complete case analysis according to modified intention-to-treat principle for 38 participants

Outcome measures	Q1 – Q0 mean difference (95%CI)			Q2 – Q0 mean difference (95%CI)			Q3 – Q0* mean difference (95%CI)		
	4-sessions (n= 12)	7-sessions (n= 12)	10-sessions (n= 14)	4-sessions (n= 12)	7-sessions (n= 12)	10-sessions (n= 14)	4-sessions (n= 12)	7-sessions (n= 12)	10-sessions (n= 14)
RDQ[a]	-3.4 (-5.0, -1.8)	-4.5 (-6.6, -2.4)	-5.0 (-7.1, -2.9)	-2.6 (-4.6, -0.5)	-2.8 (-5.4, -0.25)	-5.1 (-7.1, -3.1)	-3.3 (-5.2, -1.3)	-3.6 (-6.3, -0.9)	-5.9 (-8.0, -3.7)
Pain intensity[a]	-20.9 (-33.5, -8.3)	-27.4 (-45.7, -9.0)	-36.3 (-47.3, -25.2)	-31.4 (-48.3, -14.5)	-21.2 (-40.1, -2.3)	-34.5 (-46.7, -22.3)	-29.7 (-47.7, -11.6)	-24.2 (-43.4, -4.9)	-29.6 (-41.9, -17.3)
Pain bothersomeness[a]	-2.1 (-3.3, -0.9)	-3.4 (-5.1, -1.6)	-4.3 (-5.7, -3.0)	-3.0 (-4.3, -1.6)	-2.4 (-4.5, -0.2)	-3.7 (-5.0, -2.5)	-3.1 (-4.6, -1.6)	-2.7 (-4.8, -0.6)	-3.2 (-4.6, -1.9)
SF-12 PCS[b]	3.8 (-0.8, 8.5)	4.7 (-0.5, 10.0)	7.3 (3.1, 11.5)	4.6 (-1.0, 10.2)	3.4 (-1.8, 8.5)	10.0 (5.2, 14.7)	4.4 (-1.9, 10.6)	2.1 (-4.8, 9.1)	12.9 (9.4, 16.4)
SF-12 MCS[b]	1.6 (-4.4, 7.7)	1.7 (-4.6, 7.9)	7.9 (1.7, 14.0)	1.6 (-5.5, 8.8)	4.0 (-3.2, 11.1)	5.7 (-2.0, 13.3)	1.7 (-4.6, 7.9)	1.9 (-5.1, 9.0)	2.9 (-2.3, 8.1)
Activity disability[a]	-0.7 (-1.4, 0.1)	-0.9 (-1.9, 0)	-2.4 (-4.4, -0.4)	-0.2 (-1.4, 1.1)	-0.4 (-1.2, 0.4)	-2.3 (-4.1, -0.4)	-0.7 (-1.4, 0.1)	-0.1 (-1.6, 1.4)	-2.0 (-3.5, -0.4)

Abbreviations: CI, confidence interval; RDQ, Roland-Morris Disability Questionnaire; SF-12, Short-Form 12; PCS, physical component summary; MCS, mental component summary.

Q0, at baseline; Q1, at discharge; Q2, 6 weeks post randomization; Q3, 12 weeks post randomization.

*** Difference in group means between baseline and primary endpoint (12 weeks post randomization).**

[a] Negative values indicated improvement at each time-point (Q1,Q2,Q3) compared with baseline (Q0).

[b] Positive values indicated improvement at each time-point (Q1,Q2,Q3) compared with baseline (Q0).

5.2.3.1 Back specific function (measured on RDQ)

Overall, all three groups showed improved function at the primary endpoint (12 weeks post randomization) (Figure 5.2). Mean baseline scores of the RDQ indicated more severe functional limitations for participants in the 10-session group (mean= 8.5, standard deviation (SD) = 4.4). For participants in the 10-session group, steadily decreasing RDQ scores were demonstrated from baseline to the primary endpoint, resulting in a mean reduction of 5.9 points (95%CI: -8.0 to -3.7) at 12 weeks post randomization. For participants in the other two groups, RDQ scores decreased at the end of acupuncture treatment, but plateaued over the two follow-ups. There was a mean decrease of 3.3 points (95%CI: -5.2 to -1.3) in the 4-session group and 3.6 points (95%CI: -6.3 to -0.9) in the 7-session group at 12 weeks post randomization.

Based on the differences of group means between baseline and the primary endpoint, a minimum number of 42 participants in each group would be required to detect a 2.5-point difference in the RDQ in a fully powered trial.

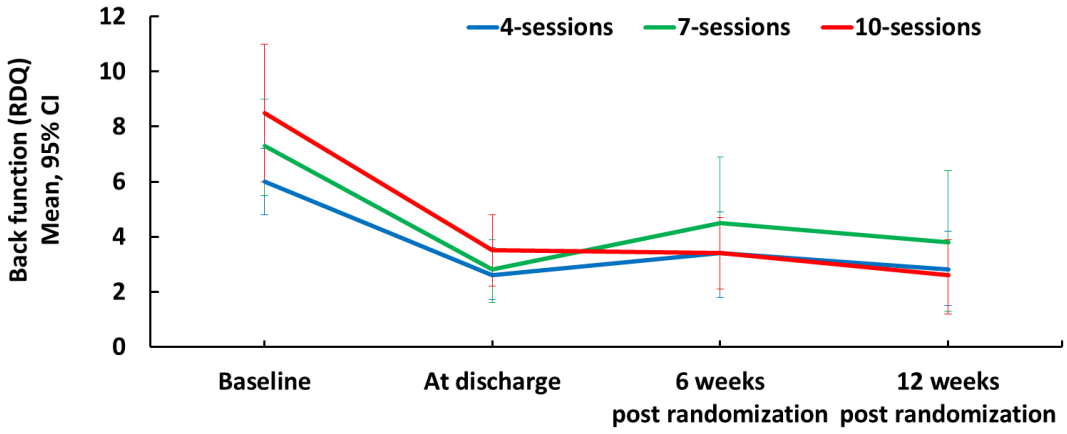

Figure 5.2. Feasibility trial: Back specific function for the three acupuncture intervention groups at the four assessment periods

5.2.3.2 Pain intensity (measured on a 100mm Visual Analogue Scale (VAS))

Overall, pain intensity decreased by the end of acupuncture intervention, and was maintained through each follow-up (Figure 5.3). On completion of treatment, participants reported a mean 67% reduction in pain in the 10-session group, a mean 64% reduction in the 7-session group, and a mean 42% reduction in the 4-session group. At the primary endpoint, participants in the 4-session group and the 10-session group experienced a mean relief of 30mm in VAS, whereas the 7-session group reported a mean reduction of 24mm (95%CI: -43.4 to -4.9). Sample size estimates to detect a 20mm change in VAS in a fully powered trial is 37 participants in each group.

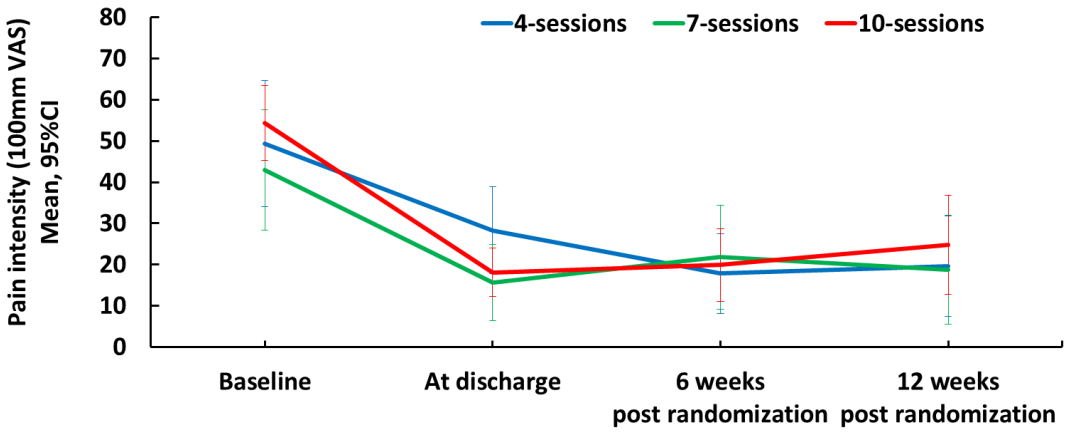

Figure 5.3. Feasibility trial: Pain intensity for the three acupuncture intervention groups at the four assessment periods

Table 5.8 illustrates participants' pain intensity before each session. Overall, pre-treatment pain decreased over time, suggesting a cumulative analgesic effect of repeated acupuncture intervention. Continuing pain reductions were reported in the 4-session and the 7-session groups, while the 10-session group presented reduction of pain with some oscillation (Figure 5.4).

Table 5.8. Feasibility trial: Pain intensity at each treatment session for the three acupuncture intervention groups

Intervention groups	Mean (SD)																			
	1st treatment		2nd treatment		3rd treatment		4th treatment		5th treatment		6th treatment		7th treatment		8th treatment		9th treatment		10th treatment	
	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post
4-session group	38.6 (18.9)	33.5 (24.9)	34.2 (21.1)	27.8 (25.3)	26.5 (23.5)	22.2 (19.8)	17.0 (15.3)	11.9 (10.7)												
7-session group	38.1 (17.3)	19.2 (11.0)	35.0 (17.9)	18.5 (8.5)	30.8 (17.9)	11.6 (7.6)	25.1 (17.9)	13.3 (12.0)	20.4 (13.0)	11.8 (7.8)	19.8 (16.4)	8.3 (11.3)	11.5 (10.8)	3.5 (3.3)						
10-session group	53.7 (15.9)	29.5 (11.5)	46.8 (14.8)	32.7 (14.2)	49.4 (15.9)	31.7 (13.8)	37.3 (19.0)	26.8 (12.9)	34.9 (18.8)	25.5 (17.3)	34.9 (19.4)	23.7 (13.9)	22.6 (11.3)	15.1 (11.7)	19.1 (16.8)	13.7 (13.4)	18.4 (13.2)	11.9 (10.3)	14.1 (9.2)	8.7 (8.2)

Abbreviation: SD, standard deviation.

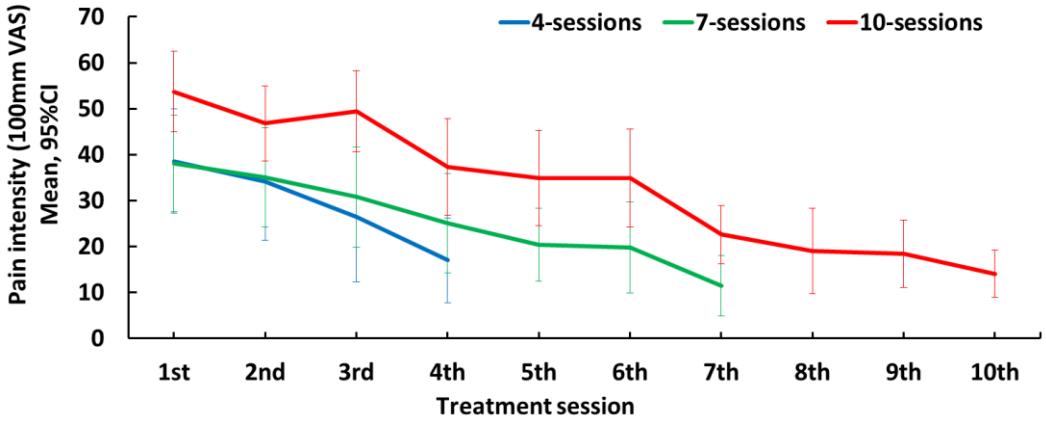

Figure 5.4. Feasibility trial: Pain intensity before each treatment session for the three acupuncture intervention groups

In the context of post-treatment pain, this also gradually decreased in all three groups (Table 5.8 and Figure 5.5). Mean post-treatment VAS scores in the 4-session group decreased by 21.6mm (95%CI: -35.1 to -8.1) after four consecutive treatments. Participants in the 7-session and the 10-session groups reported decreased pain intensity (with small variation) after successive treatment sessions. From the first to the last session, the median change in level of post-treatment pain was -15.8mm (95%CI: -23.5 to -8.1) in the 7-session group and -20.7mm (95%CI: -26.0 to -15.5) in the 10-session group.

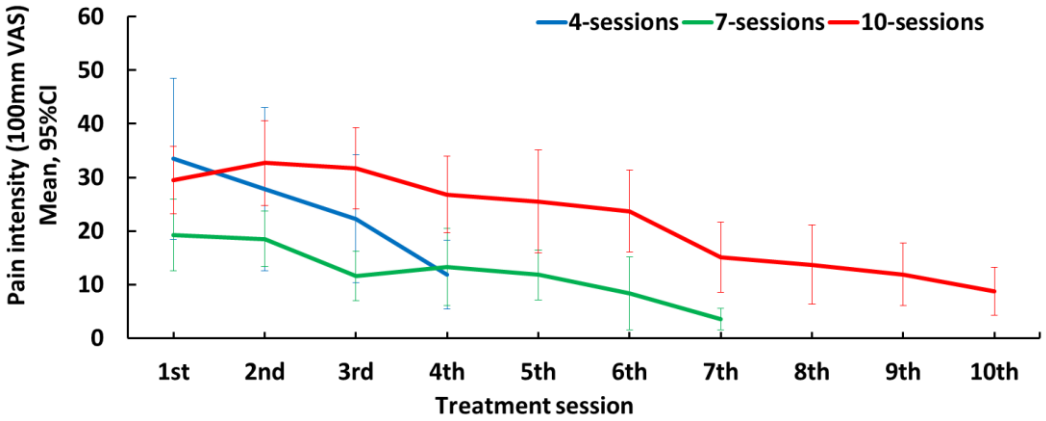

Figure 5.5. Feasibility trial: Pain intensity after each treatment session for the three acupuncture intervention groups

The treatment effects of individual acupuncture session ($VAS_{post\text{-}treatment} - VAS_{pre\text{-}treatment}$) are displayed in Figure 5.6. The outcome of each acupuncture session was instant pain relief. In

the 4-session group, participants experienced pain reduction ranging from 4.4mm to 6.4mm after each individual session. One participant reported worse pain intensity (ranged from 13mm to 78mm increase) after the first three acupuncture sessions, but requested to remain in the study. In the 7-session group, changes in pain ranged from an 8.1mm decrease in the last session to a 19.2mm decrease in the third session. Participants in the 10-session group reported the highest pain reduction after the first session, reaching a decrease of 24.3mm. Pain variability of the other nine sessions presented a similar pattern to the 7-session group, ranging from a 5.3mm decrease in the last session to a 17.7mm decrease in the third session.

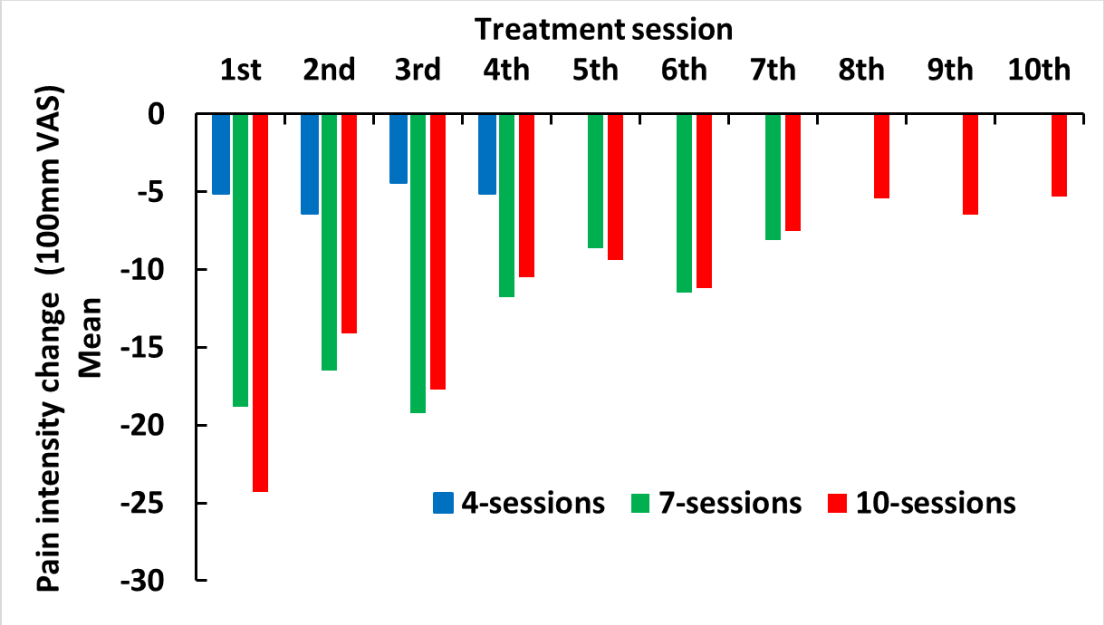

Figure 5.6. Feasibility trial: Changes of pain intensity in each treatment session for the three acupuncture intervention groups

5.2.3.3 Pain bothersomeness (measured on a 10cm VAS)

Overall, a decreased level of pain bothersomeness was detected among participants (Figure 5.7). At baseline, participants in the 10-session group indicated a higher back pain bothersomeness (mean= 6.1, SD= 2.0) compared to the other two groups. In the 10-session group, mean VAS score decreased by -3.2 (95%CI: -4.6 to -1.90) from baseline to 12 weeks

post randomization, compared to a -3.1 (95%CI: -4.6 to -1.6) decrease in the 4-session group, and a -2.7 decrease (95%CI: -4.8 to -0.6) in the 7-session group.

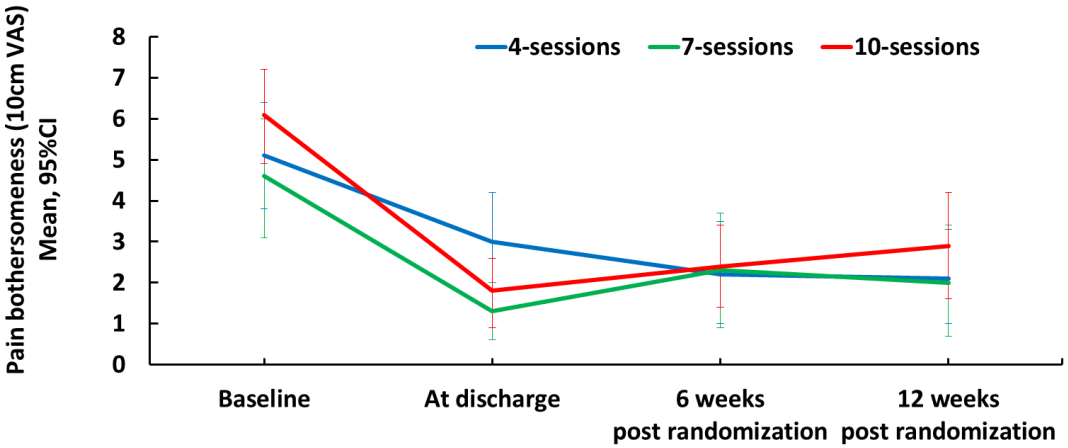

Figure 5.7. Feasibility trial: Pain bothersomeness for the three acupuncture intervention groups at the four assessment periods

5.2.3.4 Generic health status (measured on the Short-Form 12 (SF-12))

Overall, participants reported improved health over time. For physical health, increasing physical component summary (PCS) scores were found in the 10-session group: increasing (improving) from 37.1 points (SD= 5.5) at baseline to 44.4 points (SD= 8.1) at discharge, rising to 50.0 points (SD= 8.7) at the primary endpoint (Figure 5.8). In the 4-session group, a similar increasing pattern was detected: at 12 weeks post randomization, mean PCS scores increased by 4.4 points (95%CI: -1.9 to 10.6). However, the 7-session group reported a different pattern: mean PCS score increased by 4.7 points (95%CI: -0.5 to 10.0) from baseline to the end of treatments, then decreased (worsened) at follow-ups.

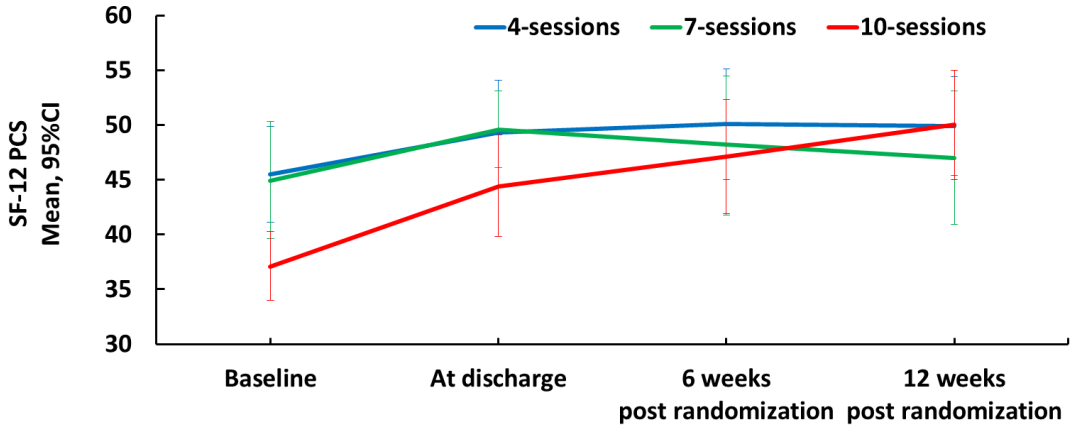

Figure 5.8. Feasibility trial: Short-Form 12 physical health for the three acupuncture intervention groups at the four assessment periods

For mental health, mean baseline mental component summary (MCS) scores indicated poorer health in participants of the 4-session group (mean= 41.7, SD= 10.4). Mean MCS scores in the 4-session group increased (improved) by 1.6 points (95%CI: -4.4 to 7.7) from baseline to the end of treatment, then remained stable in follow-ups (Figure 5.9). At the primary endpoint mean scores increased (improved) by 1.9 points (95%CI: -5.1 to 9.0) in the 7-session group, and by 2.9 points (95%CI: -2.3 to 8.1) in the 10-session group.

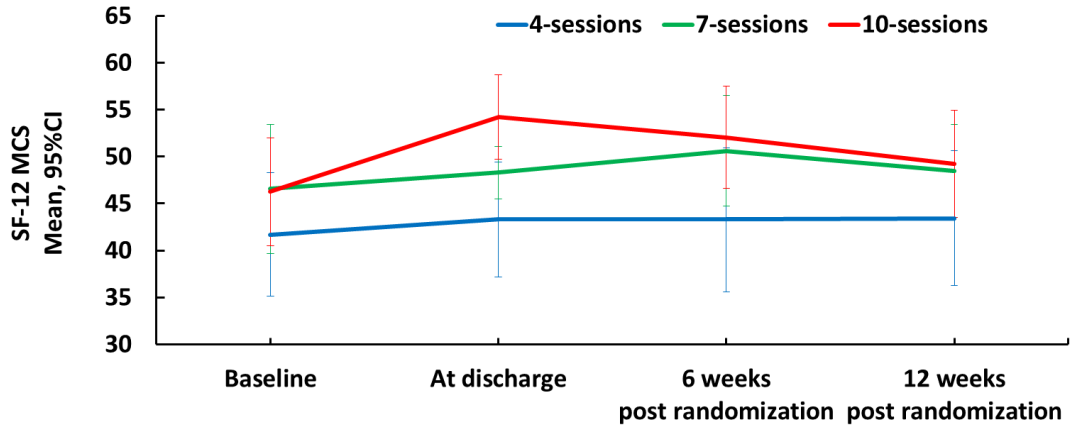

Figure 5.9. Feasibility trial: Short-Form 12 mental health for the three acupuncture intervention groups at the four assessment periods

5.2.3.5 Activity disability (measured on activity restriction days)

Overall, the three groups demonstrated a reduction in limitation in activity during the study (Figure 5.10). At baseline, the average number of days that participants reported activity restriction was 0.9 days (SD= 1.2) in the 4-session group, 1 day (SD= 1.5) in the 7-session group, and 3.3 days (SD= 3.5) in the 10-session group. From baseline to the primary endpoint, there was a mean reduction of 2 days (95%CI: -3.5 to -0.4) in the 10-session group, 0.7 days (95%CI: -1.4 to 0.1) in the 4-session group, and 0.1 days (95%CI: -1.6 to 1.4) in the 7-session group.

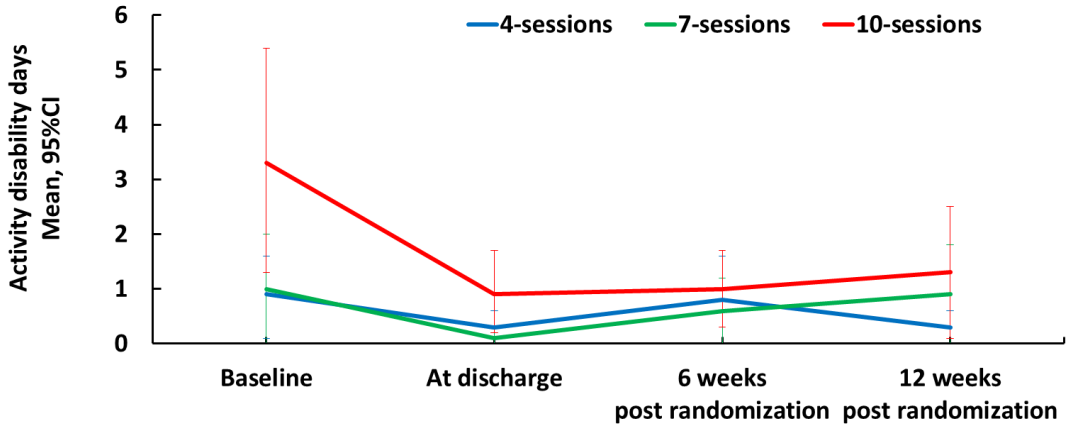

Figure 5.10. Feasibility trial: Activity restriction days for the three acupuncture intervention groups at the four assessment periods

5.2.3.6 Patient satisfaction

Overall, participants were very positive about the acupuncture treatment they received for chronic LBP. At discharge, forty of the forty-five participants who completed the outcome measure questionnaire were at least 'somewhat satisfied' with the acupuncture (Table 5.9). Over 90% of participants indicated that they were 'very satisfied' and/or 'extremely satisfied'. A higher number of treatment sessions was associated with a greater percentage of participants who were 'extremely satisfied'.

Table 5.9. Feasibility trial: Patient satisfaction with treatment

Satisfied level	Number (%) of responses		
	4-sessions (n= 13)	7-sessions (n= 13)	10-sessions (n= 14)
All things considered, how satisfied are you with the care you received?			
Extremely satisfied	4 (30.8%)	7 (53.8%)	9 (64.3%)
Very satisfied	8 (61.5%)	5 (38.5%)	4 (28.6%)
Somewhat satisfied	1	1	1

The open-ended question regarding participants' comments on acupuncture treatment revealed two main themes: the experience of the treatment process, and the impact of acupuncture (Appendix 16). In the context of treatment experience, participants consistently indicated that the acupuncture treatment was delivered in a comfortable and relaxed manner. Two participants reported that they were unable to describe the needling feeling during treatment, and suggested that the acupuncturist should provide specific categories to facilitate identification of needling sensation. In order to reduce participants' bias, one participant suggested that the acupuncturist should revise her method of inquiry when locating acupoints. In terms of the impact of acupuncture, participants indicated noticeable improvement of back pain symptoms over the study period. However, one participant commented that the effect was just temporary. Two participants reported that acupuncture had benefits other than pain relief (e.g. sound sleeping, and improved energy).

5.2.4 Sensitivity analysis

Sensitivity analysis was carried out involving forty participants, as part of which missing data from two participants at 12 weeks post randomization (one each in the 4-seesion group and 7-session group) were replaced with imputed data. Results changed negligibly from the primary analysis (Table 5.10). From baseline to the primary endpoint, while the 10-session group reported the greatest improvement in back specific function, general health status

(physical and mental), and activity disability, the 4-session group demonstrated the largest reduction in pain intensity and pain bothersomeness.

5.2.5 Adverse reactions

Thirteen mild and two moderate (needle-site bruise) adverse reactions were reported throughout the intervention period (Table 5.11). In total, the incidence of adverse reactions was 33.3% in the three intervention groups. There were no serious adverse reactions reported.

Minor needle-site bleeding and bruising were the two most common adverse reactions experienced by participants. While minor bleeding was stopped immediately after pressure with a sterile cotton ball, needle-site bruise usually lasted from 1 to 4 days. Four participants reported needle-site sharp pain during treatment. Of those, three were voluntarily withdrawn from the study (two in the 4-session group and one the 7-session group). On follow-up with these participants, the pain was generally mild after needle withdrawal, and disappeared within 10 hours without any treatment. One participant in the 7-seesion group reported increased back pain after the first treatment, and voluntarily withdrew from the study. Further follow-up with this participant indicated the aggravated symptoms were relieved the next day after the participant applied a hot-water bottle over the lumbar area. Other adverse reactions included nausea during needle stimulation, and minor drowsiness after treatment. Participants fully recovered after needle removal, and a short period of rest (10 minutes).

Table 5.10. Feasibility trial: Mean differences on secondary outcome measures over time using imputation analysis according to modified intention-to-treat principle for 40 participants

Outcome measures	Q1 – Q0 mean difference (95%CI)			Q2 – Q0 mean difference (95%CI)			Q3 – Q0* mean difference (95%CI)		
	4-sessions (n= 13)	7-sessions (n= 13)	10-sessions (n= 14)	4-sessions (n= 13)	7-sessions (n= 13)	10-sessions (n= 14)	4-sessions (n= 13)	7-sessions (n= 13)	10-sessions (n= 14)
RDQ[a]	-3.2 (-4.8, -1.7)	-3.8 (-6.2, -1.5)	-5.0 (-7.1, -2.9)	-2.7 (-4.6, -0.8)	-1.9 (-5.0, 1.2)	-5.1 (-7.1, -3.1)	-3.2 (-5.0, -1.4)	-2.2 (-6.1, 1.7)	-5.9 (-8.0, -3.7)
Pain intensity[a]	-23.4 (-36.0, -10.7)	-26.2 (-43.1, -9.3)	-36.3 (-47.3, -25.2)	-34.0 (-50.4, -17.6)	-20.6 (-37.8, -3.3)	-34.5 (-46.7, -22.3)	-32.3 (-49.7, -14.9)	-22.8 (-40.6, -4.9)	-29.6 (-41.9, -17.3)
Pain bothersomeness[a]	-2.1 (-3.2, -1.0)	-3.2 (-4.8, -1.6)	-4.3 (-5.7, -3.0)	-3.2 (-4.6, -1.9)	-2.4 (-4.3, -0.4)	-3.7 (-5.0, -2.5)	-3.3 (-4.8, -1.9)	-2.6 (-4.5, -0.6)	-3.2 (-4.6, -1.9)
SF-12 PCS[b]	3.7 (-0.6, 7.9)	4.8 (0, 9.6)	7.3 (3.1, 11.5)	5.2 (0, 10.5)	3.8 (-1.0, 8.5)	10.0 (5.2, 14.7)	4.0 (-1.8, 9.8)	1.6 (-4.9, 8.0)	12.9 (9.4, 16.4)
SF-12 MCS[b]	1.7 (-3.8, 7.3)	1.0 (-4.9, 6.9)	7.9 (1.7, 14.0)	1.5 (-5.0, 8.0)	3.4 (-3.3, 10.1)	5.7 (-2.0, 13.3)	0.6 (-5.5, 6.8)	0.7 (-6.3, 7.6)	2.9 (-2.3, 8.1)
Activity disability[a]	-0.6 (-1.3, 0.1)	-0.5 (-1.7, 0.7)	-2.4 (-4.4, -0.4)	-0.6 (-2.1, 0.9)	0.4 (-1.5, 2.3)	-2.3 (-4.1, -0.4)	-1.1 (-2.2, 0.1)	0.9 (-1.7, 3.6)	-2.0 (-3.5, -0.4)

Abbreviations: CI, confidence interval; RDQ, Roland-Morris Disability Questionnaire; SF-12, Short-Form 12; PCS, physical component summary; MCS, mental component summary.

Q0, at baseline; Q1, at discharge; Q2, 6 weeks post randomization; Q3, 12 weeks post randomization.

*** Difference in group means between baseline and primary endpoint (12 weeks post randomization).**

[a] Negative values indicated improvement at each time-point (Q1,Q2,Q3) compared with baseline (Q0).

[b] Positive values indicated improvement at each time-point (Q1,Q2,Q3) compared with baseline (Q0).

Table 5.11. Feasibility trial: Numbers of adverse reactions in 45 participants

Adverse reactions*	4-sessions (n= 15)	7-sessions (n= 15)	10-sessions (n= 15)
Needle-site pain	3	1	0
Aggravation of symptoms	0	1	0
Nausea	1	0	0
Needle-site bleeding	1	2	2
Needle-site bruise	0	1	2
Drowsiness after treatment	0	0	1
Total	5	5	5

*** As reported by the participants.**

5.3 Discussion

This study demonstrated that it was feasible and acceptable to recruit and retain participants with chronic LBP in a trial investigating the effectiveness of different session numbers of acupuncture as an adjunct to usual care. 45 participants were recruited within 10 weeks (recruitment rate of 43.7%), and agreed to be randomized. Acupuncture was demonstrated to be acceptable among participants, and high retention rates (86.7%, 86.7%, 100% for the 4, 7, 10 sessions groups, respectively) were recorded. Over 80% of participants indicated that they were 'very satisfied' and/or 'extremely satisfied' with acupuncture. Participant follow-up rates were 88.9% at discharge (Q1) and at six weeks post randomization (Q2), and 84.4% at 12 weeks post randomization (Q3). These findings are encouraging, and support the need to conduct a full-scale RCT to definitively test the optimal dose dependence for acupuncture.

5.3.1 Statement of main findings

5.3.1.1 Recruitment

The recruitment strategy of this study was demonstrated to be feasible. The targeted sample size (45 participants) was achieved within a 10-week recruitment period. Recruitment rate (43.7%) was higher than expected (which was set at 20%), and higher than some other

acupuncture studies for treating chronic LBP (varied from 24.6% to 26.8%) (Cherkin *et al*., 2009; Meng *et al*., 2003); this response supports the potential for use of the low-cost recruitment approach in a future trial. Furthermore, the favorable recruitment rate indicated high interest level for TCM acupuncture amongst the local chronic LBP population.

5.3.1.2 Retention rates

High retention rates of study participants (86.7%, 86.7%, 100% for the 4, 7, 10 sessions groups, respectively) and excellent treatment adherence indicated that TCM acupuncture is acceptable to patients with chronic LBP. The proportion of participant withdrawal (4/45 (8.9%)) during the intervention period was similar to previous acupuncture trials in chronic LBP population (varied from 8.3% to 9.1%) (Meng *et al*., 2003; Weiß, Quante, Xue, Muche, & Reuss-Borst, 2013). The semi-standardized acupuncture treatment was demonstrated to be acceptable among participants with no major deviations from the pre-specified treatment protocol.

5.3.1.3 Measurement tools and follow-up rates

Outcome questionnaires used in this study were demonstrated to be appropriate and feasible for self-completion. Participants reported increased ease of use of these questionnaires over time. The mean time taken to complete questionnaires was 4.5 minutes. Follow-up rates of study participants at the three assessment time-points met the *a priori* criteria (≥ 80%), which suggested the reminder procedure used in this study was efficient. The reminder process was developed through discussion within the research team, and may be optimized by adding advanced telephone calls ahead of the reminder emails on the due date of each questionnaire (MacLennan, McDonald, McPherson, Treweek, & Avenell, 2014).

5.3.1.4 Safety of acupuncture

There were no serious adverse events reported in this study. Mild to moderate adverse reactions to acupuncture indicated the current treatment protocol is low risk for patients with chronic LBP. The most common adverse reactions were minor needle-site bleeding and bruising that were both relieved without specific medical treatment. These adverse reactions are amongst those commonly reported in acupuncture research (Chung *et al*., 2014), and were considered to be minimal compared to the reported side effects from pharmacologic treatment such as NSAIDs (Horvath *et al*., 2015; Wehling, 2014). Four participants voluntarily withdrawn from the study due to needle-site pain during treatment (n=3) and aggravation of back pain after the first treatment (n=1). On follow-up with these participants, adverse reactions were relieved shortly (less than 24 hours) without particular medical therapy. As these four participants were acupuncture naïve, and enrolled in the study at an early stage (among the first ten recruited), lack of pre-treatment assurance concerning possibility of needling reactions and symptom aggravation may explain the withdrawals. After a research group discussion, the acupuncturist (LL) informed subsequent participants with potential reactions following acupuncture treatment; no more withdrawals due to adverse reactions were reported.

5.3.1.5 Participants' satisfaction

Participants indicated a high degree of satisfaction with acupuncture. Qualitative data in the current study suggested the acupuncture treatment was delivered in a comfortable and relaxed manner; participants reported noticeable benefits in back symptoms, sleeping and overall energy. In addition, three participants provided suggestions for a future study such as categorization of needling sensation (e.g. tingling, sharpness, numbness, heat, distension) to facilitate patient report, and changing the acupuncturist's method of inquiry when locating acupoints (i.e. to ask a participant whether a point is sensitive to touch). These results

emphasized the value of acupuncture for patients with chronic LBP and the importance of continuing to identify facilitators of acupuncture acceptability in the main trial.

5.3.1.6 Effectiveness of the interventions

Results demonstrated a trend toward decreased pain intensity with successive acupuncture treatments during the intervention periods. While each session provided instant pain relief, the greatest improvements were detected in the first three sessions. Although the three groups all perceived improved symptoms from baseline to the primary endpoint, there was a numerically larger improvement in secondary outcome measures (except for pain intensity) in the 10-session group. Participants in the 4-session group and the 10-session group experienced similar pain reduction (both pain intensity and pain bothersomeness) at 12 weeks post randomization. Sensitivity analysis using imputed data provided similar results. These observations suggest a larger definitive study is likely to elucidate the optimal number of sessions of acupuncture in the management of chronic LBP.

5.3.2 Implication for future trials

5.3.2.1 Sample size estimates

Based upon data from this feasibility study, conservatively estimated standard deviations for change scores from baseline to the primary endpoint are 4 points for the RDQ and 30mm for the pain intensity VAS. In order to provide 80% power to detect the minimal clinically important differences (MCIDs) (2.5-point in the RDQ and 20mm in the VAS) between any two groups of acupuncture using two-sided tests at the 0.05 level, the minimum number of participants needed in each group is 42 for the RDQ and 37 for the VAS. In order to allow for a 20% of withdrawal or dropout rate, these requirements become 53/group and 47/group respectively. To achieve this, 160 participants in total (three groups) will be needed at baseline for the definitive trial.

5.3.2.2 Recruitment

This feasibility study found that posting study flyers via social media (i.e. Facebook page) was the most efficient approach for recruiting participants; this highlights the importance of incorporating communication technologies into recruitment in a future trial (Gupta *et al.*, 2015; Leonard, Hutchesson, Patterson, Chalmers, & Collins, 2014; Martinez *et al.*, 2014). Additionally, the best physical places to recruit a definitive trial were community centres (e.g. noticeboards at supermarkets and hospital) where there is a large cross section of the population. As around three quarters of participants in the current study were young adults (aged between 20 to 39 years), in a future trial it will be important to recruit greater participation levels of middle-aged and old adults to broaden applicability of study conclusions to adults across the age range (not least given the prevalence profile for LBP). Possible approaches include integrating the research into existing health care sittings (e.g. primary care community health centres and relevant departments in hospitals).

An additional issue requiring attention in a future trial is the duration between participant recruitment and baseline assessment. Due to time and space limitation, there was usually a delay between recruitment and baseline assessment (time ranged from 0 to 31 days), especially in the second and third weeks when there were a large number of recruited participants. Seven participants in this trial reported baseline level of back function below the minimum eligibility criteria, thus were excluded from participation. This indicates the temporal variability of back symptoms, and a (potentially) higher level of exclusion in a larger main trial when there may be a considerable gap between recruitment and baseline assessment. For the definitive trial, it may be useful to consider extending research sites to settings with appropriate resources for carrying out acupuncture clinical research (e.g. trained personnel, and office space). This would enable recruited participants to complete

baseline assessment in a timely manner, and therefore minimize temporal symptom variability. In order to aid standardization and consistency of the trial process at different research sites, training workshops for clinical administrators and acupuncturists would be necessary prior to starting the trial. Moreover, it may be beneficial to monitor fidelity of treatment content through random observation sessions by an acupuncturist expert throughout the trial period, in addition to acupuncturists' self-reported treatment logs at the end of study.

5.3.2.3 Retention rates

This feasibility study demonstrated a high retention and adherence rate for 4, 7, or 10 sessions of acupuncture treatment. Four participants were voluntarily withdrawn from intervention in the first two sessions. Given that local participants are mostly acupuncture naïve, in order to minimize early withdrawal in a future trial, it would be important for acupuncturists to provide (emphasize) participants with detailed explanations about the proposed treatment, the needling technique, and any potential reactions following acupuncture. Apart from this, physical examination of the lumbar region suggested muscle spasm in three participants who withdrew, and in one participant in the 4-session group (but who requested to remain in the study). The acupuncturist discussed the examination results with experienced physiotherapists in the research group, and reached a diagnosis consensus. Review of eligibility screening criteria before randomization are therefore indicated for a definitive trial, to ensure that the trial recruits those patients who are most likely to physically accept and tolerate acupuncture treatment. According to clinical practice, participants with lumbar muscle spasm are more likely to experience sharp pain during needle insertion, which may be aggravated when needles are stimulated. For this reason, it may be beneficial that future trials incorporate a test of participant's needling reaction as an additional entry requirement following the screening questionnaires. For participants with

lumbar muscle spasm, a testing needle could be placed at BL25 since it is safe for needling and commonly used for LBP. Participants would be regarded as eligible if they satisfy both the paper-based screening questionnaires and the objective needling assessment. Alternatively, in order to recruit more participants with acupuncture experience (who may tolerate needling treatment better), a future trial may consider patients who received acupuncture treatment beyond the previous 6 months.

5.3.2.4 Follow-up rates

Follow-up rates of participants met the expected level (80%) at 12 weeks post randomization, and 10-session group reported the highest follow-up rate of 93.3%. Findings suggest that it may be beneficial that any definitive trial (with longer term follow-up) follows the reminder strategies used in this study. Maximizing the use of reminders, emails, and phone calls is suggested. Application of electronic questionnaires could be considered (Cope, 2014). Availability of electronic version of the questionnaires would reduce time and research costs. Moreover, the ease of access would also address the issue of the late response of postal questionnaires due to work commitments or out of town travel, which were reasons cited by participants from the current trial. In addition, as the four withdrawals (2 each in the 4-session group and the 7-session group) were not chased for follow-up outcome measure questionnaires, in order to increase follow-up rates in a future trial, all enrolled participants should be followed up.

This notwithstanding, management of missing data is worthy of note. When data are incomplete, all approaches to statistical analyses introduce a level of uncertainty (White *et al*., 2011). As incomplete data reduce power and efficiency of studies, in the main trial efforts should be made to minimize the extent of missing data by careful study design and trial monitoring (Bell *et al*., 2014; Shih, 2002; White *et al*., 2011). It has been advocated that

all randomized participants, including those who depart from their allocated intervention, should be followed up and their outcome measures included in analysis (White *et al*., 2011). While this might be difficult in practice, it is important as outcome data from withdrawals may differ from those who remain on treatment. The main trial should attempt to follow up all randomized participants, thus to enable a 'truly' intention-to-treat study design.

5.3.2.5 Measuring study outcomes

Secondary outcome measurements of this feasibility study covered the five recommended core domains of patient-based outcome measures for LBP. Results from the outcome questionnaires have been shown to be feasible to complete. Since the RDQ (Kalauokalani, Cherkin, Sherman, Koepsell, & Deyo, 2001) was argued to be better able to detect changes in LBP patients with mild to moderate disability, measuring back function by the RDQ alone may introduce biased results in a definitive trial if recruitment involves a large proportion of participants with persistent severe disability. Thus, the additional use of the Oswestry Disability Index questionnaire (Fairbank & Pynsent, 2000) may be considered in the main trial.

Exploratory findings of this study suggested a trend of increased benefits for clinical outcomes in the 10-session group. It is important to highlight that this feasibility study did not have the power to investigate changes in effectiveness between groups and that the small sample size may explain the baseline differences in outcomes between groups, and subsequent changes over time. Given the conflicting evidence and associated limitations of small participant sample of previous studies, results require replication before any strong conclusions can be drawn. It is therefore recommended that adequately powered and well-designed large-scale trials are necessary to ascertain the optimal dosage (in terms of treatment sessions) of acupuncture for chronic LBP.

The current pain intensity after each treatment session suggests a cumulative analgesic effect of successive acupuncture. After three sessions, the post-treatment pain was gradually decreased in the 10-session group. This result was reflective of previous research that showed a similar trend in pain relief of repeated electro-acupuncture in a rat model of neuropathic pain (Gao *et al*., 2014). Apart from this, it was interesting to note that participants having 4-session acupuncture made more rapid improvements than the other two groups after completion of the first four treatment sessions. As participants in the 4-session group had lower BMI and reported a lower proportion of previous LBP history at baseline, future research is suggested to further explore the relevance of these characteristics to the immediate analgesia effect of acupuncture.

5.3.3 Limitations of the study

As a feasibility study, the primary limitation of this study was the small sample size and lack of statistical power to inform conclusions on the superiority of interventions. However, this also reflects the purpose of a feasibility study, which is to test the rationale and method proposed for use in the main study (Arain *et al*., 2010). Findings of the study suggested that there is room to improve methodology, especially in reference to investigation of the longer-term effects of different dosage of acupuncture.

The study findings were based upon the acupuncture delivered by one acupuncturist in a single research centre, and therefore may not be representative of the wide population of patients and professional acupuncture practitioners. In addition, as acknowledged before, the participant age structure was skewed to young adulthood, which may limit the generalizability of the results.

The lack of control for use of other health services for LBP throughout the study period introduced a potential bias to the results of the study. Acknowledging this, this feasibility study was a pragmatic trial. In order to reflect everyday clinical contexts, the usual care that participants received during the participation period were not restricted. Built upon this study, a future, fully powered RCT will aim to definitely investigate the optimal dosage of acupuncture plus usual care for chronic LBP, thus to produce the evidence to facilitate a real choice in routine practice. Nevertheless, as the measurement of participants' medication consumption and other therapy programmes for LBP following randomization have been used in other acupuncture studies (Cherkin *et al*., 2009; Hinman *et al*., 2014; Hunter *et al*., 2012; Meng *et al*., 2003), the main trial should include these into the outcome measures, and also evaluate the cost-effectiveness of the different sessions of acupuncture treatment for patients with chronic LBP.

5.4 Conclusion

This study demonstrated the feasibility of carrying out a definitive RCT on a larger scale comparing outcomes from different session numbers of TCM acupuncture in the management of chronic LBP. Study results suggested the further exploration of the dosage dependence of TCM acupuncture that is applied in addition to usual care for patients with chronic LBP.

6 General discussion

6.1 Background

As an ancient medical procedure that is still in common usage, acupuncture has become an increasingly popular therapeutic intervention in the management of low back pain (LBP) by primary health care professionals. In contrast to such popularity, current research findings in this field are characterized by contradictory conclusions regarding effectiveness of acupuncture, poor reporting on acupuncture outcomes, and lack of optimal acupuncture treatment protocols.

The objectives of this current thesis were developed to address these gaps using a systematic, step-wise, and pragmatic approach to the research. The United Kingdom (UK) Medical Research Council (MRC) guidelines for developing and evaluating complex interventions provided the framework for the thesis development (Craig *et al*., 2008). The approach involved a comprehensive evaluation of the evidence for the effectiveness of acupuncture for LBP (Chapter 2), an in-depth review of strategies to improve on the reporting quality of acupuncture research (Chapter 3), and a preliminary test of the feasibility for conducting a fully powered randomized controlled trial (RCT) investigating the optimal number of sessions of acupuncture used as an adjunct to usual care for adults with chronic LBP (Chapters 4 and 5). The findings of this thesis have raised a number of important issues that have implications requiring further exploration. These issues are discussed in this chapter, along with recommendations for future research regarding acupuncture for the treatment of chronic LBP.

6.2 Overview of thesis

An overview of the thesis findings as well as directions for future research in accordance with the MRC framework for complex interventions (Craig *et al*., 2008) is shown in Figure 6.1.

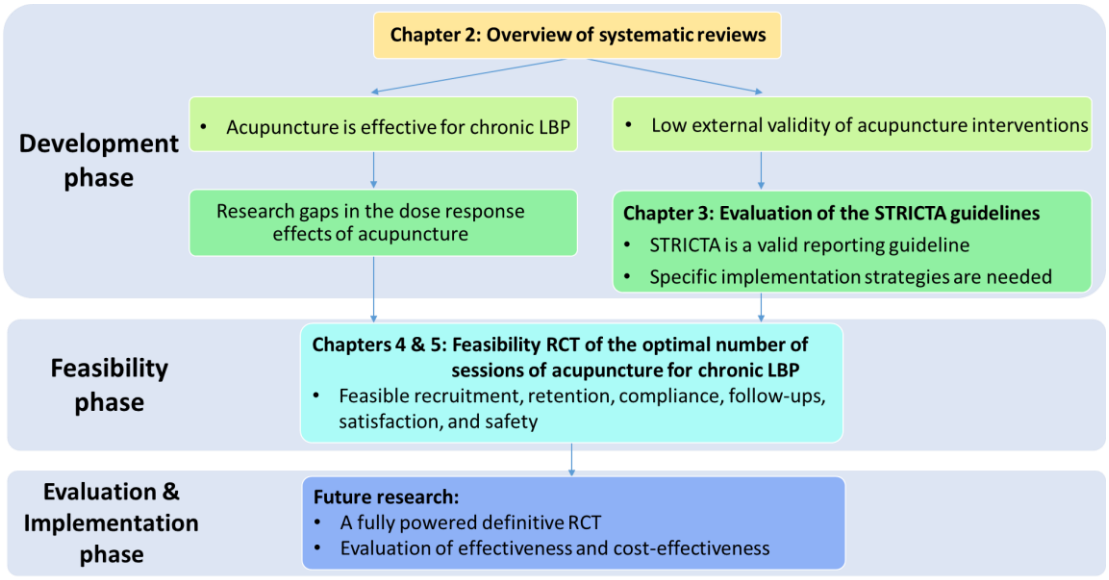

Figure 6.1. Overview of thesis: *Findings and directions for future research regarding acupuncture for the treatment of low back pain*
Abbreviation: LBP, low back pain; STRICTA, Standards for Reporting Interventions in Clinical Trials of Acupuncture; RCT, randomized controlled trial.

Despite the widespread use of acupuncture for LBP, the effectiveness of acupuncture is still controversial. Conflicting conclusions from published systematic reviews and clinical guidelines informed the need for a more comprehensive evaluation of the current evidence. Chapter 2 provided an overview of the current systematic reviews in the field of acupuncture for LBP. Evidence suggested that acupuncture is an effective treatment option for patients with chronic LBP. When compared with no treatment or used as an adjunct to conventional care, acupuncture provided significant clinical benefits including pain relief and functional improvement at short-term follow-up (less than three months after randomization). While the overall effect sizes were medium to large for both outcome measures in comparison with no treatment, the largest effect sizes for functional measures

were found when acupuncture was used as an adjunct to other conventional interventions (e.g. usual care, physiotherapy, medications, and exercises).

The overview of systematic reviews presented an assessment of both internal and external validity of the included reviews. Findings suggested there was an acceptable level of internal validity since the majority of reviews (11/16) were considered as moderate or high quality. The overview highlighted the weakness of reporting quality on acupuncture interventions; only one review (Lee *et al*., 2013) clearly presented the extracted details of acupuncture in accordance with the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines (MacPherson *et al*., 2010b). Inadequate description of acupuncture components impedes study replication and further investigation of the dosage effects of acupuncture on intervention outcomes. A progressive step toward addressing this issue is to improve the impact and utilization of STRICTA.

In this regard, the STRICTA guidelines were firstly evaluated from four aspects (i.e. development procedure, validity assessment, endorsement and adherence, and citation situation) in Chapter 3. It was demonstrated that STRICTA is a valid reporting guidelines based on robust methodology and scientific content. However specific implementation strategies including: updating the STRICTA checklist; improving the STRICTA reporting efficiency; implementing the 'Instructions to authors' for journals consistently; establishing STRICTA research centres globally; and expanding the STRICTA website, are needed for improvement in the efficacy of the STRICTA guidelines, which will serve to promote the reporting quality and reliability of acupuncture research.

Based upon the findings and issues raised from Chapters 2 and 3, along with the limited evidence available regarding the dose response effects of acupuncture in clinical settings, it

was decided to conduct a definitive RCT of rigorous internal and external validity to assess the optimal number of sessions of acupuncture in the management of chronic LBP. A feasibility study to test the rationale and method for the full scale trial was the first step in that process (Chapters 4 and 5). Given the intractable nature of chronic LBP, a multimodal treatment approach was suggested (Dale & Stacey, 2016). The study was designed using pragmatic, active controls; different sessions (4, 7 and 10) of acupuncture were used as an adjunct treatment to usual care for chronic LBP.

Results from the feasibility study demonstrated that it is feasible to carry out a definitive RCT on a larger scale comparing outcomes from different session numbers of acupuncture in the treatment of chronic LBP. High participant satisfaction as well as excellent recruitment and retention rates indicated the adjunct use of acupuncture was acceptable to a local population with chronic LBP. Acupuncture was safe for patients with chronic LBP; only mild to moderate adverse reactions of acupuncture were reported and there were no serious adverse events. Exploratory findings of the feasibility study suggested a time-dependent cumulative analgesic effects of successive acupuncture treatments for chronic LBP. Additionally, 10 sessions of acupuncture showed a trend of the greatest improvements in back function, pain, general health status, and activity disability at 12 weeks post randomization. Positive results from the feasibility study indicate the need for a future fully powered RCT investigating the dose dependence of acupuncture for chronic LBP. Moreover, further development in trial design and management based on the recommendations from the feasibility study (see Chapter 5, section 5.3.2) should be considered in the main trial.

6.3 Literature update in the field of acupuncture for low back pain

The following section reviews the systematic reviews and overviews published subsequent to completion of the work reported in Chapter 2, and provides updated evidence regarding the effectiveness of acupuncture in the management of LBP.

Findings from two recently published systematic reviews are consistent with those reported in Chapter 2, supporting the use of acupuncture for treating LBP. Qin *et al* performed a meta-analysis (moderate quality) with three RCTs on acupuncture for sciatica (Qin, Liu, Wu, Zhai, & Liu, 2015). It was demonstrated that acupuncture is more effective than conventional medication in relieving pain (mean difference (MD) = −1.23, 95% confidence interval (CI): −1.87 to −0.60). Yuan and colleagues conducted a high quality meta-analysis evaluating the effects of numerous Traditional Chinese Medicine (TCM) therapeutic interventions for neck pain and LBP (Yuan, Guo, Liu, Sun, & Zhang, 2015). Results indicated that for chronic LBP, acupuncture compared to sham acupuncture led to clinically significant lower pain intensity post-treatment (standardized mean difference (SMD) = -0.49, 95%CI: -0.76 to -0.21), and at three months follow-up (SMD= -0.45, 95%CI: -0.76 to -0.14); however, high heterogeneity were detected across studies (I^2= 72.8 and I^2= 76.9%, respectively). When compared with no treatment, acupuncture provided a medium effect size for pain relief (SMD= -0.73, 95%CI: -0.96 to -0.49) and a large effect size for functional improvement post-treatment (SMD= -0.95, 95%CI: -1.42 to - 0.48). A significant difference was observed in favor of acupuncture plus usual care over usual care alone for both pain and function outcomes in the treatment of chronic LBP.

An overview of reviews of acupuncture for chronic nonspecific LBP published in 2015 provided consistent findings to the thesis overview (Chapter 2) (Zeng & Chung, 2015). Due to different search methods (e.g. search strategy and selection criteria), only seven of the

seventeen systematic reviews are common to both overviews (Furlan *et al*., 2005b; Furlan *et al*., 2012; Keller *et al*., 2007; Manheimer *et al*., 2005; Rubinstein *et al*., 2010; Xu *et al*., 2013; Yuan *et al*., 2008). Nevertheless, evidence from this overview consistently demonstrated that acupuncture is more effective when compared with no treatment or when acting as an adjunct treatment modality to another conventional intervention. As the conclusion from our overview is generated from systematic reviews with formal analysis methodology (either meta-analysis or best evidence synthesis), Zeng and Chung's findings strengthen those of the thesis overview in two ways: by reviewing a wider range of literature including narrative reviews (Hutchinson *et al*., 2012; Trigkilidas, 2010), and through a cost-effectiveness evaluation of the use of acupuncture for treating chronic LBP that found positive results (Ambrosio, Bloor, & MacPherson, 2012; Canter, Coon, & Ernst, 2006; Cherkin, Sherman, Deyo, & Shekelle, 2003; Kim, Lee, Chae, Park, & Lee, 2012; van der Roer, Goossens, Evers, & van Tulder, 2005).

While these recent publications provide updated evidence for the use of acupuncture in the treatment of chronic LBP, the associated high risk of bias and poor external validity were identified. The methodological weaknesses were similar to the findings raised in Chapters 2 and 3, including lack of a list of excluded studies (Qin *et al*., 2015; Yuan *et al*., 2015), lack of an interest conflict statement for the included studies (Qin *et al*., 2015; Yuan *et al*., 2015), and inadequate descriptions of acupuncture interventions (Yuan *et al*., 2015). These reviews, combined with the information in the current thesis, suggest a continuous need to enhance the methodological rigor and generalizability of results in future research. The overview of reviews called for future trials to establish the standardization of acupuncture treatment protocol (Zeng & Chung, 2015). This concurs with the recommendations from the current thesis that encourages investigation of the essential characteristics of acupuncture and further analysis of dosage effects.

6.4 Research issues raised from this thesis

This thesis, along with previous literature, raise three research issues regarding acupuncture for LBP as well as the general methodology of clinical trials. These issues are discussed below, in the context of sham acupuncture, terminology of preliminary study, and correspondence between acupoints and myofascial trigger points (MTrPs). It is expected that the discussion of these issues will enlighten future acupuncture research, and provide some context for further development of clinical research methodology guidelines.

6.4.1 Issue 1: Sham acupuncture – any problems?

Overview of the literature (Chapter 2) revealed the wide use of sham acupuncture as a control arm in RCTs of acupuncture for LBP, and in systematic reviews. It is worthwhile to explore the validity of this approach.

Sham acupuncture is used to evaluate the efficacy of acupuncture by attempting to separate the specific from the non-specific effects. In the current overview (Chapter 2), sham acupuncture mainly included 'placebo acupuncture' which used needles of blunt tips without skin penetration, or 'minimal acupuncture' which inserted needles outside acupoints and/or superficially. This might be an appropriate control according to the TCM meridian theory since neither non-insertion nor insertion at non-acupoints would elicit any therapeutic effects; however other forms of Asian medicine use non-insertion or shallow-insertion needling for treatment purposes (e.g. Japanese acupuncture).

Sham acupuncture of these types are not a valid placebo control for needle acupuncture. A systematic review of acupuncture for pain disorders found a medium effect size of 0.42 (measured in SMD) associated with sham acupuncture over no treatment (Madsen,

Gøtzsche, & Hróbjartsson, 2009). Furthermore, a larger SMD of 0.62 was reported in a RCT when comparing sham acupuncture with no treatment (waiting list) in the management of chronic LBP (Brinkhaus *et al*., 2006). As shown in Figure 6.2, sham acupuncture, either placebo acupuncture or minimal acupuncture, inevitably touches the skin, and thus is not fully inert from a physiological perspective (Hopton & MacPherson, 2010; Lund & Lundeberg, 2006; Lund, Naslund, & Lundeberg, 2009). Slight skin touching of sham acupuncture would stimulate mechanoreceptors that are coupled to afferent nerve fibers, and induce emotional and hormonal reactions resulting in part at least, if not all, of the analgesia effects of acupuncture (Lund & Lundeberg, 2006; Lund *et al*., 2009). The procedure of sham acupuncture is argued to mainly test the relevance of needling effects associated with depth and site of needle insertion (Irnich, Salih, Offenbacher, & Fleckenstein, 2011); this is not therefore suitable as an inert placebo. Given this, results obtained from such comparison should be interpreted with caution.

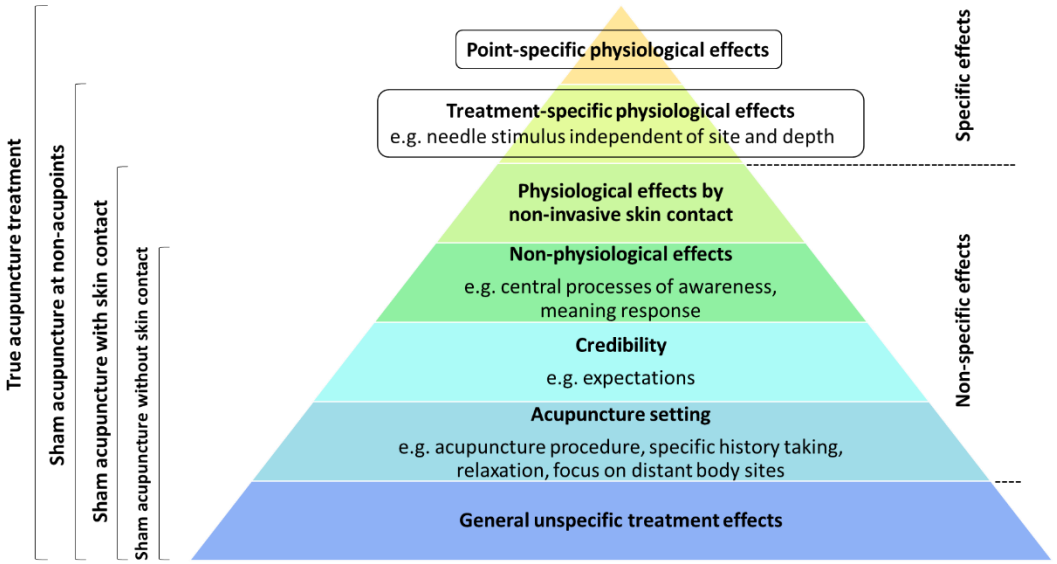

Figure 6.2. Specific and non-specific effects of acupuncture and sham acupuncture (reused with permission from the corresponding author) (Irnich *et al*., 2011)

As reported in Chapter 2, improved back function was found in both true and sham acupuncture groups in systematic reviews, but statistically significant intergroup differences

were not detected (Furlan *et al*., 2012; Lam *et al*., 2013; Lee *et al*., 2013; Manheimer *et al*., 2005; Xu *et al*., 2013; Yuan *et al*., 2008). Beyond the issue of limited differences between true and sham acupuncture (as outlined above), the two forms of acupuncture may be associated with potent non-specific effects that could lead to equivalent functional improvements, i.e. psychological (placebo) effects such as patients' expectancy, and patient-clinician relationship (Cherkin *et al*., 2009; Vickers *et al*., 2012). In addition, since none of the sham procedure would be administered only once, repeated treatment may lead to conditioning placebo responses (Lund *et al*., 2009). As complex medical interventions such as acupuncture are usually associated with higher placebo effects than placebo drugs (Paterson & Dieppe, 2005), it therefore raises the question about whether it is necessary to separate the specific from nonspecific effects of acupuncture.

Based on recent evidence, the answer might be 'no' (Hopton & MacPherson, 2010; Wang, 2012). Assuming that clinical improvement can be achieved independently of affective factors challenges the emphasis of TCM on the holistic integration of 'body and mind'; equally, Western medicine has accepted a 'biological-psychological-social' model as a frame of reference for LBP, and its management (Hopton & MacPherson, 2010; Wang, 2012). Furthermore, diagnosis of non-specific LBP is mainly based on patients' subjective description of symptoms rather than specific clinical diagnostic tests (Keller *et al*., 2007), and prognosis is predominantly associated with affective components related to patients' beliefs and expectations that the treatment will be effective (Lund & Lundeberg, 2006). Sham acupuncture attempts to isolate the physiological effects and is therefore not a perfect research choice from this perspective. Moreover, in routine clinical practice, physicians and patients do not make decisions between true and sham acupuncture, instead they pay more attention to choice between treatments, i.e. acupuncture or other therapies (Vickers *et al*., 2012). Thus it could be argued that future grant-aided research will be more cost-effective if

the research focus shifts from disentangling the effects of true and sham acupuncture, to exploring the effectiveness of acupuncture over other conventional therapies which have been proved to be effective for LBP (i.e. best current treatment). Additionally, in regard to trial design of acupuncture research, considering the inherent difficulties in construction of 'real' sham controls, observational study instead of conventional RCTs, may be a more logical option (Lund *et al*., 2009).

6.4.2 Issue 2: Terms of preliminary study - *feasibility* or *pilot*?

Chapters 4 and 5 presented a preliminary study that tested the rationale and method for a fully-powered RCT investigating the optimal number of sessions of acupuncture in addition to usual care for adults with chronic LBP. While being well conducted, categorizing the trial as a feasibility study rather than a pilot study may be challenged by some terminology purists. Considering this issue, a critical discussion on the use of the terms *feasibility* and *pilot* follows below.

According to the MRC guidelines for complex interventions, preliminary work (feasibility and/or pilot studies) carried out prior to the definitive main trial is an essential prerequisite step in exploring any novel intervention (Craig *et al*., 2008). Rigorous feasibility or pilot studies are meritorious projects that function as a vanguard for investigators and funding organizations to ensure the subsequent large RCTs are designed optimally and can be implemented in practice (Arnold *et al*., 2009; Thabane *et al*., 2010). Notwithstanding the importance of these types of studies, there is limited consideration of taxonomy and relative merits of the two terms; consequently, the terms *feasibility* and *pilot* are often confused among researchers, and used inconsistently when describing the preliminary stage of research process.

The distinction between the terms *feasibility* and *pilot* is not clear, with various definitions suggested by clinical trial methodology researchers. The MRC guidelines does not distinguish feasibility from pilot; instead, the focus is on the outcomes of the feasibility and piloting stages (Craig *et al*., 2008). Thabane *et al*, in their tutorial on pilot studies, considered the two terms synonymous: the rationale for a pilot/feasibility study includes four specific aspects: process, resources, management, and scientific (Thabane *et al*., 2010). Arnold *et al* in contrast, provided three separate definitions for the different types of preliminary work, including pilot work, pilot study, and pilot trial (Arnold *et al*., 2009). They defined pilot work as 'any background research that informs a future study'; pilot study as 'studies with a specific hypothesis, objective, and methodology'; and pilot trial as 'a standalone pilot study that includes a randomization procedure' (quoted from p. S69) (Arnold *et al*., 2009). As feasibility study does not reflect the scope of pilot studies, the use of the term *feasibility* was not encouraged by Arnold and colleagues. The UK National Institute for Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre (NETSCC) defines feasibility and pilot studies differently; the terms *feasibility study* and *pilot study* are used to distinguish different phases in the research process (Whitehead *et al*., 2014). According to NETSCC, a feasibility study is defined as "pieces of research done before a main study in order to answer the question 'Can this study be done?'" (quoted from online glossary) ("NETSCC Glossary: Feasibility study,"). It is used to assess important parameters that are needed in designing the main study, including: standard deviation of outcome measure, willingness of clinicians to recruit participants, willingness of participants to be randomized, number of eligible participants, appropriateness of the proposed outcome measures, adherence and follow-up rates, and time taken in data collection and analysis. A pilot study is defined as 'a smaller version of the main study used to test whether the components of the main study can all work together' (quoted from online glossary) ("NETSCC Glossary: Pilot study,"). It mimics the design of the main study, and focuses on the trial processes, e.g. to ensure

recruitment, randomization, treatment and follow-up assessments all proceed well. The aim of pilot studies is to increase experience of the trial personnel in running of the future trial and identify areas of the study requiring modifications for a full-scale trial.

Various definitions of the terminology has resulted in interchangeable use of the two terms. A review published in 2010 failed to find any distinguishing features of a feasibility study from a pilot study (Arain *et al*., 2010). It seemed that compared to studies labelled 'feasibility', those labelled 'pilot' are more likely to have stricter methodology components (e.g. sample size estimate, use of randomization and a control arm) and an intention for proceeding to subsequent main trials (Whitehead *et al*., 2014). But as stated in the review, it may be problematic to explore the differences between feasibility and pilot studies simply from a literature review since a trial can be labelled as either term, unless guidelines on consistent usage of these terms are established.

Accordingly, a progressive way forward to address this issue is to develop guidelines which provide a formal distinction between feasibility and pilot studies. Such guidelines are expected to identify the optimal trial components and particular reporting requirements of these types of studies. The development process may benefit from referring to Thabane's checklists for reporting results of pilot investigations (Thabane *et al*., 2010) and collaboration with the Consolidated Standards of Reporting Trials (CONSORT) group to ensure credibility. In the interim, it is suggested that all preliminary work could be described as 'feasibility', and the term 'feasibility' should be used as an general term for preliminary studies (Whitehead *et al*., 2014). A pilot study that tries out the trial procedure and also tests the feasibility of the protocol implementation, could be therefore regarded as a 'feasibility study'. The main objective of a 'feasibility study' should be to test the methodological components of conducting a main trial rather than statistical significance of treatment groups. Taking these

aspects into consideration, it is justified to describe the current preliminary study (Chapters 4 and 5) as a feasibility study. Nevertheless, further research guidelines would be appropriate to clarify and validate this, and to provide some consistency in the taxonomy.

6.4.3 Issue 3: Acupoints and MTrPs - the same stimulation points?

As reported in Chapter 1, contemporary acupuncture treatment includes various application styles, among which TCM acupuncture and Western medical acupuncture such as MTrP needling are the most popular (Kalauokalani *et al*., 2005). There is ongoing controversy surrounding the relationship between these two needling styles (Peng, Nan, Cheng, & Zhou, 2016; Zhou, Ma, & Brogan, 2015; Zhu & Most, 2016). While the Western medical acupuncture approach has roots in TCM acupuncture, MTrP needling is an adaption of classical acupuncture which recognizes mechanistic underpinnings from contemporary scientific-based medicine including anatomy, physiology, and pathology (He *et al*., 2015). The theoretical approach rejects traditional based explanations of meridians and the concepts of acupoints, and has a well-developed medical framework (e.g. terminology, theoretical constructs, and philosophies) that is (seemingly) different from TCM acupuncture (Dunning *et al*., 2014). Table 6.1 compares the two forms of needling (Dommerholt, Moral, & Gröbli, 2006; Dunning *et al*., 2014; He *et al*., 2015; Kalichman & Vulfsons, 2010; Liang, 2006).

Table 6.1. Perceived differences between TCM acupuncture and MTrP needling

		TCM acupuncture*	MTrP needling
Philosophy		Eastern energetic philosophical theory involving meridians and acupoints	Contemporary scientific neurophysiological and biomechanical principles
Objective		Control and regulate the flow and balance of energy	Deactivate trigger points at the muscle cell level and eliminate the nociceptive focus of the muscle
Basic aim		Address underlying causes (emphasise on regulation of Zang-fu functions and Qi-blood flow)	Treat symptoms
Indications		1. Pain and other diseases/disorders (e.g. depression, hypertension, leukopenia, nausea and vomiting, and stroke) 2. Improve health 3. Preventive treatment of diseases	Mainly for myofascial pain
Practitioner		Acupuncturists and therapists trained in TCM	Physiotherapists and musculoskeletal therapists
Training		University-delivered undergraduate (4-5 years) or postgraduate (1-3 years) training in TCM	Short courses often run for 2-4 days, could be as short as 12 hours of training
Needling points	Point target	TCM acupoints including 361 primary channel acupoints, extra acupoints, and Ah-shi points	MTrPs as firm, hyperirritable points located in taut bands of skeletal muscle or fascia
	Point location	Fixed except for Ah-shi points. Located in accordance to historical TCM acupuncture textbooks	Varied. Located by firm palpation of suspected taut band to elicit local tenderness, referred pain or local twitch response
	Point effects	Physiological and pathophysiological effects	Pathophysiological effects only
	Point selection	Local and distal points	Local points mainly
	Point specificity	Yes	No
	Point categorization	Yes (e.g. Five-shu points, Yuan-source points, Luo-connecting point, Back-shu point, and Front-mu point)	No

Response sought	De qi, can be heaviness, soreness, and tingling	Local twitch response with sharp pain, paraesthesia, and discomfort
Needle manipulation	1. Primary manipulation as lifting-thrusting and rotating techniques to elicit De qi; 2. Six secondary manipulation (e.g. needle-handle flicking) to strengthen needling induction; 3. Reinforcing-reducing techniques in accordance to syndrome differentiation	Not particular, can use high-pressure stimulation to elicit local twitch response
Needle retention time	Depends on the nature of diseases (e.g. hot diseases/exterior syndromes for short retention, and cold diseases/interior syndromes for long retention), average time for 10-20 minutes (could be longer if necessary)	0-30 minutes
Co-intervention while needling	Moxibustion (e.g. warm-acupuncture), and electrical stimulation (electro-acupuncture)	Needling alone (dry needling), and needling with injection (wet needling)
Frequency of treatment	Once per day, and chronic diseases may 2-3 times/week	Once per week

Abbreviations: TCM, Traditional Chinese Medicine; MTrP, myofascial trigger point.

***based upon the conventional TCM theory**

In the current feasibility study (Chapters 4 and 5), treatment was based upon TCM acupuncture that follows Meridian Theory. As different styles of acupuncture technique have different treatment protocols, Western medical acupuncture purists may criticize the design of the trial, such as the needling points used compared to the MTrP needling framework. However, further investigation of the relationship between acupoints and MTrPs suggested that the stimulation sites of TCM acupuncture and MTrP needling are actually similar. An in-depth discussion regarding the correspondence between acupoints and MTrPs is reported below.

In 1977, Melzack *et al* published the first evidence-based study comparing MTrPs with classical acupoints (Melzack, Stillwell, & Fox, 1977). They reviewed a set of 56 MTrPs, and compared these to TCM acupoints that are primarily used to treat regional pain conditions. It was found that all 56 MTrPs were within 3cm of an acupoint, and that 71% had the same pain indications as those acupoints. The discovery of anatomically defined TCM acupoints was profound as it provided a physiologic foundation for how acupuncture might work. It widely influenced research on acupuncture until 2003 when Birch published the results of his examination of the validity of Melzack's claim and investigated the two classes of points through a broader range of literature (Birch, 2003). In Birch's review, correlated TCM acupoints were defined to exhibit pressure pain, and are used primarily for pain problems. Results showed an 18% rather than 71% correspondence of MTrPs and TCM acupoints for the treatment of pain, and a meaningful correlation between MTrPs and Ah-shi points only. Subsequently, Dorsher re-examined the anatomic and clinical similarities of TCM acupoints and MTrPs and compared distributions of myofascial referred-pain patterns to acupuncture meridians (Dorsher, 2006). Dorsher used different criteria to Melzack for anatomic correspondence: two points were correlated anatomically if they are within 2cm radius of each other and enter the same muscle. Study findings demonstrated that MTrPs were highly

correlated to TCM acupoints (92% anatomic correspondence and 79.5% clinical); moreover, the myofascial referred-pain patterns of 76% of MTrPs accurately followed relevant meridian distributions. In a later study, Dorsher reviewed four acupuncture texts (three different to Birch's selection) to examine the validity of Birch's findings (Dorsher, 2008). Dorsher suggested that trigger points could conceptually be compared to classical acupoints for pain disorders, and that the clinical correspondence was over 95%. From these reviews, reported correlations between TCM acupoints and MTrPs might be difficult to be explained by chance: thus it is generally accepted by both researchers and clinicians that MTrPs are indeed relevant to acupoints. Travell and Simons, who formally established the theoretical basis of MTrP, in the second edition of their book (Simons, Travell, & Simons, 1999) reflected the results of these reviews, raising the following question - to what extent do MTrPs correlate to acupoints?

The extent of such a correlation is influenced by the operational definition of acupoints. It has been noted above that the range of correlations varied in these reviews. In the last two decades, an increasing body of literature about the practice of acupuncture has developed, including detection and description of 'new' and 'empirical' points by clinicians. It is therefore perhaps not surprising to note a higher correspondence rate in subsequent reviews that include a broader range of sources of literature. Moreover, localization of needling points is controversial. There are usually (pragmatic) adjustments to the point localization and the angle of needle insertion during the treatment process of acupuncture and MTrP needling (Habib, 2012). Molsberger and colleagues examined the localization of 23 commonly used acupoints by 71 experienced physicians with substantial training in acupuncture, and found significant variability in point locations ranging from 2.7 to 41.4 cm^2 (Molsberger, Manickavasagan, Abholz, Maixner, & Endres, 2012). Molsberger *et al* suggested that an acupoint is not a spot but an area, and thus it is highly likely that acupoints *per se*

overlap. Furthermore, the extent of any claimed correlation is also associated with the criteria of anatomic correspondence, such as a 3cm radius between two points in Melzack's review (Melzack *et al*., 1977) or an even smaller radius of 2cm in Dorsher's study (Dorsher, 2006). As acupoints are intensive in the head and distal extremities, it is very likely that several acupoints correlate to the same MTrP. It may therefore be of limited significance to explore the specific extent of these correlations until a defined location of a particular acupoint can be clarified. Additionally, since the theory of channels (meridians) is vital in localizing acupoints in clinical practice (rather missing the acupoint than missing the channel), actual acupoints location is variable. This makes the precise extent of the correlation between acupoints and MTrPs a challenging question to be answered. Apart from these, another important issue about anatomical locations of MTrPs is worthy of note. In studies on the link between MTrPs and acupoints, conclusions were based upon the premise that MTrPs have distinct anatomical locations. However, there is limited evidence to support this notion. Although Travell and Simons described specific MTrPs in numbered sequences, these are not consistent with clinical practice nor do they reveal patients' symptom manifestations (Dommerholt *et al*. 2006). It has been demonstrated that MTrPs are close to motor endplate zones that are associated with excessive release of acetylcholine (Dommerholt *et al*., 2006; Hong, 2000). But distinctive, precise anatomical locations of MTrPs are not definitively established, and consequently any comparison involving these should be interpreted with caution.

Based upon the above, the next logical question which arises is 'with which kinds of acupoints do MTrPs correlate?' Melzack (Melzack *et al*., 1977) and Dorsher (Dorsher, 2006) assessed correlations between MTrPs and primary channel acupoints and extra acupoints using the proximate pain indications of acupoints as a major criterion for correlation. Birch (Birch, 2003) claimed that MTrPs only correlated to Ah-shi points since not all acupoints

were defined by tenderness, and many of the correlating channel acupoints were not typically used for treating pain conditions according to acupuncture textbooks. However, this claim is questionable. Acupuncture literature clearly states that classical acupoints are tender and/or sensitive to pressure, particularly in pain disorders (Dorsher, 2008; O'Connor & Bensky, 1981). Moreover, in TCM meridian theory, almost every acupoint, including primary channel acupoints or extra acupoints, has both regional and distal indications, and therefore, can be used for nearby pain syndromes albeit stated or not. Thus, insistence of correspondence only between MTrPs and Ah-shi points is controversial- MTrPs correlate to all kinds of acupoints, including primary channel acupoints, extra acupoints, and Ah-shi points, at least for treating pain conditions. Given this, selection of needling sites under the MTrP needling framework may not differ from those used in this feasibility study, which followed the Meridian Theory.

6.5 Recommendations for future research

This thesis, developed in accordance with the MRC guidelines for complex interventions (Craig *et al*., 2008), has addressed several research gaps regarding acupuncture for LBP. It has developed the evidence base for the effectiveness of acupuncture in the treatment of LBP, discussed potential approaches to improve on the external validity of acupuncture research surrounding the STRICTA guidelines, and demonstrated the feasibility of conducting a larger scale RCT to investigate the dose response effects of acupuncture for chronic LBP. Based upon the findings from the thesis, further research is encouraged to focus on research areas to further develop this field. Recommendations for future research are discussed in sections 6.5.1 and 6.5.2 below.

6.5.1 Evaluation of the optimal number of sessions of acupuncture in the management of chronic LBP

In line with the MRC guidelines (Craig *et al*., 2008), in order to evaluate the optimal number of sessions of acupuncture in the management of chronic LBP, a fully powered definitive RCT, based on the recommendations from the current feasibility study, represents the next phase of investigation. Such a trial is required to test the statistical significance of outcome measures and investigate the dose dependence of acupuncture. To enable a process evaluation (Craig *et al*., 2008), complete reporting of the intervention implementation adherent to the STRICTA guidelines (MacPherson *et al*., 2010b) would be necessary.

As suggested in the feasibility study, 160 participants will be needed at baseline for the definitive trial. Considering the population size and density of New Zealand, it may be beneficial for the main trial to be conducted as a national, multi-site study. Apart from the current recruitment approaches, utilization of existing health care networks (e.g. primary care community health centres and relevant departments in hospitals) may be considered to boost recruitment rate and balance recruitment ratios (e.g. gender and age) among participants. As patient preference and previous treatment experience towards acupuncture may favour the outcome measures (Kalauokalani *et al*., 2001; Linde *et al*., 2007), in order to maintain a high external validity of the RCT (generalizability of results), the main trial may consider use of participant expectation as an extra screening criteria, and exclude participants who have a strong preference for acupuncture. Local research centres and private acupuncture clinics where there are appropriately trained personnel for carrying out acupuncture clinical research could be involved in delivery of the interventions. Prior to commencing the trial, training workshops and teaching manuals for relevant personnel (e.g. clinical administrators and acupuncturists) at each research sites would be conducted to ensure standardization and consistency of the trial process. It would also be important for

the trial lead to visit participating sites to monitor the fidelity of treatment content, and address any treatment-related issues.

Prior to randomization, more rigorous eligibility assessment, combining the screening questionnaires with a test of participants' needling reaction may help identify a study population more likely to physically accept acupuncture treatment. Potential participants should be informed with details regarding the proposed treatment, the needling technique, and any potential reactions following acupuncture before written informed consent is obtained.

As a fully powered clinical trial to investigate the dose response effects of acupuncture, the use of active controls would be maintained for the main trial. Given the intractable nature of chronic LBP, intervention groups would be 4, 7, or 10 sessions of acupuncture paired with usual care management, as in the current feasibility study. The main trial would follow the semi-standardized TCM acupuncture treatment protocol of the feasibility study which has been demonstrated to be safe, effective and acceptable for patients with chronic LBP. The semi-standardized acupuncture used here is based upon a fixed needle formula for LBP (standardized acupuncture) plus flexible supplementary points that account for possible concomitant buttock or leg pain (individualized acupuncture). This form of treatment permits a degree of standardization for the purpose of an RCT, and allows variations in the treatment process from careful observation and questioning when the participant comes back for follow-up treatment. In order to ensure a high external validity, adhering to the STRICTA guidelines for detailed reporting of the acupuncture intervention is necessary. For the individualized treatment part, the mean and range should be reported (e.g. number of needle insertions per subject per session). Acupuncture purists may disagree with the semi-standardized treatment protocol, which may not fully reflect the TCM principles (namely

syndrome differentiations). Nevertheless, evidence from recent research has supported such treatment formula: there is limited impact of acupoint prescription (i.e. whether standardized, semi-standardized, or individualized) on the effects of acupuncture for chronic pain (Cherkin *et al*., 2009; MacPherson *et al*., 2013).

The five recommended core domains of patient-based outcome measures for LBP would be retained in the main study (Bombardier, 2000). Regarding participant satisfaction, a qualitative study would be nested within the full trial. On completion of the acupuncture intervention, a focus group with study participants would be conducted to explore their attitudes and opinions of the intervention. In addition, measurement of participants' medication consumption and other therapy programmes for LBP after randomization would be included to reduce potential bias to the study results. Besides the short-term follow-up (measured in the feasibility study), outcome measures in the intermediate follow-up (≥ 3 months and < 1 year) and long-term follow-up (≥ 1 year) would be assessed in the main trial (see Chapter 1, Figure 1.4) (Craig *et al*., 2008). Electronic questionnaires rather than postal questionnaires would be used to record these outcome measures.

Moreover, in order to inform a recommendation of the optimal number of treatment sessions of acupuncture in the management of chronic LBP, in parallel with statistical analysis, an economic evaluation of the intervention is necessary (see Chapter 1, Figure 1.4) (Craig *et al*., 2008). The main trial would consider a comparison of the cost-effectiveness of the 4, 7, and 10 sessions of acupuncture used as an adjunct to usual care for patients with chronic LBP. Such economic data would be clinically relevant to patients, clinicians, researchers, and policy makers. Once sound evidence on cost-effectiveness is accumulated, it may provide stronger reasons for relevant policy changes and promote acupuncture access within current health systems (Zeng & Chung, 2015). This in turn will aid

implementation of acupuncture into current best practice, which facilitates the continuing development of acupuncture intervention for chronic LBP (see Chapter 1, Figure 1.4).

It is estimated that direct costs for a main RCT would be approximately $NZ 25,000 (including acupuncture treatment expense, study personnel training costs, study acupuncturists (n=4) salary, Research Assistant (n=1) salary). The New Zealand Health Research Council and/or the Otago Medical Research Foundation would be approached regarding the funding support.

6.5.2 Evaluation of other characteristics of acupuncture in the management of chronic LBP

Similar to the number of treatment sessions, other characteristics of acupuncture, such as frequency of sessions, depth of needle insertion, duration of treatments, and techniques and intensity of stimulation, are factors that influence response to acupuncture. To date, although several RCTs have attempted to address these factors (Itoh, Katsumi, & Kitakoji, 2004; Sator-Katzenschlager *et al*., 2004; Thomas & Lundberg, 1994; Yuan *et al*., 2009), results are usually limited by small sample size and an inappropriate emphasis on hypothesis-testing in pilot studies (Arain *et al*., 2010). Firm conclusions about optimal dose of acupuncture for treating chronic LBP have yet to be established. Although it may be assumed that more frequent treatment, deeper insertion, longer treatment duration, use of electrical stimulation, and stronger stimulation may lead to greater effects, this is not in accordance with an individual patient meta-analysis which suggested that there was little evidence that different characteristics of acupuncture modify the effect of treatment on pain outcomes for patients with chronic pain (osteoarthritis, headache, back and neck pain, and shoulder pain) (MacPherson *et al*., 2013). Due to a lack of data specific to chronic LBP, future trials involving direct comparisons of different treatment protocols are needed to

identify the most effective characteristics of acupuncture for chronic LBP. Additionally, evidence gained from future research may assist with development of clinical guidelines regarding treatment regimens of acupuncture in the management of chronic LBP, which will provide clinicians with evidence-based guidance on an adequate acupuncture dosage in this area.

There continues to be a need for higher quality RCTs investigating the essential characteristics of acupuncture for its effectiveness for chronic LBP. In addition, continual improvement in the external validity related to acupuncture treatment interventions is required. Future RCTs would be expected to strictly adhere to the STRICTA guidelines (MacPherson *et al*., 2010b). Provision of all intervention details would assist with the applicability and utilization of research results in clinical practice, and also facilitate the development of guidelines on optimal acupuncture treatment protocols. Further development strategies for STRICTA, as suggested in the current thesis (see Chapter 3, section 3.2.5), will improve the utilization of STRICTA and impact positively on the quality of reporting on acupuncture research outcomes.

6.6 Strengths of the thesis

The current thesis has been developed through a systematic, step-wise, and pragmatic research approach to investigate the three specific research questions stated in Chapter 1 (see Chapter 1, section 1.4).

Chapter 2 systematically analyzed the results of sixteen existing systematic reviews, and conducted the first overview of systematic reviews of acupuncture for LBP. Overviews are a relatively new approach to evidence synthesis and have become increasing popular in health care literature (Hartling, Chisholm, Thomson, & Dryden, 2012); this approach has particular

relevance for areas with overlapping reviews. For an overview, evidence from multiple systematic reviews relevant to a single condition is compiled and consistency of findings are explored across these reviews (Smith, Devane, Begley, & Clarke, 2011). In the current overview, both the methodological quality and external validity of systematic reviews were assessed using credible and internationally-acceptable criteria (MacPherson *et al*., 2010b; Shea *et al*., 2007); this was the first overview highlighting the importance of generalizability of systematic reviews when establishing the overall value of an intervention. Moreover, conclusions of the overview were scientifically robust and reliable as a sensitivity analysis excluding reviews of low quality supported the outcomes of the primary analysis.

The systematic and critical evaluation of the STRICTA guidelines in Chapter 3 was unique in that it was the first to review the issue. The conclusions drawn are likely to be of interest to the developers of STRICTA as well as other reporting guidelines, researchers, journal publishers, and funding organizations, as the proposed suggestions may be the catalyst to optimize subsequent STRICTA guidelines. This in turn, may lead to better quality reporting on acupuncture trials, assist interpretation and analysis, enable replication of studies, and improve the translation of research results into clinical practice.

The main strengths of the feasibility study were excellent recruitment rate, high retention and compliance, acceptable levels of follow-up, high participant satisfaction, and no associated serious adverse events. Besides these, this study was conducted with sound internal and external validity. It satisfied most of items listed by the PEDro scale (Maher *et al*., 2003) (three of the ten points were missing due to no blinding of patients, acupuncturist, and assessors- who were patients *per se* as outcomes were self-reported), therefore has a high methodological quality of 6/10. Additionally, with regards to its external validity, this trial was reported in accordance with the CONSORT statement for trials of non-

pharmacologic treatments (Boutron *et al*., 2008), and details of acupuncture intervention were described in adherence to the STRICTA guidelines (MacPherson *et al*., 2010b). As there was no restriction for usual care during the participation period, the design of the feasibility study reflected everyday clinical context of treatment.

6.7 Limitations of the thesis

The limitations of the current thesis were mainly related to the research methods used. In the overview of systematic reviews (Chapter 2), methodological quality of the included reviews were assessed by the Assessment of Multiple Systematic Reviews (AMSTAR) checklist (Shea *et al*., 2007). However, since AMSTAR provided only qualitative assessment, there was no consensus on the cut-off points for quality levels. Although the systematic review of the highest quality in the overview (Furlan *et al*., 2005b) was considered to have a very low risk of bias according to the National Institute for Health and Clinical Excellence (NICE) guidelines (Savigny *et al*., 2009), it is possible that other evaluation criteria may produce a different result for methodological quality .

The validity assessment of the STRICTA guidelines in Chapter 3 also involved a degree of subjectivity. Yet there have been no formal tools developed to evaluate the quality of reporting guidelines, the two frameworks suggested by the Enhancing the Quality and Transparency of Health Research (EQUATOR) network (Hoffmann *et al*., 2014; Moher *et al*., 2010) were transformed into two rating instruments to assess the robustness of development process and the content integrity of STRICTA. As the credibility of such assessment approach may be argued, more critical appraisals were called for to reduce subjective bias.

The primary limitation of the feasibility study was the small sample size. There was an unbalanced recruitment ratio among different age groups: as nearly 75% of participants in the current study were young adults (aged between 20 and 39), thus the wider applicability of study results may be limited. Furthermore, the lack of measurement of participants' medication consumption and other therapy programmes for LBP may be a confounding factor for the study results, which should be addressed in the subsequent main RCT.

6.8 Conclusion

The current thesis has provided evidence to add to the scientific basis underpinning the therapeutic value of acupuncture for LBP. From the overview of systematic reviews, acupuncture, either used in isolation or as an adjunct to conventional therapy, has been demonstrated as an effective clinical option for patients with chronic LBP. The need for improvements in the external validity of acupuncture research has been highlighted by the findings of the overview; potential options to improve on such reporting have been discussed surrounding the specific strategies for improving the efficacy of the STRICTA guidelines. There is currently limited evidence available regarding the dose dependence of acupuncture for chronic LBP based on the number of sessions. Results from the feasibility study demonstrated the time-dependent, cumulative analgesic effects of successive acupuncture treatments, and a trend of greatest symptom improvement in the 10-session acupuncture group. Evidence supported the decision to proceed a full-scale RCT to definitively test the dose response effects of acupuncture, and investigate the optimal number of sessions of acupuncture in the management of chronic LBP.

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Appendix 1. Overview of systematic reviews: Literature search strategy

Table 1.1. MEDLINE via Ovid interface (from inception to February 21, 2014)

Step	Search term	No. of results
1	review.pt.	1834993
2	meta analysis/	44357
3	(systematic$ adj review$).tw	51995
4	(meta analy$).tw	58477
5	or/ 1-4	1886676
6	acupuncture/	1167
7	exp acupuncture ear/	249
8	exp acupuncture therapy/	16133
9	exp acupuncture points/	3751
10	needles/	10577
11	electroacupuncture/	2424
12	trigger points/	95
13	moxibustion/	1068
14	acupuncture$.tw	14262
15	needl$.tw	84315
16	(electro$ adj acupuncture$).tw	603
17	(auricul$ adj acupuncture$).tw	241
18	(warm$ adj acupuncture$).tw	9
19	(dry needl$).tw	144
20	(trigger-point$ adj therap$).tw	60
21	or/ 6-20	104383
22	low back pain/	13616
23	back pain/	14399
24	sciatica/	4067
25	(low$ back pain$).tw	17258
26	(back pain$).tw	28577
27	backach$.tw	2035
28	lumbago$.tw	1081
29	dorsalgia$.tw	66
30	or/ 22-29	44297
31	5 and 21 and 30	240
32	animals/ not humans/	3791961
33	31 not 32	237

Abbreviations: pt, publication type; adj, adjacency; tw, text word; exp, exploded.
$ For truncation.

Table 1.2. EMBASE via Ovid interface (from inception to February 21, 2014)

Step	Search term	No. of results
1	review.pt.	2062617
2	systematic review/	70772
3	meta analysis/	80958
4	(systematic$ adj review$).tw.	67796
5	(meta analy$).tw.	79056
6	or/ 1-5	2157852
7	acupuncture/ or exp acupuncture needle/	29367
8	needle/ or exp acupuncture needle/	33506
9	electroacupuncture/	4036
10	trigger point/th	1
11	moxibustion/	1534
12	acupuncture$.tw.	21814
13	needl$.tw.	121772
14	(electro$ adj acupuncture$).tw.	910
15	(auricul$ adj acupuncture$).tw.	378
16	(warm$ adj acupuncture$).tw.	12
17	(dry needl$).tw.	217
18	(trigger point$ adj therap$).tw	67
19	or/ 7-18	157198
20	low back pain/rh, th	7306
21	backache/rh, th	3422
22	sciatica/ or exp intervertebral disk hernia/ or exp lumbar disk hernia/	20967
23	(low$ back pain$).tw.	24749
24	(back pain$).tw.	40978
25	backach$.tw.	3056
26	lumbago$.tw.	1922
27	dorsalgia$.tw.	132
28	or/ 20-27	66623
29	6 and 19 and 28	573
30	animals/ not humans/	1420149
31	29 not 30	570

Abbreviations: pt, publication type; adj, adjacency; tw, text word; exp, exploded; th, therapy; rh, rehabilitation.
$ For truncation.

Table 1.3. AMED via Ovid interface (from inception to February 21, 2014)

Step	Search term	No. of results
1	review.pt.	6652
2	exp Evidence based medicine/ or Meta analysis/	2351
3	(systematic$ adj review$).mp.	2262
4	meta analy$.mp.	965
5	or/1-4	9978
6	Acupuncture/ or exp Acupuncture therapy/	9291
7	exp Acupoints/ or Needles/	1656
8	Electroacupuncture/	744
9	Ear acupuncture/	388
10	Needling/	288
11	Moxibustion/	475
12	acupuncture$.mp.	8895
13	needl$.mp.	1637
14	(electro$ adj acupuncture$).mp.	202
15	(auricul$ adj acupuncture$).mp.	115
16	(warm$ adj acupuncture$).mp.	11
17	dry needl$.mp.	42
18	(trigger-point$ adj therap$).mp.	31
19	or/6-18	10217
20	Low back pain/	3791
21	Backache/	1709
22	Sciatica/	135
23	low$ back pain$.mp.	4895
24	back pain$.mp.	5808
25	backach$.mp.	1746
26	lumbago$.mp.	43
27	dorsalgia$.mp.	3
28	or/20-27	6642
29	5 and 19 and 28	42
30	animals/ not humans/	4282
31	29 not 30	42

Abbreviations: pt, publication type; exp, exploded; adj, adjacency; mp, title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier.
$ For truncation.

Table 1.4. Cochrane Database of Systematic Reviews via Ovid interface (from inception to February 21, 2014)

Step	Search term	No. of results
1	systematic review.pt.	5806
2	(systematic$ adj review$).mp.	6840
3	meta analy$.mp.	6828
4	or/1-3	8050
5	acupuncture$.mp.	398
6	acupuncture therap$.mp.	92
7	acupuncture point$.mp.	96
8	acupuncture ear.mp.	28
9	needl$.mp.	496
10	electroacupuncture$.mp.	78
11	(auricul$ adj acupuncture$).mp.	30
12	(warm$ adj acupuncture$).mp.	2
13	(electro$ adj acupuncture$).mp.	65
14	dry needl$.mp.	20
15	(trigger-point$ adj therap$).mp.	6
16	trigger$ point$.mp.	61
17	moxibust$.mp.	72
18	or/5-17	787
19	low$ back pain$.mp.	155
20	back pain$.tw.	318
21	backach$.mp.	88
22	lumbago$.mp.	49
23	sciatica$.mp.	64
24	dorsalgia$.mp.	35
25	or/19-24	356
26	4 and 18 and 25	87
27	human$.mp.	7049
28	26 and 27	82

Abbreviations: pt, publication type; adj, adjacency; mp, title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier.
$ For truncation.

Appendix 2. Overview of systematic reviews: Excluded systematic reviews

References	Reason for Exclusion
Pennick and Liddle (2013) *Cochrane Database of Systematic Reviews,* 8: CD001139	No separate data of acupuncture for back pain
White and Foell (2013) *Evidence-Based Medicine*, 18(6): e56	Not systematic review
Amezaga Urruela and Suarez-Almazor (2012) *Current Rheumatology Reports,* 14(6): 589-597	Not systematic review
Ernst (2012) *Focus on Alternative and Complementary Therapies,* 17(4): 223-224	Commentary
Hutchinson *et al* (2012) *Journal of Orthopaedic Surgery and Research,* 7: 36	Narrative systematic review
Marlowe (2012) *Primary Care - Clinics in Office Practice,* 39(3): 533-546	Not systematic review
Richards *et al* (2012) *Acta Obstetricia et Gynecologica Scandinavica,* 91(9): 1038-1045	Narrative systematic review
Tan (2012) *Chengdu University of Traditional Chinese Medicine: China*	Inappropriate data analysis
Vickers *et al* (2012) *Archives of Internal Medicine,* 172(19): 1444-1453	Unavailable separate data for back pain
Yu *et al* (2012) *Chinese Journal of Information on TCM,* 19(5): 27-29	No separate data available
Grazio and Balen (2011) *Acta Clinica Croatica,* 50(4): 513-530	Not systematic review
Katonis *et al* (2011) *Hippokratia,* 15(3): 205-210	Not systematic review
Li (2011) *Shanghai University of Traditional Chinese Medicine: China*	Compared different forms of acupuncture
Berman *et al* (2010) *New England Journal of Medicine,* 363(5): 454-461	Not systematic review
Furlan *et al* (2010) *Evidence Report/Technology Assessment,* (194): 1-764	Duplicated systematic reviews
Scott (2010) *Journal of the Acupuncture Association of Chartered Physiotherapists,* (3): 29-33	Not systematic review
Slattengren (2010) *Evidence-Based Practice,* 13(3): 13	Not systematic review
Trigkilidas (2010) *Annals of the Royal College of Surgeons of England,* 92(7): 595-598	Narrative systematic review
Kelly (2009) *American Family Physician,* 80(5): 481-484	Not systematic review

References	Reason for Exclusion
Vickers and Maschino (2009) *Acupuncture in Medicine,* 27(3): 126-127	Not systematic review
Rooney (2008) *Internet Journal of Advanced Nursing Practice,* 9(2): 6p	Not systematic review
Luijsterburg *et al* (2007) *European Spine Journal,* 16(7): 881-899	Unavailable data of acupuncture
Pennick and Young (2007) *Cochrane Database of Systematic Reviews,* (2): CD001139	No separate data of acupuncture for back pain
Shen *et al* (2006) *Journal of the American Academy of Orthopaedic Surgeons,* 14(8): 477-487	Not systematic review
Caroli *et al* (2005) *Geriatric and Medical Intelligence,* 14(1): 51-54	Not systematic review
Furlan *et al* (2005) *Spine,* 30(8): 944-963	Duplicated systematic reviews
Kluger and Bachmann (2005) *Deutsche Zeitschrift fur Akupunktur,* 48(4): 37-39	Commentary
Linde *et al* (2005) *Forschende Komplementarmedizin und Klassische Naturheilkunde,* 12(4): 225-227	Commentary
Liu (2005) *Chinese Journal of Clinical Rehabilitation,* 9(18): 195-197	Not systematic review
Luo and Luo (2005) *Journal of Clinical Acupuncture and Moxibustion* 21(6): 10-14	Insufficient data to judge study types
Spearing *et al* (2005) *APLAR Journal of Rheumatology,* 8(1): 5-15	Not systematic review
Ernst (2004) *Best Practice & Research. Clinical Rheumatology,* 18(4): 539-556	Not systematic review
Maher (2004) *Orthopedic Clinics of North America,* 35(1): 57-64	Not systematic review
Abdulrazzaq *et al* (2003) *Emirates Medical Journal,* 21(2): 128-132	Not systematic review
Eshkevari (2003) *Journal of the American Association of Nurse Anesthetists,* 71(5): 361-370	Not systematic review
Hanada (2003) *Best Practice & Research. Clinical Rheumatology,* 17(1): 151-166	Not systematic review
Ngu *et al* (2003) *Seminars in Spine Surgery,* 15(4): 384-392	Not systematic review
He and Ding (2002) *Chinese Journal of Clinical Rehabilitation,* 6(14): 2034-2035	Not systematic review

References	Reason for Exclusion
Young and Jewell (2002) *Cochrane Database of Systematic Reviews,* (1): CD001139	No separate data of acupuncture for back pain
Haigh (2001) *Reviews in Clinical Gerontology,* 11(3): 277-283	Not systematic review
Smith-Fassler and Lopez-Bushnell (2001) *Holistic Nursing Practice,* 15(3): 35-44	Not systematic review
Smith *et al* (2000) *Pain,* 86(1-2): 119-132	Narrative systematic review
van Tulder *et al* (2000) *Cochrane Database of Systematic Reviews,* (2): CD001351	Updated Cochrane review available
Strauss (1999) *Chiropractic Journal of Australia,* 29(3): 112-118	Narrative systematic review
van Tulder *et al* (1999) *Spine,* 24(11): 1113-1123	Duplicated systematic reviews
van Tulder and Irnich (1999) *Forschende Komplementarmedizin,* 6(3): 154-157	Commentary
Ernst (1998) *Fortschritte der Medizin,* 116(1-2): 20-26	Not systematic review
Longworth and McCarthy (1998) *Acupuncture in Medicine,* 16(1): 18-31	Not systematic review
Longworth and McCarthy (1997) *Journal of Alternative & Complementary Medicine,* 3(1): 55-76	Not systematic review
Birch *et al* (1996) *Journal of Alternative & Complementary Medicine,* 2(1): 101-124	Not systematic review
Ernst and Fialka (1993) *Fortschritte der Medizin,* 111(27): 420-422	Not systematic review
Ceniceros (1992) *Journal of Neurological and Orthopaedic Medicine and Surgery,* 13(4): 263-266	Not systematic review
Tan *et al* (1992) *Baillière's clinical rheumatology,* 6(3): 629-655	Not systematic review
Chen (1990) *American Journal of Acupuncture,* 18(4): 305-323	Not systematic review

Appendix 3. Characteristics of articles cited STRICTA 2002

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
		From English databases (Web of Science and Scopus)			
2002	Niemtzow	Acupuncture in the twenty-first century	Editorial	Journal of Alternative and Complementary Medicine	III
2002	Webster-Harrison *et al*	Acupuncture for tennis elbow: An e-mail consensus study to define a standardised treatment in a GPs' surgery	Delphi study	Acupuncture in Medicine	III
2003	Anastasi and McMahon	Testing strategies to reduce diarrhea in persons with HIV using traditional Chinese medicine: Acupuncture and moxibustion	Observational study	Journal of the Association of Nurses in AIDS Care	II
2003	Birch	Overview of models used in controlled acupuncture studies and thoughts about questions answerable by each	Review: research methodology discussions	Clinical Acupuncture and Oriental Medicine	IV
2003	Dusek *et al*	Healing prayer outcomes studies: Consensus recommendations	Recommendations	Alternative Therapies in Health and Medicine	IV
2003	Hammerschlag	Acupuncture: On what should its evidence base be based?	Commentary	Alternative Therapies in Health and Medicine	IV
2003	Streitberger *et al*	Quality standards for randomised controlled acupuncture trials (Article in German)	Review: research methodology discussions	Deutsche Zeitschrift für Akupunktur	III
2003	Usichenko and Pavlovic	Suggesting the optimal control procedure for acupressure studies	Letter	Anesthesia and Analgesia	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2003	White and Ernst	Pitfalls in conducting systematic reviews of acupuncture	Letter	Rheumatology	II
2003	Wiebrecht	Recommendations of the standards for reporting interventions in controlled trials of acupuncture (STRICTA) (Article in German)	Recommendations	Deutsche Zeitschrift für Akupunktur	III
2003	Zijlstra *et al*	Anti-inflammatory actions of acupuncture	Review	Mediators of Inflammation	II
2004	Audette and Ryan	The role of acupuncture in pain management	Review	Physical Medicine and Rehabilitation Clinics of North America	II
2004	Birch	Clinical research on acupuncture: Part 2. Controlled clinical trials, an overview of their methods	Review: research methodology discussions	Journal of Alternative and Complementary Medicine	III
2004	Cardini	Acupuncture: Scientific evidence	Review	Evidenze scientifiche in agopuntura	IV
2004	Long *et al*	Original research published in the chiropractic literature: Evaluation of the research report	Review: research methodology discussions	Journal of Manipulative and Physiological Therapeutics	II
2004	MacPherson	Pragmatic clinical trials	General article: expert opinion	Complementary Therapies in Medicine	III (2002)
2004	McCarney *et al*	An overview of two Cochrane systematic reviews of complementary treatments for chronic asthma: Acupuncture and homeopathy	Review	Respiratory Medicine	II
2004	Peuker and Filler	Guidelines for case reports of adverse events related to acupuncture	Guidelines	Acupuncture in Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2004	Rogenhofer *et al*	Acupuncture for pain in extracorporeal shockwave lithotripsy	Observational study	Journal of Endourology	II
2004	Veal	Countering misleading information	Review: research methodology discussions	Complementary Therapies in Nursing and Midwifery	IV
2004	White	Writing case reports - Author guidelines for Acupuncture in Medicine	Guidelines	Acupuncture in Medicine	III
2004	White	Methodological concerns when designing trials for the efficacy of acupuncture for the treatment of pain	Review: research methodology discussions	Complementary and Alternative Approaches to Biomedicine	IV
2005	Altman	The development of the CONSORT explanatory document	Guidelines related	Chinese Journal of Evidence-Based Medicine	I
2005	Altman and Moher	Developing guidelines for reporting healthcare research: Scientific rationale and procedures	Guidelines related	Medicina Clinica	I
2005	Baldry and Thompson	Acupuncture, Trigger Points and Musculoskeletal Pain	Book	Publisher: Elsevier Ltd	NA
2005	Castro	Integrating acupuncture in the physical medicine and rehabilitation setting	Review	Critical Reviews in Physical and Rehabilitation Medicine	II
2005	Furlan *et al*	Acupuncture and dry-needling for low back pain: An updated systematic review within the framework of the Cochrane Collaboration	Review	Spine	II
2005	Furlan *et al*	Acupuncture and dry-needling for low back pain	Review	Cochrane Database of Systematic Reviews	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2005	Herman *et al*	Is complementary and alternative medicine (CAM) cost-effective? A systematic review	Review	BMC Complementary and Alternative Medicine	IV
2005	Jedel	Acupuncture in xerostomia - A systematic review	Review	Journal of Oral Rehabilitation	II
2005	Johnston *et al*	Incorporating acupuncture into oncologic practice: How clinical need shapes physician acceptance	Commentary	Journal of Cancer Integrative Medicine	II
2005	Lechleitner *et al*	Feasibility and acceptance of acupuncture treatment in a Department of Internal Medicine (Article in German)	Observational study	Deutsche Zeitschrift für Akupunktur	III
2005	Melchart *et al*	The acupuncture randomised trial (ART) for tension-type headache - Details of the treatment	RCT	Acupuncture in Medicine	III
2005	Mills *et al*	An analysis of general medical and specialist journals that endorse CONSORT found that reporting was not enforced consistently	Review: research methodology discussions	Journal of Clinical Epidemiology	I
2005	Mills *et al*	The quality of randomized trial reporting in leading medical journals since the revised CONSORT statement	Review: research methodology discussions	Contemporary Clinical Trials	I
2005	Rathbone and Xia	Acupuncture for schizophrenia	Review	Cochrane Database of Systematic Reviews	I
2005	Smith and Hay	Acupuncture for depression	Review	Cochrane Database of Systematic Reviews	I
2005	Thomas *et al*	Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain	RCT	Health Technology Assessment	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2005	Usichenko *et al*	Auricular acupuncture for pain relief after total hip arthroplasty - A randomized controlled study	RCT	Pain	II
2005	Usichenko *et al*	Auricular acupuncture for pain relief after ambulatory knee arthroscopy - A pilot study	RCT	Evidence-Based Complementary and Alternative Medicine	IV
2005	White	Conducting and reporting case series and audits - Author guidelines for Acupuncture in Medicine	Guidelines	Acupuncture in Medicine	III
2006	Allen *et al*	Acupuncture for depression: A randomized controlled trial	RCT	Journal of Clinical Psychiatry	II
2006	Brinkhaus *et al*	Interventions and physician characteristics in a randomized multicenter trial of acupuncture in patients with low-back pain	RCT	Journal of Alternative and Complementary Medicine	III
2006	Dean *et al*	Reporting Data on Homeopathic Treatments (RedHot): A supplement to CONSORT	Guideline	Forschende Komplementarmedizin	IV
2006	Gagnier *et al*	Recommendations for reporting randomized controlled trials of herbal interventions: explanation and elaboration	Recommendations	Journal of Clinical Epidemiology	II
2006	Griggs and Jensen	Effectiveness of acupuncture for migraine: Critical literature review	Review	Journal of Advanced Nursing	II
2006	Highfield *et al*	Adolescent endometriosis-related pelvic pain treated with acupuncture: Two case reports	Case report	Journal of Alternative and Complementary Medicine	III
2006	Johnson	The clinical effectiveness of acupuncture for pain relief - You can be certain of uncertainty	Review	Acupuncture in Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2006	Kessler *et al*	A study to compare the effects of massage and static touch on experimentally induced pain in healthy volunteers	Observational study	Physiotherapy	II
2006	Lee and Chan	Acupuncture and anaesthesia	Review	Best Practice and Research: Clinical Anaesthesiology	II
2006	Lee *et al*	Acupuncture for smoking cessation?: Commentary	Commentary	Yonsei Medical Journal	I
2006	Lewis and Johnson	The clinical effectiveness of therapeutic massage for musculoskeletal pain: a systematic review	Review	Physiotherapy	II
2006	Lewith *et al*	Developing a research strategy for acupuncture	Review: research methodology discussions	Clinical Journal of Pain	II
2006	Lim *et al*	Acupuncture for treatment of irritable bowel syndrome	Review	Cochrane Database of Systematic Reviews	I
2006	Linde *et al*	Treatment in a randomized multicenter trial of acupuncture for migraine (ART migraine)	RCT	Forschende Komplementarmedizin und Klassische Naturheilkunde	IV
2006	Peters	Letter to the editor	Letter	Journal of Bodywork and Movement Therapies	II
2006	Price *et al*	Acupuncture care for breast cancer patients during chemotherapy: A feasibility study	Protocol	Integrative Cancer Therapies	II
2006	Shea	Applying evidence-based medicine to traditional Chinese medicine: Debate and strategy	Review: research methodology discussions	Journal of Alternative and Complementary Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2006	Smith *et al*	Complementary and alternative therapies for pain management in labour	Review	Cochrane Database of Systematic Reviews	I
2006	Usichenko *et al*	Auricular acupuncture reduces intraoperative fentanyl requirement during hip arthroplasty - A randomized double-blinded study	RCT	Acupuncture and Electro-Therapeutics Research	IV
2006	Walji and Boon	Redefining the randomized controlled trial in the context of acupuncture research	Review: research methodology discussions	Complementary Therapies in Clinical Practice	IV
2006	Wu *et al*	Acupuncture for stroke rehabilitation	Review	Cochrane Database of Systematic Reviews	I
2006	Zhang *et al*	Assessing the reporting quality of randomized controlled trials on acupuncture for acute ischemic stroke using the CONSORT statement and STRICTA	Review: research methodology discussions	Chinese Journal of Evidence-Based Medicine	I
2007	Anderson *et al*	In vitro fertilization and acupuncture: Clinical efficacy and mechanistic basis	Review	Alternative Therapies in Health and Medicine	IV
2007	Banzer *et al*	Acute effects of needle acupuncture on power performance during strech-shortening cycle (Article in German)	RCT	Forschende Komplementarmedizin	IV
2007	Barlas	Is all temporomandibular joint pain trigger point related and can acupuncture really help? Commentary	Commentary	Focus on Alternative and Complementary Therapies	IV
2007	Brinkhaus	The effect of acupuncture and probiotics in children with asthma: Commentary	Commentary	Focus on Alternative and Complementary Therapies	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2007	Brinkhaus and Cabrini	Does acupuncture reduce anxiety in patients undergoing cataract surgery? Commentary	Commentary	Focus on Alternative and Complementary Therapies	IV
2007	Brinkhaus *et al*	Physician and treatment characteristics in a randomised multicentre trial of acupuncture in patients with osteoarthritis of the knee	RCT	Complementary Therapies in Medicine	III (2002)
2007	Crew *et al*	Pilot study of acupuncture for the treatment of joint symptoms related to adjuvant aromatase inhibitor therapy in postmenopausal breast cancer patients	RCT	Journal of Cancer Survivorship	II
2007	Dean *et al*	Reporting data on homeopathic treatments (RedHot): a supplement to CONSORT	Guideline	Homeopathy	IV
2007	Dean *et al*	Reporting data on homeopathic treatments (RedHot): a supplement to CONSORT	Guideline	Journal of Alternative and Complementary Medicine	III
2007	Dhond *et al*	Neuroimaging acupuncture effects in the human brain	Review	Journal of Alternative and Complementary Medicine	III
2007	Ezzo *et al*	Massage for mechanical neck disorders: A systematic review	Review	Spine	II
2007	Fassoulaki *et al*	Acupressure on the extra I acupoint: The effect on bispectral index, serum melatonin, plasma β-endorphin, and stress	RCT	Anesthesia and Analgesia	II
2007	Hansson *et al*	Intramuscular and periosteal acupuncture for anxiety and sleep quality in patients with chronic musculoskeletal pain - An evaluator blind, controlled study	RCT	Acupuncture in Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2007	Harbach *et al*	Minimal immunoreactive plasma β-endorphin and decrease of cortisol at standard analgesia or different acupuncture techniques	RCT	European Journal of Anaesthesiology	II
2007	Julliard *et al*	Towards a model for planning clinical research in oriental medicine	Review: research methodology discussions	Explore: The Journal of Science and Healing	I
2007	Kalyon	Acupuncture therapy (Article in Turkish)	Review	Turkiye Fiziksel Tip ve Rehabilitasyon Dergisi	II
2007	Kvist *et al*	A randomised-controlled trial in Sweden of acupuncture and care interventions for the relief of inflammatory symptoms of the breast during lactation	RCT	Midwifery	II
2007	Leo and Ligot	A systematic review of randomized controlled trials of acupuncture in the treatment of depression	Review	Journal of Affective Disorders	II
2007	Liou *et al*	Broken needle in the cervical spine: A previously unreported complication of Xiaozendao acupuncture therapy	Case report	Journal of Alternative and Complementary Medicine	III
2007	Lu *et al*	Acupuncture for chemotherapy-induced leukopenia: Exploratory meta-analysis of randomized controlled trials	Review	Journal of the Society for Integrative Oncology	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2007	MacPherson and Schroer	Acupuncture as a complex intervention for depression: A consensus method to develop a standardised treatment protocol for a randomised controlled trial	Delphi study	Complementary Therapies in Medicine	III (2002)
2007	Prady and MacPherson	Assessing the utility of the Standards for Reporting Trials of Acupuncture (STRICTA): A survey of authors	Survey	Journal of Alternative and Complementary Medicine	III
2007	Rosenthal and Anderson	Acupuncture and in vitro fertilisation: Recent research and clinical guidelines	Review	Journal of Chinese Medicine	IV
2007	Selmer-Olsen *et al*	Does acupuncture used in nulliparous women reduce time from prelabour rupture of membranes at term to active phase of labour? A randomised controlled trial	RCT	Acta Obstetricia Et Gynecologica Scandinavica	II
2007	Usichenko *et al*	Auricular acupuncture for pain relief after ambulatory knee surgery: A randomized trial	RCT	Canadian Medical Association Journal	I
2007	Walach	RedHot	Letter	Contemporary Clinical Trials	I
2007	Wang *et al*	Effect of acupuncture-like electrical stimulation on chronic tension-type headache: A randomized, double-blinded, placebo-controlled trial	RCT	Clinical Journal of Pain	II
2007	White *et al*	Standardization of nomenclature in acupuncture research (SoNAR)	Recommendations	Evidence-Based Complementary and Alternative Medicine	IV
2008	Balk	Why we should change the course of acupuncture research	Review: research methodology discussions	Journal of Chinese Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2008	Baxter *et al*	Clinical effectiveness of laser acupuncture: A systematic review	Review	Journal of Acupuncture and Meridian Studies	IV
2008	Colbert *et al*	Magnets applied to acupuncture points as therapy - A literature review	Review	Acupuncture in Medicine	III
2008	Conn *et al*	Searching for the intervention in intervention research reports	Review: research methodology discussions	Journal of Nursing Scholarship	II
2008	Cui *et al*	Acupuncture for restless legs syndrome	Review	Cochrane Database of Systematic Reviews	I
2008	Donnellan and Sharley	Comparison of the effect of two types of acupuncture on quality of life in secondary progressive multiple sclerosis: a preliminary single-blind randomized controlled trial	RCT	Clinical Rehabilitation	II
2008	Ee *et al*	Acupuncture for pelvic and back pain in pregnancy: a systematic review	Review	American Journal of Obstetrics and Gynecology	II
2008	Enblom *et al*	Can individuals identify if needling was performed with an acupuncture needle or a non-penetrating sham needle?	RCT	Complementary Therapies in Medicine	III (2002)
2008	Fleckenstein	A systematic review of the clinical effectiveness of acupuncture for allergic rhinitis (Article in German)	Note	Deutsche Zeitschrift für Akupunktur	III
2008	Hammerschlag *et al*	Acupuncture Research	Book Chapter	Publisher: Elsevier Ltd	NA

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2008	Hopwood *et al*	Evaluating the efficacy of acupuncture in defined aspects of stroke recovery: A randomised, placebo controlled single blind study	RCT	Journal of Neurology	II
2008	Jeon *et al*	Proteomic analysis of the neuroprotective mechanisms of acupuncture treatment in a Parkinson's disease mouse model	Animal studies	Proteomics	II
2008	Lam *et al*	Efficacy and safety of acupuncture for idiopathic Parkinson's disease: A systematic review	Review	Journal of Alternative and Complementary Medicine	III
2008	Lau and Jones	A single session of Acu-TENS increases FEVI and reduces dyspnoea in patients with chronic obstructive pulmonary disease: A randomised, placebo-controlled trial	RCT	Australian Journal of Physiotherapy	II
2008	Lee	Acupuncture and acupressure for post-chemotherapy fatigue - We have only just begun: Commentary	Commentary	Focus on Alternative and Complementary Therapies	IV
2008	Lee *et al*	Auricular acupuncture for insomnia: A systematic review	Review	International Journal of Clinical Practice	I
2008	Lee *et al*	Acupuncture versus sham acupuncture for chronic prostatitis/chronic pelvic pain	RCT	American Journal of Medicine	I
2008	Lu *et al*	The value of acupuncture in cancer care	Review	Hematology/Oncology Clinics of North America	II
2008	MacPherson *et al*	Developments in acupuncture research: Big-picture perspectives from the leading edge	Conference paper	Journal of Alternative and Complementary Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2008	McDonough and McNeill	Acupuncture	Book Chapter	Book: Complementary Therapies for Physical Therapy	NA
2008	Molsberger *et al*	Chinese acupuncture for chronic low back pain: An international expert survey	Survey	Journal of Alternative and Complementary Medicine	III
2008	Myers *et al*	Massage modalities and symptoms reported by cancer patients: Narrative review	Review	Journal of the Society for Integrative Oncology	II
2008	Prady *et al*	A systematic evaluation of the impact of STRICTA and CONSORT recommendations on quality of reporting for acupuncture trials	Review: research methodology discussions	PLoS ONE	I
2008	Reider	Acronyms and anachronisms	Editorial	American Journal of Sports Medicine	II
2008	Rooney	Acupuncture in the treatment of non-specific low back pain in an adult population: A review of the evidence	Review	Internet Journal of Advanced Nursing Practice	II
2008	Sagar	Acupuncture as an evidence-based option for symptom control in cancer patients	Review	Current Treatment Options in Oncology	II
2008	Sagar and Wong	Research and regulatory issues for integrative oncology	Review: research methodology discussions	Current Oncology	II
2008	Simera *et al*	Guidelines for reporting health research: The EQUATOR network's survey of guideline authors	Survey	PLoS Medicine	III
2008	Stener-Victorin *et al*	Acupuncture in polycystic ovary syndrome: Current experimental and clinical evidence	Review	Journal of Neuroendocrinology	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2008	Stener-Victorin and Von Hagens	Acupuncture in assisted reproductive technology and PCOS	Review	Gynakologische Endokrinologie	II
2008	Usichenko	Pain treatment with methods of complementary medicine	Conference paper	Journal fur Anasthesie und Intensivbehandlung	II
2008	Wang *et al*	Acupuncture for pain relief in patients with rheumatoid arthritis: A systematic review	Review	Arthritis & Rheumatism-Arthritis Care & Research	II
2008	Wayne *et al*	Increasing research capacity at the New England School of Acupuncture through faculty and student research training initiatives	General article: education columns	Alternative Therapies in Health and Medicine	IV
2008	Wayne and Kaptchuk	Challenges inherent to t'ai chi research: Part II - Defining the intervention and optimal study design	Review: research methodology discussions	Journal of Alternative and Complementary Medicine	III
2008	White *et al*	Defining an adequate dose of acupuncture using a neurophysiological approach - A narrative review of the literature	Review	Acupuncture in Medicine	III
2008	Xie *et al*	Acupuncture for dysphagia in acute stroke	Review	Cochrane Database of Systematic Reviews	I
2008	Yeh	Commentary on the Cochrane review of Tai Chi for rheumatoid arthritis	Commentary	Explore: The Journal of Science and Healing	I
2008	Yuan *et al*	Treatment regimens of acupuncture for low back pain-A systematic review	Review	Complementary Therapies in Medicine	III (2002)
2008	Yuan *et al*	Effectiveness of acupuncture for low back pain: A systematic review	Review	Spine	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2008	Zheng *et al*	The effect of electroacupuncture on opioid-like medication consumption by chronic pain patients: A pilot randomized controlled clinical trial	RCT	European Journal of Pain	II
2009	Anastasi *et al*	Symptom management for irritable bowel syndrome: A pilot randomized controlled trial of acupuncture/moxibustion	RCT	Gastroenterology Nursing	II
2009	Andrade and Radhakrishnan	Prayer and healing: A medical and scientific perspective on randomized controlled trials	Review	Indian Journal of Psychiatry	II
2009	Bai *et al*	Spatiotemporal modulation of central neural pathway underlying acupuncture action: A systematic review	Review	Current Medical Imaging Reviews	I
2009	Benham and Johnson	Could acupuncture needle sensation be a predictor of analgesic response?	Commentary	Acupuncture in Medicine	III
2009	Borud *et al*	The Acupuncture on Hot Flushes Among Menopausal Women (ACUFLASH) study, a randomized controlled trial	RCT	Menopause-the Journal of the North American Menopause Society	II
2009	Brinkhaus	Effectiveness of diet and exercise vs. acupuncture for weight loss in obese women: Results of a pilot study - Commentary	Commentary	Focus on Alternative and Complementary Therapies	IV
2009	Cho *et al*	Acupuncture for obesity: A systematic review and meta-analysis	Review	International Journal of Obesity	II
2009	Cho and Whang	Acupuncture for alcohol dependence: A systematic review	Review	Alcoholism: Clinical and Experimental Research	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2009	Collazo Chao	Effectiveness of acupuncture in relieving pain refractory to conventional pharmacological therapy (Article in Spanish)	Observational study	Revista de la Sociedad Espanola del Dolor	II
2009	Dieterle *et al*	A prospective randomized placebo-controlled study of the effect of acupuncture in infertile patients with severe oligoasthenozoospermia	RCT	Fertility and Sterility	II
2009	Dijkers	Ensuring Inclusion of Research Reports in Systematic Reviews	Review: research methodology discussions	Archives of Physical Medicine and Rehabilitation	II
2009	Ferreira	Diagnostic accuracy of pattern differentiation algorithm based on Chinese medicine theory: A stochastic simulation study	Observational study	Chinese Medicine	IV
2009	Hielm-Bjorkman *et al*	Psychometric testing of the Helsinki chronic pain index by completion of a questionnaire in Finnish by owners of dogs with chronic signs of pain caused by osteoarthritis	Qualitative study	American Journal of Veterinary Research	II
2009	Hughes	"When I first started going I was going in on my knees, but I came out and I was skipping": Exploring rheumatoid arthritis patients' perceptions of receiving treatment with acupuncture	Qualitative study	Complementary Therapies in Medicine	III (2002)
2009	Jordan and Lewis	Improving the quality of reporting of research studies	Editorial	Musculoskeletal Care	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2009	Kottow	Could bioethics recommend acupuncture for public health programmes?	Commentary	Acupuncture in Medicine	III
2009	Lee *et al*	Acupuncture for treating hot flushes in men with prostate cancer: A systematic review	Review	Supportive Care in Cancer	II
2009	Liu *et al*	An acupuncture meta-analysis for optic atrophy: Seven randomized, controlled trials	Review	Neural Regeneration Research	II
2009	Lu *et al*	Acupuncture for chemotherapy-induced neutropenia in patients with gynecologic malignancies: A pilot randomized, sham-controlled clinical trial	RCT	Journal of Alternative and Complementary Medicine	III
2009	MacPherson and Altman	Improving the quality of reporting acupuncture interventions: describing the collaboration between STRICTA, CONSORT and the Chinese Cochrane Centre	Guidelines related	Journal of Evidence-Based Medicine	III
2009	Ospina-Díaz	Introduction to acupuncture. Basics and importance for the primary care physician (Article in Spanish)	Review	Semergen	I
2009	Park *et al*	Evaluation of manual acupuncture at classical and nondefined points for treatment of functional dyspepsia: A randomized-controlled trial	RCT	Journal of Alternative and Complementary Medicine	III
2009	Roberts *et al*	A systematic review of the clinical effectiveness of acupuncture for allergic rhinitis (Article in Spanish)	Note	Revista Internacional de Acupuntura	IV
2009	Scardina *et al*	The effect of acupuncture on oral microcirculation in healthy volunteers: An exploratory study	RCT	Acupuncture in Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2009	Schroer and MacPherson	Acupuncture, or non-directive counselling versus usual care for the treatment of depression: A pilot study	Protocol	Trials	I
2009	Scott *et al*	Trigger point injections for chronic non-malignant musculoskeletal pain: A systematic review	Review	Pain Medicine	II
2009	Stock-Schroer *et al*	Reporting experiments in homeopathic basic research (REHBaR) - A detailed guideline for authors	Guidelines	Homeopathy	IV
2009	Wesolowski *et al*	Acupuncture reveals no specific effect on primary auditory cortex: A functional magnetic resonance imaging study	Observational study	NeuroReport	II
2009	Yang *et al*	Acupuncture in patients with carpal tunnel syndrome a randomized controlled trial	RCT	Clinical Journal of Pain	II
2009	Yeung *et al*	Traditional needle acupuncture treatment for insomnia: A systematic review of randomized controlled trials	Review	Sleep Medicine	I
2009	Yeung *et al*	Electroacupuncture for primary insomnia: A randomized controlled trial	RCT	Sleep	II
2009	Zhang *et al*	Combination of acupuncture and fluoxetine for depression: A randomized, double-blind, sham-controlled trial	RCT	Journal of Alternative and Complementary Medicine	III
2009	Zheng *et al*	Acupuncture as a treatment for functional dyspepsia: Design and methods of a randomized controlled trial	RCT	Trials	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2010	Anastasi *et al*	Acupuncture/moxibustion RCT for distal sensory peripheral neuropathy in HIV/AIDS: Rationale, design, methods, procedure and logistics	Review: research methodology discussions	European Journal of Oriental Medicine	IV
2010	Asher *et al*	Auriculotherapy for pain management: A systematic review and meta-analysis of randomized controlled trials	Review	Journal of Alternative and Complementary Medicine	III
2010	Capili *et al*	Adverse event reporting in acupuncture clinical trials focusing on pain	Review: research methodology discussions	Clinical Journal of Pain	II
2010	Cho and Hwang	Acupuncture for primary dysmenorrhoea: A systematic review	Review	BJOG: An International Journal of Obstetrics and Gynaecology	II
2010	Cho and Kim	Efficacy of acupuncture in management of premenstrual syndrome: A systematic review	Review	Complementary Therapies in Medicine	III (2002)
2010	Collazo Chao	Effectiveness of acupuncture therapy for pain relief in patients with fibromyalgia (Article in Spanish)	Observational study	Revista Internacional de Acupuntura	IV
2010	Collazo	Acupuncture treatment in headache refractory to conventional therapies (Article in Spanish)	Observational study	Revista de la Sociedad Espanola del Dolor	II
2010	Cotchett *et al*	Effectiveness of dry needling and injections of myofascial trigger points associated with plantar heel pain: A systematic review	Review	Journal of Foot and Ankle Research	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2010	Crew *et al*	Randomized, blinded, sham-controlled trial of acupuncture for the management of aromatase inhibitor-associated joint symptoms in women with early-stage breast cancer	RCT	Journal of Clinical Oncology	II
2010	Gibson *et al*	Acupuncture for respiratory disorder: what's the point?	Review	Expert Review of Respiratory Medicine	I
2010	Gross *et al*	Manipulation or mobilisation for neck pain	Review	Cochrane Database of Systematic Reviews	I
2010	Kim *et al*	Effects of acupuncture on hot flashes in perimenopausal and postmenopausal women-a multicenter randomized clinical trial	RCT	Menopause	II
2010	Kim and Zhu	Acupuncture for essential hypertension	Review	Alternative Therapies in Health and Medicine	IV
2010	Kuo *et al*	Blood flow effect of acupuncture on the human meridian	Observational study	Medical Acupuncture	III
2010	Langhorst *et al*	Efficacy of acupuncture in fibromyalgia syndrome-a systematic review with a meta-analysis of controlled clinical trials	Review	Rheumatology	II
2010	Lewith	Acupuncture placebos	Review	European Journal of Oriental Medicine	IV
2010	List and Axelsson	Management of TMD: Evidence from systematic reviews and meta-analyses	Review	Journal of Oral Rehabilitation	II
2010	MacPherson	Towards better reporting of interventions in clinical trials of acupuncture	Editorial	Journal of Chinese Integrative Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2010	MacPherson *et al*	Revised standards for reporting interventions in clinical trials of acupuncture (STRICTA): Extending the consort statement (Chinese version)	Guidelines	Journal of Chinese Integrative Medicine	III
2010	MacPherson *et al*	Revised standards for reporting interventions in clinical trials of acupuncture (STRICTA): Extending the consort statement	Guidelines	Acupuncture in Medicine	III
2010	MacPherson *et al*	Revised standards for reporting interventions in clinical trials of acupuncture (STRICTA): Extending the consort statement	Guidelines	Journal of Alternative and Complementary Medicine	III
2010	MacPherson *et al*	Revised standards for reporting interventions in clinical trials of acupuncture (STRICTA): Extending the consort statement	Guidelines	PLoS Medicine	III
2010	MacPherson *et al*	Revised standards for reporting interventions in clinical trials of acupuncture (STRICTA): Extending the consort statement (Chinese version)	Guidelines	Chinese Journal of Evidence-Based Medicine	I
2010	MacPherson *et al*	Revised standards for reporting interventions in clinical trials of acupuncture (STRICTA): Extending the consort statement	Guidelines	Medical Acupuncture	III
2010	MacPherson *et al*	Revised standards for reporting interventions in clinical trials of acupuncture (STRICTA): Extending the consort statement	Guidelines	Journal of Evidence-Based Medicine	III
2010	MacPherson and Jobst	Improving the reporting of interventions in clinical trials of acupuncture: The updated and revised STRICTA	Editorial	Journal of Alternative and Complementary Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2010	Miao	Clinical critical qualitative evaluation of the selected randomized controlled trials in current acupuncture researches for low back pain	Review: research methodology discussions	Journal of Chinese Integrative Medicine	III
2010	Miao and Miao	Effect of electroacupuncture on the third lumbar transverse process syndrome: A randomized controlled trial	RCT	Medical Acupuncture	III
2010	Miller *et al*	Manual therapy and exercise for neck pain: A systematic review	Review	Manual Therapy	II
2010	Ronan *et al*	Acupuncture and schizophrenia - Effect and acceptability: Preliminary results of the first UK study	Review	European Journal of Oriental Medicine	IV
2010	Smith *et al*	Acupuncture for depression	Review	Cochrane Database of Systematic Reviews	I
2010	Son *et al*	Efficacy of ah shi point acupuncture on acne vulgaris	RCT	Acupuncture in Medicine	III
2010	Vickers *et al*	Individual patient data meta-analysis of acupuncture for chronic pain: Protocol of the Acupuncture Trialists' Collaboration	Review protocol	Trials	I
2010	White *et al*	Does needling sensation (de qi) affect treatment outcome in pain? Analysis of data from a larger single-blind, randomised controlled trial	RCT	Acupuncture in Medicine	III
2010	Wu *et al*	Acupuncture in poststroke rehabilitation: A systematic review and meta-analysis of randomized trials	Review	Stoke	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2010	Yeo *et al*	Consecutive acupuncture stimulations lead to significantly decreased neural responses	Observational study	Journal of Alternative and Complementary Medicine	III
2010	Zaringhalam *et al*	Reduction of chronic non-specific low back pain: A randomised controlled clinical trial on acupuncture and baclofen	RCT	Chinese Medicine	IV
2010	Zaslawski	Ethical considerations for acupuncture and chinese herbal medicine clinical trials: A cross-cultural perspective	Commentary	Evidence-Based Complementary and Alternative Medicine	IV
2010	Zheng *et al*	Quality of randomized controlled trials in acupuncture treatment of hepatitis B virus infection - A systematic review	Review: research methodology discussions	Acupuncture and Electro-Therapeutics Research	IV
2011	Asher *et al*	Quality of reporting on randomised controlled trials of auriculotherapy for pain	Review: research methodology discussions	Acupuncture in Medicine	III
2011	Bian *et al*	Consolidated standards of reporting trials (CONSORT) for traditional Chinese medicine: Current situation and future development	Review: research methodology discussions	Frontiers of Medicine in China	I
2011	Cohen *et al*	Acupuncture as analgesia for low back pain, ankle sprain and migraine in emergency departments: Study protocol for a randomized controlled trial	Protocol	Trials	I
2011	Cotchett *et al*	Effectiveness of trigger point dry needling for plantar heel pain: Study protocol for a randomised controlled trial	Protocol	Journal of Foot and Ankle Research	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2011	Cotchett *et al*	Consensus for dry needling for plantar heel pain (plantar fasciitis): A modified Delphi study	Delphi study	Acupuncture in Medicine	III
2011	Hammerschlag *et al*	Randomized controlled trials of acupuncture (I997-2007): An assessment of reporting quality with a CONSORT- and STRICTA-based instrument	Review: research methodology discussions	Evidence-Based Complementary and Alternative Medicine	IV
2011	Kim *et al*	Acupuncture for symptom management in hemodialysis patients: A prospective, observational pilot study	Observational study	Journal of Alternative and Complementary Medicine	III
2011	Kim *et al*	The effectiveness of moxibustion: An overview during I0 Years	Review	Evidence-Based Complementary and Alternative Medicine	IV
2011	Long *et al*	Exploring the evidence base for acupuncture in the treatment of Meniere's Syndrome-A systematic review	Review	Evidence-Based Complementary and Alternative Medicine	IV
2011	Lu *et al*	Does acupuncture improve quality of life for patients with pain associated with the spine? A systematic review	Review	Evidence-Based Complementary and Alternative Medicine	IV
2011	Man *et al*	Transcutaneous electrical nerve stimulation on ST36 and SP6 acupoints prevents hyperglycaemic response during anaesthesia: A randomised controlled trial	RCT	European Journal of Anaesthesiology	II
2011	Moher *et al*	Describing reporting guidelines for health research: A systematic review	Review: research methodology discussions	Journal of Clinical Epidemiology	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2011	Molsberger *et al*	An international expert survey on acupuncture in randomized controlled trials for low back pain and a validation of the low back pain acupuncture score	Survey	European Journal of Medical Research	I
2011	Myung *et al*	Ameliorative effect of purple bamboo salt-pharmaceutical acupuncture on cisplatin-induced ototoxicity	Animal studies	Acta Oto-Laryngologica	II
2011	Paterson *et al*	Acupuncture for 'frequent attenders' with medically unexplained symptoms: A randomised controlled trial (CACTUS study)	RCT	British Journal of General Practice	I
2011	Price *et al*	Getting inside acupuncture trials - Exploring intervention theory and rationale	Review: research methodology discussions	BMC Complementary and Alternative Medicine	IV
2011	Ronan *et al*	A case study exploration of the value of acupuncture as an adjunct treatment for patients diagnosed with schizophrenia: Results and future study design	Case series	Journal of Chinese Integrative Medicine	III
2011	Schmulson and Chang	Review article: The treatment of functional abdominal bloating and distension	Review	Alimentary Pharmacology and Therapeutics	I
2011	Schytt *et al*	Incompleteness of Swedish local clinical guidelines for acupuncture treatment during childbirth	Survey	Acta Obstetricia Et Gynecologica Scandinavica	II
2011	Smith *et al*	Development of an instrument to assess the quality of acupuncture: Results from a Delphi process	Guidelines related	Journal of Alternative and Complementary Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2011	Stock-Schroer *et al*	Reporting experiments in homeopathic basic research-Description of the checklist development	Guidelines related	Evidence-Based Complementary and Alternative Medicine	IV
2011	Stub *et al*	Acupuncture treatment for depression-A systematic review and meta-analysis	Review	European Journal of Integrative Medicine	IV
2011	Wang and Young	Needling the pain and comforting the brain: Acupuncture in the treatment of chronic migraine	Editorial	Cephalalgia	II
2011	Wetzel *et al*	The effect of auricular acupuncture on fentanyl requirement during hip arthroplasty: A randomized controlled trial	RCT	Clinical Journal of Pain	II
2011	Wright and Aickin	Improvement of menopausal symptoms with acupuncture not reflected in changes to heart rate variability	Observational study	Acupuncture in Medicine	III
2011	Xiao *et al*	Assessing the quality of reports about randomized controlled trials of acupuncture treatment on mild cognitive impairment	Review: research methodology discussions	PLoS ONE	I
2011	Xu and Chen	Acupuncture: A paradigm of worldwide cross-cultural communication	Editorial	Chinese Journal of Integrative Medicine	IV
2011	Yang *et al*	Acupuncture versus topiramate in chronic migraine prophylaxis: A randomized clinical trial	RCT	Cephalalgia	II
2011	Yeung *et al*	Electroacupuncture for residual insomnia associated with major depressive disorder: A randomized controlled trial	RCT	Sleep	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2011	Yu *et al*	Effects of electroacupuncture on Benign Prostate Hyperplasia patients with lower urinary tract symptoms: A single-blinded, randomized controlled trial	RCT	Evidence-Based Complementary and Alternative Medicine	IV
2011	Zhou *et al*	Acupuncture and auricular acupressure in relieving menopausal hot flashes of bilaterally ovariectomized Chinese women: A randomized controlled trial	RCT	Evidence-Based Complementary and Alternative Medicine	IV
2012	Chen *et al*	Designing and implementing multicenter clinical randomized controlled trials on moxibustion with large samples	Review: research methodology discussions	Journal of Traditional Chinese Medicine	IV
2012	Chung *et al*	Randomized non-invasive sham-controlled pilot trial of electroacupuncture for postpartum depression	RCT	Journal of Affective Disorders	II
2012	Collazo Cha	Acupuncture and traditional Chinese dietary therapy in the treatment of patients with fibromyalgia. A randomized prospective study (Article in Spanish)	RCT	Revista Internacional de Acupuntura	IV
2012	Duncan *et al*	Evaluating intense rehabilitative therapies with and without acupuncture for children with cerebral palsy: A randomized controlled trial	RCT	Archives of Physical Medicine and Rehabilitation	II
2012	Ferro *et al*	The combined effect of acupuncture and Tanacetum parthenium on quality of life in women with headache: Randomised study	RCT	Acupuncture in Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2012	Iseri and Cabioglu	Migraine treatment and the role of acupuncture: A literature review	Review	Journal of the Australian Traditional-Medicine Society	IV
2012	Lu *et al*	Acupuncture for dysphagia after chemoradiation in head and neck cancer: Rationale and design of a randomized, sham-controlled trial	Protocol	Contemporary Clinical Trials	I
2012	Manheimer *et al*	Acupuncture for treatment of irritable bowel syndrome	Review	Cochrane Database of Systematic Reviews	I
2012	Mathie *et al*	Method for appraising model validity of randomised controlled trials of homeopathic treatment: Multi-rater concordance study	Review: research methodology discussions	BMC Medical Research Methodology	I
2012	Patel *et al*	Massage for mechanical neck disorders	Review	Cochrane Database of Systematic Reviews	I
2012	Purepong *et al*	External validity in randomised controlled trials of acupuncture for osteoarthritis knee pain	Review: research methodology discussions	Acupuncture in Medicine	III
2012	Shuai *et al*	Issues of design and statistical analysis in controlled clinical acupuncture trials: An analysis of English-language reports from Western journals	Review: research methodology discussions	Statistics in Medicine	II
2012	Smith and Bauer	Traditional Chinese Medicine for cancer-related symptoms	Review	Seminars in Oncology Nursing	II
2012	Steinlechner	Be routinely recommended for the treatment of breech presentation?	Review	Journal of Chinese Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2012	Tam *et al*	Citation classics in the integrative and complementary medicine literature: 50 frequently cited articles	Review	European Journal of Integrative Medicine	IV
2012	van den Berg *et al*	Effect of acupuncture on pain and inflammation in patients with complex regional pain syndrome type I. A small exploratory randomized controlled trial	RCT	Conference: I5th World Congress of Pain Clinicians	NA
2012	Xue *et al*	Effect of electroacupuncture on opioid consumption in patients with chronic musculoskeletal pain: protocol of a randomised controlled trial	Protocol	Trials	I
2012	Yang *et al*	Reports quality evaluation on acupuncture for treating acute attacks of migraine	Review: research methodology discussions	Chinese Journal of Evidence-Based Medicine	I
2012	Yao *et al*	Randomized controlled trial comparing acupuncture with placebo acupuncture for the treatment of Carpal Tunnel Syndrome	RCT	PM and R	I
2013	Bai and Lao	Neurobiological foundations of acupuncture: The relevance and future prospect based on neuroimaging evidence	Review	Evidence-Based Complementary and Alternative Medicine	IV
2013	Chen *et al*	Integrating acupuncture with exercise-based physical therapy for knee osteoarthritis: A randomized controlled trial	RCT	Journal of Clinical Rheumatology	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Collazo Chao and Muñoz Reina	Scalp acupuncture and acupunture for treatment of patients with fibromyalgia. Prospective randomized study (Article in Spanish)	RCT	Revista Internacional de Acupuntura	IV
2013	Da Silva *et al*	Integrative medicine, integrative acupuncture	Editorial	European Journal of Integrative Medicine	IV
2013	Deare *et al*	Acupuncture for treating fibromyalgia	Review	Cochrane Database of Systematic Reviews	I
2013	He *et al*	Acupuncture and moxibustion for cancer-related fatigue: A systematic review and meta-analysis	Review	Asian Pacific Journal of Cancer Prevention	II
2013	Kamioka *et al*	A checklist to assess the quality of reports on spa therapy and balneotherapy trials was developed using the Delphi consensus method: The SPAC checklist	Guidelines related	Complementary Therapies in Medicine	III (2002)
2013	Li *et al*	Clinical effect of catgut implantation at acupoints for allergic rhinitis: study protocol for a randomized controlled trial	Protocol	Trials	I
2013	Lima *et al*	Acupuncture effectiveness as a complementary therapy in functional dyspepsia patients	RCT	Arquivos de Gastroenterologia	II
2013	Liu *et al*	Does traditional chinese medicine pattern affect acupoint specific effect? Analysis of data from a multicenter, randomized, controlled trial for primary dysmenorrhea	RCT	Journal of Alternative and Complementary Medicine	III
2013	Mannix *et al*	Acupuncture for managing phantom-limb syndrome: A systematic review	Review	Medical Acupuncture	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Manterola *et al*	Initiatives for reporting biomedical research results with different types of designs	Review: research methodology discussions	International Journal of Morphology	II
2013	McKeon *et al*	Acupuncture and acupressure for chemotherapy-induced nausea and vomiting: A systematic review	Review	Australian Journal of Acupuncture and Chinese Medicine	III
2013	Montgomery *et al*	The Oxford Implementation Index: A new tool for incorporating implementation data into systematic reviews and meta-analyses	Guidelines related	Journal of Clinical Epidemiology	II
2013	Paulson and Shay	Sympathetic nervous system responses to acupuncture and non-penetrating sham acupuncture in experimental forearm pain: A single-blind randomised descriptive study	RCT	Acupuncture in Medicine	III
2013	Shin *et al*	Effects of motion style acupuncture treatment in acute low back pain patients with severe disability: A multicenter, randomized, controlled, comparative effectiveness trial	RCT	Pain	II
2013	Sun *et al*	Electroacupuncture at Jing-jiaji points for neck pain caused by cervical spondylosis: A study protocol for a randomized controlled pilot trial	Protocol	Trials	I
2013	Yin *et al*	Therapeutic applications of herbal medicines for cancer patients	Review	Evidence-Based Complementary and Alternative Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Zhang *et al*	Acupuncture as prophylaxis for menstrual-related migraine: Study protocol for a multicenter randomized controlled trial	Protocol	Trials	I
2013	Zhang *et al*	The preventive and therapeutic effect of acupuncture for radiation-induced xerostomia in patients with head and neck cancer: A systematic review	Review	Integrative Cancer Therapies	II
2014	Bryant *et al*	A systematic review of the quality of reporting in published smoking cessation trials for pregnant women: An explanation for the evidence-practice gap?	Review: research methodology discussions	Implementation Science	I
2014	Cayir *et al*	Acupuncture decreases matrix metalloproteinase-2 activity in patients with migraine	Observational study	Acupuncture in Medicine	III
2014	Chu *et al*	Reporting quality of English randomized controlled trials on acupuncture for neck disorders by the CONSORT statement and STRICTA	Review: research methodology discussions	Chinese Journal of Evidence-Based Medicine	I
2014	Collazo *et al*	Randomized prospective study to assess the effectiveness of several therapeutic procedures of traditional Chinese medicine in alleviation of pain and improvement in the standard of living in patients with fibromyalgia (Article in Spanish)	RCT	Revista Internacional de Acupuntura	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Gu *et al*	Assessment of registration information on methodological design of acupuncture RCTs: A review of IV53 registration records retrieved from WHO International Clinical Trials Registry Platform	Review: research methodology discussions	Evidence-Based Complementary and Alternative Medicine	IV
2014	Haddad and Palesh	Acupuncture in the treatment of cancer-related psychological symptoms	Review	Integrative Cancer Therapies	II
2014	Kamioka *et al*	Assessing the quality of study reports on spa therapy based on randomized controlled trials by the spa therapy checklist (SPAC)	Review: research methodology discussions	Complementary Therapies in Clinical Practice	IV
2014	Kamioka *et al*	Effectiveness of animal-assisted therapy: A systematic review of randomized controlled trials	Review	Complementary Therapies in Medicine	III (2002)
2014	Kamioka *et al*	Effectiveness of horticultural therapy: A systematic review of randomized controlled trials	Review	Complementary Therapies in Medicine	III (2002)
2014	Lee *et al*	Effects of Wonli acupuncture procedure in patients with LSS: A clinical, retrospective study	Observational study	Evidence-Based Complementary and Alternative Medicine	IV
2014	Luo *et al*	Quality of reporting of randomised controlled trials of acupuncture for neurological diseases conducted in China	Review: research methodology discussions	Acupuncture in Medicine	III
2014	Ortiz *et al*	A randomised multicentre trial of acupuncture in patients with seasonal allergic rhinitis - Trial intervention including physician and treatment characteristics	RCT related	BMC Complementary and Alternative Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Park *et al*	Acupuncture for the treatment of spasticity after stroke: A meta-analysis of randomized controlled trials	Review	Journal of Alternative and Complementary Medicine	III
2014	Stevens *et al*	Relation of completeness of reporting of health research to journals' endorsement of reporting guidelines: Systematic review	Review: research methodology discussions	BMJ	I
2014	Zhang *et al*	Electroacupuncture for pressure ulcer: A study protocol for a randomized controlled pilot trial	Protocol	Trials	I
2015	Bezerra *et al*	Acupuncture to treat sleep disorders in postmenopausal women: A systematic review	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Chung *et al*	Acupuncture for residual insomnia associated with major depressive disorder: A placebo- and sham-controlled, subject- and assessor-blind, randomized trial	RCT	Journal of Clinical Psychiatry	II
2015	Garcia *et al*	Acupuncture for xerostomia in patients with cancer: An update	Review	Medical Acupuncture	III
2015	Grant *et al*	Defining the quality of acupuncture: The case of acupuncture for cancer-related fatigue	Review	Integrative Cancer Therapies	II
2015	Halsey *et al*	Acupuncture for joint symptoms related to aromatase inhibitor therapy in postmenopausal women with early-stage breast cancer: A narrative review	Review	Acupuncture in Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	Hu *et al*	Defining integrative medicine in narrative and systematic reviews: A suggested checklist for reporting	Review	European Journal of Integrative Medicine	IV
2015	Kågesten *et al*	A systematic review of reporting tools applicable to sexual and reproductive health programmes: Step I in developing programme reporting standards	Review: research methodology discussions	PLoS ONE	I
2015	Lim *et al*	Acupuncture for spasticity after stroke: A systematic review and meta-analysis of randomized controlled trials	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Liu *et al*	Acupuncture for low back pain: An overview of systematic reviews	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Liu *et al*	STRICTA: Is it time to do more?	Review: research methodology discussions	BMC Complementary and Alternative Medicine	IV
2015	Liu and Li	CONSORT and STRICTA evaluation of randomized controlled trials of acupuncture and rehabilitation for post-stroke limb spasm in recent I0 years in China	Review: research methodology discussions	Journal of Acupuncture and Tuina Science	IV
2015	Liu *et al*	Impact of the Consolidated Standards of Reporting Trials (CONSORT) checklist on reporting of randomized clinical trials in traditional Chinese medicine	Review: research methodology discussions	Journal of Evidence-Based Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	Oliveira and De Sá Ferreira	Effects of diagnostic errors in pattern differentiation and acupuncture prescription: A single-blinded, interrater agreement study	Observational study	Evidence-Based Complementary and Alternative Medicine	IV
2015	Sahin *et al*	Acupuncture relieves symptoms in chronic prostatitis/chronic pelvic pain syndrome: A randomized, sham-controlled trial	RCT	Prostate Cancer and Prostatic Diseases	II
2015	Santoro *et al*	Auricular acupressure can modulate pain threshold	Observational study	Evidence-Based Complementary and Alternative Medicine	IV
2015	Van Haselen	Towards improving the reporting quality of clinical case reports in complementary medicine: Assessing and illustrating the need for guideline development	Guidelines related	Complementary Therapies in Medicine	III (2002)
2015	Yoon *et al*	Novel intervention with acupuncture for anorexia and cachexia in patients with gastrointestinal tract cancers: A feasibility study	Observational study	Oncology Nursing Forum	II
2015	Zheng *et al*	Acupuncture for functional constipation: Protocol of an individual patient data meta-analysis	Review protocol	BMJ Open	I
2015	Zhou *et al*	Acupoint herbal patching for allergic rhinitis: A systematic review and meta-analysis of randomised controlled trials	Review	Clinical Otolaryngology	II
2016	Campbell *et al*	Physiotherapy rehabilitation for people with progressive multiple sclerosis: A systematic review	Review	Archives of Physical Medicine and Rehabilitation	II
2016	Hu *et al*	Acupuncture for pain management in cancer: A systematic review and meta-analysis	Review	Evidence-Based Complementary and Alternative Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2016	Liu and Yu	Recent approaches and development of acupuncture on chronic daily headache	Review	Current Pain and Headache Reports	II
2016	Zhong *et al*	Effectiveness of moxibustion for exercise-induced fatigue - A systematic review for randomized controlled trials	Review	Chinese Journal of Integrative Medicine	IV
		From Chinese database (China National Knowledge Infrastructure)			
2003	Liu *et al*	Improving the quality of the report of acupuncture controlled trial by using CONSORT and STRICTA	Recommendations	Chinese Acupuncture and Moxibustion	IV
2006	Zhang *et al*	Assessing the reporting quality of randomized controlled trials on acupuncture for Acute Ischemic Stroke using the CONSORT statement and STRICTA	Review: research methodology discussions	Chinese Journal of Evidence-Based Medicine	I
2007	Fei and Liu	Reporting interventions in clinical trials of acupuncture- The introduction and evaluation of the STRICTA standards	Recommendations	Journal of Traditional Chinese Medicine	IV
2008	Zhu *et al*	Use of CONSORT and STRICTA to assess the quality of randomized controlled trials of acupuncture treatment of Functional Dyspepsia	Review: research methodology discussions	Shanghai Journal of Acupuncture and Moxibustion	IV
2008	Lu *et al*	Assessing the reporting quality of randomized controlled trials on acupuncture for migraine using the CONSORT and STRICTA statement	Review: research methodology discussions	Journal of Chengdu University of Traditional Chinese Medicine	IV
2008	Ai *et al*	Assessing the reporting quality of randomized controlled trials on acupuncture in children with Cerebral Palsy in China	Review: research methodology discussions	West China Medical Journal	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2009	Liu	Clinical effect evaluation of a RCT for cotton-sheet moxibustion therapy in patients with Herpes Zoster	RCT	Doctoral dissertation in Chengdu University of Traditional Chinese Medicine	NA
2010	MacPherson *et al*	Revised standards for reporting interventions in clinical trials of acupuncture (STRICTA): Extending the consort statement (Chinese version)	Guidelines	Chinese Journal of Evidence-Based Medicine	I
2010	MacPherson *et al*	Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT statement (Chinese version)	Guidelines	Journal of Chinese Integrative Medicine	III
2010	Sun *et al*	Assessment of the reporting quality of randomized controlled trials on acupuncture for simple obesity with the CONSORT statement and STRICTA	Review: research methodology discussions	Lishizhen Medicine and Materia Medica Research	IV
2013	Zhao	Assessment of the reporting quality of randomized controlled trials on acupuncture for Perimenopausal Syndrome with the CONSORT statement and STRICTA	Review: research methodology discussions	Journal of Liaoning University of Traditional Chinese Medicine	IV
2013	Chen	Assessment of the reporting quality of randomized controlled trials on acupuncture for Irritable Bowel Syndrome with the CONSORT statement and STRICTA	Review: research methodology discussions	Journal of Liaoning University of Traditional Chinese Medicine	IV
2013	Zhong and Li	Evaluating the quality of clinical randomized controlled trials reports on acupuncture treating Chronic Atrophic Gastritis with CONSORT and STRICTA	Review: research methodology discussions	Lishizhen Medicine and Materia Medica Research	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Xu *et al*	Quality of reporting on randomised controlled trials of acupuncture for cervical vertigo	Review: research methodology discussions	Journal of Shaanxi College of Traditional Chinese Medicine	IV
2013	Wang	Regulating-acupuncture for Allergic Rhinitis: A randomized controlled trial	RCT	Doctoral dissertation in Beijing University of Chinese Medicine	NA
2013	Sun	Quality of reporting on randomized controlled trials of acupuncture for Post-stroke Spastic Hemiplegic	Review: research methodology discussions	Master thesis in Beijing University of Chinese Medicine	NA
2014	Zhu *et al*	Reporting quality of English randomized controlled trials on acupuncture for Neck Disorders by the CONSORT statement and STRICTA	Review: research methodology discussions	Chinese Journal of Evidence-Based Medicine	I
2014	Wang *et al*	On quality of randomized controlled trial of Chronic Pelvic Inflammation treated with acupuncture and moxibustion	Review: research methodology discussions	Shandong Journal of Traditional Chinese Medicine	IV
2015	Fan *et al*	Evaluation on quality of clinical trials reports about treating post-stroke depression with acupuncture and moxibustion by using CONSORT and STRICTA	Review: research methodology discussions	China Journal of Traditional Chinese Medicine and Pharmacy	IV
2015	Liu *et al*	CONSORT and STRICTA evaluation of randomized controlled trials of acupuncture and rehabilitation for post-stroke limb spasm in recent I0 years in China	Review: research methodology discussions	Journal of Acupuncture and Tuina Science	IV
2015	Wen *et al*	Analysis of the current status of RCTs evaluation with CONSORT statement and STRICTA in China	Review: research methodology discussions	Journal of Traditional Chinese Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	Wu *et al*	Analysis on quality of studies on acupuncture assisting quitting smoking in China and other countries	Review: research methodology discussions	World Chinese Medicine	IV
2016	Fan *et al*	Quality evaluation of clinical randomized controlled trials of acupuncture for the treatment of cerebral palsy in children	Review: research methodology discussions	Journal of Clinical Acupuncture and Moxibustion	IV
2016	Lai *et al*	The application of CONSORT and STRICTA in evaluating the quality of RCT report on acupuncture and moxibustion in the treatment of rheumatoid arthritis	Review: research methodology discussions	Chinese Medicine Modern Distance Education of China	IV
From Japanese database (Japan Science and Technology Information Aggregator, Electronic)					
2002	Tsukayama and Yamashta	Consensus recommendations for designing and reporting in clinical trials on acupuncture: An introduction of recommendations by STRICTA Group and IARF	Recommendations	Journal of the Japan Society of Acupuncture and Moxibustion	IV
2005	Lee *et al*	Review of pragmatic clinical trials on acupuncture	Review	Journal of the Japan Society of Acupuncture and Moxibustion	IV
2008	Kamioka *et al*	Significance of utilizing checklists and statements for improvement of the quality of studies concerning hot springs: Evidence grading and various study designs of epidemiological and clinical studies	Review: research methodology discussions	The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2010	Nabeta *et al*	Practice and educational effects of a simulated randomized controlled trial for acupuncture school teachers	Observational study	Journal of the Japan Society of Acupuncture and Moxibustion	IV
2013	MacPherson *et al*	Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT statement (Japanese version)	Guidelines	Journal of the Japan Society of Acupuncture and Moxibustion	IV
2014	Kamioka	A checklist to assess the quality of reports on spa therapy and balneotherapy trials: The SPAC checklist	Delphi study	The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine	IV
2014	Shimoichi *et al*	Acupuncture for patients with lower back pain-Systematic review of randomized controlled trials conducted in Japan	Reviews	Journal of the Japan Society of Acupuncture and Moxibustion	IV

Journal types:

I. General medical non-CAM journals;

II. Specialty medical non-CAM journals;

III. CAM journals with STRICTA endorsement;

IV. CAM journals without STRICTA endorsement.

Appendix 4. Characteristics of articles cited STRICTA 2010

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
		From English databases (Web of Science and Scopus)			
2010	Hopewell	Standards to improve the reporting of clinical trials in acupuncture	Commentary	Acupuncture in Medicine	III
2010	Kim *et al*	Psoas abscess caused by acupuncture?	Letter	Hemodialysis International	II
2010	MacPherson	Towards better reporting of interventions in clinical trials of acupuncture	Editorial	Journal of Chinese Integrative Medicine	III
2010	Moher	Reports of randomized trials: Ensure they are transparent, accurate, and complete	Editorial	Journal of Chinese Integrative Medicine	III
2010	O'Sullivan and Higginson	Clinical effectiveness and safety of acupuncture in the treatment of irradiation-induced xerostomia in patients with head and neck cancer: A systematic review	Review	Acupuncture in Medicine	III
2011	Asher *et al*	Quality of reporting on randomised controlled trials of auriculotherapy for pain	Review: research methodology discussions	Acupuncture in Medicine	III
2011	Bian *et al*	Consolidated standards of reporting trials (CONSORT) for traditional Chinese medicine: Current situation and future development	Review: research methodology discussions	Frontiers of Medicine in China	I
2011	Bian and Chang	Revised STRICTA as an extension of the CONSORT statement: More items should be involved in the checklist	Letter	Journal of Alternative and Complementary Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2011	Burgos *et al*	Construction of a scale to assess methodological quality of diagnostic tests articles (Article in Spanish)	Guidelines related	Revista Chilena De Cirugia	II
2011	Corbett and Prestwich	A questionnaire survey to determine patient's knowledge, opinions and experience of acupuncture in an NHS GP practice	Letter	Acupuncture in Medicine	III
2011	Dhillon	Researching complementary and alternative therapies: Frameworks for evaluation	Review: research methodology discussions	Cancer Forum	II
2011	Enblom *et al*	The nonpenetrating telescopic sham needle may blind patients with different characteristics and experiences when treated by several therapists	RCT	Evidence-Based Complementary and Alternative Medicine	IV
2011	Enblom *et al*	Pilot testing of methods for evaluation of acupuncture for emesis during radiotherapy: A randomised single subject experimental design	RCT	Acupuncture in Medicine	III
2011	Eysenbach and Consort-Ehlth	CONSORT-EHEALTH: Improving and standardizing evaluation reports of web-based and mobile health interventions	Guidelines related	Journal of Medical Internet Research	I
2011	Hammerschlag *et al*	Randomized controlled trials of acupuncture (I997-2007): An assessment of reporting quality with a CONSORT- and STRICTA-based instrument	Review: research methodology discussions	Evidence-Based Complementary and Alternative Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2011	He *et al*	Quality assessment of reporting of randomization, allocation concealment, and blinding in traditional chinese medicine RCTs: A review of 3I59 RCTs identified from 260 systematic reviews	Review: research methodology discussions	Trials	I
2011	Hopton and MacPherson	Assessing blinding in randomised controlled trials of acupuncture: Challenges and recommendations	Review: research methodology discussions	Chinese Journal of Integrative Medicine	IV
2011	Jedel *et al*	Impact of electro-acupuncture and physical exercise on hyperandrogenism and oligo/amenorrhea in women with polycystic ovary syndrome: A randomized controlled trial	RCT	American Journal of Physiology - Endocrinology and Metabolism	II
2011	Johnson and Bjordal	Transcutaneous electrical nerve stimulation for the management of painful conditions: Focus on neuropathic pain	Review	Expert Review of Neurotherapeutics	II
2011	Kim *et al*	Acupuncture for premenstrual syndrome: A systematic review and meta-analysis of randomised controlled trials	Review	BJOG: An International Journal of Obstetrics and Gynaecology	II
2011	Kim *et al*	Moxibustion for managing type 2 diabetes mellitus: A systematic review	Review	Chinese Journal of Integrative Medicine	IV
2011	Kim *et al*	RE: Hemopericardium following acupuncture?	Letter	Yonsei Medical Journal	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2011	Knebel *et al*	Double-blinded, randomized controlled trial comparing real versus placebo acupuncture to improve tolerance of diagnostic esophagogastroduodenoscopy without sedation: A study protocol	Protocol	Trials	I
2011	Musil	The safety, acceptability, and effectiveness of acupuncture as an adjunctive treatment for acute symptoms in bipolar disorder (Article in German)	Commentary	Deutsche Zeitschrift fur Akupunktur	III
2011	Norrbrink and Lundeberg	Acupuncture and massage therapy for neuropathic pain following spinal cord injury: An exploratory study	Observational study	Acupuncture in Medicine	III
2011	Paley and Johnson	Acupuncture for cancer-induced bone pain: A pilot study	Observational study	Acupuncture in Medicine	III
2011	Pastore *et al*	True and sham acupuncture produced similar frequency of ovulation and improved LH to FSH ratios in women with polycystic ovary syndrome	RCT	Journal of Clinical Endocrinology and Metabolism	II
2011	Price *et al*	Getting inside acupuncture trials - Exploring intervention theory and rationale	Review: research methodology discussions	BMC Complementary and Alternative Medicine	IV
2011	Raja-Khan *et al*	The physiological basis of complementary and alternative medicines for polycystic ovary syndrome	Review	American Journal of Physiology - Endocrinology and Metabolism	II
2011	Robinson *et al*	The evidence for Shiatsu: A systematic review of Shiatsu and acupressure	Review	BMC Complementary and Alternative Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2011	Sarasà	Case report: Is acupuncture useful in the treatment of cluster headache? (Article in Spanish)	Case report	Revista Internacional de Acupuntura	IV
2011	Skjeie *et al*	A pilot study of ST36 acupuncture for infantile colic	RCT	Acupuncture in Medicine	III
2011	Smith *et al*	Development of an instrument to assess the quality of acupuncture: Results from a Delphi process	Guidelines related	Journal of Alternative and Complementary Medicine	III
2011	Stener-Victorin and Manheimer	Commentary on the Cochrane review of acupuncture and assisted conception	Commentary	Explore: The Journal of Science and Healing	I
2011	Stub *et al*	Acupuncture treatment for depression-A systematic review and meta-analysis	Review	European Journal of Integrative Medicine	IV
2011	Vas	How to write a case report: A guide for authors (Article in Spanish)	Guidelines	Revista Internacional de Acupuntura	IV
2011	Witt	Clinical research on acupuncture - Concepts and guidance on efficacy and effectiveness research	Review: research methodology discussions	Chinese Journal of Integrative Medicine	IV
2011	Wong *et al*	Acupuncture for acute management and rehabilitation of traumatic brain injury	Review	Cochrane Database of Systematic Reviews	I
2011	Xu and Chen	Acupuncture: A paradigm of worldwide cross-cultural communication	Editorial	Chinese Journal of Integrative Medicine	IV
2012	Agbaje *et al*	Assessment of caries experience in epidemiological surveys: A review	Review: research methodology discussions	Community Dental Health	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2012	Cao *et al*	An updated review of the efficacy of cupping therapy	Review	PLoS ONE	I
2012	Chen *et al*	Assessing the quality of reports about randomized controlled trials of acupuncture treatment on diabetic peripheral neuropathy	Review: research methodology discussions	PLoS ONE	I
2012	Collazo and Muñoz	Prediction of variability in the response to acupuncture in patients with chronic pain (Article in Spanish)	Observational study	Revista Internacional de Acupuntura	IV
2012	Enblom *et al*	Acupuncture compared with placebo acupuncture in radiotherapy-induced nausea-A randomized controlled study	RCT	Annals of Oncology	II
2012	Förster and Stange	The CONSORT statement: The companion in pursuit of high quality phytotherapy research (Article in German)	Review: research methodology discussions	Zeitschrift fur Phytotherapie	II
2012	Fragoso and Ferreira	Immediate effects of acupuncture on biceps brachii muscle function in healthy and post-stroke subjects	RCT	Chinese Medicine	IV
2012	Fragoso and Ferreira	Evaluation of the immediate effects of manual acupuncture on brachial bicep muscle function in healthy individuals and poststroke patients: A study protocol of a parallel-group randomized clinical trial	Protocol	Journal of Chinese Integrative Medicine	III
2012	Frisk *et al*	Acupuncture improves health-related quality-of-life (HRQoL) and sleep in women with breast cancer and hot flushes	RCT	Supportive Care in Cancer	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2012	Fuller *et al*	Evaluating the impact and use of Transparent Reporting of Evaluations with Non-randomised Designs (TREND) reporting guidelines	Review protocol	BMJ Open	I
2012	He *et al*	Target points: A discussion on acupuncture treatment of primary trigeminal neuralgia	Review	Journal of Chinese Integrative Medicine	III
2012	Hehir and Williams	A survey of health professionals' views about integration of Traditional Chinese Medicine (TCM) Acupuncture into NHS Scotland	Survey	European Journal of Integrative Medicine	IV
2012	Hinman *et al*	Efficacy of acupuncture for chronic knee pain: protocol for a randomised controlled trial using a Zelen design	Protocol	BMC Complementary and Alternative Medicine	IV
2012	Kim *et al*	Cupping for treating neck pain in video display terminal (VDT) users: A randomized controlled pilot trial	RCT	Journal of Occupational Health	II
2012	Kim *et al*	Intramuscular stimulation therapy for healthcare: A systematic review of randomised controlled trials	Review	Acupuncture in Medicine	III
2012	Lægaard	Akupunktur og forskning (Article in Danish)	Review	Ugeskrift for Laeger	I
2012	Lee *et al*	The effectiveness of acupuncture research across components of the trauma spectrum response (tsr): A systematic review of reviews	Review	Systematic Reviews	I
2012	Lee *et al*	Validation study of Kim's Sham needle by measuring facial temperature: An N-of-I randomized double-blind placebo-controlled clinical trial	RCT	Evidence-Based Complementary and Alternative Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2012	Liang *et al*	The optimized acupuncture treatment for neck pain caused by cervical spondylosis: a study protocol of a multicentre randomized controlled trial	Protocol	Trials	I
2012	Lu *et al*	The feasibility and effects of acupuncture on quality of life scores during chemotherapy in ovarian cancer: Results from a pilot, randomized sham-controlled trial	RCT	Medical Acupuncture	III
2012	Lu *et al*	Acupuncture for dysphagia after chemoradiation in head and neck cancer: Rationale and design of a randomized, sham-controlled trial	Protocol	Contemporary Clinical Trials	I
2012	Lyons *et al*	Acupuncture and Chinese herbs as treatments for depression: An Australian pilot study	Observational study	Complementary Therapies in Clinical Practice	IV
2012	MacPherson *et al*	Acupuncture for irritable bowel syndrome: Primary care based pragmatic randomised controlled trial	RCT	BMC Gastroenterology	II
2012	Manheimer *et al*	Acupuncture for treatment of irritable bowel syndrome	Review	Cochrane Database of Systematic Reviews	I
2012	Molassiotis *et al*	Acupuncture for cancer-related fatigue in patients with breast cancer: A pragmatic randomized controlled trial	RCT	Journal of Clinical Oncology	II
2012	Oravecz and Mészáros	Traditional Chinese medicine: Theoretical background and its use in China (Article in Hungarian)	Review	Orvosi Hetilap	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2012	Pandolfi	The autumn of acupuncture	Review	European Journal of Internal Medicine	II
2012	Park *et al*	Effects of sweet bee venom pharmacopuncture treatment for chemotherapy-induced peripheral neuropathy: A case series	Case series	Integrative Cancer Therapies	II
2012	Purepong *et al*	External validity in randomised controlled trials of acupuncture for osteoarthritis knee pain	Review: research methodology discussions	Acupuncture in Medicine	III
2012	Qu *et al*	Does acupuncture improve the outcome of in vitro fertilization? Guidance for future trials	Review: research methodology discussions	European Journal of Integrative Medicine	IV
2012	Serra	Good publication practice, its evolution and expected impact in public health	Review: research methodology discussions	Revista Cubana de Salud Publica	II
2012	Sherman	Guidelines for developing yoga interventions for randomized trials	Review: research methodology discussions	Evidence-Based Complementary and Alternative Medicine	IV
2012	Shin *et al*	Bee venom acupuncture for chronic low back pain: A randomised, sham-controlled, triple-blind clinical trial	RCT	European Journal of Integrative Medicine	IV
2012	Smith *et al*	Using a Delphi consensus process to develop an acupuncture treatment protocol by consensus for women undergoing Assisted Reproductive Technology (ART) treatment	Delphi study	BMC Complementary and Alternative Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2012	Stener-Victorin	Reply of the authors	Letter	Fertility and Sterility	II
2012	Stuardi and MacPherson	Acupuncture for irritable bowel syndrome: Diagnosis and treatment of patients in a pragmatic trial	RCT related	Journal of Alternative and Complementary Medicine	III
2012	Vixner *et al*	Manual and electroacupuncture for labour pain: Study design of a longitudinal randomized controlled trial	RCT related	Evidence-Based Complementary and Alternative Medicine	IV
2012	Wang *et al*	Scalp acupuncture for acute ischemic stroke: A meta-analysis of randomized controlled trials	Review	Evidence-Based Complementary and Alternative Medicine	IV
2012	Witt *et al*	Effectiveness guidance document (EGD) for acupuncture research - a consensus document for conducting trials	Guidelines	BMC Complementary and Alternative Medicine	IV
2012	Witt *et al*	How well do randomized trials inform decision making: Systematic review using comparative effectiveness research measures on acupuncture for back pain	Review: research methodology discussions	PLoS ONE	I
2012	Wong *et al*	Acupuncture for acute management and rehabilitation of traumatic brain injury	Review	European Journal of Physical and Rehabilitation Medicine	II
2012	Tao *et al*	Randomized controlled trial comparing acupuncture with placebo acupuncture for the treatment of Carpal Tunnel Syndrome	RCT	PM and R	I
2012	Zaslawski and Garvey	Have you got consent? An overview of human research ethics for east asian medicine	Book chapter	Publisher: Nova Science Publishers, Inc.	NA

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2012	Zhou *et al*	Acupuncture in treating hepatic fibrosis: A review with recommendation for future studies	Review	African Journal of Traditional Complementary and Alternative Medicines	IV
2012	Zou *et al*	Traditional chinese herbal medicines for treating HIV infections and AIDS	Review	Evidence-Based Complementary and Alternative Medicine	IV
2013	Allam and Mohammed	The role of scalp acupuncture for relieving the chronic pain of degenerative osteoarthritis: A pilot study of egyptian women	Observational study	Medical Acupuncture	III
2013	Arvidsdotter *et al*	Effects of an integrative treatment, therapeutic acupuncture and conventional treatment in alleviating psychological distress in primary care patients - a pragmatic randomized controlled trial	RCT	BMC Complementary and Alternative Medicine	IV
2013	Barbour t al	Better reporting of scientific studies: Why it matters	Editorial	PLoS Medicine	III
2013	Bosch *et al*	Sleep ameliorating effects of acupuncture in a psychiatric population	RCT	Evidence-Based Complementary and Alternative Medicine	IV
2013	Cao *et al*	Acupoint stimulation for fibromyalgia: A systematic review of randomized controlled trials	Review	Evidence-Based Complementary and Alternative Medicine	IV
2013	Chen *et al*	Manual acupuncture for treatment of diabetic peripheral neuropathy: A systematic review of randomized controlled trials	Review	PLoS ONE	I
2013	Chen *et al*	Effects of acupuncture treatment on depression insomnia: a study protocol of a multicenter randomized controlled trial	Protocol	Trial	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Cheng *et al*	Extending the CONSORT Statement to moxibustion	Guidelines	Journal of Chinese Integrative Medicine	III
2013	Cheong *et al*	The effectiveness of acupuncture in prevention and treatment of postoperative nausea and vomiting - A systematic review and meta-analysis	Review	PLoS ONE	I
2013	Cheong *et al*	Acupuncture and assisted reproductive technology	Review	Cochrane Database of Systematic Reviews	I
2013	Cho *et al*	Acupuncture for chronic low back pain: A multicenter, randomized, patient-assessor blind, sham-controlled clinical trial	RCT	Spine	II
2013	Da Silva *et al*	Integrative medicine, integrative acupuncture	Editorial	European Journal of Integrative Medicine	IV
2013	D'Alessandro *et al*	Evaluation of acupuncture for Cancer symptoms in a Cancer Institute in Brazil	Observational study	Acupuncture in Medicine	III
2013	Deare	Reflections on undertaking the Cochrane review: 'Acupuncture for treating Fibromyalgia'	Commentary	Australian Journal of Acupuncture and Chinese Medicine	III
2013	Facco *et al*	Acupuncture versus valproic acid in the prophylaxis of migraine without aura: A prospective controlled study	RCT	Minerva Anestesiologica	II
2013	Ferreira *et al*	Laser acupuncture in patients with temporomandibular dysfunction: A randomized controlled trial	RCT	Lasers in Medical Science	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Gu *et al*	Registration quality assessment of acupuncture clinical trials	Review: research methodology discussions	PLoS ONE	I
2013	Heo *et al*	Acupuncture for spinal cord injury and its complications: A systematic review and meta-analysis of randomized controlled trials	Review	Evidence-Based Complementary and Alternative Medicine	IV
2013	Jiao *et al*	Review of Cochrane reviews on acupuncture: How Chinese resources contribute to Cochrane Reviews	Review: research methodology discussions	Journal of Alternative and Complementary Medicine	III
2013	Johansson *et al*	Acupuncture for ovulation induction in polycystic ovary syndrome: A randomized controlled trial	RCT	American Journal of Physiology - Endocrinology and Metabolism	II
2013	Kay Garcia *et al*	Systematic review of acupuncture in cancer care: A synthesis of the evidence	Review	Journal of Clinical Oncology	II
2013	Kim *et al*	Use of acupuncture for pain management in an academic Korean medicine hospital: A retrospective review of electronic medical records	Review	Acupuncture in Medicine	III
2013	Kim *et al*	The role of acupuncture in emergency department settings: A systematic review	Review	Complementary Therapies in Medicine	III (2002)
2013	Kim *et al*	Acupuncture for posttraumatic stress disorder: A systematic review of randomized controlled trials and prospective clinical trials	Review	Evidence-Based Complementary and Alternative Medicine	IV
2013	Kinser and Robins	Control group design: Enhancing rigor in research of mind-body therapies for depression	Review: research methodology discussions	Evidence-Based Complementary and Alternative Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Kuang *et al*	Acupuncture and clomiphene citrate for live birth in polycystic ovary syndrome: Study design of a randomized controlled trial	Protocol	Evidence-Based Complementary and Alternative Medicine	IV
2013	Landgren	Acupuncture in practice: Investigating acupuncturists' approach to treating infantile colic	Survey	Evidence-Based Complementary and Alternative Medicine	IV
2013	Lee *et al*	Scalp acupuncture for Parkinson's disease: A systematic review of randomized controlled trials	Review	Chinese Journal of Integrative Medicine	IV
2013	Lee *et al*	Acupuncture for acute low back pain: A systematic review	Review	Clinical Journal of Pain	II
2013	Lee *et al*	Moxibustion for treating knee osteoarthritis: Study protocol of a multicentre randomised controlled trial	Protocol	BMC Complementary and Alternative Medicine	IV
2013	Lee *et al*	Scalp acupuncture for stroke recovery: A systematic review and meta-analysis of randomized controlled trials	Review	European Journal of Integrative Medicine	IV
2013	Lee *et al*	Acupuncture for gouty arthritis: A concise report of a systematic and meta-analysis approach	Review	Rheumatology	II
2013	Liang *et al*	Deqi sensation in placebo acupuncture: A crossover study on chinese medicine students	RCT	Evidence-Based Complementary and Alternative Medicine	IV
2013	Lu *et al*	Quality of reporting and its correlates among randomized controlled trials on acupuncture for cancer pain: Application of the CONSORT 20I0 Statement and STRICTA	Review: research methodology discussions	Expert Review of Anticancer Therapy	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Macpherson *et al*	Acupuncture for depression: Patterns of diagnosis and treatment within a randomised controlled trial	RCT related	Evidence-Based Complementary and Alternative Medicine	IV
2013	Marx *et al*	AcuTrials®: An online database of randomized controlled trials and systematic reviews of acupuncture	Recommendations	BMC Complementary and Alternative Medicine	IV
2013	McLay *et al*	Research methodology for the study of complementary and alternative medicine in the treatment of military PTSD	Review: research methodology discussions	Psychiatric Annals	II
2013	Molassiotis *et al*	A randomized, controlled trial of acupuncture self-needling as maintenance therapy for cancer-related fatigue after therapist-delivered acupuncture	RCT	Annals of Oncology	II
2013	Nedeljković *et al*	Modalities of acupuncture treatments in assisted reproductive technology - A comparison of treatment practice in Swiss, German, and Austrian fertility centers with findings from randomized controlled trials (Article in German)	Survey	Forschende Komplementarmedizin	IV
2013	Oh *et al*	Acupuncture for treatment of arthralgia secondary to aromatase inhibitor therapy in women with early breast cancer: Pilot study	RCT	Acupuncture in Medicine	III
2013	O'Leary and Crawford	Review article: Reporting guidelines in the biomedical literature	Review: research methodology discussions	Canadian Journal of Anesthesia	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Park *et al*	Acupuncture for ankle sprain: Systematic review and meta-analysis	Review	BMC Complementary and Alternative Medicine	IV
2013	Park *et al*	Moxibustion in the management of irritable bowel syndrome: Systematic review and meta-analysis	Review	BMC Complementary and Alternative Medicine	IV
2013	Rashidi *et al*	Effects of acupuncture on the outcome of in vitro fertilisation and intracytoplasmic sperm injection in women with polycystic ovarian syndrome	RCT	Acupuncture in Medicine	III
2013	Rivers and Zollman	Reliability of surface acupuncture point location	Observational study	Medical Acupuncture	III
2013	Sardella *et al*	Acupuncture and burning mouth syndrome: A pilot study	Observational study	Pain Practice	II
2013	Simcock *et al*	Arix: A randomised trial of acupuncture V oral care sessions in patients with chronic xerostomia following treatment of head and neck cancer	RCT	Annals of Oncology	II
2013	Skjeie and Gardasevic	Medical acupuncture modality: Principles, explanatory model, and scientific developments during 2005-20I2	Review	Journal of Acupuncture and Tuina Science	IV
2013	Smith *et al*	The effect of acupuncture on post-cancer fatigue and well-being for women recovering from breast cancer: A pilot randomised controlled trial	RCT	Acupuncture in Medicine	III
2013	Towler *et al*	What is the evidence for the use of acupuncture as an intervention for symptom management in cancer supportive and palliative care: An integrative overview of reviews	Review	Supportive Care in Cancer	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Turner *et al*	An evaluation of epidemiological and reporting characteristics of Complementary and Alternative Medicine (CAM) systematic reviews (SRs)	Review: research methodology discussions	PLoS ONE	I
2013	Wong *et al*	Acupuncture for acute management and rehabilitation of traumatic brain injury	Review	Cochrane Database of Systematic Reviews	I
2013	Xu *et al*	Acupuncture for chronic low back pain in long-term follow-up: A meta-analysis of I3 randomized controlled trials	Review	American Journal of Chinese Medicine	IV
2013	Xu *et al*	Effect of acupuncture treatment for weight loss on gut flora in patients with simple obesity	Letter	Acupuncture in Medicine	III
2013	Yang *et al*	Meta-analysis of acupuncture for relieving non-organic dyspeptic symptoms suggestive of diabetic gastroparesis	Review	BMC Complementary and Alternative Medicine	IV
2013	Yang *et al*	Factors contributing to de Qi in acupuncture randomized clinical trials	Review	Evidence-Based Complementary and Alternative Medicine	IV
2013	Yun *et al*	Effect of facial cosmetic acupuncture on facial elasticity: An open-label, single-arm pilot study	Observational study	Evidence-Based Complementary and Alternative Medicine	IV
2013	Zhang *et al*	Ear acupressure for smoking cessation: Study protocol for a randomised controlled trial	Protocol	Forschende Komplementarmedizin	IV
2013	Zhang *et al*	Clinical research of traditional Chinese medicine needs to develop its own system of core outcome sets	Review: research methodology discussions	Evidence-Based Complementary and Alternative Medicine	IV
2014	Abe *et al*	Acupuncture for treating persistent pain in Brazilian para-athletes	Observational study	Medical Acupuncture	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Alraek	Designing clinical studies that take into account traditional East Asian medicine's systems and methods - With focus on pattern identification	Review: research methodology discussions	Chinese Journal of Integrative Medicine	IV
2014	Alraek	Just to be sure	Letter	Acupuncture in Medicine	III
2014	Anderson *et al*	Faculty survey to assess research literacy and evidence-informed practice interest and support at Pacific College of Oriental Medicine	Survey	Journal of Alternative and Complementary Medicine	III
2014	Appleyard *et al*	Should systematic reviews assess the risk of bias from sham-placebo acupuncture control procedures?	Review: research methodology discussions	European Journal of Integrative Medicine	IV
2014	Bae *et al*	Efficacy of acupuncture in reducing preoperative anxiety: A meta-analysis	Review	Evidence-Based Complementary and Alternative Medicine	IV
2014	Baeumler *et al*	Effects of acupuncture on sensory perception: A systematic review and meta-analysis	Review	PLoS ONE	I
2014	Cho *et al*	Acupuncture with non-steroidal anti-inflammatory drugs (NSAIDs) versus acupuncture or NSAIDs alone for the treatment of chronic neck pain: An assessor-blinded randomised controlled pilot study	RCT	Acupuncture in Medicine	III
2014	Choi *et al*	Acupuncture for the treatment of chronic obstructive pulmonary disease: A protocol of a systematic review	Review protocol	BMJ Open	I
2014	Choi *et al*	Endorsement for improving the quality of reports on randomized controlled trials of traditional medicine journals in Korea: A systematic review	Review: research methodology discussions	Trials	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Cooke *et al*	PC6 acupoint stimulation for the prevention of postcardiac surgery nausea and vomiting: A protocol for a two-group, parallel, superiority randomised clinical trial	Protocol	BMJ Open	I
2014	Crawford *et al*	The current state of the science for active self-care Complementary and Integrative Medicine therapies in the management of chronic pain symptoms: Lessons learned, directions for the future	Review: research methodology discussions	Pain Medicine	II
2014	Gadau *et al*	Acupuncture and moxibustion for lateral elbow pain: A systematic review of randomized controlled trials	Review	BMC Complementary and Alternative Medicine	IV
2014	Garrow *et al*	Role of acupuncture in the management of diabetic painful neuropathy (DPN): A pilot RCT	RCT	Acupuncture in Medicine	III
2014	Glickman-Simon and Lepper	Panax Ginseng for psychomotor performance and cognition, Spinal manipulation for Lumbar Disk Herniation, Ginger for Migraines, Music therapy for mental illness, and acupuncture for Diabetic Peripheral Neuropathy	General article: expert opinion	Explore- The Journal of Science and Healing	IV
2014	Haddad and Palesh	Acupuncture in the treatment of cancer-related psychological symptoms	Review	Integrative Cancer Therapies	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Hadianfard *et al*	Efficacy of acupuncture versus local Methylprednisolone Acetate injection in De Quervain's Tenosynovitis: A randomized controlled trial	RCT	Journal of Acupuncture and Meridian Studies	IV
2014	Hammerschlag *et al*	Nontouch biofield therapy: A systematic review of human randomized controlled trials reporting use of only nonphysical contact treatment	Review	Journal of Alternative and Complementary Medicine	III
2014	Han *et al*	Acupuncture for functional dyspepsia: Study protocol for a two-center, randomized controlled trial	Protocol	Trials	I
2014	Han *et al*	Effect of acupuncture on patients with insomnia: Study protocol for a randomized controlled trial	Protocol	Trials	I
2014	Hasegawa *et al*	Acupuncture for acute non-specific low back pain: a randomised, controlled, double-blind, placebo trial	RCT	Acupuncture in Medicine	III
2014	Hinman *et al*	Acupuncture for chronic knee pain: A randomized clinical trial	RCT	Journal of the American Medical Association	I
2014	Hoffmann *et al*	Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide	Guidelines	BMJ (Online)	I
2014	Im *et al*	Effects of acupuncture at GB20 on CO_2 reactivity in the Basilar and Middle Cerebral Arteries during Hypocapnia in healthy participants	Observational study	Journal of Alternative and Complementary Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Jerng *et al*	The effectiveness and safety of acupuncture for poor semen quality in infertile males: A systematic review and meta-analysis	Review	Asian Journal of Andrology	II
2014	Kearney	Hoping for a TREND toward PRISMA: The variety and value of research reporting guidelines	Editorial	Research in Nursing and Health	II
2014	Kim *et al*	Acupuncture as analgesia for non-emergent acute non-specific neck pain, ankle sprain and primary headache in an emergency department setting: A protocol for a parallel group, randomised, controlled pilot trial	Protocol	BMJ Open	I
2014	Kim *et al*	Assessment of the quality of reporting for treatment components in Cochrane reviews of acupuncture	Review: research methodology discussions	BMJ Open	I
2014	Kim *et al*	Assessment of the quality of reporting in randomised controlled trials of acupuncture in the Korean literature using the CONSORT statement and STRICTA guidelines	Review: research methodology discussions	BMJ Open	I
2014	Kim and Kang	Rebuttal to "Life-threatening cardiac tamponade: a rare complication of acupuncture": Who framed acupuncture?	Letter	Journal of Cardiothoracic Surgery	II
2014	Lee *et al*	Acupuncture for postoperative pain in laparoscopic surgery: A systematic review protocol	Review protocol	BMJ Open	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Legro *et al*	Improving the reporting of clinical trials of Infertility treatment (IMPRINT): Explanation and elaboration of the modification of the CONSORT statement	Guidelines	Fertility and Sterility	II
2014	Legro *et al*	Improving the reporting of clinical trials of Infertility treatments (IMPRINT): Modifying the CONSORT statement	Guidelines related	Fertility and Sterility	II
2014	Legro *et al*	Improving the reporting of clinical trials of Infertility treatments (IMPRINT): Modifying the CONSORT statement	Guidelines related	Human Reproduction	II
2014	Luo *et al*	Quality of reporting of randomised controlled trials of acupuncture for neurological diseases conducted in China	Review: research methodology discussions	Acupuncture in Medicine	III
2014	Mandiroglu *et al*	Acupuncture for neuropathic pain due to bortezomib in a patient with multiple myeloma	Case report	Acupuncture in Medicine	III
2014	Martins *et al*	Factors influencing further acupuncture usage and a more positive outcome in patients with Osteoarthritis of the knee and the hip: A 3-year follow-up of a randomized pragmatic trial	RCT	Clinical Journal of Pain	II
2014	Miller *et al*	Benefits of acupuncture for diabetic gastroparesis: a comparative preliminary study	Observational study	Acupuncture in Medicine	III
2014	Moon *et al*	Acupuncture for treating whiplash associated disorder: A systematic review of randomised clinical trials	Review	Evidence-Based Complementary and Alternative Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Moreno-Martín and Santana-Pineda	Is acupuncture effective in treatment for cervicobrachial chronic pain? Qualitative analysis of the literature (Article in Spanish)	Review	Revista Internacional de Acupuntura	IV
2014	Nandi *et al*	Acupuncture in IVF: A review of current literature	Review	Journal of Obstetrics and Gynaecology	II
2014	Ong and Claydon	The effect of dry needling for myofascial trigger points in the neck and shoulders: A systematic review and meta-analysis	Review	Journal of Bodywork and Movement Therapies	I
2014	Park *et al*	The safety of acupuncture during pregnancy: A systematic review	Review	Acupuncture in Medicine	III
2014	Phillips *et al*	A systematic review of how studies describe educational interventions for evidence-based practice: Stage I of the development of a reporting guideline	Review: research methodology discussions	BMC Medical Education	II
2014	Pirotta *et al*	Acupuncture for menopausal vasomotor symptoms: Study protocol for a randomised controlled trial	Protocol	Trials	I
2014	Seo *et al*	Bee venom acupuncture, NSAIDs or combined treatment for chronic neck pain: Study protocol for a randomized, assessor-blind trial	Protocol	Trials	I
2014	Stevens *et al*	Relation of completeness of reporting of health research to journals' endorsement of reporting guidelines: Systematic review	Review: research methodology discussions	BMJ	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Vixner *et al*	Acupuncture with manual and electrical stimulation for labour pain: A longitudinal randomised controlled trial	RCT	BMC Complementary and Alternative Medicine	IV
2014	Wang *et al*	Comparison of clinical effectiveness of acupuncture and a western drug on allergic rhinitis: Study protocol for a randomized controlled trial	Protocol	Journal of Traditional Chinese Medicine	IV
2014	Ward *et al*	Components and reporting of yoga interventions for musculoskeletal conditions: A systematic review of randomised controlled trials	Review: research methodology discussions	Complementary Therapies in Medicine	III (2002)
2014	Witt *et al*	Effectiveness guidance document (EGD) for Chinese medicine trials: A consensus document	Guidelines	Trials	I
2014	Yeo *et al*	Acupuncture on GB3IV activates the precentral gyrus and prefrontal cortex in Parkinson's disease	Observational study	BMC Complementary and Alternative Medicine	IV
2014	Yeo *et al*	Randomised clinical trial of five ear acupuncture points for the treatment of overweight people	RCT	Acupuncture in Medicine	III
2014	Young	Acupuncture and moxibustion may increase pregnancy rates in IVF after embryo implantation failure	General article: expert opinion	Integrative Medicine Alert	IV
2014	Yu *et al*	Quality assessment of randomized controlled trials reporting on knee osteoarthritis treated with warming needle moxibustion	Review: research methodology discussions	Journal of Traditional Chinese Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Zhang *et al*	Sham control methods used in ear-acupuncture/ear-acupressure randomized controlled trials: A systematic review	Review	Journal of Alternative and Complementary Medicine	III
2014	Zhuang *et al*	Quality of reporting on randomized controlled trials of acupuncture for stroke rehabilitation	Review: research methodology discussions	BMC Complementary and Alternative Medicine	IV
2014	Zorzela *et al*	Quality of reporting in systematic reviews of adverse events: Systematic review	Review: research methodology discussions	BMJ (Online)	I
2015	Arvidsdotter *et al*	Quality of life, sense of coherence and experiences with three different treatments in patients with psychological distress in primary care: A mixed-methods study	Observational study	BMC Complementary and Alternative Medicine	IV
2015	Bai *et al*	Eye acupuncture treatment for stroke: A systematic review and meta-analysis	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Benhamou *et al*	Chinese medicine for pain: An evidence-based update	Review	Douleur et Analgesie	II
2015	Bezerra *et al*	Acupuncture to treat sleep disorders in postmenopausal women: A systematic review	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Birch	Historical and clinical perspectives on de Qi: Exposing limitations in the scientific study of de Qi	Review	Journal of Alternative and Complementary Medicine	III
2015	Chai *et al*	Acupuncture for melasma in women: A systematic review of randomised controlled trials	Review	Acupuncture in Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	Cho *et al*	Acupuncture for acute postoperative pain after back surgery: A systematic review and meta-analysis of randomized controlled trials	Review	Pain Practice	II
2015	Choi *et al*	Moxibustion for the treatment of chemotherapy-induced leukopenia: A systematic review of randomized clinical trials	Review	Supportive Care in Cancer	II
2015	Chong *et al*	The BMEA study: the impact of meridian balanced method electroacupuncture on women with chronic pelvic pain - a three-arm randomised controlled pilot study using a mixed-methods approach	Protocol	BMJ Open	I
2015	Cramer *et al*	Associated factors and consequences of risk of bias in randomized controlled trials of yoga: A systematic review	Review	PLoS ONE	I
2015	De Valois *et al*	Improving well-being of prostate cancer survivors using the NADA acupuncture protocol: A clinical outcome study	Observational study	Medical Acupuncture	III
2015	Eberl *et al*	A randomised controlled trial: Can acupuncture reduce drug requirement during analgosedation with propofol and alfentanil for colonoscopy? A study protocol	Protocol	BMC Complementary and Alternative Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	Gao *et al*	Comparative effectiveness of electro-acupuncture plus lifestyle modification treatment for patients with simple obesity and overweight: Study protocol for a randomized controlled trial	Protocol	Trials	I
2015	Garcia *et al*	Systematic review of acupuncture to control hot flashes in cancer patients	Review	Cancer	II
2015	Greenlee *et al*	Methods to standardize a multicenter acupuncture trial protocol to reduce aromatase inhibitor-related joint symptoms in breast cancer patients	RCT	Journal of Acupuncture and Meridian Studies	IV
2015	Hadianfard *et al*	Efficacies of acupuncture and anti-inflammatory treatment for carpal tunnel syndrome	RCT	Journal of Acupuncture and Meridian Studies	IV
2015	Hwang *et al*	Electroacupuncture as a complement to usual care for patients with non-acute pain after back surgery: A study protocol for a pilot randomised controlled trial	Protocol	BMJ Open	I
2015	Iunes *et al*	Role of auriculotherapy in the treatment of temporomandibular disorders with anxiety in university students	RCT	Evidence-Based Complementary and Alternative Medicine	IV
2015	Ji *et al*	The efficacy of acupuncture for the treatment of sciatica: A systematic review and meta-analysis	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Jiang *et al*	Efficacy and safety of acupuncture therapy for nerve deafness: A meta-Analysis of randomized controlled trials	Review	International Journal of Clinical and Experimental Medicine	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	Jo *et al*	Effectiveness of acupuncture for primary ovarian insufficiency: A systematic review and meta-analysis	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Jung *et al*	Acupuncture for postoperative pain following total knee arthroplasty: a systematic review protocol	Review protocol	BMJ Open	I
2015	Kågesten *et al*	A systematic review of reporting tools applicable to sexual and reproductive health programmes: Step I in developing programme reporting standards	Review: research methodology discussions	PLoS ONE	I
2015	Kim *et al*	The reporting quality of acupuncture-related infections in Korean literature: A systematic review of case studies	Review: research methodology discussions	Evidence-Based Complementary and Alternative Medicine	IV
2015	Kwon *et al*	Acupuncture for the sequelae of Bell's palsy: A randomized controlled trial	RCT	Trials	I
2015	Lan *et al*	Auricular acupuncture with seed or pellet attachments for primary insomnia: A systematic review and meta-analysis	Review	BMC Complementary and Alternative Medicine	IV
2015	Li *et al*	Long-lasting reduction of blood pressure by electroacupuncture in patients with hypertension: Randomized controlled trial	RCT	Medical Acupuncture	III
2015	Lim *et al*	Standardisation of moxibustion: challenges and future development	General article: expert opinion	Acupuncture in Medicine	III
2015	Liu *et al*	Electroacupuncture for acute ischemic stroke: A meta-analysis of randomized controlled trials	Review	American Journal of Chinese Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	Liu *et al*	Methodology guideline for clinical studies investigating traditional Chinese medicine and integrative medicine	Guidelines	Complementary Therapies in Medicine	III (2002)
2015	Liu *et al*	STRICTA: Is it time to do more?	Review: research methodology discussions	BMC Complementary and Alternative Medicine	IV
2015	Liu *et al*	Acupuncture for low back pain: An overview of systematic reviews	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Liu *et al*	Effects of electroacupuncture therapy for Bell's palsy from acute stage: Study protocol for a randomized controlled trial	Protocol	Trials	I
2015	Lo *et al*	The effects of acupuncture on cerebral and muscular microcirculation: A systematic review of near-infrared spectroscopy studies	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Luo *et al*	Real world research: A complementary method to establish the effectiveness of acupuncture	General article: expert opinion	BMC Complementary and Alternative Medicine	IV
2015	Lv *et al*	Efficacy of acupuncture in children with nocturnal enuresis: A systematic review and meta-analysis of randomized controlled trials	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Lv *et al*	Acupuncture therapy versus disease-modifying antirheumatic drugs for the treatment of ankylosing spondylitis - A meta-analysis	Review	Forschende Komplementarmedizin	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	MacPherson *et al*	Alexander technique lessons or acupuncture sessions for persons with chronic neck pain: A randomized trial	RCT	Annals of Internal Medicine	II
2015	Mannocci *et al*	What is the impact of reporting guidelines on Public Health journals in Europe? The case of STROBE, CONSORT and PRISMA	Review: research methodology discussions	Journal of Public Health	II
2015	Mata *et al*	Electro-acupuncture for treatment of knee pain from osteoarthritis and the possible endocrinology changes: A study protocol for a randomized controlled trial	Protocol	Trials	I
2015	Mollart *et al*	Impact of acupressure on onset of labour and labour duration: A systematic review	Review	Women and Birth	II
2015	Oliveira and De Sá Ferreira	Effects of diagnostic errors in pattern differentiation and acupuncture prescription: A single-blinded, interrater agreement study	Observational study	Evidence-Based Complementary and Alternative Medicine	IV
2015	Prowse *et al*	Treatment fidelity over the last decade in psychosocial clinical trials outcome studies: A systematic review	Review	African Journal of Psychiatry	II
2015	Qin *et al*	Effectiveness of acupuncture for treating sciatica: A systematic review and meta-analysis	Review	Evidence-Based Complementary and Alternative Medicine	IV
2015	Qin *et al*	Acupuncture for treating sciatica: a systematic review protocol	Review protocol	BMJ Open	I
2015	Raith *et al*	Laser acupuncture for neonatal abstinence syndrome: A randomized controlled trial	RCT	Pediatrics	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	Sarkis-Onofre *et al*	Use of guidelines to improve the quality and transparency of reporting oral health research	General article: expert opinion	Journal of Dentistry	II
2015	Shamseer *et al*	CONSORT extension for reporting N-of-I trials (CENT) 20I5: Explanation and elaboration	Guidelines	BMJ	I
2015	Shu *et al*	Wrist-ankle acupuncture (WAA) for precompetition nervous syndrome: Study protocol for a randomized controlled trial	Protocol	Trials	I
2015	Sterling *et al*	Dry-needling and exercise for chronic whiplash-associated disorders: A randomized single-blind placebo-controlled trial	RCT	Pain	II
2015	Tan *et al*	Sham acupressure controls used in randomized controlled trials: A systematic review and critique	Review	PLoS ONE	I
2015	Trevelyan *et al*	Acupuncture for the treatment of phantom limb pain in lower limb amputees: Study protocol for a randomized controlled feasibility trial	Protocol	Trials	I
2015	Vixner *et al*	Acupuncture with manual and electrical stimulation for labour pain: A two month follow up of recollection of pain and birth experience	RCT	BMC Complementary and Alternative Medicine	IV
2015	Wang *et al*	Zusanli (ST36) acupoint injection for preventing postoperative ileus: A systematic review and meta-analysis of randomized clinical trials	Review	Complementary Therapies in Medicine	III (2002)
2015	Wong *et al*	Local and distant acupuncture points stimulation for chronic musculoskeletal pain: A systematic review on the comparative effects	Review	European Journal of Pain	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	Wyatt *et al*	Self-administered acupressure for persistent cancer-related fatigue: Fidelity considerations	Protocol	Alternative Therapies in Health and Medicine	IV
2015	Xue *et al*	Acupuncture for seasonal allergic rhinitis: A randomized controlled trial	RCT	Annals of Allergy Asthma & Immunology	II
2015	Yang *et al*	Evidence base of clinical studies on Tai Chi: A bibliometric analysis	Review	PLoS ONE	I
2015	Yoon *et al*	Novel intervention with acupuncture for anorexia and cachexia in patients with gastrointestinal tract cancers: A feasibility study	Observational study	Oncology Nursing Forum	II
2015	Zhang *et al*	Acupuncture treatment for chronic knee pain: Study by Hinman *et al* underestimates acupuncture efficacy	Letter	Acupuncture in Medicine	III
2015	Zhang *et al*	Acupuncture therapy for sudden sensorineural hearing loss: A systematic review and meta-analysis of randomized controlled trials	Review	PLoS ONE	I
2015	Zheng *et al*	How does acupuncture affect insulin sensitivity in women with polycystic ovary syndrome and insulin resistance? Study protocol of a prospective pilot study	Protocol	BMJ Open	I
2016	Colditz and Stoll	Reporting standards for randomized trials published in the Annals of Thoracic Surgery	Editorial	Annals of Thoracic Surgery	II

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2016	Fischer-White *et al*	An integrated methodology to assess compliance with delphi survey key components of yoga interventions for musculoskeletal conditions as applied in a systematic review of fibromyalgia studies	Review: research methodology discussions	Explore: The Journal of Science and Healing	II
2016	Fu *et al*	Consensus-based recommendations for case report in Chinese medicine (CARC)	Guidelines	Chinese Journal of Integrative Medicine	IV
2016	Garland *et al*	CHoosing Options for Insomnia in Cancer Effectively (CHOICE): Design of a patient centered comparative effectiveness trial of acupuncture and cognitive behavior therapy for insomnia	Protocol	Contemporary Clinical Trials	I
2016	Guo *et al*	Effect of acupuncture on sleep quality and hyperarousal state in patients with primary insomnia: Study protocol for a randomised controlled trial	Protocol	BMJ Open	I
2016	Hoffmann *et al*	Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide	Guidelines	Gesundheitswesen	II
2016	Kim *et al*	Clinical effect of acupotomy combined with Korean medicine: A case series of a herniated intervertebral disc	Case series	Journal of Acupuncture and Meridian Studies	IV
2016	Ko *et al*	Effect of acupuncture and its influence on cerebral activity in functional dyspepsia patients: Study protocol for a randomized controlled trial	Protocol	Trials	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2016	Lee *et al*	Acupoint herbal patching for asthma: A systematic review and meta-analysis of randomized controlled trials	Review	Medicine	I
2016	Lund and Lundeberg	Is acupuncture effective in the treatment of pain in endometriosis?	Review	Journal of Pain Research	II
2016	Musil and Kloiber	Acupuncture in mental disorders: Review of literature and possible developments Part I: Dementia, substance use disorders, eating disorders, personality disorders, attention-deficit/hyperactivity disorders	Review	Deutsche Zeitschrift fur Akupunktur	III
2016	Ormsby *et al*	Evaluation of an antenatal acupuncture intervention as an adjunct therapy for antenatal depression (AcuAnteDep): Study protocol for a pragmatic randomised controlled trial	Protocol	Trials	I
2016	Park *et al*	Pharmacopuncture in Korea: A systematic review and meta-analysis of randomized controlled trials	Review	Evidence-Based Complementary and Alternative Medicine	IV
2016	Rueda *et al*	Acupuncture treatment of shoulder impingement syndrome: A randomized controlled trial	RCT	Complementary Therapies in Medicine	III (2002)
2016	Shin *et al*	Electroacupuncture versus sham electroacupuncture for urinary retention in poststroke patients: Study protocol for a multicenter, randomized controlled trial	Protocol	Trials	I

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2016	Wu *et al*	Acupuncture for treating polycystic ovary syndrome: Guidance for future randomized controlled trials	Review	Journal of Zhejiang University	I
2016	Zhong *et al*	Effectiveness of moxibustion for exercise-induced fatigue - A systematic review for randomized controlled trials	Review	Chinese Journal of Integrative Medicine	IV
2016	Zhou *et al*	Acupuncture for chronic knee pain: A critical appraisal of an Australian randomized controlled trial	Commentary	Medical Acupuncture	III
		From Chinese database (China National Knowledge Infrastructure)			
2011	Tang *et al*	Acupuncture and guasha for stiff neck: A randomized controlled trial	RCT	Jilin Journal of Traditional Chinese Medicine	IV
2011	Fan	The literature evaluation and clinical research of treating depression with acupuncture and moxibustion	RCT, Review	Doctoral dissertation in Guangzhou University of Chinese Medicine	NA
2011	Qu	The evaluating quality research of randomized controlled trials literature on acupuncture and moxibustion on treating Scapulohumeral Periarthritis	Review: research methodology discussions	Master thesis in China Academy of Chinese Medical Sciences	NA
2012	Lin and Wu	Deconstruction of the clinical research model for acupuncture effects	General article: expert opinion	Chinese Acupuncture and Moxibustion	IV
2012	He *et al*	Target points: A discussion on acupuncture treatment of primary trigeminal neuralgia	General article: expert opinion	Journal of Chinese Integrative Medicine	III

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2012	Wang and Liang	Thoughts and prospects of research on acupoints compatibility	General article: expert opinion	Chinese Acupuncture and Moxibustion	IV
2012	Zhang *et al*	Assessing the reporting quality of randomized controlled trials on acupuncture for Diabetic Gastroparesis using the CONSORT statement and STRICTA	Review: research methodology discussions	Tianjin Journal of Traditional Chinese Medicine	IV
2012	Zhang *et al*	Methodological quality of randomized controlled trials of acupuncture for sudden hearing loss	Review: research methodology discussions	Shanghai Journal of Acupuncture and Moxibustion	IV
2012	Liu	Research on the quality of systematic reviews and randomized controlled trials of acupuncture and congnition of reporting guideline	Review: research methodology discussions	Doctoral dissertation in Lanzhou University	NA
2012	Liu	Lower extremity point acupuncture treatment of periarthritis of shoulder with shoulder movement clinical curative effect observation	RCT	Master thesis in Heilongjiang University of Chinese Medicine	NA
2012	Shi	An evaluation research of literature and clinical trial with the Back-Shu and Front-Mu acupoints of Stomach for treating Diabetic Gastroparesis	RCT, Review: research methodology discussions	Master thesis in Chengdu University of Traditional Chinese Medicine	NA
2012	Zhang	Research of clinic guide of Chinese Medicine for Nutritional Iron Deficiency Anemia	Guidelines related	Master thesis in Nanjing University of Chinese Medicine	NA
2013	Liu *et al*	Quality improvement on acupuncture intervention report: Application and perfetion of STRICTA	Commentary	Chinese Acupuncture and Moxibustion	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2013	Qu *et al*	Quality of reporting on randomized controlled trials of acupuncture for Scapulohumeral Periarthritis: A survey	Survey	Chinese Journal of Basic Medicine in Traditional Chinese Medicine	IV
2013	Shen *et al*	Quality evaluation of the randomized controlled trials on acupuncture-moxibustion for Primary Trigeminal Neuralgia by using CONSORT and STRICTA	Review: research methodology discussions	Shanghai Journal of Acupuncture and Moxibustion	IV
2013	Wang and Zhao	Quality of research report in China according to the STRICTA of 20I0 edition-Examples of RCT reports from acupuncture trials for insomnia in recent two years	Review: research methodology discussions	Journal of Clinical Acupuncture and Moxibustion	IV
2013	Xu *et al*	Assessment of reporting quality of randomized controlled trials on acupuncture for Shoulder-hand Syndrome with CONSORT statement and STRICTA	Review: research methodology discussions	Liaoning Journal of Traditional Chinese Medicine	IV
2013	Zhang	Clinical study on the Postherpetic Neuralgia with round acupuncture and its effect on IL-6	RCT	Master thesis in Nanjing University of Chinese Medicine	NA
2013	Zhang	A systematic review and the GRADE of acupuncture and moxibustion treatment for sudden hearing loss	Review	Master thesis in Nanjing University of Chinese Medicine	NA
2014	Hao	Analysis on the randomized controlled trials of acupuncture published in SCI source journal in 20II	Review: research methodology discussions	Master thesis in China Academy of Chinese Medical Sciences	NA

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2014	Jiang *et al*	Assessment of reporting quality of randomized controlled trials on acupuncture for leukocytopenia with CONSORT statement and STRICTA	Review: research methodology discussions	Modern Journal of Integrated Traditional Chinese and Western Medicine	IV
2014	Li *et al*	Evaluation of the reporting quality of randomized controlled trials on acupoints injection for asthma	Review: research methodology discussions	8th Symposium on Evidence-Based Chinese Medicine/Integrative Medicine Conference Materials	NA
2014	Liu *et al*	Study on the normative statements elements of randomized controlled trial literature on ulcerative colitis treated by acupuncture and moxibustion	Review: research methodology discussions	China Journal of Traditional Chinese Medicine and Pharmacy	IV
2014	Xu	A cumulative meta-analysis study of comparing the efficiency of the treatment of post stroke depression by acupuncture and western medicine	Review	Master thesis in Guangzhou University of Chinese Medicine	NA
2014	Yang *et al*	Proposed reporting of Tai Chi intervention in clinical trials	Guidelines	World Chinese Medicine	IV
2014	Yu *et al*	Quality assessment of randomized controlled trials reporting on knee osteoarthritis treated with warming needle moxibustion	Review: research methodology discussions	Journal of Traditional Chinese Medicine	IV
2014	Zhang *et al*	Evaluation of the reporting quality of randomized controlled trials on acupuncture for functional constipation	Review: research methodology discussions	Shanghai Journal of Acupuncture and Moxibustion	IV
2015	An *et al*	Assessing the quality of reports about randomized controlled trials of acupuncture treatment on chemotherapy-induced nausea and vomiting	Review: research methodology discussions	Liaoning Journal of Traditional Chinese Medicine	IV

Publication year	Author(s)	Article title	Study type	Journal name	Journal type
2015	He *et al*	Acupuncture treatment of male infertility: A systematic review	Review	National Journal of Andrology	II
2015	Liu *et al*	Evidence based analysis on acupuncture therapy for scapulohumeral periarthritis	Review	Journal of Liaoning University of Traditional Chinese Medicine	IV
2015	Wang	Evaluation of the effectiveness of acupoint injection in clinical practice	Review	Master thesis in Beijing University of Chinese Medicine	NA
2015	Wang	Lie between monkshood cake of acupuncture and moxibustion for the treatment of liver and kidney deficiency type research of knee osteoarthritis	Review, RCT	Master thesis in Guangzhou University of Chinese Medicine	NA
2015	Wen *et al*	Analysis of the current status of RCTs evaluation with CONSORT statement and STRICTA in China	Review: research methodology discussions	Journal of Traditional Chinese Medicine	IV
From Japanese database (Japan Science and Technology Information Aggregator, Electronic)					
2012	Kim *et al*	Cupping for treating neck pain in video display terminal (VDT) users: A randomized controlled pilot trial	RCT	Journal of Occupational Health	II

Journal types:

I. General medical non-CAM journals;

II. Specialty medical non-CAM journals;

III. CAM journals with STRICTA endorsement;

IV. CAM journals without STRICTA endorsement.

Appendix 5. Feasibility trial: Ethical approval

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

14 May 2015

Ms Lizhou Liu
325 Great King Street
School of Physiotherapy
University of Otago
Dunedin 9016

Dear Ms Liu

Re:	**Ethics ref:**	**15/NTB/54**
	Study title:	Does the dose of Traditional Chinese Medicine acupuncture in addition to usual care affect outcomes for adults with chronic low back pain? A randomized controlled feasibility study

I am pleased to advise that this application has been *approved* by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern B Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 13 May 2016.

Participant access to ACC

The Northern B Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Raewyn Sporle
Chairperson
Northern B Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
CV for CI	1	10 March 2015
Evidence of scientific review	1	14 March 2015
PIS/CF	1	11 March 2015
Protocol	2	14 March 2015
Survey/questionnaire	1	11 March 2015
PIS/CF: version 2 of the PIS/CF after the committee meeting	2	29 April 2015
Protocol: version 3 of the protocol after the committee meeting	3	29 April 2015
Survey/questionnaire: version 2 of the questionnaires after the committee meeting	2	29 April 2015
Covering Letter: version 1 of the cover letter responding to the questions raised by the Committee	1	29 April 2015
version 2 of the study flyer with a picture	2	29 April 2015

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern B Health and Disability Ethics Committee:

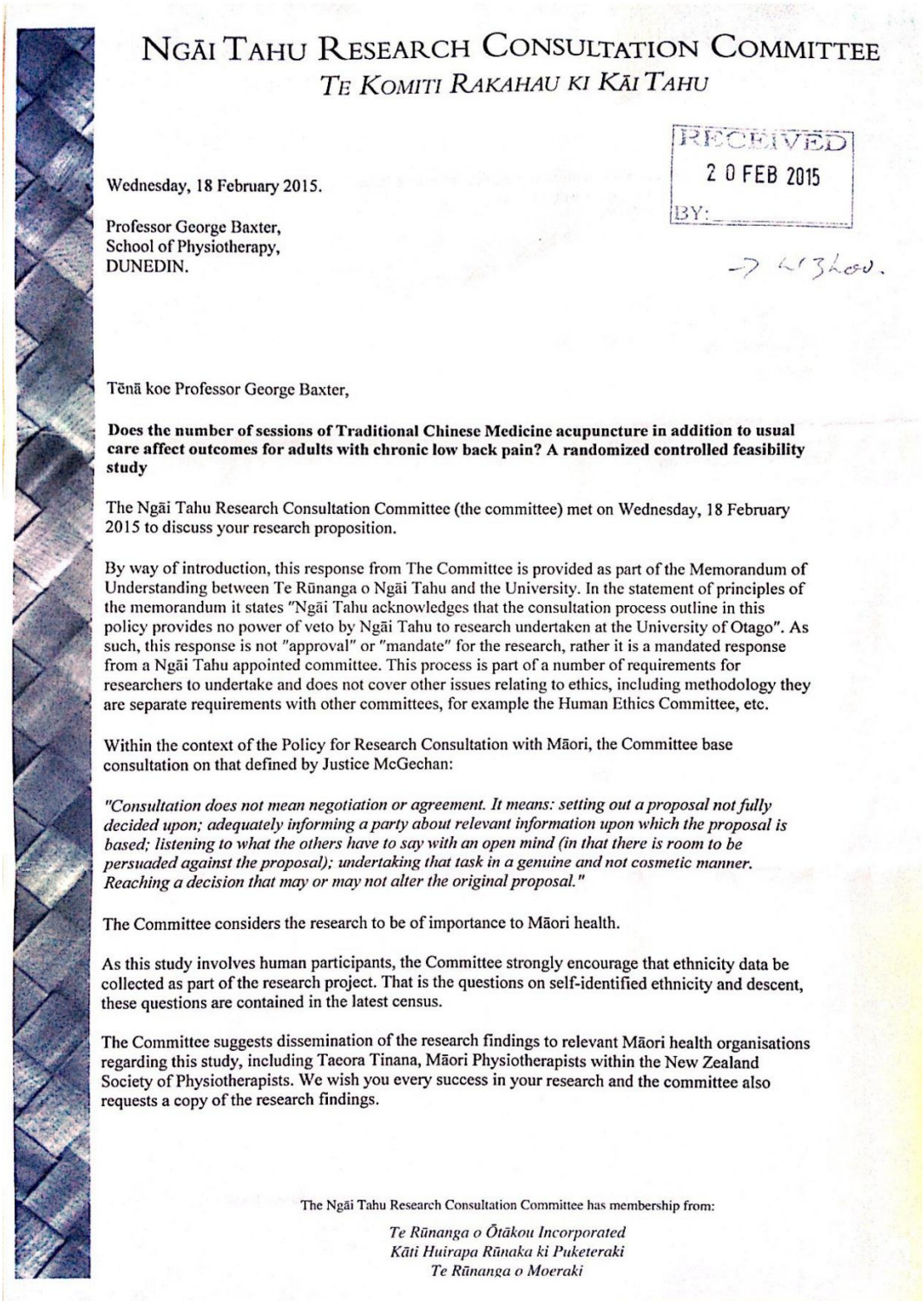
- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees,* and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Mrs Raewyn Sporle	Lay (the law)	01/07/2012	01/07/2015
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Mrs Phyllis Huitema	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
Mrs Kate O'Connor	Non-lay (other)	01/07/2012	01/07/2015
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Paul Tanser	Non-lay (health/disability service provision)	01/07/2012	01/07/2015

http://www.ethics.health.govt.nz

Appendix 6. Feasibility trial: Māori consultation



NGĀI TAHU RESEARCH CONSULTATION COMMITTEE

TE KOMITI RAKAHAU KI KĀI TAHU

RECEIVED
20 FEB 2015
BY:

Wednesday, 18 February 2015.

Professor George Baxter,
School of Physiotherapy,
DUNEDIN.

→ Kizhou.

Tēnā koe Professor George Baxter,

Does the number of sessions of Traditional Chinese Medicine acupuncture in addition to usual care affect outcomes for adults with chronic low back pain? A randomized controlled feasibility study

The Ngāi Tahu Research Consultation Committee (the committee) met on Wednesday, 18 February 2015 to discuss your research proposition.

By way of introduction, this response from The Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum it states "Ngāi Tahu acknowledges that the consultation process outline in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago". As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGechan:

"Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal."

The Committee considers the research to be of importance to Māori health.

As this study involves human participants, the Committee strongly encourage that ethnicity data be collected as part of the research project. That is the questions on self-identified ethnicity and descent, these questions are contained in the latest census.

The Committee suggests dissemination of the research findings to relevant Māori health organisations regarding this study, including Taeora Tinana, Māori Physiotherapists within the New Zealand Society of Physiotherapists. We wish you every success in your research and the committee also requests a copy of the research findings.

The Ngāi Tahu Research Consultation Committee has membership from:

Te Rūnanga o Ōtākou Incorporated
Kāti Huirapa Rūnaka ki Puketeraki
Te Rūnanga o Moeraki

NGĀI TAHU RESEARCH CONSULTATION COMMITTEE

TE KOMITI RAKAHAU KI KĀI TAHU

This letter of suggestion, recommendation and advice is current for an 18 month period from Wednesday, 18 February 2015 to 18 August 2016.

Nāhaku noa, nā



Mark Brunton
Kaiwhakahaere Rangahau Māori
Research Manager Māori
Research Division
Te Whare Wānanga o Otāgo
Ph: +64 3 479 8738
Email: mark.brunton@otago.ac.nz
Web: www.otago.ac.nz

The Ngāi Tahu Research Consultation Committee has membership from:

Te Rūnanga o Ōtākou Incorporated
Kāti Huirapa Rūnaka ki Puketeraki
Te Rūnanga o Moeraki

Appendix 7. Feasibility trial: Locality authorization approval

UNIVERSITY OF OTAGO

INTERIM LOCALITY ASSESSMENT REVIEW TEMPLATE FOR RESEARCH NOT CONDUCTED THROUGH A DHB

*Only use this form for University of Otago applications being sent to Health and Disability Ethics Committees that are **NOT being conducted through a District Health Board.*** If your *research accesses staff, patients or resources of a DHB, contact your campus Health Research Office.*

NOTE: All research proposals using University of Otago controlled or owned localities that are not being carried out in their local DHB must complete this locality assessment template.

PART ONE: UNIVERSITY OF OTAGO PRINCIPAL INVESTIGATOR TO COMPLETE THIS SECTION AND SEND TO CAMPUS HDEC MANAGER/ADVISOR*

**Campus HDEC Managers/Advisors: Dunedin - Dr Dayle Matthews, Health Research South, DSM; Christchurch – Ms Virginia Irvine, Research Office; Wellington – Dr William Levack, Department of Medicine.*

Full project title	Does the dose of Traditional Chinese Medicine acupuncture in addition to usual care affect outcomes for adults with chronic low back pain? A randomized controlled feasibility study
University of Otago locality/ies where research will take place	At the School of Physiotherapy Clinic, University of Otago
Outline of study (Copy and paste research abstract/summary)	**Background:** Chronic low back pain is a major public health problem that is associated with significant economic and social impacts. It has been demonstrated that acupuncture may be a clinically effective and a cost-effective treatment approach for chronic low back pain. To date, there exists no credible and accepted guideline on optimal acupuncture treatment protocols. Consequently, treatment regimens are arbitrarily selected based on opinion or clinical experience but not the evidence base. A few clinical trials have evaluated the dose dependence of acupuncture in terms of the number of sessions for chronic low back pain, but conclusions drawn have been conflicting. Additionally, there is a paucity of high quality evidence to support the cumulative effects of repeated acupuncture interventions. There is therefore a need to conduct a randomized controlled trial to investigate the optimal number of sessions of acupuncture in addition to usual care for adults with chronic low back pain. A feasibility study that provides the rationale for and method to be used for the full scale trial is the first step in that process. **Design:** A pragmatic parallel three-armed randomized controlled feasibility study. **Methods:** Forty-five participants with chronic low back pain will be recruited from the Dunedin community, and randomized on a 1:1:1 basis to receive usual care plus either 4 sessions (n=15), 7 sessions (n=15), or 10 sessions (n=15) of acupuncture interventions. Primary outcomes include the acceptability of and adherence to different numbers of sessions of acupuncture treatment for chronic low back pain, and the feasibility of the recruitment approaches and completion of the outcome measures specific to the trial. Secondary outcomes include back specific function, pain intensity and bothersomeness, generic health status, activity disability, and patient satisfaction. Follow up questionnaires will be collected at discharge, and 6 weeks and 12 weeks post randomization. **Discussion:** The information obtained from this feasibility study will inform the decision to conduct a full-scale randomized controlled trial to definitively test the dose dependence of acupuncture. Findings will add to the current (limited) body of high quality evidence that is available on the optimal number of sessions of acupuncture in the management of chronic low back pain as well as being clinically relevant to clinicians, researchers, and policy makers.

Contact Details

Principal Investigator	Title/Name: Ms Lizhou Liu Email: lizhou.liu@otago.ac.nz
	Dept: School of Physiotherapy Phone: (03) 479 5694

All Associate Investigator/s (copy and paste as required)	Title/Name: Professor David Baxter Email: david.baxter@otago.ac.nz	Dept: School of Physiotherapy Phone: (03) 479 7411
	Title/Name: Dr Margot Skinner Email: margot.skinner@otago.ac.nz	Dept: School of Physiotherapy Phone: (03) 479 7466
	Title/Name: Professor Suzanne McDonough Dept: School of Health Sciences, University of Ulster, Northern Ireland Email: s.mcdonough@ulster.ac.uk	Phone: +44 2890366459
	Title/Name: Ms Karen Taylor Email: karen.taylor@otago.ac.nz	Dept: School of Physiotherapy Phone: (03) 479 5757

PRINCIPAL INVESTIGATOR DECLARATION

1. All **regulatory consents** are in place if research involves administration of a new medicine. ☐
2. All **relevant** Departments, Administrators, Health Professionals have been notified about the research ☑
3. Māori Consultation has taken place ☑ (date: 18/02/2015) **or** is being undertaken. ☑
4. Other requisite cultural requirements have been undertaken. ☑
5. A copy of the full research proposal is attached (incl. budget and funding details). ☑
6. All relevant other documents (eg consent letters) are attached. ☑

Lizhen Liu — Prof David Baxter — 19/05/2015

PRINCIPAL INVESTIGATOR SIGNATURE — **DATE**

UNIVERSITY OF OTAGO CAMPUS HDEC MANAGER/ADVISOR TO COMPLETE

1. PI/AI details correct	☑	4. Other consultation	☐
2. Regulatory Consents in place	☑	5. Application attached	☑
3. Māori consultation	☑	6. Other documents attached	☑

Name Ruth Sharpe *Signature* RJ Sharpe *Date* 21/5/15

PART TWO: HEAD OF DEPARTMENT TO COMPLETE AND SIGN THIS SECTION

HoD's Declaration

I declare that

- *the Principal Investigator(s) has/have the requisite qualifications and experience to conduct of the study;*
- *the facilities are adequate for the conduct of the study;*
- *the study is supported by the Department.*

Signature:	Lhale	Date:	19/05/2015
Name:	Leigh Hale	Position:	Deputy Dean
Comments:			

HODs TO SEND HARD COPY TO THE AUTHORISER FOR THEIR CAMPUS

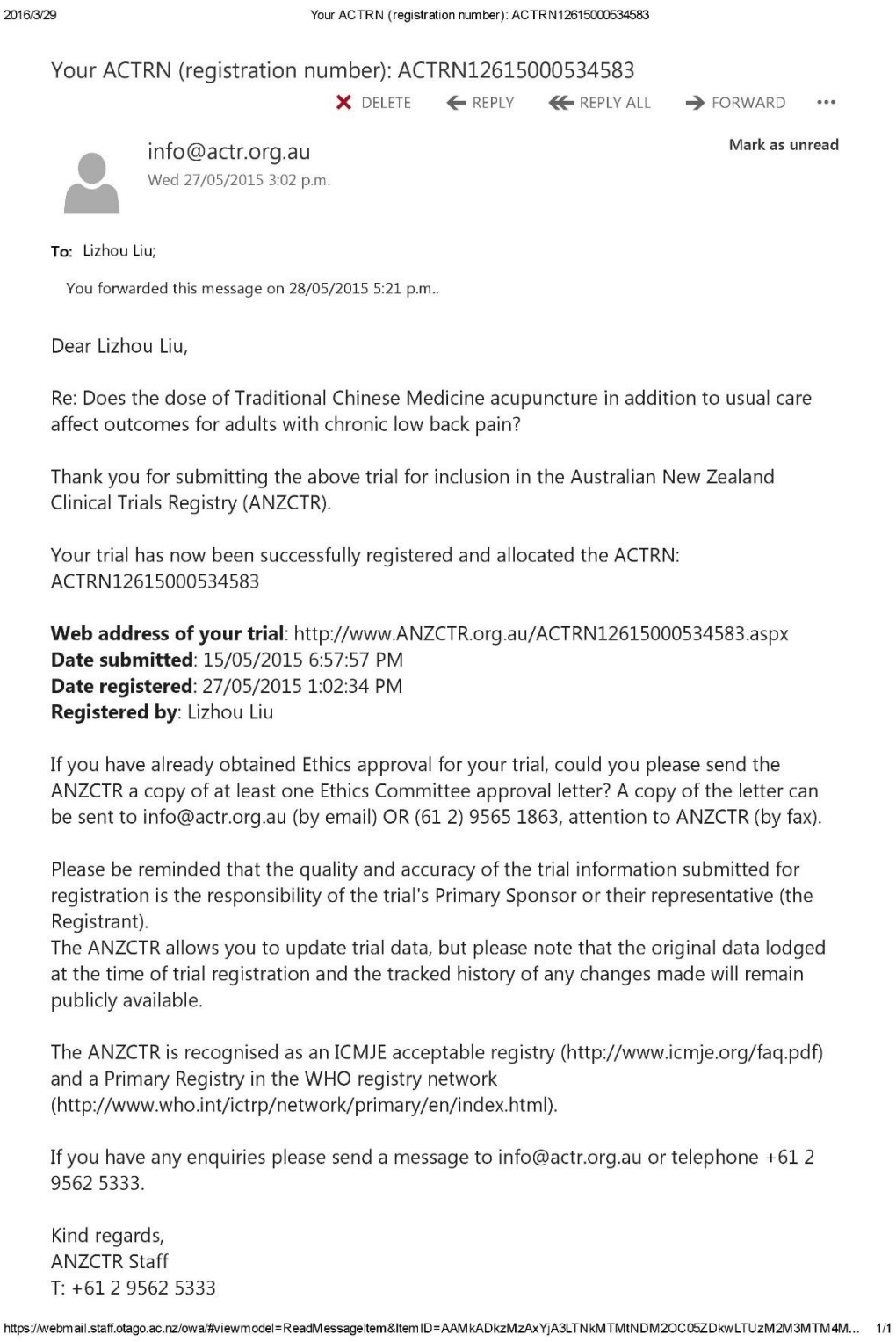
DUNEDIN: ~~Dr John Adams~~ Prof Barry Taylor, Dunedin School of Medicine
CHRISTCHURCH: Professor Peter Joyce, University of Otago, Christchurch
WELLINGTON: Professor Sunny Collings, University of Otago, Wellington

PART THREE: UNIVERSITY OF OTAGO AUTHORISATION

- *I am authorised to complete locality approval on behalf* **of the University of Otago** *that the* **University of** *Otago location indicated in the proposal is suitable for the purposes of the stated human research.*
- *I understand that I may withdraw locality approval if any significant local concerns arise. I agree to advise the principal investigator and then the relevant ethics committee should this occur.*

Signature:		Date:	22.5.15
Name:	Barry J Taylor: Dean, DSM	Position:	
Comments:	Interesting study!		

Appendix 8. Feasibility trial: Trial registration



2016/3/29 Your ACTRN (registration number): ACTRN12615000534583

Your ACTRN (registration number): ACTRN12615000534583

DELETE REPLY REPLY ALL FORWARD ...

Mark as unread

info@actr.org.au
Wed 27/05/2015 3:02 p.m.

To: Lizhou Liu;

You forwarded this message on 28/05/2015 5:21 p.m..

Dear Lizhou Liu,

Re: Does the dose of Traditional Chinese Medicine acupuncture in addition to usual care affect outcomes for adults with chronic low back pain?

Thank you for submitting the above trial for inclusion in the Australian New Zealand Clinical Trials Registry (ANZCTR).

Your trial has now been successfully registered and allocated the ACTRN: ACTRN12615000534583

Web address of your trial: http://www.ANZCTR.org.au/ACTRN12615000534583.aspx
Date submitted: 15/05/2015 6:57:57 PM
Date registered: 27/05/2015 1:02:34 PM
Registered by: Lizhou Liu

If you have already obtained Ethics approval for your trial, could you please send the ANZCTR a copy of at least one Ethics Committee approval letter? A copy of the letter can be sent to info@actr.org.au (by email) OR (61 2) 9565 1863, attention to ANZCTR (by fax).

Please be reminded that the quality and accuracy of the trial information submitted for registration is the responsibility of the trial's Primary Sponsor or their representative (the Registrant).
The ANZCTR allows you to update trial data, but please note that the original data lodged at the time of trial registration and the tracked history of any changes made will remain publicly available.

The ANZCTR is recognised as an ICMJE acceptable registry (http://www.icmje.org/faq.pdf) and a Primary Registry in the WHO registry network (http://www.who.int/ictrp/network/primary/en/index.html).

If you have any enquiries please send a message to info@actr.org.au or telephone +61 2 9562 5333.

Kind regards,
ANZCTR Staff
T: +61 2 9562 5333

https://webmail.staff.otago.ac.nz/owa/#viewmodel=ReadMessageItem&ItemID=AAMkADkzMzAxYjA3LTNkMTMtNDM2OC05ZDkwLTUzM2M3MTM4M... 1/1

Appendix 9. Feasibility trial: Study flyer



Interested participants need to:

- Be 18 years or older
- Have low back pain which has lasted for more than 3 months
- Be able to communicate in English or Mandarin

If you take part in the study, there will be no charge for the acupuncture treatments.

Each treatment session will take a maximum of 30 minutes, and will take place in the School of Physiotherapy Clinic.

If you are interested and/or would like to know more about the project, please contact:

The Clinical Research Administrator
School of Physiotherapy
University of Otago
Email: clinicalresearch.physio@otago.ac.nz
Tel: 03 479 4979

This project has been reviewed and approved by the Northern B Health and Disability Ethics Committee: Reference: 15/NTB/54.

TEAR OFF

Acupuncture in addition to usual care for chronic low back pain clinicalresearch.physio@otago.ac.nz Tel: 03 479 4979

Acupuncture in addition to usual care for chronic low back pain clinicalresearch.physio@otago.ac.nz Tel: 03 479 4979
Acupuncture in addition to usual care for chronic low back pain clinicalresearch.physio@otago.ac.nz Tel: 03 479 4979
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Acupuncture in addition to usual care for chronic low back pain clinicalresearch.physio@otago.ac.nz Tel: 03 479 4979

Appendix 10. Feasibility trial: Participant information sheet



Acupuncture in addition to usual care for chronic low back pain:

A feasibility study

Participant Information Sheet

Locality: University of Otago Ethics committee ref.: 15/NTB/54
Lead Investigator: Lizhou Liu, School of Physiotherapy, University of Otago, New Zealand

---

Thank you for showing an interest in our project. If you decide to participate, we thank you. If you decide not to take part, there will be no disadvantage to you of any kind and we thank you for considering our request. If you would like to take part now, but change your mind later, you can pull out of the study at any time without any disadvantage.

This information sheet is to help you to decide if you would like to take part. We will go through this with you and answer any questions you may have. We expect this will take about 10 minutes. You do not have to decide today whether or not to take part. Before you decide, please feel free to talk about it with other people, such as family, whānau, friends, or healthcare providers.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of this document to keep.

This document is five pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Why are we doing the study?
This small study is to see if we can conduct a full scale trial to find out the best number of sessions of Traditional Chinese Medicine (TCM) acupuncture (4 sessions, 7 sessions or 10 sessions) in addition to usual care for the treatment of chronic low back pain.

According to TCM theory, we become unwell when there is an internal imbalance within the body. This imbalance leads to a blockage in the flow of the body's vital energy (known as *qi*) along pathways known as *meridians*. TCM acupuncture selects the best points along the meridians corresponding to a particular health problem, and stimulates those points in order to restore the balance.

What Type of Participants do we need?
We are looking for people who:
- Are aged 18 years or older
- Have had low back pain for more than 3 months
- Can communicate in English or Mandarin

You will not be able to take part if you have:
(1) a history of serious spinal disorders;
(2) had spinal surgery or if you are on the waiting list for spinal surgery;
(3) been to a pain clinic or had morphine for low back pain in the last year;
(4) severe psychological disorders, or dementia;
(5) had acupuncture for low back pain in the past year;
(6) used steroids or are currently taking medication to prevent blood clots;
(7) any bleeding disorders;
(8) a fear of needles;
(9) a history of medical conditions including such as problems with your heart and/or lungs, liver or kidney disease, deep vein thrombosis, or epilepsy; or
(10) if you are pregnant or trying to become pregnant.

What are the start date, end date and sources of funding of the study?
The recruitment will run from June 2015 until the end of December 2015. This study is funded by the School of Physiotherapy, University of Otago.
We can reimburse your city bus fares, if required.

What would your participation involve?
If you are interested, you will be invited to the School of Physiotherapy Clinic to attend an initial assessment where you will be asked to fill out a screening questionnaire to see if you are eligible to take part.

All eligible participants will be required to complete the consent form and fill out some other questionnaires. We will give you three sets of questionnaires for you to complete at the end of treatment, and 6 weeks and 12 weeks after the beginning of your treatment. We will give you stamped addressed envelopes to post them back to us.

You will carry on as usual with your current regime for managing your low back pain (e.g. medications, and/or manual therapy, as directed by your health practitioner) during the course of the study.

After you have agreed to take part in the study, you will be randomly assigned to one of the three acupuncture groups (4 sessions, 7 sessions or 10 sessions) by choosing a sealed envelope. Then we will make an appointment for your first acupuncture treatment. As well as continuing your usual care for your low back pain, we will ask you to come to the School of Physiotherapy Clinic twice a week for TCM acupuncture. The length of time you will be in the study, i.e. 2 weeks, 3.5 weeks or 5 weeks, depends on which group you were randomized into.

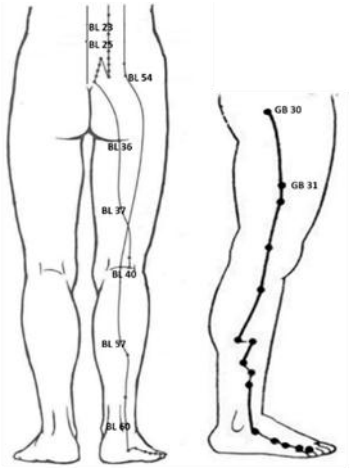

Figure 1. Potential acupoints used in study protocol

During your visits for acupuncture, you will receive TCM acupuncture by a trained acupuncturist (Lizhou Liu) using a sterile needling technique. We may use up to 10 needles per session, and these will be left in place for approximately 20 minutes. Each session will take up to 30 minutes. Figure 1 shows where we might place the needles.

When you have finished all your treatments, you will be able to carry on with your usual care as advised by your health professional. But, if at the end of the study you still have severe low back pain, we can arrange for an experienced acupuncturist in our research team (Karen Taylor), who is also a professional practice fellow at the School of Physiotherapy Clinic, to examine you and recommend appropriate action. This may involve talking to your usual care practitioner, if you agree.

Our research team will follow-up with an email/telephone call to remind you to complete the three follow-up postal questionnaires and answer any questions.

What are the possible benefits and risks to you of participating?

Benefits:

The potential benefits of taking part in this study may include being able to move more freely, and having less back and/or leg pain.

No change/worsening symptoms:

You may find there is little change regarding your symptoms or that your symptoms worsen. In this case, Karen Taylor will examine you on completion of the acupuncture treatments and recommend the appropriate action to take.

Risks and discomfort:

You may experience some pain or a little bleeding at the needling sites. These usually disappear without treatment in approximately 24 hours, and do not require any treatment. Other potential risks (e.g. organ or tissue injury, central nerve injury, and seizure) are rare. Infections (e.g. skin infection, or Hepatitis B/C infection) are also very rare, as sterile filiform, single-use needles will be used in the study. The acupuncturist will monitor your response to acupuncture, and will reassure you about any potential reactions and how best to manage them.

What will happen if you are injured in the study?

Although the risk is minimal, if you are injured or have a severe adverse reaction in this study, you may be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. In such a situation you would have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you should check with your insurer that taking part in this study will not affect your cover.

What are the rights of participants in the study?

Refusal or withdrawal of participation:

Your participation is purely voluntary. You may also withdraw from the project at any time and without any disadvantage of any kind.

As a participant in the study you have the right to access information collected about you as part of the study.

Participant information confidentiality:

Your health information in the study record will be kept confidential. All data will be stored securely on password-protected servers and all hard copies will be stored in a locked cabinet for 10 years after the project and discarded thereafter according to the University of Otago research policy. The members of the research team take the responsibility for secure storage of data.

What will happen after the study ends, or if you pull out?
During participation in the study, there is no charge for the acupuncture treatment at the School of Physiotherapy Clinic. If you choose to have treatment using acupuncture or another intervention at the School of Physiotherapy Clinic when your part in the study is finished, the usual charges will apply. On completion of the study if you continue to have symptoms and are examined by Karen Taylor, she will recommend the appropriate action to be taken.

Data information and use:
Data acquired from this study will be used in a postgraduate doctoral thesis as well as for publication in relevant health-related literature. Your anonymity will be preserved in all publications, with results reported as numbers or percentages and with any identifying characteristics removed. The published study will be available in the University of Otago Library (Dunedin, New Zealand). You will also be informed about the study findings on completion of the study. You are most welcome to request a copy of the results of the project should you wish.
It is possible that data collected during this study may be useful for future research. If this is the case, you will be asked for your consent for your data to be used, with the same guarantees of confidentiality and subject to future ethical approval.

Request for more information:
If you have any more questions about participation in the study, you may contact our Clinical Research Administrator between 8.30am and 5.00pm, Monday to Friday.

The Clinical Research Administrator, School of Physiotherapy, University of Otago
Phone: (03) 479 4979
Email: clinicalresearch.physio@otago.ac.nz

If you have any questions, concerns or complaints about the study once you have enrolled, you can contact:

Professor David Baxter
Dean, School of Physiotherapy, University of Otago
Phone: (03) 479 7411
Email: david.baxter@otago.ac.nz

If you want to talk to someone who isn't involved with the study, or ask for independent Maori health support, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Thank you again for your interest in our study.

Appendix 11. Feasibility trial: Screening questionnaire



Participant ID:

Acupuncture in addition to usual care for chronic low back pain:

A feasibility study

Screening Questionnaire

Demographic Details

Name:	Gender: □ Male □ Female	Date of Birth: __/__/___
Height (cm):	Weight (kg):	Smoker: □ Yes □ No
Ethnicity: □ New Zealand European □ Maori □ Cook Island Maori □ Samoan □ Tongan □ Niuean □ Chinese □Indian □ Other: _____		
Educational qualification: □ Below university level □ University level □ Postgraduate level		
Current employment status: □ Working full time □ Working part time □ Retired □ Student □ Not working at present		
Address:		
Email:		
Telephone No. (home):	Mobile No.:	

Low back pain history

1. Has your current episode of low back pain lasted more than 3 months?	□ Yes □ No If Yes, how long has it lasted (yrs)? ____
2. Does your back pain come along with leg pain?	□ Yes □ No
3. Have you had similar back pain before?	□ Yes □ No
4. Is there any cause for your back pain?	□ Yes □ No If Yes, please specify: _____
5. What things could make your back pain worse?	Please specify: _____
6. What things relieve your back pain?	Please specify: _____
7. Have you ever consulted any health professional about your back pain within last year?	□ Yes □ No If Yes, please specify: When _____ □ General practitioner □ Physiotherapist □ Chiropractor □ Osteopath □ Other _____
8. Have you been to pain clinic or use of morphine (or similar) for your back pain in last year?	□ Yes □ No
9. Have you had any image tests for your back pain e.g. X-ray?	□ Yes □ No If Yes, please specific the findings _____

10. Does your pain respond to (improve with) prescribed or over the counter analgesics?	□ Yes □ No □ Never used
11. Type, dose, number and frequency of pain relieving pills consumed during the last week	
12. Apart from analgesics, do you have any other drugs for back pain?	□ Yes □ No If Yes, please specify: _____
13. Have you had any spinal surgery or are you waiting for spinal surgery?	□ Yes □ No

Severity of low back pain (Roland–Morris Disability Questionnaire)

When you read the list below, please only tick the sentence if you are sure it describes you TODAY

1. I stay at home most of the time because of my back.	
2. I change position frequently to try and get my back comfortable.	
3. I walk more slowly than usual because of my back.	
4. Because of my back I am not doing any of the jobs that I usually do around the house.	
5. Because of my back, I use a handrail to get upstairs.	
6. Because of my back, I lie down to rest more often.	
7. Because of my back, I have to hold on to something to get out of an easy chair.	
8. Because of my back, I try to get other people to do things for me.	
9. I get dressed more slowly than usual because of my back.	
10. I only stand for short periods of time because of my back.	
11. Because of my back, I try not to bend or kneel down.	
12. I find it difficult to get out of a chair because of my back.	
13. My back is painful almost all the time.	
14. I find it difficult to turn over in bed because of my back.	
15. My appetite is not very good because of my back pain.	
16. I have trouble putting on my socks (or stockings) because of the pain in my back.	
17. I only walk short distances because of my back.	
18. I sleep less well on my back.	
19. Because of my back pain, I get dressed with help from someone else.	
20. I sit down for most of the day because of my back.	
21. I avoid heavy jobs around the house because of my back.	
22. Because of my back pain, I am more irritable and bad tempered with people than usual.	
23. Because of my back, I go upstairs more slowly than usual.	
24. I stay in bed most of the time because of my back.	
Total score (the total number of items ticked)	

General medical history

1.	Do you have any major medical problems or illnesses?	□ Yes □ No
2.	Are you on any medications for any illness?	□ Yes □ No
3.	Have you ever had any surgeries?	□ Yes □ No
4.	Are you pregnant now or do you have plans in the next three months?	□ Yes □ No

Acupuncture history

1.	Have you ever heard of acupuncture?	□ Yes □ No
2.	In general, what is your impression of acupuncture?	□ Negative □ Neutral □ Positive □ Not applicable
3.	Are you fear of needles?	□ Yes □ No
4.	Have you had acupuncture treatment in the past 1 year?	□ Yes □ No If Yes, please specify: _____

Appendix 12. Feasibility trial: Consent form for participants



Acupuncture in addition to usual care for chronic low back pain:

A feasibility study

Consent Form for Participants

Declaration by participant:
I have read, or have had the information read to me in English or Mandarin, and I understand the Participant Information Sheet. I have had the opportunity to ask questions and I am satisfied with the answers I have received. I know that:

1. My participation in the project is entirely voluntary;
2. I am free to withdraw from the project at any time without any disadvantage;
3. I am aware that I should continue the usual care for my low back pain during the time of the study and following completion of study;
4. I am aware that all personal information will be destroyed at the conclusion of the project but any raw data on which the results of the project depend will be retained in secure storage for ten years, after which they will be destroyed according to University of Otago research policy;
5. I am also aware that the results of the project may be published and will be available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve my anonymity.

1)	I wish to have a copy of my results	□ Yes	□ No
	If yes, please indicate your preference to receive your results	□ By email	□ By post
2)	I freely agree to participate in this study	□ Yes	
3)	I have been given a copy of the Participant Information Sheet and Consent Form to keep	□ Yes	

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:
I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.
I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

Appendix 13. Feasibility trial: Treatment log



Participant ID:

Acupuncture in addition to usual care for chronic low back pain:

A feasibility study

Treatment Log

Gender: □ Male □ Female Date of Birth: ___ / ___ / ___

Telephone: E-mail:

Trial Group: □ 4 sessions □ 7 sessions □ 10 sessions

No. of visit	Date/Reasons for non-attendance	Symptoms and clinical examination	Prescribed acupoints	Notes
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Appendix 14. Feasibility trial: Outcome questionnaires

Participant ID:
Date: ___ / ___ / ____

Questionnaire 1

Instructions: When your back hurts, you may find it difficult to do some things you normally do. This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you **TODAY**. When you read a sentence that describes you **TODAY**, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you **TODAY**.

1. I stay at home most of the time because of my back.	
2. I change position frequently to try and get my back comfortable.	
3. I walk more slowly than usual because of my back.	
4. Because of my back I am not doing any of the jobs that I usually do around the house.	
5. Because of my back, I use a handrail to get upstairs.	
6. Because of my back, I lie down to rest more often.	
7. Because of my back, I have to hold on to something to get out of an easy chair.	
8. Because of my back, I try to get other people to do things for me.	
9. I get dressed more slowly than usual because of my back.	
10. I only stand for short periods of time because of my back.	
11. Because of my back, I try not to bend or kneel down.	
12. I find it difficult to get out of a chair because of my back.	
13. My back is painful almost all the time.	
14. I find it difficult to turn over in bed because of my back.	
15. My appetite is not very good because of my back pain.	
16. I have trouble putting on my socks (or stockings) because of the pain in my back.	
17. I only walk short distances because of my back.	
18. I sleep less well on my back.	
19. Because of my back pain, I get dressed with help from someone else.	
20. I sit down for most of the day because of my back.	
21. I avoid heavy jobs around the house because of my back.	
22. Because of my back pain, I am more irritable and bad tempered with people than usual.	
23. Because of my back, I go upstairs more slowly than usual.	
24. I stay in bed most of the time because of my back.	
Total score (the total number of items ticked)	

Questionnaire 2

Instructions: Since you have reported that one of your problems is back pain and sometimes associated with leg pain, the purpose of these two lines below is for you to give us an idea about the level of your pain and its bothersomeness.

I. Please make an 'X' on the line below to show **how bad** your pain has been on average over the past week.

No pain — Worst pain ever
0 — 100

II. Please make an 'X' on the line below to show **how bothersome** your pain has been on average over the past week.

Not at all bothersome — Extremely bothersome
0 — 10

Questionnaire 3

Instructions: As your back pain may restrict your usual activity, please specify the number of restricted-activity days you experienced during the past week. Please note: in calculating the sum of restricted-activity days, each day is counted **ONLY ONCE** even if more than one type of activity restriction was involved.

Restriction of activity	**No. of restricted-activity days**
Bed day During which you stayed in bed **more than half a day** because of back pain. All hospital days for inpatients are considered bed days even if you were not in bed more than half a day.	
Work-loss day (for currently employed participants only) On which you missed **more than half a day** from job or business.	
School-loss day (for student participants only) On which you missed **more than half a day** from the school/college/university where you are currently enrolled.	
Cut-down day On which you cut down for **more than half a day** on the things you usually do.	

Questionnaire 4

Instructions: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by ticking the box that indicates your answer. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
   □1 Excellent □2 Very good □3 Good □4 Fair □5 Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

		Yes, limited a lot	Yes, limited a little	No, not limited at all
2.	**Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	□1	□2	□3
3.	Climbing **several** flights of stairs	□1	□2	□3

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
4.	**Accomplished less** than you would like	□1	□2	□3	□4	□5
5.	Were limited in the **kind** of work or other activities	□1	□2	□3	□4	□5

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
6.	**Accomplished less** than you would like	□1	□2	□3	□4	□5
7.	Did work or activities less carefully than usual	□1	□2	□3	□4	□5

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
   □1 Not at all □2 A little bit □3 Moderately □4 Quite a bit □5 Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
9.	Have you felt calm and peaceful?	□1	□2	□3	□4	□5
10.	Did you have a lot of energy?	□1	□2	□3	□4	□5
11.	Have you felt downhearted and depressed?	□1	□2	□3	□4	□5

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
□1	□2	□3	□4	□5

Questionnaire 5

Instructions: After this process of acupuncture treatment, we would like to know your opinion of the satisfaction with the treatment you received here.
Your responses will not be shown to the acupuncturist, nor will be used to judge her work. We are only interested in how you feel about the treatment after you received it.

Please answer the following question:

I. All things considered, how satisfied are you with the care you received?

□1 Extremely satisfied □2 Very satisfied □3 Somewhat satisfied
□4 Mixed (approximately equal satisfaction and dissatisfaction)
□5 Somewhat dissatisfied □6 Very dissatisfied □7 Extremely dissatisfied
□8 Not sure/no opinion

II. How do you feel about your recent acupuncture treatment and do you have any comments?
Please comment in the space below. We are interested in your comments, both favorable and critical, about the treatment.

Thanks for completing all the questionnaires. Would you please help us identify the level of difficulty you had in completing the questionnaires above?

i. Difficulty in questionnaires completion

□1 Very difficult □2 Somewhat difficult □3 Neither difficult nor easy
□4 Somewhat easy □5 Very easy

ii. Time taken to complete questionnaires _____ minutes

Thanks again for your time.

Please return the questionnaires in the stamped and addressed envelope provided.

Appendix 15. Feasibility trial: Adverse reaction form



Acupuncture in addition to usual care for chronic low back pain:

A feasibility study

Adverse Reaction Form

Report date: ___ / ___ / ____ Number of treatment: ____

Participant ID: Gender: □ Male □ Female Date of birth: ___ / ___ / ___

Relevant medical history if applicable (e.g. predisposing factors and risk factors, previous diagnoses, illnesses): _____

1. Adverse reaction date: ___ / ___ / ____ Time point: ___ : ___ am/pm
2. Study related □ Yes □ No
3. Needle length and type: _____
4. Points used (include depth and direction):
   _____
   _____
5. Type of adverse reaction
   □ Faint □ Seizure □ Headache □ Dizziness □ Drowsiness
   □ Paralysis □ Temporary paraesthesia □ Discomfort □ Sweating
   □ Fever □ Sepsis □ Hepatitis B/C □ Nausea □ Vomiting
   □ Diarrhoea □Haemorrhage □ Sever aggravation of symptoms
   □ Organ or tissue injury □ Hematoma □ Needle-site pain □ Skin infection
   □ Central nerve injury □ Needle allergy □ Broken needle
   □ Other (please specify):_____
6. Was the adverse reaction serious in nature? □ Yes □ No
   (e.g. life-threatening or death, hospitalization, or persistent or significant disability or incapacity)
7. Was the adverse reaction non-serious in nature? □ Yes □ No
8. Was the adverse reaction unanticipated? (i.e. not anticipated in nature, severity or frequency in the HDEC approved study protocol or informed consent document) □ Yes □ No
9. Was there any treatment for the adverse reaction? □ Yes □ No
   If yes, please specify (e.g. type, dose, number and frequency)
   _____
10. Current status of participant □ Good □ Fair □ Serious □ Critical
11. ACC treatment injury claim lodged? (ACC2152) □ Yes □ No
    (It is important ACC is notified if any serious adverse reactions occur)
12. Insurers notified of incident? (MPS, Aon Risk Management) □ Yes □ No
13. Any additional comments regarding this adverse reaction:_____
14. Adverse reaction identified by (name):
    Adverse reaction form completed by (name):

Appendix 16. Feasibility trial: Participants' comments on acupuncture treatment

Experience of treatment process (quotes)*
Felt very satisfied. Needles in the back of the knee were felt stronger than previous sessions… Felt more mobile after each sessions. Some needles could not be felt even though it was being moved, so unsure about what that was. Lizhou was very good about making sure I was relaxed and letting me know when needles were to be inserted. (G4/493/F/22)
I felt very good about it. It was a new experience for me but my lower back pain has been noticeably better because of it. Lizhou was also very professional and made sure I was comfortable. (G4/207/M/23)
I had tried medical acupuncture before, but this was very different. The 'twisting' of needles (very few minutes was painful) leading to a more tense experience, but I think results were better post treatment than with medical acupuncture. (G4/420/F/34)
Work was done very well. (G4/278/M/46)
Lizhou was very nice and made me feel very comfortable throughout. (G4/359/F/25)
The treatment was great, has helped me very significantly and I am very pleased. Lizhou was excellent. (G4/434/M/18)
Lizhou was very delicate and found all of my pressure points. She gave me lots of advices and made the whole process very satisfying. (G4/190/F/18)
I felt my treatment of acupuncture was given in a confident and caring way. Lizhou was quick to understand points of pain. (G7/261/F/56)
It was my first experience with acupuncture and it took me a few sessions to get used to it and 'understand'/'feel' my body's response. Also, I found a little difficult to explain my feelings (both description of pain and acu-related feelings). Having a list of some categories would be helpful of reckon. (G7/284/F/33)
Very helpful, enjoyable. I did wonder at times when I didn't 'feel' anything as the needles went in how safe it was to keep pushing them in or if I should let them keep going in further. (G7/498/M/23)
The treatment was fine, as well as the instruction given. I always felt very comfortable. However, when accessing 'spots' to put needles in, I thought this was a little too suggestive, and may confound results or at least the reporting of the patient, using words like: 'what about here or this spot' or 'last time you said here' etc. Bring in the power of suggestions, and this can introduce reported bias. Maybe not too important, but something to think about for future trials. (G7/269/F/24)
Lizhou was both friendly and professional throughout treatment. I felt completely relaxed and comfortable with her. (G7/265/F/36)
This was my first experience of acupuncture, Lizhou explained the procedure in detail and made the procedure almost painless. (G10/131/F/69)
My acupuncturist was very professional, and made my experience of acupuncture a very positive one (I had never received it before). She was really good at making me feel relaxed during the procedures and I always felt the benefits from each session the next day and afterwards. I love acupuncture now and will get more sessions somewhere in the near future. (G10/486/F/21)

I was unsure what I was supposed to feel. I have never had this kind of treatment before. (G10/463/M/27)
Acupuncturist was very welcoming, friendly, warm, easy to talk, and caring. Would highly recommend the treatment, and would do it again. (G10/382/F/44)
Very easy and great care. (G10/392/M/18)
Acupuncture was a fantastic treatment for my condition and Lizhou was very good at what she was doing. Fantastic communication and just all round. Very, very happy that my pain has reduced so much. (G10/157/F/19)
This is the first time I feel I had authentic acupuncture, Lizhou was very considerate and nice. I am extremely grateful to have been allowed into this study. (G10/241/F/49)
Impact of acupuncture (quotes)*
I feel as though the treatment has helped my lower back pain. I generally sleep better following the treatment. (G4/254/F/21)
Good treatment and improvement in my back pain. (G4/340/F/24)
For the first 2 sessions, I couldn't really feel effects of acupuncture immediately following it, but the last 2 were quite noticeable. (G4/493/F/22)
I am great and awesome now. (G4/474/M/28)
Acupuncture has helped me considerably. (G4/448/F/28)
Pain and discomfort was released after the first and second treatment, marginal gains after that. A helpful and interesting experiment that has been beneficial. Acupuncturist was caring, sensitive and competent at all times. (G4/146/M/68)
Pain relieved most times after several session. Acupuncturist was patient and nice. (G7/350/F/25)
Treatment did help specially with muscle tension and relieved pain and stiffness. (G7/261/F/56)
It was surprised at the effects. My lower back felt like a vacuum. I guess I hold muscles tight to try to protect my back after 40 years of some pain and the treatment relieved this. Some sessions had more effect than others. (G7/484/M/59)
It has been very effective for me. Lizhou has been friendly, professional and she took care to explain what she was doing. (G7/437/F/67)
I always felt good after treatment, however, I don't understand why I was becoming more sensitive to the needles. (G7/183/M/23)
I found my back hurting even worse after the first treatment, then I felt better and better after the third treatment… The acupuncturist is very professional. (G7/203/F/31)
I don't feel it has had a lasting effect. (G7/458/M/20)
I found the treatment very helpful. I now have no lower back pain and when I do it is not as bad. (G10/366/F/18)
Great thanks. My first ever experience with acupuncture and I would continue. It has helped my pain. (G10/299/F/31)
My back pain has decreased since undertaking acupuncture. I am very happy about that. (G10/396/F/23)
The treatment has helped a lot, but not cured the pain completely. (G10/489/F/42)
The treatment was much more effective than I expected and I now suffer a lot less discomfort than previously. (G10/131/F/69)

My symptoms have improved greatly over the last few weeks. (G10/486/F/21)
Instant relief which was great. Not sure if extending treatment duration would benefit more, but perhaps suggest it. (G10/460/M/22)
Have seen improvement with my back pain, but not until the last 3 sessions out of 10. The small amount of pain is remaining now. (G10/479/M/20)
My back is much less painful now after acupuncture. About five sessions I felt a major change in back pain (a lot less pain) and I had more energy. Could stand up longer. (G10/241/F/49)

Abbreviations: G4, 4-session group; G7, 7-session group; G10, 10-session group; F, female; M, male.

*** Quotes were identified by group number, followed by study number, sex, and age.**