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Acupuncture Expectancy Scale: Development and Preliminary Validation in China

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Introduction

The popularity of acupuncture has grown substantially in the United States over the last three decades, evidenced by over 8 million American adults having used acupuncture in their life time and over 2 million of them having used it on an annual basis.¹ Although well-conducted placebo controlled clinical trials have offered insights into the efficacy of acupuncture, the substantial effect seen in the placebo acupuncture groups presents a significant challenge for both evaluating the efficacy and interpreting the effectiveness of acupuncture. Many studies including several meta-analyses^{2–5} found that both real and placebo acupuncture produce statistically significant and clinically important changes when compared to no treatment or standard/enhanced medical care. These findings suggest that the effect seen in placebo acupuncture group cannot be entirely attributed to either regression to the mean or natural disease processes;⁶ thus, the "non-specific" effect of acupuncture must be responsible in part for patients' clinical response. Nevertheless, until we can parse the components that make up for the "non-specific" effect, powerful as may it be, such effect is likely to be discarded from a scientific standpoint.

Expectancy was found to be one of the central pieces in this so-called "non-specific" effect through years of psychological research.^{7, 8} In particular, response expectancy, a form of outcome expectancy defined as "expectations held by the individual about one's own emotional and physiological response" related to a situation or therapy may produce important clinical changes.⁹ In a systematic review, Crow et al.¹⁰ showed that when clinicians stated positive outcome expectancies as opposed to uncertain expectancies, most studies found improvements in patient self-reports of anxiety, pain, and distress.

A few studies have explored the relationship between expectancy and clinical outcomes in the context of acupuncture.^{11, 12} While these studies provided preliminary evidence that greater expectancy may produce better clinical response, none used a validated instrument to measure expectancy. To our knowledge, only one scale measuring a range of beliefs about acupuncture,

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Acupuncture Beliefs Scale, ¹³ underwent psychometric evaluation; however, the length (36 items) and redundancy of items (extremely high internal consistency) prevented the scale from being used widely in clinical studies. The goal of this study is to develop a simple Acupuncture Expectancy Scale that measures subjects' expectation of positive outcomes from acupuncture therapy and perform preliminary validation in the Chinese acupuncture clinical population. Only with a psychometrically sound instrument, can we begin to quantify the response expectancy in the context of acupuncture therapy and further determine its effect on patient centered clinical outcomes.

Methods

We developed an Acupuncture Expectancy Scale (AES) and then conducted a study in two phases among a convenience sample of 200 subjects (phase I, N=120; phase II, N=80) from outpatient acupuncture clinics in Beijing. In phase I, we determined the reliability of the score of the scale and performed item-reduction; in phase II, we tested construct validity by correlating the score of AES to rating sales of subject perceived efficacy, satisfaction, and confidence in the prescribed course of acupuncture. This study was approved by the Institutional Review Board at the University of Pennsylvania. Because we did not collect any personal identifiable information, voluntary provision of information was deemed to be consent.

Scale Development

One of the authors (J.M.) is a physician acupuncturist and interviewed 5 of his patients (4 women, 1 man) to generate draft items. Open-ended questions were asked to elicit participants' beliefs related to expected acupuncture efficacy for their specific goals as well as overall wellbeing. Draft items were developed and reviewed one-on-one with 4 volunteer subjects. Participants helped identify areas that lacked clarity. We initially had negatively framed items such as "My illness won't get better", but several subjects pointed out that if they did not believe that acupuncture would help them, they would not be in an acupuncturist's office in the first place; as a result we dropped such items. Items were scored on a 5-point Likert Scale ranging from "Completely Agree" (5 points) to "Not at All Agree" (1 point). The choice of using "completely agree" rather than "mostly agree" was also guided by very high initial ceiling effects (i.e. subjects choosing the extreme response) in our pilot testing. Our draft scale contained 7 items. The scale was translated into Chinese and then translated back into English by a different individual to determine language equivalence. J.M. reviewed the scale in Chinese one-on-one with 7 Chinese patients (4 women, 3 men) in the acupuncture clinic waiting area at Chaoyang Traditional Chinese Medical (TCM) Hospital in Beijing and found that questions could be clearly understood by the Chinese patients. In addition, these items addressed Chinese subjects' expected response from acupuncture. Three experienced Chinese acupuncturists also concurred with the face validity of the scale.

Study Sites

The survey was conducted in 6 outpatient acupuncture clinics affiliated with the China Beijing International Acupuncture Training Center (CBIATC) in Beijing, China between July-August 2004 (phase I) and April-May 2005 (phase II). CBIACT, affiliated with the China Academy of Traditional Chinese Medicine, serves as one of the three original training sites in China designated by the World Health Organization to educate international health professionals about acupuncture and moxibustion. We conducted the survey at the outpatient acupuncture clinics in 3 TCM Hospitals (i.e. Beijing Institute of Acupuncture and Moxibustion, Chaoyang TCM hospital, and Jintai TCM hospital), and 3 comprehensive hospitals (i.e. Military General Hospital, Number Sixth Hospital, and Hepingli Hospital).

Study Administration

We surveyed among a convenience sample of patients in waiting rooms of acupuncture clinics. We approached the study subjects about the survey before their acupuncture treatments. Most subjects filled out the survey on their own, but for those who had vision or literacy problems, the questions were read to the study subjects. Because Chinese patients prepay their 10-sessions (one course) of acupuncture treatments and are seen typically every day or every other day, these 200 subjects represented well over 1500 actual acupuncture treatments.

In phase I, we gave subjects the Acupuncture Expectancy Scale along with questions to assess the basic demographic information including age, sex, previous acupuncture experience, and chief complaints for the visit. In phase II, we added three selected items with high face validity to evaluate patient subjective impression of efficacy, satisfaction, and confidence in prescribed acupuncture treatment. These items were assessed using an 11-point rating scale (0-10) from Not at All to Very Much.

Statistical Analysis

Descriptive statistics were performed for each scale item. We examined items for missing data with a plan to discard items with more than 5% missing data. The distributions of scores on the final items were examined to assess ceiling or floor effects (i.e., the majority of respondents choosing either extreme option).¹⁴

In phase I, we evaluated item-item and item-total correlations to ensure that all items positively related to one another, but were not redundant.¹⁴ The objective was to have item-item correlations between 0.20 and 0.65 and item-total correlations above 0.20. Because of our initial high Cronbach's alpha coefficient (indicating redundant items), we removed items that had large ceiling/floor effects as well as redundancy with existing items (item-item correlation greater than 0.65) to achieve Cronbach's alpha just above 0.80, a value that is considered optimum for measuring attitude.¹⁵ Items were removed sequentially and the internal consistency of each shortened scale was recalculated. In addition, we performed principal components analysis to explore the potential number and characteristics of the domains. Interpretation of the results of the principal components analysis was guided by identifying Eigen values greater than 1 and the rotated loadings of variables on the identified components.

In phase II, we evaluated the construct validity by correlating scores on the Acupuncture Expectancy Scale and patient perceived efficacy, satisfaction, and confidence in prescribed course of acupuncture therapy. We hypothesized *a priori* that patients' expectancy positively related to their perceived efficacy, satisfaction, and confidence. In addition, we explored how expectancy may differ by age, sex, past acupuncture experience and chief complaints. All statistical analyses were performed using STATA 8.0. All statistics were two sided with an alpha of 0.05.

Results

Characteristics of Participants

A total of 200 subjects participated in this survey (see Table 1). Fifty-five percent were women. Age ranged between 8 and 82 years, with a median age of 41. Twenty-one percent of participants were new patients, and 31% had over 9 acupuncture treatments for the current presenting conditions. The top three reasons for acupuncture visits were for musculoskeletal complaints such as back pain, neck pain, arthritis (41%), neurological complaints such as poststroke rehab, facial paralysis (23%) and weight loss (10%). Most subjects cited symptoms (i.e. back pain, leg pain) or biomedical diagnosis (i.e. lumbar disc herniation, depression) as the

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chief complaints. Only one subject used a Traditional Chinese Medical diagnosis (Qi deficiency) as the chief complaint. Fifty-three percent of chief complaints were related to pain.

Scale Properties

The original 7 items were shown in Table 2. No item had over 5% missing data, ranged from 2.0% to 4.5%. While we saw no floor effects, we observed substantial ceiling effects. Between 36% and 49% of subjects endorsed the highest response options for the 4 items selected for the final version of Acupuncture Expectancy Scale. The score of the final instrument ranged from 4 to 20 out of a possible 4 to 20, with higher scores indicating greater expectancy. The mean was 16.4, with a standard deviation of 3.17, and a median of 17. Twenty-one percent of subjects had the maximum score.

We performed factor analysis using the original 7 items to explore the domains of the scale. We identified and retained one component with an Eigenvalue of 4.50, which explained over 64% of the variance. Varimax rotated loadings ranged between 0.79 and 0.83.

Reliability

Our initial 7-item draft scale had an internal consistency (Cronbach's alpha coefficient) of 0.90 which indicated redundant items. Through item reduction, our final scale had an alpha coefficient of 0.82. Corrected item-total correlations for the final scale ranged between 0.56 and 0.66.

Validity

The face validity of the scale content was confirmed by approval from seven acupuncture patients and three experienced acupuncturists. To test the construct validity, we correlated the score of the Acupuncture Expectancy Scale to the patient perceived positive outcomes (see Table 3). Expectancy of favorable outcomes was positively correlated with the patient perceived efficacy, satisfaction, and confidence in prescribed therapy (all p≤0.001). The moderate correlation coefficients of 0.44 to 0.51 further indicated that expectancy only partially relates to the perceived outcomes. As expected, expectancy was not related to age, sex, number of previous acupuncture treatments, and chief complaints in our sample.

Discussion

Response expectancy has been considered as one of the most important components in "nonspecific" therapeutic effects based on extensive psychological research.⁷ The lack of a psychometrically sound measure of response expectancy related to the outcomes of acupuncture prevents researchers from parsing out expectancy and quantifying its effects on patients' clinical response. In this study, we developed a simple 4-item Acupuncture Expectancy Scale to measure subjects' specific expectation about the outcomes of acupuncture therapy. The scale had reliable internal consistency with a Cronbach's alpha coefficient reaching 0.82. The scale demonstrated satisfactory content validity by approval from both patients and experienced acupuncturists. Principal components analysis supported a one dimensional construct of response expectancy related to acupuncture therapy. The score of the scale positively correlated with subject ratings of therapeutic efficacy, satisfaction, and confidence in prescribed acupuncture therapy.

We believe that the development of the Acupuncture Expectancy Scale offers an important addition to better define the role of response expectancy on clinical outcomes of acupuncture. Previously, Dennehy et al.¹³ developed a 36-item scale that measures subjects' beliefs in the efficacy of acupuncture for psychiatric conditions. However, no attempt was made to reduce the numbers of redundant items given the high internal consistency (Cronbach's alpha

coefficient =0.97). Our scale of 4-items with satisfactory internal consistency lessens the respondents' burden and makes measurement of expectancy in clinical trials much more achievable. While the Dennehy's scale yielded 3 factors including general endorsement of acupuncture, beliefs in scientific value and credibility of acupuncture, and beliefs about the procedures and physical experience of acupuncture, ¹³ our scale had only one domain. It is possible that many components of subjects' previous experience and belief system will help shape their expectancy toward response to acupuncture therapy, but the actual response expectancy is a one dimensional construct.

Thus far, only a few studies have explored the relationship between expectancy and clinical response to acupuncture. Birch et al¹¹ found that confidence in acupuncture treatment not the acupuncturist predicted positive outcomes in a trial of Japanese acupuncture on chronic neck pain. Kalauokalani et al¹² explored how expectation affects treatment outcomes in an unblinded clinical trial comparing acupuncture with massage for chronic low back pain. A greater proportion of individuals with higher expectation for the treatment experienced functional improvement as compared to those with lower expectations. In addition, subjects who expected greater benefit from acupuncture than from massage were more likely to experience better outcomes with acupuncture than with massage, and vice versa.¹² However, the questions used to assess expectancy were not previously validated in either of these studies.

Contrary to the above findings, So¹⁶ found that higher expectation actually negatively predicted patient perceived outcomes when using goal attainment scaling (i.e. patient serves as his/her own control) in acupuncture clinics. Although So's findings were valid in its frame of reference, the contradictory findings may result from the limitation of goal attainment scaling. Even for a successful clinical program, if the subject's high expectation is unrealistic, it may result in subjective disappointment with the therapeutic effect, thus making it difficult to assess the actual therapeutic impact on study subjects. ¹⁴ However, So's study¹⁶ does point out that a healthy dose of realistic expectation rather than the unrealistic high expectation may help increase patient satisfaction. Another possible reason for the discrepancy between So and others' studies is that the clinical context may influence the effect of expectancy on outcomes (i.e. the actual clinical setting may be different from those of clinical trials).

Measuring response expectancy of acupuncture is an important first step to understand the "non-specific" effect and potentially the mechanism of acupuncture. The size of non-specific effect of acupuncture is large, often on par with the whole effect of pharmaceuticals for similar indications. ^{17, 18} Despite many scholars' well articulated need for understanding the non-specific effects of acupuncture, 6, 19, 20 the lack of a validated measure of the specific components such as response expectancy limited our ability to uncover the bio-behavioral mechanism of acupuncture.

The bio-behavioral mechanism of acupuncture most likely rests on the interaction between the mind (psychological factors related to the acupuncture process) and the body (physiologic effects derived from the specific needling). Basic science research has shown that acupuncture needling stimulates the CNS to produce endogenous opioid in animals and in humans;^{21, 22} however, it does not explain how acupuncture provides long term symptom alleviation, as no individuals have needles inserted into their bodies constantly. It is likely that psychological processes such as response expectancy, also mediated through endorphin pathway,²³ interact with the physiological response to produce more permanent clinical improvement. It is important to emphasize that the effect of expectancy on clinical outcomes is most likely iterative rather than simple linear causal relationship; thus, using our scale with other psychological and physiological measures at multiple points in large prospective studies may help us understand the mechanism of acupuncture for chronic symptomatic illnesses. The simplicity of our scale makes such attempts feasible.

The limitations of this study need to be considered. The instrument was administered in Chinese among a highly selected clinical population. However, homogenous populations actually produce lower reliability for a scale; therefore, the score of this scale should be reliable in more diverse populations.¹⁴ The Chinese clinical population may also contribute to the large ceiling effects of the scale because of the cultural familiarity and acceptance of acupuncture. Our scaling choice of "completely agree" rather than "strongly agree" did not seem to deter subjects from choosing this extreme response. Although it is possible that acupuncture patients (either in actual practice or in clinical trials) have fairly high expectancy because acupuncture, the distribution of the score along with the reliability and validity of the English version of this instrument need to be further tested in more diverse populations outside China. In addition, we recognized the preliminary nature of the reliability and validity testing carried out by our study. Future study needs to examine the test-retest reliability to define the stability of the scale. Administering this scale prospectively in a prospective study at multiple time points will also help understand the responsiveness of the scale.

The development of a psychometrically sound measure of response expectancy related to acupuncture can facilitate future studies to better understand the complex social-behavioral aspects of acupuncture. Investigating the mind-body interactions in evaluating acupuncture as well as other complementary therapies will likely yield important knowledge that are both scientifically sound and clinically meaningful to patients who suffer from chronic and ongoing pain and other distressing symptoms.

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	Com	bined	Ph	ise I	Ph	se II
	N=200	Percent	N=120	Percent	N=80	Percent
Gender						
Women	109	54.5	68	56.7	41	51.3
Men	91	45.5	52	43.4	39	48.7
Age						
<31	48	26.5	27	25.2	21	28.4
31-40	38	21	24	22.4	14	18.9
41–50	51	28.2	30	28.1	21	28.4
>51	44	24.3	26	24.3	18	24.3
Prior Acupuncture Experience						
Never	42	21.3	20	17.0	22	27.9
1–3	40	20.3	24	20.3	16	20.2
4-9	53	27.0	38	32.2	15	19.0
≥10	62	31.4	36	30.5	26	32.9
Chief Complaint						
Neurological	45	22.5	19	15.8	26	32.5
Musculoskeletal	81	40.5	59	49.2	22	27.5
Psychological	10	5.0	5	4.2	5	6.3
Respiratory	7	3.5	4	3.3	3	3.8
Cardiovascular	2	1.0	2	1.7	0	0
Gynecologic	6	3.0	4	3.3	2	2.5
GI/Urologic	10	5.0	3	2.5	7	8.8
Dermatologic	10	5.0	7	5.8	3	3.8
Weight Loss	20	10.0	12	10.0	8	10.0
Other	6	4.5	5	4.2	4	5.0
Pain related conditions						
Yes	103	53.1	67	58.8	36	45.0
No	81	41.8	39	34.2	42	52.5
Unsure	10	5.2	8	7.0	2	2.5

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 $^{\rm *}_{\rm Sample}$ total 200, within cells totals may not sum to 200 because of missing data

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Acupuncture Expectancy Scale (N=120)

f acupuncture's effect on your illness/symptom	(5) Completely Agree, %	44	44	31	56	45	40	51
to describe your expectation of closest answer.	(4) Mostly Agree,	22	31	30	26	33	34	32
e. If we use the following sentences t each statement, please choose the	(3) Moderately Agree, %	25	19	27	13	12	16	12
• the effects of acupuncture v much do you agree? For	(2) A Little Agree, %	6	9	11	4	10	10	ŝ
different expectation for upuncture therapy, how	(1) Not at All Agree, %	0	0	_	1	0	1	0
Every individual may have after the entire course of ac		My illness will improve a lot	I will be able to cope with my illness better	The symptoms of my illness will disappear	I will be able to enjoy life more	My mood will improve	My energy level will increase	I will suffer less from this illness

* Items retained for the final scale

Table 3

Correlation between Scores of Acupuncture Expectation Scale and Perceived Outcome (N=80)

Please rate the following statements from 0 to 10, 0 being not at all, and 10 being very much:	Correlation Coefficient	p-value
Your impression of the effectiveness of the acupuncture treatment(s) that you have received thus far	0.44	0.001
Your satisfaction with the acupuncture treatment(s) that you have received thus far	0.49	< 0.001
Your confidence in the prescribed course of acupuncture treatments	0.51	< 0.001

Spearman correlations were performed

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