RETROSPECTIVE CROSS-SECTIONAL ANALYSIS OF AN ACUPUNCTURE INTERVENTION FOR CHRONIC PAIN MANAGEMENT AT GROOTE SCHUUR HOSPITAL PAIN CLINIC, CAPE TOWN, SOUTH AFRICA

Dissertation submitted in fulfillment of the requirements for the Master of Medicine (MMed) in Psychiatry degree

By

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DECLARATION

I, Nada Lagerstrom, hereby declare that the research reported in this minor dissertation is based on independent work performed by myself, under academic supervision, and that neither the whole work or a part of the work has been submitted for another degree to any other university, nor has the work been published or submitted to publication prior to registration for the abovementioned degree.

Signature: Signed by candidate

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Date: October 18, 2019

ABSTRACT

In 2015 acupuncture was introduced as an alternative intervention in the management of chronic pain, at the Chronic Pain Management Clinic of Groote Schuur Hospital, a tertiary academic hospital in Cape Town, South Africa. This study is a retrospective, cross-sectional analysis that aimed to investigate several aspects of the acupuncture intervention over a 12 month period. The main outcome measure, the Brief Pain Inventory (BPI), is a widely used, internationally validated questionnaire, containing pain intensity, pain interference, and total score. The main objective of this study was to determine if the acupuncture treatment lowered BPI scores after 6 to 9 intervention sessions. Additional objectives were to determine if there are any correlations between demographic and clinical factors and changes in BPI scores, and to describe the demographic and clinical characteristics of the study population. The data was obtained by folder reviews of 66 patients with chronic pain who were referred for acupuncture treatment between January 1, 2015 and December 31, 2015, and attended at least one treatment session. The full treatment course (6-9 sessions) was completed by 24 patients (36,3%), with an average post treatment decrease in BPI of 3,7 points. Responders (patients who obtained 2 and more point BPI decrease) comprised 70,6% of the patients who completed treatment. Decrease in BPI scores after completion of full acupuncture treatment proved to be statistically significant (p=0.002). Factors showing strongest correlation with BPI decrease were female gender and absence of medical and psychiatric co-morbidities.

Key words: chronic pain, acupuncture, BPI

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ABBREVIATIONS

AP	Acupuncture
ART	Antiretroviral Treatment
BPI	Brief Pain Inventory
CAM	Complementary and Alternative Management
CPM	Conventional Pain Management
CPMP	Chronic Pain Management Program
DG	Disability Grant
DX	Diagnosis
GAD	General Anxiety Disorder
HAMD	Hamilton Depression Scale
HIV	Human Immunodeficiency Virus
HIV SN	HIV related Sensory Neuropathy
LBP	Lower Back Pain
MDD	Major Depressive Disorder
MPQ	McGill Pain Questionnaire
NDI	Neck Disability index

NICE	National Institute for Health and Care Excellence
NNT	Numbers Needed to Treat
NNH	Numbers Needed to Harm
OA	Osteo-arthritis
OT	Occupational Therapy
PCS	Pain Catastrophizing scale
PTSD	Post Traumatic Stress Disorder
RCT	Randomized Control Trial
SD	Standard Deviation
SPSS	Statistical Package for Social Sciences
TCM	Traditional Chinese Medicine
TENS	Transcutaneous Electric Nerve Stimulation
VAS	Visual Analogue Scale

CHAPTER I

Introduction

Pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”[1].

Chronic Pain is often defined as any pain persisting longer than reasonably expected healing time for the involved tissue, usually persisting for longer than 6 months, and has a dual quality of being a symptom of another underlying condition, as well as a condition in itself [2,3,4].

The etiology and pathophysiology of chronic pain is complex and multifactorial. Some of the pathophysiological occurrences described in relation to chronic pain are: tissue inflammation with the release of cytokines which are toxic to sensory neurons, grey matter loss associated with the loss of top-down modulation of pain pathways (especially in descending opioid pathways), and a “pain memory” function of the brain (relevant to phantom pain)[2,3]. Some authors suggest that chronic pain is a learnt behavioral syndrome that starts with nociceptive injury (that acutely causes pain), the pain behavior is then rewarded internally and externally, thus self reinforcing, leading to the outcome of pain occurrence without noxious stimuli [4].

Numerous systemic disorders are considered to be either potential causes, or contributors to chronic pain syndromes, most commonly including musculoskeletal, neurological, genito-urinary and digestive tract disorders [5].

Prevalence Rates of Chronic Pain in Developed Countries. European studies report prevalence rates of chronic pain of 18%, with pain intensity

scores of more than 5 on11 point numerical rating scales [6]. Of these subjects 59% had chronic pain for 2 to 15 years, 21% reported depression secondary to chronic pain, 61% were less able to work outside home, 19% had lost work, and 13% had to change jobs. In addition, 60% of subjects paid 2 to 9 visits to the doctor over a 6 month periods. Specialists treated only 2% of subjects, and one third of the subjects were untreated [6].

The prevalence of chronic pain in the United Kingdom (UK) is estimated to be between 10% and 30% (depending on a chosen definition)[2].

In the United States of America (USA), 55% of the population report chronic pain, and 50 million Americans have some form of disability due to chronic pain related symptoms and complications [7].

Prevalence Rates of Chronic Pain in South Africa. In South Africa, it is estimated that 37% of the population has experienced chronic pain, with lower back pain being the most commonly reported chronic pain site [8].

In 2011, a research study by Igumbor et al. estimated the prevalence rate of chronic pain in rural communities to be 42,9% [9], and a similar study by Rauf et al. showed a 41% prevalence rate of chronic pain in primary health care patients in southwest Tswane [10].

An additional factor to consider in the burden of chronic pain in South Africa is the high prevalence of HIV/AIDS (7 million according to UNAIDS report of 2015)[11], which could be associated with HIV related sensory neuropathy (HIV SN). Studies show that over 70% of patients with HIV/AIDS report pain

as one of their major symptoms experienced and only 34% are adequately treated [12].

About 37% of the HIV positive patients who haven't received ARVs will be diagnosed wit HIV SN, this number increases to 60% of those who are on ART(anti-retroviral treatment) [13].

Treatment of chronic pain. British National Institute for Health and Care Excellence (NICE) guidelines recommend a multidisciplinary approach within Conventional Pain Management (CPM), with the warning that complete pain relief is rarely attainable. CPM consists of pharmacological and non-pharmacological measures, and it is broadly in keeping with chronic pain management programs internationally [3,9]. The goals of chronic pain treatment include restoration of normal functioning/minimizing disability, improving the quality of daily living, decrease of medication use, prevention of relapse of chronic pain symptoms [3], and minimizing costs associated with treatment and lifestyle demands in patients with chronic pain [3].

The treatment should be individualized, aiming at modulation of pain response, as well as interruption of reinforcement of pain related behavior [1,3,9].

Complementary and alternative management of chronic pain (CAM).
Due to the palliative nature of conventional chronic pain treatment, patients have been increasingly seeking and exploring alternative and complimentary ways of managing their symptoms, for example, acupuncture, transcutaneous electrical nerve stimulation, self-hypnosis, massage therapy, and many others [14,15,16]. Numerous scientific studies have been conducted, exploring

trends and efficacies of complementary and alternative treatment methods and the possibility of their integration into conventional medicine [17,18,19].

Acupuncture. Acupuncture, the most widely used CAM method in chronic pain management, is an ancient healing practice of Traditional Chinese Medicine (TCM), practiced by inserting thin metal needles at specific points in the body ("acu" points) [20].

Traditional Chinese medicine practitioners believe that the body's vital energy "chi" gets blocked in its flow during the disease, and that placing the needles at the given points along the fourteen energy pathways stimulates the energy flow and promotes healing [20,21,22].

Mechanism of action. During the last 50 years there has been a boom of scientific research into the mechanisms of action and efficacy of acupuncture, especially in treatment of chronic pain.

Biochemistry and neural imaging studies have shown evidence that both the central and peripheral nervous system are intimately involved in the transduction of acupuncture point stimulation via needling. The endogenous opioid system is activated by acupuncture treatment, resulting in endorphin release (which can be reversed by naloxone), and even a short-term increase in binding of opioid mu receptors has been noted [23,24,25,26]. In other studies, acupuncture was found to have anti-inflammatory activity, with an increase in blood flow and boost in blood cell count (especially enhancing lymphocytic and natural killer cell activity)[27,28,29]. Acupuncture has also been shown to play a role in the regulation of neurotransmitter levels associated with anxiety and depression [30].

Efficacy of acupuncture. Research has shown a positive effect of acupuncture for the reduction of chronic pain scores. In one study more than 30% of subjects reported a reduction of BPI score [31]. Acupuncture has also been shown to reduce migraine and chronic headache pain [32}, fibromyalgia symptoms [33,34], nausea/vomiting as a result of chemotherapy in patients with cancer [35], pain related to dental surgery [20], complex regional pain syndrome symptoms [36,37], and back and neck pain [38-43].

Side effects of acupuncture are described as rare, and are usually result of inadequately trained acupuncturist or use of non-sterile needles. Described complications range from relatively minor side effects of local pain, bruising, bleeding, drowsiness, dizziness and nausea to more severe side effects such as pneumothorax, bacterial infections, nerve injuries and viral hepatitis [20].

Currently recommended uses of acupuncture. Acupuncture has been used in China and Asia for over 4000 years, in the USA for over 200 years, and in last several decades is gaining in popularity in the rest of the Western world. It is estimated that about 3 million people in the USA use acupuncture yearly, including 150 000 children. It is even more popular in Europe with one in five persons in France using acupuncture regularly) [20].

In the **USA,** the National Institute of Health, and the Cancer Institute, recommend acupuncture as an adjunctive therapy to the conventional pain management in cancer patients (for nausea, vomiting, xerostomia, fatigue, neuropathy, insomnia, anxiety and depression), as it is shown that acupuncture, as well as being cost effective, can reduce the need for medication and improve the quality of life of patients [20].

In the **UK**, NICE guidelines first recommended acupuncture for lower back pain (LBP) in 2009 [44}, and later also for migraines and tension headaches (a course of 10 session over 5-8 weeks) in 2012 [45]. NICE guidelines explicitly do not recommend acupuncture for ostheo-arthritis (OA) [46].

In **South Africa**, acupuncture has been recognized within the scope of Physiotherapy since 1983, and in November 2000, the practice of acupuncture was regulated by Parliament (Act No 50 of 2000, published 1 December 2000 in Government Gazette, No 21825). Acupuncture practitioners are required to be registered with Allied Health Services Professional Council of South Africa [47]. In 2015, Pain Clinic at Groote Schuur Hospital offered acupuncture intervention for chronic pain management, provided by a qualified and registered acupuncturist, for the first time on the provincial and academic level.

Literature review

A structured literature review was conducted to identify studies of acupuncture as an intervention for chronic pain that included the Brief Pain Inventory (BPI), as well as other validated outcome measures. Medline, PubMed, Medscape, Google Scholar, Cochrane Database and Equador Network were searched using the keywords: chronic pain, treatment, and acupuncture, Brief Pain Inventory. Articles were included if they:

- Were published in English language
- Were published later than the year 2000

- Related to chronic pain and the use of acupuncture in the treatment of chronic pain
- Used a validated outcome measure

Examination of the literature revealed that there is an abundance of published articles on use of acupuncture for treatment of chronic pain, but mostly in developed countries of Europe, Asia and North America. Scarcity of literature originating from developing areas, including South Africa and the continent of Africa, is prominent and significant.

Numerous international studies have shown efficacy of acupuncture in lowering chronic pain and improving quality of life, although it still remains controversial in others [37].

Table 1.presents a brief summary of major findings in literature on the use of acupuncture for the management of chronic pain. No South African or African studies were identified within the literature search.

Randomized controlled trials conducted with chronic pain patients in France, Germany and USA showed that acupuncture significantly lowered the pain scores in cancer survivors and patients with fibromyalgia and lower back pain, and that the effect lasts even at 2 months follow up [34,38]. Acupuncture has often showed superior analgesic effects compared to sham acupuncture and physiotherapy [38,40].

It has been shown that use of acupuncture improves fatigue and anxiety in patients with fibromyalgia in addition to decreasing number of tender points in these patients [33].

Other studies have shown that use of acupuncture improves general satisfaction with life, decreases uses of analgesic medication and reduces number of sick days. [32,38,40,41]

Demographic data shows that acupuncture users are predominantly female, have secondary level of education and belong to middle aged population [12, 44].

The Brief Pain Inventory is commonly used for recording the pain scores, and it has been widely used and validated internationally, proven to be both specific and sensitive measure [48-53]. Unfortunatelly, there is a lack of research on factors influencing changes in BPI score, apart from specific medication or intervention, and no specific predictor for lowering BPI scores has been identified [48-53].

There seems to be scarcity of studies on acupuncture efficiency in chronic pain management from developing countries, also very few studies on the long term effects and their durability, and prominent lack of research on placebo effect in acupuncture practice.

Table 1. Overview of studies on acupuncture efficacy using a validated outcome measures

STUDY	LOCATION AND TYPE	POPULATION	OUTCOME MEASURE	RESULTS
Alimi, D et al., 2003	France RCT	N=90 patients with cancer pain Groups=3 (experimental + 2 placebo)	VAS (visual analogue scale, 0-100mm)	2 months follow up: 36% decrease in pain in experimental group, vs. 2% in placebo groups
Brinkhaus, B et al, 2006	Germany RCT	N=295 patients with chronic lower back pain (CLBP) Groups=3 (AP, sham AP, no AP)	Adapted standard pain questionnaire VAS	8 weeks: AP and sham AP significantly decreased level of pain vs. no AP (difference 21,7mm on VAS) 26&54 weeks: no significant difference
Cherkin, DC et al 2009	USA RCT	N=638 subjects with CLBP Groups=3 (AP, sham AP, casual	Rolland Disability Score, Symptom:	8 weeks: 60% of AP group significant decrease in level of pain and improved

		care)	annoyance	life quality, vs. 39%in casual care group
Diener, HC, et al 2006	Germany Prospective RCT	N=960 patients with chronic migraines Groups=3 (AP, sham AP, standard therapy)	Number of migraine days	Reduction in number of migraine days: AP 2.3 (over 4 weeks), sham AP 1.5, standard 2.1 Stat significant reduction at baseline, but not across groups
Giles, L et al. 2003	Australia RCT	N=115 patients with chronic spinal pain Groups=3 (medication, acupuncture, chiropractice)	Ostrestry Back Pain Disability Score NDI (Neck Disability Index) SF-36, VAS	Significant improvement on Ostrestry, SF 36 and NDI chiropractice (27,4%), AP 9,4% AP better results on VAS (improvement in 50% of subjects, vs. chiropractice in 42%)

Jang, Z et al. 2010	China RCT	N=186 patients with fibromyalgia Groups=3 (a. AP+cupping+medication; b. AP+cupping; c. medication only, Amitriptyline)	MPQ (McGill Pain Questionnaire) HAMD (Hamilton Depression Scale)	1.Cured+marked efficacy gr.a (65%), gr.b and c 15/16% 2. Amount of tender points decreased most in group a. 3.combined therapies effect (gr. a) superior to individual effects
Jothi, s et al. 2012	Malaysia Cross sectional	N=250 patients with chronic eye related pain	Structured questionnaire (closed ended questions)	Demographic data: Use of AP female 66% vs. 34% male; 1 month of treatment for the effect needed in 44,8%, 56% of subjects have secondary level education
Langhorst J., et al	UK Systematic	N=385 patients who received 6 – 25 sessions of	BPI	Evidence for pain reduction

2010	review	AP		P=0,04
Lee, I. Garland, SN, et al. 2016	UK Cross sectional	N=424 patients with cancer related arthralgia	PCS (Pain Catastro-phizing Scale)	Higher the PCS score, patients more likely to use AP (p=0,03) Helplessness not associated with AP use
Lee, R. et al 2013	Asia Prospective trial	Pain severity in cancer patients before and after 10 sessions of AP	BPI	Significant pain reduction P=0.001
Leibing, E et al. 2002	Germany RCT	N=131 patients with non radiating lower back pain Groups=3 (physio only, physio +20 sessions AP, sham AP)	BPI	AP superior to physio in pain intensity effect, improving disability and psychological effect No difference between AP and sham AP (placebo)

Martin, DP et al.	USA RCT	N=50 patients with fibromyalgia Groups=2 (AP vs. sham AP)	FIQ (Fibromyalgia Impact Questionnaire) MPI (Multi-dimensional Pain Inventory)	FIQ: significant improvement in AP group, highest 1 month after trial (p=0,01) Improvement in fatigue and anxiety in AP group No difference in activity levels C: AP is well tolerated, no major side effects
Ratcliffe, J et al 2006	UK RCT	N=241 patients with lower back pain Groups=2 (AP vs. casual care)	BPI Cost analysis	AP more effective in lowering the pain score, decreases usage of pain killers AP produces more health benefits, more long-term cost effective than casual care

Vas,J et al 2006	Spain Observational	N=123 patients with neck pain Groups=2 (AP vs. TENS)	VAS	Change in VAS greater for AP group (28,1% improved pain) AP improves life quality, neck mobility, reduces medication use
Weidenhammer, W et al 2007	Germany Observational	N=2564 patients with LBP – get AP over 8 weeks	BPI	6 months: 45,5% improvement in functional ability 50% reduction in number of pain days 30% reduction in work days lost

RCT=Randomized Controlled Trial; AP=Acupuncture, BPI= Brief Pain Inventory; TENS= Transcutaneous Electric Nerve Stimulation; VAS = Visual Analogue Scale; LBP = Lower Back Pain; PCS = Pain Catastrophizing Scale; FIQ = Fibromyalgia Impact Questionnaire; HAMD = Hamilton Depression Scale; NDI = Neck Disability Index

Aims and objectives

This study presented an attempt to correct the currently existing gap in available evidence of efficacy of acupuncture intervention in patients with chronic pain in South Africa.

Main objectives of the study were:

1. To determine if an acupuncture intervention produces a reduction in BPI scores after six to nine intervention sessions.
2. To identify factors associated with a reduction of a BPI scores greater than or equal to two.
3. To describe the demographic and clinical characteristics of patients undergoing the acupuncture treatment in the Chronic Pain Management Clinic at Groote Schuur Hospital, Cape Town.

Ethical considerations

Ethical approval for the study was sought and obtained from the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee ((HREC reference 677/2016) (Appendix B).

Permission for a folder access was obtained from Groote Schuur Hospital Research Committee (Appendix C).

Confidentiality. In this study, all the required information was derived from patients' folders held within the domain of Chronic Pain Management Clinic, and no patients were directly interviewed. The data extracted did not contain any personal identifying information such as name, birth date or folder number. For the practical research purposes, each of the reviewed folders was allocated a unique random three-digit number.

Beneficence. The findings of this study will be communicated to the Pain Clinic team to encourage the further use of the service.

Non-maleficence. It will be ensured that the results are adequately communicated to the relevant agencies.

Justice. The information gathered in this study will be freely available and disseminated via publications and conference presentations.

Instructions for Authors

This study will be submitted for publication to the *Clinical Journal of Pain* (http://cjp.edmgr.com), Impact Factor ISSN: 0749-8047 3.209.
Instructions for Authors are added to the Appendices section (Appendix D).

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CHAPTER II

Publication-ready Manuscript

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RETROSPECTIVE CROSS-SECTIONAL ANALYSIS OF AN ACUPUNCTURE INTERVENTION FOR CHRONIC PAIN MANAGEMENT AT GROOTE SCHUUR HOSPITAL PAIN CLINIC, CAPE TOWN, SOUTH AFRICA

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ABSTRACT

Objectives: To determine if acupuncture treatment lowers Brief Pain Inventory (BPI) score, to investigate whether there are any correlations between demographic and clinical factors and changes in BPI scores, and to describe the demographic and clinical characteristics of the study population.

Methods and analysis: Designed as a retrospective, cross - sectional study that aimed to investigate several aspects of the acupuncture intervention over the period of 12 months.

The main outcome measure used was the Brief Pain Inventory (BPI), an internationally validated questionnaire, containing: pain intensity, pain interference, and a total score.

Data was collected by folder review of 66 patients with chronic pain who were referred for acupuncture treatment between January 1, 2015 and December 31, 2015. Data was captured into the Statistical Package for Social Sciences.

Results: Total number of 66 folders was reviewed. The full treatment course (6-9 sessions) was completed by 24 patients (36,3%), with an average post treatment decrease in BPI by 3,7 points. Responders (patients who obtained 2 and more point BPI decrease) comprised 70,6% of the patients who completed treatment. Decrease in BPI scores after completion of full acupuncture treatment proved to be statistically significant (p=0.002). Factors showing strongest correlation with BPI decrease were female gender and absence of medical and psychiatric co-morbidities.

Discussion: The results are in keeping with international research in the field, showing statistically significant response to acupuncture treatment.

Key words: chronic pain, acupuncture, Brief Pain Inventory

INTRODUCTION

Background

Pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”[1].

Chronic Pain is often defined as any pain persisting longer than reasonably expected healing time for the involved tissue, usually persisting for longer than 6 months, and has a dual quality of being a symptom of another underlying condition, as well as a condition in itself [1,2,3].

Acupuncture is an ancient healing practice of Traditional Chinese Medicine (TCM), practiced by inserting thin metal needles at specific points in the body (“acu” points). Acupuncture has been used in China and Asia for over 4000 years, in the USA for over 200 years, and in last several decades is gaining in popularity in the rest of the Western world. It is estimated that about 3 million people in the USA use acupuncture yearly, including 150 000 children. It is even more popular in Europe with one in five persons in France use acupuncture regularly [4].

Traditional Chinese medicine practitioners believe that the body’s vital energy “chi” gets blocked in its flow during the disease, and that placing the needles at the given points along the fourteen energy pathways stimulates the energy flow and promotes healing [4,5,6].

During the last 50 years there has been a boom of scientific research into the mechanisms of action and efficacy of acupuncture, especially in treatment of chronic pain.

Biochemistry and neural imaging studies have shown evidence that both the central and peripheral nervous system are intimately involved in the transduction of acupuncture point stimulation via needling. The endogenous opioid system has been shown to be activated by acupuncture treatments,

resulting in endorphin release (which can be reversed by naloxone), and even in a short-term increase in binding of opioid mu receptors [7,8,9,10]. In other studies acupuncture was found to have anti-inflammatory activity, with increase in blood flow and boost in blood cell count (especially enhancing lymphocytic and natural killer cell activity)[11,12,13]. Acupuncture has also been shown to have a role in the regulation of neurotransmitter levels associated with anxiety and depression [14].

Research has shown a positive effect of acupuncture for the reduction of chronic pain scores. In one study more than 30% of subjects reported a reduction of BPI score [15]. Acupuncture has also been shown to reduce migraine and chronic headaches pain [16}, fibromyalgia symptoms [17,18], nausea/vomiting as a result of chemotherapy in patients with cancer [19], pain related to dental surgery [4], complex regional pain syndrome symptoms [20,21], and back and neck pain [22,23,24,25,25,26]. Other positive effects of acupuncture include improvement in life quality, lesser number of sick days and decreased use of analgesic medication [16,23,24,25].

In regard to associated psychiatric comorbidities, it has been shown that acupuncture use improves anxiety and chronic pain associated fatigue [27].

Several international guidelines recommend acupuncture as part of the treatment of chronic pain syndromes.

In the **USA,** the National Institute of Health, and the Cancer Institute, recommend acupuncture as an adjunctive therapy to the conventional pain management in cancer patients (for nausea, vomiting, xerostomia, fatigue, neuropathy, insomnia, anxiety and depression), as it is shown that acupuncture can reduce the need for medication and improve the quality of life of patients, as well as being cost-effective [4].

In the **UK**, NICE guidelines first recommended acupuncture for lower back pain (LBP) in 2009 [28}, and later also for migraines and tension headaches (a course of 10 session over 5-8 weeks) in 2012 [29]. NICE guidelines explicitly do not recommend acupuncture for ostheo-arthritis(OA) [30,31].

Literature review

A structured literature review was conducted to identify studies of acupuncture as an intervention for chronic pain that included the Brief Pain Inventory, as well as other validated outcome measures. Medline, PubMed, Medscape, Google Scholar, Cochrane Database and Equador Network were searched using the keywords: chronic pain, treatment, acupuncture, Brief Pain Inventory. Articles were included if they:

- Were published in English language
- Were published later than the year 2000
- Related to chronic pain and the use of acupuncture in the treatment of chronic pain
- Used a validated outcome measure

Examination of the literature revealed that there is an abundance of published articles on use of acupuncture for treatment of chronic pain, but mostly in developed countries of Europe, Asia and North America. Scarcity of literature originating from developing areas, including South Africa and the continent of Africa, is prominent and significant.

Numerous international studies have shown efficacy of acupuncture in lowering chronic pain and improving quality of life, although it still remains controversial in others.

Randomized controlled trials conducted with chronic pain patients in France, Germany and USA showed that acupuncture significantly lowered the pain scores in cancer survivors and patients with fibromyalgia and lower back pain, and that the effect lasted even at 2 months follow up [18,22].

Acupuncture has often showed superior analgesic effects compared to sham acupuncture and physiotherapy [22,24].

It has been shown that use of acupuncture improves fatigue and anxiety in patients with fibromyalgia in addition to decreasing number of tender points in these patients [17].

Other studies have shown that use of acupuncture improves general satisfaction with life, decreases uses of analgesic medication and reduces number of sick days [16,22,24,25].

Demographic data in the studies show that acupuncture users are predominantly of female gender, have secondary level of education and belong to middle aged population [26,28].

The Brief Pain Inventory is commonly used for recording the pain scores, and it has been widely used and validated internationally, proven to be both specific and sensitive measure [32,33,34,35,36,37].

AIMS AND OBJECTIVES

This study aimed to determine whether an acupuncture intervention reduced pain in chronic pain patients, to determine the factors associated with this reduction, and to describe demographic and clinical characteristics of the sample.

MATERIALS AND METHODS

Design. This study is a retrospective, cross-sectional analysis of an acupuncture intervention in treatment of chronic pain in Groote Schuur Hospital Chronic Pain Management Clinic over a 12 month period.

Study setting. The **Chronic Pain Management Clinic** is run by the Department of Anesthesia of the University of Cape Town, and it is located on the premises of Groote Schuur Hospital, a tertiary academic hospital in Cape Town, South Africa.

This is a multidisciplinary chronic pain management unit consisting of fully registered specialists in Anesthesia, Psychiatry, Physiotherapy and Psychology, as well as (at the time of the study) an appropriately qualified and registered Acupuncturist. The Pain Clinic provides a comprehensive assessment, unique (patient-tailored) treatment plan and recommendations for patients with chronic pain.

The most common conditions treated at this clinic include Complex Regional Pain Syndrome (CRPS), chronic neck, pelvic and back pain (non-surgical and post-surgical), persistent post-operative pain, post-herpetic neuralgia (shingles), pain associated with cancer, pancreatic disease, including diabetes, multiple sclerosis pain and phantom limb pain.

After a referral to the clinic, an anesthesiologist initially assesses the patient. . A comprehensive medical history is taken and thorough clinical assessment performed. As part of routine clinical practice patients complete the initial Brief Pain Inventory (BPI, Appendix A).

All patients are presented at multidisciplinary case discussion and evaluated in order to devise an appropriate management plan.

In early 2015, acupuncture was introduced as an alternative treatment for chronic pain management, for the first time in the state funded facility.

In cases when the patient is referred for the acupuncture treatment, a pre- and post-treatment BPI questionnaire is completed and scores recorded by the therapist, a qualified and accredited acupuncturist. In addition to BPI scores, it is also recorded if the patient has had an acupuncture treatment previously, if previous treatment was beneficial, and if any side effects were experienced.

Data collection. Data was obtained by folder review of all patients who were referred to acupuncture treatment between January 1, 2015 and December 31, 2015, and who attended at least one treatment session.

Inclusion criteria. Patients were included in the study if they had a diagnosis of chronic pain, were referred for acupuncture and completed treatment of at least one of six to nine one-hour acupuncture treatments.

Patients were excluded if they failed to attend any acupuncture sessions.

Measures. Demographic and clinical data was extracted from the initial clinical assessment clerking notes of the participants:

1. Demographic data: age, gender (male/female), marital status (single/married/divorced/widowed), highest level of education (nil/below matric/matric/tertiary/graduate), occupation, and income status (low/middle/high, arbitrarily cut at levels of R7500/20000/above).
2. Clinical data: time duration of current pain (in years), initial BPI score, diagnostic pain categories (according to Pain Clinic terminology), analgesia (yes/no), co-morbidities (medical and psychiatric, latter being diagnosed by using DSM-V criteria), referrals to psychology, psychiatry and physiotherapy and other allied specialties, participation in the chronic pain management program, previous experience of acupuncture (yes/no), BPI score before and after 6 - 9 sessions of acupuncture.

Brief Pain Inventory (BPI). The BPI is one of the most internationally used measurement tools for the clinical assessment of chronic pain. The Pain Research Group of the World Health Organization (WHO) Collaborating Centre initially developed it for Symptom Evaluation in Cancer Care, now the Group operates under the Department of Symptom Research at the University of Texas MD Anderson Cancer Centre. Later it was adapted for clinical pain assessments, epidemiological studies and studies of the effectiveness of pain treatments [32].

The BPI is a self-report scale that contains back and front body diagrams for identifying pain sites, four severity items and seven interference items, and a question regarding a relief achieved via medication use BPI measures: a) intensity, or severity, of pain (sensory dimension); b) interference of pain in

patient's life ("reactive" dimension). The descriptive items designed to capture the variability of pain over time are: "worst", "best", "average", and "now"[32,33].

The patient's answers for the four severity items and seven interference items are recorded on 11 point (0-10) numerical rating scale, 0 representing No Pain/No Interference, and 10 – Worst Imaginable Pain/Complete Interference. Studies show that a change of 2 points (30%) on the11 point numerical rating scale represents a clinically important difference [33,34].

Scoring of the BPI may be presented as a mean value for both Severity and Interference Scores, and it has been recommended by IMMPACT trials and FDA Draft Guidance for Industry: Patient Reported Outcome Measures, to be used in all chronic pain related clinical trials, as well as in the assessment of pain related functional impairments (especially the interference score in the latter) [32].

In this study only the mean BPI scores were used for analysis. With lack of known specific predictors for lowering the BPI scores, our data collection was based on clinical practice.

Validation. BPI has been widely validated internationally and was found to be internally reliable, consistent over time, to have good construct, to have convergent and predictive validity in assessment of chronic pain related suffering, and to represent a minimal burden for patients to record information necessary for a scientific inventory on a daily basis [35,36,37]. In South Africa, BPI has been validated in Xhosa language [38].

Language. BPI at the Chronic Pain Clinic is offered in English language only, and the official hospital translators are used to aid communication with non-English speaking patients.

Data analysis. Data was captured directly into the Statistical Package for Social Sciences (SPSS). Uni-variate statistical analysis and frequency counts were performed for the categorical demographic and clinical data. Bivariate independent t-tests and correlation analyses (parametric or non-parametric, and linear regression analyses were performed in order to determine relations

between variables (especially correlating them with changes in BPI score), and to identify any potential predictors of the acupuncture intervention efficacy. An Intention To Treat (ITT) analysis was performed in order to avoid a selection bias.

Ethical Considerations

Ethical approval for the study was sought and obtained from the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee ((HREC reference 677/2016) (Appendix B), and the permission for folder access was received from Groote Schuur Hospital assigned authorities.

Confidentiality. In this study, all the required information was derived from patients' folders held within the domain of Chronic Pain Management Clinic, and no patients were directly interviewed. The data extracted did not contain any personal identifying information such as name, birth date or folder number. For the practical research purposes, each of the reviewed folders was allocated a unique random three-digit number.

Benefits of the study. The results of the study relating to the effectiveness of acupuncture for the treatment of chronic pain in this study population will be communicated to the Pain Clinic team to encourage the further use of the service. It will be ensured that the results are adequately communicated to the relevant agencies. The information gathered in this study will be freely available and disseminated via publications and conference presentations.

RESULTS

During the one year study period 66 patients with chronic pain were referred for acupuncture treatment and completed at least one acupuncture session. Only 24 (36,3%) of patients referred for acupuncture completed a full course of 6 – 9 sessions. The rest of the patients (42, or 63,7%) completed any number between one and five sessions.

Analysis of demographic and clinical data of the total sample (N=66) is presented in **Table 1.**

Data shows that the majority of referred patients were female (75,0%), married (51,5%), with mean age of 62,5 years and secondary level education (mean 10,4 years). Most of the patients were unemployed (72,7%), with low income (83,3%).

Clinical data showed that duration of pain ranged from 0-25 years (mean 7,8), that the most prevalent conditions in the sample were lower back pain (56,0%), fibromyalgia (20,0%), neuropathies (17,0%), spinal degeneration (15,0%), and arthritic conditions (14,0%). In this sample 94% of patients had received analgesic medication prior to acupuncture treatment, with predominance of non-steroid anti-inflammatory drugs (NSAIDs) with 85,1%, followed by opioids (66,1%), and pregabalin (27,3%). Almost none of the patients were using simple analgesia, such as paracetamol, and majority was on combined treatment with two or more analgesics agents. Co-morbid conditions were common (72,7%), with 28,7% of patients having only medical comorbidities, 18,1% only psychiatric, and 19,6% having both.

The most common comorbid medical conditions were hypertension (22,7%), diabetes mellitus (13,6%) and dyslipidemia (7,5%). Among psychiatric conditions, the most common comorbidity was depression (30,3%), followed by anxiety (10,6%) and PTSD (4,5%).

Only 24% of the patients in this sample were referred for an individual psychiatric intervention, while 39% were referred for individual physiotherapy,

and 26% of the patients attended self-management group Chronic Pain Management Program (CPMP) intervention.

Table 2. shows the results of analysis of BPI scores for the whole sample (N=66). The average mean pain score on initial assessment was 7,9, the average score at the time of initiation of acupuncture treatment was 7,5, and the average score following completion of acupuncture treatment (1-9 sessions) was 6,01. This decrease in BPI score was statistically significant (p=0.0001).

Among the 24 patients who completed a full acupuncture course (6 – 9 sessions), the initial BPI of 7,9 decreased to 7,14 before acupuncture, and furthermore to 5,01 after the completion of the course, which was statistically significant (p=0.002).

Patients who did not complete a full course of 6-9 sessions (N=42, or 63,7%), but had at least 1 – 5 session, had an initial and pre-acupuncture BPI score unchanged (7,2), while the final mean score was 6,0 (p=0.0082).

Further analysis focused on the 24 patients who had completed a full acupuncture course of 6-9 sessions. Patients whose BPI score showed 2 points or more decrease after the treatment were labeled as Responders (in keeping with International guidelines), and the patients who did not achieve at least 2 point decrease in pain score were labeled Non-responders.

Table 3. shows comparisons between these 2 groups. The striking finding is that 70,8% of patients who completed the treatment responded to it significantly (p=0.0001, within the group) versus non-responders who had no significant change (p=0.1139).

Comparison of BPI scores drops between these two groups (decrease of 2,6 points for Responders, and 0,4 points for Non-Responders) was also statistically significant (p=0.0004).

Another striking finding in both groups is the predominance of female gender (82,3 % of Responders and 100% of Non-Responders), and higher

percentage of both medical and psychiatric co-morbidities, as well as referrals to Psychiatry, in the Non-Responders group.

Correlation studies performed on the whole sample (N=66) showed significant correlation between duration of pain and psychiatric co-morbidities (p=0.006), with higher number of psychiatric conditions with longer pain duration. They also showed direct correlation specialties between years of education and baseline BPI score (p=0.006), with lower BPI score in patients with higher level of education.

Correlation analysis on the data for 24 patients who completed full course of acupuncture did not show any significant associations, thus no regression study was done on this sample.

Intention to treat analysis revealed that Numbers Needed To Treat (NNT) were 5, and Numbers Needed to harm (NNH) were 47.

Table 1. Demographic and clinical data of the study sample (N=66) which include all patients who were referred for acupuncture treatment for chronic pain between January 1 and December 31, 2015

VARIABLE	N (%)
Gender	
Male	17 (25,0)
Female	49 (75,0)
Total	**66 (100)**
Age	
Range 16-85	66 (100)
Mean 62,5	
SD 15,79	
Median 55	
Marital status	
Single	13 (19,7)
Married	34 (51,5)
Divorced	10 (15,2)
Widowed	9 (13,6)
Years of education	
Primary (0-7)	8 (12,1)
Secondary (8-12)	52 (79,0)
Tertiary (>12)	6 (9,0)
Range 0-16	
Mean 10,4	
SD 3,08	

Employment	
Employed	18 (27,2)
Unemployed	48 (72,7)
Retired	14 (21,2)
Med/boarded	3 (4,5)
DG	7 (10,6)
Income	
R < 7500	55 (83,3)
R 7500-20000	8 (12,1)
R 20000-40000	3 (4,5)
Duration of pain (yrs)	
Range 0 – 25	66 (100)
Mean 7,78	
SD 6,38	
Pain dx categories	
Low back pain	37 (56,0)
Fibromyalgia	13 (20,0)
Neuropathy	11 (17,0)
Spinal degeneration	10 (15,0)
Arthritis	9 (14,0)
Other	28 (42,4)

Analgesia received	
Yes	62 (94,0)
No	4 (6,0)
Type	
Opioids	41 (66,0)
NSAIDs	53 (85,1)
Pregabalin	17 (27,3)
Co-morbidities	
Yes	48 (72,7)
No	18 (27,2)
Medical only	19 (28,7)
Psychiatric only	12 (18,1)
Both	13 (19,6)
Medical co-morbidities	
Hypertension	15 (22,7)
Diabetes Mellitus	9 (13,6)
Dyslipidemia	5 (7,5)
Other	27 (40,9)
Psychiatric co-morbidity	
Depression	20 (30,3)
Anxiety	7 (10,6)
PTSD	3 (4,5)
Other	3 (4,5)
Referral to psychiatry	

Yes	16 (24,0)
No	50 (75,0)
Referral to allied specialties	
Physio	26 (39,0)
OT	5 (7,0)
Other	8 (12,0)
CPMP	
Yes	17 (26,0)
No	26 (39,3)
Unknown	23 (34,8)

SD = standard deviation; DG = disability grant; PTSD=post-traumatic stress disorder; OT=occupational therapy; Physio=physiotherapy; CPMP=chronic pain management program); dx=diagnostic; NSAIDs=non-steroid anti-inflammatory drugs

Table 2. BPI scores for patients who received acupuncture treatment

PATIENTS	**N (%)**	**No of sessions**	**BPI**-1 (pre AP)	**BPI-2** (post AP)	*P* value
All patients referred for AP	66 (100)	Mean 3,7 Range 1-9 SD 2,5	Mean 7,58 Range 0-10 SD 1.49	Mean 6,01 Range 0-10 SD 1,83	*P<0.0001*
Patients who completed AP course (6-9 sessions)	24 (36,3)	Mean 7,5 Range 6-9 SD 1,5	Mean 7,14 Range 0-10 SD 1,17	Mean 5,01 Range 0-10 SD 1,17	*P<0.002*
Partial AP treatment (1-5 sessions)	42 (63,7)	Mean 2,5 Range 1-5 SD 1, 3	Mean 7,2 Range 0-10 SD 1,80	Mean 6,0 Range 0- 10 SD 1,91	*P=0,0082*

BPI=Brief Pain Inventory; AP=acupuncture

Table 3. Demographic and clinical comparison between two groups of patients who completed full AP course (6-9 sessions). **Responders (R)**: patients whose BPI score decreased for 2 or more points **Non-Responders (NR):** patients whose BPI score did not decrease by at least 2 points

Category	**Responders (R)** **N (%)**	**Non Responders (NR)** **N (%)**	*P value*
Completed 6-9 AP sessions **N = 24**	17 (70,8)	7 (29,2)	-
BPI score			
Pre AP	Mean 7,9 SD 1,1	5,6 1,0	*P=0.0004*
Post AP	Mean 5,3 SD 1,4	5,2 1,1	*P=1.0000*
BPI score drop	Mean 2,6	0,4	*P=0.0004*
Significance	**P=0.0001**	**P=0.1139**	
Age	Mean 54,17 Range 23-72 SD 15,79	61,37 49-78 18,30	*P=0.360*
Gender			
Male	3 (17,6)	0 (0)	-
Female	14 (82,4)	7 (100)	
Relationship			

Single	2	(11,7)	2	(28,6)	
Married	9	(52,9)	4	(57,1)	-
Divorced	3	(17,6)	0	(0)	
Widowed	3	(17,6)	1	(14,3)	
Education (years)/mean					
Mean	10,4		11,0		*P=0.4900*
Range	1-16		8-14		
SD	3,8		3,0		
Occupation					
U/E	9	(52,9)	1	(14,3)	
Employed	3	(17,6)	1	(14,3)	
Retired	3	(17,6)	3	(42,8)	-
DG	0	(0)	1	(14,3)	
M/board	1	(5,9)	1	(14,3)	
Pain duration in years					
Mean	7,78		11,6		*P=0.1923*
Range	1-20		5-25		
SD	6,38		7,01		
Baseline BPI					
Mean	7,9		8,2		*P=1.0000*
Range	5-9		6-10		
SD	1,61		1,80		
Analgesia					
Yes	17	(100)	7	(100)	-
No	0	(0)	0	(0)	

Type					
Opioids	9	(52,9)	5	(70,0)	
NSAIDs	12	(70,0)	5	(70,0)	-
Pregabalin	6	(35,3)	2	(28,6)	
Co-morbidities					
Med	8	(47,1)	4	(57,1)	
Psych	6	(35,3)	4	(57,1)	-
Both	2	(11,7)	3	(42,9)	
Medical					
HPT	1	(5,9)	2	(28,6)	-
other	5	(29,4)	4	(57,1)	
Psych					
MDD	5	(29,4)	4	(57,1)	-
GAD	2	(11,7)	2	(28,6)	
Ref to psych					
Yes	6	(35,3)	3	(42,9)	-
No	11	(64,7)	3	(42,9)	
Ref to other					
Physio	8	(47,1)	3	(42,9)	
OT	2	(11,7)	1	(14,3)	-
other	1	(5,9)	0	(0)	
CPMP					
Yes	4	(23,5)	1	(14,3)	-
No	13	(76,5)	5	(71,4)	
Previous AP					
Yes	6	(35,3)	1	(14,3)	-

No	11 (64,7)	5 (71,4)	

AP=acupuncture; BPI=Brief Pain Inventory, R=Responders; NR=Non Responders; U/E=unemployed; DG=Disability Grant; SD=Standard Deviation; HPT=hypertension; MDD=Major Depressive Disorder; GAD=Generalized Anxiety Disorder; OT=Occupational Therapy; CPMP=Chronic Pain Management Program; NSAIDs=Non-Steroid Anti-inflammatory Drugs

DISCUSSION

This cross sectional analysis in Cape Town is the first attempt to explore the efficacy of acupuncture treatment for chronic pain management in the academic environment of the tertiary state funded facility in South Africa.

A total number of 66 folders were reviewed, with the major findings being: a) that completion of a full course of acupuncture treatment (6 to 9 sessions), significantly reduces BPI scores; b) there is a direct correlation between duration of chronic pain and presence of psychiatric comorbidities; c) the majority of participants were female, married, with a mean age of 54 years, secondary level education, unemployed, with low income; d) the most commonly treated conditions were lower back pain and fibromyalgia; the pain duration spanning over years; high prevalence of medical and psychiatric comorbidities (led by depression and anxiety); e) no significant predictors to response to acupuncture treatment were identified.

Demographic data. The study results relating to the gender, relationship status and age are similar to Malaysian cross sectional study where acupuncture users were 66% female [35], as well as findings from developed countries, where the majority of chronic pain patients in acupuncture related studies were female, married and of middle age [1,2,3,38].

The average education level of participants in this study is secondary level education, which was also the finding in similar European studies [1,2,3,38}, However, the patient in this study differ in income and employment, while in

developed countries the majority of patients using acupuncture are employed and in middle income categories, patients in this study are overwhelmingly unemployed (72,7%), with 21,2% being retired, and 10,6% being on a disability grant. In this study 83,3% of patients receive very low income (below R7500 a month), which is most likely a reflection of socio-economic situation in South Africa, where patients who live in circumstances of need have less access to care and gravitate towards public health facilities.

Clinical data. The chronic pain duration in this study sample ranged from 1 to 25 years. 45,1% of the patients in the study had chronic pain for 2 to 10 years, and additional 28,2% for longer than 10 years. These findings are in keeping with some European acupuncture studies where 59% of study population had pain duration of 2-15 years [40].

The most common pain categories in this study were lower back pain (56%, fibromyalgia (20%), neuropathies and spinal degenerative conditions (15 and 14% respectively) and arthritic illnesses, which are similar internationally, with leading prevalence of lower back pain and fibromyalgia [1,2,3,38,39]. Majority of patients had received analgesia prior to acupuncture treatment, consisting of predominantly NSAIDs (85,1%), opioids (66,1%) and pregabalin (27,3%), which is in keeping with international findings [41]. Comparison between Responders and Non-responders shows higher percentage of pregabalin use in patients who showed a significant decrease in BPI score (Responders), and higher opioid use in Non-responders, with equalized use of NSAIDs.

Similar to international findings, in this study a large proportion of patients have medical and psychiatric co-morbidities (72,7%), with most common psychiatric conditions being depression (30,3%) and anxiety disorders (10,6%). In the USA a study reported higher prevalence of depression related to chronic pain (21%), followed by insomnia and fatigue [1], In our study there is higher level of anxiety disorders, which is not necessarily indication of the prevalence in the general population, as we were only analyzing data of patients referred to acupuncture. However, potentially it may be the case, as anxiety disorders could be indicative of mental health in this particular population with high level of unemployment and low economic status.

Another finding of note was the lower incidence of medical and psychiatric comorbidities in Responders (11,7%) than Non-Responders (42,9%), which impresses as a thought provoking fact, however, correlation studies did not offer a significant reveal, and further analysis is required.

South African studies on the prevalence rates of chronic pain report the prevalence of lower back pain as 37% of population (our study 56%), and high prevalence of patients with HIV related neuropathies (70% of all HIV patients)[6,41,43,46]. There were no patients with HIV referred to acupuncture by Pain Clinic and the reason for that is not clear, but it does present a potential research question.

BPI scores. International understanding is that decrease in BPI score of 2 or more points presents clinically favorable and statistically significant result [32,34].

In our study there is a significant decrease in BPI scores across the whole sample, from initial mean score of 7,9 to final 6,1 ($p<0.0001$), including patients who completed only one acupuncture treatment session. Of those who completed full course (6 – 9 sessions) 70,8% showed an average decrease of BPI scores of 2,6 points ($p<0.0004$), versus only 0,8 points decrease of BPI scores in patients who haven't completed the full course (Table 2. And Table 3.) These results are in keeping with some international studies that showed positive effect of acupuncture for reduction of chronic pain with more than 30% of subjects, responding with significant BPI reduction [28], as well as BPI reduction following acupuncture treatment for migraines [29], fibromyalgia [30,31] and back pain [35,36]. Cherkin (2009) showed response to acupuncture treatment in 60% of subjects with chronic lower back pain, versus 39% in casual group [36].

Correlation. Strong correlation was found among the initial baseline BPI score and scores before and after acupuncture across the whole sample, as well as association of education level and baseline score ($p<0.0003$), and duration of pain with psychiatric comorbidities ($p=0.0006$), showing that longer duration of pain was associated with higher rate of psychiatric illnesses.

Unfortunately, no relevant international correlation studies regarding acupuncture were identified in the literature review.

Correlation analysis across the sample of patients who completed the full treatment course did not show significant correlation between any variables and BPI reduction, thus no regression analysis was performed.

Study limitations. This study is the first exploration of acupuncture efficacy in the treatment of chronic pain in Groote Schuur Hospital and it was design as a pilot study, lacking a body of research to compare to what is relevant to South African context.

The limitations of conducting a folder review included incomplete or illegible information, which decreased the number of subjects eligible for the study. There was no direct communication with patients, which minimized opportunities to complete or correct existing data, or to explore subjective level of satisfaction with acupuncture treatment.

BPI questionnaires are offered in English only, which may have impacted on the validity of findings for non English first language speakers.

The study presented an audit of services and there was no control group of subjects.

The initial assessment form did not specifically enquire about patient's height and weight, which would be useful in calculating Body Mass Index (BMI). Research shows that BMI is a significant predictor for the treatment outcomes in patients with chronic pain [47].

Placebo effect, which could be a possible covariant in the acupuncture treatment outcomes, was not explored in this study, due to the absence of control group, as well as lack of direct communication with patients, and it was outside of the scope of this research.

The long term clinical follow up was not included, so it was not be possible to determine the length of duration of the positive outcomes (i.e. a reduction in BPI scores).

Although there is a regular psychiatric and psychology follow up at the Clinic, no specific psychiatric response was measured, and that would be out of scope of this study.

BPI was the only standardized scaled measure available for this study.

CONCLUSION

The study findings indicate that acupuncture can be effective in treatment of chronic pain (70,8% response when course completed).

It also shows that 63,7% of referred patients did not complete the course, for unknown reasons, and it would be interesting to conduct research into this fact.

Correlation and regression analysis did not identify a potential predictor for response to acupuncture treatment, and it appears that the continued research is needed.

ACKNOWLEDGEMENTS

Firstly, I would like to express the warmest gratitude to my co-authors A/Prof **Jackie Hoare** and **Dr Kerry-Ann Louw** for the unwavering support and guidance. Extended thanks to the Departments of Anesthesiology and Physiotherapy for access to the patient's folders and data.

The Department of Psychiatry and Mental Health staff and colleagues were exceptionally encouraging and supportive, as well as my family members.

ABBREVIATIONS

AP Acupuncture

ART Antiretroviral Treatment

BPI Brief Pain Inventory

CAM Complementary and Alternative Management

CPM Conventional Pain Management

CPMP Chronic Pain Management Program

DG Disability Grant

DX Diagnosis/diagnostic

GAD General Anxiety Disorder

HAMD Hamilton Depression Scale

HIV Human Immunodeficiency Virus

HIV SN HIV related Sensory Neuropathy

LBP Lower Back Pain

MDD Major Depressive Disorder

MPQ McGill Pain Questionnaire

NDI Neck Disability index

NICE National Institute for Health and Care Excellence

NNT Numbers Needed to Treat

NNH	Numbers Needed to Harm
OA	Osteo-arthritis
OT	Occupational Therapy
PCS	Pain Catastrophizing scale
PTSD	Post Traumatic Stress Disorder
RCT	Randomized Control Trial
SD	Standard Deviation
SPSS	Statistical Package for Social Sciences
TCM	Traditional Chinese Medicine
TENS	Transcutaneous Electric Nerve Stimulation
VAS	Visual Analogue Scale

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APPENDICES

A. BRIEF PAIN INVENTORY (BPI)

Brief Pain Inventory (Short Form)

Study ID# _____ Hospital # _____

Do not write above this line.

Date: _____

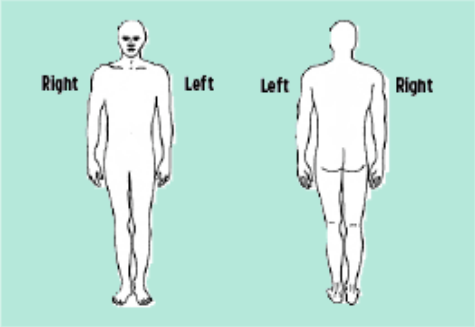
Time: _____

Name: _____
Last First Middle Initial

1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. yes 2. no

2) On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3) Please rate your pain by circling the one number that best describes your pain at its **WORST** in the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

4) Please rate your pain by circling the one number that best describes your pain at its **LEAST** in the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

5) Please rate your pain by circling the one number that best describes your pain on the **AVERAGE**.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

6) Please rate your pain by circling the one number that tell how much pain you have **RIGHT NOW**.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

7) What treatments or medications are you receiving for your pain?

_____

8) In the past 24 hours, how much **RELIEF** have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
No Relief — Complete Relief

9) Circle the one number that describes how, during the past 24 hours. **PAIN HAS INTERFERED** with your:

A. General Activity:

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely interferes

C. Walking Ability

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely interferes

D. Normal work (Includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely interferes

E. Relation with other people

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely interferes

B. ETHICS APPROVAL

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

23 September 2016

HREC REF: 677/2016

A/Prof J Hoare
Psychiatry & Mental Health
J-Block, GSH

Dear A/Prof Hoare

PROJECT TITLE: RETROSPECTIVE CROSS-SECTIONAL ANALYSIS OF AN ACUPUNCTURE INTERVENTION FOR CHRONIC PAIN MANAGEMENT AT GROOTE SCHUUR HOSPITAL PAIN CLINIC, CAPE TOWN, SOUTH AFRICA (Master's-Dr N Lagerstrom)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th September 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

The HREC acknowledge that the student, Dr Nada Lagerstrom will also be involved in this study.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 677/2016

C. FOLDER ACCESS PERMISSION

GROOTE SCHUUR HOSPITAL
Enquiries: Dr Bernadette Eick
E-mail : Bernadette.Eick@westerncape.gov.za

Associate Professor J. Hoare
Psychiatry & Mental Health
J-BLOCK

E-mail: Hoare.Jax@gmail.com / nada.lagerstrom@gmail.com / Sandra.swart@uct.ac.za

Dear A/Professor Hoare

RESEARCH PROJECT: Retrospective Cross-Sectional Analysis of an Acupuncture Intervention for Chronic Pain Management at Groote Schuur Hospital Pan Clinic, Cape Town, South Africa (Master's Dr N. Lagerstrom)

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research which is valid until **30 September 2017, subject to the approval of Professor Justiaan Swanevelder (HOD: Anaesthetics).**

Please note the following:

a) Your research may not interfere with normal patient care.
b) Hospital staff may not be asked to assist with the research.
c) No additional costs to the hospital should be incurred i.e. Lab, consumables or stationary may be used.
d) **No patient folders may be removed from the premises or be inaccessible.**
e) Please discuss the study with the HOD before commencing.
f) Please introduce yourself to the person in charge of an area before commencing.
g) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
h) Confidentiality must be maintained at all times.
i) Should you at any time require photographs of your subjects, please obtain the necessary indemnity forms from our Public Relations Office (E45 OMB or ext. 2187/2188).
j) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
k) **On completion of research, please submit a copy of the publication or report.**

I would like to wish you every success with the project.

Yours sincerely

DR BERNADETTE EICK
CHIEF OPERATIONAL OFFICER
Date: 28 October 2016
BE/vms

C.C. Mr L. Naidoo, Dr A. Krajewski, Professor D. Stein & Professor J. Swanevelder

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Journal article
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2. Todd VR. Visual information analysis: frame of reference for visual perception. In: Kramer P, Hinojosa J, eds. *Frames of reference for pediatric occupational therapy*. Philadelphia: Lippincott Williams & Wilkins, 1999:205-256.

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- Crop out any white or black space surrounding the image.
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