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# BMJ Open

## Assessment of patients' expectations: development and validation of the Expectation for Treatment Scale (ETS)

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3 **Assessment of patients' expectations: development and validation of the**  
4 **Expectation for Treatment Scale (ETS)**  
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## 1 Abstract

2 **Objective:** Development of a short instrument for the assessment of expectations  
3 (Expectation for Treatment Scale, ETS), using acupuncture as case example.

4 **Design:** Cross sectional assessment with retest after one week.

5 **Setting:** Web survey with patients suffering from pain

6 **Methods:** In a three-step approach, we reduced the initially collected number of items from  
7 17 to 9 and to 5, including expectations about coping ability, vitality, physical health and  
8 reduction of patient complaints. Items were selected according to internal consistency  
9 (Cronbach's alpha), convergent and divergent validity with related constructs (optimism,  
10 pessimism, resilience, perceived sensitivity to medicines, depression, and others), one-  
11 week retest reliability (intraclass correlation coefficient, ICC) and exploratory and  
12 confirmatory factor analysis.

13 **Results:** A total of 102 pain patients were included, and 54 of these patients completed the  
14 retest assessment. The final version of the ETS consisted of 5 items and had an excellent  
15 Cronbach's alpha (.90) with 72.33% variance on one single factor. Depression, pessimism  
16 and perceived sensitivity to medicines showed positive correlations with our expectation  
17 measure ( $r = 0.23$ ,  $r = 0.20$ ,  $r = 0.34$ , respectively), the correlation between the ETS and  
18 optimism was low ( $r = -0.07$ ), and no correlation between the ETS and resilience was found  
19 ( $r = -0.07$ ). The retest ICC was .86, which showed high stability over one week. A  
20 confirmatory factor analysis (N = 439) with data from patients with low back pain confirmed  
21 the single factor structure of the instrument.

22 **Conclusion:** The ETS showed strong psychometric properties and covered a distinct  
23 construct. As next step it will be used for other disorders and treatments in which  
24 expectations are also an important predictor of treatment effects.

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25  
26 *Keywords:* Expectations, placebo, assessment, pain, optimism, acupuncture

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1  
2 28 *Strengths and limitations of this study*  
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- 5 29 • It is the first project to systematically develop a general measure to assess patients'  
6  
7 30 expectations across medical conditions and treatments with the involvement of  
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9 31 patients, earlier scale and empirical data.  
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11 32 • The Expectation for Treatment Scale (ETS) is a short and reliable measure which  
12  
13 33 capture outcome related expectation of patients.  
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15 34 • The association between ETS and related constructs was explored.  
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17 35 • The development of the ETS was done by an online survey with pain patients and  
18  
19 36 the initial findings were confirmed by a patient sample with low back pain  
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21 37 • The transfer of the ETS in different clinical conditions and settings should be pre-  
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23 38 tested in order to explore if patients can evaluate the respective treatment on this  
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25 39 level.  
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## 42 Introduction

43 Patients' expectations alter responses to interventions in placebo research as well as in  
44 clinical studies. In experimental research the instruction to receive an active intervention  
45 goes along with large effects on pain reduction (effect size = 0.75)<sup>1</sup>. Expectations can be  
46 regarded as a major driver for changes in symptoms and other health related outcomes<sup>2</sup>.  
47 Clinical studies have revealed that patients' positive expectations are related to reduced  
48 pain after a medical treatment<sup>3-5</sup> and this phenomenon has also been observed for other  
49 medical conditions<sup>6</sup>. For acupuncture, this association was investigated in several studies  
50 with heterogeneous findings: Patients with chronic pain had higher odds (odds ratio 2.11  
51 [95%CI 1.32-3.34]) of benefitting from acupuncture treatment if they expected a better  
52 treatment response at baseline (controlled for other clinical baseline characteristics)<sup>7</sup>.  
53 However, there are also studies that found no influence of expectations on the outcome<sup>8,9</sup>.

54 These differences in the association of expectations and outcomes might be partly  
55 explained by the fact that each study used a specific measure and differences between  
56 measures might hide or exaggerate associations between expectations and intervention  
57 outcomes. Additionally, the match between expectations of patients and treatment providers  
58 might be relevant for the success of a specific treatment<sup>10</sup>.

59 Expectation is a well-known and often-used term. Nevertheless a clear definition and  
60 a sharp distinction from associated constructs is important for the development of a  
61 measure<sup>11</sup>. A basic definition suggests that "patient expectations" cover treatment-related  
62 outcome expectations<sup>12</sup>. Related constructs such as optimism, self-efficacy, and hope have  
63 some shared facets with expectations, such as positive cognition, but differ on the level of  
64 the construct<sup>13,14</sup>. Related constructs are sometimes included in expectation measures, and  
65 in other cases, only cognitions about treatment outcome relationships are included<sup>9,15,16</sup>.

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2 66 Along the definition by Bowling et al. (2012), we therefore designed our measure to assess  
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4 67 expectations related to a clinical intervention with a clinically relevant outcome from a  
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6 68 patient's perspective.  
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9 69 For further research in the field of expectations a strong measure with high  
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11 70 acceptance across clinical fields would be needed for several reasons. First, a reliable  
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13 71 measure with high internal consistency at a specific time point is a prerequisite to use  
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15 72 expectations as a robust predictor. Second, ceiling effects were a common problem in the  
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17 73 measurement of expectations, since patients who are seeking help from a specific  
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19 74 treatment often expect a large benefits and one established expectation measure  
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21 75 (Acupuncture Expectancy Scale (AES))<sup>17</sup>. Therefore, some authors have used the term  
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23 76 "realistically expect" to capture expectations in a recent study with a comprehensive 10-item  
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25 77 assessment of expectations, hope and beliefs (EXPECT)<sup>18</sup> with limmited internal  
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27 78 consistency. Third, a measurement of expectation should be stable in a reasonable  
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29 79 timeframe: The EXPECT scale showed only a moderate retest reliability with an intra-class  
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31 80 correlation of ICC = 0.75. Most importantly, the association of EXPECT with the established  
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33 81 AES, a benchmark measure for the field of acupuncture, was unexpectedly low ( $r = .54$ ).  
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39 82 This study aimed to develop a measure to capture patient expectations with a short  
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41 83 scale in a reliable way. The newly developed scale (Expectation for Treatment Scale, ETS)  
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43 84 ideally has a strong association with available measures of expectations, moderate  
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45 85 associations with related constructs (e.g., optimism, pessimism) and no association with  
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47 86 personality (e.g., neuroticism). Furthermore, it should be constructed in a way that it can be  
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49 87 adapted to other treatments and used in a universal way in different clinical fields  
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51 88 independent of patients' complaints.  
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## 90 **Methods**

91 To address the problem of the abovementioned ceiling effects, we developed the  
92 items of our scale (ETS) in a pilot study with pain patients in our outpatient clinic to measure  
93 expected benefits before treatment from the patient's perspective. Based on existing  
94 questionnaires on patient expectations<sup>9 17 19-22</sup>. We created a list of 17 items covering  
95 different facets of expectations. After testing the items, we selected items with low  
96 skewness, a large range of responses (i.e., variation), and high correlations between items.

## 98 **Participants**

99 For the main validation, study subjects of the convenience sample were recruited in  
100 different ways. Three regional patient organizations distributed the information, and we used  
101 several email distribution lists (including the University of Zurich, Switzerland and the  
102 Charité University Hospital Berlin, Germany). Furthermore, patients from the previous year  
103 seeking treatment for a musculoskeletal condition at the Institute for Complementary and  
104 Integrative Medicine of the University Hospital Zurich were contacted by email. All  
105 participants had to be at least at age 18 and according to their own evaluation sufficient  
106 knowledge to understand German language.

107 The study link was accessed by 522 subjects and 244 started with the survey. In total  
108 142 subjects were excluded due to insufficient pain (N = 113), missing data in the nine  
109 items version of the ETS (N = 14) and more than 20% missing across all items (N = 13).  
110 Data from patients suffering from pain (N = 102) with retest data from 54 patients were  
111 available.

## 112 **Procedures**

113 Subjects who decided to participate activated an access link to the online survey  
114 provided via email. The survey was hosted by <https://www.soscisurvey.de/>, and all data  
115 were collected electronically and anonymously. Participants were able to complete the  
116 survey within 15 minutes. All questions were created in a forced choice format, meaning  
117 that subjects were not able to continue to the next set of questions without completion of the  
118 previous ones. Upon starting the survey, a short address of welcome, followed by an  
119 introduction to the study, was provided. Subjects who agreed to be contacted again for the  
120 retest assessment provided their email address at the end of the survey. The retest sample  
121 received a consecutive ETS one week after completion of the first survey. The study was  
122 granted ethics approval by the local ethics committee (Kantonale Ethikkommission Zürich,  
123 No. 48-2015).

124

## 125 **Measures**

126 The survey included demographic information (age, gender, education, employment  
127 status, and country of residence), questions about any previous experience with  
128 acupuncture (current or earlier), the degree to which the acupuncture treatment has been  
129 successful (numeric rating scale from 1 to 10) and the reason for the treatment (pain,  
130 mental health or non-specific). Patients who suffered from pain (binary variable with yes vs.  
131 no options) were asked to give information about their pain. We assessed average pain  
132 intensity (numeric rating scale from 1 to 10) if a physician was consulted or if any other kind  
133 of therapy was used and the number of days of restriction due to pain. Subsequently,

1  
2 134 subjects filled in the 9-item ETS. Below we provide a detailed description of all measures in  
3  
4 135 this study.

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### 7 8 9 137 *Expectation for Treatment Scale*

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12 138 The first version of the ETS consisted of nine items (e.g., “I expect the treatment  
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14 139 [acupuncture] will help me to cope with my complaints.”). Each item was to be rated on a  
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16 140 four-point scale ranging from 1 to 4 (partially disagree, partially agree, agree, definitely  
17  
18 141 agree). We decided to use a four-point scale instead of a five-point scale for two reasons.  
19  
20 142 First, the chosen format forces the patient to provide an answer with a direction (higher or  
21  
22 143 lower than the middle answer choice) instead of opting for the middle category, which can  
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24 144 often be the case in situations of insecurity (such as the estimation of future events here)<sup>23</sup>.  
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26 145 Second, the lowest answer on the scale of “definitely disagree” can be considered  
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28 146 unexpected for patients motivated to undergo an acupuncture treatment. After the statistical  
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30 147 analyses, the nine-item version was reduced to a final 5-item version of the ETS. A detailed  
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32 148 description of these five items is provided in Table 1.  
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39 150 Insert Table 1 about here

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### 43 44 152 *Optimism and pessimism*

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47 153 Both concepts were assessed using the German version of the Life Orientation  
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49 154 Test—Revised<sup>24</sup>. The questionnaire consists of six self-report items (plus four filler items),  
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51 155 each rated on a five-point Likert scale ranging from 0 (strongly disagree) to 4 (strongly  
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53 156 agree). The data were separated into optimism and pessimism scores, as recommended by  
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55 157 Glaesmer et al. (2008). Each possible score ranged from 0 to 12, indicating that higher  
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2 158 values display either a higher peculiarity for optimism or pessimism. In the present study,  
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4 159 the Cronbach's alpha was acceptable for optimism (0.72) and questionable for pessimism  
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6 160 (0.60).

### 9 161 *Depression*

11  
12 162 The Patient Health Questionnaire (PHQ-9) is widely used as a standard instrument  
13  
14 163 for diagnosing depression in primary care and is considered to be well validated<sup>25</sup>. The  
15  
16 164 PHQ-9 consists of nine questions operating according to the modified Diagnostic and  
17  
18 165 Statistical Manual, Fourth Edition criteria. Patients indicated their answers on a scale  
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21 166 ranging from 0 (not at all) to 3 (almost every day)<sup>26</sup>. A higher score indicates a higher  
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23 167 severity of depressive symptoms (ranging between 0 and 27). In the present study, the  
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25 168 internal consistency of the scale was excellent (Cronbach's alpha = 0.90).

### 28 169 *Resilience*

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31 170 As a protective personality factor, resilience was appraised using the Resilience  
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33 171 Scale<sup>27</sup>. In the current study, we used the German Version Resilienzskala (RS-11)<sup>28</sup>. The  
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35 172 instrument consists of eleven questions with seven response alternatives ranging from 1  
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38 173 (disagree) to 7 (fully agree). Higher scores indicate higher resilience. In the present study,  
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40 174 the internal consistency was excellent (Cronbach's alpha = 0.90).

### 42 175 *Body-Efficacy Expectation*

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45 176 To measure beliefs concerning bodily coping capabilities, the Body-Efficacy  
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47 177 Expectation (BEE) questionnaire<sup>29</sup> was used. The instrument consists of five items using a  
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50 178 four-point Likert scale ranging from 1 (not true at all) to 4 (exactly true). A higher score  
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52 179 indicates stronger beliefs in one's bodily coping capabilities. In the present study, the  
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54 180 Cronbach's alpha was 0.75, indicating an acceptable internal consistency.

### 181 *Perceived Sensitivity to Medicines*

182 To assess the individual's sensitivity to medicines, we used the Perceived Sensitivity  
183 to Medicines scale (PSM)<sup>30</sup>. The PSM is considered a reliable and valid measure  
184 composed of five self-report questions to assess perceived sensitivity to the potential  
185 adverse effects of medicines. Responses are scored on a five-point Likert scale, and  
186 patients' item scores are summed to provide a total score ranging between 5 and 25. Higher  
187 scores point toward a high perceived sensitivity to the potential adverse effects of  
188 medicines. In the current study, the scale showed excellent internal consistency  
189 (Cronbach's alpha = 0.94).

### 190 *Neuroticism and openness to experience*

191 To assess the distinctness of neuroticism and openness to experience among  
192 patients, we used the corresponding subscales of the NEO Five Factor Inventory (NEO-FFI)  
193<sup>31</sup>. To that end, 23 questions were extracted from the 60-item NEO-FFI. The instrument  
194 utilizes a five-point Likert response format, from 1 (strongly refuse) to 5 (strongly agree). A  
195 higher score indicates a higher value for neuroticism and openness to experience. In the  
196 present study, the Cronbach's alpha was 0.85 for neuroticism and 0.72 for openness to  
197 experience, which indicates good to acceptable internal consistency.

### 198 *Acupuncture Expectancy Scale*

199 Mao and colleagues developed the AES aiming to measure patients' expected  
200 response from acupuncture<sup>17</sup>, which was developed for only one clinical intervention (i.e.  
201 acupuncture). The instrument consists of four items. The answers are given using a five-  
202 point Likert scale ranging from 1 (not at all agree) to 5 (completely agree). A higher score  
203 points toward higher expectancies. In the present study, the internal consistency of the  
204 scale was considered good (Cronbach's alpha = 0.88).

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5 206 **Statistical Analyses**

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8 207 All data analyses were executed using SPSS (version 22, SPSS Inc., Chicago,  
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10 208 Illinois, USA). As a first step, we used the nine items of the first ETS version to explore  
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13 209 homogeneity and diversity between items. We conducted a descriptive analysis of the data  
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15 210 with the aim of detecting possible floor or ceiling effects and assessing the distribution of the  
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17 211 data. Internal consistency was examined through reliability analyses (Cronbach's alpha),  
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19 212 with the item-total correlation corrected and the Cronbach's alpha if the item is deleted.  
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21 213 Retest reliability for the nine items was assessed by the intraclass correlation coefficient  
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23 214 (ICC). We set for each item a minimal acceptable ICC of .60 and for the total score an ICC  
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25 215 of .80. Three criteria guided the decision to keep an item for the final version: 1) it should  
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27 216 have a high item-total correlation corrected and no low internal consistency if deleted, 2) the  
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29 217 item should not overlap too strongly in content with another item that might be included, and  
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31 218 3) the item should not contribute to ceiling effects in the final version of the scale, which  
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34 219 means items with lower values were preferred.

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38 220 In a second step, we used the reduced version of the scale to generate a total sum  
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40 221 score of the five items (ranging from 5 to 20). To examine divergent and convergent validity,  
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42 222 correlations between the ETS sum score and the other measures were calculated. We  
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44 223 assumed a very high correlation between the ETS and the most strongly related construct ( $r$   
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46 224  $> .70$ ; AES), moderate correlations with strongly related constructs ( $r > .30$ ; LOT-R  
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48 225 optimism, inverse with LOT-R pessimism), small correlations with less related constructs ( $r$   
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50 226  $> .20$ ; PHQ-9; RS-11, BEE) and no correlation with unrelated constructs (PSM, NEO-FFI  
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52 227 neuroticism, NEO-FFI openness to experience).

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2 228 To test our assumption of one general factor an explorative factor analysis using a  
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4 229 varimax rotation, an Eigenvalue of more than one and the Scree test was used with the 5  
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6 230 ETS items to determine the number of underlying factors. In addition we conducted a  
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9 231 confirmatory factor analysis with an independent sample of chronic low back pain patients,  
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11 232 which had been included in a randomized controlled trial (registration number DRKS-  
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13 233 ID: DRKS00010191). These patients filled in the ETS. The data has been used to test the  
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16 234 single factor structure. The best model used correlated error terms between item 2 and item  
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18 235 5 and is shown in Figure 1. Multiple goodness of fit tests <sup>32</sup> were used to evaluate model,  
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20 236 including the comparative fit index (CFI; <sup>33</sup>), the normed fit index (NFI; <sup>32</sup>) the goodness of fit  
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22 237 index (GFI; <sup>34</sup>) and the root mean squared error of approximation (RMSEA). A CFI greater  
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25 238 than 0.90 indicates a good fit to the data <sup>35</sup>. A NFI and GFI greater than 0.90 indicates a  
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27 239 good fit to the data <sup>36</sup>. A RMSEA with values of less than 0.08 indicates a good fit to the  
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29 240 data <sup>37</sup>, while values greater than 0.10 suggest strongly that the model fit is unsatisfactory.  
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32 241 The Chi-square goodness of fit test can be regarded as a general test for the acceptability  
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34 242 of the model: a statistically significant  $\chi^2$  indicates that a significant proportion of variance  
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36 243 remains unexplained by the model <sup>32</sup>. Confirmatory factor analysis was conducted with the  
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39 244 Analysis of Moment Structures (AMOS) software version 25 which is part of the SPSS  
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41 245 package.

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## 248 **Results**

### 249 **Sample characteristics**

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2 250 Three-quarters of the patients were female, one-third had a high school degree or  
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4 251 higher vocational training and approximately 70% were currently employed. Approximately  
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6 252 two-thirds of the surveys were conducted with patients in Switzerland, and one-third came  
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9 253 from Germany. The characteristics of patients with current pain are displayed in Table 2.  
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11 254 Descriptive information about the scales used in the study is presented in the appendix.  
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16 255 Insert Table 2 about here  
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### 21 256 **First version of the ETS**

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24 257 In an initial analysis, we included nine items of the ETS. Descriptive results and  
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27 258 results from scale analyses are presented in the appendix. In general, the standard  
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29 259 deviations showed large variance, with the exception of item 6 (“The treatment  
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31 260 [acupuncture] is in general effective”) and item 7 (“I myself have positive expectations about  
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33 261 the treatment [acupuncture]”). The mean value of item 6 was relatively high, which can be  
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35 262 seen as an indicator of a ceiling effect. Therefore, we decided to exclude item 6 (i.e.,  
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37 263 general expectations about the effectiveness of the treatment [acupuncture]) and item 7  
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39 264 (i.e., personal expectation of a treatment) from the final ETS.  
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43 265 The item-total correlation corrected and the Cronbach’s alpha if an item is deleted  
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45 266 are indicators for the coherence of the single item meaning with the total scale (see  
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47 267 appendix). The item-total correlation corrected did not give any strong reason for the  
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49 268 exclusion of items. However, there had been some items with very high total correlations  
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51 269 between items (item 2 and item 9). Item 2 (“I expect my complaints will be much better  
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53 270 because of the treatment [acupuncture]”) and item 9 (“I expect that after the treatment  
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55 271 [acupuncture] my complaints will be considerably better”) were very similar in terms of their  
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1  
2 272 wording, and we decided to keep only one of the items for the final version. The reason  
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4 273 behind this decision was that the ICC value for item 2 was lower than that of item 9. In  
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6 274 addition, the mean value for item 9 was lower than the mean of item 2, which consequently  
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9 275 can contribute to a larger variation in the final scale since ceiling effects can be avoided.  
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11 276 The decision to exclude item 1 was based on content. Based on pre-study feedback, a  
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13 277 misunderstanding of “clearly reduced” became evident. Furthermore, item 1 (“I expect the  
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15 278 treatment [acupuncture] will clearly reduce my complaints”) and item 4 (“I expect the  
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17 279 treatment [acupuncture] will make my complaints disappear”) covered similar topics. The  
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20 280 factor loading confirmed our earlier decision to eliminate item 6 (“The treatment  
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22 281 [acupuncture] is in general effective”) since the factor loading was relatively low. All items of  
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25 282 the first version contributed to one single factor with 65.51% of explained variance.  
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27 283 Additional information concerning the normal distribution for the 9-item ETS version, the 5-  
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29 284 item ETS version as well as for the AES items can be found in the appendix. It becomes  
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31  
32 285 apparent that the 9-item ETS version total score is normally distributed. For the 5-items ETS  
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34 286 version and the AES items there had been substantial number of subjects with either the  
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36 287 lowest or the highest score on the scale.  
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38  
39 288 The final version of the ETS consists of five items: the previous item 3 (“I expect the  
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41 289 treatment [acupuncture] will help me to cope with my complaints”) covers coping ability,  
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43 290 item 4 (“I expect the treatment [acupuncture] will make my complaints disappear”) covers  
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45 291 total absence of complaints, item 5 (“I expect the treatment [acupuncture] will improve my  
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47 292 energy”) covers an energy increase, item 8 (“I expect the treatment [acupuncture] will  
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49 293 improve my physical performance”) covers an improvement of physical functioning and item  
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51 294 9 (“I expect that after the treatment [acupuncture] my complaints will be considerably  
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53  
54 295 better”) covers a considerable decrease in symptoms. To summarize, the ETS captures an  
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2 296 expected decrease in symptoms, an expected increase in energy and expected overall  
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4 297 wellbeing after a treatment.  
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9 298 Insert Table 3 about here  
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13 299 The Cronbach's alpha of the final version was 0.90, which is an excellent value for a  
14  
15 300 very short scale (Table 3). Retest reliability was excellent for the five items. All items  
16  
17 301 contributed substantially to the final scale, and the factor loading indicated a single factor  
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19 302 structure with 72.33% of explained variance.  
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### 26 303 **Convergent and divergent validity**

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29 304 We expected a moderate correlation between the ETS and the LOT-R optimism and  
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31 305 an inverse correlation with pessimism. However, these assumptions were not confirmed by  
32  
33 306 our findings (Table 4). Interestingly, higher pessimism was moderately associated with  
34  
35 307 higher expectations, both for the ETS and the AES. The ETS showed a small but significant  
36  
37 308 correlation with the PHQ-9, which is in line with our assumption. The correlation between  
38  
39 309 the ETS and the RS-11 or the BEE was close to zero, which is unexpected according to our  
40  
41 310 assumptions. However, we found a moderate correlation between the ETS and the PSM,  
42  
43 311 for which higher expectations were associated with a higher sensitivity to medication. The  
44  
45 312 shared aspect of this association is the responsiveness to a medical treatment. Personality  
46  
47 313 traits (NEO-FFI) were not associated with the ETS, which is in line with our assumptions.  
48  
49 314 The ETS score has a very high correlation ( $> .90$ ) with the AES which can be regarded as  
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51 315 benchmark measure for acupuncture expectations.  
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2 316 Insert Table 4 about here  
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7 317 **Confirmatory factor analysis**  
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10 318 In addition we conducted a CFA with the data from the 439 ETS questionnaires mentioned  
11  
12 319 above with the model presented in Figure 1. The factor loadings were between 0.609 (Item  
13  
14 320 2) and 0.796 (Item 4). We found an acceptable model fit in the Chi-square statistics with  
15  
16 321 (Chi-square = 5.859, d.f. = 4, p = .210) indicating that the model is able to explain the data  
17  
18 322 structure in general. The CFI was .998 in our model and indicates a very good model fit.  
19  
20 323 Similarly the NFI (.993) and GFI (.995) confirms the excellent model fit. The RMSEA (.033)  
21  
22 324 suggests also that the model with one single factor explains the data very well. The good  
23  
24 325 internal consistency of the ETS in this sample (Cronbach alpha = .836) confirmed the  
25  
26 326 findings of the scale development.  
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33 328 Insert Figure 1 about here  
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39 330 **Discussion**  
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42 331 The ETS is a well-validated and brief 5-item scale for measuring patient's  
43  
44 332 expectations with excellent test-retest properties. We had been able to overcome ceiling  
45  
46 333 effects, which had been a limitation of earlier measures<sup>17</sup>. This improvement might be the  
47  
48 334 consequence of using only four response categories instead of a larger scale with rather  
49  
50 335 inadequate categories, (namely, "definitely disagree"). The ETS has excellent measurement  
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52 336 properties concerning Cronbach's alpha, retest reliability over one week and single factor  
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1  
2 337 structure was replicated in a clinical sample. The ETS can be used for research and clinical  
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4 338 purposes equally.

6 339 The ETS could be adapted to other clinical situations and treatments beyond  
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9 340 acupuncture, which is an important step toward implementing treatment expectations as  
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11 341 working mechanisms among a variety of patient populations in a standardized way. Pain  
12  
13 342 disorders, mental disorders and functional symptoms might be the most appropriate fields,  
14  
15 343 since clinical research indicates the high relevance of expectations for treatment outcomes.  
16  
17 344 The ETS can be used by patients with lower levels of health literacy, since items are kept  
18  
19 345 very descriptive and intuitive. We avoided the use of percentages, technical terms and  
20  
21 346 probabilities to make the ETS as easy to administer in patients as possible. Compared to  
22  
23 347 the EXPECT scale<sup>18</sup>, we did not ask for specific improvement according to symptoms,  
24  
25 348 which can be challenging task for patients.

29 349 Earlier findings about the expectation outcome association in clinical studies had  
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31  
32 350 been limited by the diversity of measures. A strong measure is a prerequisite to accurately  
33  
34 351 predict treatment responders based on pre-treatment expectations. After further  
35  
36 352 investigation of the results from a systematic review by Prady and colleagues<sup>15</sup>, we found  
37  
38 353 that out of ten trials, only five provided their exact item wording for measuring expectations.  
39  
40 354 Since the assessment instruments are not available, it is difficult to replicate the studies.  
41  
42 355 Three out of the five mentioned studies used only one item in order to assess expectations.  
43  
44 356 There is no reporting at all of Cronbach's alpha in the two remaining studies.

48 357 As mentioned earlier, the ETS showed a substantial correlation with the AES.  
49  
50 358 Nevertheless, there are some differences worthy of mention between the two measures. In  
51  
52 359 contrast to Jun Mao and his colleagues, we included measures of convergent and divergent  
53  
54 360 validity in our study in order to enhance information about the unique aspects of  
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56 361 expectations compared to related constructs. Moreover, the ETS can be used for a

1  
2 362 multitude of interventions and can easily be adapted to other clinical situations, since no  
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4 363 illness-specific symptoms are mentioned in the scale. Furthermore, there are differences  
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6 364 concerning item wording and scaling (four vs. five response categories) between the ETS  
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9 365 and the AES.

10  
11 366 Another notable issue that deserves to be discussed is the moderate correlation  
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13 367 between high pessimism and high expectations for both the ETS and the AES. Our initial  
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15 368 assumption was to find a negative association between both expectation measures and  
16  
17 369 pessimism, which was not confirmed. Furthermore, we found no correlation between  
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19 370 optimism and the ETS in our study. The findings about negative cognitions (pessimism) are  
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21 371 in line with our results of the small but significant correlation of the ETS and depression  
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23 372 (PHQ-9). A possible explanation for both findings might be that in pain patients, depression  
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25 373 might be associated with more severe medical symptoms, which might lower patients'  
26  
27 374 expectations in some cases depending on treatment history.

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31 375 Expectations are used in clinical populations as observational data, but experimental  
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33 376 studies suggest that expectations can be changed by verbal interventions themselves<sup>1 38</sup>. A  
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35 377 study of pain patients receiving acupuncture showed larger treatment effects if the patients  
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37 378 received a briefing about expectations in advance<sup>39</sup>. However, the study only used  
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39 379 observer ratings to check for the adequate manipulation of expectations by therapists. The  
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41 380 real change of expectations from a patient's perspective was not measured, and therefore,  
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43 381 other working mechanisms (like empathy or adherence to recommendations) might have  
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45 382 influenced the results.

## 51 383 **Limitations**

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54 384 There are some limitations to our study. First, even though collection of data via a  
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56 385 web survey holds many advantages, there are also some downsides to this method since

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2 386 recruitment is done in an unstructured way. Since the ETS questionnaire was also validated  
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4 387 in a paper-based version in a clinical population this limitation is of minor importance.  
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6 388 Second, in order to enhance the external validity of our study other clinical populations  
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9 389 should be investigated in order to prove the validity of our scale across clinical conditions.  
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11 390 So far the application seems feasible and valid for patients with pain. Third, there might be  
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13 391 clinical intervention where patients might have a very vague idea about procedures and  
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15 392 outcomes. we did not collect data from a clinical pain population *prior* to their acupuncture  
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17 393 treatment. The patients from our sample provided information about their previous  
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19 394 experience with acupuncture, but such an assessment could be done more  
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21 395 comprehensively in order to capture the underlying beliefs and experiences of patients and  
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23 396 their relevance for expectations.  
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## 28 397 **Conclusion**

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31 398 The ETS is a short and validated measure that can be used in the German and  
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33 399 English languages and can contribute to the understanding of patient expectations for  
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35 400 treatment outcomes. The field of acupuncture served as example to develop the ETS, but it  
36  
37 401 could be easily adapted for other treatments and clinical contexts. The ETS fills a gap by  
38  
39 402 providing a strong and flexible measure that can serve as a basis for upcoming predictor  
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41 403 analyses of treatment expectations in clinical studies.  
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45

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## 57 408 **Declaration of competing interests**

1  
2 409 The present research was conducted in the absence of any commercial or financial  
3  
4 410 relationships that could be construed as a potential conflict of interest.  
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#### 8 9 10 412 **Authorship and contributorship**

11  
12  
13 413 JB was involved in the conception and execution of the scale and survey, the  
14  
15 414 analysis and interpretation of data, the writing of the first draft and the revision of the  
16  
17 415 manuscript. AK was involved in the analysis and interpretation of data and the writing of the  
18  
19 416 manuscript. SL was involved in programming and conducting the survey, managing and  
20  
21 417 analysing data, and revising the manuscript. CW was involved in the conception of the scale  
22  
23 418 and survey, the interpretation of the data and the revision of the manuscript.  
24  
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#### 30 420 **License for publication statement**

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#### 56 431 **Data sharing statement**

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2 432 Date are available from the first author on request.

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7 434 **Acknowledgement**

8  
9  
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11  
12  
13 436 phrasing of questions in our scale.

14  
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## 50 Tables and Figures

51  
52  
53 560 Table 1. Description of the 5 final items in English and German

54  
55 561 Table 2. Sample characteristics of subjects with current pain (N = 102)

56  
57 562 Table 3. Scale and factor analysis of the 5 item ETS for subjects with current pain (N = 102)

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563 Table 4. Convergent and divergent validity of the 5 item version of the ETS for subjects with  
564 current pain (N = 102)  
565 Figure 1. Confirmatory factor analysis with factor loadings (N = 439) of the final 5 item ETS  
566 version in patients with chronic low back pain

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1  
2 Table 1. Description of the 5 final items in English and German  
3

4 Description: The overarching construct of ETS is treatment-related outcome expectation of  
5 patients. Outcomes of interest for patients are coping (item 1), vitality (item 3) and physical  
6 health (item 4). Two items (items 2 and 5) capture the reduction of patient complaints, either  
7 an absence or a considerable reduction thereof. The scale can be adapted to specific  
8 treatments of interest. Instead of the term “treatment” a specific term can be used (i.e.  
9 acupuncture, counseling, physiotherapy). We used the term complaints [german  
10 Beschwerden] as already used by other authors like in the symptom checklist (SCL-90-R)  
11 <sup>40</sup>. Therefore, any kind of complaints can be captured and allow the use of this instrument  
12 across patient groups and settings. The term complaints can be adapted if needed to the  
13 clinical situation if one specific target symptom is predominant (i.e. pain, depression,  
14 nausea). The scale should be used in a clinical setting by patients with sufficient German or  
15 English language skills.  
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34 English version  
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36 There are several statements below that capture your expectations about the [acupuncture]  
37 treatment. Please indicate to what extent these statements apply to you personally. **There**  
38 **are no right or wrong answers. We are only interested in your current personal**  
39 **thoughts.**  
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48 *Please select one option.*  
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partially disagree	partially agree	agree	definitely agree

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1 I expect the treatment [acupuncture] will help me to cope with my 1 2 3 4  
complaints.

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2 I expect the treatment [acupuncture] will make my complaints 1 2 3 4  
disappear.

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3 I expect the treatment [acupuncture] will improve my energy. 1 2 3 4

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4 I expect the treatment [acupuncture] will improve my physical 1 2 3 4  
performance.

---

5 I expect that after the treatment [acupuncture] my complaints will 1 2 3 4  
be considerably better.

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\*We used the term acupuncture in our study. The general version of ETS uses the term  
treatment.

567

German version

Im Folgenden finden Sie einige Aussagen darüber, was man von einer Behandlung [Akupunktur] erwarten kann. Geben Sie bitte an, inwieweit die einzelnen Aussagen für Sie persönlich zutreffen. **Es gibt keine richtigen und falschen Antworten. Uns interessiert nur, was Sie persönlich denken.**

Bitte wählen Sie **eine** Antwort aus.

1	2	3	4
trifft eher nicht zu	trifft eher zu	trifft sehr zu	trifft völlig zu

1	Ich erwarte, dass ich durch die Behandlung [Akupunktur] mit meinen Beschwerden besser umgehen kann.	1	2	3	4
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2	Ich erwarte, dass meine Beschwerden durch die Behandlung [Akupunktur] verschwinden.	1	2	3	4
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3	Ich erwarte, dass sich meine Energie durch die Behandlung [Akupunktur] verbessert.	1	2	3	4
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4	Ich erwarte durch die Behandlung [Akupunktur] eine verbesserte körperliche Leistungsfähigkeit.	1	2	3	4
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5	Ich erwarte, dass sich nach der Behandlung [Akupunktur] meine Beschwerden deutlich verbessern.	1	2	3	4
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1  
2 \*Wir haben den Begriff Akupunktur in unserer Studie verwendet. Die allgemeine Version  
3  
4 des ETS verwendet den Begriff Behandlung.  
5

6 Scoring of the questionnaire  
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9 Add up the score of the individual items and use the number of filled in questions as  
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11 denominator.  
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Table 2. Sample characteristics of subjects with current pain (N = 102)

	Frequencies // Mean (SD)	Percentage
Age	49.16 (14.04)	
Gender		
Female	76	75%
Male	26	25%
Education		
Vocational school	39	38%
Higher school certificate or Higher vocational training	29	28%
University	34	33%
Employment status		
Working	72	71%
Retired	10	10%
Other	20	20%
Country of residence		
Switzerland	68	67%
Germany	34	33%
Acupuncture experience		
Current	13	13%
Earlier	51	50%



1				
2	None	38	37%	569
3				570
4	Success of acupuncture	6.5 (2.80)		571
5				572
6	[range 1-10]*			573
7				574
8	Reason for treatment**			575
9				576
10	Pain	55	86%	577
11				578
12	Mental health	13	20%	579
13				580
14	Other	24	38%	581
15				582
16				583
17	General Health***	3.21 (.92)		584
18				585
19	Pain characteristics			586
20				587
21	Intensity [range 0-10]****	6.5 (1.92)		588
22				589
23	Physician consulted*****	68	67%	590
24				591
25	Any treatment*****	66	65%	592
26				593
27	Days of restriction due to			594
28				595
29	pain*****	46.76 (63.74)		596
30				597
31	Location*****			598
32				599
33	Back	58	57%	600
34				
35	Neck	44	43%	
36				
37	Knee	21	21%	
38				
39	Head	20	20%	
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41	Hip	16	16%	
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43	Other	33	32%	
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2 601 \*Range from no success (1) to very successful (10) treatment outcome of the last  
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4 602 acupuncture treatment  
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6 603 \*\*Multiple answers were possible  
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9 604 \*\*\*Range from 1 = excellent to 5 = bad  
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11 605 \*\*\*\*0 indicating no pain and 10 indicating maximum pain  
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13 606 \*\*\*\*\*In the last 6 month period  
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16 607 \*\*\*\*\*Multiple answers were possible  
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Table 3. Scale and factor analysis of the 5 item ETS for subjects with current pain (N = 102)

Item	Mean (SD)	Item-total correlation corrected	Cronbach's alpha if item deleted	Factor loading	Retest ICC [95%-CI]
Item 3	2.38 (1.03)	.727	.887	.826	.697 [.517,.818]
Item 4	1.97 (.96)	.736	.883	.834	.724 [.556,.835]
Item 5	2.41 (1.0)	.776	.875	.865	.840 [.732,.907]
Item 8	2.33 (.83)	.817	.869	.891	.749 [.592,.851]
Item 9	2.52 (.90)	.737	.883	.834	.836 [.725,.904]
			Cronbach's $\alpha$	% of variance	
ETS 5			.901	72.325	.856 [.757,.917]

Item 3: I expect the treatment [acupuncture] will help me to cope with my complaints.

Item 4: I expect the treatment [acupuncture] will make my complaints disappear.

Item 5: I expect the treatment [acupuncture] will improve my energy.

Item 8: I expect the treatment [acupuncture] will improve my physical performance.

Item 9: I expect that after the treatment [acupuncture] my complaints will be considerably better.

Table 4. Convergent and divergent validity of the 5 item version of the ETS for subjects with current pain (N = 102). Pearson Correlation, Significance level (2-tailed), N of patients.

	ETS	LOT-R Optimism	LOT-R Pessimism	PHQ-9	RS-11	BEE	PSM	NEO-FFI Neuroticism	NEO-FFI Openness to experience
ETS	1								
	102								
LOT-R Optimism	-.066	1							
	99	99							
LOT-R Pessimism	.204*	-.247*	1						
	.043	.014							
	99	99	99						
PHQ-9	.233*	-.567**	.312**	1					
	.020	.000	.002						
	100	99	99	100					
RS-11	-.073	.546**	-.460**	-.572**	1				
	.474	.000	.000	.000					
	99	99	99	99	99				

1									
2	BEE	.032	.259**	-.074	-.176	.407**	1		
3									
4		.754	.010	.468	.081	.000			
5		99	99	99	99	99	99		
6									
7	PSM	.344**	-.078	.201*	.306**	-.049	.011	1	
8									
9		.000	.445	.046	.002	.631	.912		
10		100	99	99	100	99	99	100	
11									
12	NEO-FFI	.104	-.578**	.467**	.631**	-.682**	-.284**	.238*	1
13									
14	Neuroticism	.316	.000	.000	.000	.000	.005	.020	
15		95	95	95	95	95	95	95	95
16									
17	NEO-FFI	-.072	.297**	-.167	-.090	.302**	.122	.132	-.130
18									1
19	Openness to	.492	.004	.109	.386	.003	.241	.205	.211
20		94	94	94	94	94	94	94	94
21	experience								
22									
23									
24	Cronbach Alpha	.901	.727	.608	.900	.900	.757	.940	.854
25									.726

26 609 \*\*Correlation is significant at the 0.01 level (2-tailed)

28  
29 610 \*Correlation is significant at the 0.05 level (2-tailed)

31 611 ETS = Expectation for Treatment Scale; LOT-R = Life-Orientation Test; PHQ-9 = Patients Health Questionnaire-9; RS-11 = Die

33 612 Resilienzskala - Ein Fragebogen zur Erfassung der psychischen Widerstandsfähigkeit als Personenmerkmal; BEE = Body-

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36 613 Efficacy Expectation; PSM = The Perceived Sensitivity to Medicines Scale; NEO-FFI = NEO Five-Factor Inventory

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615 Figure 1. Confirmatory factor analysis with factor loadings (N = 439) of the final 5 item ETS  
616 version in patients with chronic low back pain

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## 617 Appendix (Barth et al.)

APPENDIX Table 1: Sample characteristics in scales in subjects with current pain (N = 102)

	Median
	Mean (SD)
ETS (9 items)	22
(range 9-36)	22.63 (.64)
ETS (5 items)	11
(range 5-20)	11.62 (4.01)
AES	12.0
(range 4-20)	11.82 (4.10)
PHQ-9	7
(range 0-27)	8.46 (6.06)
RS-11	60
(range 11-77)	58.36 (11.13)
BEE	14
(range 5-20)	13.71 (2.90)

PSM	11
(range 5-25)	12.77 (6.13)
LOT-R Optimism	8
(range 0-12)	7.93 (2.77)
LOT-R Pessimism	8
(range 0-12)	7.93 (2.38)
NEO-FFI Neuroticism	21
(range 0-48)	21.08 (8.19)
NEO-FFI Openness to experience	30
(range 0-44)	29.84 (5.77)

Expectation for Treatment Scale; AES= Acupuncture Expectancy Scale; LOT-R= Life-Orientation Test; PHQ-9= Patients Health Questionnaire-9; RS-11= Die Resilienzskala - Ein Fragebogen zur Erfassung der psychischen Widerstandsfähigkeit als Personenmerkmal; BEE= Body-Efficacy Expectation; PSM= The Perceived Sensitivity to Medicines Scale; NEO-FFI= NEO Five-Factor Inventory



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623 Appendix Table 2. Between item correlations for sample with current pain (N = 102). Pearson Correlation and significance (2-

Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	624	625	626	627	628	629	630	631	632	633	634	635	636	637	638
									tail	d).	**Co	rrela	tion	is	signi	fica	nt at	the	0.01	level	(2-	tail	d).

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Item 1	1								639	
Item 2	.840**	1							640	
	.000								641	Item
Item 3	.636**	.605**	1						642	1: I
	.000	.000							643	exp
Item 4	.568**	.627**	.580**	1					644	ect
	.000	.000	.000						645	the
Item 5	.533**	.611**	.664**	.637**	1				646	treat
	.000	.000	.000	.000					647	men
Item 6	.540**	.556**	.442**	.437**	.505**	1			648	t
	.000	.000	.000	.000	.000				649	[acu
Item 7	.692**	.679**	.541**	.575**	.509**	.521**	1		650	pun
	.000	.000	.000	.000	.000	.000			651	ctur
Item 8	.528**	.571**	.673**	.664**	.762**	.470**	.631**	1	652	e]
	.000	.000	.000	.000	.000	.000	.000		653	will
Item 9	.733**	.754**	.605**	.673**	.603**	.592**	.701**	.673**	654	clea
	.000	.000	.000	.000	.000	.000	.000	.000	655	rly

656 reduce my complaints.

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2 657 Item 2: I expect my complaints will be much better because of the treatment [acupuncture].  
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4  
5 658 Item 3: I expect the treatment [acupuncture] will help me to cope with my complaints.  
6  
7 659 Item 4: I expect the treatment [acupuncture] will make my complaints disappear.  
8  
9 660 Item 5: I expect the treatment [acupuncture] will improve my energy.  
10  
11 661 Item 6: The treatment [acupuncture] is in general effective.  
12  
13  
14 662 Item 7: I myself have positive expectations about the treatment [acupuncture].  
15  
16 663 Item 8: I expect the treatment [acupuncture] will improve my physical performance.  
17  
18 664 Item 9: I expect that after the treatment [acupuncture] my complaints will be considerably better.  
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Appendix Table 3. Scale and factor analysis of the 9 item ETS for subjects with current pain (N = 102)

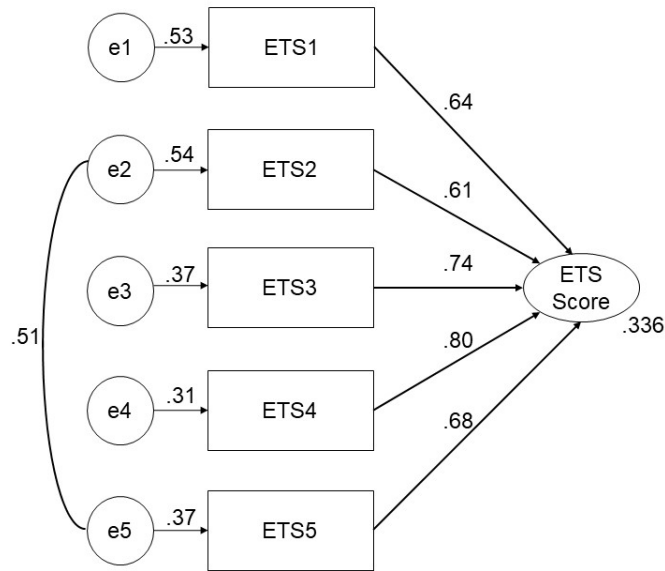
Item	Mean (SD)	Item-total correlation corrected	Cronbach's alpha if item deleted	Factor loading	Retest ICC [95%-CI]
Item 1	2.71 (1.0)	.782	.920	.839	.684 [.499,.810]
Item 2	2.66 (.93)	.816	.918	.863	.725 [.557,.836]
Item 3**	2.38 (1.03)	.736	.924	.790	.697 [.517,.818]
Item 4**	1.97 (.96)	.735	.923	.793	.724 [.556,.835]
Item 5**	2.41 (1.0)	.745	.923	.799	.840 [.732,.907]
Item 6	2.97 (.59)	.612	.931	.685	.649 [.450,.787]
Item 7	2.68 (.65)	.744	.924	.806	.658 [.462,.793]
Item 8**	2.33 (.83)	.772	.921	.821	.749 [.592,.851]
Item 9**	2.52 (.90)	.826	.917	.874	.836 [.725,.904]
			Cronbach's $\alpha$	% of	
				variance	
ETS 9			.930	65.512	.879 [.794,.930]

\*\*marked items are included in the final version of its scale

- 1  
2 669  
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4 670 Item 1: I expect the treatment [acupuncture] will clearly reduce my complaints.  
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6 671 Item 2: I expect my complaints will be much better because of the treatment [acupuncture].  
7  
8 672 Item 3: I expect the treatment [acupuncture] will help me to cope with my complaints.  
9  
10 673 Item 4: I expect the treatment [acupuncture] will make my complaints disappear.  
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12 674 Item 5: I expect the treatment [acupuncture] will improve my energy.  
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15 675 Item 6: The treatment [acupuncture] is in general effective.  
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17 676 Item 7: I myself have positive expectations about the treatment [acupuncture].  
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19 677 Item 8: I expect the treatment [acupuncture] will improve my physical performance.  
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21 678 Item 9: I expect that after the treatment [acupuncture] my complaints will be considerably better.  
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Item 3 corresponds to ETS1  
 Item 4 corresponds to ETS2  
 Item 5 corresponds to ETS3  
 Item 8 corresponds to ETS4  
 Item 9 corresponds to ETS5

Chi-square = 5.859 (d.f. = 4),  
 p = .210; RMSEA = 0.033;  
 CFI = 0.998; NFI = 0.993;  
 GFI = 0.996

e1 to e5: Error terms

Figure 1. Confirmatory factor analysis with factor loadings (N = 439) of the final 5 item ETS version in patients with chronic low back pain

190x338mm (96 x 96 DPI)

# BMJ Open

## Assessment of patients' expectations: development and validation of the Expectation for Treatment Scale (ETS)

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-026712.R1
Article Type:	Research
Date Submitted by the Author:	10-Feb-2019
Complete List of Authors:	Barth, Jürgen; University Hospital Zurich, Institute for Complementary and Integrative Medicine Kern, Alexandra; Institute for Complementary and Integrative Medicine, University Hospital Zurich and University Zurich, Zurich Switzerland Lüthi, Sebastian; Institute for Complementary and Integrative Medicine, University Hospital Zurich and University of Zurich, Zurich, Switzerland Witt, Claudia M.; Institute for Complementary and Integrative Medicine, University Hospital Zurich and University of Zurich, Zurich, Switzerland; Institute for Social Medicine, Epidemiology and Health Economics, Charité
<b>Primary Subject Heading</b>:	Complementary medicine
Secondary Subject Heading:	Patient-centred medicine, Research methods
Keywords:	expectations, placebo, assessment, pain, acupuncture
<p>Note: The following files were submitted by the author for peer review, but cannot be converted to PDF. You must view these files (e.g. movies) online.</p> <p>ETS_STROBE_checklist_cross-sectional_20190118.doc</p>	

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Manuscripts



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3 **Assessment of patients' expectations: development and validation of the**  
4  
5 **Expectation for Treatment Scale (ETS)**  
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8 Running title: Expectation for Treatment Scale (ETS)  
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10 Submission to British Medical Journal  
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58 Word count: 4526  
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60

## 1 Abstract

2 **Objective:** The development of a short self-report instrument for the assessment of  
3 expectations (Expectation for Treatment Scale, ETS), using acupuncture as a case  
4 example.

5 **Design:** A cross-sectional assessment with retest after one week.

6 **Setting:** A web-based survey with patients suffering from pain.

7 **Methods:** In a three-step approach, we reduced the initially collected number of items from  
8 17 to 9 and to 5, including expectations about coping ability, vitality, physical health and  
9 reduction of patient complaints. Items were selected according to internal consistency  
10 (Cronbach's alpha), convergent and divergent validity with related constructs (optimism,  
11 pessimism, resilience, perceived sensitivity to medicines, depression, and others), one-  
12 week retest reliability (intraclass correlation coefficient, ICC) and exploratory and  
13 confirmatory factor analysis.

14 **Results:** A total of 102 pain patients were included, and 54 of these patients completed the  
15 retest assessment. The final version of the ETS consisted of 5 items and had an excellent  
16 Cronbach's alpha (.90), with 72.33% variance on one single factor. Depression, pessimism  
17 and perceived sensitivity to medicines showed positive correlations with our expectation  
18 measure ( $r = 0.23$ ,  $r = 0.20$ ,  $r = 0.34$ , respectively), the correlation between the ETS and  
19 optimism was low ( $r = -0.07$ ), and no correlation between the ETS and resilience was found  
20 ( $r = -0.07$ ). Convergent validity was confirmed with a high correlation ( $r > .90$ ) between ETS  
21 and a treatment-specific measure of expectations. The retest ICC was .86, which showed  
22 high stability over one week. A confirmatory factor analysis (N = 439) with data from  
23 patients with low back pain confirmed the single-factor structure of the instrument.

1  
2 24 **Conclusion:** The ETS showed strong psychometric properties and covered a distinct  
3  
4 25 construct. As a next step, the ETS might be implemented in different clinical conditions and  
5  
6 26 settings to investigate psychometrics and its predictive power for treatment outcomes.  
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10 27  
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12 28 *Keywords:* Expectations, placebo, assessment, pain, optimism, acupuncture  
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- 5 31 • It is the first project to systematically develop a general measure to assess patients'  
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7 32 expectations across medical conditions and treatments with the involvement of  
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9 33 patients, earlier scales and empirical data.  
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11 34 • The Expectation for Treatment Scale (ETS) is a short and reliable measure that  
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13 35 captures outcome-related expectations of patients.  
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15 36 • The association between the ETS and related constructs was explored.  
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17 37 • The development of the ETS was done via an online survey with pain patients, and  
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19 38 the initial findings were confirmed using confirmatory factor analysis in a patient  
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21 39 sample with low back pain.  
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23 40 • The transfer of the ETS in different clinical conditions and settings should be pre-  
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25 41 tested to explore whether patients can evaluate the respective treatment at this level.  
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## 44 Introduction

45 Patients' expectations alter responses to interventions in placebo research and in clinical  
46 studies. In experimental research, the instruction to receive an active intervention  
47 accompanies large effects on pain reduction (effect size = 0.75)<sup>1</sup>. Expectations can be  
48 considered a major driver of changes in symptoms and other health-related outcomes<sup>2</sup>.  
49 Clinical studies have revealed that patients' positive expectations are related to reduced  
50 pain after a medical treatment<sup>3-5</sup>, and this phenomenon has also been observed for other  
51 medical conditions<sup>6</sup>. For acupuncture, this association was investigated in several studies  
52 with heterogeneous findings: Patients with chronic pain had higher odds (odds ratio 2.11  
53 [95% CI 1.32-3.34]) of benefitting from acupuncture treatment if they expected a better  
54 treatment response at baseline (controlled for other clinical baseline characteristics)<sup>7</sup>.  
55 However, there are also studies that found no influence of expectations on the outcome<sup>8,9</sup>.

56 These differences in the association of expectations and outcomes might be partly  
57 explained by the fact that each study used a newly invented measure, and differences  
58 between measures might hide or exaggerate associations between expectations and  
59 intervention outcomes. Additionally, the match between expectations of patients and  
60 treatment providers might be relevant for the success of a specific treatment<sup>10</sup>.

61 Expectation is a well-known and oft-used term. A clear definition and a sharp  
62 distinction from associated constructs is important for the development of a measure<sup>11</sup>. In  
63 the context of medical treatments, the term "expectations" describes cognitions about  
64 treatment-related health outcomes in the future after a specific intervention<sup>12,13</sup>. Patients can  
65 consider a treatment more or less beneficial for their complaints or disease at a specific  
66 time-point (i.e., outcome expectations)<sup>13</sup>. Role expectations also capture the role of a

1  
2 67 patient and the therapist during the treatment. In other words, a patient might consider  
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4 68 himself rather inactive during treatment in defining treatment goals and expects an active  
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6 69 therapist to achieve a good treatment outcome. However, our purpose was to develop a  
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8 70 scale on “patient expectations” that covers treatment-related outcome expectations.  
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10  
11 71 Bowling et al. (2012) provide an insightful summary about the theoretical underpinning of  
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13 72 expectations<sup>14</sup>. Related constructs such as optimism, self-efficacy, and hope share some  
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15 73 facets with expectations but differ on the level of the construct<sup>15 16</sup>. Optimism can be viewed  
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17 74 as a trait characteristic of a person with high stability over time and situations. Optimism is  
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19 75 defined as “the extent to which people hold generalized factorable expectancies for their  
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21 76 future” (Carver et al, 2010, p. 879)<sup>16</sup>. Self-efficacy is also a construct at a general level (i.e.,  
22  
23 77 “Perceived self-represents an optimistic sense of personal competence [...]”; Scholz et al.,  
24  
25 78 2002; p. 342)<sup>17</sup>. If self-efficacy is related to a specific behaviour or problem, it captures the  
26  
27 79 strength of a belief to cope in a situation successfully (for example Pain Self-Efficacy  
28  
29 80 Questionnaire; PSEQ)<sup>18</sup>. Hope should also be considered conceptually different:  
30  
31  
32 81 “Expectations and hopes are very different concepts. Hopes tend to be based more upon  
33  
34 82 emotions or wishes, things that individuals want reality to be, whereas expectations tend to  
35  
36 83 rely more heavily upon rational thought and logical reasoning” Woolhead et al., 2003 p.  
37  
38 84 1656)<sup>19</sup>. Related constructs are sometimes included in expectation measures, whereas in  
39  
40 85 other cases, only cognitions about treatment outcome relationships are included<sup>9 20 21</sup>.  
41  
42  
43 86 Following the definition by Bowling et al. (2012), we therefore designed our measure to  
44  
45 87 assess expectations related to a clinical intervention with a clinically relevant outcome from  
46  
47 88 a patient’s perspective.  
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53 89 Earlier findings about the expectation outcome association in clinical studies have  
54  
55 90 been limited by the diversity of measures. Several authors claimed diversity in covered  
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1  
2 91 concepts, time-point of assessment and problems to evaluate the validity of the  
3  
4 92 measures<sup>22–24</sup>. A strong measure is a prerequisite to accurately predict treatment responses  
5  
6 93 based on pretreatment expectations. A closer investigation of the results from a systematic  
7  
8  
9 94 review about acupuncture expectation measures by Prady and colleagues<sup>20</sup> showed that of  
10  
11 95 ten trials, only five provided their exact item wording for measuring expectations. Because  
12  
13 96 many of the assessment instruments are not publicly available, it is difficult to replicate the  
14  
15  
16 97 studies. Three of the five mentioned studies used only one item to assess expectations.  
17  
18 98 There is no reporting at all of Cronbach's alpha in the two remaining studies.  
19  
20

21 99 For further research in the field of expectations, a strong measure with high  
22  
23 100 acceptance across clinical fields would be needed for several reasons. First, a reliable  
24  
25 101 measure with high internal consistency at a specific time-point is a prerequisite to use  
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27  
28 102 expectations as a robust predictor. Second, ceiling effects were a common problem in the  
29  
30 103 measurement of expectations, because patients who are seeking help from a specific  
31  
32 104 treatment often expect large benefits; otherwise, they would not be attracted by this  
33  
34  
35 105 treatment. This problem was apparent in an established expectation measure for  
36  
37 106 acupuncture treatment that served as a benchmark measure for our scale (Acupuncture  
38  
39 107 Expectancy Scale (AES))<sup>25</sup>. Ceiling effects are particularly problematic because the  
40  
41 108 predictive power of such skewed variables is low. In the case of expectations, many  
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43  
44 109 research questions address the prediction of treatment outcomes; therefore, a measure with  
45  
46 110 sufficient variation between patients is needed. Some authors have used the term  
47  
48 111 "realistically expect" to capture expectations in a recent study with a comprehensive 10-item  
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50  
51 112 assessment of expectations, hope and beliefs (EXPECT)<sup>26</sup> with limited internal consistency.  
52  
53 113 Third, a measurement of expectation should be stable in a reasonable timeframe: The  
54  
55 114 EXPECT scale showed only a moderate retest reliability, with an intra-class correlation of  
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1  
2 115 ICC = 0.75. Most importantly, the association of EXPECT with the established AES, a  
3  
4 116 benchmark measure for the field of acupuncture, was unexpectedly low ( $r = .54$ ).  
5  
6

7 117 This study aimed to develop a measure to reliably capture patient expectations with a  
8  
9 118 short scale. The newly developed scale (Expectation for Treatment Scale, ETS) ideally has  
10  
11 119 a strong association with available measures of expectations, moderate associations with  
12  
13 120 related constructs (e.g., optimism and pessimism) and no association with personality (e.g.,  
14  
15 121 neuroticism). Furthermore, it should be constructed such that it can be adapted to other  
16  
17 122 treatments and used universally in different clinical fields independent of patients'  
18  
19 123 complaints.  
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24 124

## 28 125 **Methods**

29  
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31  
32 126 To address the problem of the abovementioned ceiling effects, we developed the items of  
33  
34 127 our scale (ETS) in a pilot study with pain patients in our outpatient clinic to measure  
35  
36 128 expected benefits before treatment from the patient's perspective. Based on existing  
37  
38 129 questionnaires on patient expectations<sup>9 25 27–30</sup>, we created a list of 17 items covering  
39  
40 130 different facets of expectations that fit with our aim to develop a measure for treatment-  
41  
42 131 related outcome expectations.  
43  
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45

### 49 133 **Patient and Public Involvement**

50  
51 134 Twenty patients completed the questionnaires, provided sociodemographic information  
52  
53 135 and were asked for written comments about the accessibility of the questions. In addition,  
54  
55 136 two patients were interviewed by a qualitative researcher. Two health professionals (one  
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1  
2 137 acupuncturist and a doctor assistant) also verbally commented about the appropriateness of  
3  
4 138 the questions. Based on these data, we selected items with low skewness and a large  
5  
6 139 range of responses (i.e., variation). High correlations between items and the findings from  
7  
8  
9 140 the qualitative feedback were also considered.

10  
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12 141

## 13 14 15 142 Participants

16  
17 143 For the main validation, study subjects of the convenience sample were recruited  
18  
19 144 using different methods. Three regional patient organizations distributed the information,  
20  
21 145 and we used several email distribution lists (including the University of Zurich, Switzerland  
22  
23 146 and the Charité University Hospital Berlin, Germany). Furthermore, patients from the  
24  
25 147 previous year seeking treatment for a musculoskeletal condition at the Institute for  
26  
27  
28 148 Complementary and Integrative Medicine of the University Hospital Zurich were contacted  
29  
30  
31 149 by email. All participants were required to be at least age 18 and, according to their own  
32  
33 150 evaluation, have sufficient knowledge to understand German. The included pain patients  
34  
35 151 had to suffer from at least some pain at the day of the assessment (> 0 on a numeric rating  
36  
37  
38 152 scale from 0 (no pain) to 10 (worst pain)).

39  
40  
41 153 The study link was accessed by 522 subjects, and 244 started the survey. In total,  
42  
43 154 142 subjects were excluded due to insufficient pain (N = 113), missing data in the nine-item  
44  
45 155 version of the ETS (N = 14) and more than 20% missing responses across all items (N =  
46  
47  
48 156 13). Data from patients suffering from pain (N = 102) with retest data from 54 patients were  
49  
50 157 available.

## 51 52 53 54 55 56 158 Procedures

1  
2 159 Subjects who decided to participate activated an access link to the online survey  
3  
4 160 provided via email. The survey was hosted by <https://www.soscisurvey.de/>, and all data  
5  
6 161 were collected electronically and anonymously. Participants were able to complete the  
7  
8 162 survey within 15 minutes. All questions were created in a forced choice format, meaning  
9  
10 163 that subjects were not able to continue to the next set of questions without completing the  
11  
12 164 previous set. Upon starting the survey, a short welcome message, followed by an  
13  
14 165 introduction to the study, was provided. Subjects who agreed to be contacted again for the  
15  
16 166 retest assessment provided their email address at the end of the survey. The retest sample  
17  
18 167 received a follow-up ETS one week after completion of the first survey. The study was  
19  
20 168 granted ethics approval by the local ethics committee (Kantonale Ethikkommission Zürich,  
21  
22 169 No. 48-2015).

26  
27  
28 170

## 30 171 Measures

31 172 The survey included demographic information (age, gender, education, employment  
32  
33 173 status, and country of residence), questions about any previous experience with  
34  
35 174 acupuncture (current or earlier), the degree to which the acupuncture treatment was  
36  
37 175 successful (numeric rating scale from 1 to 10, indicating no success to much success) and  
38  
39 176 the reason for the treatment (pain, mental health or non-specific). Patients who suffered  
40  
41 177 from pain (binary variable with yes vs. no option) were asked to give information about their  
42  
43 178 pain. We assessed average pain intensity (numeric rating scale from 1 to 10, indicating no  
44  
45 179 pain to worse pain), whether a physician was consulted, whether any other type of therapy  
46  
47 180 was used and the number of days of restriction due to pain. Subsequently, subjects  
48  
49 181 completed the 9-item ETS. Below, we provide a detailed description of all measures in this  
50  
51 182 study.

1  
2 1833  
4  
5 184 *Expectation for Treatment Scale*

6  
7 185       The first version of the ETS consisted of nine items (e.g., “I expect the treatment  
8  
9 186 [acupuncture] will help me to cope with my complaints.”). Each item was to be rated on a  
10  
11 187 four-point scale ranging from 1 to 4 (partially disagree, partially agree, agree, definitely  
12  
13 188 agree). We decided to use a four-point scale instead of a five-point scale for two reasons.  
14  
15 189 First, the chosen format forces the patient to provide an answer with a direction (higher or  
16  
17 190 lower than the middle answer choice) instead of opting for the middle category, which often  
18  
19 191 occurs in situations of insecurity (such as the present estimation of future events)<sup>31</sup>.  
20  
21 192 Second, the lowest answer on the scale of “definitely disagree” can be considered  
22  
23 193 unexpected for patients motivated to undergo an acupuncture treatment. After the statistical  
24  
25 194 analyses, the nine-item version was reduced to a final 5-item version of the ETS. A detailed  
26  
27 195 description of these five items is provided in the appendix Table 1. These five items were  
28  
29 196 translated into English by two bilingual researchers and translated back into German by two  
30  
31 197 other bilingual researchers. The wording was improved based on feedback from Dr. George  
32  
33 198 Lewith. The final English version is presented in the appendix Table 1.  
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42  
43 200 *Optimism and pessimism*

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45 201       Both concepts were assessed using the German version of the Life Orientation Test –  
46  
47 202 Revised<sup>32</sup>. The questionnaire consists of six self-report items (plus four filler items), each  
48  
49 203 rated on a five-point Likert scale ranging from 0 (strongly disagree) to 4 (strongly agree).  
50  
51 204 The data were separated into optimism and pessimism scores, as recommended by  
52  
53 205 Glaesmer et al. (2008). Each score can range from 0 to 12, with higher values indicating  
54  
55  
56  
57  
58  
59

206 either higher optimism or pessimism. In the present study, the Cronbach's alpha was  
207 acceptable for optimism (0.72) and questionable for pessimism (0.60).

### 208 *Depression*

209 The Patient Health Questionnaire (PHQ-9) is widely used as a standard instrument  
210 for diagnosing depression in primary care and is considered well validated<sup>33</sup>. The PHQ-9  
211 consists of nine questions operating according to the modified Diagnostic and Statistical  
212 Manual, Fourth Edition criteria. Patients indicated their answers on a scale ranging from 0  
213 (not at all) to 3 (almost every day)<sup>34</sup>. A higher score indicates a higher severity of depressive  
214 symptoms (ranging between 0 and 27). In the present study, the internal consistency of the  
215 scale was excellent (Cronbach's alpha = 0.90).

### 216 *Resilience*

217 As a protective personality factor, resilience was appraised using the Resilience  
218 Scale<sup>35</sup>. In the current study, we used the German Version Resilienzskala (RS-11)<sup>36</sup>. The  
219 instrument consists of eleven questions, with seven response alternatives ranging from 1  
220 (disagree) to 7 (fully agree). Higher scores indicate higher resilience. In the present study,  
221 the internal consistency was excellent (Cronbach's alpha = 0.90).

### 222 *Body-Efficacy Expectation*

223 To measure beliefs concerning bodily coping capabilities, the Body-Efficacy  
224 Expectation (BEE) questionnaire<sup>37</sup> was used. The instrument consists of five items using a  
225 four-point Likert scale ranging from 1 (not true at all) to 4 (exactly true). A higher score  
226 indicates stronger beliefs in one's bodily coping capabilities. In the present study, the  
227 Cronbach's alpha was 0.75, indicating acceptable internal consistency.

1  
2 228 *Perceived Sensitivity to Medicines*

3  
4 229 To assess the individual's sensitivity to medicines, we used the Perceived Sensitivity  
5  
6 230 to Medicines scale (PSM)<sup>38</sup>. The PSM is considered a reliable and valid measure composed  
7  
8  
9 231 of five self-report questions to assess perceived sensitivity to the potential adverse effects  
10  
11 232 of medicines. Responses are scored on a five-point Likert scale, and patients' item scores  
12  
13 233 are summed to provide a total score ranging between 5 and 25. Higher scores point  
14  
15 234 towards a high perceived sensitivity to the potential adverse effects of medicines. In the  
16  
17  
18 235 current study, the scale showed excellent internal consistency (Cronbach's alpha = 0.94).  
19  
20

21 236 *Neuroticism and openness to experience*

22  
23 237 To assess the distinctiveness of neuroticism and openness to experience among  
24  
25 238 patients, we used the corresponding subscales of the NEO Five-Factor Inventory (NEO-  
26  
27  
28 239 FFI)<sup>39</sup>. To that end, 23 questions were extracted from the 60-item NEO-FFI. The instrument  
29  
30 240 utilizes a five-point Likert response format, from 1 (strongly refuse) to 5 (strongly agree). A  
31  
32 241 higher score indicates a higher value for neuroticism and openness to experience. In the  
33  
34  
35 242 present study, the Cronbach's alpha was 0.85 for neuroticism and 0.72 for openness to  
36  
37 243 experience, which indicates good to acceptable internal consistency.  
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40 244 *Acupuncture Expectancy Scale*

41  
42 245 Mao and colleagues developed the AES to measure patients' expected response  
43  
44 246 from acupuncture<sup>25</sup>. The scale was developed for only one clinical intervention (i.e.,  
45  
46  
47 247 acupuncture). The instrument consists of four items. The answers are given using a five-  
48  
49 248 point Likert scale ranging from 1 (not at all agree) to 5 (completely agree). A higher score  
50  
51 249 points towards higher expectancies. In the present study, the internal consistency of the  
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53  
54 250 scale was considered good (Cronbach's alpha = 0.88).  
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57 251

## 252 Statistical Analyses

253 All data analyses were executed using SPSS (version 22, SPSS Inc., Chicago,  
254 Illinois, USA). As a first step, we used the nine items of the first ETS version to explore  
255 homogeneity and diversity between items. We conducted a descriptive analysis of the data  
256 to detect possible floor or ceiling effects and assess the distribution of the data. Internal  
257 consistency was examined through reliability analyses (Cronbach's alpha), with the  
258 corrected item-total correlation and the Cronbach's alpha if the item is deleted. Retest  
259 reliability for the nine items was assessed by the intraclass correlation coefficient (ICC). We  
260 set for each item a minimal acceptable ICC of .60 and for the total score an ICC of .80.  
261 Three criteria guided the decision to keep an item for the final version: 1) it should have a  
262 high corrected item-total correlation and no low internal consistency if deleted, 2) the item  
263 should not overlap too strongly in content with another item that might be included, and 3)  
264 the item should not contribute to ceiling effects in the final version of the scale, which means  
265 items with lower values were preferred.

266 In a second step, we used the reduced version of the scale to generate a total sum  
267 score of the five items (ranging from 5 to 20). To examine divergent and convergent validity,  
268 correlations between the ETS sum score and the other measures were calculated. We  
269 assumed a very high correlation between the ETS and the most strongly related construct ( $r$   
270  $> .70$ ; AES), moderate correlations with strongly related constructs ( $r > .30$ ; LOT-R  
271 optimism, inverse with LOT-R pessimism), small correlations with less related constructs ( $r$   
272  $> .20$ ; PHQ-9; RS-11, BEE) and no correlation with unrelated constructs (PSM, NEO-FFI  
273 neuroticism, NEO-FFI openness to experience).

274 To test our assumption of one general factor, an explorative factor analysis using a  
275 varimax rotation, an Eigenvalue of more than one and the Scree test was used with the 5

ETS items to determine the number of underlying factors. In addition, we conducted a confirmatory factor analysis with an independent sample of chronic low back pain patients, which had been included in a randomized controlled trial (registration number DRKS-ID: DRKS00010191). These patients completed the ETS. The data were used to test the single-factor structure. The best model used correlated error terms between item 2 and item 5 and is shown in Figure 1. Multiple goodness of fit tests<sup>40</sup> were used to evaluate the model, including the comparative fit index (CFI;<sup>41</sup>), the normed fit index (NFI;<sup>40</sup>), the goodness of fit index (GFI;<sup>42</sup>) and the root mean squared error of approximation (RMSEA). A CFI greater than 0.90 indicates a good fit to the data<sup>43</sup>. An NFI and GFI greater than 0.90 indicates a good fit to the data<sup>44</sup>. A RMSEA with values of less than 0.08 indicates a good fit to the data<sup>45</sup>, whereas values greater than 0.10 suggest strongly that the model fit is unsatisfactory. The Chi-square goodness of fit test can be considered a general test for the acceptability of the model; a statistically significant  $\chi^2$  indicates that a significant proportion of variance remains unexplained by the model<sup>40</sup>. Confirmatory factor analysis was conducted with the Analysis of Moment Structures (AMOS) software version 25 which is part of the SPSS package.

## Results

### Sample characteristics

Three-quarters of the patients were female, one-third had a high school degree or higher vocational training, and approximately 70% were currently employed. Approximately two-thirds of the surveys were conducted with patients in Switzerland, and one-third came from Germany. The characteristics of patients with current pain are displayed in Table 1.

1  
2 299 Descriptive information about the scales used in the study is presented in the appendix  
3  
4 300 Table 2.

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10 301 Insert Table 1 about here  
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16 302 First version of the ETS

17  
18 303 In an initial analysis, we included nine items of the ETS. Descriptive results and  
19  
20 304 results from scale analyses are presented in the appendix Table 3. In general, the standard  
21  
22 305 deviations showed large variances, with the exception of item 6 (“The treatment  
23  
24 306 [acupuncture] is in general effective”) and item 7 (“I myself have positive expectations about  
25  
26 307 the treatment [acupuncture]”). The mean value of item 6 was relatively high, which can be  
27  
28 308 considered an indicator of a ceiling effect. Therefore, we decided to exclude item 6 (i.e.,  
29  
30 309 general expectations about the effectiveness of the treatment [acupuncture]) and item 7  
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32 310 (i.e., personal expectation of a treatment) from the final ETS.  
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37 311 The item-total correlation and the Cronbach’s alpha if an item is deleted are  
38  
39 312 indicators for the coherence of the single item meaning with the total scale (see appendix  
40  
41 313 Table 4). The corrected item-total correlation did not give any strong reason for the  
42  
43 314 exclusion of items. However, there were items with very high total correlations between  
44  
45 315 items (item 2 and item 9). Item 2 (“I expect my complaints will be much better because of  
46  
47 316 the treatment [acupuncture]”) and item 9 (“I expect that after the treatment [acupuncture],  
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49 317 my complaints will be considerably better”) were very similar in terms of their wording;  
50  
51 318 therefore, we decided to keep only one of the items for the final version. The reason for this  
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53 319 decision was that the ICC value for item 2 was lower than that of item 9. In addition, the  
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1  
2 320 mean value for item 9 was lower than the mean of item 2, which consequently can  
3  
4 321 contribute to a larger variation in the final scale because ceiling effects can be avoided. The  
5  
6 322 decision to exclude item 1 was based on content. Our pilot study indicated problems with  
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8  
9 323 understanding the meaning of “clearly reduced”. Furthermore, item 1 (“I expect the  
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11 324 treatment [acupuncture] will clearly reduce my complaints”) and item 4 (“I expect the  
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13 325 treatment [acupuncture] will make my complaints disappear”) covered similar topics. The  
14  
15 326 factor loading confirmed our earlier decision to eliminate item 6 (“The treatment  
16  
17 327 [acupuncture] is in general effective”) because the factor loading was relatively low. All  
18  
19 328 items of the first version contributed to one single factor with 65.51% of explained variance.  
20  
21 329 The 9-item ETS version total score is normally distributed. For the 5-item ETS version and  
22  
23 330 the AES items, there were a substantial number of subjects with either the lowest or the  
24  
25 331 highest score on the scale.  
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30 332 The final version of the ETS consists of five items: the previous item 3 (“I expect the  
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32 333 treatment [acupuncture] will help me to cope with my complaints”) covers coping ability;  
33  
34 334 item 4 (“I expect the treatment [acupuncture] will make my complaints disappear”) covers  
35  
36 335 total absence of complaints; item 5 (“I expect the treatment [acupuncture] will improve my  
37  
38 336 energy”) covers an energy increase; item 8 (“I expect the treatment [acupuncture] will  
39  
40 337 improve my physical performance”) covers an improvement of physical functioning; and  
41  
42 338 item 9 (“I expect that after the treatment [acupuncture] my complaints will be considerably  
43  
44 339 better”) covers a considerable decrease in symptoms. To summarize, the ETS captures an  
45  
46 340 expected decrease in symptoms, an expected increase in energy and expected overall  
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51 341 wellbeing after a treatment.  
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57 342 Insert Table 2 about here  
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5 343 The Cronbach's alpha of the final version was 0.90, which is an excellent value for a  
6  
7 344 very short scale (Table 3). Retest reliability was excellent for the five items. All items  
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9 345 contributed substantially to the final scale, and the factor loading indicated a single factor  
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11 346 structure with 72.33% of explained variance.  
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### 18 347 Convergent and divergent validity

19  
20 348 We expected a moderate correlation between the ETS and the LOT-R optimism and  
21  
22 349 an inverse correlation with pessimism. However, these assumptions were not confirmed by  
23  
24 350 our findings (Table 3). Interestingly, higher pessimism was moderately associated with  
25  
26 351 higher expectations, both for the ETS and the AES. The ETS showed a small but significant  
27  
28 352 correlation with the PHQ-9, which is consistent with our assumption. The correlation  
29  
30 353 between the ETS and the RS-11 or the BEE was close to zero, which is unexpected  
31  
32 354 according to our assumptions. However, we found a moderate correlation between the ETS  
33  
34 355 and the PSM, for which higher expectations were associated with a higher sensitivity to  
35  
36 356 medication. The shared aspect of this association is the responsiveness to a medical  
37  
38 357 treatment. Personality traits (NEO-FFI) were not associated with the ETS, which is  
39  
40 358 consistent with our assumptions. The ETS score has a very high correlation (> .90) with the  
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42 359 AES, which can be considered a benchmark measure for acupuncture expectations.  
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51 360 Insert Table 3 about here  
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### 57 361 Confirmatory factor analysis

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1  
2 362 In addition, we conducted a CFA with the data from the 439 ETS questionnaires mentioned  
3  
4 363 above with the model presented in Figure 1. The factor loadings were between 0.609 (Item  
5  
6 364 2) and 0.796 (Item 4). We found an acceptable model fit in the Chi-square statistics (Chi-  
7  
8  
9 365 square = 5.859, d.f. = 4,  $p = .210$ ), indicating that the model is able to explain the data  
10  
11 366 structure in general. The CFI was .998 in our model, indicating a very good model fit.  
12  
13 367 Similarly, the NFI (.993) and GFI (.995) confirm the excellent model fit. The RMSEA (.033)  
14  
15 368 also suggests that the model with one single factor explains the data very well. The good  
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17  
18 369 internal consistency of the ETS in this sample (Cronbach's alpha = .836) confirmed the  
19  
20 370 findings of the scale development.  
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26 372 Insert Figure 1 about here  
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## 33 374 Discussion

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37 375 The ETS is a well-validated and brief 5-item scale for measuring patient  
38  
39 376 expectations, with excellent test-retest properties. We were able to overcome ceiling effects,  
40  
41 377 which had been a limitation of earlier measures<sup>25</sup>. This improvement might result from using  
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43  
44 378 only four response categories instead of a larger scale with rather inadequate categories  
45  
46 379 (namely, "definitely disagree"). The ETS has excellent measurement properties concerning  
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48  
49 380 Cronbach's alpha; retest reliability over one week and single factor structure were replicated  
50  
51 381 in a clinical sample. The ETS can be used for research and clinical purposes equally.  
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54 382 The ETS could be adapted to other clinical situations and treatments beyond  
55  
56 383 acupuncture, which would be an important step towards implementing treatment  
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1  
2 384 expectations as standardized working mechanisms among a variety of patient populations.  
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4 385 Pain disorders, mental disorders and functional symptoms might be the most appropriate  
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6 386 fields, because clinical research indicates the high relevance of expectations for treatment  
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9 387 outcomes.

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12 388 As mentioned earlier, the ETS showed a substantial correlation with the AES.  
13  
14 389 Nevertheless, there are differences worthy of mention between the two measures. In  
15  
16 390 contrast to Jun Mao and his colleagues, we included measures of convergent and divergent  
17  
18 391 validity in our study to enhance information about the unique aspects of expectations  
19  
20 392 compared with related constructs. Moreover, the ETS can be used for a multitude of  
21  
22 393 interventions and can easily be adapted to other clinical situations because no illness-  
23  
24 394 specific symptoms are mentioned in the scale. Furthermore, there are differences  
25  
26 395 concerning item wording and scaling (four vs. five response categories) between the ETS  
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28 396 and the AES.  
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33 397 Another notable issue that deserves discussion is the moderate correlation between  
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35 398 high pessimism and high expectations for both the ETS and the AES. Our initial assumption  
36  
37 399 was that we would find a negative association between both expectation measures and  
38  
39 400 pessimism. This assumption was not confirmed. Furthermore, we found no correlation  
40  
41 401 between optimism and the ETS in our study. The findings about negative cognitions  
42  
43 402 (pessimism) are consistent with our result of a small but significant correlation of the ETS  
44  
45 403 and depression (PHQ-9). A possible explanation for both findings might be that in pain  
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47 404 patients, depression might be associated with more-severe medical symptoms that might  
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49 405 lower patients' expectations in some cases depending upon treatment history.  
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## 407 Limitations

408 There are limitations to our study. First, although collection of data via a web-based  
409 survey holds many advantages, there are also downsides to this method because  
410 recruitment is done using an unstructured approach. Because the ETS questionnaire was  
411 also validated in a paper-based version in a clinical population, this limitation is of minor  
412 importance. Second, to enhance the external validity of our study, other clinical populations  
413 should be investigated to prove the validity of our scale across clinical conditions. Thus far,  
414 the application appears feasible and valid for patients with pain. Third, there might be  
415 clinical intervention in situations in which patients might have a very vague idea about  
416 procedures and outcomes. We did not collect data from a clinical pain population *prior* to  
417 their acupuncture treatment. The patients from our sample provided information about their  
418 previous experience with acupuncture, but such an assessment could be done more  
419 comprehensively to capture the underlying beliefs and experiences of patients and their  
420 relevance for expectations.

## 421 Conclusion

422 The ETS is a short and validated measure that can contribute to the understanding of  
423 patient expectations for treatment outcomes. The field of acupuncture served as example to  
424 develop the ETS, but it could be easily adapted for other treatments and clinical contexts.  
425 The ETS fills a gap by providing a strong and flexible measure that can serve as a basis for  
426 upcoming predictor analyses of treatment expectations in clinical studies.

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3  
4 432 No, there are no competing interests for any author.  
5  
6

7 433 Authorship and contributorship

8  
9 434 JB was involved in the conception and execution of the scale and survey, the  
10  
11 435 analysis and interpretation of data, the writing of the first draft and the revision of the  
12  
13 436 manuscript. AK was involved in the analysis and interpretation of data and the writing of the  
14  
15 437 manuscript. SL was involved in programming and conducting the survey, managing and  
16  
17 438 analysing the data, and revising the manuscript. CW was involved in the conception of the  
18  
19 439 scale and survey, the interpretation of the data and the revision of the manuscript.  
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53 452 **Data-sharing statement**

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56 453 Date are available from the first author on request.  
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4

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9 457 phrasing of questions in our scale.

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## 12 **Tables and Figures**

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15 596 Table 1. Sample characteristics of subjects with current pain (N = 102)  
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18 597 Table 2. Scale and factor analysis of the 5-item ETS for subjects with current pain (N = 102)  
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21 598 Table 3. Convergent and divergent validity of the 5-item version of the ETS for subjects with  
22 current pain (N = 102). Pearson Correlation, Significance level (2-tailed), N of patients  
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26 600 Figure 1. Confirmatory factor analysis with factor loadings (N = 439) of the final 5-item ETS  
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29 601 version in patients with chronic low back pain  
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Table 1. Sample characteristics of subjects with current pain (N = 102)

	Frequencies //	Percentage
	Mean (SD)	
Age	49.16 (14.04)	
Gender		
Female	76	75%
Male	26	25%
Education		
Vocational school	39	38%
Higher school certificate or Higher vocational training	29	28%
University	34	33%
Employment status		
Working	72	71%
Retired	10	10%
Other	20	20%
Country of residence		
Switzerland	68	67%
Germany	34	33%
Acupuncture experience		
Current	13	13%

1			
2	603	Earlier	51 50%
3			
4	604	None	38 37%
5			
6	605	Success of acupuncture	6.5 (2.80)
7			
8			
9	606	[range 1–10]*	
10			
11	607	Reason for treatment**	
12			
13	608	Pain	55 86%
14			
15			
16	609	Mental health	13 20%
17			
18	610	Other	24 38%
19			
20			
21	611	General Health***	3.21 (.92)
22			
23	612	Pain characteristics	
24			
25	613	Intensity [range 0–10]****	6.5 (1.92)
26			
27	614	Physician consulted*****	68 67%
28			
29	615	Any treatment*****	66 65%
30			
31			
32	616	Days of restriction due to	
33			
34	617	pain*****	46.76 (63.74)
35			
36			
37	618	Location*****	
38			
39	619	Back	58 57%
40			
41	620	Neck	44 43%
42			
43	621	Knee	21 21%
44			
45	622	Head	20 20%
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47	623	Hip	16 16%
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49	624	Other	33 32%
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628 \*Range from no success (1) to very successful (10) treatment outcome of the last

629 acupuncture treatment

630 \*\*Multiple answers were possible.

631 \*\*\*Range from 1 = excellent to 5 = bad

632 \*\*\*\*0 indicating no pain and 10 indicating maximum pain

633 \*\*\*\*\*In the last 6-month period

634 \*\*\*\*\*Multiple answers were possible.

635

Table 2. Scale and factor analysis of the 5-item ETS for subjects with current pain (N = 102)

Item	Mean (SD)	Item-total correlation corrected	Cronbach's alpha if item deleted	Factor loading	Retest ICC [95%-CI]
Item 3	2.38 (1.03)	.727	.887	.826	.697 [.517, .818]
Item 4	1.97 (.96)	.736	.883	.834	.724 [.556, .835]
Item 5	2.41 (1.0)	.776	.875	.865	.840 [.732, .907]
Item 8	2.33 (.83)	.817	.869	.891	.749 [.592, .851]
Item 9	2.52 (.90)	.737	.883	.834	.836 [.725, .904]
			Cronbach's $\alpha$	% of variance	
ETS 5			.901	72.325	.856 [.757, .917]

Item 3: I expect the treatment [acupuncture] will help me to cope with my complaints.

Item 4: I expect the treatment [acupuncture] will make my complaints disappear.

Item 5: I expect the treatment [acupuncture] will improve my energy.

1  
2 Item 8: I expect the treatment [acupuncture] will improve my physical performance.  
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4  
5 Item 9: I expect that after the treatment [acupuncture], my complaints will be considerably  
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7 better.  
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Table 3. Convergent and divergent validity of the 5-item version of the ETS for subjects with current pain (N = 102). Pearson Correlation, Significance level (2-tailed), N of patients

Correlation	ETS	LOT-R Optimism	LOT-R Pessimism	PHQ-9	RS-11	BEE	PSM	NEO-FFI Neuroticism	NEO-FFI Openness to experience
ETS	1								
	102								
LOT-R Optimism	-.066	1							
	.517								
	99	99							
LOT-R Pessimism	.204*	-.247*	1						
	.043	.014							
	99	99	99						
PHQ-9	.233*	-.567**	.312**	1					
	.020	.000	.002						
	100	99	99	100					
RS-11	-.073	.546**	-.460**	-.572**	1				
	.474	.000	.000	.000					
	99	99	99	99	99				



BEE	.032	.259**	-.074	-.176	.407**	1			
	.754	.010	.468	.081	.000				
	99	99	99	99	99	99			
PSM	.344**	-.078	.201*	.306**	-.049	.011	1		
	.000	.445	.046	.002	.631	.912			
	100	99	99	100	99	99	100		
NEO-FFI	.104	-.578**	.467**	.631**	-.682**	-.284**	.238*	1	
Neuroticism	.316	.000	.000	.000	.000	.005	.020		
	95	95	95	95	95	95	95	95	
NEO-FFI	-.072	.297**	-.167	-.090	.302**	.122	.132	-.130	1
Openness to	.492	.004	.109	.386	.003	.241	.205	.211	
experience	94	94	94	94	94	94	94	94	94
Cronbach's Alpha	.901	.727	.608	.900	.900	.757	.940	.854	.726

\*\*Correlation is significant at the 0.01 level (2-tailed).

\*Correlation is significant at the 0.05 level (2-tailed).

ETS = Expectation for Treatment Scale; LOT-R = Life-Orientation Test; PHQ-9 = Patient Health Questionnaire-9; RS-11 = Die

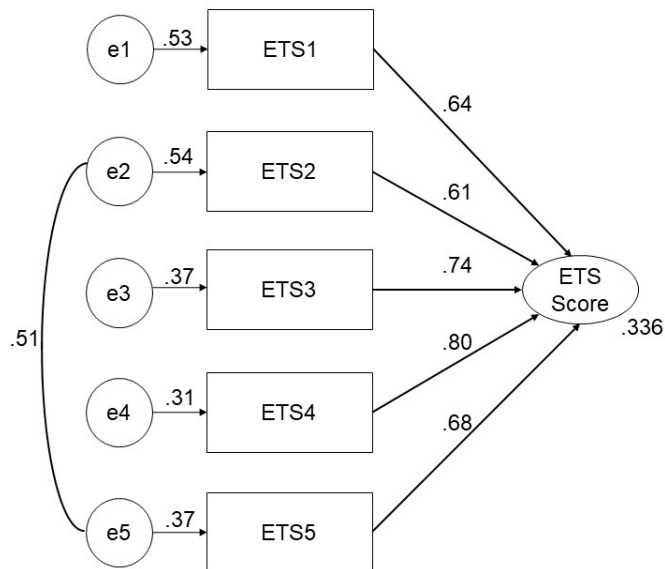
Resilienzskala - Ein Fragebogen zur Erfassung der psychischen Widerstandsfähigkeit als Personenmerkmal; BEE = Body-

Efficacy Expectation; PSM = Perceived Sensitivity to Medicines Scale; NEO-FFI = NEO Five-Factor Inventory

## Expectation for Treatment Scale (ETS)

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6 Figure 1. Confirmatory factor analysis with factor loadings (N = 439) of the final 5-item  
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8 ETS version in patients with chronic low back pain  
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Item 3 corresponds to ETS1  
 Item 4 corresponds to ETS2  
 Item 5 corresponds to ETS3  
 Item 8 corresponds to ETS4  
 Item 9 corresponds to ETS5

Chi-square = 5.859 (d.f. = 4),  
 p = .210; RMSEA = 0.033;  
 CFI = 0.998; NFI = 0.993;  
 GFI = 0.996

e1 to e5: Error terms

Confirmatory factor analysis with factor loadings (N = 439) of the final 5-item ETS version in patients with chronic low back pain.

## Appendix (Barth et al.; ETS)

## APPENDIX Table 1. Description of the 5 final items in English and German

Table 1. Description of the 5 final items in English and German

Description: The overarching construct of ETS is treatment-related outcome expectation of patients. Outcomes of interest for patients are coping (item 1), vitality (item 3) and physical health (item 4). Two items (items 2 and 5) capture the reduction of patient complaints, either an absence or a considerable reduction thereof. The scale can be adapted to specific treatments of interest. Instead of the term “treatment”, a specific term can be used (e.g., acupuncture, counselling, or physiotherapy). We used the term complaints [German Beschwerden] as previously used by other authors as in the symptom checklist (SCL-90-R)<sup>46</sup>. Therefore, any type of complaint can be captured and allow the use of this instrument across patient groups and settings. The term complaints can be adapted if needed to the clinical situation if one specific target symptom is predominant (e.g., pain, depression, or nausea). The scale should be used in a clinical setting by patients with sufficient German or English language skills.

English version

There are several statements below that capture your expectations about the [acupuncture] treatment. Please indicate to what extent these statements apply to you personally. **There are no right or wrong answers. We are only interested in your current personal thoughts.**

*Please select for each statement **one** response.*

1. I expect the treatment [acupuncture] will help me to cope with my complaints.

partially disagree	partially agree	agree	definitely agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. I expect the treatment [acupuncture] will make my complaints disappear.

partially disagree	partially agree	agree	definitely agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. I expect the treatment [acupuncture] will improve my energy.

partially disagree	partially agree	agree	definitely agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1  
2  
3 4. I expect the treatment [acupuncture] will improve my physical performance.

5 partially disagree

6 partially agree

7 agree

8 definitely agree

9

10

11

12

13 5. I expect that after the treatment [acupuncture], my complaints will be  
14 considerably better.

15 partially disagree

16 partially agree

17 agree

18 definitely agree

19

20

21

22

23 \*We used the term acupuncture in our study. The general version of ETS uses the  
24 term treatment.

## German version

Im Folgenden finden Sie einige Aussagen darüber, was man von einer Behandlung [Akupunktur] erwarten kann. Geben Sie bitte an, inwieweit die einzelnen Aussagen für Sie persönlich zutreffen. **Es gibt keine richtigen und falschen Antworten. Uns interessiert nur, was Sie persönlich denken.**

Bitte wählen Sie für jede Aussage **eine** Antwort aus.

1. Ich erwarte, dass ich durch die Behandlung [Akupunktur] mit meinen Beschwerden besser umgehen kann.

trifft eher nicht zu	trifft eher zu	trifft sehr zu	trifft völlig zu
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Ich erwarte, dass meine Beschwerden durch die Behandlung [Akupunktur] verschwinden.

trifft eher nicht zu	trifft eher zu	trifft sehr zu	trifft völlig zu
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3. Ich erwarte, dass sich meine Energie durch die Behandlung [Akupunktur] verbessert.

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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Ich erwarte durch die Behandlung [Akupunktur] eine verbesserte körperliche Leistungsfähigkeit.

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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. Ich erwarte, dass sich nach der Behandlung [Akupunktur] meine Beschwerden deutlich verbessern.

trifft eher nicht zu	trifft eher zu	trifft sehr zu	trifft völlig zu
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*Wir haben den Begriff Akupunktur in unserer Studie verwendet. Die allgemeine Version des ETS verwendet den Begriff Behandlung.

### Scoring of the questionnaire

The values from the 5 single items are summed to build the ETS sum score (min 5, max 20). If one item has a missing value, the sum score can be calculated.

Therefore, the values of the remaining 4 items are summed, divided by 4 and multiplied by 5. However, multiple imputation procedures to impute the missing value should be preferred over this re-calculation. In the case of more than one missing value, imputation procedures are needed, and no manual recalculation should be considered.

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APPENDIX Table 2: Sample characteristics in scales in subjects with current pain (N = 102)

	Median Mean (SD)
ETS (9 items) (range 9–36)	22 22.63 (.64)
ETS (5 items) (range 5–20)	11 11.62 (4.01)
AES (range 4–20)	12.0 11.82 (4.10)
PHQ-9 (range 0–27)	7 8.46 (6.06)
RS-11 (range 11–77)	60 58.36 (11.13)
BEE (range 5–20)	14 13.71 (2.90)
PSM (range 5–25)	11 12.77 (6.13)
LOT-R Optimism (range 0–12)	8 7.93 (2.77)
LOT-R Pessimism (range 0–12)	8 7.93 (2.38)
NEO-FFI Neuroticism (range 0–48)	21 21.08 (8.19)
NEO-FFI Openness to experience (range 0–44)	30 29.84 (5.77)

Expectation for Treatment Scale; AES= Acupuncture Expectancy Scale; LOT-R= Life-Orientation Test; PHQ-9= Patient Health Questionnaire-9; RS-11= Die Resilienzskala - Ein Fragebogen zur Erfassung der psychischen Widerstandsfähigkeit als Personenmerkmal; BEE= Body-Efficacy Expectation; PSM= Perceived Sensitivity to Medicines Scale; NEO-FFI= NEO Five-Factor Inventory



Appendix Table 3. Scale and factor analysis of the 9-item ETS for subjects with current pain (N = 102)

Item	Mean (SD)	Item-total correlation corrected	Cronbach's alpha if item deleted	Factor loading	Retest ICC [95%–CI]
Item 1	2.71 (1.0)	.782	.920	.839	.684 [.499, .810]
Item 2	2.66 (.93)	.816	.918	.863	.725 [.557, .836]
Item 3**	2.38 (1.03)	.736	.924	.790	.697 [.517, .818]
Item 4**	1.97 (.96)	.735	.923	.793	.724 [.556, .835]
Item 5**	2.41 (1.0)	.745	.923	.799	.840 [.732, .907]
Item 6	2.97 (.59)	.612	.931	.685	.649 [.450, .787]
Item 7	2.68 (.65)	.744	.924	.806	.658 [.462, .793]
Item 8**	2.33 (.83)	.772	.921	.821	.749 [.592, .851]
Item 9**	2.52 (.90)	.826	.917	.874	.836 [.725, .904]
			Cronbach's $\alpha$	% of variance	
ETS 9			.930	65.512	.879 [.794, .930]

\*\*marked items are included in the final version of its scale.

Item 1: I expect the treatment [acupuncture] will clearly reduce my complaints.

Item 2: I expect my complaints will be much better because of the treatment [acupuncture].

Item 3: I expect the treatment [acupuncture] will help me to cope with my complaints.

Item 4: I expect the treatment [acupuncture] will make my complaints disappear.

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3 Item 5: I expect the treatment [acupuncture] will improve my energy.  
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5 Item 6: The treatment [acupuncture] is in general effective.  
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7 Item 7: I myself have positive expectations about the treatment [acupuncture].  
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9 Item 8: I expect the treatment [acupuncture] will improve my physical performance.  
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11 Item 9: I expect that after the treatment [acupuncture], my complaints will be considerably better.  
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Appendix Table 4. Between-item correlations for sample with current pain (N = 102). Pearson Correlation and significance (2-tailed). \*\*Correlation is significant at the 0.01 level (2-tailed).

	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9
Item 1	1								
Item 2	.840** .000	1							
Item 3	.636** .000	.605** .000	1						
Item 4	.568** .000	.627** .000	.580** .000	1					
Item 5	.533** .000	.611** .000	.664** .000	.637** .000	1				
Item 6	.540** .000	.556** .000	.442** .000	.437** .000	.505** .000	1			
Item 7	.692** .000	.679** .000	.541** .000	.575** .000	.509** .000	.521** .000	1		
Item 8	.528** .000	.571** .000	.673** .000	.664** .000	.762** .000	.470** .000	.631** .000	1	
Item 9	.733** .000	.754** .000	.605** .000	.673** .000	.603** .000	.592** .000	.701** .000	.673** .000	1

Item 1: I expect the treatment [acupuncture] will clearly reduce my complaints.

Item 2: I expect my complaints will be much better because of the treatment [acupuncture].

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3 Item 3: I expect the treatment [acupuncture] will help me to cope with my complaints.  
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5 Item 4: I expect the treatment [acupuncture] will make my complaints disappear.  
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7 Item 5: I expect the treatment [acupuncture] will improve my energy.  
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9 Item 6: The treatment [acupuncture] is in general effective.  
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11 Item 7: I myself have positive expectations about the treatment [acupuncture].  
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13 Item 8: I expect the treatment [acupuncture] will improve my physical performance.  
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15 Item 9: I expect that after the treatment [acupuncture], my complaints will be considerably better.  
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60TROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	page
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	8
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	9
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	n.a.
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	10-13
Bias	9	Describe any efforts to address potential sources of bias	n.a.
Study size	10	Explain how the study size was arrived at	n.a.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	n.a.
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	14-15
		(b) Describe any methods used to examine subgroups and interactions	n.a.
		(c) Explain how missing data were addressed	n.a.
		(d) If applicable, describe analytical methods taking account of sampling strategy	n.a.
		(e) Describe any sensitivity analyses	n.a.
<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	15 and Table 2
		(b) Give reasons for non-participation at each stage	n.a.
		(c) Consider use of a flow diagram	n.a.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	n.a.
		(b) Indicate number of participants with missing data for each variable of interest	n.a.
Outcome data	15*	Report numbers of outcome events or summary measures	n.a.

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2	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
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	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
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	<b>Discussion</b>		
	Key results	18	Summarise key results with reference to study objectives
			19
	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
			21
	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
			21
	Generalisability	21	Discuss the generalisability (external validity) of the study results
			21
	<b>Other information</b>		
	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based
			21

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

# BMJ Open

## Assessment of patients' expectations: development and validation of the Expectation for Treatment Scale (ETS)

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Secondary Subject Heading:	Patient-centred medicine, Research methods
Keywords:	expectations, placebo, assessment, pain, acupuncture
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ETS_STROBE_checklist_cross-sectional_20190118.doc	

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Manuscripts

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3 **Assessment of patients' expectations: development and validation of the**  
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5 **Expectation for Treatment Scale (ETS)**  
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8 Running title: Expectation for Treatment Scale (ETS)  
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10 Submission to British Medical Journal  
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59 Word count: 4526  
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## 1 Abstract

2 **Objective:** The development of a short self-report instrument for the assessment of  
3 expectations (Expectation for Treatment Scale, ETS), using acupuncture as a case  
4 example.

5 **Design:** A cross-sectional assessment with retest after one week.

6 **Setting:** A web-based survey with patients suffering from pain.

7 **Methods:** In a three-step approach, we reduced the initially collected number of items from  
8 17 to 9 and to 5, including expectations about coping ability, vitality, physical health and  
9 reduction of patient complaints. Items were selected according to internal consistency  
10 (Cronbach's alpha), convergent and divergent validity with related constructs (optimism,  
11 pessimism, resilience, perceived sensitivity to medicines, depression, and others), one-  
12 week retest reliability (intraclass correlation coefficient, ICC) and exploratory and  
13 confirmatory factor analysis.

14 **Results:** A total of 102 pain patients were included, and 54 of these patients completed the  
15 retest assessment. The final version of the ETS consisted of 5 items and had an excellent  
16 Cronbach's alpha (.90), with 72.33% variance on one single factor. Depression, pessimism  
17 and perceived sensitivity to medicines showed positive correlations with our expectation  
18 measure ( $r = 0.23$ ,  $r = 0.20$ ,  $r = 0.34$ , respectively), the correlation between the ETS and  
19 optimism was low ( $r = -0.07$ ), and no correlation between the ETS and resilience was found  
20 ( $r = -0.07$ ). Convergent validity was confirmed with a high correlation ( $r > .90$ ) between ETS  
21 and a treatment-specific measure of expectations. The retest ICC was .86, which showed  
22 high stability over one week. A confirmatory factor analysis (N = 439) with data from  
23 patients with low back pain confirmed the single-factor structure of the instrument.

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24 **Conclusion:** The ETS showed strong psychometric properties and covered a distinct  
25 construct. As a next step, the ETS might be implemented in different clinical conditions and  
26 settings to investigate psychometrics and its predictive power for treatment outcomes.

27  
28 *Keywords:* Expectations, placebo, assessment, pain, optimism, acupuncture

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2 30 Strengths and limitations of this study  
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- 5 31 • It is the first project to systematically develop a general measure to assess patients'  
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7 32 expectations across medical conditions and treatments with the involvement of  
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9 33 patients, earlier scales and empirical data.  
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11 34 • The Expectation for Treatment Scale (ETS) is a short and reliable measure that  
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13 35 captures outcome-related expectations of patients.  
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15 36 • The association between the ETS and related constructs was explored.  
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17 37 • The development of the ETS was done via an online survey with pain patients, and  
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19 38 the initial findings were confirmed using confirmatory factor analysis in a patient  
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21 39 sample with low back pain.  
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23 40 • The transfer of the ETS in different clinical conditions and settings should be pre-  
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25 41 tested to explore whether patients can evaluate the respective treatment at this level.  
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## 44 Introduction

45 Patients' expectations alter responses to interventions in placebo research and in clinical  
46 studies. In experimental research, the instruction to receive an active intervention  
47 accompanies large effects on pain reduction (effect size = 0.75)<sup>1</sup>. Expectations can be  
48 considered a major driver of changes in symptoms and other health-related outcomes<sup>2</sup>.  
49 Clinical studies have revealed that patients' positive expectations are related to reduced  
50 pain after a medical treatment<sup>3-5</sup>, and this phenomenon has also been observed for other  
51 medical conditions<sup>6</sup>. For acupuncture, this association was investigated in several studies  
52 with heterogeneous findings: Patients with chronic pain had higher odds (odds ratio 2.11  
53 [95% CI 1.32-3.34]) of benefitting from acupuncture treatment if they expected a better  
54 treatment response at baseline (controlled for other clinical baseline characteristics)<sup>7</sup>.  
55 However, there are also studies that found no influence of expectations on the outcome<sup>8,9</sup>.

56 These differences in the association of expectations and outcomes might be partly  
57 explained by the fact that each study used a newly invented measure, and differences  
58 between measures might hide or exaggerate associations between expectations and  
59 intervention outcomes. Additionally, the match between expectations of patients and  
60 treatment providers might be relevant for the success of a specific treatment<sup>10</sup>.

61 Expectation is a well-known and oft-used term. A clear definition and a sharp  
62 distinction from associated constructs is important for the development of a measure<sup>11</sup>. In  
63 the context of medical treatments, the term "expectations" describes cognitions about  
64 treatment-related health outcomes in the future after a specific intervention<sup>12,13</sup>. Patients can  
65 consider a treatment more or less beneficial for their complaints or disease at a specific  
66 time-point (i.e., outcome expectations)<sup>13</sup>. Role expectations also capture the role of a

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2 67 patient and the therapist during the treatment. In other words, a patient might consider  
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4 68 himself rather inactive during treatment in defining treatment goals and expects an active  
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6 69 therapist to achieve a good treatment outcome. However, our purpose was to develop a  
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9 70 scale on “patient expectations” that covers treatment-related outcome expectations.  
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11 71 Bowling et al. (2012) provide an insightful summary about the theoretical underpinning of  
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13 72 expectations<sup>14</sup>. Following the definition by Bowling et al. (2012), we therefore designed our  
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15 73 measure to assess expectations related to a clinical intervention with a clinically relevant  
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18 74 outcome from a patient’s perspective.  
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21 75 Earlier findings about the expectation outcome association in clinical studies have  
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23 76 been limited by the diversity of measures. Several authors claimed diversity in covered  
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25 77 concepts, time-point of assessment and problems to evaluate the validity of the measures<sup>15-</sup>  
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28 78 <sup>17</sup>. A strong measure is a prerequisite to accurately predict treatment responses based on  
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30 79 pretreatment expectations. A closer investigation of the results from a systematic review  
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32 80 about acupuncture expectation measures by Prady and colleagues<sup>18</sup> showed that of ten  
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35 81 trials, only five provided their exact item wording for measuring expectations. Because  
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37 82 many of the assessment instruments are not publicly available, it is difficult to replicate the  
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40 83 studies. Three of the five mentioned studies used only one item to assess expectations.  
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42 84 There is no reporting at all of Cronbach’s alpha in the two remaining studies.  
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45 85 For further research in the field of expectations, a strong measure with high  
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47 86 acceptance across clinical fields would be needed for several reasons. First, a reliable  
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49 87 measure with high internal consistency at a specific time-point is a prerequisite to use  
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51 88 expectations as a robust predictor. Second, ceiling effects were a common problem in the  
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54 89 measurement of expectations, because patients who are seeking help from a specific  
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56 90 treatment often expect large benefits; otherwise, they would not be attracted by this  
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2 91 treatment. This problem was apparent in an established expectation measure for  
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4 92 acupuncture treatment that served as a benchmark measure for our scale (Acupuncture  
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6 93 Expectancy Scale (AES))<sup>19</sup>. Ceiling effects are particularly problematic because the  
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8 94 predictive power of such skewed variables is low. In the case of expectations, many  
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10 95 research questions address the prediction of treatment outcomes; therefore, a measure with  
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12 96 sufficient variation between patients is needed. Some authors have used the term  
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14 97 “realistically expect” to capture expectations in a recent study with a comprehensive 10-item  
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16 98 assessment of expectations, hope and beliefs (EXPECT)<sup>20</sup> with limited internal consistency.  
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18 99 Third, a measurement of expectation should be stable in a reasonable timeframe: The  
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20 100 EXPECT scale showed only a moderate retest reliability, with an intra-class correlation of  
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22 101 ICC = 0.75. Most importantly, the association of EXPECT with the established AES, a  
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24 102 benchmark measure for the field of acupuncture, was unexpectedly low ( $r = .54$ ).  
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30 103 This study aimed to develop a measure to reliably capture patient expectations with a  
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32 104 short scale. The newly developed scale (Expectation for Treatment Scale, ETS) ideally has  
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34 105 a strong association with available measures of expectations, moderate associations with  
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36 106 related constructs (e.g., optimism and pessimism) and no association with personality (e.g.,  
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38 107 neuroticism). Furthermore, it should be constructed such that it can be adapted to other  
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40 108 treatments and used universally in different clinical fields independent of patients’  
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## 50 51 111 **Methods**

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55 112 To address the problem of the abovementioned ceiling effects, we developed the items of  
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57 113 our scale (ETS) in a pilot study with pain patients in our outpatient clinic to measure  
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2 114 expected benefits before treatment from the patient's perspective. Based on existing  
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4 115 questionnaires on patient expectations<sup>9 19 21-24</sup>, we created a list of 17 items covering  
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6 116 different facets of expectations that fit with our aim to develop a measure for treatment-  
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9 117 related outcome expectations. We had been particularly interested in questionnaires from  
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11 118 the field of acupuncture research and other non-pharmacological interventions, and the  
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13 119 questions should be applicable in an applied context. The first and senior author were  
14  
15  
16 120 responsible for the selection of these items.  
17

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19 121

## 20 21 22 122 Patient and Public Involvement

23  
24 123 Twenty patients completed the questionnaires, provided sociodemographic information  
25  
26 124 and were asked for written comments about the accessibility of the questions. In addition,  
27  
28 125 two patients were interviewed by a qualitative researcher. Two health professionals (one  
29  
30 126 acupuncturist and a doctor assistant) also verbally commented about the appropriateness of  
31  
32  
33 127 the questions. Based on these data, we selected items with low skewness and a large  
34  
35 128 range of responses (i.e., variation). High correlations between items and the findings from  
36  
37  
38 129 the qualitative feedback were also considered.  
39

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## 42 43 44 131 Participants

45  
46 132 For the main validation, study subjects of the convenience sample were recruited  
47  
48 133 using different methods. Three regional patient organizations distributed the information,  
49  
50 134 and we used several email distribution lists (including the University of Zurich, Switzerland  
51  
52  
53 135 and the Charité University Hospital Berlin, Germany). Furthermore, patients from the  
54  
55 136 previous year seeking treatment for a musculoskeletal condition at the Institute for  
56  
57

1  
2 137 Complementary and Integrative Medicine of the University Hospital Zurich were contacted  
3  
4 138 by email. All participants were required to be at least age 18 and, according to their own  
5  
6 139 evaluation, have sufficient knowledge to understand German. The included pain patients  
7  
8  
9 140 had to suffer from at least some pain at the day of the assessment (> 0 on a numeric rating  
10  
11 141 scale from 0 (no pain) to 10 (worst pain)).  
12  
13

14 142 The study link was accessed by 522 subjects, and 244 started the survey. In total,  
15  
16 143 142 subjects were excluded due to insufficient pain (N = 113), missing data in the nine-item  
17  
18 144 version of the ETS (N = 14) and more than 20% missing responses across all items (N =  
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20  
21 145 13). Data from patients suffering from pain (N = 102) with retest data from 54 patients were  
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23 146 available.  
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## 29 147 Procedures

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31 148 Subjects who decided to participate activated an access link to the online survey  
32  
33 149 provided via email. The survey was hosted by <https://www.soscisurvey.de/>, and all data  
34  
35  
36 150 were collected electronically and anonymously. Participants were able to complete the  
37  
38 151 survey within 15 minutes. All questions were created in a forced choice format, meaning  
39  
40 152 that subjects were not able to continue to the next set of questions without completing the  
41  
42  
43 153 previous set. Upon starting the survey, a short welcome message, followed by an  
44  
45 154 introduction to the study, was provided. Subjects who agreed to be contacted again for the  
46  
47 155 retest assessment provided their email address at the end of the survey. The retest sample  
48  
49  
50 156 received a follow-up ETS one week after completion of the first survey. The study was  
51  
52 157 granted ethics approval by the local ethics committee (Kantonale Ethikkommission Zürich,  
53  
54 158 No. 48-2015).  
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2 1593  
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5 160 Measures

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7 161 The survey included demographic information (age, gender, education, employment  
8  
9 162 status, and country of residence), questions about any previous experience with  
10  
11 163 acupuncture (current or earlier), the degree to which the acupuncture treatment was  
12  
13 164 successful (numeric rating scale from 1 to 10, indicating no success to much success) and  
14  
15 165 the reason for the treatment (pain, mental health or non-specific). Patients who suffered  
16  
17 166 from pain (binary variable with yes vs. no option) were asked to give information about their  
18  
19 167 pain. We assessed average pain intensity (numeric rating scale from 1 to 10, indicating no  
20  
21 168 pain to worse pain), whether a physician was consulted, whether any other type of therapy  
22  
23 169 was used and the number of days of restriction due to pain. Subsequently, subjects  
24  
25 170 completed the 9-item ETS. Below, we provide a detailed description of all measures in this  
26  
27 171 study.  
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36 173 *Expectation for Treatment Scale*

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38 174 The first version of the ETS consisted of nine items (e.g., “I expect the treatment  
39  
40 175 [acupuncture] will help me to cope with my complaints.”). Each item was to be rated on a  
41  
42 176 four-point scale ranging from 1 to 4 (partially disagree, partially agree, agree, definitely  
43  
44 177 agree). We decided to use a four-point scale instead of a five-point scale for two reasons.  
45  
46 178 First, the chosen format forces the patient to provide an answer with a direction (higher or  
47  
48 179 lower than the middle answer choice) instead of opting for the middle category, which often  
49  
50 180 occurs in situations of insecurity (such as the present estimation of future events)<sup>25</sup>.  
51  
52 181 Second, the lowest answer on the scale of “definitely disagree” can be considered  
53  
54 182 unexpected for patients motivated to undergo an acupuncture treatment. After the statistical  
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1  
2 183 analyses, the nine-item version was reduced to a final 5-item version of the ETS. A detailed  
3  
4 184 description of these five items is provided in the appendix Table 1. These five items were  
5  
6 185 translated into English by two bilingual researchers and translated back into German by two  
7  
8  
9 186 other bilingual researchers. The wording was improved based on feedback from Dr. George  
10  
11 187 Lewith. The final English version is presented in the appendix Table 1.  
12  
13

14 188

### 17 189 *Optimism and pessimism*

19 190 Both concepts were assessed using the German version of the Life Orientation Test –  
20  
21 191 Revised<sup>26</sup>. The questionnaire consists of six self-report items (plus four filler items), each  
22  
23  
24 192 rated on a five-point Likert scale ranging from 0 (strongly disagree) to 4 (strongly agree).  
25  
26 193 The data were separated into optimism and pessimism scores, as recommended by  
27  
28  
29 194 Glaesmer et al. (2008). Each score can range from 0 to 12, with higher values indicating  
30  
31 195 either higher optimism or pessimism. In the present study, the Cronbach's alpha was  
32  
33 196 acceptable for optimism (0.72) and questionable for pessimism (0.60).  
34  
35

### 36 197 *Depression*

38 198 The Patient Health Questionnaire (PHQ-9) is widely used as a standard instrument  
39  
40  
41 199 for diagnosing depression in primary care and is considered well validated<sup>27</sup>. The PHQ-9  
42  
43 200 consists of nine questions operating according to the modified Diagnostic and Statistical  
44  
45 201 Manual, Fourth Edition criteria. Patients indicated their answers on a scale ranging from 0  
46  
47 202 (not at all) to 3 (almost every day)<sup>28</sup>. A higher score indicates a higher severity of depressive  
48  
49  
50 203 symptoms (ranging between 0 and 27). In the present study, the internal consistency of the  
51  
52 204 scale was excellent (Cronbach's alpha = 0.90).  
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## 205 *Resilience*

206 As a protective personality factor, resilience was appraised using the Resilience  
207 Scale<sup>29</sup>. In the current study, we used the German Version Resilienzskala (RS-11)<sup>30</sup>. The  
208 instrument consists of eleven questions, with seven response alternatives ranging from 1  
209 (disagree) to 7 (fully agree). Higher scores indicate higher resilience. In the present study,  
210 the internal consistency was excellent (Cronbach's alpha = 0.90).

## 211 *Body-Efficacy Expectation*

212 To measure beliefs concerning bodily coping capabilities, the Body-Efficacy  
213 Expectation (BEE) questionnaire<sup>31</sup> was used. The instrument consists of five items using a  
214 four-point Likert scale ranging from 1 (not true at all) to 4 (exactly true). A higher score  
215 indicates stronger beliefs in one's bodily coping capabilities. In the present study, the  
216 Cronbach's alpha was 0.75, indicating acceptable internal consistency.

## 217 *Perceived Sensitivity to Medicines*

218 To assess the individual's sensitivity to medicines, we used the Perceived Sensitivity  
219 to Medicines scale (PSM)<sup>32</sup>. The PSM is considered a reliable and valid measure composed  
220 of five self-report questions to assess perceived sensitivity to the potential adverse effects  
221 of medicines. Responses are scored on a five-point Likert scale, and patients' item scores  
222 are summed to provide a total score ranging between 5 and 25. Higher scores point  
223 towards a high perceived sensitivity to the potential adverse effects of medicines. In the  
224 current study, the scale showed excellent internal consistency (Cronbach's alpha = 0.94).

## 225 *Neuroticism and openness to experience*

226 To assess the distinctiveness of neuroticism and openness to experience among  
227 patients, we used the corresponding subscales of the NEO Five-Factor Inventory (NEO-  
228 FFI)<sup>33</sup>. To that end, 23 questions were extracted from the 60-item NEO-FFI. The instrument

1  
2 229 utilizes a five-point Likert response format, from 1 (strongly refuse) to 5 (strongly agree). A  
3  
4 230 higher score indicates a higher value for neuroticism and openness to experience. In the  
5  
6 231 present study, the Cronbach's alpha was 0.85 for neuroticism and 0.72 for openness to  
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8  
9 232 experience, which indicates good to acceptable internal consistency.

### 10 11 12 233 *Acupuncture Expectancy Scale*

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14 234 Mao and colleagues developed the AES to measure patients' expected response  
15  
16 235 from acupuncture<sup>19</sup>. The scale was developed for only one clinical intervention (i.e.,  
17  
18 236 acupuncture). The instrument consists of four items. The answers are given using a five-  
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20  
21 237 point Likert scale ranging from 1 (not at all agree) to 5 (completely agree). A higher score  
22  
23 238 points towards higher expectancies. In the present study, the internal consistency of the  
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25  
26 239 scale was considered good (Cronbach's alpha = 0.88).

### 27 28 29 240 30 31 241 *Statistical Analyses*

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34 242 All data analyses were executed using SPSS (version 22, SPSS Inc., Chicago,  
35  
36 243 Illinois, USA). As a first step, we used the nine items of the first ETS version to explore  
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38 244 homogeneity and diversity between items. We conducted a descriptive analysis of the data  
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41 245 to detect possible floor or ceiling effects and assess the distribution of the data. Internal  
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43 246 consistency was examined through reliability analyses (Cronbach's alpha), with the  
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45 247 corrected item-total correlation and the Cronbach's alpha if the item is deleted. Retest  
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48 248 reliability for the nine items was assessed by the intraclass correlation coefficient (ICC). We  
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50 249 set for each item a minimal acceptable ICC of .60 and for the total score an ICC of .80.  
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52 250 Three criteria guided the decision to keep an item for the final version: 1) it should have a  
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54 251 high corrected item-total correlation and no low internal consistency if deleted, 2) the item  
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57 252 should not overlap too strongly in content with another item that might be included, and 3)

1  
2 253 the item should not contribute to ceiling effects in the final version of the scale, which means  
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4 254 items with lower values were preferred.  
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6  
7 255 In a second step, we used the reduced version of the scale to generate a total sum  
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9 256 score of the five items (ranging from 5 to 20). To examine divergent and convergent validity,  
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11 257 correlations between the ETS sum score and the other measures were calculated. The  
12  
13 258 selection of measures was based on theoretical assumptions: With another measure of  
14  
15 259 expectations (AES) we hypothesised very high correlations, since three of the five items of  
16  
17 260 the ETS cover similar topics as the AES (coping, disappearance of complaints, energy)  
18  
19 261 even though instruction and response options differ. We assumed a very high correlation  
20  
21 262 between the ETS and the most strongly related construct (correlation about .70; AES) and a  
22  
23 263 moderate correlation with strongly related constructs (correlation about .30; LOT-R  
24  
25 264 optimism, inverse with LOT-R pessimism). Optimism can be viewed as a trait characteristic  
26  
27 265 of a person with high stability over time and situations. Optimism is defined as “the extent to  
28  
29 266 which people hold generalized favourable expectancies for their future” (Carver et al, 2010,  
30  
31 267 p. 879)<sup>34</sup>. We included optimisms and the counterpart pessimism to assess the overlap  
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33 268 between expectation and this personality trait.  
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40 269 Smaller correlations with less related constructs (correlation about .20; PHQ-9; RS-  
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42 270 11, BEE) were assumed. Explanatory styles (i.e. expectation about future events) are  
43  
44 271 associated with depressed mood with similar correlations<sup>35</sup>. Self-efficacy is also a construct  
45  
46 272 at a general level (i.e., “Perceived self-represents an optimistic sense of personal  
47  
48 273 competence [...]”; Scholz et al., 2002; p. 342)<sup>36</sup>. If self-efficacy is related to a specific  
49  
50 274 behaviour or problem, it captures the strength of a belief to cope in a situation successfully  
51  
52 275 (for example Pain Self-Efficacy Questionnaire; PSEQ)<sup>37</sup>. In our study we used the Body  
53  
54 276 Efficacy Expectation (BEE) since this scale assess the “conviction that one’s body is able to  
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1  
2 277 heal and take care of itself by dealing with pathogens and other health-threatening  
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4 278 demands on its own.” (Schützler & Witt, 2013; p. 2). Resources for health also capture  
5  
6 279 positive beliefs on how to deal with a difficult situation in life. We hypothesized for both  
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8  
9 280 dimension only low correlations since such resources are rather general and neither related  
10  
11 281 to a specific disorder nor to a specific time-point in life. Finally we assumed no correlation  
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13 282 with unrelated constructs (PSM, NEO-FFI neuroticism, NEO-FFI openness to experience),  
14  
15 283 however we wanted to assess these dimension since the ETS might be used in upcoming  
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17  
18 284 placebo / nocebo research and several studies have shown that these dimensions are  
19  
20 285 possibly related to placebo / nocebo responses<sup>38 39</sup>.

23 286 To test our assumption of one general factor, an explorative factor analysis using a  
24  
25 287 varimax rotation, an Eigenvalue of more than one and the Scree test was used with the 5  
26  
27  
28 288 ETS items to determine the number of underlying factors. In addition, we conducted a  
29  
30 289 confirmatory factor analysis with an independent sample of chronic low back pain patients,  
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32 290 which had been included in a randomized controlled trial (registration number DRKS-ID:  
33  
34 291 DRKS00010191). These patients completed the ETS. The data were used to test the  
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36  
37 292 single-factor structure. The best model used correlated error terms between item 2 and item  
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39 293 5 and is shown in Figure 1. Multiple goodness of fit tests<sup>40</sup> were used to evaluate the model,  
40  
41 294 including the comparative fit index (CFI;<sup>41</sup>), the normed fit index (NFI;<sup>40</sup>), the goodness of fit  
42  
43 295 index (GFI;<sup>42</sup>) and the root mean squared error of approximation (RMSEA). A CFI greater  
44  
45 296 than 0.90 indicates a good fit to the data<sup>43</sup>. An NFI and GFI greater than 0.90 indicates a  
46  
47 297 good fit to the data<sup>44</sup>. A RMSEA with values of less than 0.08 indicates a good fit to the  
48  
49 298 data<sup>45</sup>, whereas values greater than 0.10 suggest strongly that the model fit is  
50  
51 299 unsatisfactory. The Chi-square goodness of fit test can be considered a general test for the  
52  
53 300 acceptability of the model; a statistically significant  $\chi^2$  indicates that a significant proportion

1  
2 301 of variance remains unexplained by the model<sup>40</sup>. Confirmatory factor analysis was  
3  
4 302 conducted with the Analysis of Moment Structures (AMOS) software version 25 which is  
5  
6 303 part of the SPSS package.  
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9 304

## 13 305 **Results**

### 18 306 Sample characteristics

20 307 Three-quarters of the patients were female, one-third had a high school degree or  
21  
22 308 higher vocational training, and approximately 70% were currently employed. Approximately  
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24 309 two-thirds of the surveys were conducted with patients in Switzerland, and one-third came  
25  
26  
27 310 from Germany. The characteristics of patients with current pain are displayed in Table 1.  
28  
29 311 Descriptive information about the scales used in the study is presented in the appendix  
30  
31  
32 312 Table 2.

37  
38 313 Insert Table 1 about here  
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### 43 314 First version of the ETS

46 315 In an initial analysis, we included nine items of the ETS. Descriptive results and  
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48 316 results from scale analyses are presented in the appendix Table 3. In general, the standard  
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50 317 deviations showed large variances, with the exception of item 6 (“The treatment  
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52 318 [acupuncture] is in general effective”) and item 7 (“I myself have positive expectations about  
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54 319 the treatment [acupuncture]”). The mean value of item 6 was relatively high, which can be  
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1  
2 320 considered an indicator of a ceiling effect. Therefore, we decided to exclude item 6 (i.e.,  
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4 321 general expectations about the effectiveness of the treatment [acupuncture]) and item 7  
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6 322 (i.e., personal expectation of a treatment) from the final ETS.  
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9 323 The item-total correlation and the Cronbach's alpha if an item is deleted are  
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11 324 indicators for the coherence of the single item meaning with the total scale (see appendix  
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13  
14 325 Table 4). The corrected item-total correlation did not give any strong reason for the  
15  
16 326 exclusion of items. However, there were items with very high total correlations between  
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18 327 items (item 2 and item 9). Item 2 ("I expect my complaints will be much better because of  
19  
20 328 the treatment [acupuncture]") and item 9 ("I expect that after the treatment [acupuncture],  
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22 329 my complaints will be considerably better") were very similar in terms of their wording;  
23  
24 330 therefore, we decided to keep only one of the items for the final version. The reason for this  
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26 331 decision was that the ICC value for item 2 was lower than that of item 9. In addition, the  
27  
28 332 mean value for item 9 was lower than the mean of item 2, which consequently can  
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30 333 contribute to a larger variation in the final scale because ceiling effects can be avoided. The  
31  
32 334 decision to exclude item 1 was based on content. Our pilot study indicated problems with  
33  
34 335 understanding the meaning of "clearly reduced". Furthermore, item 1 ("I expect the  
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36 336 treatment [acupuncture] will clearly reduce my complaints") and item 4 ("I expect the  
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38 337 treatment [acupuncture] will make my complaints disappear") covered similar topics. The  
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40 338 factor loading confirmed our earlier decision to eliminate item 6 ("The treatment  
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42 339 [acupuncture] is in general effective") because the factor loading was relatively low. All  
43  
44 340 items of the first version contributed to one single factor with 65.51% of explained variance.  
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46 341 The 9-item ETS version total score is normally distributed. For the 5-item ETS version and  
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48 342 the AES items, there were a substantial number of subjects with either the lowest or the  
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50 343 highest score on the scale.  
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1  
2 344 The final version of the ETS consists of five items (see Table 2): the previous item 3  
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4 345 (“I expect the treatment [acupuncture] will help me to cope with my complaints”) covers  
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6 346 coping ability; item 4 (“I expect the treatment [acupuncture] will make my complaints  
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8 347 disappear”) covers total absence of complaints; item 5 (“I expect the treatment  
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10 348 [acupuncture] will improve my energy”) covers an energy increase; item 8 (“I expect the  
11  
12 349 treatment [acupuncture] will improve my physical performance”) covers an improvement of  
13  
14 350 physical functioning; and item 9 (“I expect that after the treatment [acupuncture] my  
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16 351 complaints will be considerably better”) covers a considerable decrease in symptoms. To  
17  
18 352 summarize, the ETS captures an expected decrease in symptoms, an expected increase in  
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20 353 energy and expected overall wellbeing after a treatment.  
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28 354 Insert Table 2 about here  
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34 355 The Cronbach’s alpha of the final version was 0.90, which is an excellent value for a  
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36 356 very short scale (Table 2). Retest reliability was excellent for the five items. All items  
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38 357 contributed substantially to the final scale, and the factor loading indicated a single factor  
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40 358 structure with 72.33% of explained variance.  
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47 359 Convergent and divergent validity  
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49 360 We expected a moderate correlation between the ETS and the LOT-R optimism and  
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51 361 an inverse correlation with pessimism. However, these assumptions were not confirmed by  
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53 362 our findings (Table 3). Interestingly, higher pessimism was moderately associated with  
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55 363 higher expectations, both for the ETS and the AES. The ETS showed a small but significant  
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2 364 correlation with the PHQ-9, which is consistent with our assumption. The correlation  
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4 365 between the ETS and the RS-11 or the BEE was close to zero, which is unexpected  
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6 366 according to our assumptions. However, we found a moderate correlation between the ETS  
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9 367 and the PSM, for which higher expectations were associated with a higher sensitivity to  
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11 368 medication. The shared aspect of this association is the responsiveness to a medical  
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13 369 treatment. Personality traits (NEO-FFI) were not associated with the ETS, which is  
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16 370 consistent with our assumptions. The ETS score has a very high correlation ( $> .90$ ) with the  
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18 371 AES, which can be considered a benchmark measure for acupuncture expectations.  
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24 372 Insert Table 3 about here  
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### 30 373 Confirmatory factor analysis

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32 374 In addition, we conducted a CFA with the data from the 439 ETS questionnaires mentioned  
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34 375 above with the model presented in Figure 1. The factor loadings were between 0.609 (Item  
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36  
37 376 2) and 0.796 (Item 4). We found an acceptable model fit in the Chi-square statistics (Chi-  
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39 377 square = 5.859, d.f. = 4,  $p = .210$ ), indicating that the model is able to explain the data  
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41 378 structure in general. The CFI was .998 in our model, indicating a very good model fit.  
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44 379 Similarly, the NFI (.993) and GFI (.995) confirm the excellent model fit. The RMSEA (.033)  
45  
46 380 also suggests that the model with one single factor explains the data very well. The good  
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48 381 internal consistency of the ETS in this sample (Cronbach's alpha = .836) confirmed the  
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50 382 findings of the scale development.  
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56 384 Insert Figure 1 about here  
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6 386 **Discussion**

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10 387 The ETS is a well-validated and brief 5-item scale for measuring patient  
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12 388 expectations, with excellent test-retest properties. We were able to overcome ceiling effects,  
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14 389 which had been a limitation of earlier measures<sup>19</sup>. This improvement might result from using  
15  
16 390 only four response categories instead of a larger scale with rather inadequate categories  
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18 391 (namely, “definitely disagree”). The ETS has excellent measurement properties concerning  
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20 392 Cronbach’s alpha; retest reliability over one week and single factor structure were replicated  
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22 393 in a clinical sample. The ETS can be used for research and clinical purposes equally.  
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26 394 The ETS could be adapted to other clinical situations and treatments beyond  
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28 395 acupuncture, which would be an important step towards implementing treatment  
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30 396 expectations as standardized working mechanisms among a variety of patient populations.  
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32 397 Pain disorders, mental disorders and functional symptoms might be the most appropriate  
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34 398 fields, because clinical research indicates the high relevance of expectations for treatment  
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36 399 outcomes.  
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41 400 Another notable issue that deserves discussion is the moderate correlation between  
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43 401 high pessimism and high expectations for both the ETS and the AES. Our initial assumption  
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45 402 was that we would find a negative association between both expectation measures and  
46  
47 403 pessimism. This assumption was not confirmed. Furthermore, we found no correlation  
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49 404 between optimism and the ETS in our study, which is contrary to the underlying theoretical  
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51 405 framework of Bowling et al. in this study. The findings about negative cognitions  
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53 406 (pessimism) are consistent with our result of a small but significant correlation of the ETS  
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55 407 and depression (PHQ-9). A possible explanation for both findings might be that in pain  
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2 408 patients, depression might be associated with more-severe medical symptoms that might  
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4 409 lower patients' expectations in some cases depending upon treatment history.  
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#### 10 411 Limitations

11  
12 412 There are limitations to our study. First, although collection of data via a web-based  
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14 413 survey holds many advantages, there are also downsides to this method because  
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16  
17 414 recruitment is done using an unstructured approach. Because the ETS questionnaire was  
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19 415 also validated in a paper-based version in a clinical population, this limitation is of minor  
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21 416 importance. Second, to enhance the external validity of our study, other clinical populations  
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24 417 should be investigated to prove the validity of our scale across clinical conditions. Thus far,  
25  
26 418 the application appears feasible and valid for patients with pain. Third, there might be  
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28 419 clinical intervention in situations in which patients might have a very vague idea about  
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31 420 procedures and outcomes. We did not collect data from a clinical pain population *prior* to  
32  
33 421 their acupuncture treatment. The patients from our sample provided information about their  
34  
35 422 previous experience with acupuncture, but such an assessment could be done more  
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38 423 comprehensively to capture the underlying beliefs and experiences of patients and their  
39  
40 424 relevance for expectations.  
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#### 43 425 Conclusion

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45 426 The ETS is a short and validated measure that can contribute to the understanding of  
46  
47 427 patient expectations for treatment outcomes. The field of acupuncture served as example to  
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50 428 develop the ETS, but it could be easily adapted for other treatments and clinical contexts.  
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52 429 The ETS fills a gap by providing a strong and flexible measure that can serve as a basis for  
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54 430 upcoming predictor analyses of treatment expectations in clinical studies.  
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1  
2 431 Funding  
3

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## 10 457 **Data-sharing statement**

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13 458 Date are available from the first author on request.  
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25

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## 23 24 25 26 **Tables and Figures**

27  
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29 602 Table 1. Sample characteristics of subjects with current pain (N = 102)

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32 603 Table 2. Scale and factor analysis of the 5-item ETS for subjects with current pain (N = 102)

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37 605 current pain (N = 102). Pearson Correlation, Significance level (2-tailed), N of patients

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40 606 Figure 1. Confirmatory factor analysis with factor loadings (N = 439) of the final 5-item ETS  
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42 607 version in patients with chronic low back pain  
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Table 1. Sample characteristics of subjects with current pain (N = 102)

	Frequencies //	Percentage
	Mean (SD)	
Age	49.16 (14.04)	
Gender		
Female	76	75%
Male	26	25%
Education		
Vocational school	39	38%
Higher school certificate or Higher vocational training	29	28%
University	34	33%
Employment status		
Working	72	71%
Retired	10	10%
Other	20	20%
Country of residence		
Switzerland	68	67%
Germany	34	33%
Acupuncture experience		
Current	13	13%

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2	609	Earlier	51 50%
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4	610	None	38 37%
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6	611	Success of acupuncture	6.5 (2.80)
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8			
9	612	[range 1–10]*	
10			
11	613	Reason for treatment**	
12			
13	614	Pain	55 86%
14			
15	615	Mental health	13 20%
16			
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18	616	Other	24 38%
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21	617	General Health***	3.21 (.92)
22			
23	618	Pain characteristics	
24			
25	619	Intensity [range 0–10]****	6.5 (1.92)
26			
27	620	Physician consulted*****	68 67%
28			
29	621	Any treatment*****	66 65%
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32	622	Days of restriction due to	
33			
34	623	pain*****	46.76 (63.74)
35			
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37	624	Location*****	
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39	625	Back	58 57%
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41	626	Neck	44 43%
42			
43	627	Knee	21 21%
44			
45	628	Head	20 20%
46			
47	629	Hip	16 16%
48			
49	630	Other	33 32%
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5 634 \*Range from no success (1) to very successful (10) treatment outcome of the last

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7 635 acupuncture treatment

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10 636 \*\*Multiple answers were possible.

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13 637 \*\*\*Range from 1 = excellent to 5 = bad

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16 638 \*\*\*\*0 indicating no pain and 10 indicating maximum pain

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19 639 \*\*\*\*\*In the last 6-month period

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22 640 \*\*\*\*\*Multiple answers were possible.

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Table 2. Scale and factor analysis of the 5-item ETS for subjects with current pain (N = 102)

Item	Mean (SD)	Item-total correlation corrected	Cronbach's alpha if item deleted	Factor loading	Retest ICC [95%-CI]
Item 3	2.38 (1.03)	.727	.887	.826	.697 [.517, .818]
Item 4	1.97 (.96)	.736	.883	.834	.724 [.556, .835]
Item 5	2.41 (1.0)	.776	.875	.865	.840 [.732, .907]
Item 8	2.33 (.83)	.817	.869	.891	.749 [.592, .851]
Item 9	2.52 (.90)	.737	.883	.834	.836 [.725, .904]
			Cronbach's $\alpha$	% of variance	
ETS 5			.901	72.325	.856 [.757, .917]

Item 3: I expect the treatment [acupuncture] will help me to cope with my complaints.

Item 4: I expect the treatment [acupuncture] will make my complaints disappear.

Item 5: I expect the treatment [acupuncture] will improve my energy.

1  
2 Item 8: I expect the treatment [acupuncture] will improve my physical performance.  
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5 Item 9: I expect that after the treatment [acupuncture], my complaints will be considerably  
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7 better.  
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Table 3. Convergent and divergent validity of the 5-item version of the ETS for subjects with current pain (N = 102). Pearson Correlation, Significance level (2-tailed), N of patients

Correlation	ETS	LOT-R Optimism	LOT-R Pessimism	PHQ-9	RS-11	BEE	PSM	NEO-FFI Neuroticism	NEO-FFI Openness to experience
ETS	1								
	102								
LOT-R Optimism	-.066	1							
	.517								
	99	99							
LOT-R Pessimism	.204*	-.247*	1						
	.043	.014							
	99	99	99						
PHQ-9	.233*	-.567**	.312**	1					
	.020	.000	.002						
	100	99	99	100					
RS-11	-.073	.546**	-.460**	-.572**	1				
	.474	.000	.000	.000					
	99	99	99	99	99				

BEE	.032	.259**	-.074	-.176	.407**	1			
	.754	.010	.468	.081	.000				
	99	99	99	99	99	99			
PSM	.344**	-.078	.201*	.306**	-.049	.011	1		
	.000	.445	.046	.002	.631	.912			
	100	99	99	100	99	99	100		
NEO-FFI	.104	-.578**	.467**	.631**	-.682**	-.284**	.238*	1	
Neuroticism	.316	.000	.000	.000	.000	.005	.020		
	95	95	95	95	95	95	95	95	
NEO-FFI	-.072	.297**	-.167	-.090	.302**	.122	.132	-.130	1
Openness to	.492	.004	.109	.386	.003	.241	.205	.211	
experience	94	94	94	94	94	94	94	94	94
Cronbach's Alpha	.901	.727	.608	.900	.900	.757	.940	.854	.726

\*\*Correlation is significant at the 0.01 level (2-tailed).

\*Correlation is significant at the 0.05 level (2-tailed).

ETS = Expectation for Treatment Scale; LOT-R = Life-Orientation Test; PHQ-9 = Patient Health Questionnaire-9; RS-11 = Die

Resilienzskala - Ein Fragebogen zur Erfassung der psychischen Widerstandsfähigkeit als Personenmerkmal; BEE = Body-

Efficacy Expectation; PSM = Perceived Sensitivity to Medicines Scale; NEO-FFI = NEO Five-Factor Inventory

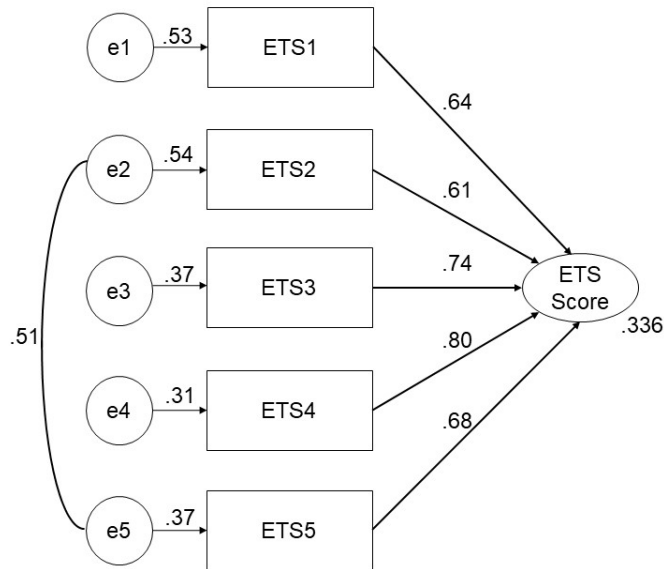


## Expectation for Treatment Scale (ETS)

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6 Figure 1. Confirmatory factor analysis with factor loadings (N = 439) of the final 5-item  
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8 ETS version in patients with chronic low back pain  
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Item 3 corresponds to ETS1  
 Item 4 corresponds to ETS2  
 Item 5 corresponds to ETS3  
 Item 8 corresponds to ETS4  
 Item 9 corresponds to ETS5

Chi-square = 5.859 (d.f. = 4),  
 p = .210; RMSEA = 0.033;  
 CFI = 0.998; NFI = 0.993;  
 GFI = 0.996

e1 to e5: Error terms

Confirmatory factor analysis with factor loadings (N = 439) of the final 5-item ETS version in patients with chronic low back pain.

## Appendix (Barth et al.; ETS)

## APPENDIX Table 1. Description of the 5 final items in English and German

## Table 1. Description of the 5 final items in English and German

Description: The overarching construct of ETS is treatment-related outcome expectation of patients. Outcomes of interest for patients are coping (item 1), vitality (item 3) and physical health (item 4). Two items (items 2 and 5) capture the reduction of patient complaints, either an absence or a considerable reduction thereof. The scale can be adapted to specific treatments of interest. Instead of the term “treatment”, a specific term can be used (e.g., acupuncture, counselling, or physiotherapy). We used the term complaints [German Beschwerden] as previously used by other authors as in the symptom checklist (SCL-90-R)<sup>46</sup>. Therefore, any type of complaint can be captured and allow the use of this instrument across patient groups and settings. The term complaints can be adapted if needed to the clinical situation if one specific target symptom is predominant (e.g., pain, depression, or nausea). The scale should be used in a clinical setting by patients with sufficient German or English language skills.

English version

There are several statements below that capture your expectations about the [acupuncture] treatment. Please indicate to what extent these statements apply to you personally. **There are no right or wrong answers. We are only interested in your current personal thoughts.**

Please select for each statement **one** response.

1. I expect the treatment [acupuncture] will help me to cope with my complaints.

partially disagree	partially agree	agree	definitely agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. I expect the treatment [acupuncture] will make my complaints disappear.

partially disagree	partially agree	agree	definitely agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. I expect the treatment [acupuncture] will improve my energy.

partially disagree	partially agree	agree	definitely agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1  
2  
3 4. I expect the treatment [acupuncture] will improve my physical performance.

5 partially disagree

6 partially agree

7 agree

8 definitely agree

9

10

11

12

13 5. I expect that after the treatment [acupuncture], my complaints will be  
14 considerably better.

15 partially disagree

16 partially agree

17 agree

18 definitely agree

19

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23 \*We used the term acupuncture in our study. The general version of ETS uses the  
24 term treatment.  
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## German version

Im Folgenden finden Sie einige Aussagen darüber, was man von einer Behandlung [Akupunktur] erwarten kann. Geben Sie bitte an, inwieweit die einzelnen Aussagen für Sie persönlich zutreffen. **Es gibt keine richtigen und falschen Antworten. Uns interessiert nur, was Sie persönlich denken.**

Bitte wählen Sie für jede Aussage **eine** Antwort aus.

1. Ich erwarte, dass ich durch die Behandlung [Akupunktur] mit meinen Beschwerden besser umgehen kann.

trifft eher nicht zu	trifft eher zu	trifft sehr zu	trifft völlig zu
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Ich erwarte, dass meine Beschwerden durch die Behandlung [Akupunktur] verschwinden.

trifft eher nicht zu	trifft eher zu	trifft sehr zu	trifft völlig zu
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3. Ich erwarte, dass sich meine Energie durch die Behandlung [Akupunktur] verbessert.

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4. Ich erwarte durch die Behandlung [Akupunktur] eine verbesserte körperliche Leistungsfähigkeit.

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5. Ich erwarte, dass sich nach der Behandlung [Akupunktur] meine Beschwerden deutlich verbessern.

trifft eher nicht zu	trifft eher zu	trifft sehr zu	trifft völlig zu
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*Wir haben den Begriff Akupunktur in unserer Studie verwendet. Die allgemeine Version des ETS verwendet den Begriff Behandlung.

### Scoring of the questionnaire

The values from the 5 single items are summed to build the ETS sum score (min 5, max 20). If one item has a missing value, the sum score can be calculated. Therefore, the values of the remaining 4 items are summed, divided by 4 and multiplied by 5. However, multiple imputation procedures to impute the missing value should be preferred over this re-calculation. In the case of more than one missing value, imputation procedures are needed, and no manual recalculation should be considered.

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APPENDIX Table 2: Sample characteristics in scales in subjects with current pain (N = 102)

	Median Mean (SD)
ETS (9 items) (range 9–36)	22 22.63 (.64)
ETS (5 items) (range 5–20)	11 11.62 (4.01)
AES (range 4–20)	12.0 11.82 (4.10)
PHQ-9 (range 0–27)	7 8.46 (6.06)
RS-11 (range 11–77)	60 58.36 (11.13)
BEE (range 5–20)	14 13.71 (2.90)
PSM (range 5–25)	11 12.77 (6.13)
LOT-R Optimism (range 0–12)	8 7.93 (2.77)
LOT-R Pessimism (range 0–12)	8 7.93 (2.38)
NEO-FFI Neuroticism (range 0–48)	21 21.08 (8.19)
NEO-FFI Openness to experience (range 0–44)	30 29.84 (5.77)

Expectation for Treatment Scale; AES= Acupuncture Expectancy Scale; LOT-R= Life-Orientation Test; PHQ-9= Patient Health Questionnaire-9; RS-11= Die Resilienzskala - Ein Fragebogen zur Erfassung der psychischen Widerstandsfähigkeit als Personenmerkmal; BEE= Body-Efficacy Expectation; PSM= Perceived Sensitivity to Medicines Scale; NEO-FFI= NEO Five-Factor Inventory

Appendix Table 3. Scale and factor analysis of the 9-item ETS for subjects with current pain (N = 102)

Item	Mean (SD)	Item-total correlation corrected	Cronbach's alpha if item deleted	Factor loading	Retest ICC [95%–CI]
Item 1	2.71 (1.0)	.782	.920	.839	.684 [.499, .810]
Item 2	2.66 (.93)	.816	.918	.863	.725 [.557, .836]
Item 3**	2.38 (1.03)	.736	.924	.790	.697 [.517, .818]
Item 4**	1.97 (.96)	.735	.923	.793	.724 [.556, .835]
Item 5**	2.41 (1.0)	.745	.923	.799	.840 [.732, .907]
Item 6	2.97 (.59)	.612	.931	.685	.649 [.450, .787]
Item 7	2.68 (.65)	.744	.924	.806	.658 [.462, .793]
Item 8**	2.33 (.83)	.772	.921	.821	.749 [.592, .851]
Item 9**	2.52 (.90)	.826	.917	.874	.836 [.725, .904]
			Cronbach's $\alpha$	% of variance	
ETS 9			.930	65.512	.879 [.794, .930]

\*\*marked items are included in the final version of its scale.

Item 1: I expect the treatment [acupuncture] will clearly reduce my complaints.

Item 2: I expect my complaints will be much better because of the treatment [acupuncture].

Item 3: I expect the treatment [acupuncture] will help me to cope with my complaints.

Item 4: I expect the treatment [acupuncture] will make my complaints disappear.



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3 Item 5: I expect the treatment [acupuncture] will improve my energy.  
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5 Item 6: The treatment [acupuncture] is in general effective.  
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7 Item 7: I myself have positive expectations about the treatment [acupuncture].  
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9 Item 8: I expect the treatment [acupuncture] will improve my physical performance.  
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11 Item 9: I expect that after the treatment [acupuncture], my complaints will be considerably better.  
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Appendix Table 4. Between-item correlations for sample with current pain (N = 102). Pearson Correlation and significance (2-tailed).  
\*\*Correlation is significant at the 0.01 level (2-tailed).

	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9
Item 1	1								
Item 2	.840** .000	1							
Item 3	.636** .000	.605** .000	1						
Item 4	.568** .000	.627** .000	.580** .000	1					
Item 5	.533** .000	.611** .000	.664** .000	.637** .000	1				
Item 6	.540** .000	.556** .000	.442** .000	.437** .000	.505** .000	1			
Item 7	.692** .000	.679** .000	.541** .000	.575** .000	.509** .000	.521** .000	1		
Item 8	.528** .000	.571** .000	.673** .000	.664** .000	.762** .000	.470** .000	.631** .000	1	
Item 9	.733** .000	.754** .000	.605** .000	.673** .000	.603** .000	.592** .000	.701** .000	.673** .000	1

Item 1: I expect the treatment [acupuncture] will clearly reduce my complaints.

Item 2: I expect my complaints will be much better because of the treatment [acupuncture].

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3 Item 3: I expect the treatment [acupuncture] will help me to cope with my complaints.  
4

5 Item 4: I expect the treatment [acupuncture] will make my complaints disappear.  
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7 Item 5: I expect the treatment [acupuncture] will improve my energy.  
8

9 Item 6: The treatment [acupuncture] is in general effective.  
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11 Item 7: I myself have positive expectations about the treatment [acupuncture].  
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13 Item 8: I expect the treatment [acupuncture] will improve my physical performance.  
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15 Item 9: I expect that after the treatment [acupuncture], my complaints will be considerably better.  
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60TROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	page
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	8
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	9
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	n.a.
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	10-13
Bias	9	Describe any efforts to address potential sources of bias	n.a.
Study size	10	Explain how the study size was arrived at	n.a.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	n.a.
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	14-15
		(b) Describe any methods used to examine subgroups and interactions	n.a.
		(c) Explain how missing data were addressed	n.a.
		(d) If applicable, describe analytical methods taking account of sampling strategy	n.a.
		(e) Describe any sensitivity analyses	n.a.
<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	15 and Table 2
		(b) Give reasons for non-participation at each stage	n.a.
		(c) Consider use of a flow diagram	n.a.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	n.a.
		(b) Indicate number of participants with missing data for each variable of interest	n.a.
Outcome data	15*	Report numbers of outcome events or summary measures	n.a.

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2	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
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8			(b) Report category boundaries when continuous variables were categorized
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11			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
12	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
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15	<b>Discussion</b>		
16	Key results	18	Summarise key results with reference to study objectives
17			19
18	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
19			21
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21	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
22			21
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25	Generalisability	21	Discuss the generalisability (external validity) of the study results
26			21
27	<b>Other information</b>		
28	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based
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30			
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\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).