

Acupuncture as an adjunct therapy for Post-Traumatic Stress Disorder (PTSD) systematic review & further research strategy.

Introduction

Post-Traumatic Stress Disorder (PTSD) is a prevalent and disabling anxiety disorder that presents as both a psychological and physical condition that can develop after exposure to very frightening or distressing events where grave physical harm occurred or was threatened (Gersons et al., 2000; NICE, 2006; Bisson and Andrew, 2007; NHS, 2009, p216; Stein et al., 2009; NIMH, 2010).

Reference to PTSD type symptoms can be seen from the diary of Samuel Pepys recording of the Great Fire of London, 2nd September 1666, where he details his dreams of “fire and falling down” which, even after six months, were still causing him dream disturbances and talks of the “sequelae of the disaster for others, including attempted suicide”(Figley, 1985; Turnbull, 1998).

PTSD has also been variously known throughout history as shell shock, combat neurosis, battle fatigue, gross stress reaction, anxiety neurosis, soldier’s heart and railway spine are to name but a few (Van der Kolk et al., 1996, p48, 164; Turnbull, 1998; Stein et al., 2006; Psychiatric Disorders, 2010; Stein et al., 2010, p 569-583). The German neurologist Herman Oppenheim was the first used the term traumatic neurosis in 1889 (Van der Kolk et al., 1996, p48) but it was only recently, in 1980, that PTSD was added to psychiatric nomenclature and a diagnostic criteria became established in the American Psychiatric Associations (APA) Diagnostic and Statistical Manual of Mental Disorders 3rd edition (DSM-III) which was a refinement and continuation of criteria in the World Health Organisation’s (WHO) International Classification of Diseases 9th edition (ICD-9) released in 1977 (WHO, 1977; APA, 1980; Figley, 1985; Van der Kolk et al., 1996, p61; Turnbull, 1998; Stein et al., 2006; Jones and Wessely, 2007; WHO, 2010).

PTSD is a heterogeneous, complex and often comorbid condition which psychologically can present with the following symptoms or combination of symptoms (APA, 2000; Pease et al., 2009; Stein et al., 2010, p583):

- Intrusive, distressing recollections - thoughts, images
- Repeated, distressing dreams
- Through flashbacks, hallucinations or illusions, acts or feels as if the event were

recurring

- Marked mental distress in reaction to internal or external cues that symbolize or resemble the event
- Tries to avoid thoughts, feelings or conversations concerned with the event
- Cannot recall an important feature of the event
- Marked loss of interest or participation in activities important to the patient
- Feels detached or isolated from other people
- Restriction in ability to love or feel other strong emotions
- Feels life will be brief or unfulfilled (lack of marriage, job, and children)
- Insomnia (initial or interval)
- Irritability
- Poor concentration
- Hyper-vigilance
- Tries to avoid activities, people or places that recall the event
- Increased startle response

PTSD can produce neurobiological and biological changes such as the release of adrenocorticotrophic hormone (ACTH), cortisol and catecholamine which can result in the up-regulation of adrenaline production and the down-regulation of endorphin production, manifesting as rapid heartbeat and elevated respiration blood pressure (Turnbull, 1998; Stein et al., 2010, p569).

Warfare is not the only cause of PTSD, the WHO estimates that a third of all cases in women and one fifth in men are attributable to child sex abuse (WHO, 2009) and it is now accepted that any traumatic event, physical or psychological, can lead to PTSD (APA, 1980; WHO, 2005; Stein et al., 2006; NHS, 2009).

The WHO in the International Statistical Classification of Diseases 10th edition (ICD-10) (2005) under code F43.1 states that PTSD '*Arises as a delayed or protracted response to a stressful event or situation (of either brief or long duration) of an exceptionally threatening or catastrophic nature, which is likely to cause pervasive distress in almost anyone. Predisposing factors, such as personality traits (e.g. compulsive, asthenic) or previous history of neurotic illness may lower the threshold for the development of the syndrome or aggravate its course, but they are neither necessary nor sufficient to explain its occurrence.*'

In 2000 it was estimated by the WHO that PTSD accounts for 0.4% of years lost due to disability (YLD) globally which is equivalent to schizophrenia and in 2001 this was revised to 0.6% (Ayuso-Mateos, 2000) representing the most recent figures available from the WHO.

Cultural and Historical significance

It is highly unlikely that PTSD is a modern condition as though out human history there have been traumatic events, such as wars, natural disasters and other traumatic events, which could have resulted in symptoms that we classify today as PTSD. It is unfortunate that historically, due to the incomplete understanding of psychological behaviours, there have been instances where PTSD has been classified as cowardice or personal weakness (PsychiatricDisorders, 2010).

Unlike modern western biomedicine (biomedicine), which uses PTSD as a label for a group of symptoms that can occur in a patient or group of patients, Traditional Chinese Medicine (TCM) would look at how the presenting symptoms effects the patient and present a diagnosis accordingly. There are many syndromes within TCM that can be said to have similarities to PTSD such as:

- Fear and Palpitations
- Panic Throbbing
- Agitation and restlessness (Fanzao)
- Rebellious Qi of the Penetrating Vessel (Chong Mai)
- Apprehension that turns to anxiety (Chu Ti)
- Disturbance of the Shen
- Liver Fire insulting the Heart

However these syndromes could also be said to be comparable to anxiety disorder or depression in the same way that PTSD has some similar presentations to anxiety disorder or depression (Maciocia, 1989, p252-253; Larre and Rochat de la Vallée, 1995, p85; Flaws and Lake, 2001, p125-129; Rossi and Caretto, 2007,p 314-318; Maciocia, 2009, p440; Pease et al., 2009).

It is interesting to note that when reading some of the names used, for what became known as PTSD, such as “disorderly action of the heart” or “neurocirculatory asthenia” (Van der Kolk et al., 1996, p48) we can see that the early psychologists were attempting to describe what they saw presenting in their patients without the benefit of modern investigative techniques and equipment. This practical way of naming a condition in a manner that describes its symptomology corresponds to how ancient Chinese physicians would describe disease in TCM.

As TCM has its basis in Taoist and Confusion philosophy it uses a more poetic language, based on seasons, features of landscape and human interaction with nature, with which to describe the differences between harmony or health and disharmony or sickness and is an empirical body of knowledge that has been compiled over many thousands of years (Lewin, 1974; Kaptchuk, 2000,

p7; Dechar, 2006, p3-4; Maciocia, 2009, p 313).

The earliest surviving Chinese medical text that describes recognisable psychiatric disorders is the Huang Ti Nei Ching Su Wen also referred to as Huángdì Nèijīng which translates to Yellow Emperor's Inner Canon (Flaws and Lake, 2001, p3-5). There is no firm date of publication of this text but Chinese historians have verified that major contents of this text had appeared in other historical documents during what is now called the Warring States Period of 475 BCE to 221 BCE (Veith, 1973; Flaws and Lake, 2001, p3-5; Zhu, 2001, p1). It is possible to describe the Huángdì Nèijīng as an attempt to systematise the empirical data that was available to TCM practitioners at that time (Willmont, 2009, p7).

Kaptchuk (2000, p2) states that *“Chinese medicine is a coherent and independent system of thought and practice that has been developed over two millennia”* and he goes on to say *“that TCM is also rooted in the philosophy, logic, sensibility and habits of a civilization entirely foreign to our own. It has therefore developed its own perception of health and illness”*. It is this contextual and cultural difference that can cause TCM diagnosis to be misunderstood and this is compounded by the lack of comparable anatomical descriptions to the west (Veith, 1973; Kaptchuk, 2000, p 76-78; Pease et al., 2009).

Understanding that the philosophy and language that underpins TCM is alien to western philosophy, and thus biomedicine, it is possible to demonstrate how words, common to both disciplines, can be misunderstood. As an example many western medical practitioners would be reluctant to accept that will-power resides in the Kidneys, or that the mood is regulated, in part, by the Liver (Hammer, 1990, p65 & 109; Kaptchuk, 2000, p81-88). However the use of the word Kidney or Liver is a rough translation of a concept of TCM that covers many aspects, both physical, emotional and in some cases spiritual, and is not just a description of the internal organ.

As a counterpoint the western biological view of the Liver is of a physical structure that is responsible for numerous physiological activities such as synthesising bile, metabolising carbohydrates, proteins and fats, regulating blood sugar and removing excess amino acids etc. (Martin, 2007). However in TCM the Liver is responsible for ensuring the smooth flow of Qi, storing the blood and coordinates the digestive function (Maciocia, 1989, p117; Kaptchuk, 2000, p76).

There are other anatomical features such as the pancreas, nervous system or adrenal glands, that are not recognised in TCM and conversely western medical science does not identify the ‘Triple Burner’ as an organ or wind as a factor of disease (Kaptchuk, 2000, p2-4).

The lexicological differences are the root of the fundamental incompatibility between biomedicine and TCM and must be seen and understood as a caveat to any interpretations when dealing with the language of TCM from a western perspective. It is this very lack of comparable terminology, as demonstrated in a study by Sinclair-Lian (2006) noting that the 12 patients with a diagnosis of PTSD presented with 12 different TCM diagnoses, which compels any review of acupuncture treatments for PTSD to search exclusively for biomedical diagnostic terminology and to avoid TCM syndromes.

Tests for PTSD

There are a number of structured diagnostic interviews for PTSD, such as the Structured Interview for PTSD (SI-PTSD) the PTSD Interview (PTSD-I), the PTSD Symptom Scale Interview (PSS-I) (Blake et al., 1995). However the gold standard for assessment currently is the Clinician Administered PTSD Scale (CAPS) a 30 item structured interview that correlates to the DSM-IV diagnostic criteria for PTSD (Blake et al., 1995; Weathers et al., 2001; Stein et al., 2009; USDVA, 2010).

The CAPS test was developed at the National Centre for PTSD and was designed to overcome the limitations of other PTSD tests by covering and measuring all 17 items of the diagnostic criteria in the DSM-III and can be used either as a dichotomous (present/absent) or continuous measure of PTSD symptom severity and intensity by using a 5 point (0 to 4) Likert scale (Blake et al., 1995; Weathers et al., 2001).

As the diagnostic criteria for PTSD has evolved, with the DSM-IV in 1994, so the CAPS test has evolved and revised to bring it up to date with the current PTSD criteria. Improvements such as incorporating user feedback has been added (Weathers et al., 2001) and this process and evolution will no doubt continue with the release of the DSM-V which is (at time of writing) planned for May 2013 (APA, 2009).

Common Treatments for PTSD

Various forms of interventions are currently advocated in the treatment of PTSD, which include but are not limited to, cognitive-behavioural therapy (CBT), eye movement desensitisation and reprocessing (EMDR) and pharmacotherapy (Van der Kolk et al., 1996, p417; NICE, 2006; Stein et al., 2006; Bisson and Andrew, 2007; NHS, 2009).

Treatments such as psychodynamic psychotherapy, psychological debriefing in the immediate

aftermath of trauma and hypnotherapy are widely used but controlled studies are lacking to support these treatments (Brom et al., 1989; Ursano et al., 2004; Stein et al., 2006; Benedek et al., 2009). There is however a growing body of evidence that suggest cognitive behavioural treatments immediately after the event can be effective such as Exposure-Based CBT and EMDR (Gersons et al., 2000; Ursano et al., 2004; Benedek et al., 2009).

In October 2004 the American Psychiatric Association (APA) published the Practice Guideline for the Treatment of Patients with Acute Stress Disorder (ASD) and PTSD which was followed up by a Guideline Update in 2009 taking into account more recent evidence (Ursano et al., 2004; Benedek et al., 2009).

According to the APA 2004 “The goals of treatment for individuals with a diagnosis of ASD or PTSD include reducing the severity of ASD or PTSD symptoms, preventing or treating trauma-related comorbid conditions that may be present or emerge, improving adaptive functioning and restoring a psychological sense of safety and trust, limiting the generalization of the danger experienced as a result of the traumatic situation(s), and protecting against relapse”

However both the 2004 guidance, and the 2009 guidance update, state that there is no specific pharmacologic intervention for PTSD and that the studies supporting pharmacologic interventions are of small population samples. However there does seem to be a benefit versus placebo for the use of Selective Serotonin Reuptake Inhibitors (SSRIs), and the 2009 guidance concludes that *“the best evidence from recent studies bolsters support for exposure-based psychotherapies”* and goes on to state that *“Emerging evidence to suggest the potential for psychotherapy to be facilitated by at least one recently identified pharmacological agent”* (Ursano et al., 2004; Benedek et al., 2009).

The APA guidance is reflected by the UK National Institute for Health and Clinical Excellence (NICE) guidance CG026 (NICE, 2006) and the Royal College of Psychiatry (RCP) (RCP, 2010) which states that PTSD treatment should ideally be a combination of CBT/EMDR and pharmacology, however CBT/EMDR should be offered first. The RCP (2010) does note that acupuncture does not *“help PTSD directly, but can help to control your distress, hyper arousal, the feeling of being 'on guard' all the time”* however they offer no evidence or citation for this statement.

The International Society for Traumatic Stress Studies (ISTSS) offer similar guidance on CBT/EMDR and pharmacology as recognised treatment for PTSD in their most recent publication of Effective Treatments for PTSD but do not list acupuncture as a recognised treatment (Foa and International Society for Traumatic Stress Studies., 2009).

Review Objectives

1. To identify and discuss appropriate research methodologies and experiment design for investigation in this area to facilitate inclusion criteria design
2. To design an effective search strategy in order to identify and collect all studies and literature relevant to this review
3. To subject collected data to inclusion criteria for review
4. To review data and provide an estimate of the effectiveness of acupuncture as an adjunct treatment for PTSD
5. To identify, discuss and document current research methodologies and experiment design that provide objective measurement of acupuncture as an adjunct treatment for PTSD to facilitate research in this area

Acceptable Research Methodologies for Inclusion Criteria

One of the most dogged questions in modern acupuncture research is how should research experiments be designed (MacPherson et al., 2002)? Biomedical research has set the Randomised Control/Clinical Trials (RCT) as the gold standard for pharmaceutical research (Verhagen et al., 2001; MacPherson et al., 2002; Kane, 2004, p87; Paterson, 2005; Stein et al., 2006; Kelley and Kaptchuk, 2010). However there is debate amongst academics as to whether RCT's should be the gold standard for non-pharmaceutical complex interventions such as physiotherapy, acupuncture and psychology (Bowling, 2002, p226-228; Paterson, 2005).

Quantitative research is a method of testing a hypothesis and RCT's are but one experimental method within this research paradigm (Coolican, 1999, p452). RCT's are experiments with which to statistically assess the outcome between a control group, that is not exposed, and an experimental group that is exposed to an intervention, also known as the independent variable. Participants in the two groups should be assigned randomly and none of the participants or practitioners in the experiment should know if they are receiving the independent variable or placebo.

When participants or practitioners are unaware of which group or individuals are receiving the independent variable this is known as a double blind RCT. The control and experimental groups should be investigated under, as near as is possible, identical conditions except for the independent variable (Bowling, 2002, p216; Verhoef et al., 2002; Denscombe, 2007, p48-52; MacPherson, 2008, p 114-116).

With the use of double blind techniques the RCT seeks to understand if a treatment or intervention does or does not work and seeks to isolate the independent variable, as much as is possible, from any contamination such as:

- Prescriber such as empathy or lack of, knowledge, charisma etc.
- Setting/physical environment where the test or prescription takes place could be conducive or inappropriate
- Researcher allegiance regarding what treatments they are trained in or have a preference to deliver
- Group sampling may be biased to participants with a certain condition
- Patient participation and co-operation
- Practitioners resistance to providing different standards of care
- Practitioners resistance to a new treatment that has an untested efficacy versus a known treatment
- Practitioners having their treatments measured against the treatments of their colleagues

(Peters, 2001; Bowling, 2002, p226-228; MacPherson, 2008, p 114-116; Wampold et al., 2010b)

Fundamentally if a treatment, other than a pharmacological intervention, is the independent variable, for example if practitioners are being asked to provide two different standards of care, then the risk of contamination increases.

Conversely TCM acupuncture (TCMA) seeks to look at the person as a whole, to understand all the factors that make up the person's life such as; what they eat, how they structure their time, how a certain condition affects them etc. The very factors that can hinder RCT experimental design are the factors that TCM is keen to investigate. So is it correct to subject TCMA to a mythology that fails to take into account this potentially significant information?

Researchers in Psychiatry and Psychology have put forward a similar argument, and whilst practitioners in those areas might not enjoy any similarities being drawn to TCM there do seem to be many areas that overlap, especially when it comes to research. This can be demonstrated by the use of language in psychiatric studies where the distinction is made between efficacy (whether a treatment works) and effectiveness (whether the treatment works in practice) (Schnurr, 2007).

There is a desire in medical science to bring all interventions under the microscope of RCT, and certainly acupuncturists in the west with the goal of being accepted by medical professionals

have attempted to subject TCMA to the full rigours of RCT understanding.

Inclusion Criteria

In the area of literature review RCT's are considered the gold standard for review when analysing data from medical studies. RCT's are a powerful methodology for determining the relative efficacy of medical treatments, but clinical trials are complex and subject to numerous threats to validity.

However it is important to consider the inclusion of Case Studies (CS) when assessing literature. Qualitative research is generally not considered the gold standard for demonstrating the efficacy of a medical intervention, however CS are a very useful tool for developing a body of knowledge which may lead to a testable hypothesis (Bowling, 2002, p67). Although CS are used as a methodology in the social sciences when looking at individuals or groups they do potentially have the following limitations:

- You cannot generalize from a single case
- The case study contains a bias toward verification
- Too much scope for researchers own bias

On the other hand funding for acupuncture RCT's is generally limited so the available RCT knowledge base is small. As case studies can be used to formulate hypothesis which in turn can and do lead to further research. However with all systematic reviews the validity of the conclusions will depend on the quality of the included primary studies (Verhagen et al., 2001).

The decision was taken to allow both RCT's and Case Studies to be included for review for the following reasons:

- Lack of large scale RCT's in this research area
- Case studies are used to develop and initially test hypothesis in research (Bowling, 2002, p67)
- Case studies may provide essential clinical and environmental information that may not be recorded in a RCT

However it should be noted that RCT's and CS will be reviewed and assessed separately as direct comparison between these different mythologies would be inappropriate.

Types of studies

RCT (placebo controlled, pragmatic, comparative and wait list trials) and high quality case studies completed prior to the end of 2000 were considered for inclusion regardless of publication. Unpublished abstracts and reports were also considered. Studies were limited to the English language only. Differences between trials were not used to exclude studies however RCT's and CS's were not compared as like for like.

Types of participants

All studies of subjects with PTSD, as determined either by the study's authors or by a trained medical professional were included. There was no restriction of severity or duration of symptoms, age, gender, ethnicity or economic status of subjects.

Types of interventions

The review was of acupuncture as an adjunct therapy for PTSD so all studies that used a recognised, either by the American Psychological Association (APA) or the National Institute for Health and Clinical Excellence (NICE), interventions such as pharmacology, EMBR, CBT etc. and acupuncture were included for review. The use of acupuncture as the sole treatment was not used to exclude studies.

Types of outcome measures

The gold standard for measuring PTSD symptoms is CAPS (Blake et al., 1995), however a number of self-reporting scales are available for use. As CAPS is an extensive and detailed interviews it is common for studies to use more easily deployed outcome measures. CAPS measurement was preferred but the use of other recognised outcome measures was not used to exclude studies such as:

- Posttraumatic Symptom Scale-Self Report (PSS-SR)
- MYMOP (measure your medical outcome profile)
- POMS (Profile of mood states)

Search methods for identification of studies

Systematic searches of computerised databases were searched via the University of Salford e-Library, hand search of any relevant journals not available in electronic form, searches of reference lists, known websites and personal communication with key workers. All searches focused on abstract, title and keywords.

Search Strings for computerised databases and indexes

As previously discussed there is no direct translation of the biomedical condition PTSD to any one TCM condition or group of conditions therefore TCM search terms were used.

- Post Traumatic Stress Disorder AND Acupuncture
- Posttraumatic Stress Disorder AND Acupuncture
- Post-Traumatic Stress Disorder AND Acupuncture
- PTSD AND Acupuncture

Databases searched

Database	Dates searched from	Results	Removed for Relevance	Documents not Available	Repeat Find	Total for Review
Applied Social Sciences Index & Abstracts (CSA)	1982	0	0	0	0	0
CINAHL (EBSCO)	1982	25	7	11	0	7
MEDLINE (Ovid)	1950	3	0	1	2	1
PsycINFO (Ovid)	1806	6	0	6	0	0
Sociological Abstracts (CSA)	1952	2	0	2	0	0
ScienceDirect (Elsevier)	1995	4	1	0	1	3
Cochrane Collaboration	1993	1	0	0	1	0
PILOTS (a specialized PTSD index maintained by the National PTSD Centre in the USA)	Index	1	0	0	1	0
AMED – The Allied and Complementary Medicine Database	1985	1	0	0	1	0
PubMed Central		12	4	4	4	0
AIM - Acupuncture in Medicine (BMJ)	1982	0	0	0	0	0
ARRC – British Acupuncture Council Research Resource Centre	2008	3	0	0	0	3
Acupuncture Today	2000	41	34	0	1	1
American Journal of Chinese Medicine (AJCM),	1973	0	0	0	0	0
British Medical Journal (BMJ),	1840	5	4	0	0	2
BioMed Central – Chinese Medicine	2006	0	0	0	0	0
Chinese Medicine Times - eJournal	2006	0	0	0	0	0
European Journal of Oriental Medicine	1993	0	0	0	0	0

JAMA – Journal of the American Medical Association	1883	0	0	0	0	0
Shanghai Journal of Acupuncture & Moxibustion	2009	0	0	0	0	0
ECOJ – English China Online Journals	1997	No Access – See Appendix access request	0	0	0	0
Journal of Chinese Medicine (JCM)	1979	2	0	0	2	0
AMED – Allied and Complementary Medicine	1985	1	0	0	1	0
EMBASE - Excerpta Medica database	1980	No Access	N/A	N/A	N/A	N/A
WHO ICTRP		4	N/A	N/A	N/A	N/A

One reviewer (JHS) carried out the search process and articles were selected based on title, abstract and search terms. In many cases results were removed for relevance due to only covering PTSD and not Acupuncture. Where electronic versions were not available an attempt was made to secure a copy by searching for the specific article by name and author on Google scholar and by hand in the Salford University Library.

Access to English China Online Journals and The Excerpta Medica database (EMBASE) was not available to students of Salford University. Email attempts were made to gain termory access but these were denied (see appendix 2 for details)

Emails were also sent to the following due to either their knowledge of work conducted in this area or their positions within organisations that may be conducting research (see Appendix 2 for email correspondence):

- Richard C. Niemtzow, MD, PHD, MPH
- Professor Simon Wessely
- Jeanette Akhter, M.D., M.Ac.
- The Henry M. Jackson Foundation for the Advancement of Military Medicine
- Thomas W. Findley MD PhD
- Kathleen Ray
- Michelle Kennedy Prisco
- Colonel Charles Engle
- Dr. Shelly Menolascino

Data collection and analysis

Twenty five documents were retrieved using the search strategy. These documents were then subjected to the inclusion criteria by JHS resulting in one document meeting the inclusion criteria. The table below details the reasons for exclusion.

Author	Title	Date	Available	Meets Inclusion Criteria?	Reason for Exclusion?
Hollifield, M.	Acupuncture for posttraumatic stress disorder: a randomized controlled pilot trial.	2007	Yes	Yes	Included
Engle, C.	Unknown	2008	No	No	Reference to research in Journal interview with Dr Engle no data for the study was available.
Sinclair-Lian	Developing a traditional Chinese medicine diagnostic structure for post-traumatic stress disorder.	2006	Yes	No	Developing a diagnostic framework for PTSD but no clinical trial data. Used as precursor to Hollifield 2007
Gaeddert, A.	Ask the herbalist. Can herbal medicine help people with anxiety, panic & PTSD?	2002	Yes	No	Information article
Chang, J.C.	AOM program helps vets recover from PTSD.	2010	Yes	No	Information article
Chang, J.C.	Comprehensive military PTSD treatment programs.	2009	Yes	No	Information article
Chang, J.C.	Weighing the costs: integrative PTSD programs for veterans.	2009	Yes	No	Information article
Collinge, W.	Integrating complementary therapies into community mental health practice: an exploration.	2003	Yes	No	Not confined to PTSD Not confined to Acupuncture
Pease, M.	Acupuncture for refugees with posttraumatic stress disorder: initial experiences establishing a community clinic.	2007	Yes	No	Not Clinical Trial Limited Data No outcome measures No Control group
Eisenlohr, V.	Akupunktur – eine neue Option in der Behandlung traumatisierter Bundeswehrsoldaten?	2010	Yes	No	Not in English Language
Oschman, J.L.	Trauma energetics	2006	Yes	No	Not clinical trial Not acupuncture
Collinge, W.	Integrating complementary therapies into community mental health practice: an exploration.	2003	Yes	No	Not limited to PTSD Not limited to acupuncture as treatment protocol Small sample size No Outcome measures
Pilkington, K.	Acupuncture for anxiety	2007	No	No	Systematic Review

	and anxiety disorders – a systematic literature review				Does not cover PTSD
Acupuncture Research Council (ARRC)	Acupuncture and Depression		Yes	No	Briefing Paper from the British Acupuncture Council (BAcC)
ARRC	Depression Anxiety and Acupuncture	2002	Yes	No	Briefing Paper from BAcC and Acupuncture Research Resource Centre (ARRC)
ARRC	National Guidelines on Mental Health	2009	Yes	No	Briefing Paper from BAcC
Dunas, F.	Trauma: The Hidden Pathogenic Factor	2009	Yes	No	Information article
Porter, K.	Refugees: Feeling At Home With Acupuncture	2008	Yes	No	Information article
Beychok, T.	Healing Old Wounds With Acupuncture	2008	Yes	No	Information article
Paterson, C.	Characteristic and incidental (placebo) effects in complex interventions such as acupuncture	2005	Yes	No	Educational article
Tang, J. L	Review of randomised controlled trials of traditional Chinese medicine	1999	Yes	No	Review of methodologies in research
Gaeddert, A.	Townsend letter for doctors and patients	2002	Yes	No	Information article
NCT01060553	Pilot of Acupuncture to Improve Quality of Life in Veterans With Traumatic Brain Injury (TBI) and PTSD	2010	Yes	No	Clinical Trial outline on www.clinicaltrial.gov
NCT00868517	Examining the Effect of Acupuncture on Sleep Difficulties Related to Post Traumatic Stress Disorder	2009	Yes	No	Clinical Trial outline on www.clinicaltrial.gov
NCT00320138	Acupuncture for the Treatment of Posttraumatic Stress Among Military Personnel	2006	Yes	No	Clinical Trial outline on www.clinicaltrial.gov
NCT00055354	Acupuncture for the Treatment of Post-Traumatic Stress Disorder (PTSD)	2002	Yes	No	Clinical Trial outline on www.clinicaltrial.gov

Data Review

There is scarce clinical data to support the efficacy of acupuncture for PTSD either as a primary or adjunct therapy in the English language. There are a total of two RCT studies conducted in this area, Hollifield 2007 (Hollifield et al., 2007) and Engle 2008 (Wendling, 2008). The author has attempted to secure data from Engle 2008 via email and telephone but the data has not be forthcoming (see Appendix 2).

The United States Army Medical Corps, at time of writing, has never published or subject to peer review a study conducted in 2008 by Colonel Charles Engle, the author made repeated attempts requesting the data from this study (see Appendix 2). The only data that can be found was an article in Clinical Psychiatry News (Patrice, 2008) where Dr Engle talked about the findings. However this data does not meet the inclusion criteria for this review.

Reviews of quantitative data generally present a meta-analysis of the data by using statistical tools to combine pooled data sets from different studies (Bowling, 2002, p136). As there is only one set of data meta-analysis is impossible as it requires a minimum of two sets of data.

Hollifield (2007) study randomly assigned 73 patients, who had been subjected to the studies inclusion criteria, into three groups receiving either acupuncture, group CBT or wait-list control (WLC). Individuals in both group CBT and acupuncture groups received a total of 24 hours of therapy over a 12 week period. Of the initial 73 only 61 completed the trial and 58 completed the 3 month follow up.

Recruitment to the RCT was via various methods (including fly posters and local advertising) and the initial diagnosis was established using the Posttraumatic Symptom Scale-Self Report (PSS-SR) and depending on results subjects were invited to interview for diagnosis by a trained medical professional where subjects were also screened for eligibility by the inclusion criteria of the study. Randomisation into the different groups was achieved using a computerized random numbers procedure without restrictions and this process was concealed from clinicians.

Acupuncture treatments were based on a standard set of anterior and posterior body points that were selected for their clinical efficacy in the treatment of PTSD. Another 15 acupuncture points were available for use depending on the patients TCM diagnosis. These treatment points were based on previous work presented by Sinclair-Lian (Sinclair-Lian et al., 2006) of which Hollifield was a co-author.

The data does show a reduction in reported symptoms using PSS-SR in both the group CBT and acupuncture groups compared with wait list control (WLC) group. Overall 63% of the acupuncture group had scores below the ≥ 16 entry criterion level after treatment comparing favourably with 36% of the group CBT and only 17% of the WLC. The acupuncture group 63% was maintained for the 3 month follow up. The group CBT participants at the 3 month follow up had increased their numbers to below the ≥ 16 entry criterion level to 53%.

Whilst the Hollifield (2007) data is encouraging and has provided a good foundation for future studies it is important to be aware that the inclusion criteria for the Hollifield (2007) study did not require the cessation of medication that “*was in use for the treatment of another psychiatric disorder such as depression*”. As current medication for depression is also used for PTSD this does present a potential contamination in this study, however there is a requirement that the “*current treatment was stable for 3 months or more*”.

Hollifield (2007) does note limitations to this study of which this review author agrees:

- Group CBT is not a recognised treatment for PTSD (NICE, 2006; Cukor et al., 2009) furthermore there is sparse evidence to suggest that group CBT is more effective than wait list control groups and none to suggest that group CBT is better than single patient CBT (Bisson and Andrew, 2007).
- Limitations of the study are consistent with the early-phase nature of the trial and that effects could be due to nonspecific therapist factors.

This study does provide the first published clinical evidence that acupuncture is an effective adjunct therapy for the treatment of PTSD and provides a good starting point for further research into this area.

Further research strategies

When researching use of Acupuncture for the treatment of PTSD, either as a primary or adjunct therapy, there are four areas of difficulty.

1. What research methodology to use in order to understand acupuncture as a complex and interactive treatment that is, in traditional acupuncture, tailored to the individual
2. Difficulties in recruiting and retaining participants with PTSD
3. Comorbid nature of PTSD and participants presenting with concurrent treatment regimes
4. Potential range of diagnosis from different TCM practitioners

Research Methodology

The APA PTSD Guideline Update (2009) were critical of small numbers of participants in studies, subjects receiving multiple treatment regimes, inadequate controls and lack of replication (Benedek et al., 2009). Understanding that pharmacological research in this area can prove difficult it is not surprising that acupuncture research, with its own unique difficulties, in to PTSD can present many challenges.

As an example of issues with acupuncture research two recent three arm studies compared acupuncture to sham acupuncture, where needles are inserted just beneath the skin in points not associated with acupuncture or meridians and usual treatment. In both studies acupuncture was found to be superior to usual treatment but not significantly better than sham acupuncture (Linde et al., 2005; Melchart et al., 2005; MacPherson, 2008, p 122).

In 1995 the WHO (1995), Regional Office for the Western Pacific, published Guidelines for Clinical Research on Acupuncture. This document notes that the quality of research *“still varies considerably”* and that *“the need for basic principles which can be followed by researchers involved in clinical research on acupuncture has been raised on several occasions”*. This view was echoed in the National Institutes of Health (NIH) Consensus Development Conference on Acupuncture statement in 1997 and more recently in 2007 by the Society for Acupuncture Research (SAR) (NHI, 1998; Langevin et al., 2011).

This repeated call for the quality of acupuncture research to be raised could be due to:

- Lack of trained researchers in this field
- Lack of funding
- Lack of an agreed research mythology in this area of research

Fifteen years after the publication of the WHO guidelines there is still debate, within acupuncture, regarding which research paradigm should be used to demonstrate the efficacy of interventions (Jones and Wessely, 2007; Bovey, 2010). David St George (2000), senior lecture in clinical epidemiology and chief advisor for integrated health to the New Zealand Ministry of Health (NZMOH, 2011), stated that Complimentary Alternative Medicine (CAM) *“should avoid biomedical agendas and instead do their own research”* going on to describe orthodox medicine’s methods as *“over-quantitative, insufficiently tuned to the subjective experiences of patients and practitioners, blind to healing phenomena based on vital forces and the servants of an establishment whose main interests in CAM is to swallow the bits it finds attractive and spit out the rest”*.

In the biomedical research environment there is evidence emerging to suggest that CAM researchers will actively adjust their self-presentation style, carefully self-censor or reframe any unconventional ideas or beliefs that are not currently supported and to blur the boundaries between CAM and biomedical research (Polich et al., 2010).

The goal of any research is to discover the answer to a question without bias. If research in this area is to provide meaningful data, that facilitates a greater understanding of a therapies efficacy, it is important that all the factors of the intervention are understood and ways of conducting experimentation be designed or modified to capture and analyse this data. The application of the basic experimental principles of design, conduct, analyse and report should be adhered to in order to conduct sound peer reviewed research (WHO, 1995).

Just as TCM looks at the patient as a whole system, thus research into this field must look at all the factors in TCM as a whole system and avoid an overly reductionist method. Such factors as the therapist, the setting of the therapy, patient cooperation and belief in the intervention and the actual intervention should be measured in order to adequately asses the treatments efficacy in regards to these factors. There is growing evidence that studies, of all kinds, are failing to account for and measure the effects of the therapist. As an example rarely do RCT account for therapists skill, enthusiasm and warmth (Schnurr, 2007).

RCT's can potentially fail to fully understand, consider, monitor or explain any effects outside of the treatment such as placebo, which has been described as "the difference in outcome between a placebo treated group and an untreated control group in an unbiased experiment" (Peters, 2001, p180). Some recent research even goes so far as to conclude that the placebo effect can generate genuine psychobiological events which are attributable to the overall therapeutic context (Finniss et al., 2010).

One possible method for assessing placebo would be to use a three arm trial where there is a control group that receives no intervention, which is also known as a wait list control group, a placebo group that receives a placebo intervention and an independent variable group which receives the treatment to be tested.

It is clear that research into TCM and CAM therapies; due to the nature of data (the intervention, environmental effects, patient cooperation, therapist effects and placebo etc.) demonstrates that conventional RCT's are not best suited to investigate these factors (Verhoef et al., 2005).

Generally RCT's demonstrate poor external validity, which is to say they do not present a generalizable view of the real world and bear little resemblance to common practice (Bowling, 2002, p227; Hotopf, 2002; Verhoef et al., 2005; MacPherson, 2008,p 114-115). Kelly (2010) notes that "RCT methodology is effective at drawing reliable inferences at the level of the group, but inferences at the level of the individual cannot be made with similar confidence"

As an example an RCT may attempt to recruit participants that present with no comorbid conditions, however in the real world patients often present with many complaints. Also it could be said that practitioners involved in the RCT will be specialist in their field rather than more generalised practitioners (Bowling, 2002, p227).

However RCT's do have good internal validity which is to say that they are of good design with minimal bias and the results can be believed even if the results don't necessarily hold true in real world practice (Hotopf, 2002; MacPherson, 2008, p114).

It should not be concluded that RCT's do not play a part in discovering the efficacy of a treatment, but the data RCT's generate must be taken in context and not be seen as the final arbiter of an intervention. Similarly Qualitative research can rely too much on subjective experiences which could be contaminated by a charismatic therapist, a patient not wanting to offend or in the hope of a treatment working where all else has failed.

Whole Systems Research (WSR) has been proposed as a possible solution to this research dilemma and has many mythologies at its disposal such as; pragmatic trials, factorial designs, preference trials etc. Using both qualitative and quantitative methodologies WSR seeks to understand the:

- Complexity and uniqueness of the healing systems under investigation
- Patient/Practitioner relationship
- Individual patient centered approach for diagnosis and treatment
- Willingness of the patient to engage with the healing process

(Verhoef et al., 2005; MacPherson, 2008, p 114-124)

The pragmatic randomised control trial (PRCT) is a mythology promoted in WSR (Verhoef et al., 2005) that could be used to determine the efficacy of acupuncture in the clinical setting. PRCT seek to understand and account for the heterogeneity of patients, reduce inclusion criteria to allow for comorbid conditions, can include a wide range of clinical groups or presentation that may cover many different diagnosis and look to understand complex interventions delivered in the real world (Hotopf, 2002; Kane, 2004, p87-88).

However the PRCT does not seek to understand the specific aspect of the treatment that is

beneficial rather it seeks to demonstrate the efficacy between different packages of treatment in a real world setting allowing practitioners to adjust treatment based upon their clinical judgment (Kane, 2004, p87; MacPherson, 2008, p119)

MacPherson (2008, p119) states that *“Pragmatic trials are considered a strong design for acupuncture studies because they allow the acupuncturist to deliver the type of care that most resembles what they do in practice”* going on to note that *“they also avoid the vexing issue of designing a suitable sham control”*.

Clearly this mythology can allow for contamination in respect to practitioner/patient relationship and practitioner experience which needs to be accounted for when collecting data (Kane, 2004, p87-88) but for many practitioners these contaminations are part of the treatment process.

Design Considerations

When designing an experimental model to capture data from TCM it is critical to understand what data must be collected, how this data should be recorded and how this data should be analysed.

The data to be collected can be listed as:

- The effect of the intervention
- The effect of the therapist
- The effect of the environment
- The effect of the patient
- Outcome

Intervention

As acupuncture is a complex intervention its effects should be measured against another recognised treatment, which is understood and has demonstrated a statistically reliable outcome, or waitlist control where there is a statistically understood natural outcome. The use of PRCTs are ideal for this method of investigation and a review with meta-analysis of previous studies into the recognised treatment or wait list will facilitate a historical improvement rate within a population.

Certainly it would be useful to understand exactly which acupuncture point was responsible for any improvement but this research should be conducted after it has been ascertained if acupuncture is affective. So any initial investigation should concentrate on allowing the practitioner to use their best clinical judgment rather than specifying points and constraining the natural therapeutic process.

Therapist

Lewis et al. (2010) notes that *“it is possible that estimates of treatment efficacy and effectiveness may be confounded by differences between practitioners”* and furthermore *“This may be particularly apparent where practitioners of differing ability and competence are allocated to different arms of a trial.”*

It can be argued that for some complex treatments, for instance TCM or psychotherapy, that the practitioner effect can explain the variance in outcome of the specific treatment (Lewis et al., 2010; Wampold et al., 2010a)

But what is the therapist effect and how does research understand this? Some of the questions that need to be addressed during any experiment are:

- Do different therapists get different results when treating the same condition with the same intervention?
- Do therapists get different results when treating different kinds of patient e.g. older versus younger, male versus female or those who have a belief in the healing system versus those who do not? In other words does a therapist seem to be more successful with a certain type of client?
- Do different therapists have different abilities?
- Do therapists have a like or dislike of a therapy?
- Is there a particular look that the therapist can adopt to be more successful e.g. is a therapist dressed as a soldier more effective than a therapist dressed in Tibetan monk robes?
- Do different therapists arrive at different diagnosis for the same patient?

Experimental design would also need to take into account of specific questions regarding acupuncture practitioners:

- Does the practitioner have a regularly used favourite acupuncture point
- What style of practitioner is the acupuncturist: TCM, Five Elements, Korean, Japanese etc.
- What diagnostic process did the practitioner use: 8 questions, Five Elements etc.

Researching acupuncture as a treatment of PTSD it is possible, with correct design, that the therapist effect can be understood and tested regardless of standard/pre-determined acupuncture points or non-standard/individualised treatments protocols. This information can then be analysed and results reported.

It is pragmatic to a system of health that is individually tailored to say that not only should we measure the effectiveness of an intervention but we should also measure the effectiveness of the therapists. A research mythology does not have to be limited to the treatment being the only variable under observation, with modern computer statistical analysis assigning the practitioner as a variable becomes only as time consuming as inputting the data.

Environment

Environmentally there could be many factors that have an effect on the treatment such as:

- Does a noisy environment have a different success rate to a quiet environment
- Do particular smells have an effect on a treatment protocol
- If a patient has to wait a long time in a noisy waiting room does this affect the outcome

Patient

In biomedicine and CAM patient participation and acceptance is crucial. Only in the most severe cases of incapacity or mental illness can medication be administered without patient consent in biomedicine and any treatment is generally an agreement between patient and clinician regardless of the evidence base (Hotopf, 2002).

In CAM it is highly unlikely that a therapy will be administered without patient participation and agreement, but this does not necessarily imbue belief or trust in that intervention but rather merely shows agreement to participate. When designing an experiment it may be useful to understand if a participant has any belief, prior conception or understanding of a CAM or TCM intervention. This could be achieved in a pre-selection interview or questionnaire and followed up to see if attitudes had changed or been modified after exposure to the intervention or therapy.

Outcomes

The final arbiter to any treatments efficacy must still be outcome measures and choosing the right outcome measure for any research must also reflect the real world and should be measured in real world terms such as:

- Return to work
- Reduction in pain or symptomology
- Reduction in hospitalisation
- Reduction in negative behaviour
- Elevation of overall mood
- Cost effectiveness

With all research there is a time and cost implication of measuring outcomes and with acupuncture we are not looking for a change that can be directly observed, such as a change in blood chemistry where a blood test could well be the test of choice. Using an established outcome measuring questionnaire, which has undergone testing, can be a pragmatic way of collecting this data as the results will be of general wellbeing or a change in behaviour (Kane, 2004, p80-81)

Listed below are some of the more used questionnaires in acupuncture research (MacPherson, 2008, p84):

- Measure Yourself Medical Outcome Profile with additional open questions (MYMOP)
- Medication Change Questionnaire
- Wellbeing questionnaire (W-BQ12)
- Patient Enablement Index (PEI)
- SF-6D for economic evaluation

Within PTSD research the CAPS scale is generally considered the gold standard and is capable not only of diagnosis but continual monitoring, however as previously discussed it does rely on trained practitioners and is a time consuming structured interview. Other alternatives are:

Inherent Issues with PTSD

Issues with TCM Diagnosis

Conclusion

It is clear, from the number of articles published on the subject in dedicated acupuncture and TCM journals, that there are a growing number of dedicated people who work with acupuncture in the area of PTSD. That being said there is scarce evidence to prove its efficacy in terms of RCT or any other data collection paradigms including Case Studies Cohort or Historical.

It would seem that, in the USA at least, the military are leading the way in this area of research and, as of 2008, are providing funding of \$5 million per year for alternative methods of treatments (Chang, 2009) which includes acupuncture as well as other complimentary therapies. Unfortunately whatever research that has been conducted by the US Military has not been

published to date and data has proven hard to acquire. That being said, it is unlikely that the US Military would continue to invest in this area if there were not evidence to support or justify this level of investment. Currently acupuncture is used as part of the available treatment program for PTSD along with yoga, massage, meditation and reiki at Fort Bliss Restoration and Resilience Centre and the Warrior Combat Stress Reset Program at Fort Hood (Chang, 2009).

The United States federal government, as of financial year 2010, invested \$128.8 million in to CAM research through the National Institute of Health's (NIH) National Centre for Complementary and Alternative Medicine (NCCAM) with the view to sponsor and conduct research into CAM (NIH, 2010).

Acupuncturist without Borders (AWB) provides acupuncture clinics and training in areas of disaster and report of their successes in dedicated TCM and Acupuncture journals, such as *Acupuncture Today* (Chaney, 2008; Porter and Sommers, 2008; Pease et al., 2009). However none of the articles is peer reviewed or presents any data other than generalised clinical observations and reflection.

Most recently AWB as raised \$20,000 (as of May 2010) with the aim of helping trauma recovery after the Haitian earthquake of January 2010 (Fried, 2010) and provided training to local acupuncturists in Chile after the February earthquake (Georgieff, 2010). The primary treatment used by AWB is the National Acupuncture Detoxification Association (NADA) protocol which uses auricular acupuncture to treat PTSD (Johnson, 2010).

The NADA protocol has also been used to help sufferers of PTSD after the Twin Towers terrorist attack of September 11th 2001 (9/11). At St. Vincent's Catholic Medical Centre in association with the American Red Cross provided a free clinic in New York which came to an end in 2007 (Beychok, 2008). Even though a film documentary was produced (Cooley, 2009) no data has been published regarding this work even though the work itself is cited in articles supporting the treatment of PTSD.

Currently the New York County (NYC) 9/11 benefit program for mental health and substance use services does not include acupuncture of any kind as a treatment for PTSD (DOHMH, 2009). The author contacted one of the lead Psychiatrist of this facility, Dr. Shelly Menolascino, in order to seek any unpublished data that could be used in this review (see Appendix 2 for details).

Editorials, articles, personal reflection and letters, whilst valuable when generating a question

for experimentation, cannot be used to provide substantial evidence of the efficacy of acupuncture in the treatment of PTSD and more high quality research is needed in this area. Hollifield (2007) does demonstrate that acupuncture is a superior intervention than wait list control or group CBT and as such can be used to guide further research in this area and this is supported by the article with Dr Engle of unpublished data reported by Wendling (2008).

The New England School of Acupuncture has received a grant of \$1.2 million to conduct a study of acupuncture as a treatment of PTSD and at the Oregon College of Oriental Medicine doctoral fellow Sarah Hardesty is currently designing a pragmatic pilot study into PTSD. In combination the two studies being conducted by the Veterans Association in Washington DC and New Jersey and the previous study from Hollifield there is a reasonable hope that a meta-analysis of all the data may be conducted in the next two years.

The benefits of any research into PTSD cannot be underestimated in the current global climate of continuing conflict and natural disasters that effect ever larger populations it is a safe assumption that the rates of PTSD within the global population will continue to rise and any intervention that has a demonstrable efficacy should be a priority for researchers globally. The case for acupuncture is currently small but of sufficient strength to warrant further research and as noted by the WHO (1995) requires simple equipment and is inexpensive which makes it ideally suited to all environments.

Whilst funding for research will always be an issue it should not be impossible for regional organisations, such as SAR in the United States of America or the British Acupuncture Council (BAcC) in the United Kingdom, to encourage or require acupuncture training organisations to increase training in the area of good research practices. It is also incumbent on these regional organisations to develop an international standard and framework for research practice to enhance and standardise international research in this area.

Final Thoughts

The only thing that is absolutely guaranteed in a piece of research is that further research will always be necessary especially within CAM and TCM. Furthermore the methods and practices within this research must evolve in such a way that all relevant data regarding the effects of the intervention, the therapist be taken into account. Only when researchers in this area can demonstrate exactly what it is that is providing a healing affect will we be able to understand the modalities of this healing.

Word count 8784

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Appendix 1 – List of documents located during search

Author	Title	Review?	Review Number	Year Published	Database	Relevant	Retrieved
Hollifield M	Acupuncture for posttraumatic stress disorder: a randomized controlled pilot trial.	Yes	1	2007	CINAHL	Y	Y
Sinclair-Lian NA	Developing a traditional Chinese medicine diagnostic structure for post-traumatic stress disorder.	No	2	2006	CINAHL	Y	Y
Unknown	Complementary and alternative medicine.	N/A		2004	CINAHL	Not Relevant	
Abstracts	Abstracts of the 22nd Annual Scientific Meeting, American Pain Society, March 20-23, 2003.	N/A		2003	CINAHL	Not Relevant	
Gaeddert A	Ask the herbalist. Can herbal medicine help people with anxiety, panic & PTSD?	No	3	2002	CINAHL	Y	Y
Bell S	Headaches: assessment and management.	N/A		2002	CINAHL	Not Relevant	
Gardner-Abb	Needle	N/A		2002	CINAHL	Not Relevant	

ate S	techniques. Gentle treatment for general anxiety disorder, post-traumatic stress and episodic anxiety.						
Abstracts	The Gerontological Society of America 53rd Annual Scientific Meeting, November 17-21, 2000, Washington, DC.	N/A		2000	CINAHL	Not Relevant	
Abstracts	1999 Academy Annual Assembly Abstracts. Paper presentations and poster presentations.	N/A		1999	CINAHL	Outside Inclusion Criteria	
	Chronic fatigue syndrome.	N/A		1999	CINAHL	Outside Inclusion Criteria	
Abstracts	Abstracts: the Eleventh Annual Symposium of the Society for Acupuncture Research, October 1-3, 2004, San Francisco, California.	N/A		2004	CINAHL	Not Relevant	
Abstracts	Abstracts: the Tenth Symposium of the Society for Acupuncture Research, November 15-16, 2003, Harvard Graduate School of Education, Cambridge, Massachusetts.	N/A		2004	CINAHL	Not Relevant	
Abstracts	2002 Academy Annual Assembly Abstracts [corrected] [published erratum	N/A		2002	CINAHL	Not Relevant	

	appears in ARCH PHYS MED REHABIL 2002 Dec;83(12):1807]... 63rd Annual Assembly of the American Academy of Physical Medicine and Rehabilitation in conjunction with the American Hospital Section for Long-Term Care and						
Abstracts	3rd World Congress in Neurological Rehabilitation Venice, Italy.	N/A		2002	CINAHL	Not Relevant	
Book	Chapter 3: Physical therapy.	N/A		1993	CINAHL	Outside Inclusion Criteria	
Unknown	Acute pain management: operative or medical procedures and trauma. Clinical practice guideline.	N/A		1992	CINAHL	Outside Inclusion Criteria	
Abstracts	Conference on Emergency Medicine, Oxford, 27-30 September 1998.	N/A		1998	CINAHL	Not Relevant	
Chang JC	AOM program helps vets recover from PTSD.	No	4	2010	CINAHL	Y	Y
Chang JC	Comprehensive military PTSD treatment programs.	No	5	2009	CINAHL	Y	Y
Chang JC	Weighing the costs: integrative PTSD programs for veterans.	No	6	2009	CINAHL	Y	Y
Wright C	Acupuncture for PTSD in refugees: a secondary analysis.	N/A		2007	CINAHL	Not Available	

Flint GA	Emotional freedom techniques: a safe treatment intervention for many trauma based issues.	N/A		2006	CINAHL	Not Relevant	Book
Collinge W	Integrating complementary therapies into community mental health practice: an exploration.	No	7	2003	CINAHL	Y	Y
Devitt M	UNM explores role of acupuncture in treating PTSD: participants wanted for study.	N/A		2003	CINAHL	Not Relevant	
	Proceedings of the American Burn Association, 34th Annual Meeting, Thursday Saratoga, April 24-27, 2002, Hyatt Regency Chicago, Chicago, Illinois.	N/A		2003	CINAHL	Not Relevant	
Hollifield M	Acupuncture for posttraumatic stress disorder: a randomized controlled pilot trial.	Yes	1	2007	Medline	Repeat	Y
Gorisse E	Treatment of idiopathic facial pain following implant placement	N/A		2010	Medline	Not Relevant	
Pease M	Acupuncture for refugees with posttraumatic stress disorder: initial experiences establishing	No	8	2007	Medline	Y	Y

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	a community clinic.						
Kubo, Chiharu [Ed]	Psychosomatic medicine: Proceedings of the 18th World Congress on Psychosomatic Medicine, held in Kobe Japan, between 21 and 26 August 2005.	N/A		2006	PsvcINFO	Not Relevant	
Kalayjian, Ani	Trauma and the media: How movies can create and relieve trauma. [References]	N/A		2010	PsvcINFO	Not Relevant	
Diepold, John H Jr	Evolving thought field therapy: The clinician's handbook of diagnoses, treatment, and therapy. [References]	N/A		2004	PsvcINFO	Not Relevant	
Sorensen, James L [Ed]	Drug abuse treatment through collaboration: Practice and research partnerships that work.	N/A		2003	PsvcINFO	Not Relevant	
Bach. Amv K	VIII: Linkages between behavioral, psychosocial, and physical disorders.	N/A		1998	PsvcINFO	Outside Inclusion Criteria	
Blechman, Elaine A	Behavioral medicine and women: A comprehensive handbook.	N/A		1998	PsvcINFO	Outside Inclusion Criteria	
Thompson, Jennifer Jo	Reconsidering the Placebo Response from a Broad Anthropological Perspective	N/A		2009	Sociological Abstracts	Not Relevant	
Lohr, Jeffrey M.	Threats To Evidence-Based Treatment Of Trauma:	N/A		2008	Sociological Abstracts	Not Relevant	

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	Professional Issues And Implications						
V. Eisenlohr	Akupunktur – eine neue Option in der Behandlung traumatisierter Bundeswehrsoldaten?	No	9	2010	ScienceDirect (Elsevier)	German Language	Y
Pease M	Acupuncture for refugees with posttraumatic stress disorder: initial experiences establishing a community clinic.	No	8	2007	ScienceDirect (Elsevier)	Repeat	Y
James L. Oschman	Trauma energetics	No	10	2006	ScienceDirect (Elsevier)	Y	Y
Marisa Pease	Acupuncture for Refugees With Posttraumatic Stress Disorder: Initial Experiences Establishing a Community Clinic				ScienceDirect (Elsevier)		
Hollifield M	Acupuncture for posttraumatic stress disorder: a randomized controlled pilot trial.	Yes	1	2007	Cochrane Library	Repeat	Y
Hollifield M	Acupuncture for posttraumatic stress disorder: a randomized controlled pilot trial.	Yes	1	2007	PILOTS	Repeat	Y
Collinge W	Integrating complementary therapies into community mental health practice: an exploration.	No	11	2003	AMED	Y	Y

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Gorisse. E	[Treatment of idiopathic facial pain following implant placement]	N/A		2010	PubMed	Repeat	
Pease, Marisa	Acupuncture for refugees with posttraumatic stress disorder: initial experiences establishing a community clinic.	N/A		2007	PubMed	Repeat	
Hollifield, Michael	Acupuncture for posttraumatic stress disorder: a randomized controlled pilot trial.	N/A		2007	PubMed	Repeat	
Collinge, William	Integrating complementary therapies into community mental health practice: an exploration.	N/A		2005	PubMed	Repeat	
Streitberger, Konrad	Acupuncture in diagnosing prehospital unconsciousness.	N/A		2005	PubMed	Not Relevant	
Folkes, Crvstal E	Thought field therapy and trauma recovery.	N/A		2002	PubMed	Not Relevant	
Rosner, R	Between search and research: how to find your way around? Review of the article "Thought Field Therapy- soothing the bad moments of Kosovo".	N/A		2001	PubMed	Not Relevant	
Johnson. C	Thought Field Therapy- soothing the bad moments of Kosovo.	N/A		2001	PubMed	Not Relevant	
Du. L N	Naloxone and electroacupuncture (EA) improve the	N/A		1998	PubMed	Outside Inclusion Criteria	

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	immune function of traumatized rats.						
Ulett. G A	Conditioned healing with electroacupuncture.	N/A		1996	PubMed	Outside Inclusion Criteria	
Poliakova, A G	[Use of reflexotherapy in patients with sequelae of injuries]	N/A		1988	PubMed	Outside Inclusion Criteria	
	Thought Field Therapy clinical applications: utilization in an HMO in behavioral medicine and behavioral health services.						
Pilkington K	Acupuncture for anxiety and anxiety disorders – a systematic literature review	No	12	2007	AIM	Y	Y
Briefing Paper	Acupuncture and Depression	No	13	?	ARRC	Y	Y
Briefing Paper	Depression Anxiety and Acupuncture	No	14	2002	ARRC	Y	Y
Briefing Paper	National Guidelings on Mental Health	No	15	2009	ARRC	Y	Y
Michael Devitt	UNM Explores Role of Acupuncture in Treating PTSD	N/A		2003	Acupuncture Today	Not Relevant	N
Editorial Staff	Acupuncturists Without Borders: Hurricane Katrina Relief Efforts	N/A		2005	Acupuncture Today	Not Relevant	N
Editorial Staff	News in Brief – From the July 2006 Issue of Acupuncture Today	N/A		2006	Acupuncture Today	Not Relevant	N
Joe C. Chang	AOM	N/A		2010	Acupuncture	Repeat	Y

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	Program Helps Vets Recover from PTSD				Today		
Editorial Staff	Acupuncturists Without Borders: Hurricane Katrina Relief Effort	N/A		2005	Acupuncture Today	Not Relevant	N
Ellen Evans	In the Heart of Texas at SW Symposium	N/A		2010	Acupuncture Today	Not Relevant	N
Felice Dunas	Trauma: The Hidden Pathogenic Factor	No	16	2009	Acupuncture Today	Y	Y
Poll Result	Do you perform NADA treatment for posttraumatic stress disorder, or other similar disorders?	N/A		2009	Acupuncture Today	Not Relevant	N
Andrew Rader	Emotional Freedom	N/A		2005	Acupuncture Today	Not Relevant	N
Editorial Staff	AOM Flying High With the Air Force	N/A		2009	Acupuncture Today	Not Relevant	N
Andrew Rader	Nightmares, Dreams and Visualization	N/A		2009	Acupuncture Today	Not Relevant	Y
Kristen Porter	Refugees: Feeling At Home With Acupuncture	No	17	2008	Acupuncture Today	Y	Y
Andrew Gaeddert	Can Herbal Medicine Help People with Anxiety, Panic & PTSD?	No	18	2002	Acupuncture Today	Y	Y
Christine Lainig	A Golden Opportunity: Screening for Abuse	N/A		2001	Acupuncture Today	Not Relevant	N
<i>Greaorv Ross</i>	We Get Letters & E-Mail	N/A		2009	Acupuncture Today	Not Relevant	
Maria Dolores Diaz	Update on the Honduras Healing Recovery Project: Acupuncture	N/A		2005	Acupuncture Today	Not Relevant	
Tina Bevchok	Healing Old Wounds With Acupuncture	No	19	2008	Acupuncture Today	Y	Y
Joe C. Chang	Comprehensive Military PTSD Treatment	No	20	2009	Acupuncture Today	Y	Y

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	Programs						
Search Listing	Acupuncture Poll Archives - 2009	N/A		2009	Acupuncture Today	Not Relevant	N
	Lead by Example			2009	Acupuncture Today	Not Relevant	N
Editorial Staff	Army To Include AOM for Pain Treatment	N/A		2010	Acupuncture Today	Not Relevant	N
Editorial Staff	Reach Out and Touch in Person	N/A		2008	Acupuncture Today	Not Relevant	N
Bruce H. Robinson, MD	Dealing With Problem Patients	N/A		2010	Acupuncture Today	Not Relevant	N
Gregory Ross	Not the Emperor's Acupuncture	N/A		2008	Acupuncture Today	Not Relevant	N
Marv Chaney	AWB National Veterans' Project Provides Community Training ...	N/A		2008	Acupuncture Today	Not Relevant	N
Gregory Ross	The Little Laughing Lady	N/A		2008	Acupuncture Today	Not Relevant	N
Joe C. Chang	Weighing the Costs	No	21	2009	Acupuncture Today	Y	Y
Bruce H. Robinson	Bridging the Gap	N/A		2009	Acupuncture Today	Not Relevant	N
Joe C. Chang	Acupuncture Collaboration with the US Navy and the US Marines	N/A		2009	Acupuncture Today	Not Relevant	N
Editorial Staff	Acupuncturists Team Up To Provide Relief in Haiti	N/A		2010	Acupuncture Today	Not Relevant	N
Kirk Moulton	Bringing Qi and Light to Burma	N/A		2009	Acupuncture Today	Not Relevant	N
Misha Cohen	Gynecology Guidelines	N/A		2003	Acupuncture Today	Not Relevant	N
Search Listing	General Acupuncture	N/A		N/A	Acupuncture Today	Not Relevant	N
Search Listing	Acupuncture Techniques	N/A		N/A	Acupuncture Today	Not Relevant	N
Andrew Gaeddert	Acupuncture Today is a leading provider of acupuncture news, info ...	N/A		N/A	Acupuncture Today	Not Relevant	N
Search Listing	Acupuncture & Acupressure	N/A		N/A	Acupuncture Today	Not Relevant	N
Marc O'Regan	Caring for the Victims of the Pakistan Earthquake: A Report on ...	N/A		2006	Acupuncture Today	Not Relevant	N

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Search Listing	Herbal Medicine	N/A		N/A	Acupuncture Today	Not Relevant	N
Maria Dolores	Update on the Honduras Healing Recovery Project: Acupuncture ...	N/A		2005	Acupuncture Today	Not Relevant	N
Joe C. Chang	CAM For Prenatal Care	N/A		2010	Acupuncture Today	Not Relevant	N
Darren Starwvnn	Color Light Acupuncture Techniques for Treatment of Pain ...	N/A		2008	Acupuncture Today	Not Relevant	N
Joe C. Chang	Becoming a Patient	N/A		2010	Acupuncture Today	Not Relevant	N
Linda Franck	Should NICE evaluate complementary and alternative medicine?	N/A		2007	BMJ	Not Relevant	N
Harvey Marcovitch	What's new this month in BMJ Journals	N/A		2006	BMJ	Not Relevant	N
Fiona Godlee	Simple problems please, and one at a time	N/A		2005	BMJ	Not Relevant	N
Kristina M Adams,	Healthcare challenges from the developing world: post-immigration refugee medicine	N/A		2004	BMJ	Not Relevant	N
Charlotte Paterson	Characteristic and incidental (placebo) effects in complex interventions such as acupuncture	No	22	2005	BMJ	Y	Y
Tang, J. L	Review of randomised controlled trials of traditional Chinese medicine	No	23	1999	BMJ	Y	Y
Collinge W	Integrating complementary therapies into community mental health	No	7	2003	AMED	Y	Y

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Author	Title	Review?	Number	Year	Database	Relevant	Printed
	practice: an exploration.						
Hollifield M	Acupuncture for posttraumatic stress disorder: a randomized controlled pilot trial.	Yes	1	2007	JCM	Y	Y
NCT01060553	Pilot of Acupuncture to Improve Quality of Life in Veterans With Traumatic Brain Injury (TBI) and PTSD	No Data	24	2010	ICTRP	v	v
NCT00868517	Examining the Effect of Acupuncture on Sleep Difficulties Related to Post Traumatic Stress Disorder	No Data	25	2009	ICTRP	v	v
NCT00320138	Acupuncture for the Treatment of Posttraumatic Stress Among Military Personnel	No Data	26	2006	ICTRP	v	v
NCT00055354	Acupuncture for the Treatment of Post-Traumatic Stress Disorder (PTSD)	No Data	27	2002	ICTRP	v	v
Author	Title	Review?	Number	Year	Database	Relevant	Printed

Appendix 2 – Requests for data

Email from Richard C. Niemtow 12th August 2010

Do a Google search for PTSD Acupuncture WRAMC and you will find a completed military trial that should help you.

Best wishes,

Richard

Richard C. Niemtow, MD, PHD, MPH

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Colonel, USAF, MC, FS (Retired)
CAM Consultant USAF Surgeon General
President American Acad of Med Acup
Editor in Chief:Medical Acupuncture
Senior Editor:JACM
SEND ALL E-MAIL TO N5EV@AOL.COM
E-MAIL SCAN: ESET SMART SECURITY VERSION 4.0
SPYWARE DOCTOR and MALWAREBYTES
OS:WINDOWS7
Residence:9800 Cherry Hill Road
College Park,Maryland 20740 USA
Home Telephone:301-937-7424
Mobile:619-647-7274
FAX:301-595-8382
E-FAX:240-757-0054
Web Site:WWW.N5EV.COM

Clinical Schedule: www.calendarwiz.com/n5evappointments

From: JHS [<mailto:jason@hartleymsmith.com>]
Sent: Wednesday, August 11, 2010 11:18 AM
To: n5ev@aol.com
Subject:

Dear Mr Niemtzw

My name is Jason and I am currently writing my dissertation (Acupuncture as an adjunct therapy for Post Traumatic Stress Disorder (PTSD) (Review)) for my degree in Acupuncture at Salford University (England) and I came across your name in relation to work with PTSD and the US Air Force.

I was wondering if you are aware of any other clinical trials in the area of acupuncture and PTSD apart from the one conducted in 2007 by M Hollifield? I have found numerous articles and commentaries in this field but it would seem to be lacking in studies.

Many thanks for your time in advance

Jason Hartley-Smith

Email from Professor Simon Wessely 17th August 2010

Am not aware of any trials I am afraid in the UK. Doubt that any are being done. I know for sure that none are being done in the UK Military

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Good luck

SW

PS the history of shell shock is written and was published a few years ago! John Wiley, From Shell Shock to PTSD

Professor Simon Wessely
Vice Dean, Institute of Psychiatry,
Head, Department of Psychological Medicine,
Director, King's Centre for Military Health Research,
King's College London

THIS SEPTEMBER FOR THE FINAL TIME I AM CYCLING TO PARIS TO RAISE FUNDS FOR THE ROYAL BRITISH LEGION TO SUPPORT EX SERVICEMEN AND WOMEN IN NEED.

IF YOU WISH TO SPONSOR ME PLEASE VISIT <http://www.justgiving.com/Simon-Wessely>

From: Jason Hartley-Smith [mailto:J.Hartley-Smith@edu.salford.ac.uk]

Sent: 17 August 2010 17:33

To: Wessely, Simon

Subject:

Professor Wessely

My name is Jason and I am currently a 3rd year student at the University of Salford. I am currently writing my dissertation into - Acupuncture as an adjunct therapy for Post Traumatic Stress Disorder. So basically I am looking to review all the current information on using Acupuncture with therapies such as CBT, EMDR and pharmacology.

Looking at the Kings Centre for Military Health it lists you as having interests into medicine and psychiatry and that you are publishing a new history of shell shock which is why I am sending you this email.

From my research it is clear that the United States armed forces are conducting some trials into this area and there have been some positive results so my question is are you aware of the UK armed forces conducting any research on these lines? Or know of anyone with an interest into this area who you feel it would be possible for me to talk to?

I am looking for good Controlled Trials if possible but I will also be reviewing any trials that are of lesser quality in order to avoid any of the research pitfalls when I get to my Masters – which hopefully will be a primary research in this area.

It may be worth stating that I am not out to give acupuncture a good or bad name; rather I am

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looking to see if this area warrants further research as it could potentially be an excellent experiment to take forward to PhD circumstance permitting. I would also state that I am aware that certain areas of medicine have a rather, how shall I say, poor view of acupuncture. From this stand point the more research that can demonstrate the benefit or lack thereof can only help our overall understanding of this field and help direct practitioners to areas where positive benefit can be demonstrated.

If you feel that you have time for a quick conversation please give me a call on either.

01612721172 or 07946313129

My thanks in advance for your time and any response you are able to offer.

Jason Hartley-Smith

Email from Thomas W. Findley MD PhD 17th November 2010

Jason,

I will be presenting preliminary data next March 21, 2011 at a conference in Washington DC
www.battlefieldhealthcare.com

We certainly expect to have a publication some time in 2011 but in any case you can refer to the abstract from my presentation.

Needless to say I don't have anything to share yet

If we knew what we were doing, it wouldn't be called research, would it?

-- Albert Einstein

Thomas W. Findley MD PhD
Center for Healthcare Knowledge Management
VA New Jersey Healthcare System
385 Tremont St East Orange NJ
973-676 1000 x 2713 fax 973 395 7114

thomas.findley@va.gov

Professor, Physical Medicine and Rehabilitation
UMDNJ - New Jersey Medical School

From: JHS [<mailto:jason@hartleymsmith.com>]

Sent: Tuesday, November 16, 2010 12:42 PM

To: Ray, Kathleen G.

Cc: Findley, Thomas W.

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Subject:

Kathleen Ray

Many apologies for taking up your time and in advance I hope you don't mind. I understand (from an out of office reply) that Thomas Findley is on extended medical leave and I am directed to you.

I am currently studying for my degree at Salford University in the UK and I am writing my dissertation on the roll of acupuncture as an adjunct therapy for the treatment of PTSD. I am conducting a literature review rather than conducting primary research. It would seem that the UK armed forces are not conducting any investigations into this area but the US military seem to be showing interest.

In my search for material to review I found on clinicaltrials.gov NCT01060553 of which your name (Thomas and Kathleen) are contacts. I notice that as of 15^{13th} July 2010 you were still recruiting.

So my questions are:

1. Has the trial begun as yet?
2. Do you have a finish date as yet?
3. Will this data be published or available before 2011?

I would like to include this data in my research paper but of course this will be dependent on if the research is ready before the deadline for my paper.

Having never asked anyone for data before from potentially un-published work I am not sure of the response I will get, so apologies if I am asking for something that is frowned upon.

Many thanks for your kind time in advance

Jason Hartley-Smith

Email from Kathleen Ray 17th November 2010

Hi Jason,

Our trial has just started, it is a pilot study and we will only be looking at 60 vets, 30 with treatment and 30 without. We will not have available data for at least 6-8 months as we have just started. This study will be the foundation for a multi-site grant that we will apply for in June 2011 and start, most likely, January 2012. Tom (Findley) will be back in a few weeks so he will be able to answer any questions you may have. I have attached an article by Hollifield; we are using the same protocol. I will look around for some more information for you. Best of luck.

Kathleen

Kathleen Ray, LCSW/MSW
Research Assistant

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REAP
VA Medical Center
385 Tremont Ave
East Orange, NJ 07018

973.676.1000 x1187
Fax 973.395.7114

kathleen.ray2@va.gov

From: JHS [mailto:jason@hartleysmith.com]

Sent: Tuesday, November 16, 2010 12:42 PM

To: Ray, Kathleen G.

Cc: Findley, Thomas W.

Subject:

Kathleen Ray

Many apologies for taking up your time and in advance I hope you don't mind. I understand (from an out of office reply) that Thomas Findley is on extended medical leave and I am directed to you.

I am currently studding for my degree at Salford University in the UK and I am writing my dissertation on the roll of acupuncture as an adjunct therapy for the treatment of PTSD. I am conducting a literature review rather than conducting primary research. It would seem that the UK armed forces are not conducting any investigations into this area but the US military seem to be showing interest.

In my search for material to review I found on clincialtrials.gob NCT01060553 of which your name (Thomas and Kathleen) are contacts. I notice that as of 1513th July 2010 you were still recruiting.

So my questions are:

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2. Do you have a finish date as yet?
3. Will this data be published or available before 2011?

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Having never asked anyone for data before from potentially un-published work I am not sure of the response I will get, so apologies if I am asking for something that is frowned upon.

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Many thanks for your kind time in advance

Jason Hartley-Smith

Email from Michelle Kennedy Prisco 16th November 2010

Hi Jason:

Good to hear from you. The study is in full swing presently. We anticipate that we will be recruiting Veterans for inclusion in the study for the next 9 months or so. I do not anticipate having the data analyses completed and ready for publication before the end of the calendar year 2011. I hope this answers your questions.

Thank you for your interest in VA research and please do not hesitate to contact us for any further questions or concerns.

Sincerely,

Michelle Kennedy Prisco, MSN, ANP-C
Nurse Practitioner
War Related Illness and Injury Study Center
Washington D.C. VA Medical Center
Room GD215a
50 Irving Street, NW
Washington, D.C. 20422

Telephone: (202) 745-8000 ext 6235

Toll-Free (800) 722-8340

Pager: (202) 516-3699

Fax: (202) 518-4666

Email: michelle.prisco@va.gov

<http://www.warrelatedillness.va.gov/dc>

From: Jason Hartley-Smith [mailto:J.Hartley-Smith@edu.salford.ac.uk]

Sent: Tuesday, November 16, 2010 12:18 PM

To: Prisco, Michelle K

Subject: Question about your study NCT00868517 - Examining the Effect of Acupuncture on Sleep Difficulties related to PTSD

Michelle Prisco

Many apologies for taking up your time and in advance I hope you don't mind.

I am currently studding for my degree at Salford University in the UK and I am writing my dissertation on the roll of acupuncture as an adjunct therapy for the treatment of PTSD. I am conducting a literature review rather than conducting primary research. It would seem that the

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UK armed forces are not conducting any investigations into this area but the US military seem to be showing interest.

In my search for material to review I found on clinicaltrials.gov NCT00868517 of which your name is a contact. I notice that as of 15th June 2010 you were still recruiting.

So my questions are:

1. Has the trial begun as yet?
2. Do you have a finish date as yet?
3. Will this data be published before 2011?

I would like to include this data in my research paper but of course this will be dependent on if the research is ready before the deadline for my paper.

Having never asked anyone for data before from potentially un-published work I am not sure of the response I will get, so apologies if I am asking for something that is frowned upon.

Many thanks for your kind time in advance

Jason Hartley-Smith

Appendix 3 – Requests for access to database

Email to request access to ECOJ – English China Online Journals

Sent 12th August 2010 to overseas@wanfangdata.com

Hello

I filled out the form for a Trial to your site but there was a technical error.

I am an undergraduate student researching mental health and acupuncture any access you can afford me to your site would be most welcome.

I am studying Traditional Chinese Medicine at the University of Salford in England and there are a few journals on your site I would be most interested in searching.

Many thanks for your kind time

Jason Hartley-Smith

