PATIENT CONFIDENCE IN ACUPUNCTURE:

RETURNING FOR CARE AND PAIN REDUCTION

by

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CERTIFICATE OF APPROVAL

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Abstract

Background: Placebo effects such as patient confidence in treatment are suspected to influence patient compliance and treatment outcomes and are especially important to recognize in observational and non placebo-controlled clinical trials. **Objectives**: This study was undertaken to evaluate patient-reported confidence in acupuncture treatment as a possible factor in patient compliance (i.e. returning for a 5th visit) and change in pain severity. **Methods**: Confidence was measured with a -2 to 2 scale and pain was measured with a 0 to 10 scale in questionnaires completed by patients at an Oriental medicine teaching clinic. Possible associations in this retrospective non-randomized cohort study were analyzed by logistic and linear regression. **Results**: Data were obtained on a series of 1213 adult patients seeking acupuncture treatment for joint and muscle pain. At baseline, 874 patients (72%) expressed either a positive or negative opinion in their confidence in the acupuncture treatment. Of the original cohort, 104 patients (8.6%) returned for a 5th visit. This study failed to detect a significant difference between types or levels of confidence and returning for a 5th visit; however a weak inverse association was observed between level of confidence and improvement in pain.

Introduction

Acupuncture

The National Center of Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH) describes acupuncture as a "healing practice" that "aims to restore and maintain health through stimulation of specific points on the body." In this therapy of traditional Chinese medicine, thin solid single-use sterile needles are inserted at specific points on the body to address disharmonies in the circulation of *qi* and *xue* ('blood') through a system of 12 regular meridians and 8 extra meridians by strengthening or draining as indicated by the individual's presentation of *qi* and *xue* (Kaptchuk, 1983; Shanghai College of Traditional Medicine, 1981).

Acupuncture Use in the United States

There is a large and increasing use of acupuncture in the United States, often for the treatment of pain. In 2007, an estimated 3.1 million adults in the United States, with a total of 17.6 million visits, used acupuncture in the previous year. This is an increase from an estimated 2.1 million adults who previously used acupuncture in 2002 as reported by the National Health Interview Survey (NHIS) at the National Center for Health Statistics, Centers for Disease Control and Prevention (Barnes et al., 2008). Among these patients, the median number of treatments per year was 2.42, 95% confidence interval (CI): 2.10 to 2.75 (Nahin et al., 2009). Acupuncture has been recognized by the World Health

Organization (WHO) and Cochrane systematic reviews as an effective treatment as demonstrated in controlled trials for a wide range of ailments including a variety of pain issues (WHO, 2003; Green et al., 2005; Trinh et al., 2006). The chief health concern for patients at the Oregon College of Oriental Medicine (OCOM) teaching clinic has been muscle and joint pain (58%) followed by anxiety or excess worry (4%) (Marx et al., 2012).

Placebo-Controlled Trials

The randomized double-blinded placebo-controlled trial is the gold standard in research design. A placebo-controlled trial is a study design that compares a specific treatment, or a verum (a.k.a. 'true') treatment, to a placebo treatment, or sham treatment, which is something that is commonly agreed upon as being inert, or 'not true'. A three-arm placebo-controlled study design may compare a verum treatment to both a placebo treatment and a no-treatment (i.e., wait list) group. Frequently, randomized three-arm trials of acupuncture are not able to demonstrate a significant difference between acupuncture treatment and placebo or sham treatment but are able to demonstrate a difference between acupuncture treatment and no treatment; and are able to demonstrate a difference between placebo and no treatment. This situation raises two questions: "What if the defined placebo treatment is not truly inert?" and "What is the unmeasured non-specific effect, or placebo effect, of the placebo treatment?" (Finniss et al., 2010; Thompson et al., 2009; Ezzo, 2000; Manheimer, 2007)

In the most general sense for clinical research and practice, placebo effects are any positive treatment outcomes that are not attributed to the specific treatment intervention, and have become an important issue in acupuncture research. Measurements of psychosocial factors that might contribution to the placebo effect are commonly included in acupuncture studies (Ezzo et al., 2000; Manheimer et al., 2007; Miller et al., 2009).

The Placebo Effect

Psychosocial factors such as patient expectancy, classical conditioning, the therapeutic patient-provider relationship and sociocultural 'meaning' are all believed to play a role in the placebo effect. Other psychosocial factors potentially involved include patient learning, memory, motivation, somatic focus, reward, anxiety reduction and meaning that might be attributed to patient attitudes and beliefs or to the context and relationship of the clinical encounter. Of the possible patient and clinic factors contributing to the placebo effect, there has been research interest in patient expectancy (Finiss et al., 2010; Thompson et al., 2009).

Patients' expectation of benefit from treatment has been shown to contribute to the placebo effect (Miller et al., 2009). An example of patient expectancy is a patient reported confidence in treatment which is described as an 'outcome expectation', i.e., the patient expects that his/her treatment outcome will be benefited by an external action rather than benefited by individual action and self-efficacy, the so-called 'efficacy expectation'. Patient confidence as an

outcome expectation may reflect a combination of hope, wishful thinking, belief in potency of the procedure, and faith in the provider (Bandura, 1977). Yet, interestingly, David et al. (2004) found that expectancy and hope are different psychological constructs.

Confidence and treatment outcomes

Confidence is frequently measured by a single survey question adapted from the treatment credibility scale developed by Borkovec and Nau in 1972: "How confident do you feel that this treatment can alleviate your complaint" with a five-point Likert-type response scale ranging from 'very confident' to 'very doubtful' (Vincent & Lewith, 1995). Measurements of patient expectations and confidence in treatment are frequently included in acupuncture studies and have been shown to have a positive association with treatment outcomes in acupuncture studies (Wasan et al., 2010; Foster et al., 2010; Kong et al., 2009; Linde et al., 2007; Weinland et al., 2010).

Confidence and patient compliance

Because acupuncture treatments are considered to have a cumulative effect, returning for treatment is important for treatment to be successful. At least two published studies have investigated patient confidence in treatment and its association with adherence to treatment programs. Fischer et al. (2010) found that patients with lower confidence had an increased chance of missing an appointment in a pulmonary rehabilitation program. Other factors that increased

the chance of missing an appointment were living alone, smoking and a lower fat-free body mass. In another study by Daugherty (2005), 20% of multiple sclerosis patients who didn't complete the prescribed medication therapy attributed their non-completion to having a lower confidence in the treatment. If patient compliance is connected to confidence in the treatment, then assessing patient confidence becomes important for receiving cumulative effects of treatment and for preventing loss to follow-up in research trials.

Data Collection Program at an Oriental Medicine College

The effects of patient confidence in treatment have mostly been investigated in the context of randomized clinical trials but those effects may differ for patients seeking treatment in a clinic setting. Therefore practice-based research may have important information to contribute to understanding placebo effects, patient compliance and treatment outcomes (Sherman et al., 2004; Barlow et al., 2011). The cultivation of patient confidence in treatment has been explored as a therapeutic tool for guiding patients to their best possible health outcomes and may be a necessary component of patient care (Miller et al., 2009; Thompson et al., 2009).

Since 2009, the Oregon College of Oriental Medicine has been collecting patient-centered and practice-based data at their teaching clinic. At the beginning of their 1st and 5th visits, patients are asked to complete standardized and validated questionnaires including the Measure Your Medical Outcome Profile (MYMOP) and five short forms and a single question from the Patient Reported

Outcome Measurement Information System (PROMIS) including global physical health, global mental health, physical functioning, pain interference, and pain severity. The questionnaires also include questions about patient demographics, checklists for pain locations and health issues and the question, "As of today, how confident, or doubtful, are you that acupuncture will work for you?" to measure a patient's confidence in acupuncture (Marx et al., 2012).

Objectives

There were three objectives for this study. The first objective was to evaluate whether patients who presented with joint and muscle pain at the OCOM teaching clinic were more or less likely to return for a 5th treatment if they had an opinion, either positive or negative opinion, on confidence in acupuncture treatment, as compared to having no opinion, after adjusting for other determinants of adherence. Secondly, this study considered if patients were more or less likely to continue treatment through five visits if they reported more confidence in acupuncture at their first visit, compared to less confidence, after adjusting for other determinants of adherence. The third study objective was to evaluate whether the baseline level of confidence in acupuncture for patients with joint and muscle pain who returned for a fifth treatment was associated with improvement in pain, after adjusting for other potential determinants of pain.

Methods

Design and setting

This was a non-randomized cohort study of a consecutive series of patients who received care at the Oregon College of Oriental Medicine (OCOM) teaching clinic in Portland, Oregon between November 1, 2009 and June 30, 2011. Patient data were collected by self-completed questionnaires prior to receipt of individualized acupuncture treatment on the 1st and 5th visits.

Participants

Patients at the teaching clinic are treated by student interns who are in their final year of the Master of Acupuncture and Oriental Medicine program under the supervision of licensed acupuncturists with a minimum of five years practice experience. The sample was comprised of patients whose primary treatment concern was joint or muscle pain. Patients were excluded if they were younger than 20 years of age or were 80 years and older. Pregnant women and patients whose course of treatment from their first visit to fifth visit exceeded six month's time were also excluded. Patients who returned to the clinic for herbal treatment, massage, community-style acupuncture, or to be treated by a member of the faculty or a doctoral resident within their first four visits were not included. Only patients who expressed a positive or negative opinion were included in the data set used to evaluate the second study question (more confident versus less confident); and only patients who returned for their 5th visit were included in the data set to evaluate the third study question (level of confidence). Observations in

the data were excluded if they had a D or F grade from the OCOM data entry quality control check.

Pregnant women, children, and older patients were excluded since acupuncture protocols for treating joint and muscle pain are different for these groups. Fewer points are needled, the insertion of needles is shallower, and needles are retained for a shorter time (Auteroche et al., 1989; Chen & Wang, 1988; Cheng, 1987). Therefore, in order to minimize differences in treatment protocols that may influence patient retention and outcomes, the study sample was limited to non-pregnant patients between 20 and 80 years of age. An additional reasoning was that pregnant women seeking treatment for low back pain associated with late term pregnancy are likely to have that health concern resolved on the event of their delivery, prior to a 5th acupuncture visit.

Patients whose course of treatment from their 1st to 5th visit exceeded 6 months (180 days) were excluded from the analysis of change in pain (question #3) because this length of time is clinically impractical for acupuncture treatment of health concerns. Weekly acupuncture treatment is the most common practice in the United States; even more frequently spaced treatments, two to five treatments in a week, are considered by many acupuncture practitioners as necessary for successful outcomes and is the common practice in China (Dharmananda, 2004).

Human Subjects Protection

The data collection and analysis protocol (IRB11-037) were approved by the Oregon College of Oriental Medicine in 2011, and this data analysis was approved by the Institutional Review Board of the Oregon Health &Science University (IRB00008486) in 2012. All data were de-identified.

Data Source and Measurements

At their first treatment, patients are informed in writing and verbally that their data may be used in research. Those who provide written consent are then asked to complete several questionnaires as part of the intake form. The general demographic questionnaire includes questions about age, race, and previous experience with acupuncture and a question about patients' confidence in acupuncture treatment.

Questionnaires about health status characteristics include the MYMOP (Measure Your Medical Outcome Profile) instrument and several PROMIS (Patient Reported Outcomes Measurement Information System) instruments. The MYMOP instrument asks patients to name their primary medical problem for which they are seeking treatment and to rate the severity of that problem over the last week on a 7-point scale. The MYMOP instrument also asks patients to rate an activity that their medical problems makes difficult or prevents them from doing, and their general feeling of wellbeing during the previous week. The elements of the PROMIS instrument that are included in the intake form are:

global mental health (4 items), global physical health (4 items), severity of pain (1 item), pain interference (7 items), and physical functioning (10 items). These sets of questions from the PROMIS are well validated and standardized by the National Institutes of Health (NIH) (Hays et al., 2009; Reeve et al., 2007). The intake form also includes a 19-item checklist to specify location of pain and a 21-item checklist for other health problems.

The same questionnaires are given to patients prior to treatment on their fifth visit. Each patient's primary health concern as written on the first visit's MYMOP questionnaire is inserted into their fifth visit's MYMOP questionnaire by clinic staff. As the point in clinical treatment where a change in symptoms could be expected, the fifth visit was selected by expert acupuncture practitioners who serve on the College Research Committee which oversees the clinic outcomes research program (Marx et al., 2012).

Research Questions

#1: Among patients with joint and muscle pain at an Oriental medicine teaching clinic, do more patients return for a 5th treatment if they reported an opinion on acupuncture compared to patients who didn't report an opinion, after adjusting for other determinants of adherence?

#2: Among patients with joint and muscle pain at an Oriental medicine teaching clinic who reported an opinion on acupuncture, do more patients return for a 5th visit if they reported more confidence in acupuncture treatment compared

to those who reported less confidence, after adjusting for other determinants of adherence?

#3: Among patients with joint and muscle pain who returned for a 5th visit at an Oriental medicine teaching clinic, do patients with higher confidence in acupuncture report greater decrease in pain compared patients with lower confidence, after adjusting for other determinants of pain reduction?

Outcome Variables

The outcome variables are whether or not a patient returned for the fifth visit and the change in pain severity between first and fifth visits. The change in pain severity was calculated as the level of pain severity at the 5th visit minus the level of pain severity at the 1st visit when the level of pain severity was reported on a 0 to 10 scale, with 0 representing no pain and 10 indicating 'worst imaginable pain'. Negative integers for change in pain indicate a decrease in pain at the 5th visit, zero indicates no change, and positive integers indicate in increase in pain.

Predictor Variables

In the OCOM clinic intake form, confidence in treatment is measured at the patient's first visit by the question, "As of today, how confident or doubtful are you that acupuncture will work for you?". The possible responses are: "Very confident", "A bit confident", "Neutral", "A bit doubtful", and "Very doubtful".

The predictor variables were three separate representations of a patient's confidence in acupuncture treatment for the three different study objectives that included whether the patient reported confidence, either more or less, in acupuncture (opinion on confidence), whether the patient was more or less confident (direction of confidence) and the patient's level of confidence in acupuncture treatment.

Having an opinion on confidence was coded as a dichotomous variable (opinion or no opinion). The opinion category included the responses 'very confident', 'a bit confident', 'a bit doubtful' and 'very doubtful'. The no opinion category included the 'neutral' responses and non-responders, and was the referent variable.

The direction of a patient's confidence in acupuncture treatment was represented by the dichotomous variable (negative, positive). The positive category included 'very confident' and 'a bit confident'; and the negative category included 'a bit doubtful' and 'very doubtful' and was the referent variable. 'Neutral' and non-responders are not included.

The level of confidence in acupuncture was represented by a scale of -2 to 2, where -2 indicated 'very doubtful', 2 indicated 'very confident' and 0 indicated 'neutral' or no response.

Controlling for possible confounders or effect modifiers

Co-variables used in analysis as possible confounders or effect modifiers described the following characteristics: patient characteristics, health status characteristics, and treatment context characteristics.

Co-variables for patient characteristics

Co-variables from the demographic questionnaire included current age in years at first visit, gender, and race/ethnicity. The reference variable for gender was set to 'female'. The OCOM patient survey presented the race/ethnicity question as 'optional' and half of the study sample did not respond so race/ethnicity was coded into three categories: 'white', 'other than white' and 'no response'. The reference variable was set to 'white'.

Sherman et al. (2004) found that patients with chronic low back pain were less than half as likely to have higher expectations of acupuncture treatment when they were over 65 years of age. Ford et al (2010) found African American patients more likely to report higher confidence in treatment in a sample of critically ill patients at a medical university intensive care unit. Therefore, it was important to control for age and race as possible modifiers of confidence in treatment.

Co-variables for health status characteristics

Characteristics of health status were included in the analyses in order to adjust for patients' baseline health status, pain levels and quality of life. For

example, someone with lower health status and physical functioning may have more difficulty returning to the clinic for five visits; or a patient starting with greater pain severity has the potential for larger change in pain at the 5th visit compared to someone with lower pain severity at baseline. As well, Ford et al. (2010) found that patients with lower quality of life prior to treatment for critical illness reported lower confidence in treatment efficacy.

The health status co-variables included sums from two checklists, two dichotomous questions and four instruments from the 1st visit intake questionnaire. The two checklists included a 19-item checklist to specify the location of pain (19 options including 'other') represented in the analyses by a sum of locations checked by the patient; and a 20-item checklist to identify health concerns other than joint and muscle pain (20 options including 'other') represented by a sum of health concerns other than joint and muscle pain, non-pain symptoms. The two questions used in analyses were "Do you now have any chronic (or long term) diseases?" and "Are you now receiving health care elsewhere for your condition(s)?" with two possible responses: no or yes.

Acupuncture is commonly used as complementary care to conventional medicine (also termed 'Western medicine', 'biomedicine', or 'allopathic medicine'). As complementary care, acupuncture providers consider acupuncture treatments to amplify or have synergistic effects on other medical care. While most research has looked at acupuncture as alternative care to conventional medicine, a number of studies have looked at acupuncture as adjuvant to conventional care and found the combination superior to conventional care alone

(Berman et al., 1999; Berman et al., 2004; Kjendahl, et al., 1997; Wong, et al., 1999; Elden, 2005). In order to control for possible synergistic effects, a dichotomous variable was included to represent whether or not a patient was receiving health care elsewhere for their condition.

The four health status instruments included scores for global physical health, global mental health and physical functioning from PROMIS, and the MYMOP score.

The scores for the PROMIS measures were a sum of four items each for global physical health and global mental health with a possible range of 4 to 20, and a sum of 10 items for physical functioning with a possible range of 10 to 50. The PROMIS instrument includes a single item to measure the severity of pain on a 0 to 10 scale. This item was recoded into a five-point scale, 1 to 5 (1 = 0; 2 = 1 through 3; 3 = 4 through 6; 4 = 7 through 9; and 5 = 10) for the calculation of the global physical health score (Hays et al., 2009) and was used individually as a baseline measurement of pain severity. Larger numbers for the PROMIS scores in this study indicate worse health or physical functioning. This is different from the conventional PROMIS coding and standardized t-scores where higher scores on global health, mental and physical health, and physical functioning represent better health and functioning.

A patient's MYMOP score was the average of the three scores, 0 to 6, for the following items: the 'main health concern' and its impact on 'one activity' that was indicated by the patient, and its impact on general 'wellness'. Larger numbers for the MYMOP score indicate worse health and less wellbeing. The

MYMOP questionnaire also included an item for duration of the patient's main health concern (0 to 4 weeks, 4 to 12 weeks, 3 months to 1 year, 1 to 5 years and over 5 years). This was recoded into categories of acute and chronic where 'acute' was defined as the onset of pain occurring within the past three months, the reference level, and 'chronic' defined as three months or more of pain for the duration of pain (Ezzo et al., 2000).

In order to maximize recall accuracy, the MYMOP and PROMIS surveys asked the patient to consider the previous seven days when responding to the questions.

Cases with missing or incomplete items for MYMOP or PROMIS instruments were excluded.

Co-variables for treatment context characteristics

Co-variables specific to the treatment context included patients' prior experience with acupuncture, average days between visits, and the academic quarter. Experience with acupuncture was measured with the question: "Have you ever had acupuncture treatment(s) before today?" with three choices: "Yes - many times" (the reference variable), "Yes - a few times" or "No - never" with an additional category for patients who did not respond to this question. Individuals who had tried acupuncture before have been shown to be four times more likely to have high expectations (Sherman et al., 2004).

The average days between visits was calculated as the length of time between the 1st visit and 5th visit, measured in days, divided by five. Harris et al.

(2005) found greater analgesic effect with more frequent acupuncture treatments when three treatments weekly were compared to weekly treatments. In order to control for possible dosing effects of treatment frequency, a variable for the average days between each treatment was included in the analysis.

A variable for academic quarter was included in the analyses in order to control for intern experience and confidence. The academic quarter was categorized as 'fall' (September through December) when interns begin to see patients in the clinic, 'winter' (December through April), 'spring' (April through June) and 'summer' (July through August) which is the end of an intern's clinic training. 'Fall' was set as the reference variable. OCOM interns may be expected to have more experience during summer quarter compared to the fall quarter when they had newly entered the clinic. As Lewy et al. (2009) found that pediatric residents increased their confidence after receiving more training, it could be expected that OCOM interns would be more confident as they build experience over the academic year and have more confidence in acupuncture during the summer quarter compared to the fall. Provider confidence may have an influence on treatment outcomes as a component of the mutual supportive patient-provider relationship (Finniss, 2010). Therefore, the inclusion of academic quarter as a proxy for intern confidence is important for evaluating the influence of patient confidence on patient compliance (returning for a 5^{th} visit) and treatment outcomes.

Further Controls for Bias

Acupuncture is part of the larger system of acupuncture and Oriental medicine therapies. In addition to the insertion of needles, an acupuncture provider might utilize other treatment modalities such as massage (*shiatsu*, *sotai* or *tuina*), mind-body exercises (*qigong* or *taiji quan*) or herbal formulations for internal or external use. (NCCAM; Kaptchuk, 1983) In order to eliminate the possible effects on treatment outcome by Oriental medicine therapies other than acupuncture, only patients with five consecutive acupuncture visits are asked to complete the 5th visit patient questionnaires.

Statistical Methods

For the statistical analyses of the first and second questions, logistic regression was used to investigate the odds of returning for the fifth visit (the outcome of interest) for each individual predictor including the characteristics of patient demographics, health status and treatment context. For the third study question, linear regression was used to investigate crude associations between the change in pain as the dependent variable and each individual predictor previously listed. Predictor variables having an association with the outcome of interest where the p-value was less than 0.20 were eligible for inclusion in the full multivariable model for the related question. Variables with demographic or clinical interest advanced, regardless of p-value. Backwards elimination removed individual variables successively by the largest p-value. All remaining variables in the reduced models had p-values < 0.05. The likelihood ratio test (LRT), or

partial F-test, was calculated to compare each full model to its final reduced model. Interactions between the three separate variables for opinion/confidence and the remaining predictor variables in the reduced models were checked and those with p-values < 0.05 were kept in the final models. Final model diagnostics included the Hosmer and Lemeshow goodness-of-fit test for questions #1 and #2; residual plots for question #3; and qq-plots of residuals to assess approximate normality for question #3.

Correlation matrices involving predictors were investigated if distortions between crude and adjusted estimated effects raised suspicions of collinearity. MYMOP was examined as a sum of 3 items with a range of 0 to 18 instead of an average of 3 items with a range of 0 to 6 in order to detect potential scaling problems. No collinearity problems were detected, with all pairwise correlations among the predictors in the final models having a Pearson correlation coefficient less than 0.70

Analyses were conducted using SPSS Version 19 statistical software and p-values for the LRT and partial-F test statistics were calculated in Microsoft Excel.

Results

Question #1: Does having an opinion on acupuncture, or not, have an association with returning for a 5th treatment?

A sample of 1,213 individuals was used to investigate the association between having an opinion on confidence in acupuncture and returning for a fifth visit. The average age in the study sample was 49 years and almost two thirds were women. Almost half of the patients did not report their race and of those who did report their race/ethnicity, 81% identified as white. See table 1 for patient characteristics and table 2 for race/ethnicity categories.

Most patients (73%) reported having chronic pain. Half were receiving healthcare elsewhere for their joint and muscle pain and 50% of the sample had previously experienced acupuncture at least a few times.

Most patients (72%) reported an opinion, either positive or negative, on their confidence in acupuncture at their first visit; the remaining 28% did not respond to the question or indicated a neutral position on the question.

TABLE 1. CHARACTERISTICS OF PATIENTS TREATED FOR JOINT AND MUSCLE PAIN (N=1213)

	n	**(%) or** ±SD
Returned for 5th visit (Y)		
No	1107	(91)
Yes	106	(9)
Confidence in acupuncture		
Very doubtful	6	(1)

A bit doubtful	35	(3)
Neutral	295	(24)
A bit confident	392	(32)
Very confident	441	(36)
No response	44	(4)
Opinion on confidence in acupuncture (X)		
No opinion	339*	(28)
Opinion	874	(72)
Gender		
Female	788	(65)
Male	425	(35)
Age at first visit (years)	49.0 (mean)	±14.9
Race/Ethnicity categories		
White	489	(40)
Not white	122	(10)
No response	602	(50)
Academic quarter		
Fall	290	(24)
Winter	414	(34)
Spring	370	(30.5)
Summer	139	(11.5)
Chronic (or long term) diseases		
No	892	(73.5)
Yes	321	(26.5)

Duration of pain symptoms		
Acute (less than 3 months)	325	(27)
Chronic (3 months or more)	888	(73)
Had acupuncture before?		
Yes, many times	269	(22)
Yes, a few times	345	(28)
No, never	455	(38)
No response	144	(12)
Receiving healthcare elsewhere		
No	596	(49)
Yes	617	(51)
Global Mental Health (4 - 20) †	10.18 (mean)	±3.27
Global Physical Health (4 - 20) †	10.74 (mean)	±2.86
MYMOP score (0 - 6)	3.46 (mean)	±1.13
Physical functioning (10 - 50) †	20.48 (mean)	±7.82
Severity of pain (0 - 10)	5.44 (mean)	±2.30
Sum of non-pain health concerns (0 - 19)	4.79 (mean)	±2.83
Sum of pain locations (0 - 19)	4.52 (mean)	±3.11

* Includes 44 no response.

† Larger number for the raw score indicates worse condition.

Possible ranges for scales are given in parenthesis.

SD = standard deviation; MYMOP = Measure Your Medical Outcome Profile.

TABLE 2. RACE/ETHNICITY (611 responses from N=1213)

	n	**(%)**
White or Caucasian	93	(81)
Hispanic	36	(6)
Asian	30	(5)
More than 1 category	16	(3)
Black or African American	15	(2)
American Indian or Alaska Native	8	(1)
Native Hawaiian or other Pacific Islander	7	(1)
Other race/ethnicity	6	(1)

Average severity of pain was 5, the mid-point of the 11-point Likert-type response scale (0 = 'no pain' to 10 = 'worst imaginable pain'). On average, at least four locations for pain were reported: the five most common were low back (53%), shoulder (50%), neck (44%), upper back (37%) and knee (30%).

Close to one-fourth of the study sample reported having at least one chronic or long term condition and an average of four non-pain health concerns from a list of 20 common health problems. More than a quarter of the sample reported obesity or weight problems and one fifth reported high blood pressure (hypertension). See table 3 for frequency statistics for seven commonly reported chronic non-pain health problems.

TABLE 3. CHRONIC NON-PAIN HEALTH PROBLEMS (N=1213)

	n	**(%)**
Obesity or weight problems	330	(27)
High blood pressure (hypertension)	238	(20)
Asthma or breathing problems	144	(12)
Diabetes	87	(7)
Heart problems or heart disease	81	(7)
Addictions or related problems	76	(6)
Cancer	39	(3)

Eight co-variables met the critical value of p-value < 0.20 in bivariate logistic regression analysis with returning for 5th visit and were potential candidates for a multivariable model. They were: race, age, MYMOP score, global physical health, sum of pain locations, experience with acupuncture, academic quarter and receiving healthcare elsewhere. Gender was not significant but was included for clinical relevance for a total of nine co-variables in the initial full multivariable model with opinion on confidence.

In order to arrive at the most parsimonious model, a backwards elimination method was used; variables with the largest p-values were removed one-by-one until all remaining variables had $p < 0.05$. The final reduced multivariate model included race, sum of pain locations, and academic quarter as contributing statistically significant information with p-values <0.05. Opinion on

confidence in acupuncture treatment, age and gender were not statistically significant but were retained as clinically relevant. The reduced model did not appear to lose important information from the full model with a likelihood ratio test statistic of X^2 (8 df) = 8.63, $p = 0.37$; and the Hosmer and Lemeshow goodness-of-fit test statistic for the reduced model indicated an acceptable model diagnostic ($X^2 = 7.29$, 8 df, $p = 0.51$). See Appendix 1 for crude and adjusted odds ratios for each variable, 95% confidence intervals and *p*-values.

Relationship between opinion and returning for 5th visit

Within this sample, 9% returned for a 5th consecutive acupuncture treatment. Of the patients who reported an opinion on confidence in acupuncture, 10% returned for a 5th visit, compared to 7% of those who did not report an opinion. After adjusting for gender, age, race, sum of pain locations and academic quarter, there was some indication ($p = 0.24$) that patients who reported an opinion were more likely to return for a 5th visit, with the adjusted odds being 34% higher (95% confidence interval: 18% lower odds to 119% higher odds) for those with an opinion relative to those with no opinion. See appendix 1 for adjusted odds ratios and 95% confidence intervals.

Co-variables and returning for 5th visit

Three co-variables contributed significant information in the final model, with a *p*-value < 0.05, including the sum of pain locations, race, and academic

quarter. For each additional reported location of pain, the adjusted odds of returning for a 5th visit increased by 7% (95% CI: 1% to 14%), $p = 0.02$.

From the patients who identified with a race/ethnicity other than 'white or Caucasian', only 3% returned for a 5th visit compared to 8% of those who identified as white. For patients who reported their race as 'other', the estimated odds of returning for a 5th visit were less than half as great as the odds of returning for the patients who reported their race as 'white' (estimated OR = 0.41, 95% CI: 0.14 to 1.18; $p = 0.10$). Among the patients who did not respond to the race/ethnicity question, 11% returned for a 5th visit and their estimated odds of returning for a fifth visit were 2.53 times as great as the odds of returning for those who reported their race as 'white' (estimated OR = 2.53, 95% CI: 1.53 to 4.20; $p < 0.001$).

Compared to patients who started treatment in the fall, the odds of returning for a 5th visit were more than three times as great for the patients who started in the winter (estimated OR = 3.31, 95% CI: 1.74 to 6.28; $p < 0.001$). For patients who started treatment in the spring, the odds of returning for a 5th visit were almost twice (estimated OR = 1.90, 95% CI: 1.04 to 3.49; $p = 0.04$) the corresponding odds of returning for those who started in the fall; and for patients who started treatment in the summer, the odds of returning were only 14% less than the odds of returning for patients starting in the fall (estimated OR = 0.86, 95% CI: 0.37 to 1.96; $p = 0.72$). Of the patients who started treatment in the fall,

7% (n = 19) returned for a 5th visit, compared to 11% n = 45) of those who started in the winter, 9% (n=33) in spring, and 7% (n = 9) in summer.

Question #2: Does having more or less confidence in acupuncture treatment have an association with returning for a 5th visit?

A subset of the study sample who reported an opinion on acupuncture treatment (N=874) was used in the analysis of the relationship between direction of confidence in acupuncture, both more or less confident, and returning for 5th visit. Almost all (95%) reported more confidence in acupuncture, having checked 'Very confident' or 'A bit confident'. See table 4 for more information about characteristics of patients in this sample.

TABLE 4. CHARACTERISTICS OF PATIENTS TREATED FOR JOINT AND MUSCLE PAIN (N=874)

Returned for 5th visit (Y)	**n**	**(%) or ±SD**
No	791	(90.5)
Yes	83	(9.5)
Direction of confidence in acupuncture (X)		
Negative	41	(5)
Positive	833	(95)
Gender		
Female	592	(68)

Male	282	(32)
Age at first visit (years)	49.01 (mean)	±14.66
Race/Ethnicity		
White	365	(42)
Not white	76	(9)
No response	433	(49)
Academic quarter		
Fall	209	(24)
Winter	301	(34)
Spring	273	(31)
Summer	91	(10)
Chronic (or long term) diseases		
No	641	(73)
Yes	233	(27)
Duration of pain symptoms		
Acute (less than 3 months)	249	(28.5)
Chronic (3 months or more)	625	(71.5)
Global Mental health score (4 - 20) †	10.12 (mean)	±3.29
Global Physical health score (4 - 20)†	10.68 (mean)	±2.84
Had acupuncture before?		
Yes, many times	236	(27)
Yes, a few times	281	(32)
No, never	269	(31)
No response	88	(10)
MYMOP score (0 - 6)	3.44 (mean)	±1.11
Receiving healthcare elsewhere		
No	440	(50)
Yes	434	(50)
Physical functioning score (10 - 50) †	20.37 (mean)	±7.74 (SD)
Severity of pain, score (0 - 10)	5.44 (mean)	±2.32 (SD)

Sum of non-pain health concerns (0 - 19)	4.90 (mean)	±2.86 (SD)
Sum of pain locations (0 - 19)	4.62 (mean)	±3.09 (SD)

† Larger number for the raw score indicates worse condition.

Possible ranges for scales are given in parenthesis.

SD = standard deviation; MYMOP = Measure Your Medical Outcome Profile.

Nine co-variables were included in the initial full multivariable logistic regression analysis having $p < 0.20$ in a bivariate relationship with returning for a 5th visit: age, race, sum of pain locations, addictions or related problems, experience with acupuncture, receiving healthcare elsewhere and three interactions with age, MYMOP score and sum of pain locations by direction of confidence. Gender, academic quarter and MYMOP score were not significant individually but were included for clinical relevance or accompanying an interaction in the full multivariable analysis, for a total of twelve co-variables plus the direction of confidence (more confident or less confident).

The reduced model included direction of opinion, age, gender, race, academic quarter, MYMOP score, sum of pain locations and the interaction for direction of opinion by MYMOP score. Only race, academic quarter and the interaction for the direction of confidence by the MYMOP score were statistically significant. Age and gender were retained for clinical importance. If the sum of pain locations is dropped from the model, then the likelihood ratio test comparing the full to the reduced model is approaching significance ($p = 0.07 < 0.10$), while

if the sum of pain locations is retained in the reduced model, then the LRT comparing full to reduced model is not significant (X^2 =10.89, 7 df, p = 0.14). The Hosmer and Lemeshow goodness-of-fit test statistic indicated an acceptable final model (X^2 =5.50, 8 df, p = 0.70). See Appendix 2 for crude and adjusted odds ratios.

Direction of confidence and returning for 5th visit

Did more patients who were more confident in acupuncture return for a 5th visit compared to patients with less confidence? Of the patients who reported more confidence in acupuncture, 10% (n = 80) returned for a 5th visit compared to 7% (n = 3) of patients who reported less confidence. There was a significant interaction between the MYMOP score and the direction of confidence with returning for a 5th visit (estimated OR = 2.71, 95% CI: 1.07 to 6.83; p = 0.04). Among the patients who reported more confidence in acupuncture, the odds of returning for a 5th visit increased by 13% for each additional unit of the MYMOP score while holding other variables constant (estimated OR = 1.13, 95% CI: 0.91 to 1.42; p = 0.28); and of those who reported less confidence, the odds of returning decreased by 58% for each additional unit of MYMOP score (estimated OR = 0.42, 95% CI: 0.17 to 1.03; p = 0.06). See figure 1 for a graph of the estimated log-odds of returning for a 5th visit for a 50 year old female patient with joint and muscle pain in three locations by each additional level of MYMOP score if either more or less confident.

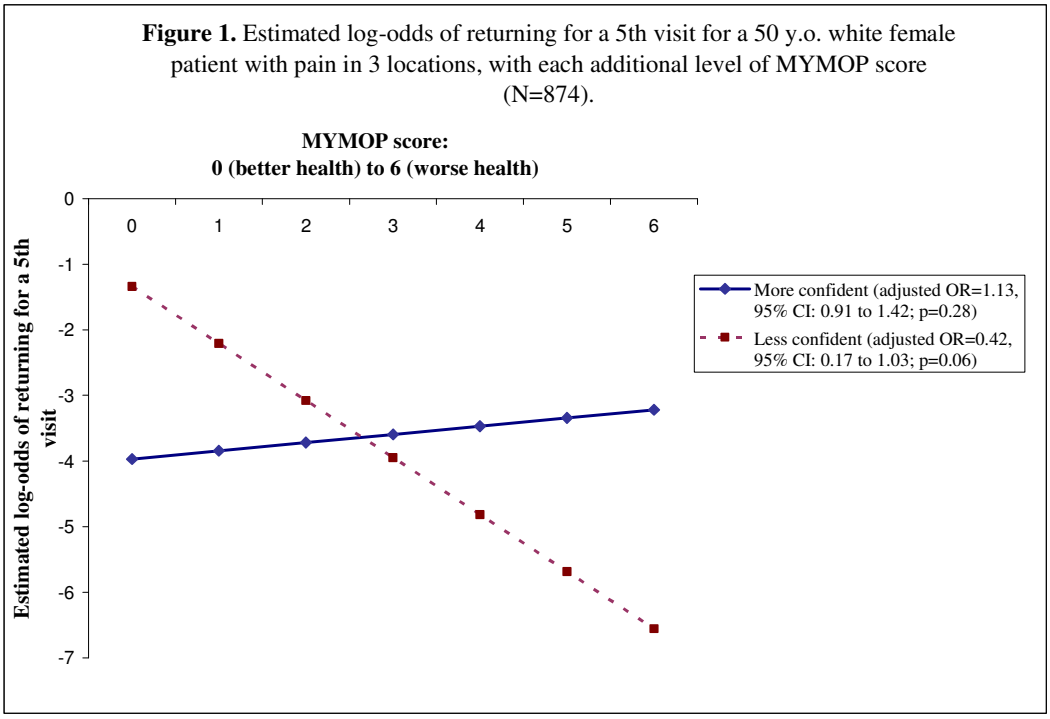

Figure 1. Estimated log-odds of returning for a 5th visit for a 50 y.o. white female patient with pain in 3 locations, with each additional level of MYMOP score (N=874).

Co-variables and returning for a 5th visit

The co-variables that contributed significant information to the final model with a *p*-value < 0.05 included race and academic quarter. Among the patients who identified with a race category other than 'white', only 4% (n=3) returned for a 5th visit compared to 8% (n=28) of those who identified themselves as 'white'. For patients who reported their race as other than 'white', the odds of returning for a 5th visit were 52% less than those reporting as 'white' (estimated OR = 0.48, 95% CI: 0.14 to 1.65; $p = 0.25$). Of the non-responders to race/ethnicity question, 12% (n=52) returned for a 5th visit and their odds of returning were almost three times as much as the odds of returning for patients who identified as 'white' (estimated OR = 2.71, 95% CI: 1.51 to 4.85; $p < 0.01$).

Among the patients who started treatment in the fall academic quarter, 7% (n=15) returned for a 5th visit, compared to 11% (n=34) of the patients who started treatment in the winter, 10% (n=26) in spring, and 9% (n=8) in summer. For patients whose first treatment occurred in the winter, the odds of returning for a 5th visit were more than three times as much as the odds of returning for patients who started in the fall (estimated OR = 3.22, 95% CI: 1.54 to 6.72; $p < 0.01$). The odds of returning for a 5th visit for patients who started treatment during spring or summer quarters were as much as the odds of returning for patients who started treatment in the fall, $p > 0.05$.

Question #3: Does a patient's level of confidence have an association with the change in pain at the 5th visit?

Among joint and muscle pain patients who returned for a 5th visit within 6 months of their first visit (N=104), almost two thirds were women, averaging 51 years of age. The average time between 1st and 5th treatments was less than 9 days.

The mean change in pain severity was a decrease of 1.88 with a range of -10 to 6 where change in pain was calculated as the 5th visit pain level minus the 1st visit pain level. A negative number for the change in pain indicated less pain at the 5th visit compared to the first. Please refer to table 5 for more information about characteristics of patients' demographics, health status and treatment context.

At the different levels of confidence for patients who returned for a 5th visit, 41% (n=43) reported that they were 'very confident' that acupuncture would work for them, 35% (n=36) were 'a bit confident', 21% were neutral (n=21) or did not respond (n=1) and 3% (n=3) were 'a bit doubtful'. No patients reported being 'very doubtful'.

TABLE 5. CHARACTERISTICS OF PATIENTS TREATED FOR JOINT AND MUSCLE PAIN WHO RETURNED FOR 5TH VISIT (N=104)

Difference in pain severity (Y)	**mean or n**	**±SD or (%)**
5th visit pain score – 1st visit pain score		
(possible range is -10 to 10)	-1.88 (mean)	±2.74
Level of confidence (X) (-2 to 2)*‡	1.14 (mean)	±0.85
Age at first treatment (years)	51.08 (mean)	±14.10
Gender		
Female	67	(64)
Male	37	(36)
Race		
White	36	(35)
Not white	4	(4)
No response	64	(62)
Academic quarter		
Fall	9	(9)
Winter	33	(32)
Spring	44	(42)

Summer	18	(17)
Chronic (or long term) diseases		
No	74	(71)
Yes	30	(29)
Duration of pain symptoms		
Acute (less than 3 months)	25	(24)
Chronic (3 months or more)	79	(76)
Had acupuncture before?		
Yes, many times.	21	(20)
Yes, a few times.	36	(35)
No, never.	22	(21)
No response.	25	(24)
Receiving healthcare elsewhere		
No	42	(40)
Yes	62	(60)
Average days between treatments	8.50 (mean)	±5.39
Baseline severity of pain (0 - 10)	5.59 (mean)	±2.27
Global mental health score (4 - 20)†	10.14 (mean)	±3.63
Global physical health score (4 - 20)†	11.20 (mean)	±2.97
MYMOP profile score (0 - 6)	3.62 (mean)	±1.16
Physical functioning score (10 - 50)†	20.98 (mean)	±8.18
Sum of non-pain health concerns (0 - 19)	4.92 (mean)	±2.81
Sum of pain locations (0 - 19)	5.31 (mean)	±3.62

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* Levels of confidence in acupuncture are -2 (Very doubtful), -1 (A bit doubtful), 0 (Neutral or no response‡), 1 (A bit confident), and 2 (Very confident).

‡ Includes 1 no response.

† Larger number for the raw score indicates worse condition.

Possible ranges for scales are given in parenthesis.

SD = standard deviation; MYMOP = Measure Your Medical Outcome Profile.

Having a chronic or long term diseases was reported by 29% (n=30). Frequencies for seven commonly reported chronic or long term diseases are listed in table 6.

TABLE 6: CHRONIC NON-PAIN HEALTH CONCERNS (N=104)

	n	**(%)**
Obesity or weight problems	29	(28)
High blood pressure (hypertension)	21	(20)
Asthma or breathing problems	10	(10)
Diabetes	6	(6)
Heart problems or heart disease	5	(5)
Cancer	3	(3)
Addictions or related problems	2	(2)

Thirteen co-variables were included in the full multivariable linear regression analysis having met a critical value of $p < 0.20$ in bivariate analysis in relationship with the change in pain. Those co-variables included global physical health, MYMOP score, physical functioning, severity of pain, duration of pain, sum of non-pain health concerns, addictions or related problems, diabetes, high blood pressure, experience with acupuncture, receiving healthcare elsewhere and

two interactions for level of confidence by race and by had acupuncture before. Age, gender, race, average days between treatments and academic quarter were not significant individually but were included in the full multivariable analysis as clinically relevant. There was a total of 17 co-variables plus level of confidence in the full model.

The potential of a collinearity problem was investigated because a change in slope direction was noted between the crude and adjusted parameter estimates for global physical health and MYMOP score. However, it was dismissed because no variance inflation factor (VIF) was greater than 4.0 and all Pearson correlation coefficients were < 0.70. A VIF greater than 10.0 is the rule of thumb for identifying a collinearity problem (Kleinbaum et al., 1998).

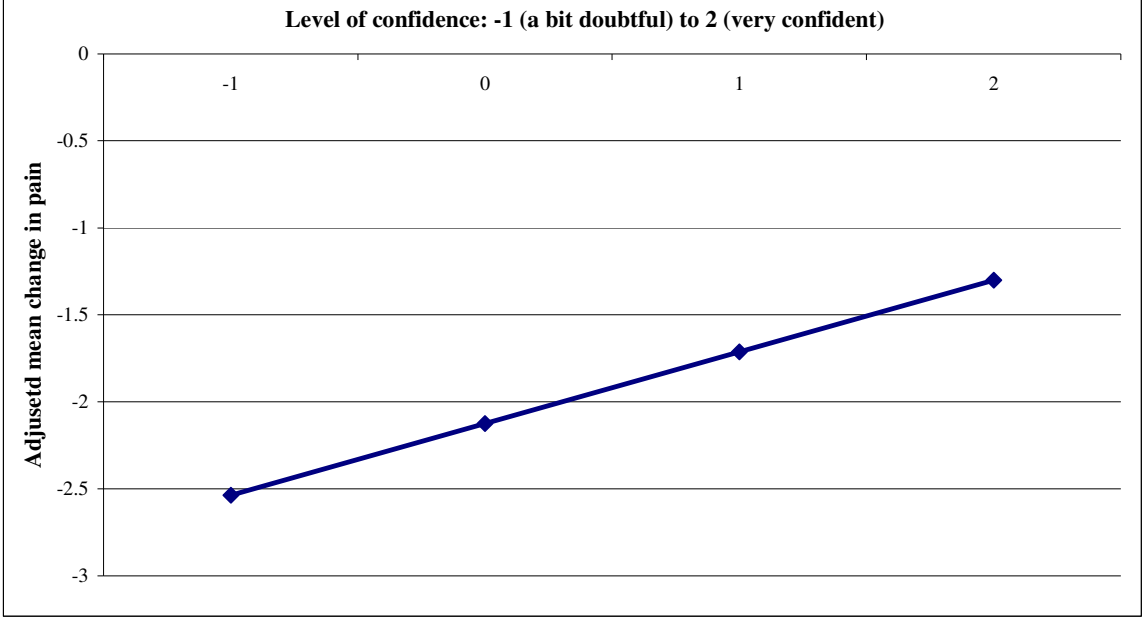
The reduced model included the level of confidence, age, gender, race, academic quarter, duration of pain, global physical health, MYMOP score, physical functioning, severity of pain and days between treatments. Only duration of pain, global physical health, MYMOP score, physical functioning and severity of pain were statistically significant. The *p*-value for level of confidence approached significance, $p = 0.06$, but was not less than the critical value of 0.05. Age, gender, race, academic quarter and days between treatments were retained for clinical importance. Representing the information that was lost in the reduction process, the (partial) *F*-statistic was 0.53 which is less than the critical test value for the *F* distribution (1.88, with 12 and 77 df), therefore the reduced model does not appear to have lost important information from the full model

(Microsoft Excel). See Appendix 3 for crude and adjusted slopes with 95% confidence intervals and *p*-values.

Level of confidence and change in pain by 5th visit

As the level of confidence in acupuncture increased by one unit, from -1 ('a bit doubtful') to 2 ('very confident'), the adjusted mean change in pain increased by 0.41 unit (95% CI: -0.02 to 0.85; $p = 0.06$), after adjusting for other variables. Please refer to figure 2 for a graph of the association between change in pain and level of confidence. To further explain the observed positive association between mean change in pain and level of confidence, patients who were 'very confident' in acupuncture had an adjusted mean decrease in pain by 0.70 points at their 5th visit (95% CI: -3.61 to 2.217). At the lowest level of confidence reported in this sample, patients who were 'a bit doubtful' that acupuncture treatment would help them experienced an adjusted mean decrease in pain of 1.93 points at their 5th visit (95% CI: -5.04 to 1.17). Although not statistically significant, level of confidence may be worth considering as a clinical factor with a *p*-value approaching significance ($p = 0.06$).

Figure 2. Adjusted mean change in pain by level of confidence in acupuncture for a 50 y.o. white female with acute baseline pain severity of 3, MYMOP score of 3 and physical health score of 10 averaging 7 days between treatments (N=104).



Co-variables and change in pain by 5th visit

Five co-variables contributed significant information to *change in pain* at the 5th visit. They were duration of pain, either acute or chronic, and the scores for the severity of baseline pain, global physical health, physical functioning, and MYMOP score at the first visit.

The patients with chronic joint and muscle pain, lasting three or more months, experienced an increase in pain by 1.08 points (95% CI: 0.14 to 2.02) at their 5th visit ($p = 0.03$) compared to the patients with acute pain after adjusting for other variables.

Both of the scores for severity of baseline pain and physical functioning had a negative association with the change in pain at the 5th visit. For each additional point in baseline pain severity at the 1st visit, the change in 5th visit pain

decreased by 1.24 points (95% CI: -1.48 to 1.00; $p < 0.001$) when holding all other variables constant. As the physical functioning score increased by one point, where larger numbers indicated worsening functioning, the change in pain at the 5th visit decreased by 0.07 points (95% CI: -0.14 to 0.00; $p = 0.04$).

Global physical health at the first visit was positively associated with change in pain severity at the fifth visit. As the global physical health score at the first visit increased by one point, where larger numbers indicated poorer health, the change in pain at the 5th visit increased by 0.32 point (95% CI: 0.09 to 0.54; $p < 0.01$) when controlling for other variables.

Discussion

Key Results

The majority of this sample of OCOM patients with joint and muscle pain (N=1213) reported having an opinion on confidence in acupuncture, either negative or positive, 874 (72%). Of those reporting an opinion, most patients reported that they were 'very confident' or 'a bit confident' in acupuncture treatment, 833 (69%).

This study found no statistically significant associations between confidence in acupuncture treatment and returning for a 5th visit. Of the patients who reported an opinion on confidence in acupuncture (N = 1213), the odds of returning were slightly greater than those who did not report an opinion. Among the patients who reported an opinion (N = 874), the odds of returning decreased with each additional level of the MYMOP score for patients who reported less

confidence in acupuncture, and the odds of returning increased with each additional level of the MYMOP score for patients who reported more confidence (see figure 1). These findings of positive associations are similar to those of Fischer et al (2010) and Daugherty (2005), patients with less confidence were less compliant with treatment than patients with more confidence.

This study found a weak inverse association between level of confidence in acupuncture treatment and improvement in pain at the 5th visit. Among the 104 patients who returned for a 5th visit, the adjusted mean change in pain was positively associated with confidence in treatment where the change in pain increased with each increase in level of confidence, i.e., improvement in pain decreased as confidence increased (see figure 2). This observed association between patient confidence and change in pain is similar to results found by So (2002) where treatment benefits decreased for patients who reported greater expectations for acupuncture treatment. However, more frequently published reports have shown that treatment outcomes improve as confidence or expectation increases (Foster et al., 2010; Kong et al., 2009; Linde et al., 2007; Weinland et al., 2010).

Limitations

Large patient attrition

There is large potential for loss-to-follow-up bias in the analysis of treatment outcomes with less then 10% of patients returning for their fifth acupuncture visit to complete the second questionnaire. A patient's pain may

have resolved before the fifth visit or it may have gotten worse. If the pain resolved and the patient did not return, the remaining data would be biased in the direction of poorer overall improvement in pain. On the other had, if a patient's pain was worse and the patient did not return for a fifth visit, the bias would be reflect as false improvement in pain. Knowing why patients do not return for their 5th visit could help to minimize such bias.

Looking closer at the sample that did not return for a 5th visit (n=1107), more of those patients were white (75% vs. 40%), started treatment in the fall (25% vs. 9%) and had never had acupuncture before (38% vs. 21%). They appear to be very slightly healthier with similar or slightly lower scores for each of the health status characteristics. Of the patients who did not return for a 5th visit, fewer did not respond to the questions about race/ethnicity (6% vs. 50%) or experience with acupuncture (11% vs. 24%). Otherwise the two groups of patients are very similar in level of confidence, gender and age. One could reasonably argue that patients might not return if they have never had acupuncture before. Perhaps they are just 'testing the waters' to see what it means to experience an acupuncture treatment; or that they might not return after starting treatment during the fall when interns could be outwardly nervous or winter holiday activities distracted patients from continuing treatment. Because all of the health status characteristics are similar or slightly lower for the patients who did not return for a 5th visit, indicating slightly better health overall, their pain may have resolved before the 5th visit. All three of the final models adjusted for the academic quarter when a patient started treatment; and all explored the inclusion

of the patient's experience with acupuncture in bivariate analysis but none adjusted for it in the final models.

Missing co-variables information

A limitation of this study is the missing information that could potentially be important for controlling confounding and bias including: English fluency, matched provider-patient confidence, patient confidence at the fifth visit, zip code, and biomedical diagnostic code.

Not being able to control for a patient's level of fluency in English may introduce measurement bias due to the increased potential for patient misinterpreting the questionnaires, especially the many questions used for measure health status characteristics. This potential for inaccuracy could lead to a decreased ability to control for health status as a confounding effect. Not being able to control for English fluency could bias study findings towards or away from the null thus limiting study results. The OCOM intake questionnaire has started collecting this information and it will be available for future studies.

There is no available measurement for provider-reported confidence in treatment matched to the patient-reported confidence. Interns and supervisors are asked to estimate their confidence in whether a patient will respond to treatment, reported as a prognosis in each patient's medical record. Currently, there are no available data that capture this estimation of prognosis, but these data may become available when the college clinic implements an electronic medical

records (EMR) system. Foster (2010) found that provider expectation did not contribute to treatment outcomes, but Finniss (2010) reported on studies by Kelley (2009) and Conboy (1985) that did show an influence on treatment outcomes by physician expectation. Even after adjusting for intern confidence and increased clinic-based skills by academic quarter, study findings might be strengthened by the ability to control for provider or intern confidence matched to patient confidence.

Similar to the matching of patient-provider confidence, the quality of the patient-provider relationship has been proposed by Kelley (2009) to be an important contributor to treatment outcomes. There is a possibility that a patient at the OCOM teaching clinic could be seen by a different intern-supervisor team at each visit which could weaken the patient-provider relationship and potentially deter a patient from continuing with treatment or minimize the treatment response. The OCOM clinic's planned electronic medical records (EMR) system will make it possible to identify interns and supervisors at each visit. With these data, it will be possible to evaluate patient-provider interactions and their associations with treatment outcomes and patient retention.

Confidence in acupuncture could change after a patient's first treatment. This may influence whether a patient continues to a 5^{th} treatment and, depending upon when confidence changes, it may influence the treatment outcome. While Avants et al. (2000) did not find a change in patient-perceived credibility of auricular acupuncture for cocaine dependence between first and last treatment, the

patients at the OCOM teaching clinic may be different enough that this variable could contribute important information to measuring the effects of patient confidence.

The lack of information about patient income may not be too great of a concern for this study because of the low cost of treatment, but it could be a potential positive confounder and have the same directional effects on patient confidence, ability to return for five visits and direction of change in pain severity. Not being able to control for patient income decreases the internal validity of these study results. Information about patient income has recently been added to the OCOM patient intake form and can be used in future studies.

Distance needed to travel may be an important factor in returning for a 5th acupuncture visit to the clinic. In fact, in a chart review study of the OCOM patient population, Cooper (2011) suggests there is a difference that is approaching significance between patients who travel less than 20 miles compared to those who travel more than 20 miles ($p = 0.08$). Patients' zip codes, which can be used to estimate distance traveled, were not included in the dataset used in this analysis as an oversight and because the OHSU IRB required all personal identifiers to be removed.

An objective diagnostic measure, such as a biomedical diagnostic code, would strengthen this study's ability to adjust for differences between patients that may be associated with confidence in treatment, compliance, and outcome. For example, a patient with severe hip degeneration has a much poorer prognosis

for pain reduction compared to a patient with a muscle strain in the hip muscles. This lack of a biomedical diagnosis is common limitation for acupuncture studies where biomedical diagnostic codes are beyond the scope of practice for acupuncturists unless the study occurs in an integrative medical setting. While some level of heterogeneity in the study sample can be controlled by patient-reported variables, an objective measure has greater accuracy than subjective self-reported measures.

Inclusion of 'no response' for question #1

Finally, a potential misclassification bias may have been introduced by classifying people who did not respond to the question about confidence in acupuncture as having 'no opinion'. It is possible that patients did not answer this question for another reason, such as not seeing the question. In a comparison analysis that excluded patients who did not respond to the question about confidence, the results are very similar to the results given for question #1, an adjusted OR of 1.23 (95% CI: 0.74 to 2.02; $p = 0.43$) versus an adjusted OR of 1.34 (95% CI: 0.82 to 2.19; $p = 0.24$), indicating the potential for misclassification bias is small.

Inadvertent inclusion of newest patients

Inadvertently, patients were included in this study who would not have had the opportunity to return for a 5th visit within 180 days before the data were sent for analysis. The dataset included 1213 new patients with joint and muscle

pain enrolled between November 1, 2009 and June 30, 2011. This total includes 450 patients whose first visit was after December 31, 2010. To be included in the analyses, the 5th visit had to occur within 180 days. The patient sample of 450 that should have been excluded is very similar to the sample used in this study's analysis for the average age, gender and characteristics of health status. The differences are found in the direction of confidence and who responded to the questions about race/ethnicity and previous experience with acupuncture. More of the group that should have been excluded were more confident (71% vs. 68%); more indentified as 'white' (75% vs. 40%) and other than 'white' (19% vs. 10%); and more reported never having had acupuncture before (50% vs. 38%). Fewer did not respond to the questions about race/ethnicity (6% vs. 50%) and previous experience with acupuncture (1% vs. 12%). Because one third of the sample for analysis of question #1 and half of the sample for question #2 may not have had an opportunity to return for a 5th visit, this inadvertent inclusion and classification as not returning for a 5th visit may have introduced a large bias to the results.

Generalizability

Overall, the patient demographics in this study sample are very similar to the national population of patients that use acupuncture; most are white women over 40 years of age (Tindle, 2005). The patients in this study have access to many different interns at the OCOM clinic who come from a wide geographic area with a variety of personalities and backgrounds. Thus, OCOM patients may be similar to the larger U.S. patient population with access to a variety of acupuncture providers, which is in contrast to clinical trials in which only a few

providers may provide treatments. Results from future analyses of these data may generalize to other health care centers with acupuncture programs that employ multiple acupuncturists and where patients may be treated by different providers at each visit.

The acupuncture treatments provided at OCOM are based on general theories of traditional Chinese medicine, and so future study results might not apply to patients who are treated by providers who exclusively practice another form of acupuncture such as 5-Element.

OCOM patients have self-referred for care and are thus interested in acupuncture as a treatment option and have some level of motivation to travel to the clinic. These findings may therefore not generalize to non-voluntary patient populations, such as court-mandated acupuncture programs for drug treatment. However, these results can be generalized to individuals who are self-motivated to contact a licensed acupuncturist in their community for treatment.

Suggestions for future study design

A stronger design for evaluating the effects of patient confidence in acupuncture treatment on patient compliance and severity of pain in the setting of the OCOM clinic would be an observational (non-randomized) prospective cohort study. Elements of the design would include scheduling each patient's treatment with the same provider, use of additional questions to obtain information about patient's income and fluency in English, administering a provider-questionnaire at the first visit to measure his/her confidence in acupuncture treatment for the

individual patient, measuring pain at each visit, and administering an exit questionnaire to a random sample.

Scheduling each patient's visit with the same provider creates continuity in care and eliminates the need to account for patients re-establishing patient-provider relationships and accounts for differences in treatment styles between each visit. As well, this may encourage patients to continue until their fifth visit and decrease loss-to-follow.

Questions about patient income and language fluency have been recently added to the intake questionnaire and are currently in use. In addition, the word 'optional' has been removed from the instructions for the race and ethnicity question and a response option, decline to answer, has been added. Including these changes in co-variable analysis could enhance precision. In addition, home zip code will be included as a covariate in future analyses to represent distance traveled as a possible factor in returning for a 5^{th} visit.

The provider's confidence in acupuncture treatment working for an individual patient could be matched to the patient's confidence in acupuncture with a provider questionnaire in order to account for provider confidence as a factor of the patient-provider relationship and its effect on treatment outcomes. This questionnaire could include provider's age and gender as co-variables to better define factors involved in the patient-provider relationship.

If the study objectives are to evaluate the effects of patient confidence in a real world practice, then providers would not be blinded to the patient's reported confidence in treatment. This would provide an opening for discussion about

patient concerns with treatment and provider recommendations for treatment frequency and outcome goals therefore allowing for a more complete development of the patient/provider relationship. Otherwise, providers would be blinded to patient responses for confidence in treatment and not be given access to patient intake questionnaires other than basic demographics, chief complaint and medical history.

The clinic recently instituted a procedure for interns to document each patient's treatment plan including the expected frequency and number of visits to reach an outcome goal, and then to discuss the treatment plan with each new patient. Having a treatment plan with a recommended number and frequency of treatments may increase patient compliance. Details of the treatment plan and an evaluation of patient satisfaction at the end of the recommended course of treatment would contribute to evaluating treatment outcomes and important characteristics of patient-provider relationships (Marx et al., 2012).

The exit questionnaire could be administered to a random sample of patients who did not return for a 5th visit after 180 days from their first visit. Patients would be sent the questionnaire by mail with self-addressed stamped envelope or with information to complete the questionnaire online. The questionnaire would include a question about current pain severity and confidence in acupuncture. With assurance of confidentiality, patients could be asked the reason for not continuing with treatment whether adverse experience, finances, time availability, resolution or worsening of health concern, or other. A variable for the number of treatments would be included in the analysis, between 1 and 5

treatments. This would provide an end outcome measurement and number of treatments (dosing) for patients who do not continue through to a 5th treatment and contribute to a better, although not complete, understanding of patient attrition.

In order to contribute to the understanding of treatment effects on health status characteristics or contribute to either controlled trials or comparative effectiveness research (CER) of acupuncture, future data analyses could evaluate the effects of confidence in treatment on outcomes other than change in pain, such as change in physical functioning or global physical or mental health. CER compares the positive and negative effects of available medical modalities "to prevent, diagnose, treat and monitor a clinical condition or to improve the delivery of care" in order to "assist consumers, clinicians, purchasers, and policy makers to make informed decision that will improve health care at both the individual and population levels" (Institute of Medicine, 2009, p.1; Witt et al., 2012).

Summary and Conclusion

Although none of the null hypotheses could be rejected at a significance level of 0.05 and caution should be followed in their interpretation because of the inadvertent inclusion of cases, these results do not necessarily refute suggestions that controlling for patient confidence in acupuncture treatment as a non-specific or placebo effect is important for research in acupuncture outcomes. The promotion of patient confidence in treatment is worth considering in clinic or other practice settings for reducing patient attrition and promoting positive

treatment outcomes. Future reanalysis will be aided by such additional information as English fluency, adjunctive treatment and provider confidence, as they become available.

Other information

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APPENDIX 1. INDIVIDUAL AND ADJUSTED TEST STATISTICS FOR QUESTION #1

Do more patients who have an opinion on acupuncture return for a 5th treatment compared to those without an opinion?

(results built using 1213 records)

Y = Returned for a 5th visit (no, yes)

Variable	*Crude*		*Adjusted*	
	OR* (95% CI)	**P-value**	**OR* (95% CI)**	**p-value**
Opinion	1.44 (0.89, 2.33)	**0.14**	1.34 (0.82, 2.19)	0.24
Gender				
Female	---	---	---	---
Male	1.09 (0.72, 1.64)	0.69	1.09 (0.71, 1.68)	0.70
Age				
Per 1 year	1.01 (1.00, 1.02)	**0.18**	1.01 (1.00, 1.02)	0.17
Race		**0.03**		**<0.001**
White	---	---	---	---
Non-white	0.40 (0.14, 1.15)	0.09	0.41 (0.14, 1.18)	0.10
No response	1.41 (0.93, 2.15)	0.11	2.54 (1.53, 4.20)	<0.001

Academic quarter		**0.18**		**<0.01**
Fall	---	---	---	---
Winter	1.74 (1.00, 3.04)	0.05	3.31 (1.74, 6.28)	<0.001
Spring	1.40 (0.78, 2.51)	0.26	1.90 (1.04, 3.49)	0.04
Summer	0.99 (0.44, 2.24)	0.98	0.86 (0.37, 1.96)	0.72
Chronic or long term conditions (yes)	1.11 (0.71, 1.72)	0.65	---	---
Duration of joint and muscle pain		---		---
Acute (under 3 months)	---	---	---	---
Chronic, 3 months or more)	1.20 (0.76, 1.92)	0.44	---	---
Global Mental health				
Per 1 unit increase	1.00 (0.94, 1.06)	0.90	---	---
Global Physical health				
Per 1 unit increase	1.06 (0.99, 1.13)	**0.13**	---	---
Had acupuncture before?		**0.05**		
Yes, many times.	---	---	---	---
Yes, a few times.	0.70 (0.39, 1.26)	0.23	---	---
No, never.	0.86 (0.51, 1.47)	0.59	---	---
No response.	1.67 (0.90, 3.10)	0.11	**---**	**---**

MYMOP profile score				
Per 1 unit increase	1.14 (0.95, 1.37)	**0.15**	---	---
Physical Functioning				
Per 1 unit increase	1.01 (0.98, 1.03)	0.62	---	---
Receiving health care elsewhere (yes)	1.40 (0.94, 2.10)	**0.10**	---	---
Severity of pain scale at first visit (0 to 10)				
Per 1 additional level of pain	1.03 (0.94, 1.12)	0.57	---	---
Sum of non-pain health concerns				
Per 1 additional health concern	1.02 (0.95, 1.09)	0.67	---	---
Sum of pain locations				
Per 1 additional location	1.08 (1.02, 1.14)	**0.01**	1.07 (1.01, 1.14)	**0.02**

*Estimates odds ratios calculated by logistic regression with SPSS statistical package.

Crude **p-values** in **bold** met critical value p<0.20.

Variables in **bold** remained in the adjusted multivariable model having met critical value, p<0.05, or by clinical interest.

MYMOP=Measure Your Medical Outcome Profile.

APPENDIX 2. INDIVIDUAL AND ADJUSTED LOGISTIC REGRESSION STATISTICS FOR QUESTION #2

Do more patients with higher confidence return for a 5th visit compared to those with lower confidence?

(results built using 874 records)

Y = Returned for a 5th visit (no, yes)

Variable	*Crude*		*Adjusted*	
	OR* (95% CI)	**P-value**	**OR* (95% CI)**	**p-value**
Direction of confidence (more confident)	1.35 (0.41, 4.46)	0.63	---	---
Gender (male)	1.08 (0.67, 1.74)	0.76	1.09 (0.66, 1.79)	0.76
Age				
Per 1 additional year	1.01 (1.00, 1.02)	**0.18**	1.01 (1.00, 1.03)	0.19
Race		**0.03**		**<0.01**
White	---	---	---	---
Non-white	0.50 (0.15, 1.67)	0.26	0.48 (0.14, 1.65)	0.25
No response	1.64 (1.01, 2.66)	0.04	2.70 (1.51, 4.85)	<0.01
Academic quarter		0.48		**0.01**
Fall	---	---	---	---
Winter	1.65 (0.87, 3.11)	0.12	3.22 (1.54, 6.72)	<0.01
Spring	1.36 (0.70, 2.64)	0.36	1.76 (0.88, 3.53)	0.11

Summer	1.25 (0.51, 3.05)	0.63	1.04 (0.42, 2.58)	0.94
Addictions or related problems	0.32 (0.08, 1.33)	**0.12**	**---**	**---**
Chronic or long term conditions (yes)	1.06 (0.64, 1.76)	0.82	---	---
Duration of pain (Chronic, ≥3 months)	1.04 (0.63, 1.73)	0.87	---	---
Global Mental health				
Per 1 unit increase	0.99 (0.93, 1.07)	0.86	---	---
Global Physical health				
Per 1 unit increase	1.04 (0.97, 1.13)	0.28	---	---
Had acupuncture before?		**0.09**		
Yes, many times.	---	---	---	---
Yes, a few times.	0.83 (0.45, 1.53)	0.55	---	---
No, never.	0.95 (0.52, 1.75)	0.88	---	---
No response.	2.00 (0.99, 4.06)	0.06	**---**	**---**
MYMOP score				
Per 1 unit increase	1.12 (0.91, 1.38)	0.27	---	---
MYMOP score **(per 1 unit increase) by** ***direction of confidence***			---	---
Less confident	**---**	**---**	0.42 (0.17, 1.03)	0.06
More confident	---	---	1.13 (0.91, 1.42)	0.28

Physical Functioning				
Per 1 unit increase	1.00 (0.97, 1.03)	0.90	---	---
Receiving health care elsewhere (yes)	1.44 (0.91, 2.27)	**0.12**	---	---
Severity of pain scale at first visit (0 to 10)				
Per 1 level of pain increase	1.04 (0.94, 1.14)	0.49	---	---
Sum of non-pain health concerns				
Per 1 additional health concern	1.01 (0.94, 1.10)	0.76	---	---
Sum of pain locations				
Per 1 additional location	1.08 (1.01, 1.16)	**0.02**	1.07 (1.00, 1.15)	0.06

*Estimates odds ratios calculated by logistic regression with SPSS statistical package.

Crude **p-values** in **bold** met critical value p<0.20.

Variables in **bold** remained in the adjusted multivariable model having met critical value, p<0.05, or by clinical interest.

MYMOP=Measure Your Medical Outcome Profile, PROMIS=Patient Reported Outcomes Measurement Information System.

ADDENDIX 3: CRUDE AND ADJUSTED STATISTICS FOR QUESTION #3 (results built using 104 records)

Does level of confidence have an effect on change in pain at the 5th visit?

[CHANGE IN SEVERITY OF PAIN (0 to 10) AT 5TH VISIT = PAIN AT 5th VISIT – PAIN AT 1ST VISIT]

Variable	*Crude*			*Adjusted*		
	B*	**(95% CI)**	***p*-value**	***B****	**(95% CI)**	***p*-value**
Level of confidence (-2 to 2)						
Per one level increase	0.03	(-0.60, 0.66)	0.93	0.41	(-0.02, 0.85)	0.06
Gender (male)	-0.32	(-1.44, 0.80)	0.57	-0.05	(-0.87, 0.77)	0.91
Age						
Per 1 additional year	0.01	(-0.02, 0.06)	0.27	0.01	(-0.02, 0.04)	0.41
Race			0.32	0.69		
White	---		---	---		---
Non-white	-1.83	(-4.70, 1.03)	0.21	-0.22	(-2.19, 1.75)	0.82
No response	-0.63	(-1.76, 0.50)	0.27	0.34	(-0.60, 1.28)	0.47
Academic quarter			0.60	0.08		
Fall	---		---	---		---
Winter	-0.51	(-2.56, 1.55)	0.63	-0.32	(-1.70, 1.06)	0.64
Spring	0.23	(-1.77, 2.23)	0.82	0.28	(-1.16, 1.72)	0.70

Summer	0.44 (-1.79, 2.68)	0.69	1.12	(-0.37, 2.61)	0.14
Addictions or related problems (yes)	0.32 (0.08, 1.33)	**0.12**	**---**		**---**
Average days between treatments					
Per 1 additional day	0.02 (-0.08, 0.12)	0.76	-0.05	(-0.12, 0.03)	0.21
Chronic or long term conditions (yes)	-0.43 (-1.61, 0.75)	0.47	---		---
Diabetes (yes)	-2.25 (-4.51, 0.00)	**0.05**	**---**		**---**
Duration of pain (Chronic ≥3 months)	**2.01 (0.82, 3.20)**	**<0.01**	1.08	(0.14, 2.02)	**0.03**
Global Mental Health**					
Per 1 unit increase	0.00 (-0.15, 0.15)	1.00	---		---
Global Physical Health**					
Per 1 unit increase	-0.23 (0.40, -0.05)	**0.01**	0.32	(0.09, 0.54)	**<0.01**
Had acupuncture before?		0.86			---
Yes, many times.	---	---	---		---
Yes, a few times.	0.37 (-1.15, 1.88)	0.63	---		---
No, never.	0.01 (-1.67, 1.69)	0.99	---		---
No response.	0.58 (-1.05, 2.21)	0.48	**---**		**---**
High blood pressure (yes)	-0.99 (-2.31, 0.33)	**0.14**	**---**		**---**
Measure your medical outcome profile (MYMOP) score					
Per 1 unit increase	-0.52 (-0.97, -0.06)	**0.03**	0.71	(0.23, 1.19)	**<0.01**

Physical Functioning**					
Per 1 unit increase	-0.05 (-0.11, 0.02)	**0.18**	-0.07	(-0.14, 0.00)	**0.04**
Receiving health care elsewhere (yes)	-0.67 (-1.75, 0.42)	0.22	---		---
Severity of pain at first visit (0 to 10)					
Per 1 additional level of pain	-0.81 (-0.99, -0.63)	**<0.000**	-1.24	(-1.48, 0.00)	**<0.001**
Sum of non-pain health concerns					
Per 1 additional non-pain health concern	-0.14 (-0.33, 0.05)	**0.14**	---		---
Sum of pain locations					
Per 1 additional pain location	-0.06 (-0.21, 0.09)	0.41	---		---

*general linear regression analysis (SPSS)

** A sum of scores for global physical health (4 items), global mental health (4 items) and physical function (10 items).

Crude **p-values** in **bold** met critical value p<0.20.

Variables in **bold** remained in the adjusted multivariable model having met critical value, p<0.05, or by clinical interest.

MYMOP=Measure Your Medical Outcome Profile, average of 3 scores (0 to 6).