Willfulness to try acupuncture again: reports from patients on their treatment reactions in a low back pain trial

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ABSTRACT
Background Reactions to treatment are common following acupuncture. Understanding how these reactions are interpreted by patients is largely unexplored.
Objective To examine patients’ ratings of the severity and bothersomeness of a range of common treatment reactions, and to assess their impact on willingness to try acupuncture again.
Methods Self-reported ratings of the frequency, severity and bothersomeness of treatment reactions from 133 patients in the acupuncture arm of a pragmatic randomised controlled trial of acupuncture for chronic low back pain are described and analysed.
Results A total of 133 acupuncture patients reported at 3 months reactions that they had experienced at any time during a course of up to 10 acupuncture treatment sessions. They received a total of 1150 treatments, an average of 8.6 sessions per patient. All patients reported treatment reactions, most commonly relaxation (84%, n = 112), which was significantly associated with willingness to try acupuncture again, (χ² = 7.860, df = 1, p = 0.005). Only 16% (n = 21) were unwilling to experience a specific treatment reaction again, and 9% (n = 12) were unwilling to try acupuncture again. The most ‘bothersome’ reaction was a temporary worsening of symptoms (29%, n = 38), though this was not associated with an unwillingness to try acupuncture again (χ² = 3.82, df = 1, p>0.536). Those unwilling to try acupuncture again reported significantly less reduction in their pain at 3 months (mean (SE) SF-36 bodily pain score at 3 months 30.453 (3.598) vs 19.30 (1.128); p = 0.003).
Conclusion Among this group of patients seeking help for low back pain, the experience of treatment reactions was universal. There was no evidence that the bothersomeness of treatment reactions was associated with patient’s willingness to try acupuncture again. The benefit of pain reduction over the course of treatment appeared to outweigh self-rated bothersome reactions to treatment.

INTRODUCTION
With increasing concern about side effects of mainstream treatments,1–3 patients are turning to acupuncture4–6 as a relatively safe and effective treatment for low back pain. The National Institute for Health and Clinical Excellence guidelines now recommend acupuncture as an adjunct to usual care for low back pain.7 However, varying degrees of adverse reactions are experienced by patients. The literature on adverse events after acupuncture encompasses case reports, practitioner and patient surveys and prospective surveys.8,9 Serious adverse events are rare and the overall risk is very low provided that the acupuncture is carried out by well-trained practitioners.10,11 Minor reactions to treatment, such as a temporary worsening of symptoms, dizziness, tiredness, relaxation, becoming energised or hunger are commonly reported12,13 Whether patients interpret reactions as positive or negative will vary with individual experience, and this variation may also be influenced by factors such as culture, expectations and the disease being treated.14

The experience of a treatment reaction associated with acupuncture may either be construed by patients as an acceptable component of the healing process or evaluated as too risky to want to engage in further treatment. Within this context, patients seeking acupuncture treatment are faced with the decision to trade off potential benefits of acupuncture against the risk of experiencing negative and/or unacceptable treatment reactions. The impact that adverse reactions might have on patients willing to continue with acupuncture in exchange for the benefits of the treatment is unknown. Set in the context of treatment for low back pain, the aim of this paper is to determine what factors have an impact on the willingness to try acupuncture again after experiencing a treatment reaction.

METHODS
Participants and setting Patients aged 18–65 with a history of non-specific low back pain for a period of 4–52 weeks were recruited from 89 GP primary care practices to a pragmatic randomised controlled trial of acupuncture for low back pain. Those randomised to acupuncture received a course of up to 10 acupuncture sessions over 3 months. The original study was approved by York Ethics Committee (ISRCTN80764175) and full details are reported elsewhere.15 In a postal questionnaire at 3 months after randomisation, a total of 133 patients reported their treatment reactions related to acupuncture. Twenty people who were allocated to acupuncture did not return their 3-month follow-up questionnaire.

Intervention Six acupuncturists with a minimum of 3 years’ experience and registered with the British Acupuncture Council delivered up to 10 weekly treatments tailored to individual patients’ needs. Additional care such as massage and acupuncture-
specific advice was provided if appropriate by acupuncturists. Details of the acupuncture treatments are published elsewhere.  

**Outcome measures**  

The primary clinical outcome measure for the trial was the bodily pain dimension of the short-form health survey (SF-36). For this substudy, the outcomes reported at 3 months were (1) reactions to treatment, and their severity and bothersomeness; (2) willingness to experience this reaction again and (3) willingness to try acupuncture again. Patients rated the frequency, severity and bothersomeness of minor treatment reactions. Based on the previous research, commonly reported treatment reactions were selected for a checklist, with options covering temporary worsening of pain symptoms, dizziness, tiredness, relaxation, becoming energised, hungry and any ‘other’ reaction reported by patients. To assess severity, patients were asked ‘How would you describe the strength of your response’ for each of the treatment reactions, with the severity classified by patients as ‘1 = mild’, ‘2 = moderate’ or ‘3 = severe’. To assess bothersomeness, patients were asked ‘How much did this response bother you at the time?’ ‘0 = not at all’, ‘1 = a bit’, ‘2 = quite a lot’ and ‘3 = a great deal’. Patients were asked two further questions: ‘Would you be prepared to experience it (the reaction) again?’ and ‘Would you be happy to try acupuncture again.’ The willingness to experience the same reaction again was recorded in a dichotomous variable: 1 = yes, 0 = no, and, the willingness to try acupuncture again: 1 = yes, 0 = no.  

**Analytical methods**  

Descriptive statistical analysis was used to examine the proportion of patients reporting treatment reactions, the bothersomeness and severity of the reactions, the unwillingness of those patients to experience the reaction again and the unwillingness to receive acupuncture again. Univariate analysis using the χ² test identified which reactions were associated with willingness or unwillingness to try acupuncture again. An analysis of covariance was conducted on patients’ SF-36 bodily pain scores reported at 3 months with the baseline SF-36 bodily pain score added as a covariate to determine differences in pain outcome at 3 months. All analysis was conducted using SPSS version 17.  

**RESULTS**  

**Treatment reactions**  

The group of 133 patients who responded at 3 months received a total of 1150 treatments (range 1–10, mean 8.6 treatments per patient, SD = 2.1). All 133 patients reported at least one reaction to treatment and the most commonly reported reaction was feeling relaxed followed by a temporary worsening of symptoms (table 1). Of these patients, 79% (n = 105) experienced multiple reactions (mode and median =3), 29% (n = 38) were bothered by the reaction quite a lot or a great deal and 82% (n = 109) reported their reaction (whether positive or negative) as moderate to severe. When asked about any other reactions, three patients reported problems associated with the acupuncture needles, four reported pain or numbness in their back or legs, one reported emotional trauma and one reported feeling thirsty. The results are summarised in table 1.  

**Unwillingness to experience a treatment reaction again**  

Of the 133 patients experiencing a treatment reaction, when asked, ‘Would you be willing to experience the reaction again’, 16% (n = 21) reported that they would be unwilling to experience the reaction again. Five people did not answer the question, of whom three reported feeling relaxed and two reported a temporary worsening of symptoms. Each treatment reaction was examined using the median value of reported rating to determine what effect the bothersomeness and severity of the reaction had on the willingness to experience the reaction again. We found that people who were unwilling to experience the reaction again reported greater severity of tiredness and needle-related reactions, and were also bothered quite a lot by the tiredness, relaxation and needle-related symptoms. There was no evidence that patient reports of the degree of severity or bothersomeness of the temporary worsening of symptoms or dizziness differed between groups. Table 2 summarises the results.  

**Unwillingness to try acupuncture again**  

Of the 133 patients experiencing a treatment reaction, 9% (n = 12) reported that they would be unwilling to try acupuncture again, resulting in the early cessation of treatment in eight of these 12 cases.  

Univariate analysis established that relaxation was significantly associated with willingness to try acupuncture again (χ² = 7.860, df = 1, p = 0.005). Subsequent analysis found that relaxation was significantly greater among those willing to try acupuncture again than among those who were unwilling (U = 437.00, p = 0.002), confirming relaxation as a positive reaction. Temporary worsening of symptoms was the most frequently reported negative reaction; however, there was no association with an unwillingness to have acupuncture again (χ² = 3.822, df = 1, p>0.536). The cell counts for the other five reactions were insufficient to conduct further univariate analysis.  

**Table 1**  

Summary of 133 patient’s self-reported ratings of reactions to acupuncture treatment (some people rated more than one reaction)  

<table>
<thead>
<tr>
<th>Reactions</th>
<th>Proportion with a reaction after any treatment, % (n)</th>
<th>Proportion rating a reaction as moderate or severe, % (n)</th>
<th>Proportion who were bothered by a reaction ‘quite a lot’ or ‘a great deal’, % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary worsening of symptoms</td>
<td>63 (84)</td>
<td>44 (59)</td>
<td>23 (30)</td>
</tr>
<tr>
<td>Dizziness/light headed</td>
<td>27 (36)</td>
<td>5 (7)</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Tired/drowsiness</td>
<td>49 (65)</td>
<td>17 (22)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Feeling energised</td>
<td>38 (50)</td>
<td>24 (32)</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Feeling relaxed</td>
<td>84 (112)</td>
<td>59 (79)</td>
<td>5 (7)</td>
</tr>
<tr>
<td>Feeling hungry</td>
<td>8 (10)</td>
<td>2 (3)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Other reactions</td>
<td>7 (9)</td>
<td>5 (6)</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Total number of patients</td>
<td>100 (133)</td>
<td>82 (109)</td>
<td>29 (38)</td>
</tr>
</tbody>
</table>

Missing data n = 20 did not return a 3-month questionnaire: 9/20 people received nine or more sessions, 2/20 people received one session, 9/20 did not attend a session.
One might hypothesise that multiple reactions would be more prevalent among those who were unwilling to have acupuncture again. However, figure 1 indicates the opposite; where the 12 people who were unwilling to have acupuncture again experienced a total of 25 reactions (median = 2), compared with a total of 251 reactions (median = 3) reported by the 121 people who were willing to have acupuncture again. Further analysis of the 25 reactions experienced by those unwilling to try acupuncture again showed that temporary worsening of symptoms, combined with either dizziness, light-headedness, tiredness or lethargy accounted for 61% of the reactions (see figure 2). Within that number, six patients reported a moderate to severe temporary worsening of symptoms that they were not prepared to experience again.

We compared changes in bodily pain scores at 3 months between those willing and those unwilling to try acupuncture again. When baseline scores for the SF-36 bodily pain scale of the SF-36 are used as a covariate, the results of the analysis of covariance indicate that those unwilling to try acupuncture again reported significantly less reduction in pain following acupuncture treatment than those who were willing to try acupuncture again. The result is summarised in table 3.

### Table 2
Summary of the patients’ reports of severity and bothersomeness of the reactions and willingness to experience the reaction again.

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Severity of the reaction (1 = mild, 2 = moderate, 3 = severe)</th>
<th>Would you be prepared to experience the reaction again?</th>
<th>Yes, N (median)</th>
<th>No, N (median)</th>
<th>Total, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary worsening of symptoms</td>
<td></td>
<td>Yes, N (median)</td>
<td>70 (1)</td>
<td>10 (1)</td>
<td>80</td>
</tr>
<tr>
<td>Dizziness/light-headedness</td>
<td></td>
<td>Yes, N (median)</td>
<td>29 (1)</td>
<td>5 (1)</td>
<td>34</td>
</tr>
<tr>
<td>Tiredness/lethargy</td>
<td></td>
<td>Yes, N (median)</td>
<td>56 (1)</td>
<td>7 (2)</td>
<td>63</td>
</tr>
<tr>
<td>Feeling energised</td>
<td></td>
<td>Yes, N (median)</td>
<td>47 (2)</td>
<td>1 (1)</td>
<td>48</td>
</tr>
<tr>
<td>Relaxation</td>
<td></td>
<td>Yes, N (median)</td>
<td>97 (2)</td>
<td>2 (1)</td>
<td>99</td>
</tr>
<tr>
<td>Hunger</td>
<td></td>
<td>Yes, N (median)</td>
<td>8 (1)</td>
<td>1 (2)</td>
<td>9</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>Yes, N (median)</td>
<td>5 (2)</td>
<td>4 (3)</td>
<td>9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Bothersomeness of the reaction (0 = not at all, 1 = a bit, 2 = quite a lot, 3 = a great deal)</th>
<th>Would you be prepared to experience the reaction again?</th>
<th>Yes, N (median)</th>
<th>No, N (median)</th>
<th>Total, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary worsening of symptoms</td>
<td></td>
<td>Yes, N (median)</td>
<td>70 (2)</td>
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<td>80</td>
</tr>
<tr>
<td>Dizziness/light-headedness</td>
<td></td>
<td>Yes, N (median)</td>
<td>29 (2)</td>
<td>5 (2)</td>
<td>34</td>
</tr>
<tr>
<td>Tiredness/lethargy</td>
<td></td>
<td>Yes, N (median)</td>
<td>56 (1)</td>
<td>7 (2)</td>
<td>63</td>
</tr>
<tr>
<td>Feeling energised</td>
<td></td>
<td>Yes, N (median)</td>
<td>47 (1)</td>
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</tr>
<tr>
<td>Relaxation</td>
<td></td>
<td>Yes, N (median)</td>
<td>97 (1)</td>
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</tr>
</tbody>
</table>

**DISCUSSION**

All patients who submitted data in this primary care trial of acupuncture for low back pain reported at least one reaction to treatment. All 100% (n = 133) reported treatment reactions, most commonly relaxation (84%, n = 112). A temporary worsening of symptoms was the most prevalent negative reaction, and the most ‘bothersome’ (29%, n=58), and one that more patients would prefer not to experience again. However, over the whole sample the temporary worsening of symptoms was not associated with an unwillingness to have acupuncture again. Overall, only 9% of these patients were sufficiently bothered by their treatment reactions to put them off trying acupuncture in the future.

Although willingness to try acupuncture again is positively associated with the experience of relaxation, it appears that the predominant factor in a patient’s willingness to try acupuncture again is the amount of pain relief experienced over the course of treatment. On average, the patients not willing to try acupuncture again experienced significantly less reduction in pain than those willing to try acupuncture again.

The nature of the bothersome reactions and the number experiencing them is unsurprising as they are commonly reported. To our knowledge, this is the first time that a study has focused on how reactions to treatment are interpreted by patients in

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**Table 3** Differences in reduction in pain between those willing and those unwilling to have acupuncture again.

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Would you be willing to try acupuncture again?</th>
<th>Yes (n = 121)</th>
<th>No (n = 12)</th>
<th>Mean difference</th>
<th>SE</th>
<th>Statistic</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference in SF-36 bodily pain score at 3 months</td>
<td></td>
<td></td>
<td></td>
<td>11.323</td>
<td>3.774</td>
<td>F = 9.0, df = 1, p = 0.003</td>
<td>3.857 to 18.790</td>
</tr>
</tbody>
</table>

The data met assumptions for testing using analysis of covariance.

Five points change on the SF-36 bodily pain score represents a clinically significant change in pain.

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**Figure 1**
Frequencies of reported multiple reactions by all 133 patients.

**Figure 2**
Proportions of reactions reported by patients who were unwilling to try acupuncture again (n=12).
the context of their overall care. The findings here may be considered in the context of a risk–benefit scenario that can affect the personal decision-making process. Promotion of healthy lifestyle messages of diet and exercise has exposed the public to a ‘no pain no gain’ metaphor, which is founded within the model of risk–benefit.18 19 The results here can also be explained within this familiar narrative. Specifically, beneficial treatment reactions obtained through the process of the treatment, rather than outcomes of treatment may be described as ‘process utility’. The likelihood of experiencing positive treatment outcomes that might emerge over time can be weighed against the potential risk of experiencing a negative treatment reaction. A positive experience of reduced pain at the end of treatment appears to outweigh treatment reactions. When asked about future intention to try acupuncture again, it appears that the experience of benefit outweighs the risk of reaction for the great majority of patients.

Limitations
The study relied on patient’s recall of events at 3 months to assess the level of severity and bothersomeness of reactions at the time during a course of up to 10 sessions of treatment. Memory is fallible and recall could be subject to suggestion by completing the questionnaire itself. Treatment reactions recorded by patients and therapists at the time of treatment would provide a more immediate measure, and permit a correlation with data at the end of a course of treatment to assess the reliability of reporting symptoms. Also, where possible, physical measurements such as recording of presyncopal and syncopal episodes, for example, may be a more reliable measure of severity than relying on patient’s interpretation of dizziness and light headedness. The small sample size for the group of people who were unwilling to try acupuncture again could have underpowered the analysis, and data were not explored for individual practitioner effects or the potential influence of massage and self-help advice.

Future research
Focusing on adverse events has been necessary to evaluate the safety of acupuncture. Collecting information on only the nature and severity of the event ignores how such reactions are perceived and how they affect engagement and adherence to future treatment. Research could usefully explore patients’ expectation of treatment reactions and how they might affect the actual reactions to treatment, adherence to treatment and clinical effectiveness. Future research could also focus on the physical measurement of reactions compared with the perception of treatment reactions. There are also implications for policy and practice; the results suggest that patients considering acupuncture as a treatment for back pain should be advised to expect a 29% chance of experiencing a bothersome reaction to treatment, but that this may not necessarily indicate a poor outcome.

CONCLUSION
All patients in this trial of acupuncture for low back pain experienced a reaction to treatment, most commonly relaxation, which was associated with willingness to try acupuncture again. Temporary worsening of symptoms was the most bothersome reaction. The great majority (91%) of patients were not put off trying acupuncture again. For the majority, the benefit of reduced pain over the course of treatment outweighed negative experiences associated with treatment reactions.

Summary points
- We surveyed patients in a randomised controlled trial about the side effects of acupuncture.
- All 133 who responded had at least one side effect.
- 9% of patients would not have acupuncture again, probably because of both side effects and lack of pain relief.

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Competing interests None.

Ethics approval This study was conducted with the approval of the York Research Ethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES
Willingness to try acupuncture again: reports from patients on their treatment reactions in a low back pain trial

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