A review of psychosocial predictors of treatment outcomes: what factors might determine the clinical success of acupuncture for pain?

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Abstract

This narrative review examines the psychosocial factors that might predict clinical outcomes in acupuncture for pain. Given existing evidence concerning the clinical effectiveness and safety of acupuncture in painful conditions it is important to consider how clinicians might further improve their effectiveness. The relevant theoretical frameworks focus primarily on the patient, suggesting that their background characteristics and their beliefs about pain and acupuncture should be considered as potential predictors of outcome. The self-regulation model within health psychology helps us understand how people manage their health and integrate interventions like acupuncture into the management their illness. It also implies that the therapeutic relationship, in particular patients' perceptions of that relationship are likely to be related to outcome. The empirical literature in this area is sparse. However, the findings to date do suggest that a number of psychosocial factors, in particular patients' beliefs about acupuncture are significant predictors of treatment outcomes from acupuncture for pain. Factors related to the therapeutic relationship are also likely to be important in facilitating good clinical outcomes. We discuss the limitations of the existing studies and make recommendations for future research in this area. If we can better understand the psychosocial factors involved in acupuncture then we should be able to enhance acupuncture treatments and improve outcomes for patients. These observations will therefore have potential to allow us to develop techniques that may improve clinical outcomes in the treatment of pain.

Introduction: Acupuncture for Pain

Chronic pain is common and costly and existing treatments have limited success: 40% of chronic pain patients in a recent (2003) European survey reported inadequate pain management with 13% of those surveyed having used acupuncture for their pain.[1] In the USA 4.1% of the total population surveyed in 2002 had visited an acupuncturist at some time [2] as had 1.6% of the UK general public(1998).[3] Many British GPs also hold positive beliefs about this intervention. the British Medical Acupuncture Society estimates that approximately 3500 doctors use acupuncture themselves while two thirds of GPs believe acupuncture should be available on the National Health Service.[4]

There is growing evidence from randomised controlled trials (RCTs) and meta-analyses that acupuncture has clinically significant effects (efficacy over placebo controls) in chronic back pain[5-8] and other painful conditions including neck pain[9;10] osteoarthritis of the knee[11] migraine[12] and tension headache.[13;14] There is good evidence that acupuncture is both extremely safe [15;16] as well as being a cost-effective intervention for persistent[17] and chronic low back pain[18], chronic neck pain[19] and headache.[20] There is also growing indirect evidence that acupuncture has large non-specific clinical effects, in addition to any specific efficacy. The variation in the proportion of patients reporting improvements across different individual trials suggests the presence of mediating factors that contribute to positive clinical outcomes. Furthermore, in RCTs both placebo acupuncture and real acupuncture can have similarly large effects compared to waiting list controls or 'treatment as usual' [7]. The difference in effectiveness of

acupuncture and no acupuncture is far greater than the difference between acupuncture and so-called 'placebo acupuncture'. This is similar to the situation for anti-depressants and psychotherapy, both of which are considered effective treatments and both of which have repeatedly demonstrated large non-specific effects and smaller specific effects.[21;22]

The broader chronic pain literature has a growing focus on treatment process and predictors of outcome.[23] Psychosocial factors have been shown to be important predictors of outcomes such as disability, even when controlling for demographic, clinical and physiological factors.[24;25] This focus is designed to improve understanding of how individual treatments produce successful outcomes and to suggest whether specific treatments should be targeted to particular patient groups. In the case of acupuncture, the relative contribution of non-specific effects to overall treatment effectiveness is consistent with the suggestion that psychosocial factors such as patient beliefs about illness and treatment and the therapeutic relationship make a very large contribution to its clinical effectiveness.[26] This makes it both important and feasible to study the psychosocial factors that predict outcomes from acupuncture in the same way as one would for all interventions for chronic pain. The aim of this review is to collate and critique the theoretical and empirical literature concerning the psychosocial factors that might predict outcomes from acupuncture for pain while recognising that it is probably an effective and cost effective clinical intervention. If we can identify psychosocial factors that predict outcomes in acupuncture then we can use this knowledge clinically to improve the effectiveness of acupuncture for patients with pain.

Identifying Psychosocial Factors that might be Associated With Acupuncture Outcomes in Pain.

It is one thing to accept that factors other than needle placement might be relevant to acupuncture outcomes, it is quite another to be able to identify them. In this section we consider the insights available from theoretical frameworks and qualitative research concerning which psychosocial factors might be associated with outcomes and why.

Relevant Theoretical Frameworks

Theoretical frameworks from placebo research, chronic pain and health psychology identify psychosocial factors that might be associated with treatment outcomes in acupuncture for pain. These frameworks suggest patients' beliefs about and experiences of both chronic pain and acupuncture are probably important determinants of treatment outcomes.

Placebo Theories

According to placebo theorists two psychological mechanisms, conditioning and expectancies, are thought to underlie placebo effects.[27] Put very simply, a patient is thought to respond to an inert placebo intervention (often a pill) through a) largely unconscious learning mechanisms (i.e. conditioning) through which the placebo intervention (the stimulus) generates pain relief through its (unconscious, learnt) association with previous pain-reducing treatments and/or b) largely conscious mechanisms (i.e. expectancy) through which a patient's conscious anticipation that pain reduction (a non-volitional

response) will follow a (placebo) intervention has a direct causal effect on the actual non-volitional response of pain reduction.[28] Empirical evidence suggests that conscious expectations mediate the role of conditioning in the context of pain and other conscious physiological processes,[29-31] suggesting patients' expectations of acupuncture in particular might be directly associated with clinical outcome. Indeed there is good evidence that patients' expectations of outcomes are associated with actual outcomes: in one systematic review 15 of 16 high quality original studies found a significant effect of expectations on outcomes.[32] Placebo theories and studies thus suggest that expectations of acupuncture and, indirectly, past experience of acupuncture might be associated with acupuncture outcomes in pain. Clinically it might be particularly important for patients to have a successful first experience of acupuncture and also to expect to experience pain relief from acupuncture.

A Cognitive Behavioural Model of Pain

The fear-avoidance behavioural-cognitive model of chronic pain [e.g. 33;34] suggests that patients' beliefs about and responses to pain are key determinants of pain chronicity and can thus strongly influence treatment outcome. According to this theory, patients are more likely to develop chronic pain if they interpret their pain as threatening. This catastrophising then triggers pain related-fear which is linked to avoidance behaviours and hyper-vigilance to physical sensations. Patients then become more disabled and decrease their activities still further, developing negative affectivity (i.e. depression). Finally patients interpret their pain as more threatening, and the

cycle continues. This framework thus focuses on patients' perceptions of pain. The back pain literature supports the importance of patients' pain beliefs for outcomes of multidisciplinary and conventional primary care interventions for back pain. Patients who do not perceive their back pain as threatening (i.e. those who have low scores on measures of catastrophising) or who consider their back pain as less threatening as it improves over the course of treatment have better treatment outcomes.[24;35-38] Patients who report less pain-related fear or who experience decreasing pain-related fear during a course of treatment experience better treatment outcomes.[37;39-45] Patients who have increased confidence in their ability to manage or cope with pain (higher pain self-efficacy) have improved outcomes[43;46]; cross-sectional studies also find associations between functional self-efficacy and physical function.[47;48] Empirical evidence supports the theoretical proposition that specific dimensions of pain beliefs are associated with treatment outcomes in chronic pain and knowing this may help practitioners become better therapists. Three specific factors, catastrophising, fear and anxiety pain responses, and pain self-efficacy, should be considered as potential predictors of acupuncture outcomes.

A Framework from Health Psychology

Health psychology theory suggests that patients' beliefs about treatment and illness, while important, are not the only potential psychosocial predictors of treatment outcome. An extended version of Leventhal's common sense model of self-regulation [49;50] also incorporates patients' initial experiences of treatment as potential influences on outcomes. According to this model,

people construct representations of their illness and use these to select a potentially effective treatment for their condition. Having initiated a treatment, people then continue to use (adhere to) that treatment while evaluating their experiences of both the treatment itself and the practitioner. Both adherence and patients' appraisals of treatment can influence health status. This model also situates the individual within their broader context, specifying that background variables (such as pain duration, gender, age, work status, psychological health etc.) are related to peoples' beliefs about illness and treatment. This model holds true across a range of settings[51] for example empirical evidence in back pain shows that psychological ill-health is associated with poor outcomes.[39;42;43;52-54] In addition there is evidence from conventional medicine that patients who have positive evaluations of their practitioner also have better treatment outcomes.[55] According to this model then we should consider two further groups of factors as potential predictors of acupuncture outcomes in pain: background factors (e.g. personal psychological characteristics) and patients' early experiences of the intervention itself including their therapeutic relationship. For clinicians this suggests a focus on the interpersonal aspects of the consultation in addition to the acupuncture intervention might itself help improve clinical outcomes.

Qualitative Research on Acupuncture.

Qualitative research mostly aims to explore phenomena using a bottom-up approach, grounding emergent themes and theories in participants' everyday experiences. As such, qualitative studies can provide insight into the psychosocial aspects of treatment that acupuncture patients and practitioners

value, and hence suggest factors that might be associated with outcomes. Di Blasi suggests that qualitative methods have an important contribution to make in identifying factors that contribute to treatment effects in particular contexts.[56] Indeed this literature does highlight potential predictors of outcome that are not emphasised in the theoretical frameworks reviewed above.

The Therapeutic Relationship

A number of qualitative studies suggest that both patients and practitioners value the therapeutic relationship in acupuncture.[57-62] The valued features include its collaborative nature (in comparison to more paternalistic relationships found in conventional medicine), and patients' sense of feeling cared for and their perceptions of practitioners as empathic. These features could be associated directly with positive outcomes, and there is quantitative evidence to support this.[55] It is also possible that patients who value collaborative therapeutic relationships are more likely to benefit from acupuncture than patients who value more paternalistic relationships. Patients and practitioners also value a holistic focus within the therapeutic relationship, which involves a broad approach to health and wellbeing rather than a focus on a single problem.[57;58;60;61] Again, a holistic therapeutic style might in itself promote positive outcomes and/or patients who prefer a holistic style might respond better to acupuncture than others. There might be potential for clinicians to enhance outcomes through focusing on patient preferences and their own orientation and beliefs in relation to the therapeutic relationship.

Patient Factors

Specific patient-related factors that might be associated with acupuncture outcomes relate to treatment seeking, expectations, perceptions of needling, and personality. Acupuncture patients often seek out acupuncture themselves (particularly in private practice in the UK), but they can also be offered it by a treating clinician such as a physiotherapist; whether acupuncture is patient-initiated or clinician-initiated might conceivably impact outcome [59] through an influence on patients' expectations. Whether or not acupuncture treatment is self-initiated, patients come to it with a range of expectations about different aspects of treatment.[62-64] In one study patients' expectations (in acupuncture and homeopathy and osteopathy) included complete cure and improved ability to cope with symptoms. They also expected symptomatic relief and improved quality of life as well as interventions with fewer risks than conventional treatments.[64] Patients' expectations regarding a range of outcomes (not just pain) need to be considered as potential outcome predictors. Some patients also hold specific expectations concerning acupuncture needles[62;63] suggesting that apprehension or anxiety about needles might influence outcomes. Similarly some patients perceive their experiences of needling sensation as important features of acupuncture.[59;63] The possibility that needling sensation (deqi) might be important for acupuncture outcome is consistent with acupuncture theory.[65] Some qualitative studies, particularly those carried out with a longitudinal perspective, demonstrate the extent of changes that can occur over treatment including changes in patients' beliefs, goals and health

behaviours.[60-62;62] Patients who are ready to make changes, or who are open to new experiences, might be more likely to benefit from acupuncture. Fostering such positive patient attitudes (if realistic and ethical) might be one way in which clinicians could enhance treatments.

Practitioner Factors

Two studies suggest that practitioners' training, skills, and attitudes form an important part of the context of acupuncture; these factors might also therefore be associated with treatment outcomes.[61;66] There are differences between acupuncturists from different theoretical perspectives (TCM/5-elements compared to western acupuncture) in terms of their therapeutic intentions and approaches to treatment.[66] Patterson and Britten describe how acupuncturists' diagnostic and needling skills form an important part of their process model of acupuncture treatment.[61] Patients' perceptions of an acupuncturist's skills might also be associated with treatment outcome indirectly, for example a patient who has low confidence in their acupuncturist's technical skills might therefore also have lower expectations of the efficacy of their treatment, which could then contribute to poorer outcomes.

Empirical evidence of associations between psychosocial factors and clinical outcomes

Figure 1 specifies the psychosocial factors that should be considered as potential determinants of acupuncture outcomes in pain. We have shown how theoretical frameworks and qualitative studies suggest that incorporating an

awareness of these factors into clinical practice might enhance patient outcomes. While we have highlighted the potential relevance of this work to clinical practice, it would be unwise and unscientific to recommend changes to practice at this stage; our ideas are purely theoretical at the moment and require evaluation in a relevant clinical environment. In this section we examine the relevant empirical evidence that might contribute to the future development of recommendations concerning practice. We have identified previous studies that have sought to determine whether psychosocial factors predict outcome in acupuncture for pain-related conditions. The literature is relatively sparse, consisting of a loose collection of individual papers which tend to raise more questions than they answer. While we acknowledge that additional studies have been conducted in other populations [e.g. 67;68;69;70;71;72;73;74] this review is limited to studies carried out in painful conditions. Using modern meta-analytic techniques is precluded by the enormous heterogeneity within this literature, not only in relation to quality but also in terms of basic study design, potential predictors assessed, and outcomes measured. Instead we offer a narrative summary of the published empirical studies before making recommendations for future work to overcome existing limitations.

Insert Figure 1 Here

Patient Factors

Beliefs about Acupuncture

Strong evidence for the role of expectations comes from an interesting analysis by Kalauokalani and colleagues.[75] As part of an RCT for back pain, patients' expectations of massage and acupuncture were assessed before randomisation to one of those treatments. Not only were expectations of benefit associated with positive outcomes but also those patients who expected acupuncture to be superior to massage and received acupuncture had better outcomes than those who received massage, and vice versa. These results held when controlling for a number of covariates, such as baseline health status and socio-demographic factors, although other psychosocial variables (e.g. empathy) were not assessed. Patients with higher expectations had relative odds of improvement that were five times greater than those with lower expectations. Kalauakalani et al also found that patients' general expectations of improvement were not associated with outcomes; patients needed to have expectations that a specific intervention might help them.

Prospective studies have also reported these associations between positive expectations and outcomes. Linde et al[76] pooled data from four very large German acupuncture studies involving RCTs of acupuncture for migraine, tension-type headache, chronic low back pain and knee osteoarthritis. There was a significant relationship between positive expectations (measured at baseline and after 3 sessions) and outcomes (at treatment completion and 6 month follow-up), even when controlling for medical and socio-demographic covariates in a multivariate analysis. In a smaller prospective observational study Harborow and Ogden[77] found that positive expectations at baseline predicted positive changes in overall well-

being in a sample of patients with various conditions. Meng et al[78] investigated the impact of expectations on outcome in an RCT of acupuncture for chronic low back pain. Patients who had previous positive experiences of acupuncture had better outcomes than those who reported previous neutral or negative acupuncture experiences, as did patients who reported "positive impressions" of acupuncture.

Weaker evidence for associations between expectations and outcome is provided by studies that measure expectation retrospectively, or use measures of treatment credibility as a proxy for expectation. Vas et al[10] found that patients' confidence in using acupuncture treatment in the future or recommending it to others (at the end of treatment) was highly correlated with pain outcomes in an RCT of acupuncture for neck pain. Bausell et al[79] analysed data from two RCTs of acupuncture analgesia for pain after dental surgery. Although there was no difference between placebo and acupuncture groups participants' beliefs had a significant effect on outcomes: participants who believed they had real treatment reported significantly less pain than those who believed they had received the placebo treatment.

A number of further studies report mixed findings. Birch and Jamison[80] carried out a small RCT of Japanese acupuncture for myofascial neck pain. Before treatment they assessed patients' past experiences and expectations of acupuncture, and towards the end of treatment they assessed patients' confidence in the acupuncturist and ratings of the credibility of treatment. The only psychosocial factors associated statistically with improvement in pain at the end of treatment were having had previous acupuncture and being confident that acupuncture could alleviate pain in the

future (pre-treatment expectations did not predict outcomes). In their RCT of acupuncture for persistent low back pain Thomas et al[6] examined associations between bodily pain at 24 months and baseline responses to two items: belief that acupuncture could help back pain and expectations of having some improvement in back pain in 6 months time. Patients who expected their back pain to improve had better outcomes than those who did not expect improvement, but patients who were unsure whether their back problem might be helped by acupuncture had better outcomes than those who thought that acupuncture would probably help their back.

Negative findings have also been reported. Lao et al studied the impact of psychological factors on outcomes in a small RCT of acupuncture for pain control after dental surgery.[81] Acupuncture was superior to placebo in controlling dental pain and there were no between-group differences on patients' pre-treatment or post-treatment acupuncture-related beliefs. This pattern of results was interpreted as evidence that psychological factors are not associated with outcome, but no direct test of that hypothesis was reported and so this must be interpreted cautiously. Baischer found no association between expectations and outcome in a small scale observational study of acupuncture for migraine.[82] MacPherson and colleagues similarly found no significant association between expectations and outcomes in a retrospective UK-based observational study.[83] One prospective observational study found that people who had lower, not higher, expectations received significantly more benefit from acupuncture.[84]

Published work on treatment beliefs has focused on patients' expectations. However one study by Lu and colleagues[85] suggests that

needle phobia, as well as more general expectations of acupuncture, are associated with outcomes. They compared acupuncture and hypnosis in patients with head and neck pain, and noted a tendency for patients who had positive attitudes towards acupuncture to experience better outcomes and for patients with acute pain who were needle phobic to experience worse outcomes than those who were not needle phobic.

Beliefs about Pain

We identified four studies of pain-related beliefs and acupuncture outcomes. Kreitler et al investigated cognitive orientation in chronic pain patients undergoing acupuncture and found that patients' beliefs about goals, norms, oneself and their general beliefs were strong predictors of improvement after treatment (accounting for 85% of the variance).[86] The patients who received the most benefit were those whose beliefs were more strongly oriented towards pain relief across the four domains. None of the beliefs were actually explicitly related to either pain or acupuncture, highlighting the importance of the patients' broader psychosocial context. So[84] looked at more general illness beliefs and found that patients who held beliefs that 'powerful others' control their health were more likely to benefit from acupuncture. Other beliefs (hopefulness and belief in mind-body dualism) were not significantly associated with outcomes. Toomey et al found no difference between responders and non-responders on a measure of locus of control.[87]. Creamer et al also reported no association between self-efficacy and clinical outcomes in a small retrospective study of acupuncture for knee osteoarthritis.[88]

Personal Characteristics

One early clinical observational study investigated potential psychological mediators of response to acupuncture in chronic pain patients.[87] Toomey et al found that responders (n=17) were less likely than non-responders (n=21) to be depressed or exhibit a personality cluster characterised by passivity, overly conventional and stereotyped thought and behaviour, and lack of spontaneity. Responders also had lower levels of stress than non-responders, but there were no differences on a number of other dimensions, including locus of control.

Tavola et al examined personality in an RCT of acupuncture for headache.[89] Outcome was not associated with any single dimension on an established personality measure (the MMPI), but the pattern of scores 'Conversion V' was associated with poor acupuncture outcomes. (The Conversion V pattern of scores entails high scores of hysteria and hypochondriasis and low scores of depression.) In Baischer's small scale observational study of acupuncture for migraine better outcomes were associated with higher scores on the personality traits extroversion, composure, and sociability, and lower scores on inhibition.[82]

Depression has predicted outcomes in two RCTs. Karst and colleagues carried out an RCT of acupuncture for tension headache.[90] Higher depression scores predicted poorer outcomes (higher religiousness scores predicted better outcomes). Furthermore, depression and baseline headache frequency were stronger predictors of outcome than whether a participant received verum or placebo acupuncture. Depression also

predicted outcomes in a large multicentre observational study of acupuncture for chronic low back pain.[91] People without depression showed significantly higher improvement in physical health than those with depression; depression did not however relate to changes in pain intensity.

Additional studies have found no significant associations between acupuncture outcomes and personal characteristics. Creamer et al found no evidence for a relationship between clinical outcomes and depression or helplessness, and only non-significant trends for anxiety and fatigue to be negatively associated with pain outcomes.[88] In an early study of acupuncture for dental analgesia a number of personal characteristics (personality, suggestibility, anxiety, un-specified 'attitudes') did not predict analgesia.[92] Kreitler also found no evidence of an association between personality and acupuncture outcomes.[86] In an RCT of acupuncture and physiotherapy for headache/migraine there were no significant associations between outcomes and seven psychosocial variables (anxiety, depression, psychiatric morbidity, somatisation, illness behaviour, social problems, and quality of marital relationships).[93]

Therapeutic Relationship Factors

Compared to the number of studies that have focused on patient factors there have been few published studies on the therapeutic relationship in relation to acupuncture outcomes. Berk et al investigated the role of treatment context, and operationalised that concept in such a way as to incorporate both patients' expectations and the therapeutic relationship.[94] Within an RCT of acupuncture for shoulder pain they compared the effect of real acupuncture

and placebo acupuncture each carried out in positive and negative contexts. Patients in the positive context were read positive statements about the effectiveness of acupuncture and were actively engaged in the therapeutic process by the acupuncturist while those in the negative context were read statements that emphasized the doubts and inconsistencies surrounding acupuncture and were discouraged from any communication during treatment. Patients in the positive condition reported more improvements in pain and there were no associations between pain outcomes and scores on validated measures of suggestion and hypnotic susceptibility. These results strongly suggest that the context of the therapeutic relationship is related to acupuncture outcomes, and also highlight the need for further work to elucidate the complex relationships among multiple possible factors.

In a retrospective UK-based observational study improvements in wellbeing and changes in one's main complaint were associated with a stronger sense of enablement in a sample of patients with various complaints.[83] Patients who perceived their practitioner as more empathetic reported higher enablement scores; enablement scores were not however associated with patients' expectations of treatment and neither empathy nor patient expectations were associated with other outcomes. In a later prospective observational study Price and colleagues investigated the relationships between empathy, enablement, and outcomes in patients receiving acupuncture for various complaints.[95] Empathy was associated with both enablement and health outcomes, and the association between increased perceptions of practitioner empathy and better health outcomes remained significant after statistically controlling for demographic factors and

baseline health measures. Indeed perceptions of empathy explained a significant proportion of the variance in outcomes (16%) suggesting that it might have a clinically important effect on outcome.

Practitioner Factors

We could identify few published studies on whether factors related to the practitioner are associated with acupuncture outcomes. Harborow and Ogden[77], as well as measuring patients' expectations of outcome, also measured referring GPs' beliefs about prognosis and the acupuncturist's expectations of success. In addition to patients' expectations predicting outcome, acupuncturists' (but not GPs') positive expectations also predicted positive changes in overall well-being in their patients. Birch and Jamison[80] focused on patients' treatment beliefs (see above), but also measured patients' confidence in their acupuncturist, which was not associated with outcome. A large German observational study of acupuncture for chronic pain found a negligible difference in outcome between practitioners with different amounts of training (140 hours versus 350 hours training).[96]

Current Limitations and Directions for Future Research

Study design

The majority of studies have been conducted in RCT settings[6;10;74-76;79-81;88-91;93]; some observational studies have been carried out in the context of usual clinical practice, with either cross-sectional/retrospective designs [83] or prospective designs[77;84;86;91;95]. The relative strengths of RCT and observational study designs are summarised in Table 1. While RCTs clearly

offer a number of advantages their low external validity constitutes a serious limitation for the study of psychosocial predictors of outcome, to the extent that we would recommend more use of observational designs in future as this will be the only way to understand these potentially important predictors of outcome. Researchers are beginning to explore the contextual differences between RCTs and normal clinical contexts.[97;98] The evidence suggests that trial settings can have very different implications and meanings for patients and practitioners (compared to usual clinical practice) which will likely translate into differences in expectations and the therapeutic relationship if not other psychosocial factors too. An investigation of certain psychosocial factors within a trial setting might thus have very limited validity when the findings are transferred to every day clinical practice: observational designs should therefore be considered as offering a vital, ecologically valid, perspective on psychosocial predictors of outcome in acupuncture. However observational studies must be of high quality: adherence to recent gold standards for epidemiological studies could enhance the design and reporting of observational studies of predictors of acupuncture outcomes.[99] There is a lack of potentially useful mixed methods designs that incorporate qualitative approaches. Individual patients' and practitioners' perspectives could be studied using mixed methods to enable explication of the psychosocial processes of change that occur during acupuncture treatment.

Insert Table 1 Here

Statistical power and controlling for confounders

Many studies reviewed above rely on small samples of participants[e.g. n<50, 77;80;81;82;85;86;87;88;89;94;95] which can lead to under-powered analyses. While small scale studies are helpful for providing initial tests and generating hypotheses, they have limited potential for furthering our understanding in this area. Importantly, small samples preclude the much-needed inclusion of more than one psychosocial factor within each study and the use of sophisticated multivariate statistics to control for potential confounders.

Results from the back pain literature illustrate the importance of carrying out multivariate analyses of psychosocial predictors of outcome. For example age and pre-treatment pain intensity[41;45;53;100-102] as well as duration of pain episode[41;101-104] and gender[35;40;42;43;104] have all been shown to influence outcome. Employment and compensation status have also been associated with outcomes.[35;36;40;101;105]. It would seem prudent to take into account both demographic and clinical factors in future analyses of psychosocial predictors of acupuncture outcomes in pain. Larger samples are required in order to conduct the necessary multivariate analyses, and could be achieved either through single large-scale studies [e.g. 91] or through pooling data from multiple smaller studies.[e.g. 76]

Validity of measurements

Measures of psychosocial constructs need to be pilot-tested and have strong psychometric properties in order to be considered valid. A number of studies have used un-validated measures of important variables such as expectations[6;76;77;79] and this clearly raises questions about the validity of

their findings. As White has suggested, the poor availability of validated measures of expectancy might explain negative findings.[106]. The variation in quality and nature of measures used also makes collating and interpreting the differences across individual studies rather problematic. We recommend the use of standardised core outcome measures [e.g. 107] to improve comparisons across studies, with the proviso that supplementary acupuncture-specific measures are considered. The further development and consistent use of valid measures of relevant psychosocial factors is also important; a number of existing measures could be improved with further psychometric development.[108-110]

Theoretical considerations

Many of the studies reviewed above demonstrate little explicit a priori theoretical justification for the factors examined as potential predictors of outcome, and most have not been carried out within existing theoretical frameworks. Future studies would greatly benefit from being grounded within theoretical frameworks and explicitly testing specific hypotheses. It would be impossible to measure all psychosocial factors that could be related to outcome, and taking a theory driven approach can help to identify factors most likely to affect outcome and to develop well-grounded, specific and testable hypotheses. Furthermore, the use of theory-driven and hypothesis testing approaches could enhance the comparability of individual studies and result in a more cohesive body of knowledge in this area.

Identifying psychosocial predictors of outcome in acupuncture has wider implications for understanding which aspects of acupuncture might be

considered characteristic and which might be considered incidental. According to Paterson and Dieppe[111] it is vital to think about acupuncture and other complex interventions in these terms in order to develop appropriate tests of efficacy and effectiveness. Making direct comparisons of psychosocial predictors of outcome across different treatments (e.g. acupuncture and conventional physiotherapy for back pain) has the potential to inform this debate. Such studies have not yet been conducted.

Conclusions

The existing literature concerning psychosocial predictors of outcome in acupuncture for pain is both limited and diffuse. Nevertheless the results suggest this is an important area for future work. While acknowledging a probable publication bias, the findings to date do suggest that a number of psychosocial factors, in particular patients' beliefs about acupuncture, predict treatment outcomes in acupuncture for pain to a significant extent. There is a considerable gap between the psychosocial factors are implicated in outcomes by theoretical frameworks and qualitative studies and those factors that have been studied in the context of quantitative RCTs and observational studies. In particular there needs to be a greater focus in quantitative studies on examining the role of factors related to the practitioner and the therapeutic relationship. Overall theory driven, well-powered multivariate studies which incorporate well-validated measures carried out in every day clinical practice are needed to further advance our understanding of the factors that predict outcome from acupuncture. Until the evidence-base in this area is improved it will be impossible to derive concrete and evidence based recommendations

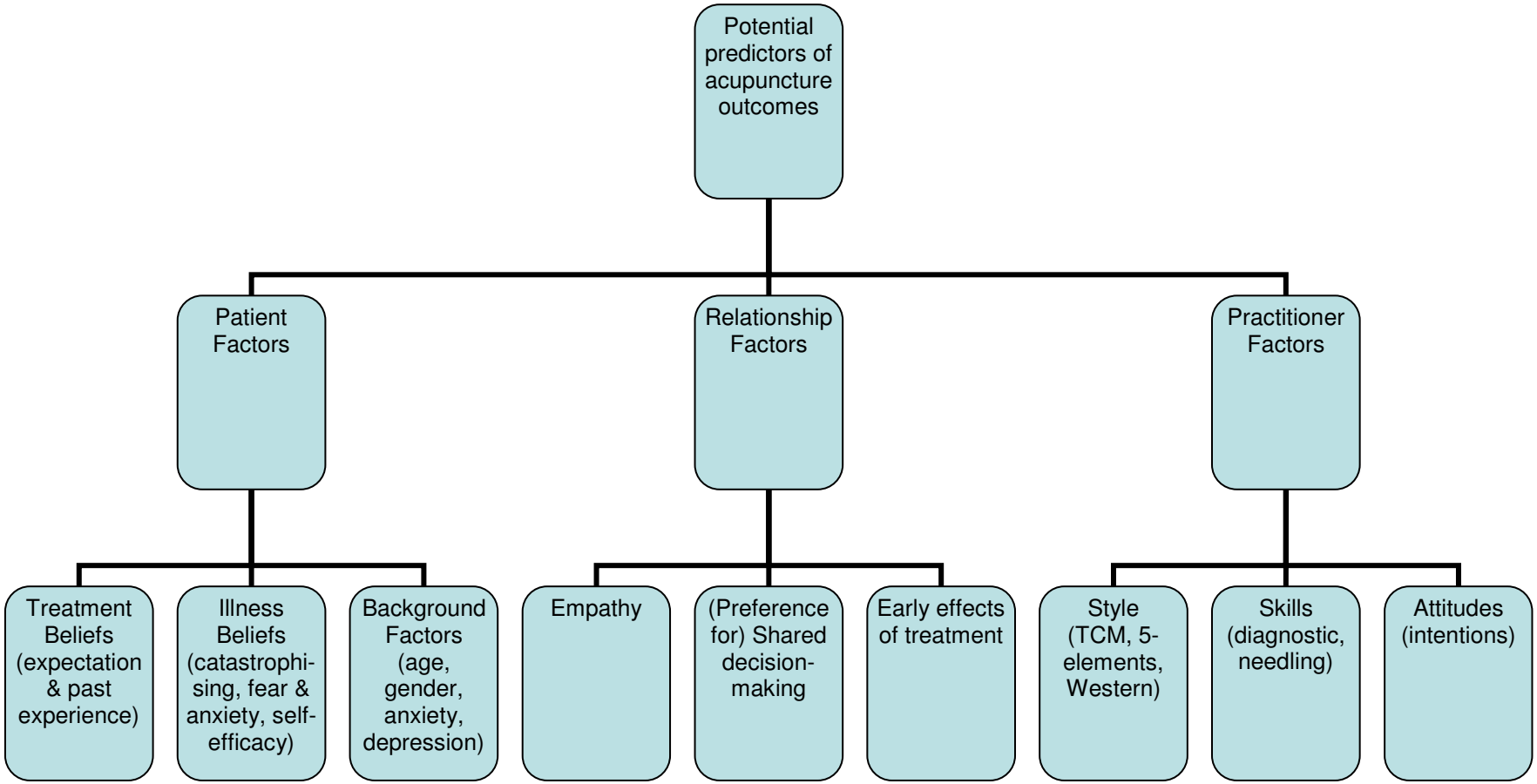
for clinical practice. Instead we make the much more tentative suggestion that a focus on certain psychosocial factors has the potential to enhance patient outcomes; the circumstantial evidence for this is now growing and further research is needed in this area. In particular we would advocate that practitioners develop an improved awareness of the potential impact of patients' outcome expectations as well as a positive therapeutic relationship.

Table 1

A comparison of the strengths of using RCTs and observational designs to investigate predictors of acupuncture outcomes

Strengths of RCT designs	Strengths of observational designs
• More control over the treatment and to an extent the practitioner (increasing the homogeneity of both) • More 'captive audience' (participants who are already involved in the research and who can complete additional measures of psychosocial factors relatively easily, although this might be considered overly burdensome for them) • Established procedures for outcomes assessment (less burdensome for researchers) • Established inclusion and exclusion criteria for patients (increasing the homogeneity of participants).	• Greater external, or ecological, validity: patient and practitioner beliefs are more similar to those encountered in everyday practice, therapeutic relationship factors are more similar to those encountered in everyday practice, patients are more similar to those encountered in everyday practice (e.g. not just attending and being treated for one condition)

Figure 1. Psychosocial factors that should be considered as potential predictors of outcome in acupuncture for pain (according to relevant theory and qualitative findings).



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