Lifestyle advice and self-care integral to acupuncture treatment for patients with chronic neck pain: secondary analysis of outcomes within a randomized controlled trial

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**ABSTRACT**

**Background:** Lifestyle advice is widely considered as an integral component of acupuncture treatment. However it is unclear whether lifestyle advice and related self-care are important for sustaining benefit over the longer term. In a novel secondary analysis of trial data, this paper explores the nature and impact of acupuncture-related diagnosis, and associated lifestyle advice and self-care, in patients with chronic neck pain.

**Design:** In a three-arm, randomized, controlled multicentre trial with 12 months follow-up, a total of 517 patients with chronic neck pain were randomised in equal proportions to acupuncture, Alexander Technique or usual care alone.

**Methods:** For each acupuncture patient, practitioners reported treatment components that included an acupuncture-related diagnosis and provision of associated lifestyle advice. Patients reported at baseline, 3, 6 and 12 months on variables related to treatment, which included aspects of self-care, self-efficacy, and lifestyle advice acted upon, as well as pain and disability scores. Congruence between practitioner advice and patient take-up was assessed using Chi Square test. Impact of lifestyle advice and self-efficacy on outcome was evaluated using regression models.

**Results:** Among patients randomised to acupuncture, the most common diagnostic framework involving the Zang Fu syndromes for 139/160 (87%) patients. Lifestyle advice was provided by practitioners to 134/160 (84%) of patients, most commonly related to exercise, relaxation, diet, rest and work. Significant congruence with patient take-up was found for diet, rest and work. Moreover patients in the acupuncture group improved their ability to use what they had learnt and increased their self-efficacy. In turn these characteristics were found to be associated with significant reductions in pain and disability scores at 12 months.

**Conclusion:** Acupuncture-related lifestyle advice helped patients improve the way they live and care for themselves, enhanced self-efficacy and ability to use what they had learnt. These changes were associated with reductions in pain and disability at 12 months.

**INTRODUCTION**

Lifestyle advice is widely considered as being integral to treatment by acupuncture practitioners who use the principles of traditional Chinese medicine in routine practice. For example, in the UK, lifestyle advice relevant to an acupuncture diagnosis is provided by practitioners to 56% of their patients, which rises to 85% of patients of practitioners who provide a predominantly traditional Chinese medical style of treatment.(1) In Europe and China acupuncture advice provided by practitioners is primarily related to diet (73% and 67% respectively) and exercise (50% and 49%).(2) Further studies have elaborated on the role of lifestyle advice and self-care within traditional acupuncture consultations(3) and the “co-construction” of self-care within the context of the therapeutic relationship in a way that is different from that of a conventional medical consultation.(4)

While acupuncture has been most commonly characterised by the insertion of needles, in traditional East Asian medicine, lifestyle advice and its intended to impact on self-care make acupuncture a complex intervention, complex because there are multiple treatment components that are guided by the same over-arching theoretical perspective designed to impact on outcome.(5) The question as to whether the lifestyle advice and related self-care actually do an impact in terms of helping promote longer-term benefit is important and needs addressing. This question is relevant to the long term benefits that have been reported in trials of traditional acupuncture within which the provision of lifestyle advice as a treatment component has been supported. Qualitative data related to the trial of acupuncture for low back pain(6) has suggested the importance of life-style advice(7)(8), as well as from trials of for irritable bowel syndrome(9)(10) and for depression(11)(12). What is needed however is quantitative data to establish whether lifestyle advice, when it is an integral component of acupuncture treatment, enhances overall benefit.

This paper expands on the primary results of the ATLAS (Alexander Technique Lessons or Acupuncture Sessions) chronic neck pain trial published previously.(13) In a population that had experienced chronic neck pain for on average 6 years, we found that there were statistically significant benefits at 6 and 12 months for patients who received either Alexander Technique plus usual care or acupuncture plus usual care when compared to those receiving usual care alone. We also found that the self-efficacy of patients in both the acupuncture and the Alexander Technique arms improved when compared to usual care at 6 months. Improved patient self-efficacy meant that patients learned and used better strategies for reducing pain without resorting to medication. Moreover this improvement in self-efficacy was associated with significant reductions in neck pain at 6 and 12 months.

There is a need to better understand these longer-term benefits and whether life-style advice translates into better self-care and improved self-efficacy. In pre-specified secondary analyses, our aim in this paper is to explore whether there were acupuncture-specific diagnostic variables or lifestyle related factors that might help explain the reported longer-term benefits at 6 and 12 months.

**METHODS**

**Trial design**

The design involved a pragmatic three-arm trial with patients randomised in equal proportions to acupuncture, to Alexander Technique or to usual medical care alone. All patients continued to receive usual medical care throughout the trial. Patients were recruited from primary care by first identifying potential participants from GP databases. Patients were invited to return baseline questionnaires and consent forms, which were then screened for eligibility by members of the research team at the University of York. A minimum score of 28% was required on the Northwick Park neck pain and disability Questionnaire (NPQ)(14), a percentage-based scale which was our primary outcome measure. A total of 517 patients were recruited and randomised between March 2012 and April 2013.

**Acupuncture treatment**

Those randomised to acupuncture were offered up to 12 sessions and those randomised to Alexander Technique were offered up to 20 sessions. To be eligible to provide treatments within the trial, acupuncture practitioners were required to be members of the British Acupuncture Council with at least three years post-qualification experience and a commitment to continuing professional development. Moreover they agreed to provide a style of acupuncture based on traditional Chinese medicine principles, the most commonly used approach to the provision of acupuncture in the UK.(1) As this was a pragmatic clinical trial, practitioners were encouraged to practice as closely as possible to how they would routinely.(15) Acupuncture practised in this way can be considered a complex intervention,(5) and integral to treatment were the acupuncture diagnosis-related components, such as explanations of the diagnosis and diagnosis-specific lifestyle advice.(7)

**Data collected from practitioners at the end of treatment**

Practitioners documented in their logbooks data for each patient: their acupuncture-related diagnosis; the points used each session; the auxiliary modalities provided; and the lifestyle advice given over the course of treatment. Using the Eight Principles framework, practitioners identified whether the neck pain was an External, an Internal or a Mixed Internal and External condition. Practitioners assessed whether their patients could be diagnosed as predominantly having had one of two common clusters of Zang-fu syndromes: predominantly Liver related syndromes that included Liver Qi Stagnation, Liver Yin Xu, Liver Yang Rising and Liver Fire, and predominantly Spleen related syndromes that included Spleen Qi and Yang Xu, Kidney Qi and Yang Xu, and Internal Damp. Clustering in this way helped when conducting subsequent analyses. Moreover practitioners provided a rationale for any lifestyle advice related to acupuncture theory.

**Data collected from participants at baseline, 6 and 12 months**

At baseline, data were collected for each participant on a number of factors including the duration of their neck pain, age, gender and home city as well as GP practice. At baseline, 6 and 12 months, we also assessed patients’ perceived stress levels using the four-question Perceived Stress Scale (PSS), each item scored 0 to 4 with total scores 0 to 16.(16) At baseline, 6 and 12 months self-efficacy was determined by the 5-question pain management subscale of the Chronic Pain Self-Efficacy Scale scored 0 to 8.(17) At 6 and 12 months, data was collected on self-care, the extent that it took place, and the extent that it was perceived to be beneficial. Patients responded to the question, “Can you use/apply the things you learned from the treatment/care in everyday life situations, to reduce pain?” with responses: never, seldom, occasionally, often, every day, (scored 0 to 4 respectively). Patients responded to the question, “To what extent are you able to put into practice the advice or teaching you received?” on an 11-point scale of increments of 1 from 0 (not at all) to 10 (completely). Using the same 11-point scale, patients respond to the question, “To what extent are the changes you have been making helpful to you?” Patients responded (yes/no) to the question, “During the treatment/care you received in the last 6 months, did you learn to improve the way you live and care for yourself?” Patients also reported whether they made changes related to: diet, exercise, relaxation, rest, and work.

**Analysis**

Analyses were conducted in Stata version 13 using two sided significance tests at the 5% significance level (StataCorp. 2013. *Stata Statistical Software: Release 13*. College Station, TX: StataCorp LP). All comparisons of acupuncture and usual care were conducted on an intention to treat basis, including all patients in the groups to which they were randomised. Descriptives were reported as means and standard deviations for continuous variables and counts and percentages for categorical variables.

The association between practitioner reported advice and patient reported lifestyle changes were also explored using Chi-squared tests. The Eight Principles and Zang-fu clusters, and their relationship with NPQ change scores at 6 and 12 months, were presented as means with 95% confidence intervals.

Ability to make improvements in living/self-care and changes in diet, exercise, relaxation, rest and work at 6 and 12 months were analysed individually by logistic regression. Patient reported perceived stress, self-efficacy, ability to use what has been learned, number of lifestyle changes, extent put into practice advice or teaching and extent to which changes were helpful at 6 and 12 months were analysed individually by linear regression. To explore the impact of patient reported variables measured during the intervention period and changes in NPQ outcomes at 6 and 12 months linear regression was utilised. NPQ outcomes were analysed individually at each time point and included the patient reported variables (or changes in these variables from baseline) as fixed effect covariates in the model. All regression analyses made adjustments for baseline NPQ scores, duration of neck pain, age, gender and city as a fixed effect and GP practice as a random effect using robust standard errors (Stata *regress* command with cluster option).

**RESULTS**

Of the 173 participants randomised to acupuncture, 162 (94%) received at least one treatment, 125 (72%) attended all 12 sessions, and 11 (6%) did not attend for any treatment. Of the 162 patients attending at least one treatment, 2 withdrew from the trial. A total of 1775 treatments were received, and the average number of sessions attended was 11(range = 1 to 12, median 12). Treatments were provided by 18 acupuncture practitioners (15 female), each of whom treated on average 10 patients (range 2 to 22). The acupuncture points used and auxiliary treatments provided are documented in the Supplementary Data. Other components of treatment are presented below.

**Traditional acupuncture diagnosis**

Practitioners were asked to record their methods of diagnosis within a traditional Chinese medicine theoretical framework (Table 1). The three predominant frameworks used were Zang Fu (139/160; 87%), Fundamental Substances (117/160; 73%) and Eight Principles (94/160; 59%). Using the Eight Principles, practitioners documented their assessment on whether their patient’s neck pain could be diagnosed as more External, more Internal, or a mixed Internal and External condition. Most commonly, practitioners reported it to be a mixed Internal and External condition (86/160; 54%). For patients diagnosed as having a Zang Fu disharmony, practitioners categorised the syndromes in the majority of their patients as either predominantly Liver related (84/160; 53%), followed by Spleen (53/160; 33%) and ‘neither’ (2/160; 1%).

**Insert Table 1.**

Practitioners reported up to five key symptoms that guided their diagnosis of either the Liver or Spleen clusters. Within the Liver cluster, we found the most commonly reported symptoms to be stress (38/84; 45%), muscular tension/stiffness (31/84; 37%) and headache/migraine (28/84; 33%) (Table 2). Within the Spleen cluster, we found the most commonly reported symptoms to be pain (33/53; 62%) and tiredness/fatigue (16/53; 30%).

**Insert Table 2.**

**Practitioner-reported advice offered to patients based on the acupuncture diagnosis**

Within the protocol for treatment and integral to the provision of acupuncture, practitioners were encouraged to provide life-style advice where appropriate, provided that it was linked to traditional acupuncture theory and the patient’s diagnosis. Practitioners reported in the logbooks that they gave advice to make lifestyle changes to 134 (134/160; 84%) patients in total. This was most commonly related to advice about exercise (72/134; 54%), relaxation (59/134; 44%), diet (54/134; 40%), rest (47/134: 35%), work (31/134; 23%), and other advice (29/134; 22%).

The practitioners also reported in the logbooks the reasons for the advice based on traditional acupuncture theories. Advice related to exercise was most commonly to move the Liver Qi Stagnation (67/72; 93%). Advice related to relaxation was also predominantly to move the Liver Qi (33/59; 56%) but also to strengthen Spleen/Kidneys (12/59; 20%). Dietary advice was predominantly to strengthen the Spleen and resolve Damp (34/54; 63%) but also to tonify the Yin and Blood (17/54; 31%). Advice regarding work was commonly focussed on moving the Liver Qi (16/31; 52%). The “other advice” was often to protect the channels from external pathogenic factors and move channel stagnation (17/29; 59%), and also to advise on a referral (8/29; 28%).

**Relationship between the advice given by a practitioner and whether the advice was acted upon by the patient**

We compared data related to advice from practitioner logbooks with that reported by patients in questionnaires at 6 and 12 months. We found some evidence of a significant or near significant congruence between advice reported by practitioners and lifestyle changes reported by patients at 12 months related to diet and rest and work (Table 3).

**Insert Table 3.Relationship between traditional acupuncture medical diagnosis and outcome**

The relationship between practitioner-reported traditional acupuncture medical diagnoses and patient-reported changes in pain (NPQ) scores at 6 and 12 months are presented in Table 4. Most notably, the mean NPQ change scores were larger (with larger negative reductions indicating better outcomes) at both 6 and 12 months when the neck pain was classified as predominantly External (a channel only problem) compared to predominantly Internal (a Zang-fu problem) or to mixed Internal and External problem (involving both channel and Zang-fu).

**Insert Table 4.**

**Self-care and lifestyle when comparing acupuncture and usual care groups at 6 and 12 months**

The results of the regression analyses are presented in Table 5. There was evidence of a difference between acupuncture and usual care at 12 months in patient-reported self-efficacy, the number of life-style changes made, the ability to make improvements in living/self-care, and in making specific lifestyle changes related to diet, exercise, relaxation, resting and work.

**Insert Table 5.**

The above changes associated with the interventions at 6 and 12 months were analysed to see if differences from usual care were also associated with changes in NPQ pain and disability scores (Table 6). A lessening of intervention effects, as shown in Table 6, indicates the possibility that the associated variables were acting as mediators. There is evidence of significant reductions in NPQ scores at 12 months related to: changes in self-efficacy, ability to use what has been learnt, and changes in perceived stress.

**Insert Table 6.**

 **DISCUSSION**

**Principle findings**

Our key finding is that life-style advice based specifically on acupuncture theory leads to active patient engagement, which in turn is an important contributor to overall benefits over the longer-term. At 12 months follow-up we found some evidence of congruence between practitioner reported lifestyle advice and the actual lifestyle changes reported by patients receiving acupuncture related to diet, rest and work. Compared to the patients receiving usual care alone, we found that patients in the acupuncture group made more lifestyle changes related to diet, exercise, relaxation, rest and work and improved their self-efficacy, which is their ability to reduce their neck pain without resorting to medication. We found that patients in the acupuncture group improved their ability to use what they had learnt and increased their self-efficacy when compared to usual care alone and in turn these characteristics were found to be associated with significant reductions in NPQ pain and disability scores at 12 months. Overall we have shown that the characteristics of the acupuncture provision in a pragmatic trial of acupuncture for chronic neck pain go well beyond acupuncture needling alone, and specifically that pattern-related lifestyle advice has an impact on outcome.

**Strengths and weaknesses**As with any secondary analysis of data from a clinical trial that was powered for the main comparison, the desire to establish whether or not there were treatment components mediating outcomes may have been compromised by low statistical power. Moreover we conducted multiple exploratory analyses, and if the results had been based on chance alone, we would have expected that one in twenty would be statistically significant. However a strength of the study is that we pre-specified the analyses that we conducted in a statistical plan, a plan that was finalised prior to conducting the primary analysis. Nevertheless, our results should be seen as exploratory.

Our data include many statistically insignificant outcomes, which is almost inevitable, given that the trial was not sufficiently powered for sub-group analyses. These non-significant results are difficult to interpret, as it is not clear whether the sub-group analysis is underpowered to find a small association, or whether it means that no association exists. Randomised controlled trials may not be the best way to determine the relative impact of the different lifestyle categories. Observational studies may also have a role. Larger sample sizes will almost certainly be needed.

A limitation of our study is that we only recruited acupuncturists who practised acupuncture according to traditional acupuncture principles. While this might be the predominant style of practice world-wide, as well as in the UK,(1) we caution against drawing conclusions about acupuncture when practised using other treatment styles. We also note that there is some evidence of equivalence in outcomes across different styles and/or associated with different characteristics of acupuncture and of acupuncture practitioners.(18) We acknowledge that as the trial was conducted in primary care in the UK, we must generalise with caution to other populations. Moreover our results are relevant primarily to patients who, when recruited to the trial, had neck pain for an average duration of six years, and 75% were taking medication (60% related to neck pain).

 **Implications for research and practice**

Pragmatic trials are not designed to separate out the extent that any putative benefits might be “specific” or “non-specific” to the intervention. Our data is based on common practice among traditional acupuncture practitioners, whereby needling is one component of treatment but so too is the provision of life-style advice.(1) Our data shows the way that lifestyle advice is specific to the diagnosis and is also associated with outcome, and therefore cannot be labelled “non-specific”. This point was made clearly by Paterson & Dieppe(5) when they describe explanatory trial designs that attempt to divide an intervention into characteristic (specific) and incidental (placebo, non-specific) elements as being neither meaningful nor feasible when evaluating complex non-pharmaceutical interventions, attempts that may generate false negative results. As an alternative, pragmatic designs can evaluate complex interventions, and also pre-specify and monitor the key variables that are thought to mediate outcomes. In this way we can better understand the take up of lifestyle advice by patients, and the strategies that might enhance patient benefits. Further research into the reasons why patients might, or might not take up lifestyle advice, and what strategies practitioners could use to enhance compliance with advice, could help improve practice.

Our documentation on the reported symptoms of chronic neck pain, using the framework of traditional Chinese medical diagnostic principles, contributes to our understanding of neck pain. In particular we noted the considerable overlap between physical and affective aspects of chronic neck pain, particularly stress, suggesting that acupuncture might be of special value when mental and emotional symptoms are involved along with physical symptoms. We suggest that it would be useful to extend the focus of acupuncture research beyond the treatment of single conditions, and explore the impact of treatment where such co-morbidities are common

**Conclusion**

We have reported in detail the intervention data for acupuncture in the ATLAS trial, including treatment variables that potentially mediated outcome. We have provided evidence that practitioners actively initiate the active engagement by the patient through targeted lifestyle advice, and that this makes a difference in the way patients learn to improve the way they live and care for themselves. This results in enhanced self-efficacy which in turn is associated with greater reductions in pain and disability at 12 months. These data, when combined, provide a case to consider traditional acupuncture more than just a needle-related intervention, but rather a complex intervention that combines both acupuncture needling alongside acupuncture-related lifestyle advice that actively engages the patient in the own recovery.

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**Disclosure Statement**

No competing financial interests exist.

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SUPPLEMENTARY DATA

**Acupuncture needling and auxiliary treatment provided**

Practitioners were asked to report the acupuncture points used for each patient in each treatment session. A total of 259 different individual acupuncture points were used at least once and 25,696 points were needled across all sessions. The 20 most commonly used acupuncture points are detailed in Table 4. The two most common points, GB-20 and GB-21, are local neck pain points. Variations in the points reflected the diagnosis made, for example, patients diagnosed with Liver related cluster more commonly received points designed to move stagnation, such as LIV-3, and those with a Spleen cluster more commonly received points for tonification, such as SP-

**Table A1 Most Commonly Used Acupuncture Points**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Rank | Acupuncture point name | No. of patients used on (n=160) | No. of times point used over trial | Mean no. of times used within each course of treatment | % times used compared to all points on the whole trial |
| 1 | Gallbladder 20 | 152(95%) | 1175 | 7.7 | 4.6% |
| 2 | Gallbladder 21 | 143(89%) | 1090 | 7.6 | 4.2% |
| 3 | Large Intestine 4 | 104(65%) | 519 | 5.0 | 2.0% |
| 4 | Liver 3 | 100(63%) | 587 | 5.9 | 2.3% |
| 5 | Bladder 10 | 91(57%) | 390 | 4.3 | 1.5% |
| 6 | Spleen 6 | 87(54%) | 288 | 3.3 | 1.1% |
| 7 | Small Intestine 3 | 84(53%) | 395 | 4.7 | 1.5% |
| 8 | Bladder 18 | 82(51%) | 327 | 4.0 | 1.3% |
| 9 | *Ah Shi* point | 79(49%) | 1291 | 16.3 | 5.0% |
| 10 | Du 14 | 76(48%) | 289 | 3.8 | 1.1% |
| 11 | Bladder 23 | 75(47%) | 371 | 4.9 | 1.4% |
| 12 | Kidney 3 | 74(46%) | 239 | 3.2 | 0.9% |
| 13 | Bladder 13 | 73(46%) | 266 | 3.6 | 1.0% |
| 14 | Bladder 11 | 72(45%) | 207 | 2.9 | 0.8% |
| 15 | Stomach 36 | 71(44%) | 270 | 3.8 | 1.1% |
| 16 | *San Jiao* 5 | 69(43%) | 299 | 4.3 | 1.2% |
| 17 | Small Intestine 13 | 66(41%) | 249 | 3.8 | 1.0% |
| 18 | Bladder 15 | 64(40%) | 271 | 4.2 | 1.1% |
| 19 | Bladder 12 | 63(39%) | 221 | 3.5 | 0.9% |
| 20 | Bladder 60 | 59(37%) | 159 | 2.7 | 0.6% |

The 25,696 individual needle insertions equates to a mean of 14 insertions per patient per session (median=14), with a range of 5 to 35. The two most common deepest needling depths reported were 1cm (reported by 34% of practitioners) and 1.5cm (33%). The majority of practitioners (90%) sought a *deqi* response when treating their patients, and the most common needle stimulation methods were Even (63/160; 39%), Tonifying, Reducing and Even (44/160; 28%) and Reducing and Even (20/160; 13%). On average, practitioners retained the needles for around 20 minutes, which varied to some extent by patient, such that 73% of practitioners reported a minimum needle retention time as 15 to 20 minutes and 93% reported a maximum needle retention time of between 20 and 30 minutes. 100% of practitioners used stainless steel needles to administer their treatments.

The use of auxiliary interventions based on the diagnosis was permitted within the treatment protocol guidelines. The most commonly used additional therapy was acupressure massage (used at least once on 109 of the 160 patients; 68%), followed by cupping (41/160; 26%) and the use of a heat lamp (40/160; 25%), moxibustion (38/160; 24%), electro-acupuncture (7/160; 4%), and ear seeds (6/160, 4%).

**Table 1. Theoretical frameworks used for acupuncture-specific diagnosis**

|  |  |  |
| --- | --- | --- |
| Traditional acupuncture diagnosis | Frequency (n=160) | Percentage |
| **Overall Theoretical Framework** Zang Fu Syndromes | 139 | 86.9 |
| Fundamental Substances | 117 | 73.1 |
| Eight Principles | 94 | 58.8 |
| Pathogenic Factors | 36 | 22.5 |
| Eight Extra Vessels | 17 | 10.6 |
| Four Levels | 4 | 2.5 |
| Six Divisions | 3 | 1.9 |
| Five Elements | 3 | 1.9 |
| Other | 3 | 1.9 |
|  |  |  |
| **Eight Principle Diagnosis** |  |  |
| Mixed Internal & External | 86 | 53.8 |
| Predominantly External | 41 | 25.6 |
| Predominantly Internal | 33 | 20.6 |
|  |  |  |
| **Zang Fu Syndromes Clusters**  |  |  |
| Liver cluster: Liver Qi Stagnation, Liver Yin Xu, Liver Yang Rising and Liver Fire | 84 | 52.5 |
| Spleen cluster: Spleen Qi and Yang Xu, Kidney Yang Xu, and Internal Damp | 53 | 33.1 |
| Neither of the above two clusters | 2 | 1.5 |
|  |  |  |

**Table 2. Most Commonly reported symptoms in those diagnosed with predominantly Liver or Spleen cluster pathology**

|  |  |  |
| --- | --- | --- |
| Rank | No. times symptom reported for patients with Liver cluster pathology (n=84) | No. times symptom reported for patients with Spleen cluster pathology (n=53)  |
| 1 | Stress | 38(45.2%) | Pain | 33(62.3%) |  |
| 2 | Muscular Tension / Stiffness | 31(36.9%) | Tiredness / Fatigue | 16(30.2%) |  |
| 3 | Headache / Migraine | 28(33.3%) | Bloating | 5(9.4%) |  |
| 4 | Pain | 26(31.0%) | Cold Aversion | 5(9.4%) |  |
| 5 | Sleep Disturbances / Insomnia | 15(17.9%) | Cold Extremities | 5(9.4%) |  |
| 6 | Irritability | 14(16.7%) | Heavy Limbs | 5(9.4%) |  |
| 7 | Anger | 11(13.1%) | Digestive Problems | 4(7.5%) |  |
| 8 | Depression | 7(8.3%) | Headache / Migraine | 4(7.5%) |  |
| 9 | Frustration | 4(4.8%) | Oedema | 4(7.5%) |  |
| 10 | Menstrual Irregularities | 4(4.8%) | Overweight | 4(7.5%) |  |
| 11 | Red Face | 4(4.8%) | Low Bone Density | 3(5.7%) |  |
| 12 | Anxiety | 3(3.6%) | Poor Appetite | 3(5.7%) |  |
| 13 | Fluctuating Mood  | 3(3.6%) | Prolapse | 3(5.7%) |  |

**Table 3: Congruence between advice given (practitioner data) and advice taken up (patient data)**.

|  |  |  |
| --- | --- | --- |
|  |  | Patients reported making changes (Yes/No) |
| Practitioner advice given | Yes/No | 6 months | Chi-squared |  | 12 months | Chi-squared |
|  |  | Yes | No |  |  | Yes | No |  |
| Diet | Yes | 12 (23.1) | 40 (76.9) | 0.88 | Yes | 14 (27.5) | 37 (72.6) | 0.07 |
|  | No | 18 (22.0) | 64 (78.1) | No | 11 (14.3) | 66 (85.7) |
|  |  | Yes | No |  |  | Yes | No |  |
| Exercise | Yes | 27 (38.0) | 44 (62.0) | 0.12 | Yes | 24 (34.8) | 45 (65.2) | 0.92 |
|  | No | 16 (25.4) | 47 (74.6) | No | 20 (33.9) | 39 (66.1) |
|  |  | Yes | No |  |  | Yes | No |  |
| Relaxation | Yes | 22 (38.6) | 35 (61.4) | 0.28 | Yes | 20 (35.7) | 36 (64.3) | 0.25 |
|  | No | 37 (48.0) | 40 (52.0) | No | 33 (45.8) | 39 (54.2) |
|  |  | Yes | No |  |  | Yes | No |  |
| Rest | Yes | 12 (26.7) | 33 (73.3) | 0.46 | Yes | 8 (18.6) | 35 (81.4) | 0.06 |
|  | No | 29 (33.0) | 59 (67.1) | No | 29 (34.5) | 55 (65.5) |
|  |  | Yes | No |  |  | Yes | No |  |
| Work | Yes | 14 (45.2) | 17 (54.8) | 0.002 | Yes | 11 (37.9) | 18 (62.1) | 0.003 |
|  | No | 18 (17.8) | 83 (82.2) | No | 13 (13.4) | 84 (86.6) |

**Table 4: Eight principles and Zang-fu clusters: relationship to NPQ change scores at 6 and 12 months**

|  |  |  |
| --- | --- | --- |
| **Acupuncture-related diagnostic methods** | **NPQ change scores between baseline and 6 months** | **NPQ change scores between baseline and 12 months** |
|  | **N** | **%** | **Mean (95% CI)** | **N** | **%** | **Mean (95% CI)** |
| **Eight Principles1** |  |  |  |  |  |  |
| External | 41 | 27 | -15.33 (-20.15 to -10.51) | 37 | 25 | -20.29 ( - 24.98 to -15.60) |
| Internal | 30 | 20 | -13.37 ( -18.98 to -7.75) | 29 | 20 | -8.41 (-14.15 to -2.66) |
| Mixed Internal and External | 82 | 54 | -10.58 (-13.32 to -7.84) | 80 | 55 | -10.55 (-13.31 to -7.78) |
|  |  |  |  |  |  |  |
| **Zang-fu Clusters2** |  |  |  |  |  |  |
| Liver Cluster | 82 | 62 | -12.29 (-15.06 to -9.52) | 76 | 60 | -10.32 ( -13.45 to -7.18) |
| Spleen Cluster | 48 | 36 | -9.97 ( -14.49 to -5.45) | 48 | 38 | -11.30 ( -15.30 to -7.30) |
| Other3 | 2 | 2 | - | 2 | 2 | - |
| 1  Missing data: 3 Internal and 4 Mixed Internal and External patients did not provide NPQ scores at 6 months; and 4 External, 4 Internal and 6 Mixed Internal and External patients did not provide NPQ scores at 12 months2 Missing data: 2 Liver and 5 Spleen Cluster patients did not provide NPQ data at 6 months; and 8 Liver and 5 Spleen Cluster patients did not provide NPQ data at 12 months.3 Insufficient data for analysis |

**Table 5: Patient-reported variables comparing acupuncture and usual care groups at 6 and 12 months**

|  |  |  |
| --- | --- | --- |
|  | **6 months** | **12 months**  |
| **Characteristic** | **Acupuncture** | **Usual care alone** | **Difference** **(95% CI)** | **p-value** | **Acupuncture** | **Usual care alone** | **Difference** **(95% CI)** | **p-value** |
|  | N, **Mean (SD)** | **N, Mean (SD)** |  |  | **N, Mean (SD)** | **N, Mean (SD)** |  |  |
| Chronic Pain Self Efficacy Scale (scored 0 to 8) | 151, 4.80 (1.80) | 139, 3.92 (1.52) | 0.82 (-0.49 to 1.16) | <0.001 | 144, 4.88 (1.79) | 139, 4.14 (1.68) | 0.65 (0.18 to 1.13) | 0.009 |
| Perceived Stress Scale (scored 0 to 16) | 151, 5.85 (3.29) | 144, 5.67 (3.23) | 0.14 (-0.58 to 0.87) | 0.69 | 145, 5.92 (3.43) | 140, 5.84 (3.48) | 0.11 (-0.53 to 0.75) | 0.74 |
| “Can you use/apply the things you learned from the treatment in everyday life situations to reduce pain?”(0 to 4) | 147, 1.75 (1.21) | 125, 1.45 (1.11) | 0.29 (-0.01 to 0.60) | 0.06 | 144, 1.70 (1.16) | 128, 1.48 (1.09) | 0.23 (-0.06 to 0.52) | 0.12 |
| Number of lifestyle changes (1 to 5) | 156, 1.46 (1.50) | 148, 0.41 (0.86) | 1.04 (0.73 to 1.36) | <0.001 | 150, 1.38 (1.36) | 144, 0.58 (1.13) | 0.81 (0.55 to 1.07) | <0.001 |
| “To what extent are you able to put into practice the advice you received?”(0 to 10) | 107, 5.68 (3.13) | 43, 4.28 (3.20) | 1.52 (0.48 to 2.55) | 0.005 | 104, 5.46 (2.80) | 44, 5.16 (3.26) | 0.30 (-0.95 to 1.55) | 0.63 |
| To what extent are the changes you have been making helpful to you?(0 to 10) | 106, 5.77 (3.07) | 45, 4.29 (2.98) | 1.52 (0.53 to 2.50) | 0.004 | 103, 5.76 (2.75) | 46, 4.91 (2.95) | 0.82 (-0.49 to 2.12) | 0.21 |
|  |
|  | **6 months** | **12 months**  |
| **Characteristic**(Yes/No responses) | **Acupuncture** | **Usual care alone** | **Odds ratio (95% CI)** | **p-value** | **Acupuncture** | **Usual care alone** | **Odds ratio (95% CI)** | **p-value** |
| “Did you learn to improve the way you live and care for yourself?**”** | 87/149 (58.4) | 29/128 (22.7) | 5.35 (3.47 to 8.23) | <0.001 | 90/144 (62.5) | 31/123 (25.2) | 5.39 (3.32 to 8.74) | <0.001 |
| Did you make any changes to: | N=156 | N=148 |  |  | N=150 | N=144 |  |  |
| Diet | 32 (20.5) | 8 (5.4) | 5.32 (2.29 to 12.32) | <0.001 | 28 (18.7) | 13 (9.0) | 2.74 (1.45 to 5.21) | 0.002 |
| Exercise | 48 (30.8) | 27 (18.2) | 2.10 (1.17 to 3.79) | 0.01 | 52 (34.7) | 24 (16.7) | 2.62 (1.57 to 4.38) | <0.001 |
| Relaxation | 67 (42.9) | 13 (8.8) | 8.14 (4.13 to 16.05) | <0.001 | 60 (40.0) | 16 (11.1) | 6.06 (3.86 to 9.52) | <0.001 |
| Rest | 45 (28.8) | 8 (5.4) | 7.22 (3.31 to 15.78) | <0.001 | 41 (27.3) | 18 (12.5) | 2.85 (1.63 to 5.01) | <0.001 |
| Work | 35 (22.4) | 5 (3.4) | 8.19 (3.75 to 17.86)  | <0.001 | 26 (17.3) | 12 (8.3) | 2.22 (1.03 to 4.75) | 0.04 |
| Note: The analyses made adjustments for baseline NPQ scores, duration of neck pain, age, gender and city as a fixed effect and GP practice as a random effect using robust standard errors.  |

**Table 6: Impact of factors measured during the intervention period on NPQ scores at 6 and 12 months.**

|  |  |  |
| --- | --- | --- |
| **Characteristic** | **6 months** | **12 months** |
| **Difference in percentage points between acupuncture and usual care (95% CI)** | **p-value** | **Difference in percentage points between acupuncture and usual care (95% CI)** | **p-value** |
| **Intervention effects (primary results)** | -5.56 (-8.33 to -2.78) | <0.001 | -3.92 (-6.87 to -0.97) | 0.009 |
| **Self-efficacy** |  |  |  |  |
|  Intervention | -3.31 (-5.62 to -0.99) | 0.007 | -2.28 (-5.28 to 0.73) | 0.132 |
|  Change in self-efficacy | -3.01 (-3.75 to -2.26) | <0.007 | -3.34 (-4.38 to -2.31) | <0.001 |
| **Ability to use what has been learnt** |  |  |  |  |
|  Intervention | -5.57 (-7.98 to -3.16) | <0.001 | -3.16 (-6.08 to -0.24) | 0.035 |
|  Ability to use what has been learnt | -2.70 (-4.17 to -1.23) | 0.001 | -2.13 (-3.53 to -0.73) | 0.004 |
| **Ability to make improvements in living self-care** |  |  |  |  |
|  Intervention | -5.12 (-7.92 to -2.32) | 0.001 | -2.55 (-5.74 to 0.64) | 0.113 |
|  Ability to make improvements in living/self-care | -3.90 (-7.17 to -0.63) | 0.021 | -2.35 (-5.73 to 1.03) | 0.166 |
| **Summary of lifestyle change** |  |  |  |  |
|  **Diet** |  |  |  |  |
|  Intervention  | -4.95 (-7.48 to -2.42) | <0.001 | -4.02 (-6.87 to -1.17) | 0.007 |
|  Diet change | -2.59 (-6.58 to 1.40) | 0.195 | -0.33 (-5.18 to 4.52) | 0.891 |
|  **Exercise** |  |  |  |  |
|  Intervention  | -4.94 (-7.60 to -2.28) | 0.001 | -3.54 (-6.45 to -0.62) | 0.019 |
|  Exercise change | -3.15 (-6.10 to -0.20) | 0.037 | -2.93 (-6.92 to 1.07) | 0.145 |
|  **Relaxation** |  |  |  |  |
|  Intervention  | -3.26 (-6.18 to -0.34) | 0.030 | -4.04 (-7.28 to -0.80) | 0.016 |
|  Relaxation change | -6.22 (-10.57 to -1.87) | 0.006 | -0.04 (-4.54 to 4.47) | 0.987 |
|  **Resting** |  |  |  |  |
|  Intervention  | -4.64 (-7.49 to -1.80) | 0.002 | -4.08 (-7.02 to -1.15) | 0.008 |
|  Rest change | -3.15 (-6.83 to 0.54) | 0.092 | 0.22 (-4.29 to 4.72) | 0.923 |
|  **Work** |  |  |  |  |
|  Intervention  | -4.49 (-7.14 to -1.84) | 0.002 | -3.80 (-6.42 to -1.18) | 0.006 |
|  Work change | -4.63 (-8.46 to -0.80) | 0.019 | -3.05 (-8.33 to 2.22) | 0.246 |
|  **Number of lifestyle changes** |  |  |  |  |
|  Intervention  | -3.44 (-6.29 to -0.59) | 0.020 | -3.58 (-6.82 to -0.35) | 0.031 |
|  Number of lifestyle changes | -1.84 (-3.01 to -0.67) | 0.003 | -0.58 (-2.08 to 0.92) | 0.436 |
| **Extent able to put into practice advice**  |  |  |  |  |
|  Intervention  | -4.07 (-8.23 to 0.11) | 0.056 | -3.41 (-8.15 to 1.33) | 0.152 |
|  Extent able to put into practice advice/teaching | -0.72 (-1.24 to -0.19) | 0.009 | 0.02 (-0.00 to 0.05) | 0.073 |
| **Extent changes have been helpful** |  |  |  |  |
|  Intervention  | -3.49 (-7.67 to 0.68) | 0.098 | -3.31 (-7.87 to 1.25) | 0.149 |
|  Extent changes have been helpful | -1.08 (-1.77 to -0.39) | 0.003 | 0.02 (-0.01 to 0.05) | 0.153 |
| **Change in perceived stress** |  |  |  |  |
|  Intervention | -5.76 (-8.01 to -3.51) | <0.001 | -370 (-6.44 to -0.95) | 0.010 |
|  Change in perceived stress | 0.48 (0.05 to 0.92) | 0.032 | 0.78 (0.30 to 1.25) | 0.002 |