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Development of the generic, multidimensional Treatment Expectation Questionnaire (TEX-Q)

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Development of the generic, multidimensional Treatment Expectation Questionnaire (TEX-Q)

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Abstract

Objectives: Patients´ expectations - as a central mechanism of placebo and nocebo effects - are an important predictor of health outcomes. However, the lack of a way to assess expectations across different settings restricts progress in understanding the role of expectations and to quantify their importance in medical and psychological treatments. The aim of this study was to develop a theory-based, generic, multidimensional measure assessing patient expectations of medical and psychological treatments.

Design: The Treatment Expectation Questionnaire (TEX-Q) was developed based on the Integrative Model of Expectations (Laferton, Kube, Salzmann, Auer & Shedden-Mora, 2017) and a systematic literature review of treatment expectation scales. After creating a comprehensive item pool, the scale was further refined by the use of expert ratings, and patient interviews.

Results: The 2x2x2 multidimensional structure of the TEX-Q assesses two expectation constructs (probabilistic vs. value-based) across two outcome domains with two valences (direct benefits and adverse events, broader positive and negative impact), plus process and behavioural control expectations. We examined 583 items from 38 scales identified in the systematic review, and developed 78 initial items. Content validity was then rated by 13 experts according to item fit and comprehensibility. The best 53 items were further evaluated for comprehensibility, acceptability, phrasing preference and understanding by interviewing 11 patients prior to treatment using the "think aloud"-technique. This resulted in a first 35-item version of the TEX-Q.

Conclusions: The TEX-Q is a generic, multidimensional measure to assess patient expectations of medical and psychological treatments and allows comparing the impact of multidimensional expectations across different conditions. The final TEX-Q will be available after psychometric validation.

Keywords: expectations, expectancy, scale, assessment, placebo, nocebo

Article Summary

Strength and limitations of this study

- Construction of a generic, multidimensional scale measuring patients´ treatment expectations
- Conceptual model contains eight subscales for outcome expectations and two process expectations
- Three-step empirical process: systematic review, expert ratings & cognitive patient interviews
- Generation & iterative reformulation of items informed by the empirical steps
- Generic nature of the TEX-Q needs further research in additional clinical settings

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Introduction

Patients' treatment expectations are an important predictor of outcome for a broad range of medical and psychological treatments (1-3). As non-specific treatment components, they can induce subjective and psychological changes and are a central mechanism driving placebo and nocebo effects (4). Positive treatment expectations have been linked to health outcomes for a variety of different illnesses and treatments including cancer (5), stroke (6), musculoskeletal disorders (7, 8), pain (9), surgery (10, 11), antidepressant medication (12), and psychotherapy (3). Furthermore, negative expectations have been linked to the occurrence of adverse events in the treatment of a number of illnesses (5, 13, 14). Generally, studies find a moderate overall effect of patients' expectations on outcomes (15, 16).

The large number of treatment expectation measures has been identified as an important limitation for the integration of the existing evidence across different treatments and diseases in several systematic reviews (1, 15-17). On the level of assessment, this stems from most studies developing a single treatment or disease measure of expectations (18) often using single-item or very brief non-validated ad-hoc instruments (10, 15). Other questionnaires only assess partial aspects of expectations, e.g., only positive expectations (19) or do not distinguish between the type of expectation assessed (20).

On the conceptual level, there is a diversity of underlying theories on expectations, being one of the most studied constructs in psychology (21). The theoretical conception of the TEX-Q is based on our *Integrative Model of Expectations* in patients undergoing medical treatment (18), and on an extensive review of the expectation literature. The model defines treatment expectations as future-directed cognitions that focus on the incidence or non-incidence of a specific event or experience. In general, it distinguishes between *probabilistic* expectations, describing realistic estimations about the future, and *ideal* or *value-based* expectation, describing what someone would like or dislike to happen (e.g. hopes, fears). It defines *treatment expectations* in distinction from *behavioral expectations* about the subjective control over the treatment as well as generalized expectations (e.g., generalized self-efficacy, optimism) and expectations about the timeline of diseases, treatments, behavior or related outcomes. Regarding treatment expectations, the model distinguishes between *outcome-related expectations* about benefits and side-effects of the treatment and *structural and process-related expectations* about the course of the treatment itself. Furthermore, it differentiates outcomes continuously ranging from internal effects (e.g., symptom improvement) to external effects (e.g., impact on patients' social life). The *Integrative Model* itself aims to integrate several central expectation theories. For further conceptual clarity, two of those theories with high relevance for the development of the TEX-Q are discussed in more detail.

The most central understanding of treatment expectations was provided by Kirsch's *Response Expectancy Theory* (22). Here he distinguishes between two kinds of general *outcome expectations*: *stimulus expectancies,* which are a person's expectation of external stimuli as an outcome, and *response expectancies,* which refer to a person´s expectations of a non-volitional internal response as an outcome. Response expectancies are particularly relevant in treatment contexts. They provide a description of patients' expectations in a broad range of treatment situations ranging from their position of passive recipients in some instances (e.g., expecting that taking metformin will lower your blood sugar in diabetes) to more active patient roles involving volitional health-directed behavior (e.g. expecting that changing your lifestyle will lower your blood sugar).

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Another important theory influencing the development of the TEX-Q is Leventhal's *Common Sense Model of Illness Representation* (23). This model describes patients' subjective representations of their illness and its consequences for their lives. It differentiates beliefs about the *causes* of the illness, its *timeline*, the *identity* of the illness through its associated symptoms and the possibility to *control* the illness through *personal behavior* and the *treatment* itself. The model does not refer to expectations explicitly, but they are regarded as important general constructs underlying illness beliefs (24). Thus, the model presents an elaborate differentiation of patients' illness and treatment beliefs that can also be applied as a framework for the differentiation of treatment expectations.

To facilitate a comprehensive understanding of treatment expectations and overcome the limitations of previous scales we developed the Treatment Expectation Questionnaire (TEX-Q). It was constructed with the following five aims: (1) The scale will be able to measure treatment expectations generically and comparably for different medical and psychological treatments; (2) The scale will be multidimensional, taking into account aspects of treatment expectations with potential predictive links to treatment outcomes; (3) The scale will be sensitive to change in order to capture effects of expectation management interventions; (4) The scale's conceptual framework is applicable for research and everyday clinical practice.

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Methods

Overview of the development process

The development process of the TEX-Q followed three main steps (see Figure 1): Firstly, we developed a conceptual structure for the TEX-Q and created a comprehensive item pool. This step was based on the Integrative Model of Expectations (18) and a systematic literature review of treatment expectation scales. Secondly, expert ratings were obtained to evaluate the items content validity. Thirdly, we conducted qualitative cognitive interviews with patients to evaluate the comprehensibility and acceptance of the items and the fit among our target population. Ethical approval was obtained from the Medical Chamber Hamburg, Germany. Informed consent was obtained from all participants of the study. The TEX-Q was developed in German. Preliminary English translations of its contents are used in this paper. A final translation will be available after the finalization of its psychometric validation.

<Insert Figure 1 here>

Conceptual structure & generation of item list

Our first goal was to assemble a comprehensive list of existing scales relevant to the development process through a literature review of generic and treatment-specific scales. To do this we completed a systematic literature search of the PubMed and PsycINFO databases (last date of search: 01.08.2018). The search was designed to include all published articles describing empirical studies with adults that featured a scale to measure patient expectations written since 1900 in English language (for the specific search-term see Appendix A). The articles found were then screened in two steps, firstly regarding titles and abstracts and secondly regarding the full texts of the remaining articles. A review protocol can be obtained from the authors.

Second, the systematic review was complemented by a critical review of treatment-specific expectation scales. As a systematic review of treatment-specific scales would have by far exceeded reasonable capacities for our purpose, our approach was non-systematic. This review was based on our *Integrative Model of Expectations* (18), treatment-specific reviews of expectation scales (6, 10, 15, 17, 25-27) and treatment-specific scales identified in our search for generic scales. For all identified expectation scales, the references of the respective publications were screened and additional scales were included.

The identified scales were assessed in conjunction with our theoretical model to finalize the conceptual structure and subscales of the TEX-Q. The items from each identified scale provided the pool from which we derived our items. Through the exclusion of duplicates and items that did not fit with the model we created the first list of potential items for the TEX-Q.

Evaluation of content validity

Our next empirical aim was the evaluation of content validity. To do this we sent our item list to 13 experts from the fields of placebo research, psychosomatic medicine and clinical psychology. They were requested to rate each item on a six-point-Likert scale according to: (1) comprehensibility, (2) fit to our theoretical construct (which we introduced attached to the rating), and (3) overall quality of the

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item. Furthermore, they were asked to provide open feedback for each item. After ranking the items for each dimension and taking into account the commentaries given, we decided on the inclusion and eventual rewording of the most appropriate items.

Evaluation of comprehensibility and acceptance – patient involvement

Next, we evaluated the comprehensibility of the items, their acceptability and fit to our model in a clinical sample. We therefore conducted cognitive interviews with patients. We recruited a convenience sample of 11 patients waiting for psychological or surgical treatments at the University Medical Center Hamburg-Eppendorf and the Schön Hospital Hamburg-Eilbek. They were interviewed by male and female researchers with prior experience with this assessment. Data saturation was discussed regularly and found to be sufficient within this sample.

The patients were asked to complete the potential TEX-Q items, some of them in different phrasings to examine the differences, while speaking out their thoughts (thinking-aloud technique (28)). Furthermore they were asked open questions about prior experiences and expectations with their symptoms and treatment and about specific aspects of the phrasing of the items. The interviews took about 1 hour each. The interviews were audio-recorded and the answers to the open questions were transcribed verbatim. Additionally, the researcher took field notes of any observed difficulty the patients had in filling out the questionnaire.

The transcripts and notes from the interviews were qualitatively analyzed using thematic analysis (29). Two different analyses were conducted. Firstly, we looked at how patients expressed their expectations throughout the interviews, examining their fit to our conceptual model. Secondly, we examined the material for all criticism about the questionnaire and its items. Categories for both analyses were created both deductively based on our conceptions and inductively derived from the interviews. The analyses of the interviews then informed the final discussion and selection process from which the research team chose the wording of the items for the TEX-Q.

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Results

Literature review: Conceptual model of the TEX-Q

From the literature we developed a 2x2x2 concept to operationalize outcome expectations for the TEX-Q (Figure 2). Firstly, we distinguished probabilistic expectations, describing realistic assumptions about what is likely to happen (e.g., expecting symptom improvement) from value-based expectations, describing more affective, less rational feelings like hopes or fears (e.g., hoping to be pain-free). Secondly, we distinguished expectations about beneficial outcomes (e.g., treatment success) from expectations about harmful outcomes (e.g., complications). Thirdly we distinguished expectations about direct, symptom-related treatment outcomes (e.g., benefit or side effects) from expectations about the broader impacts of the treatment (e.g., improved quality of life or reduced functioning). The eight terms depicted in the central cells of the figure describe the resulting theorized subscales of the TEX-Q. In addition to the aforementioned scales measuring outcome expectations we included two subscales measuring expectations about the structure of the treatment itself. Those include process related expectations (e.g., a pleasant procedure) and the expected behavioural control of the treatment (e.g., being able to influence treatment success). In total this led to ten different theorized subscales for the TEX-Q. Although we are aware of the complexity of our structure, our rationale was to capture most potentially relevant aspects of expectations with predictive value for outcome.

<Insert Figure 2 here>

Literature review: Generation of item list

For generic treatment expectation scales, our systematic search strategy identified 9312 articles.
Our additional search strategy for scales assessing expectations about specific treatments lead to the inclusion of further 33 relevant articles, resulting in a total of 9345 articles. After the removal of duplicates, 7888 records remained. The screening of titles and abstracts lead to the exclusion of 7849 articles that did not mention instruments measuring expectations. After assessment of the remaining 40 articles in full text, one article was excluded for not presenting an expectation measurement. A detailed overview of the review process is depicted in the PRISMA flowchart in Appendix B (Figure 3). The search strategies resulted in 39 articles containing 38 different relevant scales in total, of which 13 where multidimensional and 25 were unidimensional, the latter relating to 16 different treatments. Table 1 provides a comprehensive list of all scales found. The scales contained a total of 583 relevant items that provided inspiration for our primary item pool.

Based on this list, all authors took part in an iterative open discussion about the construction of the scale and its potential items. In that process, we reformulated several items to make them applicable for a generic questionnaire and constructed additional ones. With the deletion of duplicate items as well as those we consensually found to not fit our conceptual model. We then selected 78 Items that provided the basis for the further validity testing of the TEX-Q.

Expert-ratings: Evaluation of content validity

The ratings showed a high level of approval for our items, with each global rating ranging between 4.0 and 5.9 (M = 4.35, SD = .30) on a 6-point likert-scale. All items were rated as comprehensible (range:

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4.5 – 5.9, *M* = 4.55, *SD* = .31) and fitting our theoretical framework (range: 4.9 - 6.0, *M* = 4.32, *SD* = .21).

The commentary section of the ratings contained criticism about the wording of several items. Eight different items were supposed to double-load on more than one of the theoretical subdimensions. In 15 items the use of technical terms, e.g. *functionality (*German: *Funktionsfähigkeit)*, and *adverse effects (negative Effekte)*, were criticized for being potentially difficult to understand for patients. The synonymous use of different verbs for expectations and hopes, e.g., *to hope (hoffen)* and *to wish for (sich wünschen)* was identified as a problem.

The rating results guided the further discussion process in the research team that resulted in the rewording of several items and a ranking of the items for each subscale according to the received rating and its variance. It was followed with a reduction to 53 items with 5-6 items per subscale by consensual decision in the research team.

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Table 1: Comprehensive list of scales measuring patients' treatment expectations

Instrument	Treatment specificity	Dimensionality	No. of relevant items
Illness Perception Questionnaire IPQ-R/B-IPQ (30, 31)	Generic	Multi	32
Milwaukee Psychotherapy Expectancies Questionnaire M-PEQ (32)	Generic	Multi	13
Patient Centered Outcomes Questionnaire PCOQ (33)	Generic	Multi	5
Patient Questionnaire on Therapy Expectation and Evaluation PATHEV (34)	Generic	Multi	7
Questionnaire for Patients' Expectations of Healthcare QPEHC (16)	Generic	Multi	36
Credibility/Expectancy Questionnaire CEQ (35)	Generic	Single	6
Expectations for Activities of Daily Living ADL-E (36)	Generic	Single	22
Expected illness-related disability PDI-E (37)	Generic	Single	7
General Assessment of Expected Side Effects Scale GASE-EXPECT (38)	Generic	Single	36
General Self-Efficacy Scale GSE (39)	Generic	Single	10
Life-Orientation-Test LOT-R (40)	Generic	Single	6
Physical Functioning Quality of Life Component Score PCS-E (41)	Generic	Single	13
Positive Health Expectations Scale PHES (20)	Generic	Single	7
Stanford Expectations of Treatment Scale SETS (42)	Generic	Single	9
Treatments Representations Inventory TRI (43)	Generic	Single	28
Expectations About Counseling - Brief Form EACB (44)	Specific	Multi	66
Expectations of Gynecological Treatment Questionnaire EGTQ (45)	Specific	Multi	24
Exercise Outcomes Expectations Questionnaire EOE-Q (46)	Specific	Multi	20
Expectations Towards ICD therapy EXPECT-ICD (47)	Specific	Multi	10
Orthodontic Treatment Expectations (48)	Specific	Multi	15
Self-Efficacy Expectations and Outcome Expectations SE- & OE-ICD (49)	Specific	Multi	17
Smoking Abstinence Expectancies Questionnaire SAEQ (50)	Specific	Multi	28
Psychosocial Treatment Expectations Questionnaire PTEQ (51)	Specific	Multi	13
Acupuncture expectancy scale AES (52)	Specific	Single	7
Anaesthesiological Questionnaire ANP-E (53)	Specific	Single	17
Cardiac Surgery Patient Expectations Questionnaire C-SPEQ (54)	Specific	Single	20
Chiropractic Patients' Expectations (55)	Specific	Single	15
Control Attitudes Scale-Revised CAS-R (56)	Specific	Single	3
Expectations for Complementary and Alternative Medicine Treatments Questionnaire EXPECT (57)	Specific	Single	13
Expectations Questionnaire EQ (58)	Specific	Single	6
Future Expectations Regarding Life with Heart Disease scale FERLHDS (59)	Specific	Single	18
Hospital for Special Surgery Knee Surgery Expectations Survey KSES (19)	Specific	Single	23
Knee Self-Efficacy Scale K-SES (60)	Specific	Single	22
Musculoskeletal Outcomes Data Evaluation and Management System MODEMS (61)	Specific	Single	6
New Knee Society Knee Scoring System NKSSS (62)	Specific	Single	8
Patient Shoulder Outcome Expectancies PSOE (63)	Specific	Single	3
Sample Patient Questionnaire SPQ (64)	Specific	Single	12
Treatment-specific Optimism TSO (65)	Specific	Single	10

Notes. Multi = several expectation dimensions are each assessed by an independent scale; *Single* = only one expectation dimension is assessed; *Generic* = not directly referring to a specific treatment, *Specific* = directly referring to a specific treatment. The format of the table has been adapted from Laferton et al. (18).

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Cognitive interviews: Evaluation of comprehensibility and acceptance

The qualitative analysis of patients' treatment expectations identified eight major expectation themes. Of these, six themes fitted our theoretical model, with 60 statements that could clearly be assigned to one of the hypothesized sub-dimensions of the TEX-Q. The two other themes were the absence of expectations (e.g., "I do not expect anything in particular", ID: 1001) with 11 mentions, and an unspecific feeling of stress about the treatment mentioned two times (e.g. "I am tense how this will proceed" ID: 1003). The results of this analysis was interpreted as support for our conception of the TEX-Q. Therefore this conception was retained for the construction of the scale.

The analysis of criticism about the items, derived from the interview transcripts as well as the interviewers' notes, lead to identification of four major aspects of criticism. Each of these aspects had implications for the presentation and phrasing of the TEX-Q that directly informed our construction of the scales' initial version (Table 2). Furthermore, various item-level criticisms on the content and wording of specific items were identified as minor themes of criticism and lead to a modification or deletion of the respective items.

Table 2: Aspects of qualitative analysis & consequences for questionnaire development

Aspects of criticism	Illustrative examples	Implications for development process
Aspect 1: Commentary on the preferred wording of the anchors of the likert-scales	**"The anchors don't match the question, seems like they are asking for two different things in one question."** Commentary about Item 2b: How much improvement in your condition do you expect? Anchors: 0 (no change)/10 (largest possible improvement) (ID: 1002)	➢ Changing the anchors to every item ➢ Using the same specific phrasing for the low and the high anchor
Aspect 2: Comparison of analogue phrasings for key constructs *to hope/ to expect/ to fear* with phrasings like *to think* or *to whish*	**"To wish for something isn't reality, you can wish for inaccessible things, to hope for something is more realistic.''** (ID: 1004)	➢ Only using "to hope", "to expect" and "to fear" in every item ➢ Deleting all analogical phrases
Aspect 3: Evaluation of the theoretical differentiation between probabilistic and value-based expectation	**"To expect and to hope are different from each other. You can hope for a lot more than expect. To expect is more realistic."** (ID: 1009)	➢ Retaining the differentiation between hope and expect
Aspect 4: Comparison of two different versions of exemplary items: *change-question-* or *statement-*formulation	**"The phrasing of 24a triggers burdens when you're at the beginning of the treatment, 24b doesn't trigger burdens.'** Commentary about item 24a) vs. 24b): 24a) I expect to be burdened by the treatment. 24b) How much burden do you expect your treatment will cause? (ID: 1005)	➢ Inconclusive preferences among the interviewees ➢ Choosing *change-question* format for better acceptability & comprehensibility in some items
Item-level criticism: Commentary on the content or wording of specific items	**"Item sounds like it is just for psychotherapy."** Commentary about item 15: I expect to take part more actively in social life due to treatment. (ID: 1007)	➢ Rewording of items ➢ Deletion of items ➢ Consideration in the discussion about the final item-selection

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The Treatment Expectation Questionnaire

After completion of the aforementioned steps of gathering empirical evidence, the construction of the initial TEX-Q version was accomplished in a final item selection process. It contains 35 items on the 10 different subscales derived from our theoretical model with 3-4 items in each subscale. Every item contains either the verb to expect, to hope or to fear and is formulated as a question asking for the amount of change the patients expect to experience following their treatment. Each item is presented on a 10-point-likert-scale with specific anchors, the lower anchor always indicating no expected change. Example items for each subscale of the TEX-Q in preliminary translation are shown in table 3.

Table 3: Illustrative TEX-Q items for each subscale

Expected benefits												
How much relief do you expect in your symptoms?												
no relief	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	greatest relief imaginable
Expected positive impact												
How much improvement do you expect regarding your daily life (e.g., occupation, household, social life)?												
no improvement	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	greatest improvement imaginable
Expected harm												
To what extent do you expect risks from your treatment?												
no risks	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	greatest risks imaginable
Expected negative impact												
To what extent do you expect your quality of life will be impeded?												
no impediment	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	greatest impediment imaginable
Desired benefits												
How much benefit do you hope for from this treatment?												
no benefit	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	greatest benefit imaginable
Desired impact												
How much improvement do you hope for considering your emotional state?												
no improvement	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	greatest improvement imaginable
Feared harm												
To what extent do you fear risks from the treatment?												
no risk	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	greatest risk imaginable
Feared negative impact												
How much of an impediment do you expect considering your responsibilities (e.g. at home, at work, in the family)?												
no impediment	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	greatest impediment imaginable
Process related expectations												
To what extent do you expect to be satisfied with the treatment process?												
not satisfied at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	most satisfying process imaginable
Expected behavioural control of the treatment												
How much do you expect your behaviour can influence treatment success?												
no influence	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	greatest influence imaginable

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Discussion

This study describes the successful development of the Treatment Expectation Questionnaire (TEX-Q), a new scale for generically and multidimensionally measuring expectations of medical or psychological treatments. To accomplish this, an elaborate development process was necessary that incorporated the complex and diverse literature and evidence on expectations. The final TEX-Q will be available in German and English after psychometric evaluation. The scale is based on a comprehensive review of literature that provided an overview of existing treatment expectation scales and items. The evidence gathered from the review empirically validated our integrative model of patient expectations (18) as well as our conceptualization for the TEX-Q with 10 sub-dimensions derived from it. In line with our results, our model has further been empirically supported by a recent systematic review of expectation measurement in orthopedic surgery (66). Few generic multidimensional scales, but several good treatment-specific measures were found and served as a source for our items. These items were modified and reformulated in the course of the development of the scale. This was informed by feedback from external experts in the field of placebo-, psychosomatic and clinical psychology research and by patient feedback.

The TEX-Q has advantages over previous measures of treatment expectations. Its fully generic nature enables the comparability of assessments across different treatments and conditions. It thus presents an advantage over treatment specific measurements as well as generic scales with limited scope, such as scales limited to psychotherapy (32, 34), scales solely focusing expectations regarding symptoms (i.e. pain), but not expectations regarding a broader impact on life (i.e. quality of life) (33, 67). It furthermore has a theory-based, multidimensional structure, covering different aspects of treatment expectations about symptom change, possible adverse events and the broader impact of the treatment and its process. This distinguishes the TEX-Q from established generic instrument like the Questionnaire for Patient Expectations of Health Care (16), which mostly focuses on expectations about the structure and process of the treatment process or the Credibility/Expectancy Questionnaire (35) and the newly developed Expectation for Treatment Scale (68), which only assess positive outcome expectations.

Several issues within the development process need to be considered. A major challenge of developing a generic measure of treatment expectations was that it was impossible, at least empirically, to take every possible medical application specifically into account. While the scale could be developed and tested in a variety of different clinical settings, involving different surgical as well as psychological treatments, further settings, like pharmacological or physical therapy treatments, could have been beneficial. The development might therefore have been shaped by the treatments of patients interviewed, as well as other conditions of the development process, such as the limited scope of the research team or the experts involved for feedback. In future, we will test the TEX-Q in additional clinical settings to further broaden the empirical basis for the argument of the generic applicability of the TEX-Q. Another limitation lies on the conceptual level. Further expectation constructs mentioned by some authors had to be excluded from the TEX-Q for the sake of feasibility and applicability. Especially the work of Bowling et al. (16) is to be mentioned here, whose focus on treatment process expectations allowed them a more nuanced assessment, e.g. including items on expectations about the doctor-patient communication style or information provision. Another aspect is the exclusion of expectations about the *timeline* of the treatment and effects caused by it, e.g. their duration and

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sustainability. While it was hoped initially the TEX-Q that could measure such expectations, it was not feasible at the item level to ask for the many possible treatment trajectories.

The development of the TEX-Q facilitates a broad range of possibilities for future research, both in the evaluation and further development of the scale itself, as well as its use in applied research. Further validation of the scale in different clinical settings is necessary to confirm the psychometric properties of the TEX-Q. Other planned steps include the development of a brief version, evaluation of sensitivity to change and translation of the scale into other languages. An important contribution of the TEX-Q is that it will enable a comparison of the data gathered across studies on different conditions and treatments. Thereby, it will produce integrated evidence leading to further knowledge about the role of patients' treatment expectations. Furthermore, the subscales of the TEX-Q can be used to further differentiate the effects of the aspects of treatment expectations between conditions and treatment outcomes. The knowledge gained can also contribute to the development of interventions designed to use expectation related placebo effects to improve outcomes of everyday clinical practices.

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Literature

1. Mondloch MV, Cole DC, Frank JW. Does how you do depend on how you think you'll do? A systematic review of the evidence for a relation between patients' recovery expectations and health outcomes. Canadian Medical Association Journal. 2001;165(2):174-9.
2. Rief W, Glombiewski JA, Gollwitzer M, Schubo A, Schwarting R, Thorwart A. Expectancies as core features of mental disorders. Curr Opin Psychiatry. 2015;28(5):378-85.
3. Constantino MJ, Arnkoff DB, Glass CR, Ametrano RM, Smith JZ. Expectations. J Clin Psychol. 2011;67(2):184-92.
4. Enck P, Bingel U, Schedlowski M, Rief W. The placebo response in medicine: minimize, maximize or personalize? Nat Rev Drug Discov. 2013;12(3):191-204.
5. Colagiuri B, Zachariae R. Patient expectancy and post-chemotherapy nausea: a meta-analysis. Annals of Behavioral Medicine. 2010;40(1):3-14.
6. Jones F, Riazi A. Self-efficacy and self-management after stroke: a systematic review. Disability and rehabilitation. 2011;33(10):797-810.
7. Mahomed NN, Liang MH, Cook EF, Daltroy LH, Fortin PR, Fossel AH, et al. The importance of patient expectations in predicting functional outcomes after total joint arthroplasty. The Journal of rheumatology. 2002;29(6):1273-9.
8. van den Akker-Scheek I, Stevens M, Groothoff JW, Bulstra SK, Zijlstra W. Preoperative or postoperative self-efficacy: which is a better predictor of outcome after total hip or knee arthroplasty? Patient Education and Counseling. 2007;66(1):92-9.
9. Smeets RJ, Beelen S, Goossens ME, Schouten EG, Knottnerus JA, Vlaeyen JW. Treatment expectancy and credibility are associated with the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. The Clinical Journal of Pain. 2008.
10. Auer CJ, Glombiewski JA, Doering BK, Winkler A, Laferton JAC, Broadbent E, et al. Patients' Expectations Predict Surgery Outcomes: A Meta-Analysis. Int J Behav Med. 2016;23(1):49-62.
11. Juergens MC, Seekatz B, Moosdorf RG, Petrie KJ, Rief W. Illness beliefs before cardiac surgery predict disability, quality of life, and depression 3 months later. Journal of psychosomatic research. 2010;68(6):553-60.
12. Shedden-Mora MC, Nestoriuc Y, Rief W. Lessons learned from placebo groups in antidepressant trials. Philos Trans R Soc Lond B Biol Sci. 2011;366(1572):1879-88.
13. Nestoriuc Y, von Blanckenburg P, Schuricht F, Barsky AJ, Hadji P, Albert U-S, et al. Is it best to expect the worst? Influence of patients' side-effect expectations on endocrine treatment outcome in a 2-year prospective clinical cohort study. Annals of Oncology. 2016;27(10):1909-15.
14. Nestoriuc Y, Orav EJ, Liang MH, Horne R, Barsky AJ. Prediction of nonspecific side effects in rheumatoid arthritis patients by beliefs about medicines. Arthritis Care Res (Hoboken). 2010;62(6):791-9.
15. van Hartingsveld F, Ostelo RW, Cuijpers P, de Vos R, Riphagen II, de Vet HC. Treatment-related and patient-related expectations of patients with musculoskeletal disorders: a systematic review of published measurement tools. The Clinical Journal of Pain. 2010;26(6):470-88.
16. Bowling A, Rowe G, Lambert N, Waddington M, Mahtani K, Kenten C, et al. The measurement of patients' expectations for health care: a review and psychometric testing of a measure of patients' expectations: Prepress Projects Limited; 2012.
17. Zywiel MG, Mahomed A, Gandhi R, Perruccio AV, Mahomed NN. Measuring expectations in orthopaedic surgery: a systematic review. Clin Orthop Relat Res. 2013;471(11):3446-56.
18. Laferton JAC, Kube T, Salzmann S, Auer CJ, Shedden-Mora MC. Patients' Expectations Regarding Medical Treatment: A Critical Review of Concepts and Their Assessment. Front Psychol. 2017;8:233.
19. Mancuso CA, Sculco TP, Wickiewicz TL, Jones EC, Robbins L, Warren RF, et al. Patients' expectations of knee surgery. JBJS. 2001;83(7):1005-12.
20. Leedham B, Meyerowitz BE, Muirhead J, Frist WH. Positive expectations predict health after heart transplantation. Health Psychology. 1995;14(1):74.

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21. Maddux J. Expectations and health. Cambridge Handbook of Psychology, Health and Medicine. 2007:87-92.
22. Kirsch I. Response expectancy as a determinant of experience and behavior. Am Psychol. 1985;40(11):1189-202.
23. Leventhal H, Meyer D, Nerenz D. D.(1980). The common sense represen tation of illness danger. Medical Psychology New York: Pergamon. 1980.
24. Cameron LD, Leventhal H. The self-regulation of health and illness behaviour: psychology press; 2003.
25. Colagiuri B, Zachariae R. Patient expectancy and post-chemotherapy nausea: a meta-analysis. Ann Behav Med. 2010;40(1):3-14.
26. Fadyl J, McPherson K. Return to work after injury: a review of evidence regarding expectations and injury perceptions, and their influence on outcome. J Occup Rehabil. 2008;18(4):362-74.
27. Haanstra TM, van den Berg T, Ostelo RW, Poolman RW, Jansma IP, Cuijpers P, et al. Systematic review: do patient expectations influence treatment outcomes in total knee and total hip arthroplasty? Health and quality of life outcomes. 2012;10(1):152.
28. Beatty PC, Willis GB. Research Synthesis: The Practice of Cognitive Interviewing. Public Opinion Quarterly. 2007;71(2):287-311.
29. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77-101.
30. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception questionnaire. Journal of psychosomatic research. 2006;60(6):631-7.
31. Moss-Morris R, Weinman J, Petrie K, Horne R, Cameron L, Buick D. The Revised Illness Perception Questionnaire (IPQ-R). Psychology & Health. 2002;17(1):1-16.
32. Norberg MM, Wetterneck CT, Sass DA, Kanter JW. Development and psychometric evaluation of the Milwaukee Psychotherapy Expectations Questionnaire. Journal of clinical psychology. 2011;67(6):574-90.
33. Robinson ME, Brown JL, George SZ, Edwards PS, Atchison JW, Hirsh AT, et al. Multidimensional success criteria and expectations for treatment of chronic pain: the patient perspective. Pain Medicine. 2005;6(5):336-45.
34. Schulte D. Patients' outcome expectancies and their impression of suitability as predictors of treatment outcome. Psychotherapy Research. 2008;18(4):481-94.
35. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. Journal of behavior therapy and experimental psychiatry. 2000;31(2):73-86.
36. Dohnke B, Müller-Fahrnow W, Knäuper B. Der Einfluss von Ergebnis-und Selbstwirksamkeitserwartungen auf die Ergebnisse einer Rehabilitation nach Hüftgelenkersatz. Zeitschrift für Gesundheitspsychologie. 2006;14(1):11-20.
37. Laferton JAC, Shedden-Mora MC, Auer CJ, Moosdorf R, Rief W. Enhancing the efficacy of heart surgery by optimizing patients' preoperative expectations: study protocol of a randomized controlled trial. American heart journal. 2013;165(1):1-7.
38. von Blanckenburg P, Schuricht F, Albert U-S, Rief W, Nestoriuc Y. Optimizing expectations to prevent side effects and enhance quality of life in breast cancer patients undergoing endocrine therapy: study protocol of a randomized controlled trial. BMC Cancer. 2013;13(1):426.
39. Schwarzer R, Jerusalem M. The general self-efficacy scale (GSE). Anxiety, Stress, and Coping. 2010;12:329-45.
40. Scheier MF, Carver CS. Optimism, coping, and health: assessment and implications of generalized outcome expectancies. Health psychology. 1985;4(3):219.
41. Powell R, Johnston M, Smith WC, King PM, Chambers WA, Krukowski Z, et al. Psychological risk factors for chronic post-surgical pain after inguinal hernia repair surgery: a prospective cohort study. European journal of pain. 2012;16(4):600-10.
42. Younger J, Gandhi V, Hubbard E, Mackey S. Development of the Stanford Expectations of Treatment Scale (SETS): a tool for measuring patient outcome expectancy in clinical trials. Clin Trials. 2012;9(6):767-76.

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43. Hirani SP, Patterson DL, Newman SP. What do coronary artery disease patients think about their treatments? An assessment of patients' treatment representations. Journal of health psychology. 2008;13(3):311-22.
44. Tinsley H. Expectations About Counseling: Unpublished test manual. Carbondale, IL: Southern Illinois University at Carbondale, Department of Psychology. 1982.
45. Marchant-Haycox S, Liu D, Nicholas N, Salmon P. Patients' expectations of outcome of hysterectomy and alternative treatments for menstrual problems. Journal of behavioral medicine. 1998;21(3):283-97.
46. Gecht MR, Connell KJ, Sinacore JM, Prohaska TR. A survey of exercise beliefs and exercise habits among people with arthritis. Arthritis & Rheumatology. 1996;9(2):82-8.
47. Habibovic M, Pedersen SS, van den Broek KC, Denollet J. Monitoring treatment expectations in patients with an implantable cardioverter-defibrillator using the EXPECT-ICD scale. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology. 2014;16(7):1022-7.
48. Bos A, Hoogstraten J, Prahl-Andersen B. Expectations of treatment and satisfaction with dentofacial appearance in orthodontic patients. American journal of orthodontics and dentofacial orthopedics. 2003;123(2):127-32.
49. Dougherty CM, Johnston SK, Thompson EA. Reliability and validity of the self-efficacy expectations and outcome expectations after implantable cardioverter defibrillator implantation scales. Applied nursing research. 2007;20(3):116-24.
50. Abrams K, Zvolensky MJ, Dorman L, Gonzalez A, Mayer M. Development and validation of the smoking abstinence expectancies questionnaire. Nicotine & Tobacco Research. 2011;13(12):1296-304.
51. de Carvalho Leite JC, Seminotti N, Freitas PF, de Lourdes Drachler M. The Psychosocial Treatment Expectations Questionnaire (PTEQ) for Alcohol Problems. European Journal of Psychological Assessment. 2011.
52. Mao JJ, Armstrong K, Farrar JT, Bowman MA. Acupuncture expectancy scale: development and preliminary validation in China. Explore: The Journal of Science and Healing. 2007;3(4):372-7.
53. Hüppe M, Klotz K-F, Heinzinger M, Prüßmann M, Schmucker P. Beurteilung der perioperativen Periode durch Patienten Erste Evaluation eines anästhesiologischen Nachbefragungsbogens. Der Anaesthesist. 2000;49(7):613-24.
54. Holmes SD, Fornaresio LM, Miller CE, Shuman DJ, Ad N. Development of the cardiac surgery patient expectations questionnaire (C-SPEQ). Quality of Life Research. 2016;25(8):2077-86.
55. Sigrell H. Expectations of chiropractic patients: the construction of a questionnaire. Journal of manipulative and physiological therapeutics. 2001;24(7):440-4.
56. Moser DK, Riegel B, McKinley S, Doering LV, Meischke H, Heo S, et al. The Control Attitudes Scale-Revised: Psychometric evaluation in three groups of cardiac patients. Nursing research. 2009;58(1):42.
57. Jones SM, Lange J, Turner J, Cherkin D, Ritenbaugh C, Hsu C, et al. Development and Validation of the EXPECT Questionnaire: Assessing Patient Expectations of Outcomes of Complementary and Alternative Medicine Treatments for Chronic Pain. J Altern Complement Med. 2016;22(11):936-46.
58. Razmjou H, Finkelstein JA, Yee A, Holtby R, Vidmar M, Ford M. Relationship between preoperative patient characteristics and expectations in candidates for total knee arthroplasty. Physiotherapy Canada. 2009;61(1):38-45.
59. Axelrad KJ. Locus of control and causal attributions as they relate to expectations for coping with a heart attack. 1982.
60. Thomeé P, Währborg P, Börjesson M, Thomeé R, Eriksson BI, Karlsson J. A new instrument for measuring self-efficacy in patients with an anterior cruciate ligament injury. Scandinavian Journal of Medicine & Science in Sports. 2006(16):181-7.
61. Tashjian RZ, Bradley MP, Tocci S, Rey J, Henn RF, Green A. Factors influencing patient satisfaction after rotator cuff repair. Journal of shoulder and elbow surgery. 2007;16(6):752-8.

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62. Noble PC, Scuderi GR, Brekke AC, Sikorskii A, Benjamin JB, Lonner JH, et al. Development of a new Knee Society scoring system. Clinical Orthopaedics and Related Research®. 2012;470(1):20-32.
63. O'Malley KJ, Roddey TS, Gartsman GM, Cook KF. Outcome expectancies, functional outcomes, and expectancy fulfillment for patients with shoulder problems. Medical care. 2004;42(2):139-46.
64. Habib SB, Sonoda L, See TC, Ell PJ, Groves AM. How do patients perceive the benefits and risks of peripheral angioplasty? Implications for informed consent. Journal of Vascular and Interventional Radiology. 2008;19(2):177-81.
65. Cohen L, de Moor C, Amato RJ. The association between treatment-specific optimism and depressive symptomatology in patients enrolled in a Phase I cancer clinical trial. Cancer. 2001;91(10):1949-55.
66. Cortes A, Meints SM, Katz JN. Characterizing the Use of Expectations in Orthopedic Surgery Research: A Scoping Review. ACR Open Rheumatol. 2019;1(7):440-451.
67. Page MG, Ziemianski D, Martel MO, Shir Y. Development and validation of the Treatment Expectations in Chronic Pain Scale. Br J Health Psychol. 2019;24(3):610-28.
68. Barth J, Kern A, Luthi S, Witt CM. Assessment of patients' expectations: development and validation of the Expectation for Treatment Scale (ETS). BMJ Open. 2019;9(6):e026712.

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Patient consent for publication
Obtained.

Data sharing statement
Datasets and statistical codes are available from the figshare-repository at https://figshare.com/projects/TEX-Q/72347.

Author Statement
JA was involved in the conception of the scale, data acquisition, data analysis and interpretation, the writing of first draft and revision. BL was involved in the conception of the scale, data interpretation and the revising of the manuscript. MG was involved in the data acquisition, data analysis and interpretation, and the revising of the manuscript. KP was involved in the conception of the scale, data interpretation and the revising of the manuscript. JL was involved in the conception of the scale, data interpretation and the revising of the manuscript. YN was involved in the scale conception, data interpretation and critically revised the manuscript. MSM was involved in the conception of the scale, data acquisition, data analysis and interpretation, the writing of first draft and revision. All authors approved the final version of this manuscript.

Figure Legends

Figure 1: Figure 1: Overview of the development process

Figure 2: Conceptual structure of the TEX-Q treatment expectation scales.
Note. Cells describe the theorized subscales of the TEX-Q.

Figure 3: Prism flowchart of the literature search

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APPENDIX

A: Description of the literature review

Databases: Pubmed, Psycinfo (through OVID)

Filter: Adult (19+) AND human AND English AND 1900-current

Search terms: (((treat* OR therap*) AND (measure* OR assess* OR diagnost* OR questionnaire OR scale OR instrument) AND (expectation* OR expectanc*)).ti,ab.) NOT ((life expectancy).ti,ab.)

B: PRISMA-Flowchart

<Insert Figure 3 here>

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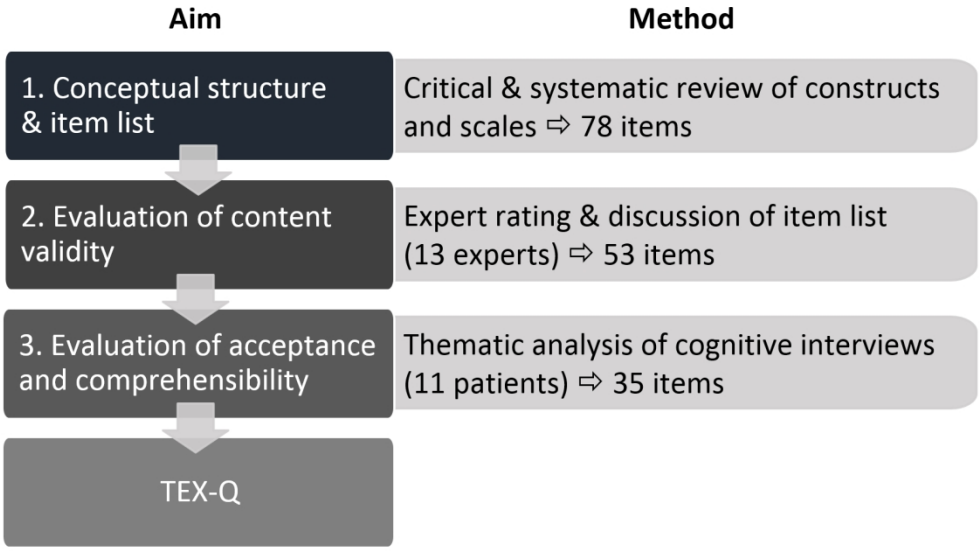

Figure 1: Overview of the development process

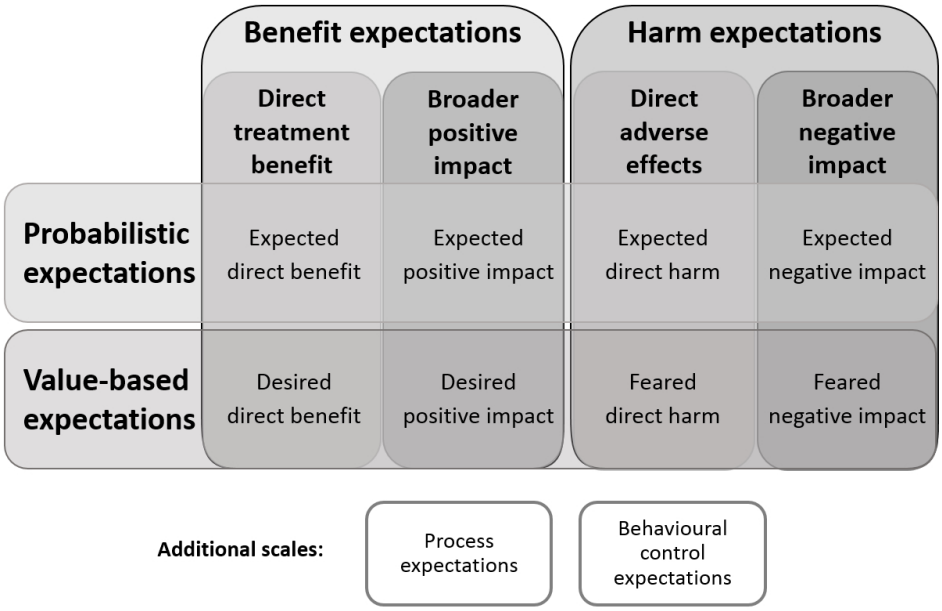

Figure 2: Conceptual structure of the TEX-Q treatment expectation scales.
Note. Cells describe the theorized subscales of the TEX-Q.

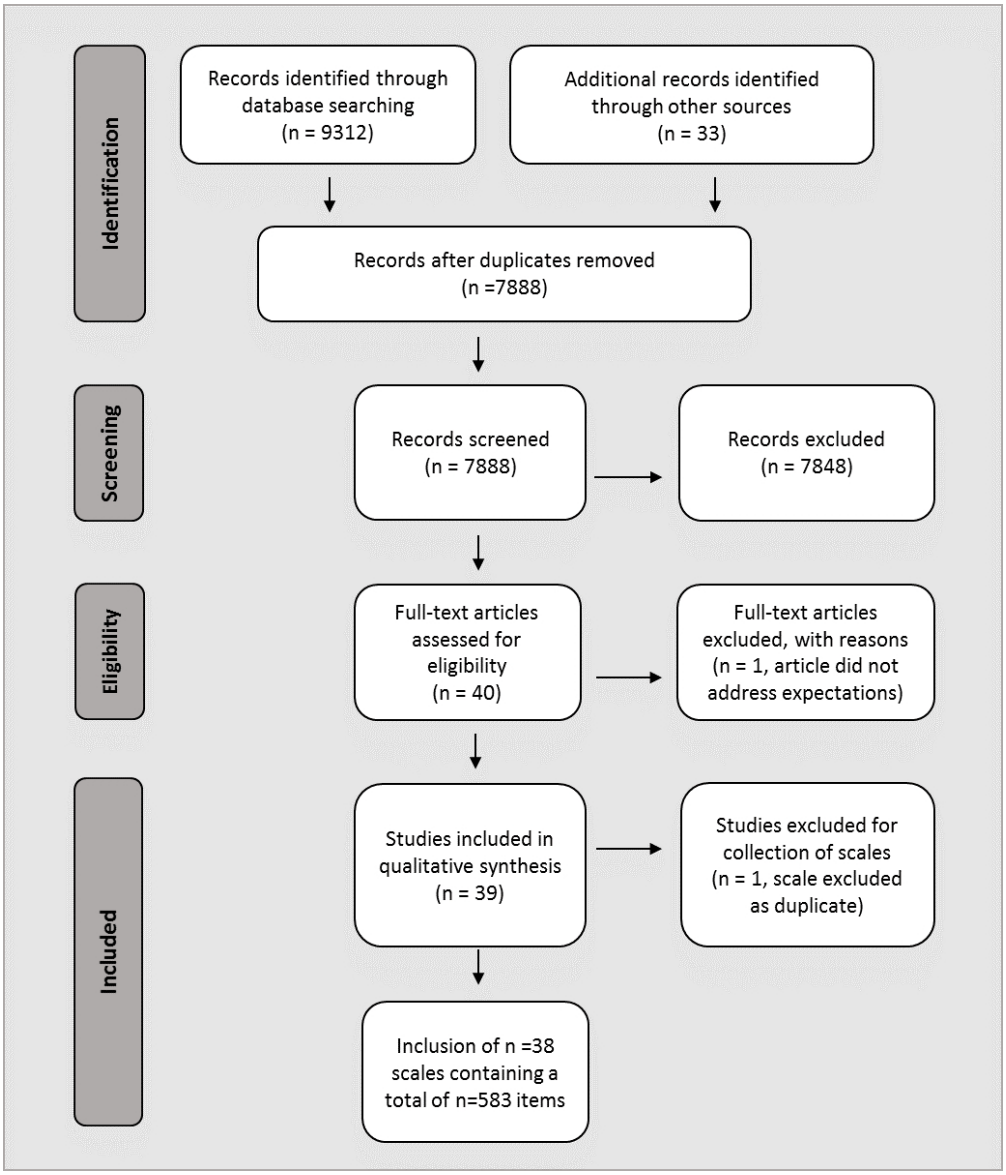

Figure 3: Prism flowchart of the literature search

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Development of the generic, multidimensional Treatment Expectation Questionnaire (TEX-Q) through systematic literature review, expert surveys and qualitative interviews

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Development of the generic, multidimensional Treatment Expectation Questionnaire (TEX-Q) through systematic literature review, expert surveys and qualitative interviews

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Abstract

Objectives: Patients´ expectations - as a central mechanism of placebo and nocebo effects - are an important predictor of health outcomes. However, the lack of a way to assess expectations across different settings restricts progress in understanding the role of expectations and to quantify their importance in medical and psychological treatments. The aim of this study was to develop a theory-based, generic, multidimensional measure assessing patient expectations of medical and psychological treatments.

Design: The Treatment Expectation Questionnaire (TEX-Q) was developed based on the Integrative Model of Expectations (Laferton, Kube, Salzmann, Auer & Shedden-Mora, 2017) and a systematic literature review of treatment expectation scales. After creating a comprehensive item pool, the scale was further refined by the use of expert ratings, and patient interviews.

Setting: Patients were recruited in primary care at two hospitals in Hamburg, Germany.

Participants: 13 scientific experts participated in the expert survey. 11 patients waiting for psychological or surgical treatments participated in the qualitative interviews.

Results: The 2x2x2 multidimensional structure of the TEX-Q assesses two expectation constructs (probabilistic vs. value-based) across two outcome domains with two valences (direct benefits and adverse events, broader positive and negative impact), plus process and behavioural control expectations. We examined 583 items from 38 scales identified in the systematic review, and developed 78 initial items. Content validity was then rated by experts according to item fit and comprehensibility. The best 53 items were further evaluated for comprehensibility, acceptability, phrasing preference and understanding by interviewing patients prior to treatment using the "think aloud"-technique. This resulted in a first 35-item version of the TEX-Q.

Conclusions: The TEX-Q is a generic, multidimensional measure to assess patient expectations of medical and psychological treatments and allows comparing the impact of multidimensional expectations across different conditions. The final TEX-Q will be available after psychometric validation.

Keywords: expectations, expectancy, scale, assessment, placebo, nocebo

Article Summary

Strength and limitations of this study

- Construction of a generic, multidimensional scale measuring patients´ treatment expectations
- Conceptual model contains eight subscales for outcome expectations and two process expectations
- Three-step empirical process: systematic review, expert ratings & cognitive patient interviews
- Generation & iterative reformulation of items informed by the empirical steps
- Generic nature of the TEX-Q needs further research in additional clinical settings

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Introduction

Patients' treatment expectations are an important predictor of outcome for a broad range of medical and psychological treatments (1-3). As non-specific treatment components, they can induce subjective and psychological changes and are a central mechanism driving placebo and nocebo effects (4). Positive treatment expectations have been linked to health outcomes for a variety of different illnesses and treatments including cancer (5), stroke (6), musculoskeletal disorders (7, 8), pain (9), surgery (10, 11), antidepressant medication (12), and psychotherapy (3). Furthermore, negative expectations have been linked to the occurrence of adverse events in the treatment of a number of illnesses (5, 13, 14). Generally, studies find a moderate overall effect of patients' expectations on outcomes (15, 16).

The large number of treatment expectation measures has been identified as an important limitation for the integration of the existing evidence across different treatments and diseases in several systematic reviews (1, 15-17). On the level of assessment, this stems from most studies developing a single treatment or disease measure of expectations (18) often using single-item or very brief non-validated ad-hoc instruments (10, 15). Other questionnaires only assess partial aspects of expectations, e.g., only positive expectations (19) or do not distinguish between the type of expectation assessed (20).

On the conceptual level, there is a diversity of underlying theories on expectations, being one of the most studied constructs in psychology (21). The theoretical conception of the TEX-Q is based on our *Integrative Model of Expectations* in patients undergoing medical treatment (18), and on an extensive review of the expectation literature. The model defines treatment expectations as future-directed cognitions that focus on the incidence or non-incidence of a specific event or experience. In general, it distinguishes between *probabilistic* expectations, describing realistic estimations about the future, and *ideal* or *value-based* expectation, describing what someone would like or dislike to happen (e.g. hopes, fears). It defines *treatment expectations* in distinction from *behavioral expectations* about the subjective control over the treatment as well as generalized expectations (e.g., generalized self-efficacy, optimism) and expectations about the timeline of diseases, treatments, behavior or related outcomes. Regarding treatment expectations, the model distinguishes between *outcome-related expectations* about benefits and side-effects of the treatment and *structural and process-related expectations* about the course of the treatment itself. Furthermore, it differentiates outcomes continuously ranging from internal effects (e.g., symptom improvement) to external effects (e.g., impact on patients' social life). The *Integrative Model* itself aims to integrate several central expectation theories. For further conceptual clarity, two of those theories with high relevance for the development of the TEX-Q are discussed in more detail.

The most central understanding of treatment expectations was provided by Kirsch's *Response Expectancy Theory* (22). Here he distinguishes between two kinds of general *outcome expectations*: *stimulus expectancies,* which are a person's expectation of external stimuli as an outcome, and *response expectancies,* which refer to a person´s expectations of a non-volitional internal response as an outcome. Response expectancies are particularly relevant in treatment contexts. They provide a description of patients' expectations in a broad range of treatment situations ranging from their position of passive recipients in some instances (e.g., expecting that taking metformin will lower your blood sugar in diabetes) to more active patient roles involving volitional health-directed behavior (e.g. expecting that changing your lifestyle will lower your blood sugar).

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Another important theory influencing the development of the TEX-Q is Leventhal's *Common Sense Model of Illness Representation* (23). This model describes patients' subjective representations of their illness and its consequences for their lives. It differentiates beliefs about the *causes* of the illness, its *timeline*, the *identity* of the illness through its associated symptoms and the possibility to *control* the illness through *personal behavior* and the *treatment* itself. The model does not refer to expectations explicitly, but they are regarded as important general constructs underlying illness beliefs (24). Thus, the model presents an elaborate differentiation of patients' illness and treatment beliefs that can also be applied as a framework for the differentiation of treatment expectations.

To facilitate a comprehensive understanding of treatment expectations and overcome the limitations of previous scales we developed the Treatment Expectation Questionnaire (TEX-Q). It was constructed with the following five aims: (1) The scale will be able to measure treatment expectations generically and comparably for different medical and psychological treatments; (2) The scale will be multidimensional, taking into account aspects of treatment expectations with potential predictive links to treatment outcomes; (3) The scale will be sensitive to change in order to capture effects of expectation management interventions; (4) The scale's conceptual framework is applicable for research and everyday clinical practice.

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Methods

Overview of the development process

The development process of the TEX-Q followed three main steps (see Figure 1): Firstly, we developed a conceptual structure for the TEX-Q and created a comprehensive item pool. This step was based on the Integrative Model of Expectations (18) and a systematic literature review of treatment expectation scales. Secondly, expert ratings were obtained to evaluate the items content validity. Thirdly, we conducted qualitative cognitive interviews with patients to evaluate the comprehensibility and acceptance of the items and the fit among our target population. Ethical approval was obtained from the Medical Chamber Hamburg, Germany. Informed consent was obtained from all participants of the study. The TEX-Q was developed in German. Preliminary English translations of its contents are used in this paper. A final translation will be available after the finalization of its psychometric validation.

Insert Figure 1 here

Figure 1: Overview of the development process

Conceptual structure & generation of item list

The conceptual structure of the TEX-Q was developed based on the most relevant expectation theories (22, 23) incorporated in our Integrative Model of Expectations (18). Our goal for the conceptual structure was to cover a relevant range of treatment-related expectation constructs with potential predictive value for outcome. At the same time, we aimed to include concepts that can be generically assessed.

First, a comprehensive list of existing scales relevant to the development process was assembled through a literature review of generic and treatment-specific scales. To do this we completed a systematic literature search of the PubMed and PsycINFO databases (last date of search: 01.08.2018). The search was designed to include all published articles describing empirical studies with adults that featured a scale to measure patient expectations written since 1900 in English language (for the specific search-term see Appendix A). The articles found were then screened in two steps, firstly regarding titles and abstracts and secondly regarding the full texts of the remaining articles. A review protocol can be obtained from the authors.

Second, the systematic review was complemented by a critical review of treatment-specific expectation scales. As a systematic review of treatment-specific scales would have by far exceeded reasonable capacities for our purpose, our approach was non-systematic. This review was based on our *Integrative Model of Expectations* (18), treatment-specific reviews of expectation scales (6, 10, 15, 17, 25-27) and treatment-specific scales identified in our search for generic scales. For all identified expectation scales, the references of the respective publications were screened and additional scales were included.

The identified scales were assessed in conjunction with our theoretical model to finalize the conceptual structure and subscales of the TEX-Q. The items from each identified scale provided the pool from which we selected our items. Through the exclusion of duplicates and items that did not fit with the model we created the first list of potential items for the TEX-Q.

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Evaluation of content validity

Our next empirical aim was the evaluation of content validity. To do this we sent our item list to 13 experts from the fields of placebo research, psychosomatic medicine and clinical psychology. They were requested to rate each item on a six-point-Likert scale according to: (1) comprehensibility, (2) fit to our theoretical construct (which we introduced attached to the rating), and (3) overall quality of the item. Furthermore, they were asked to provide open feedback for each item. After ranking the items for each dimension and taking into account the commentaries given, we decided on the inclusion and eventual rewording of the most appropriate items.

Evaluation of comprehensibility and acceptance – patient involvement

Next, we evaluated the comprehensibility of the items, their acceptability and fit to our model in a clinical sample. We therefore conducted cognitive interviews with patients. We recruited a convenience sample of 11 patients waiting for psychological or surgical treatments at the University Medical Center Hamburg-Eppendorf and the Schön Hospital Hamburg-Eilbek. In the selection of these patients for the interviews, we aimed to maximize the diversity of conditions and treatments. Patients were interviewed by male and female researchers with prior experience with this assessment (JA, MG). Data saturation was discussed regularly and data collection was continued until we found it to be sufficient within this sample.

Based on a semi-structured interview guide (see Appendix B), the patients were asked to complete the potential TEX-Q items, some of them in different phrasings to examine the differences, while speaking out their thoughts (thinking-aloud technique (28)). Furthermore, they were asked open questions about prior experiences and expectations with their symptoms and treatment and about specific aspects of the phrasing of the items. The interviews took about 1 hour each. The interviews were audio-recorded and the answers to the open questions were transcribed verbatim. Additionally, the researcher took field notes of any observed difficulty the patients had in filling out the questionnaire.

The transcripts and notes from the interviews were qualitatively analyzed using thematic analysis (29). Two different analyses were conducted. Firstly, we looked at how patients expressed their expectations throughout the interviews, examining their fit to our conceptual model. Secondly, we examined the material for all criticism about the questionnaire and its items. Categories for both analyses were created both deductively based on our conceptions and inductively derived from the interviews. The analyses of the interviews then informed the final discussion and selection process from which the research team chose the wording of the items for the TEX-Q.

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Results

Literature review: Conceptual model of the TEX-Q

The literature review generally provided additional support for the Integrative Model of Expectations (18), with all reviewed items fitting to one or more of the aspects of expectations differentiated in the model. Some of the scales reviewed, however, focused more specifically on one or more aspects of the model and therefore introduced additional, more nuanced differentiations within it. Our rationale was to capture the most potentially relevant aspects of this expectations with predictive value for outcome in the TEX-Q. Hence, we developed a 2x2x2 concept to operationalize outcome expectations in the questionnaire (Figure 2).

Firstly, we distinguished probabilistic expectations, describing realistic assumptions about what is likely to happen (e.g., expecting symptom improvement) from value-based expectations, describing more affective, less rational feelings like hopes or fears (e.g., hoping to be pain-free). Our rational here was to capture the potentially different predictive value of these expectation constructs as theorized in the literature (16, 18). Secondly, we distinguished expectations about beneficial outcomes (e.g., treatment success) from expectations about harmful outcomes (e.g., complications). This inclusion was based on empirical evidence from the literature pointing to these aspects being separate dimensions rather than two sides of a unidimensional structure (30). Thirdly, we distinguished expectations about direct, symptom-related treatment outcomes (e.g., benefit or side effects) from expectations about the broader impacts of the treatment (e.g., improved quality of life or reduced functioning). We thereby introduced a categorial operationalisation of the range of possible treatment outcomes described in the Integrative Model of Expectations as relevant for different treatment outcomes to secure generic applicability (18, 22). The eight terms depicted in the central cells of Figure 2 describe the resulting theorized subscales of the TEX-Q. In addition to the aforementioned scales measuring outcome expectations, we included two additional subscales. The first was process related expectations (e.g., a straight-forward procedure), based on the assumption the expectations and experiences of the treatment process will be related to treatment outcome particularly in long-lasting treatments (18, 23, 24). The second was the expected behavioural control of the treatment (e.g., being able to influence treatment success), based on the rationale these capture situation-specific correlates of generalized self-efficacy (31). In total this led to ten different theorized subscales for the TEX-Q.

We refrained from the inclusion of further nuanced views from the conceptualisation of the TEX-Q for the sake of its applicability and generic nature. We also excluded general expectation constructs from our conceptualisation, as the TEX-Q was planned to focus on expectations about medical and psychological treatments, and good measures for relevant general expectation constructs like self-efficacy or optimism already exist (32, 33). Furthermore, we had to exclude the timeline dimension of treatment expectations due to the dissimilarity of timelines in different treatments and the resulting lack of potential generic formulations possible in its operationalisation.

Insert Figure 2 here

Figure 2: Conceptual structure of the TEX-Q treatment expectation scales.

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Note. Cells describe the theorized subscales of the TEX-Q.

Literature review: Generation of item list

For generic treatment expectation scales, our systematic search strategy identified 9312 articles. The additional critical review of treatment-specific expectation scales lead to the inclusion of further 33 relevant articles, resulting in a total of 9345 articles. After the removal of duplicates, 7888 records remained. The screening of titles and abstracts lead to the exclusion of 7849 articles that did not mention instruments measuring expectations. After assessment of the remaining 40 articles in full text, one article was excluded for not presenting an expectation measurement. A detailed overview of the review process is depicted in the PRISMA flowchart in Appendix C (Figure 3). The search strategies resulted in 39 articles containing 38 different relevant scales in total, of which 13 where multidimensional and 25 were unidimensional, the latter relating to 16 different treatments. Table 1 provides a comprehensive list of all scales found. The scales contained a total of 583 relevant items that provided inspiration for our primary item pool.

Based on this list, all authors took part in an iterative discussion process about the construction of the scale and its potential items. In that process, the items were further evaluated regarding their fit to our conceptual model, their applicability as generic items and our overall impression of them. Several items were reformulated to make them more generic and additional ones were constructed. With the deletion of duplicates and those substantially overlapping content wise, as well as those we consensually found to not fit our conceptual model, we selected 78 items, each clearly associated with one of our conceptual subscales. These provided the basis for the further development of the TEX-Q.

Expert-ratings: Evaluation of content validity

The ratings showed a high level of approval for our items, with each global rating ranging between 4.0 and 5.9 (M = 4.35, SD = .30) on a 6-point likert-scale. All items were rated as comprehensible (range: 4.5 – 5.9, M = 4.55, SD = .31) and fitting our theoretical framework (range: 4.9 - 6.0, M = 4.32, SD = .21).

The commentary section of the ratings contained criticism about the wording of approximately one third of the items. Eight different items were supposed to double-load on more than one of the theoretical subdimensions. In 15 items the use of technical terms, e.g. *functionality (*German: *Funktionsfähigkeit)*, and *adverse effects (negative Effekte)*, were criticized for being potentially difficult to understand for patients. The synonymous use of different verbs for expectations and hopes, e.g., *to hope (hoffen)* and *to wish for (sich wünschen)* was identified as a problem.

The rating results guided the further discussion process in the research team that resulted in the rewording of several items and a ranking of the items for each subscale according to the received rating and its variance. It was followed with a reduction to 53 items with 5-6 items per subscale by consensual decision in the research team.

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Table 1: Comprehensive list of scales measuring patients' treatment expectations

Instrument	Treatment specificity	Dimensionality	No. of relevant items
Illness Perception Questionnaire IPQ-R/B-IPQ (34, 35)	Generic	Multi	32
Milwaukee Psychotherapy Expectancies Questionnaire M-PEQ (36)	Generic	Multi	13
Patient Centered Outcomes Questionnaire PCOQ (37)	Generic	Multi	5
Patient Questionnaire on Therapy Expectation and Evaluation PATHEV (38)	Generic	Multi	7
Questionnaire for Patients' Expectations of Healthcare QPEHC (16)	Generic	Multi	36
Credibility/Expectancy Questionnaire CEQ (39)	Generic	Single	6
Expectations for Activities of Daily Living ADL-E (40)	Generic	Single	22
Expected illness-related disability PDI-E (41)	Generic	Single	7
General Assessment of Expected Side Effects Scale GASE-EXPECT (42)	Generic	Single	36
General Self-Efficacy Scale GSE (32)	Generic	Single	10
Life-Orientation-Test LOT-R (33)	Generic	Single	6
Physical Functioning Quality of Life Component Score PCS-E (43)	Generic	Single	13
Positive Health Expectations Scale PHES (20)	Generic	Single	7
Stanford Expectations of Treatment Scale SETS (30)	Generic	Single	9
Treatments Representations Inventory TRI (44)	Generic	Single	28
Expectations About Counseling - Brief Form EACB (45)	Specific	Multi	66
Expectations of Gynecological Treatment Questionnaire EGTQ (46)	Specific	Multi	24
Exercise Outcomes Expectations Questionnaire EOE-Q (47)	Specific	Multi	20
Expectations Towards ICD therapy EXPECT-ICD (48)	Specific	Multi	10
Orthodontic Treatment Expectations (49)	Specific	Multi	15
Self-Efficacy Expectations and Outcome Expectations SE- & OE-ICD (50)	Specific	Multi	17
Smoking Abstinence Expectancies Questionnaire SAEQ (51)	Specific	Multi	28
Psychosocial Treatment Expectations Questionnaire PTEQ (52)	Specific	Multi	13
Acupuncture expectancy scale AES (53)	Specific	Single	7
Anaesthesiological Questionnaire ANP-E (54)	Specific	Single	17
Cardiac Surgery Patient Expectations Questionnaire C-SPEQ (55)	Specific	Single	20
Chiropractic Patients' Expectations (56)	Specific	Single	15
Control Attitudes Scale-Revised CAS-R (57)	Specific	Single	3
Expectations for Complementary and Alternative Medicine Treatments Questionnaire EXPECT (58)	Specific	Single	13
Expectations Questionnaire EQ (59)	Specific	Single	6
Future Expectations Regarding Life with Heart Disease scale FERLHDS (60)	Specific	Single	18
Hospital for Special Surgery Knee Surgery Expectations Survey KSES (19)	Specific	Single	23
Knee Self-Efficacy Scale K-SES (61)	Specific	Single	22
Musculoskeletal Outcomes Data Evaluation and Management System MODEMS (62)	Specific	Single	6
New Knee Society Knee Scoring System NKSSS (63)	Specific	Single	8
Patient Shoulder Outcome Expectancies PSOE (64)	Specific	Single	3
Sample Patient Questionnaire SPQ (65)	Specific	Single	12
Treatment-specific Optimism TSO (66)	Specific	Single	10

Notes. Multi = several expectation dimensions are each assessed by an independent scale; *Single* = only one expectation dimension is assessed; *Generic* = not directly referring to a specific treatment, *Specific* = directly referring to a specific treatment. The format of the table has been adapted from Laferton et al. (18).

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Cognitive interviews: Evaluation of comprehensibility and acceptance

The qualitative analysis of patients' treatment expectations identified eight major expectation themes. Of these, six themes fitted our theoretical model, with 60 statements that could clearly be assigned to one of the hypothesized sub-dimensions of the TEX-Q. The two other themes were the absence of expectations (e.g., "I do not expect anything in particular", ID: 1001) with 11 mentions, and an unspecific feeling of stress about the treatment mentioned two times (e.g. "I am tense how this will proceed" ID: 1003). The results of this analysis were interpreted as support for our conception of the TEX-Q. Therefore, this conception was retained for the construction of the scale.

The analysis of criticism about the items, derived from the interview transcripts as well as the interviewers' notes, lead to identification of four major aspects of criticism. Each of these aspects had implications for the presentation and phrasing of the TEX-Q that directly informed our construction of the scales' initial version (Table 2). Especially aspect 4 was broadly discussed with the aim to capture both the probabilistic and strength related aspects of expectations in an easily comprehensible way, resulting in the reformulation of all remaining items into a change question format and the addition of a brief introductory text asking patients to assess their expectations "as realistically as possible". Furthermore, various item-level criticisms on the content and wording of specific items were identified as minor themes of criticism and lead to a modification or deletion of the respective items.

Table 2: Aspects of qualitative analysis & consequences for questionnaire development

Aspects of criticism	Illustrative examples	Implications for development process
Aspect 1: Commentary on the preferred wording of the anchors of the likert-scales	**"The anchors don't match the question, seems like they are asking for two different things in one question."** Commentary about Item 2b: How much improvement in your condition do you expect? Anchors: 0 (no change)/10 (largest possible improvement) (ID: 1002)	➢ Changing the anchors to every item ➢ Using the same specific phrasing for the low and the high anchor
Aspect 2: Comparison of analogue phrasings for key constructs *to hope/ to expect/ to fear* with phrasings like *to think* or *to whish*	**"To wish for something isn't reality, you can wish for inaccessible things, to hope for something is more realistic.''** (ID: 1004)	➢ Only using "to hope", "to expect" and "to fear" in every item ➢ Deleting all analogical phrases
Aspect 3: Evaluation of the theoretical differentiation between probabilistic and value-based expectation	**"To expect and to hope are different from each other. You can hope for a lot more than expect. To expect is more realistic."** (ID: 1009)	➢ Retaining the differentiation between hope and expect
Aspect 4: Comparison of two different versions of exemplary items: *change-question-* or *statement-*formulation	**"The phrasing of 24a triggers burdens when you're at the beginning of the treatment, 24b doesn't trigger burdens.'** Commentary about item 24a) vs. 24b): 24a) I expect to be burdened by the treatment. 24b) How much burden do you expect your treatment will cause? (ID: 1005)	➢ Inconclusive preferences among the interviewees ➢ Choosing *change-question* format for better acceptability & comprehensibility in some items
Item-level criticism: Commentary on the content or wording of specific items	**"Item sounds like it is just for psychotherapy."** Commentary about item 15: I expect to take part more actively in social life due to treatment. (ID: 1007)	➢ Rewording of items ➢ Deletion of items ➢ Consideration in the discussion about the final item-selection

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The Treatment Expectation Questionnaire

After completion of the aforementioned steps of gathering empirical evidence, the construction of the initial TEX-Q version was accomplished in a final item selection process. It contains 35 items on the 10 different subscales derived from our theoretical model with 3-4 items in each subscale. Every item contains either the verb to expect, to hope or to fear and is formulated as a question asking for the amount of change the patients expect to experience following their treatment. Each item is presented on a 10-point-likert-scale with specific anchors, the lower anchor always indicating no expected change. Example items for each subscale of the TEX-Q in preliminary translation are shown in Table 3.

Table 3: Illustrative TEX-Q items for each subscale

Expected benefits												
How much relief in your symptoms do you expect from the treatment?												
no relief	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	complete relief
Expected positive impact												
How much improvement do you expect in your ability to do your daily activities (e.g., occupation, household, social life)?												
no improvement	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	complete improvement
Expected harm												
To what extent do you expect risks from your treatment?												
no risks	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extreme risks
Expected negative impact												
How much do you expect the treatment will reduce your quality of life?												
not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extremely
Desired benefits												
How much benefit do you hope for from the treatment?												
no benefit	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extreme benefit
Desired impact												
How much improvement do you hope for considering your emotional state?												
no improvement	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extreme improvement
Feared harm												
To what extent do you fear risks from the treatment?												
no risk	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extreme risk
Feared negative impact												
How much do you fear the treatment will limit your day-to-day responsibilities (e.g., at home, at work, in the family)?												
not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extremely
Process related expectations												
To what extent do you expect to be satisfied with the treatment procedure or process?												
not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extremely
Expected behavioural control of the treatment												
To what extent do you expect your own behaviour to influence the success of the treatment?												
Not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extremely

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Discussion

This study describes the successful development of the Treatment Expectation Questionnaire (TEX-Q), a new scale for generically and multidimensionally measuring expectations of medical or psychological treatments. To accomplish this, an elaborate development process was necessary that incorporated the complex and diverse literature and evidence on expectations. The final TEX-Q will be available in German and English after psychometric evaluation. The scale is based on a comprehensive review of literature that provided an overview of existing treatment expectation scales and items. The evidence gathered from the review empirically validated our Integrative Model of Expectations (18) as well as our conceptualization for the TEX-Q with 10 sub-dimensions derived from it. In line with our results, our model has further been empirically supported by a recent systematic review of expectation measurement in orthopedic surgery (67). Few generic multidimensional scales, but several good treatment-specific measures were found and served as a source for our items. These items were modified and reformulated in the course of the development of the scale. This was informed by feedback from external experts in the field of placebo-, psychosomatic and clinical psychology research and by patient feedback.

The TEX-Q has advantages over previous measures of treatment expectations. Its fully generic nature enables the comparability of assessments across different treatments and conditions. It thus presents an advantage over treatment specific measurements as well as generic scales with limited scope, such as scales limited to psychotherapy (36, 38), scales solely focusing expectations regarding symptoms (i.e. pain), but not expectations regarding a broader impact on life (i.e. quality of life) (37, 68). It furthermore has a theory-based, multidimensional structure, covering different aspects of treatment expectations about symptom change, possible adverse events and the broader impact of the treatment and its process. This distinguishes the TEX-Q from established generic instrument like the Questionnaire for Patient Expectations of Health Care (16), which mostly focuses on expectations about the structure and process of the treatment process or the Credibility/Expectancy Questionnaire (39) and the newly developed Expectation for Treatment Scale (69), which only assess positive outcome expectations.

Several issues within the development process need to be considered. A major challenge of developing a generic measure of treatment expectations was that it was impossible, at least empirically, to take every possible medical application specifically into account. While the scale could be developed and tested in a variety of different clinical settings, involving different surgical as well as psychological treatments, further settings, like pharmacological or physical therapy treatments, could have been beneficial. The development might therefore have been shaped by the treatments of patients interviewed, as well as other conditions of the development process, such as the limited scope of the research team or the experts involved for feedback. In future, we will test the TEX-Q in additional clinical settings to further broaden the empirical basis for the argument of the generic applicability of the TEX-Q. Another limitation lies on the conceptual level. Although the theory-based construction of the questionnaire grounded in the Integrative Model of Expectations (18) provided a valuable framework for its subdimensions, it may thereby also have led to the exclusion of additional dimensions that could have emerged in a purely empirical concept development. Furthermore, expectation constructs mentioned by some authors had to be excluded from the TEX-Q for the sake of feasibility and applicability. Especially the work of Bowling et al. (16) is to be mentioned here, whose focus on treatment process expectations allowed them a more nuanced assessment, e.g. including

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items on expectations about the doctor-patient communication style or information provision. Another aspect is the exclusion of expectations about the *timeline* of the treatment and effects caused by it, e.g. their duration and sustainability. While it was hoped initially the TEX-Q that could measure such expectations, it was not feasible at the item level to ask for the many possible treatment trajectories.

The development of the TEX-Q facilitates a broad range of possibilities for future research, both in the evaluation and further development of the scale itself, as well as its use in applied research. Further validation of the scale in different clinical settings is necessary to confirm the psychometric properties of the TEX-Q and possibly further reduce its number of items. Therefore, the psychometric evaluation with patients from four different clinical settings will be published elsewhere. Other planned steps include the development of a brief version, evaluation of sensitivity to change and translation of the scale into other languages. An important contribution of the TEX-Q is that it will enable a comparison of the data gathered across studies on different conditions and treatments. Thereby, it will produce integrated evidence leading to further knowledge about the role of patients' treatment expectations. Furthermore, the subscales of the TEX-Q can be used to further differentiate the effects of the aspects of treatment expectations between conditions and treatment outcomes. The knowledge gained can also contribute to the development of interventions designed to use expectation related placebo effects to improve outcomes of everyday clinical practices.

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Literature

1. Mondloch MV, Cole DC, Frank JW. Does how you do depend on how you think you'll do? A systematic review of the evidence for a relation between patients' recovery expectations and health outcomes. Canadian Medical Association Journal. 2001;165(2):174-9.
2. Rief W, Glombiewski JA, Gollwitzer M, Schubo A, Schwarting R, Thorwart A. Expectancies as core features of mental disorders. Curr Opin Psychiatry. 2015;28(5):378-85.
3. Constantino MJ, Arnkoff DB, Glass CR, Ametrano RM, Smith JZ. Expectations. J Clin Psychol. 2011;67(2):184-92.
4. Enck P, Bingel U, Schedlowski M, Rief W. The placebo response in medicine: minimize, maximize or personalize? Nat Rev Drug Discov. 2013;12(3):191-204.
5. Colagiuri B, Zachariae R. Patient expectancy and post-chemotherapy nausea: a meta-analysis. Annals of Behavioral Medicine. 2010;40(1):3-14.
6. Jones F, Riazi A. Self-efficacy and self-management after stroke: a systematic review. Disability and rehabilitation. 2011;33(10):797-810.
7. Mahomed NN, Liang MH, Cook EF, Daltroy LH, Fortin PR, Fossel AH, et al. The importance of patient expectations in predicting functional outcomes after total joint arthroplasty. The Journal of rheumatology. 2002;29(6):1273-9.
8. van den Akker-Scheek I, Stevens M, Groothoff JW, Bulstra SK, Zijlstra W. Preoperative or postoperative self-efficacy: which is a better predictor of outcome after total hip or knee arthroplasty? Patient Education and Counseling. 2007;66(1):92-9.
9. Smeets RJ, Beelen S, Goossens ME, Schouten EG, Knottnerus JA, Vlaeyen JW. Treatment expectancy and credibility are associated with the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. The Clinical Journal of Pain. 2008.
10. Auer CJ, Glombiewski JA, Doering BK, Winkler A, Laferton JAC, Broadbent E, et al. Patients' Expectations Predict Surgery Outcomes: A Meta-Analysis. Int J Behav Med. 2016;23(1):49-62.
11. Juergens MC, Seekatz B, Moosdorf RG, Petrie KJ, Rief W. Illness beliefs before cardiac surgery predict disability, quality of life, and depression 3 months later. Journal of psychosomatic research. 2010;68(6):553-60.
12. Shedden-Mora MC, Nestoriuc Y, Rief W. Lessons learned from placebo groups in antidepressant trials. Philos Trans R Soc Lond B Biol Sci. 2011;366(1572):1879-88.
13. Nestoriuc Y, von Blanckenburg P, Schuricht F, Barsky AJ, Hadji P, Albert U-S, et al. Is it best to expect the worst? Influence of patients' side-effect expectations on endocrine treatment outcome in a 2-year prospective clinical cohort study. Annals of Oncology. 2016;27(10):1909-15.
14. Nestoriuc Y, Orav EJ, Liang MH, Horne R, Barsky AJ. Prediction of nonspecific side effects in rheumatoid arthritis patients by beliefs about medicines. Arthritis Care Res (Hoboken). 2010;62(6):791-9.
15. van Hartingsveld F, Ostelo RW, Cuijpers P, de Vos R, Riphagen II, de Vet HC. Treatment-related and patient-related expectations of patients with musculoskeletal disorders: a systematic review of published measurement tools. The Clinical Journal of Pain. 2010;26(6):470-88.
16. Bowling A, Rowe G, Lambert N, Waddington M, Mahtani K, Kenten C, et al. The measurement of patients' expectations for health care: a review and psychometric testing of a measure of patients' expectations: Prepress Projects Limited; 2012.
17. Zywiel MG, Mahomed A, Gandhi R, Perruccio AV, Mahomed NN. Measuring expectations in orthopaedic surgery: a systematic review. Clin Orthop Relat Res. 2013;471(11):3446-56.
18. Laferton JAC, Kube T, Salzmann S, Auer CJ, Shedden-Mora MC. Patients' Expectations Regarding Medical Treatment: A Critical Review of Concepts and Their Assessment. Front Psychol. 2017;8:233.
19. Mancuso CA, Sculco TP, Wickiewicz TL, Jones EC, Robbins L, Warren RF, et al. Patients' expectations of knee surgery. JBJS. 2001;83(7):1005-12.
20. Leedham B, Meyerowitz BE, Muirhead J, Frist WH. Positive expectations predict health after heart transplantation. Health Psychology. 1995;14(1):74.

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21. Maddux J. Expectations and health. Cambridge Handbook of Psychology, Health and Medicine. 2007:87-92.
22. Kirsch I. Response expectancy as a determinant of experience and behavior. Am Psychol. 1985;40(11):1189-202.
23. Leventhal H, Meyer D, Nerenz D. D.(1980). The common sense represen tation of illness danger. Medical Psychology New York: Pergamon. 1980.
24. Cameron LD, Leventhal H. The self-regulation of health and illness behaviour: psychology press; 2003.
25. Colagiuri B, Zachariae R. Patient expectancy and post-chemotherapy nausea: a meta-analysis. Ann Behav Med. 2010;40(1):3-14.
26. Fadyl J, McPherson K. Return to work after injury: a review of evidence regarding expectations and injury perceptions, and their influence on outcome. J Occup Rehabil. 2008;18(4):362-74.
27. Haanstra TM, van den Berg T, Ostelo RW, Poolman RW, Jansma IP, Cuijpers P, et al. Systematic review: do patient expectations influence treatment outcomes in total knee and total hip arthroplasty? Health and quality of life outcomes. 2012;10(1):152.
28. Beatty PC, Willis GB. Research Synthesis: The Practice of Cognitive Interviewing. Public Opinion Quarterly. 2007;71(2):287-311.
29. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77-101.
30. Younger J, Gandhi V, Hubbard E, Mackey S. Development of the Stanford Expectations of Treatment Scale (SETS): a tool for measuring patient outcome expectancy in clinical trials. Clin Trials. 2012;9(6):767-76.
31. Schwarzer R. Optimism, vulnerability, and self-beliefs as health-related cognitions: a systematic overview. Psychol. Health. 1994;9(3):161–180.
32. Schwarzer R, Jerusalem M. The general self-efficacy scale (GSE). Anxiety, Stress, and Coping. 2010;12:329-45.
33. Scheier MF, Carver CS. Optimism, coping, and health: assessment and implications of generalized outcome expectancies. Health psychology. 1985;4(3):219.
34. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception questionnaire. Journal of psychosomatic research. 2006;60(6):631-7.
35. Moss-Morris R, Weinman J, Petrie K, Horne R, Cameron L, Buick D. The Revised Illness Perception Questionnaire (IPQ-R). Psychology & Health. 2002;17(1):1-16.
36. Norberg MM, Wetterneck CT, Sass DA, Kanter JW. Development and psychometric evaluation of the Milwaukee Psychotherapy Expectations Questionnaire. Journal of clinical psychology. 2011;67(6):574-90.
37. Robinson ME, Brown JL, George SZ, Edwards PS, Atchison JW, Hirsh AT, et al. Multidimensional success criteria and expectations for treatment of chronic pain: the patient perspective. Pain Medicine. 2005;6(5):336-45.
38. Schulte D. Patients' outcome expectancies and their impression of suitability as predictors of treatment outcome. Psychotherapy Research. 2008;18(4):481-94.
39. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. Journal of behavior therapy and experimental psychiatry. 2000;31(2):73-86.
40. Dohnke B, Müller-Fahrnow W, Knäuper B. Der Einfluss von Ergebnis-und Selbstwirksamkeitserwartungen auf die Ergebnisse einer Rehabilitation nach Hüftgelenkersatz. Zeitschrift für Gesundheitspsychologie. 2006;14(1):11-20.
41. Laferton JAC, Shedden-Mora MC, Auer CJ, Moosdorf R, Rief W. Enhancing the efficacy of heart surgery by optimizing patients' preoperative expectations: study protocol of a randomized controlled trial. American heart journal. 2013;165(1):1-7.
42. von Blanckenburg P, Schuricht F, Albert U-S, Rief W, Nestoriuc Y. Optimizing expectations to prevent side effects and enhance quality of life in breast cancer patients undergoing endocrine therapy: study protocol of a randomized controlled trial. BMC Cancer. 2013;13(1):426.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

43. Powell R, Johnston M, Smith WC, King PM, Chambers WA, Krukowski Z, et al. Psychological risk factors for chronic post-surgical pain after inguinal hernia repair surgery: a prospective cohort study. European journal of pain. 2012;16(4):600-10.
44. Hirani SP, Patterson DL, Newman SP. What do coronary artery disease patients think about their treatments? An assessment of patients' treatment representations. Journal of health psychology. 2008;13(3):311-22.
45. Tinsley H. Expectations About Counseling: Unpublished test manual. Carbondale, IL: Southern Illinois University at Carbondale, Department of Psychology. 1982.
46. Marchant-Haycox S, Liu D, Nicholas N, Salmon P. Patients' expectations of outcome of hysterectomy and alternative treatments for menstrual problems. Journal of behavioral medicine. 1998;21(3):283-97.
47. Gecht MR, Connell KJ, Sinacore JM, Prohaska TR. A survey of exercise beliefs and exercise habits among people with arthritis. Arthritis & Rheumatology. 1996;9(2):82-8.
48. Habibovic M, Pedersen SS, van den Broek KC, Denollet J. Monitoring treatment expectations in patients with an implantable cardioverter-defibrillator using the EXPECT-ICD scale. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology. 2014;16(7):1022-7.
49. Bos A, Hoogstraten J, Prahl-Andersen B. Expectations of treatment and satisfaction with dentofacial appearance in orthodontic patients. American journal of orthodontics and dentofacial orthopedics. 2003;123(2):127-32.
50. Dougherty CM, Johnston SK, Thompson EA. Reliability and validity of the self-efficacy expectations and outcome expectations after implantable cardioverter defibrillator implantation scales. Applied nursing research. 2007;20(3):116-24.
51. Abrams K, Zvolensky MJ, Dorman L, Gonzalez A, Mayer M. Development and validation of the smoking abstinence expectancies questionnaire. Nicotine & Tobacco Research. 2011;13(12):1296-304.
52. de Carvalho Leite JC, Seminotti N, Freitas PF, de Lourdes Drachler M. The Psychosocial Treatment Expectations Questionnaire (PTEQ) for Alcohol Problems. European Journal of Psychological Assessment. 2011.
53. Mao JJ, Armstrong K, Farrar JT, Bowman MA. Acupuncture expectancy scale: development and preliminary validation in China. Explore: The Journal of Science and Healing. 2007;3(4):372-7.
54. Hüppe M, Klotz K-F, Heinzinger M, Prüßmann M, Schmucker P. Beurteilung der perioperativen Periode durch Patienten Erste Evaluation eines anästhesiologischen Nachbefragungsbogens. Der Anaesthesist. 2000;49(7):613-24.
55. Holmes SD, Fornaresio LM, Miller CE, Shuman DJ, Ad N. Development of the cardiac surgery patient expectations questionnaire (C-SPEQ). Quality of Life Research. 2016;25(8):2077-86.
56. Sigrell H. Expectations of chiropractic patients: the construction of a questionnaire. Journal of manipulative and physiological therapeutics. 2001;24(7):440-4.
57. Moser DK, Riegel B, McKinley S, Doering LV, Meischke H, Heo S, et al. The Control Attitudes Scale-Revised: Psychometric evaluation in three groups of cardiac patients. Nursing research. 2009;58(1):42.
58. Jones SM, Lange J, Turner J, Cherkin D, Ritenbaugh C, Hsu C, et al. Development and Validation of the EXPECT Questionnaire: Assessing Patient Expectations of Outcomes of Complementary and Alternative Medicine Treatments for Chronic Pain. J Altern Complement Med. 2016;22(11):936-46.
59. Razmjou H, Finkelstein JA, Yee A, Holtby R, Vidmar M, Ford M. Relationship between preoperative patient characteristics and expectations in candidates for total knee arthroplasty. Physiotherapy Canada. 2009;61(1):38-45.
60. Axelrad KJ. Locus of control and causal attributions as they relate to expectations for coping with a heart attack. 1982.

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61. Thomeé P, Währborg P, Börjesson M, Thomeé R, Eriksson BI, Karlsson J. A new instrument for measuring self-efficacy in patients with an anterior cruciate ligament injury. Scandinavian Journal of Medicine & Science in Sports. 2006(16):181-7.
62. Tashjian RZ, Bradley MP, Tocci S, Rey J, Henn RF, Green A. Factors influencing patient satisfaction after rotator cuff repair. Journal of shoulder and elbow surgery. 2007;16(6):752-8.
63. Noble PC, Scuderi GR, Brekke AC, Sikorskii A, Benjamin JB, Lonner JH, et al. Development of a new Knee Society scoring system. Clinical Orthopaedics and Related Research®. 2012;470(1):20-32.
64. O'Malley KJ, Roddey TS, Gartsman GM, Cook KF. Outcome expectancies, functional outcomes, and expectancy fulfillment for patients with shoulder problems. Medical care. 2004;42(2):139-46.
65. Habib SB, Sonoda L, See TC, Ell PJ, Groves AM. How do patients perceive the benefits and risks of peripheral angioplasty? Implications for informed consent. Journal of Vascular and Interventional Radiology. 2008;19(2):177-81.
66. Cohen L, de Moor C, Amato RJ. The association between treatment-specific optimism and depressive symptomatology in patients enrolled in a Phase I cancer clinical trial. Cancer. 2001;91(10):1949-55.
67. Cortes A, Meints SM, Katz JN. Characterizing the Use of Expectations in Orthopedic Surgery Research: A Scoping Review. ACR Open Rheumatol. 2019;1(7):440-451.
68. Page MG, Ziemianski D, Martel MO, Shir Y. Development and validation of the Treatment Expectations in Chronic Pain Scale. Br J Health Psychol. 2019;24(3):610-28.
69. Barth J, Kern A, Luthi S, Witt CM. Assessment of patients' expectations: development and validation of the Expectation for Treatment Scale (ETS). BMJ Open. 2019;9(6):e026712.

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Competing interests statement

We declare that we have no significant competing financial, professional, or personal interests that might have influenced the performance or presentation of the work described in this manuscript.

Patient consent for publication

Obtained.

Data sharing statement

Datasets and statistical codes are available from the figshare-repository at https://figshare.com/projects/TEX-Q/72347.

Author Statement

JA was involved in the conception of the scale, data acquisition, data analysis and interpretation, the writing of first draft and revision. BL was involved in the conception of the scale, data interpretation and the revising of the manuscript. MG was involved in the data acquisition, data analysis and interpretation, and the revising of the manuscript. KP was involved in the conception of the scale, data interpretation and the revising of the manuscript. JL was involved in the conception of the scale, data interpretation and the revising of the manuscript. YN was involved in the scale conception, data interpretation and critically revised the manuscript. MSM was involved in the conception of the

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scale, data acquisition, data analysis and interpretation, the writing of first draft and revision. All authors approved the final version of this manuscript.

APPENDIX

Appendix A: Description of the literature review

Appendix B: Interview guide

Appendix C: PRISMA-Flowchart

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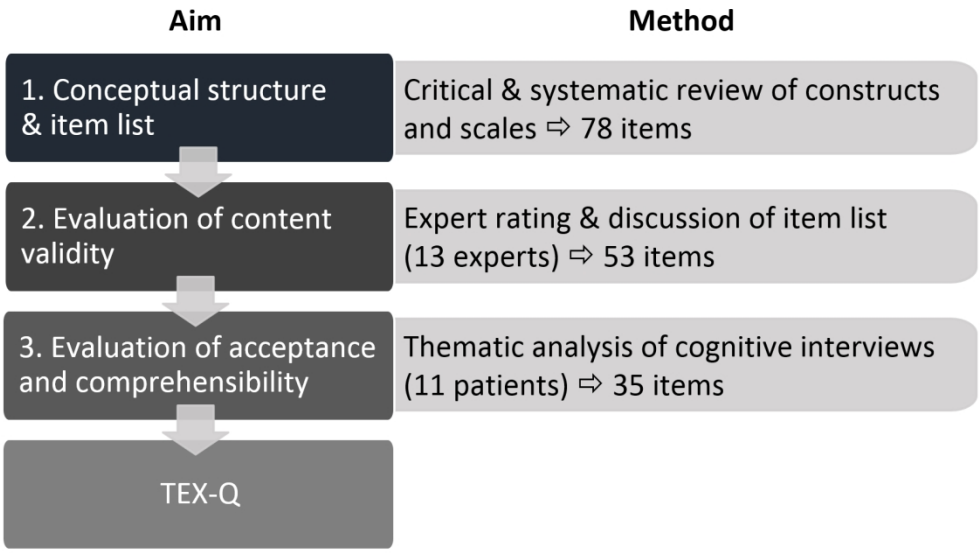

Figure 1: Overview of the development process

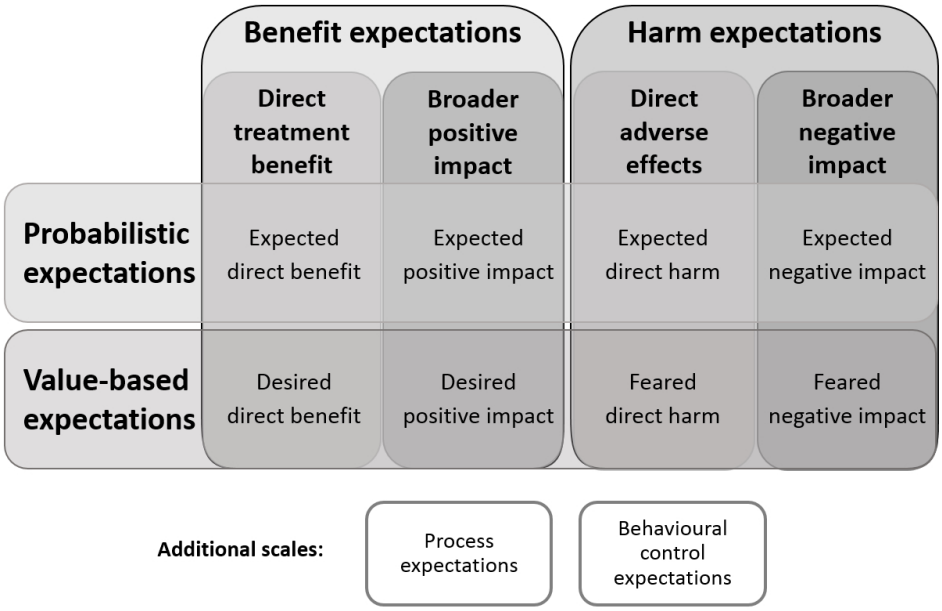

Figure 2: Conceptual structure of the TEX-Q treatment expectation scales.
Note. Cells describe the theorized subscales of the TEX-Q.

Appendix A – Alberts et al. TEX-Q

Appendix A: Description of the literature review

Databases: Pubmed, Psycinfo (through OVID)

Filter: Adult (19+) AND human AND English AND 1900-current

Search terms: (((treat* OR therap*) AND (measure* OR assess* OR diagnost* OR questionnaire OR scale OR instrument) AND (expectation* OR expectanc*)).ti,ab.) NOT ((life expectancy).ti,ab.)

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Appendix B – Alberts et al. TEX-Q

Department of Psychosomatic Medicine and Psychotherapy
University Medical Center Hamburg-Eppendorf

INTERVIEW GUIDE

COGNITIVE INTERVIEWS

Study
Development and psychometric evaluation of a generic, multidimensional Treatment Expectation Questionnaire (TEX-Q)

Study ID:

Comment: the interviewer will read out the following study information to the participant.

Introduction

Thank you for coming in and taking the time to take part in our interview today.
Before we start with the main part of our interview, I would like to explain the background of our study and introduce you to today`s procedure. Please read the study information and consent form carefully. If you agree and want to take part in our interview I would like you to sign the consent form. Please ask any questions at any time.
I will record our interview with this audio recorder [*show recorder*] so I do not need to write down everything you say and we can talk openly and freely.
From time to time I will take some additional notes.

Explanation of the project

This questionnaire deals with the subject of patient expectations. We aim to apply this questionnaire in order to assess the expectations that a person has regarding a planned treatment. To ensure that the questionnaire is useful and comprehensible, we would like to ask you for your evaluation today.
In this interview, we would especially like to know your impressions of the questionnaire.
In the following, I will ask you to complete the present questionnaire.

Explanation of the procedure

I would like you to read each presented statement or question very carefully, read it out loud and mark the answer that applies to you.
While you do this, I would like to know what you think and feel. Please express all occurring thoughts out loud so I can hear them. Please express your thoughts WHILE marking the item.
If you find a statement understandable, please tell me about it. If you find a statement incomprehensible, please tell me about it as well.

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Appendix B – Alberts et al. TEX-Q

In case you do not understand the statement or the question or you do not know how to answer the question, please let me know why this is the case. I would like you to tell me if you like the question or dislike the item and why you do so. If a phrasing appears particularly appropriate or inappropriate to you, I would like you to share your thoughts about the item.
This interview will be conducted openly, none of your answers will have any negative consequences for you. For us, it is relevant to make sure that our questionnaire is comprehensible; there are no right or wrong answers. It is totally fine if you do not want to answer a particular statement, there will be no disadvantages for you. Please do not hold back any thoughts; every thought could be interesting and helpful for us.
In some parts of this questionnaire, we will present two different phrasings for the same question. Please read both of the phrasings carefully and tell me your thoughts about them. If you prefer one phrasing over the other, please tell me about it. We would like to know which of these phrasings you prefer.
You can help us at this phase of our questionnaire development by sharing your thoughts and impressions on the present statements.
[*Hand out questionnaire to participant*]

Section 1: Sociodemographic information

[Information is not displayed here.]

Section 2: information on the disease and treatment

1. For which disease or complaints are you currently seeking treatment?

2. What treatment will you receive?

3. What do you hope for from this treatment?

4. What are your concerns about this treatment?

5. What do you realistically expect from this treatment?

negative expectations	☐ -5	☐ -4	☐ -3	☐ -2	☐ -1	☐ 0	☐ +1	☐ +2	☐ +3	☐ +4	☐ +5	positive expectations

6. Overall, which expectations regarding the treatment are predominant?

7. Overall, how much improvement do you expect from this treatment?

no improvement	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	maximum improvement

8. Have you received this treatment before?
   0 ☐ yes 1 ☐ no

9. If yes, what experiences have you had with this treatment?

10. If yes, how would you rate your previous experiences with this treatment?

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Appendix B – Alberts et al. TEX-Q

negative experiences	☐ -5	☐ -4	☐ -3	☐ -2	☐ -1	☐ 0	☐ +1	☐ +2	☐ +3	☐ +4	☐ +5	positive experiences

11. Have you previously had other treatments for the same disease or complaints?
    0 ☐ yes 1 ☐ no

12. If yes, what experiences have you had with the previous treatments for your disease or complaints?

13. If yes, how would you rate your overall experiences with the treatments so far?

negative experiences	☐ -5	☐ -4	☐ -3	☐ -2	☐ -1	☐ 0	☐ +1	☐ +2	☐ +3	☐ +4	☐ +5	positive experiences

Section 3: TEX-Q items

Prior to presenting the TEX-Q items:

The following questions and statements are about the changes that you expect from the treatment.
In this part, we will present 53 different items, 16 of them are using two different phrasings for the same question. Please read both of the phrasings carefully and tell me your thoughts about them. If you prefer one phrasing over the other, please tell me about it. We would like to know which of these phrasings you prefer.

Comment: 53 Items are presented to the participant, 16 items are presented in two different versions. The items are not displayed here.

After presenting the TEX-Q items:

Thank you for your help! We have reached the end of the questionnaire.

1. Is there anything you would like to tell me right now? What do you think, how do you feel right now? How did you feel about answering the questionnaire?
2. Can you give me a final conclusion on the comprehensibility of the questionnaire?
3. Is there anything you think this is missing from this questionnaire?

Further questions if the topics have not been discussed yet:

1. Do you think that the terms “hope” and “expect” have different meanings?
2. Please tell me your thoughts about the following statement:
   “I expect the treatment to improve my functionality”.
   How do you define functionality? *[We aimed to know if the term functionality (German: Funktionsfähigkeit) is comprehensible]*

References

Our guideline was influenced by the following references:

1. Charters, E. (2003). The Use of Think-aloud Methods in Qualitative Research. An Introduction to Think-aloud Methods. *Brock Education Vol. 12, No. 2.*
2. Häder, M. Empirische Sozialforschung. Eine Einführung. (2010). 2. edition. *VS Verlag für Sozialwissenschaften*. 393-394.

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Appendix B – Alberts et al. TEX-Q

3. Sherman, K. J., Eaves, E. R., Ritenbaugh, C., Hsu, C., Cherkin, D. C., & Turner, J. A. (2014). Cognitive interviews guide design of a new CAM patient expectations questionnaire. *BMC Complementary and Alternative Medicine*, 14(1), 39.
4. van Oort, L., Schröder, C., French, D. P. (2011). What do people think about when they answer the Brief Illness Perception Questionnaire? A 'think-aloud' study. *British Journal of Health Psychology*, 231-245.

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Appendix C – Alberts et al. TEX-Q

Appendix C: PRISMA flowchart of the literature search

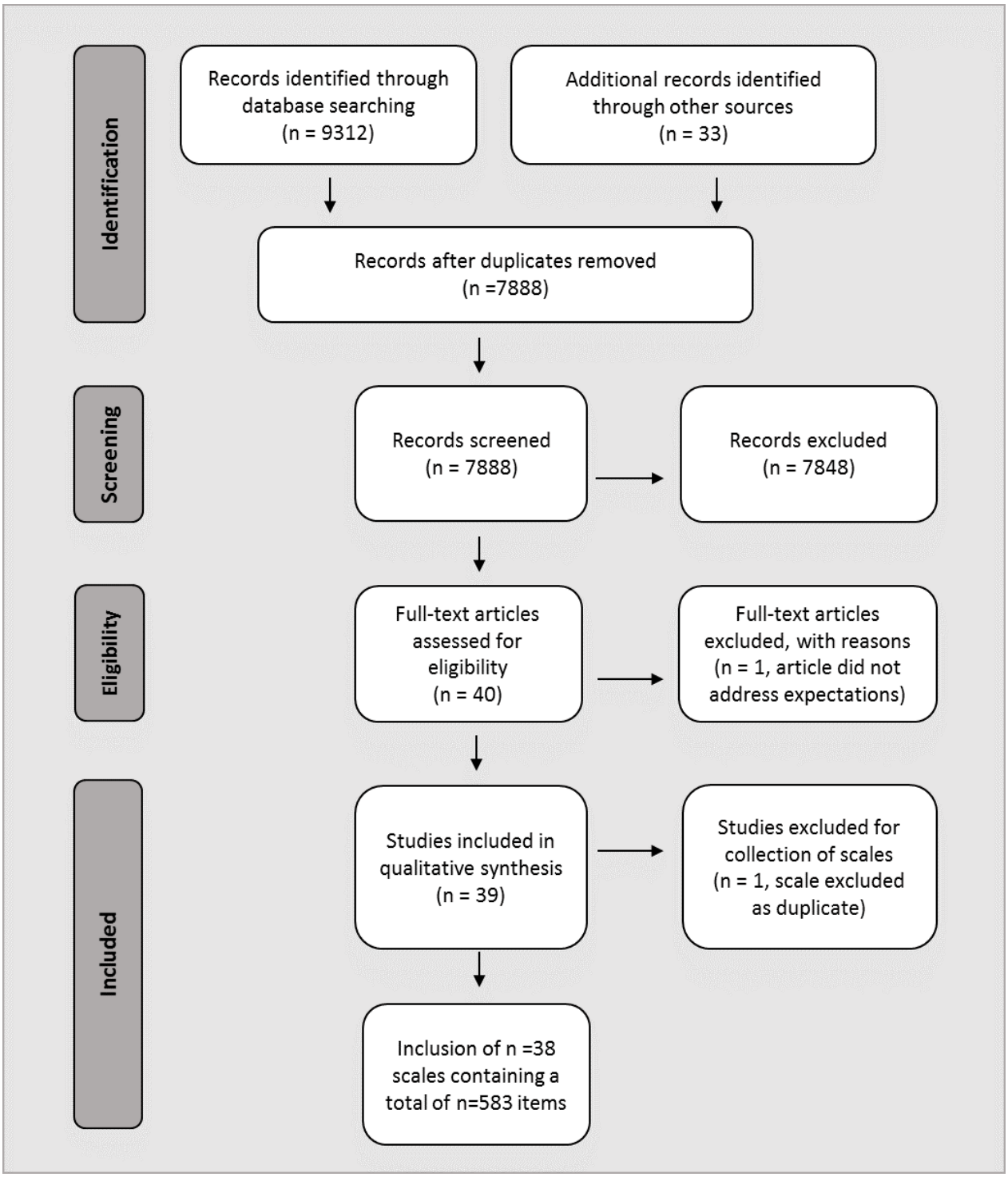

Figure 3: PRISMA flowchart of the literature search

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BMJ Open

Development of the generic, multidimensional Treatment Expectation Questionnaire (TEX-Q) through systematic literature review, expert surveys and qualitative interviews

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Complete List of Authors:	Alberts, Jannis; University Medical Center Hamburg-Eppendorf, Psychosomatic Medicine and Psychotherapy Löwe, Bernd; University Medical Center, HamburgEppendorf, Psychosomatic Medicine and Psychotherapy Glahn, Maja; University Medical Center, HamburgEppendorf, Psychosomatic Medicine and Psychotherapy Petrie, Keith; University of Auckland, Psychological Medicine Laferton, Johannes; Psychologische Hochschule Berlin, Clinical Psychology and Psychotherapy Nestoriuc, Yvonne; Helmet Schmidt University, Department of Psychology Shedden-Mora, Meike; Universitatsklinikum Hamburg Eppendorf Medizinische Klinik und Poliklinik II Onkologie Hamatologie, Psychosomatic Medicine and Psychotherapy
Primary Subject Heading:	Global health
Secondary Subject Heading:	Mental health, Qualitative research, Research methods
Keywords:	GENERAL MEDICINE (see Internal Medicine), MENTAL HEALTH, PREVENTIVE MEDICINE, QUALITATIVE RESEARCH, STATISTICS & RESEARCH METHODS, THERAPEUTICS

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Development of the generic, multidimensional Treatment Expectation Questionnaire (TEX-Q) through systematic literature review, expert surveys and qualitative interviews

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Abstract

Objectives: Patients´ expectations - as a central mechanism of placebo and nocebo effects - are an important predictor of health outcomes. However, the lack of a way to assess expectations across different settings restricts progress in understanding the role of expectations and to quantify their importance in medical and psychological treatments. The aim of this study was to develop a theory-based, generic, multidimensional measure assessing patient expectations of medical and psychological treatments.

Design: The Treatment Expectation Questionnaire (TEX-Q) was developed based on the Integrative Model of Expectations (Laferton, Kube, Salzmann, Auer & Shedden-Mora, 2017) and a systematic literature review of treatment expectation scales. After creating a comprehensive item pool, the scale was further refined by the use of expert ratings, and patient interviews.

Setting: Patients were recruited in primary care at two hospitals in Hamburg, Germany.

Participants: 13 scientific experts participated in the expert survey. 11 patients waiting for psychological or surgical treatments participated in the qualitative interviews.

Results: The 2x2x2 multidimensional structure of the TEX-Q assesses two expectation constructs (probabilistic vs. value-based) across two outcome domains with two valences (direct benefits and adverse events, broader positive and negative impact), plus process and behavioural control expectations. We examined 583 items from 38 scales identified in the systematic review, and developed 78 initial items. Content validity was then rated by experts according to item fit and comprehensibility. The best 53 items were further evaluated for comprehensibility, acceptability, phrasing preference and understanding by interviewing patients prior to treatment using the "think aloud"-technique. This resulted in a first 35-item version of the TEX-Q.

Conclusions: The TEX-Q is a generic, multidimensional measure to assess patient expectations of medical and psychological treatments and allows comparing the impact of multidimensional expectations across different conditions. The final TEX-Q will be available after psychometric validation.

Keywords: expectations, expectancy, scale, assessment, placebo, nocebo

Article Summary

Strength and limitations of this study

- Construction of a generic, multidimensional scale measuring patients´ treatment expectations
- Conceptual model contains eight subscales for outcome expectations and two process expectations
- Three-step empirical process: systematic review, expert ratings & cognitive patient interviews
- Generation & iterative reformulation of items informed by the empirical steps
- Generic nature of the TEX-Q needs further research in additional clinical settings

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Introduction

Patients' treatment expectations are an important predictor of outcome for a broad range of medical and psychological treatments (1-3). As non-specific treatment components, they can induce subjective and psychological changes and are a central mechanism driving placebo and nocebo effects (4). Positive treatment expectations have been linked to health outcomes for a variety of different illnesses and treatments including cancer (5), stroke (6), musculoskeletal disorders (7, 8), pain (9), surgery (10, 11), antidepressant medication (12), and psychotherapy (3). Furthermore, negative expectations have been linked to the occurrence of adverse events in the treatment of a number of illnesses (5, 13, 14). Generally, studies find a moderate overall effect of patients' expectations on outcomes (15, 16).

The large number of treatment expectation measures has been identified as an important limitation for the integration of the existing evidence across different treatments and diseases in several systematic reviews (1, 15-17). On the level of assessment, this stems from most studies developing a single treatment or disease measure of expectations (18) often using single-item or very brief non-validated ad-hoc instruments (10, 15). Other questionnaires only assess partial aspects of expectations, e.g., only positive expectations (19) or do not distinguish between the type of expectation assessed (20).

On the conceptual level, there is a diversity of underlying theories on expectations, being one of the most studied constructs in psychology (21). The theoretical conception of the TEX-Q is based on our *Integrative Model of Expectations* in patients undergoing medical treatment (18), and on an extensive review of the expectation literature. The model defines treatment expectations as future-directed cognitions that focus on the incidence or non-incidence of a specific event or experience. In general, it distinguishes between *probabilistic* expectations, describing realistic estimations about the future, and *ideal* or *value-based* expectation, describing what someone would like or dislike to happen (e.g. hopes, fears). It defines *treatment expectations* in distinction from *behavioral expectations* about the subjective control over the treatment as well as generalized expectations (e.g., generalized self-efficacy, optimism) and expectations about the timeline of diseases, treatments, behavior or related outcomes. Regarding treatment expectations, the model distinguishes between *outcome-related expectations* about benefits and side-effects of the treatment and *structural and process-related expectations* about the course of the treatment itself. Furthermore, it differentiates outcomes continuously ranging from internal effects (e.g., symptom improvement) to external effects (e.g., impact on patients' social life). The *Integrative Model* itself aims to integrate several central expectation theories. For further conceptual clarity, two of those theories with high relevance for the development of the TEX-Q are discussed in more detail.

The most central understanding of treatment expectations was provided by Kirsch's *Response Expectancy Theory* (22). Here he distinguishes between two kinds of general *outcome expectations*: *stimulus expectancies,* which are a person's expectation of external stimuli as an outcome, and *response expectancies,* which refer to a person´s expectations of a non-volitional internal response as an outcome. Response expectancies are particularly relevant in treatment contexts. They provide a description of patients' expectations in a broad range of treatment situations ranging from their position of passive recipients in some instances (e.g., expecting that taking metformin will lower your blood sugar in diabetes) to more active patient roles involving volitional health-directed behavior (e.g. expecting that changing your lifestyle will lower your blood sugar).

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Another important theory influencing the development of the TEX-Q is Leventhal's *Common Sense Model of Illness Representation* (23). This model describes patients' subjective representations of their illness and its consequences for their lives. It differentiates beliefs about the *causes* of the illness, its *timeline*, the *identity* of the illness through its associated symptoms and the possibility to *control* the illness through *personal behavior* and the *treatment* itself. The model does not refer to expectations explicitly, but they are regarded as important general constructs underlying illness beliefs (24). Thus, the model presents an elaborate differentiation of patients' illness and treatment beliefs that can also be applied as a framework for the differentiation of treatment expectations.

To facilitate a comprehensive understanding of treatment expectations and overcome the limitations of previous scales we developed the Treatment Expectation Questionnaire (TEX-Q). It was constructed with the following five aims: (1) The scale will be able to measure treatment expectations generically and comparably for different medical and psychological treatments; (2) The scale will be multidimensional, taking into account aspects of treatment expectations with potential predictive links to treatment outcomes; (3) The scale will be sensitive to change in order to capture effects of expectation management interventions; (4) The scale's conceptual framework is applicable for research and everyday clinical practice.

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Methods

Overview of the development process

The development process of the TEX-Q followed three main steps (see Figure 1): Firstly, we developed a conceptual structure for the TEX-Q and created a comprehensive item pool. This step was based on the Integrative Model of Expectations (18) and a systematic literature review of treatment expectation scales. Secondly, expert ratings were obtained to evaluate the items content validity. Thirdly, we conducted qualitative cognitive interviews with patients to evaluate the comprehensibility and acceptance of the items and the fit among our target population. Ethical approval was obtained from the Medical Chamber Hamburg, Germany. Informed consent was obtained from all participants of the study. The TEX-Q was developed in German. Preliminary English translations of its contents are used in this paper. A final translation will be available after the finalization of its psychometric validation.

Insert Figure 1 here

Figure 1: Overview of the development process

Conceptual structure & generation of item list

The conceptual structure of the TEX-Q was developed based on the most relevant expectation theories (22, 23) incorporated in our Integrative Model of Expectations (18). Our goal for the conceptual structure was to cover a relevant range of treatment-related expectation constructs with potential predictive value for outcome. At the same time, we aimed to include concepts that can be generically assessed.

First, a comprehensive list of existing scales relevant to the development process was assembled through a literature review of generic and treatment-specific scales. To do this we completed a systematic literature search of the PubMed and PsycINFO databases (last date of search: 01.08.2018). The search was designed to include all published articles describing empirical studies with adults that featured a scale to measure patient expectations written since 1900 in English language (for the specific search-term see Appendix A). The articles found were then screened in two steps, firstly regarding titles and abstracts and secondly regarding the full texts of the remaining articles. A review protocol can be obtained from the authors.

Second, the systematic review was complemented by a critical review of treatment-specific expectation scales. As a systematic review of treatment-specific scales would have by far exceeded reasonable capacities for our purpose, our approach was non-systematic. This review was based on our *Integrative Model of Expectations* (18), treatment-specific reviews of expectation scales (6, 10, 15, 17, 25-27) and treatment-specific scales identified in our search for generic scales. For all identified expectation scales, the references of the respective publications were screened and additional scales were included.

The identified scales were assessed in conjunction with our theoretical model to finalize the conceptual structure and subscales of the TEX-Q. The items from each identified scale provided the pool from which we selected our items. Through the exclusion of duplicates and items that did not fit with the model we created the first list of potential items for the TEX-Q.

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Evaluation of content validity

Our next empirical aim was the evaluation of content validity. To do this we sent our item list to 13 experts from the fields of placebo research, psychosomatic medicine and clinical psychology. They were requested to rate each item on a six-point-Likert scale according to: (1) comprehensibility, (2) fit to our theoretical construct (which we introduced attached to the rating), and (3) overall quality of the item. Furthermore, they were asked to provide open feedback for each item. After ranking the items for each dimension and taking into account the commentaries given, we decided on the inclusion and eventual rewording of the most appropriate items.

Evaluation of comprehensibility and acceptance

Next, we evaluated the comprehensibility of the items, their acceptability and fit to our model in a clinical sample. We therefore conducted cognitive interviews with patients. We recruited a convenience sample of 11 patients waiting for psychological or surgical treatments at the University Medical Center Hamburg-Eppendorf and the Schön Hospital Hamburg-Eilbek. In the selection of these patients for the interviews, we aimed to maximize the diversity of conditions and treatments. Patients were interviewed by male and female researchers with prior experience with this assessment (JA, MG). Data saturation was discussed regularly and data collection was continued until we found it to be sufficient within this sample.

Based on a semi-structured interview guide (see Appendix B), the patients were asked to complete the potential TEX-Q items, some of them in different phrasings to examine the differences, while speaking out their thoughts (thinking-aloud technique (28)). Furthermore, they were asked open questions about prior experiences and expectations with their symptoms and treatment and about specific aspects of the phrasing of the items. The interviews took about 1 hour each. The interviews were audio-recorded and the answers to the open questions were transcribed verbatim. Additionally, the researcher took field notes of any observed difficulty the patients had in filling out the questionnaire.

The transcripts and notes from the interviews were qualitatively analyzed using thematic analysis (29). Two different analyses were conducted. Firstly, we looked at how patients expressed their expectations throughout the interviews, examining their fit to our conceptual model. Secondly, we examined the material for all criticism about the questionnaire and its items. Categories for both analyses were created both deductively based on our conceptions and inductively derived from the interviews. The analyses of the interviews then informed the final discussion and selection process from which the research team chose the wording of the items for the TEX-Q.

Patient and Public Involvement

The development of the TEX-Q was evaluated through patient involvement in the third empirical step, as presented above in detail. Through the qualitative interviews, the phrasing of our items was adjusted according to their priorities, experience and preferences. The results of their involvement will be disseminated to the patients through the publication of the final TEX-Q questionnaire.

There was no further patient or public involvement in the design, recruitment or conduct of the study.

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Results

Literature review: Conceptual model of the TEX-Q

The literature review generally provided additional support for the Integrative Model of Expectations (18), with all reviewed items fitting to one or more of the aspects of expectations differentiated in the model. Some of the scales reviewed, however, focused more specifically on one or more aspects of the model and therefore introduced additional, more nuanced differentiations within it. Our rationale was to capture the most potentially relevant aspects of this expectations with predictive value for outcome in the TEX-Q. Hence, we developed a 2x2x2 concept to operationalize outcome expectations in the questionnaire (Figure 2).

Firstly, we distinguished probabilistic expectations, describing realistic assumptions about what is likely to happen (e.g., expecting symptom improvement) from value-based expectations, describing more affective, less rational feelings like hopes or fears (e.g., hoping to be pain-free). Our rational here was to capture the potentially different predictive value of these expectation constructs as theorized in the literature (16, 18). Secondly, we distinguished expectations about beneficial outcomes (e.g., treatment success) from expectations about harmful outcomes (e.g., complications). This inclusion was based on empirical evidence from the literature pointing to these aspects being separate dimensions rather than two sides of a unidimensional structure (30). Thirdly, we distinguished expectations about direct, symptom-related treatment outcomes (e.g., benefit or side effects) from expectations about the broader impacts of the treatment (e.g., improved quality of life or reduced functioning). We thereby introduced a categorial operationalisation of the range of possible treatment outcomes described in the Integrative Model of Expectations as relevant for different treatment outcomes to secure generic applicability (18, 22). The eight terms depicted in the central cells of Figure 2 describe the resulting theorized subscales of the TEX-Q. In addition to the aforementioned scales measuring outcome expectations, we included two additional subscales. The first was process related expectations (e.g., a straight-forward procedure), based on the assumption the expectations and experiences of the treatment process will be related to treatment outcome particularly in long-lasting treatments (18, 23, 24). The second was the expected behavioural control of the treatment (e.g., being able to influence treatment success), based on the rationale these capture situation-specific correlates of generalized self-efficacy (31). In total this led to ten different theorized subscales for the TEX-Q.

We refrained from the inclusion of further nuanced views from the conceptualisation of the TEX-Q for the sake of its applicability and generic nature. We also excluded general expectation constructs from our conceptualisation, as the TEX-Q was planned to focus on expectations about medical and psychological treatments, and good measures for relevant general expectation constructs like self-efficacy or optimism already exist (32, 33). Furthermore, we had to exclude the timeline dimension of treatment expectations due to the dissimilarity of timelines in different treatments and the resulting lack of potential generic formulations possible in its operationalisation.

Insert Figure 2 here

Figure 2: Conceptual structure of the TEX-Q treatment expectation scales.
Note. Cells describe the theorized subscales of the TEX-Q.

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Literature review: Generation of item list

For generic treatment expectation scales, our systematic search strategy identified 9312 articles. The additional critical review of treatment-specific expectation scales lead to the inclusion of further 33 relevant articles, resulting in a total of 9345 articles. After the removal of duplicates, 7888 records remained. The screening of titles and abstracts lead to the exclusion of 7849 articles that did not mention instruments measuring expectations. After assessment of the remaining 40 articles in full text, one article was excluded for not presenting an expectation measurement. A detailed overview of the review process is depicted in the PRISMA flowchart in Appendix C (Figure 1). The search strategies resulted in 39 articles containing 38 different relevant scales in total, of which 13 where multidimensional and 25 were unidimensional, the latter relating to 16 different treatments. Table 1 provides a comprehensive list of all scales found. The scales contained a total of 583 relevant items that provided inspiration for our primary item pool.

Based on this list, all authors took part in an iterative discussion process about the construction of the scale and its potential items. In that process, the items were further evaluated regarding their fit to our conceptual model, their applicability as generic items and our overall impression of them. Several items were reformulated to make them more generic and additional ones were constructed. With the deletion of duplicates and those substantially overlapping content wise, as well as those we consensually found to not fit our conceptual model, we selected 78 items, each clearly associated with one of our conceptual subscales. These provided the basis for the further development of the TEX-Q.

Expert-ratings: Evaluation of content validity

The ratings showed a high level of approval for our items, with each global rating ranging between 4.0 and 5.9 (*M* = 4.35, *SD* = .30) on a 6-point likert-scale. All items were rated as comprehensible (range: 4.5 – 5.9, *M* = 4.55, *SD* = .31) and fitting our theoretical framework (range: 4.9 - 6.0, *M* = 4.32, *SD* = .21).

The commentary section of the ratings contained criticism about the wording of approximately one third of the items. Eight different items were supposed to double-load on more than one of the theoretical subdimensions. In 15 items the use of technical terms, e.g. *functionality (*German: *Funktionsfähigkeit)*, and *adverse effects (negative Effekte)*, were criticized for being potentially difficult to understand for patients. The synonymous use of different verbs for expectations and hopes, e.g., *to hope (hoffen)* and *to wish for (sich wünschen)* was identified as a problem.

The rating results guided the further discussion process in the research team that resulted in the rewording of several items and a ranking of the items for each subscale according to the received rating and its variance. It was followed with a reduction to 53 items with 5-6 items per subscale by consensual decision in the research team.

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Table 1: Comprehensive list of scales measuring patients' treatment expectations

Instrument	Treatment specificity	Dimensionality	No. of relevant items
Illness Perception Questionnaire IPQ-R/B-IPQ (34, 35)	Generic	Multi	32
Milwaukee Psychotherapy Expectancies Questionnaire M-PEQ (36)	Generic	Multi	13
Patient Centered Outcomes Questionnaire PCOQ (37)	Generic	Multi	5
Patient Questionnaire on Therapy Expectation and Evaluation PATHEV (38)	Generic	Multi	7
Questionnaire for Patients' Expectations of Healthcare QPEHC (16)	Generic	Multi	36
Credibility/Expectancy Questionnaire CEQ (39)	Generic	Single	6
Expectations for Activities of Daily Living ADL-E (40)	Generic	Single	22
Expected illness-related disability PDI-E (41)	Generic	Single	7
General Assessment of Expected Side Effects Scale GASE-EXPECT (42)	Generic	Single	36
General Self-Efficacy Scale GSE (32)	Generic	Single	10
Life-Orientation-Test LOT-R (33)	Generic	Single	6
Physical Functioning Quality of Life Component Score PCS-E (43)	Generic	Single	13
Positive Health Expectations Scale PHES (20)	Generic	Single	7
Stanford Expectations of Treatment Scale SETS (30)	Generic	Single	9
Treatments Representations Inventory TRI (44)	Generic	Single	28
Expectations About Counseling - Brief Form EACB (45)	Specific	Multi	66
Expectations of Gynecological Treatment Questionnaire EGTQ (46)	Specific	Multi	24
Exercise Outcomes Expectations Questionnaire EOE-Q (47)	Specific	Multi	20
Expectations Towards ICD therapy EXPECT-ICD (48)	Specific	Multi	10
Orthodontic Treatment Expectations (49)	Specific	Multi	15
Self-Efficacy Expectations and Outcome Expectations SE- & OE-ICD (50)	Specific	Multi	17
Smoking Abstinence Expectancies Questionnaire SAEQ (51)	Specific	Multi	28
Psychosocial Treatment Expectations Questionnaire PTEQ (52)	Specific	Multi	13
Acupuncture expectancy scale AES (53)	Specific	Single	7
Anaesthesiological Questionnaire ANP-E (54)	Specific	Single	17
Cardiac Surgery Patient Expectations Questionnaire C-SPEQ (55)	Specific	Single	20
Chiropractic Patients' Expectations (56)	Specific	Single	15
Control Attitudes Scale-Revised CAS-R (57)	Specific	Single	3
Expectations for Complementary and Alternative Medicine Treatments Questionnaire EXPECT (58)	Specific	Single	13
Expectations Questionnaire EQ (59)	Specific	Single	6
Future Expectations Regarding Life with Heart Disease scale FERLHDS (60)	Specific	Single	18
Hospital for Special Surgery Knee Surgery Expectations Survey KSES (19)	Specific	Single	23
Knee Self-Efficacy Scale K-SES (61)	Specific	Single	22
Musculoskeletal Outcomes Data Evaluation and Management System MODEMS (62)	Specific	Single	6
New Knee Society Knee Scoring System NKSSS (63)	Specific	Single	8
Patient Shoulder Outcome Expectancies PSOE (64)	Specific	Single	3
Sample Patient Questionnaire SPQ (65)	Specific	Single	12
Treatment-specific Optimism TSO (66)	Specific	Single	10

Notes. Multi = several expectation dimensions are each assessed by an independent scale; *Single* = only one expectation dimension is assessed; *Generic* = not directly referring to a specific treatment, *Specific* = directly referring to a specific treatment. The format of the table has been adapted from Laferton et al. (18).

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Cognitive interviews: Evaluation of comprehensibility and acceptance

The qualitative analysis of patients' treatment expectations identified eight major expectation themes. Of these, six themes fitted our theoretical model, with 60 statements that could clearly be assigned to one of the hypothesized sub-dimensions of the TEX-Q. The two other themes were the absence of expectations (e.g., "I do not expect anything in particular", ID: 1001) with 11 mentions, and an unspecific feeling of stress about the treatment mentioned two times (e.g. "I am tense how this will proceed" ID: 1003). The results of this analysis were interpreted as support for our conception of the TEX-Q. Therefore, this conception was retained for the construction of the scale.

The analysis of criticism about the items, derived from the interview transcripts as well as the interviewers' notes, lead to identification of four major aspects of criticism. Each of these aspects had implications for the presentation and phrasing of the TEX-Q that directly informed our construction of the scales' initial version (Table 2). Especially aspect 4 was broadly discussed with the aim to capture both the probabilistic and strength related aspects of expectations in an easily comprehensible way, resulting in the reformulation of all remaining items into a change question format and the addition of a brief introductory text asking patients to assess their expectations "as realistically as possible". Furthermore, various item-level criticisms on the content and wording of specific items were identified as minor themes of criticism and lead to a modification or deletion of the respective items.

Table 2: Aspects of qualitative analysis & consequences for questionnaire development

Aspects of criticism	Illustrative examples	Implications for development process
Aspect 1: Commentary on the preferred wording of the anchors of the likert-scales	**"The anchors don't match the question, seems like they are asking for two different things in one question."** Commentary about Item 2b: How much improvement in your condition do you expect? Anchors: 0 (no change)/10 (largest possible improvement) (ID: 1002)	➢ Changing the anchors to every item ➢ Using the same specific phrasing for the low and the high anchor
Aspect 2: Comparison of analogue phrasings for key constructs *to hope/ to expect/ to fear* with phrasings like *to think* or *to whish*	**"To wish for something isn't reality, you can wish for inaccessible things, to hope for something is more realistic.''** (ID: 1004)	➢ Only using "to hope", "to expect" and "to fear" in every item ➢ Deleting all analogical phrases
Aspect 3: Evaluation of the theoretical differentiation between probabilistic and value-based expectation	**"To expect and to hope are different from each other. You can hope for a lot more than expect. To expect is more realistic."** (ID: 1009)	➢ Retaining the differentiation between hope and expect
Aspect 4: Comparison of two different versions of exemplary items: *change-question-* or *statement-*formulation	**"The phrasing of 24a triggers burdens when you're at the beginning of the treatment, 24b doesn't trigger burdens.'** Commentary about item 24a) vs. 24b): 24a) I expect to be burdened by the treatment. 24b) How much burden do you expect your treatment will cause? (ID: 1005)	➢ Inconclusive preferences among the interviewees ➢ Choosing *change-question* format for better acceptability & comprehensibility in some items
Item-level criticism: Commentary on the content or wording of specific items	**"Item sounds like it is just for psychotherapy."** Commentary about item 15: I expect to take part more actively in social life due to treatment. (ID: 1007)	➢ Rewording of items ➢ Deletion of items ➢ Consideration in the discussion about the final item-selection

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The Treatment Expectation Questionnaire

After completion of the aforementioned steps of gathering empirical evidence, the construction of the initial TEX-Q version was accomplished in a final item selection process. It contains 35 items on the 10 different subscales derived from our theoretical model with 3-4 items in each subscale. Every item contains either the verb to expect, to hope or to fear and is formulated as a question asking for the amount of change the patients expect to experience following their treatment. Each item is presented on a 10-point-likert-scale with specific anchors, the lower anchor always indicating no expected change. Example items for each subscale of the TEX-Q in preliminary translation are shown in Table 3.

Table 3: Illustrative TEX-Q items for each subscale

Expected benefits												
How much relief in your symptoms do you expect from the treatment?												
no relief	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	complete relief
Expected positive impact												
How much improvement do you expect in your ability to do your daily activities (e.g., occupation, household, social life)?												
no improvement	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	complete improvement
Expected harm												
To what extent do you expect risks from your treatment?												
no risks	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extreme risks
Expected negative impact												
How much do you expect the treatment will reduce your quality of life?												
not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extremely
Desired benefits												
How much benefit do you hope for from the treatment?												
no benefit	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extreme benefit
Desired impact												
How much improvement do you hope for considering your emotional state?												
no improvement	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extreme improvement
Feared harm												
To what extent do you fear risks from the treatment?												
no risk	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extreme risk
Feared negative impact												
How much do you fear the treatment will limit your day-to-day responsibilities (e.g., at home, at work, in the family)?												
not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extremely
Process related expectations												
To what extent do you expect to be satisfied with the treatment procedure or process?												
not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extremely
Expected behavioural control of the treatment												
To what extent do you expect your own behaviour to influence the success of the treatment?												
Not at all	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	extremely

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Discussion

This study describes the successful development of the Treatment Expectation Questionnaire (TEX-Q), a new scale for generically and multidimensionally measuring expectations of medical or psychological treatments. To accomplish this, an elaborate development process was necessary that incorporated the complex and diverse literature and evidence on expectations. The final TEX-Q will be available in German and English after psychometric evaluation. The scale is based on a comprehensive review of literature that provided an overview of existing treatment expectation scales and items. The evidence gathered from the review empirically validated our Integrative Model of Expectations (18) as well as our conceptualization for the TEX-Q with 10 sub-dimensions derived from it. In line with our results, our model has further been empirically supported by a recent systematic review of expectation measurement in orthopedic surgery (67). Few generic multidimensional scales, but several good treatment-specific measures were found and served as a source for our items. These items were modified and reformulated in the course of the development of the scale. This was informed by feedback from external experts in the field of placebo-, psychosomatic and clinical psychology research and by patient feedback.

The TEX-Q has advantages over previous measures of treatment expectations. Its fully generic nature enables the comparability of assessments across different treatments and conditions. It thus presents an advantage over treatment specific measurements as well as generic scales with limited scope, such as scales limited to psychotherapy (36, 38), scales solely focusing expectations regarding symptoms (i.e. pain), but not expectations regarding a broader impact on life (i.e. quality of life) (37, 68). It furthermore has a theory-based, multidimensional structure, covering different aspects of treatment expectations about symptom change, possible adverse events and the broader impact of the treatment and its process. This distinguishes the TEX-Q from established generic instrument like the Questionnaire for Patient Expectations of Health Care (16), which mostly focuses on expectations about the structure and process of the treatment process or the Credibility/Expectancy Questionnaire (39) and the newly developed Expectation for Treatment Scale (69), which only assess positive outcome expectations.

Several issues within the development process need to be considered. A major challenge of developing a generic measure of treatment expectations was that it was impossible, at least empirically, to take every possible medical application specifically into account. While the scale could be developed and tested in a variety of different clinical settings, involving different surgical as well as psychological treatments, further settings, like pharmacological or physical therapy treatments, could have been beneficial. The development might therefore have been shaped by the treatments of patients interviewed, as well as other conditions of the development process, such as the limited scope of the research team or the experts involved for feedback. In future, we will test the TEX-Q in additional clinical settings to further broaden the empirical basis for the argument of the generic applicability of the TEX-Q. Other important limitations lie on the conceptual level. Our item phrasing is ambiguous with regard to two different aspects of expectations, assessing the magnitude of an expected change as well as the expected probability of its occurrence to some extent. The relevance of this differentiation was pointed out in the Integrative Model of Expectations (18) and is further supported by recent empirical evidence (70). Based on Kirsch's (22) theoretical considerations regarding the probabilistic nature of non-volitional expectations, and on Sherman's (71) in-depth analysis of patients' understanding of treatment expectations, our phrasing aimed to capture best both aspects of

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magnitude and probability. To prevent ambiguity, each of these aspects could have been assessed in a separate item (e.g., "How likely do you think your symptoms will improve?" and "How much improvement do you expect?"), but we refrained from it for the sake of our scale's brevity and applicability. This may lead to differences in individual interpretations of our items and thereby lower their quality. Furthermore, although the theory-based construction of the questionnaire grounded in the Integrative Model of Expectations (18) provided a valuable framework for its subdimensions, it may thereby also have led to the exclusion of additional dimensions that could have emerged in a purely empirical concept development. Furthermore, expectation constructs mentioned by some authors had to be excluded from the TEX-Q for the sake of feasibility and applicability. Especially the work of Bowling et al. (16) is to be mentioned here, whose focus on treatment process expectations allowed them a more nuanced assessment, e.g. including items on expectations about the doctor-patient communication style or information provision. Another aspect is the exclusion of expectations about the *timeline* of the treatment and effects caused by it, e.g. their duration and sustainability. While it was hoped initially the TEX-Q that could measure such expectations, it was not feasible at the item level to ask for the many possible treatment trajectories.

The development of the TEX-Q facilitates a broad range of possibilities for future research, both in the evaluation and further development of the scale itself, as well as its use in applied research. Further validation of the scale in different clinical settings is necessary to confirm the psychometric properties of the TEX-Q and possibly further reduce its number of items. Therefore, the psychometric evaluation with patients from four different clinical settings will be published elsewhere. Other planned steps include the development of a brief version, evaluation of sensitivity to change and translation of the scale into other languages. An important contribution of the TEX-Q is that it will enable a comparison of the data gathered across studies on different conditions and treatments. Thereby, it will produce integrated evidence leading to further knowledge about the role of patients' treatment expectations. Furthermore, the subscales of the TEX-Q can be used to further differentiate the effects of the aspects of treatment expectations between conditions and treatment outcomes. The knowledge gained can also contribute to the development of interventions designed to use expectation related placebo effects to improve outcomes of everyday clinical practices.

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Literature

1. Mondloch MV, Cole DC, Frank JW. Does how you do depend on how you think you'll do? A systematic review of the evidence for a relation between patients' recovery expectations and health outcomes. Canadian Medical Association Journal. 2001;165(2):174-9.
2. Rief W, Glombiewski JA, Gollwitzer M, Schubo A, Schwarting R, Thorwart A. Expectancies as core features of mental disorders. Curr Opin Psychiatry. 2015;28(5):378-85.
3. Constantino MJ, Arnkoff DB, Glass CR, Ametrano RM, Smith JZ. Expectations. J Clin Psychol. 2011;67(2):184-92.
4. Enck P, Bingel U, Schedlowski M, Rief W. The placebo response in medicine: minimize, maximize or personalize? Nat Rev Drug Discov. 2013;12(3):191-204.
5. Colagiuri B, Zachariae R. Patient expectancy and post-chemotherapy nausea: a meta-analysis. Annals of Behavioral Medicine. 2010;40(1):3-14.
6. Jones F, Riazi A. Self-efficacy and self-management after stroke: a systematic review. Disability and rehabilitation. 2011;33(10):797-810.
7. Mahomed NN, Liang MH, Cook EF, Daltroy LH, Fortin PR, Fossel AH, et al. The importance of patient expectations in predicting functional outcomes after total joint arthroplasty. The Journal of rheumatology. 2002;29(6):1273-9.
8. van den Akker-Scheek I, Stevens M, Groothoff JW, Bulstra SK, Zijlstra W. Preoperative or postoperative self-efficacy: which is a better predictor of outcome after total hip or knee arthroplasty? Patient Education and Counseling. 2007;66(1):92-9.
9. Smeets RJ, Beelen S, Goossens ME, Schouten EG, Knottnerus JA, Vlaeyen JW. Treatment expectancy and credibility are associated with the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. The Clinical Journal of Pain. 2008.
10. Auer CJ, Glombiewski JA, Doering BK, Winkler A, Laferton JAC, Broadbent E, et al. Patients' Expectations Predict Surgery Outcomes: A Meta-Analysis. Int J Behav Med. 2016;23(1):49-62.
11. Juergens MC, Seekatz B, Moosdorf RG, Petrie KJ, Rief W. Illness beliefs before cardiac surgery predict disability, quality of life, and depression 3 months later. Journal of psychosomatic research. 2010;68(6):553-60.
12. Shedden-Mora MC, Nestoriuc Y, Rief W. Lessons learned from placebo groups in antidepressant trials. Philos Trans R Soc Lond B Biol Sci. 2011;366(1572):1879-88.
13. Nestoriuc Y, von Blanckenburg P, Schuricht F, Barsky AJ, Hadji P, Albert U-S, et al. Is it best to expect the worst? Influence of patients' side-effect expectations on endocrine treatment outcome in a 2-year prospective clinical cohort study. Annals of Oncology. 2016;27(10):1909-15.
14. Nestoriuc Y, Orav EJ, Liang MH, Horne R, Barsky AJ. Prediction of nonspecific side effects in rheumatoid arthritis patients by beliefs about medicines. Arthritis Care Res (Hoboken). 2010;62(6):791-9.
15. van Hartingsveld F, Ostelo RW, Cuijpers P, de Vos R, Riphagen II, de Vet HC. Treatment-related and patient-related expectations of patients with musculoskeletal disorders: a systematic review of published measurement tools. The Clinical Journal of Pain. 2010;26(6):470-88.
16. Bowling A, Rowe G, Lambert N, Waddington M, Mahtani K, Kenten C, et al. The measurement of patients' expectations for health care: a review and psychometric testing of a measure of patients' expectations: Prepress Projects Limited; 2012.
17. Zywiel MG, Mahomed A, Gandhi R, Perruccio AV, Mahomed NN. Measuring expectations in orthopaedic surgery: a systematic review. Clin Orthop Relat Res. 2013;471(11):3446-56.
18. Laferton JAC, Kube T, Salzmann S, Auer CJ, Shedden-Mora MC. Patients' Expectations Regarding Medical Treatment: A Critical Review of Concepts and Their Assessment. Front Psychol. 2017;8:233.
19. Mancuso CA, Sculco TP, Wickiewicz TL, Jones EC, Robbins L, Warren RF, et al. Patients' expectations of knee surgery. JBJS. 2001;83(7):1005-12.
20. Leedham B, Meyerowitz BE, Muirhead J, Frist WH. Positive expectations predict health after heart transplantation. Health Psychology. 1995;14(1):74.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

21. Maddux J. Expectations and health. Cambridge Handbook of Psychology, Health and Medicine. 2007:87-92.
22. Kirsch I. Response expectancy as a determinant of experience and behavior. Am Psychol. 1985;40(11):1189-202.
23. Leventhal H, Meyer D, Nerenz D. D.(1980). The common sense represen tation of illness danger. Medical Psychology New York: Pergamon. 1980.
24. Cameron LD, Leventhal H. The self-regulation of health and illness behaviour: psychology press; 2003.
25. Colagiuri B, Zachariae R. Patient expectancy and post-chemotherapy nausea: a meta-analysis. Ann Behav Med. 2010;40(1):3-14.
26. Fadyl J, McPherson K. Return to work after injury: a review of evidence regarding expectations and injury perceptions, and their influence on outcome. J Occup Rehabil. 2008;18(4):362-74.
27. Haanstra TM, van den Berg T, Ostelo RW, Poolman RW, Jansma IP, Cuijpers P, et al. Systematic review: do patient expectations influence treatment outcomes in total knee and total hip arthroplasty? Health and quality of life outcomes. 2012;10(1):152.
28. Beatty PC, Willis GB. Research Synthesis: The Practice of Cognitive Interviewing. Public Opinion Quarterly. 2007;71(2):287-311.
29. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77-101.
30. Younger J, Gandhi V, Hubbard E, Mackey S. Development of the Stanford Expectations of Treatment Scale (SETS): a tool for measuring patient outcome expectancy in clinical trials. Clin Trials. 2012;9(6):767-76.
31. Schwarzer R. Optimism, vulnerability, and self-beliefs as health-related cognitions: a systematic overview. Psychol. Health. 1994;9(3):161–180.
32. Schwarzer R, Jerusalem M. The general self-efficacy scale (GSE). Anxiety, Stress, and Coping. 2010;12:329-45.
33. Scheier MF, Carver CS. Optimism, coping, and health: assessment and implications of generalized outcome expectancies. Health psychology. 1985;4(3):219.
34. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception questionnaire. Journal of psychosomatic research. 2006;60(6):631-7.
35. Moss-Morris R, Weinman J, Petrie K, Horne R, Cameron L, Buick D. The Revised Illness Perception Questionnaire (IPQ-R). Psychology & Health. 2002;17(1):1-16.
36. Norberg MM, Wetterneck CT, Sass DA, Kanter JW. Development and psychometric evaluation of the Milwaukee Psychotherapy Expectations Questionnaire. Journal of clinical psychology. 2011;67(6):574-90.
37. Robinson ME, Brown JL, George SZ, Edwards PS, Atchison JW, Hirsh AT, et al. Multidimensional success criteria and expectations for treatment of chronic pain: the patient perspective. Pain Medicine. 2005;6(5):336-45.
38. Schulte D. Patients' outcome expectancies and their impression of suitability as predictors of treatment outcome. Psychotherapy Research. 2008;18(4):481-94.
39. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. Journal of behavior therapy and experimental psychiatry. 2000;31(2):73-86.
40. Dohnke B, Müller-Fahrnow W, Knäuper B. Der Einfluss von Ergebnis-und Selbstwirksamkeitserwartungen auf die Ergebnisse einer Rehabilitation nach Hüftgelenkersatz. Zeitschrift für Gesundheitspsychologie. 2006;14(1):11-20.
41. Laferton JAC, Shedden-Mora MC, Auer CJ, Moosdorf R, Rief W. Enhancing the efficacy of heart surgery by optimizing patients' preoperative expectations: study protocol of a randomized controlled trial. American heart journal. 2013;165(1):1-7.
42. von Blanckenburg P, Schuricht F, Albert U-S, Rief W, Nestoriuc Y. Optimizing expectations to prevent side effects and enhance quality of life in breast cancer patients undergoing endocrine therapy: study protocol of a randomized controlled trial. BMC Cancer. 2013;13(1):426.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

43. Powell R, Johnston M, Smith WC, King PM, Chambers WA, Krukowski Z, et al. Psychological risk factors for chronic post-surgical pain after inguinal hernia repair surgery: a prospective cohort study. European journal of pain. 2012;16(4):600-10.
44. Hirani SP, Patterson DL, Newman SP. What do coronary artery disease patients think about their treatments? An assessment of patients' treatment representations. Journal of health psychology. 2008;13(3):311-22.
45. Tinsley H. Expectations About Counseling: Unpublished test manual. Carbondale, IL: Southern Illinois University at Carbondale, Department of Psychology. 1982.
46. Marchant-Haycox S, Liu D, Nicholas N, Salmon P. Patients' expectations of outcome of hysterectomy and alternative treatments for menstrual problems. Journal of behavioral medicine. 1998;21(3):283-97.
47. Gecht MR, Connell KJ, Sinacore JM, Prohaska TR. A survey of exercise beliefs and exercise habits among people with arthritis. Arthritis & Rheumatology. 1996;9(2):82-8.
48. Habibovic M, Pedersen SS, van den Broek KC, Denollet J. Monitoring treatment expectations in patients with an implantable cardioverter-defibrillator using the EXPECT-ICD scale. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology. 2014;16(7):1022-7.
49. Bos A, Hoogstraten J, Prahl-Andersen B. Expectations of treatment and satisfaction with dentofacial appearance in orthodontic patients. American journal of orthodontics and dentofacial orthopedics. 2003;123(2):127-32.
50. Dougherty CM, Johnston SK, Thompson EA. Reliability and validity of the self-efficacy expectations and outcome expectations after implantable cardioverter defibrillator implantation scales. Applied nursing research. 2007;20(3):116-24.
51. Abrams K, Zvolensky MJ, Dorman L, Gonzalez A, Mayer M. Development and validation of the smoking abstinence expectancies questionnaire. Nicotine & Tobacco Research. 2011;13(12):1296-304.
52. de Carvalho Leite JC, Seminotti N, Freitas PF, de Lourdes Drachler M. The Psychosocial Treatment Expectations Questionnaire (PTEQ) for Alcohol Problems. European Journal of Psychological Assessment. 2011.
53. Mao JJ, Armstrong K, Farrar JT, Bowman MA. Acupuncture expectancy scale: development and preliminary validation in China. Explore: The Journal of Science and Healing. 2007;3(4):372-7.
54. Hüppe M, Klotz K-F, Heinzinger M, Prüßmann M, Schmucker P. Beurteilung der perioperativen Periode durch Patienten Erste Evaluation eines anästhesiologischen Nachbefragungsbogens. Der Anaesthesist. 2000;49(7):613-24.
55. Holmes SD, Fornaresio LM, Miller CE, Shuman DJ, Ad N. Development of the cardiac surgery patient expectations questionnaire (C-SPEQ). Quality of Life Research. 2016;25(8):2077-86.
56. Sigrell H. Expectations of chiropractic patients: the construction of a questionnaire. Journal of manipulative and physiological therapeutics. 2001;24(7):440-4.
57. Moser DK, Riegel B, McKinley S, Doering LV, Meischke H, Heo S, et al. The Control Attitudes Scale-Revised: Psychometric evaluation in three groups of cardiac patients. Nursing research. 2009;58(1):42.
58. Jones SM, Lange J, Turner J, Cherkin D, Ritenbaugh C, Hsu C, et al. Development and Validation of the EXPECT Questionnaire: Assessing Patient Expectations of Outcomes of Complementary and Alternative Medicine Treatments for Chronic Pain. J Altern Complement Med. 2016;22(11):936-46.
59. Razmjou H, Finkelstein JA, Yee A, Holtby R, Vidmar M, Ford M. Relationship between preoperative patient characteristics and expectations in candidates for total knee arthroplasty. Physiotherapy Canada. 2009;61(1):38-45.
60. Axelrad KJ. Locus of control and causal attributions as they relate to expectations for coping with a heart attack. 1982.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

61. Thomeé P, Währborg P, Börjesson M, Thomeé R, Eriksson BI, Karlsson J. A new instrument for measuring self-efficacy in patients with an anterior cruciate ligament injury. Scandinavian Journal of Medicine & Science in Sports. 2006(16):181-7.
62. Tashjian RZ, Bradley MP, Tocci S, Rey J, Henn RF, Green A. Factors influencing patient satisfaction after rotator cuff repair. Journal of shoulder and elbow surgery. 2007;16(6):752-8.
63. Noble PC, Scuderi GR, Brekke AC, Sikorskii A, Benjamin JB, Lonner JH, et al. Development of a new Knee Society scoring system. Clinical Orthopaedics and Related Research®. 2012;470(1):20-32.
64. O'Malley KJ, Roddey TS, Gartsman GM, Cook KF. Outcome expectancies, functional outcomes, and expectancy fulfillment for patients with shoulder problems. Medical care. 2004;42(2):139-46.
65. Habib SB, Sonoda L, See TC, Ell PJ, Groves AM. How do patients perceive the benefits and risks of peripheral angioplasty? Implications for informed consent. Journal of Vascular and Interventional Radiology. 2008;19(2):177-81.
66. Cohen L, de Moor C, Amato RJ. The association between treatment-specific optimism and depressive symptomatology in patients enrolled in a Phase I cancer clinical trial. Cancer. 2001;91(10):1949-55.
67. Cortes A, Meints SM, Katz JN. Characterizing the Use of Expectations in Orthopedic Surgery Research: A Scoping Review. ACR Open Rheumatol. 2019;1(7):440-451.
68. Page MG, Ziemianski D, Martel MO, Shir Y. Development and validation of the Treatment Expectations in Chronic Pain Scale. Br J Health Psychol. 2019;24(3):610-28.
69. Barth J, Kern A, Luthi S, Witt CM. Assessment of patients' expectations: development and validation of the Expectation for Treatment Scale (ETS). BMJ Open. 2019;9(6):e026712.
70. Devlin EJ, Whitford HS, Denson LA, Potter AE. 'Measuring up': A comparison of two response expectancy assessment formats completed by men treated with radiotherapy for prostate cancer. J Psychosom Res. 2020;132:109979.
71. Sherman, KJ, Eaves, ER, Ritenbaugh, C, Hsu, C, Cherkin, DC, Turner, JA. Cognitive interviews guide design of a new CAM patient expectations questionnaire. BMC Complement Altern Med. 2014; 14, 39.

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Competing interests statement

We declare that we have no significant competing financial, professional, or personal interests that might have influenced the performance or presentation of the work described in this manuscript.

Patient consent for publication

Obtained.

Data sharing statement

Datasets and statistical codes are available from the figshare-repository at https://figshare.com/projects/TEX-Q/72347.

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Author Statement

JA was involved in the conception of the scale, data acquisition, data analysis and interpretation, the writing of first draft and revision. BL was involved in the conception of the scale, data interpretation and the revising of the manuscript. MG was involved in the data acquisition, data analysis and interpretation, and the revising of the manuscript. KP was involved in the conception of the scale, data interpretation and the revising of the manuscript. JL was involved in the conception of the scale, data interpretation and the revising of the manuscript. YN was involved in the scale conception, data interpretation and critically revised the manuscript. MSM was involved in the conception of the scale, data acquisition, data analysis and interpretation, the writing of first draft and revision. All authors approved the final version of this manuscript.

APPENDIX

Appendix A: Description of the literature review

Appendix B: Interview guide

Appendix C: PRISMA-Flowchart

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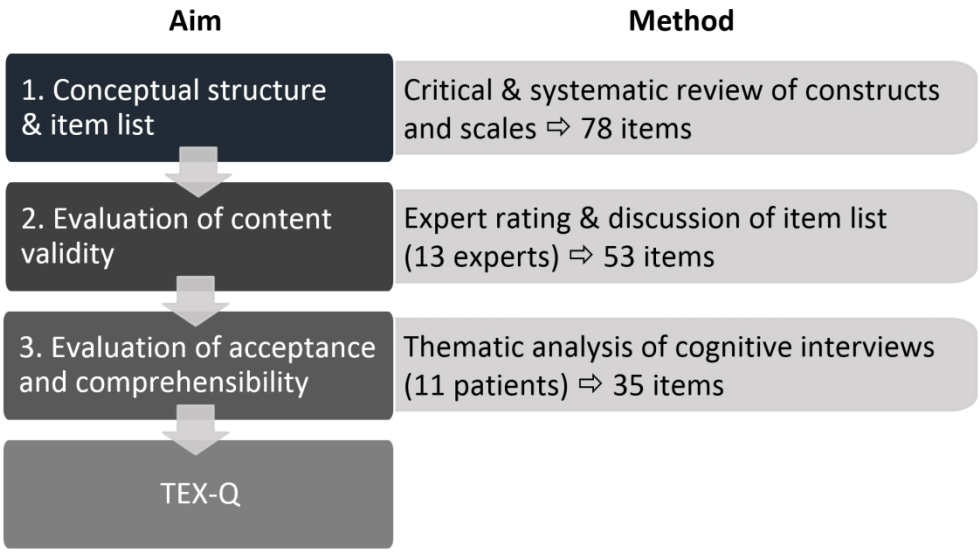

Figure 1: Overview of the development process

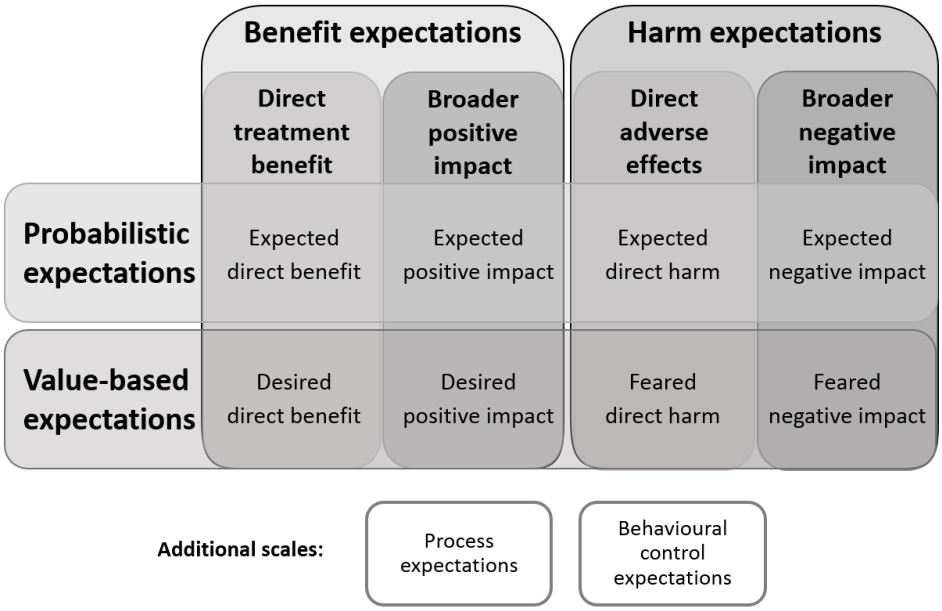

Figure 2: Conceptual structure of the TEX-Q treatment expectation scales.
Note. Cells describe the theorized subscales of the TEX-Q.

Appendix A – Alberts et al. TEX-Q

Appendix A: Description of the literature review

Databases: Pubmed, Psycinfo (through OVID)

Filter: Adult (19+) AND human AND English AND 1900-current

Search terms: (((treat* OR therap*) AND (measure* OR assess* OR diagnost* OR questionnaire OR scale OR instrument) AND (expectation* OR expectanc*)).ti,ab.) NOT ((life expectancy).ti,ab.)

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Appendix B – Alberts et al. TEX-Q

Department of Psychosomatic Medicine and Psychotherapy
University Medical Center Hamburg-Eppendorf

INTERVIEW GUIDE

COGNITIVE INTERVIEWS

Study
Development and psychometric evaluation of a generic, multidimensional Treatment Expectation Questionnaire (TEX-Q)

Study ID:

Comment: the interviewer will read out the following study information to the participant.

Introduction

Thank you for coming in and taking the time to take part in our interview today.
Before we start with the main part of our interview, I would like to explain the background of our study and introduce you to today`s procedure. Please read the study information and consent form carefully. If you agree and want to take part in our interview I would like you to sign the consent form. Please ask any questions at any time.
I will record our interview with this audio recorder [*show recorder*] so I do not need to write down everything you say and we can talk openly and freely.
From time to time I will take some additional notes.

Explanation of the project

This questionnaire deals with the subject of patient expectations. We aim to apply this questionnaire in order to assess the expectations that a person has regarding a planned treatment. To ensure that the questionnaire is useful and comprehensible, we would like to ask you for your evaluation today.
In this interview, we would especially like to know your impressions of the questionnaire.
In the following, I will ask you to complete the present questionnaire.

Explanation of the procedure

I would like you to read each presented statement or question very carefully, read it out loud and mark the answer that applies to you.
While you do this, I would like to know what you think and feel. Please express all occurring thoughts out loud so I can hear them. Please express your thoughts WHILE marking the item.
If you find a statement understandable, please tell me about it. If you find a statement incomprehensible, please tell me about it as well.

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In case you do not understand the statement or the question or you do not know how to answer the question, please let me know why this is the case. I would like you to tell me if you like the question or dislike the item and why you do so. If a phrasing appears particularly appropriate or inappropriate to you, I would like you to share your thoughts about the item.
This interview will be conducted openly, none of your answers will have any negative consequences for you. For us, it is relevant to make sure that our questionnaire is comprehensible; there are no right or wrong answers. It is totally fine if you do not want to answer a particular statement, there will be no disadvantages for you. Please do not hold back any thoughts; every thought could be interesting and helpful for us.
In some parts of this questionnaire, we will present two different phrasings for the same question. Please read both of the phrasings carefully and tell me your thoughts about them. If you prefer one phrasing over the other, please tell me about it. We would like to know which of these phrasings you prefer.
You can help us at this phase of our questionnaire development by sharing your thoughts and impressions on the present statements.
[*Hand out questionnaire to participant*]

Section 1: Sociodemographic information

[Information is not displayed here.]

Section 2: information on the disease and treatment

1. For which disease or complaints are you currently seeking treatment?

2. What treatment will you receive?

3. What do you hope for from this treatment?

4. What are your concerns about this treatment?

5. What do you realistically expect from this treatment?

negative expectations	☐ -5	☐ -4	☐ -3	☐ -2	☐ -1	☐ 0	☐ +1	☐ +2	☐ +3	☐ +4	☐ +5	positive expectations

6. Overall, which expectations regarding the treatment are predominant?

7. Overall, how much improvement do you expect from this treatment?

no improvement	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	maximum improvement

8. Have you received this treatment before?
   0 ☐ yes 1 ☐ no

9. If yes, what experiences have you had with this treatment?

10. If yes, how would you rate your previous experiences with this treatment?

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Appendix B – Alberts et al. TEX-Q

negative experiences	☐ -5	☐ -4	☐ -3	☐ -2	☐ -1	☐ 0	☐ +1	☐ +2	☐ +3	☐ +4	☐ +5	positive experiences

11. Have you previously had other treatments for the same disease or complaints?
    0 ☐ yes 1 ☐ no

12. If yes, what experiences have you had with the previous treatments for your disease or complaints?

13. If yes, how would you rate your overall experiences with the treatments so far?

negative experiences	☐ -5	☐ -4	☐ -3	☐ -2	☐ -1	☐ 0	☐ +1	☐ +2	☐ +3	☐ +4	☐ +5	positive experiences

Section 3: TEX-Q items

Prior to presenting the TEX-Q items:

The following questions and statements are about the changes that you expect from the treatment.
In this part, we will present 53 different items, 16 of them are using two different phrasings for the same question. Please read both of the phrasings carefully and tell me your thoughts about them. If you prefer one phrasing over the other, please tell me about it. We would like to know which of these phrasings you prefer.

Comment: 53 Items are presented to the participant, 16 items are presented in two different versions. The items are not displayed here.

After presenting the TEX-Q items:

Thank you for your help! We have reached the end of the questionnaire.

1. Is there anything you would like to tell me right now? What do you think, how do you feel right now? How did you feel about answering the questionnaire?
2. Can you give me a final conclusion on the comprehensibility of the questionnaire?
3. Is there anything you think this is missing from this questionnaire?

Further questions if the topics have not been discussed yet:

1. Do you think that the terms “hope” and “expect” have different meanings?
2. Please tell me your thoughts about the following statement:
   “I expect the treatment to improve my functionality”.
   How do you define functionality? *[We aimed to know if the term functionality (German: Funktionsfähigkeit) is comprehensible]*

References

Our guideline was influenced by the following references:

1. Charters, E. (2003). The Use of Think-aloud Methods in Qualitative Research. An Introduction to Think-aloud Methods. *Brock Education Vol. 12, No. 2.*
2. Häder, M. Empirische Sozialforschung. Eine Einführung. (2010). 2. edition. *VS Verlag für Sozialwissenschaften*. 393-394.

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3. Sherman, K. J., Eaves, E. R., Ritenbaugh, C., Hsu, C., Cherkin, D. C., & Turner, J. A. (2014). Cognitive interviews guide design of a new CAM patient expectations questionnaire. *BMC Complementary and Alternative Medicine*, 14(1), 39.
4. van Oort, L., Schröder, C., French, D. P. (2011). What do people think about when they answer the Brief Illness Perception Questionnaire? A 'think-aloud' study. *British Journal of Health Psychology*, 231-245.

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Appendix C – Alberts et al. TEX-Q

Appendix C: PRISMA flowchart of the literature search

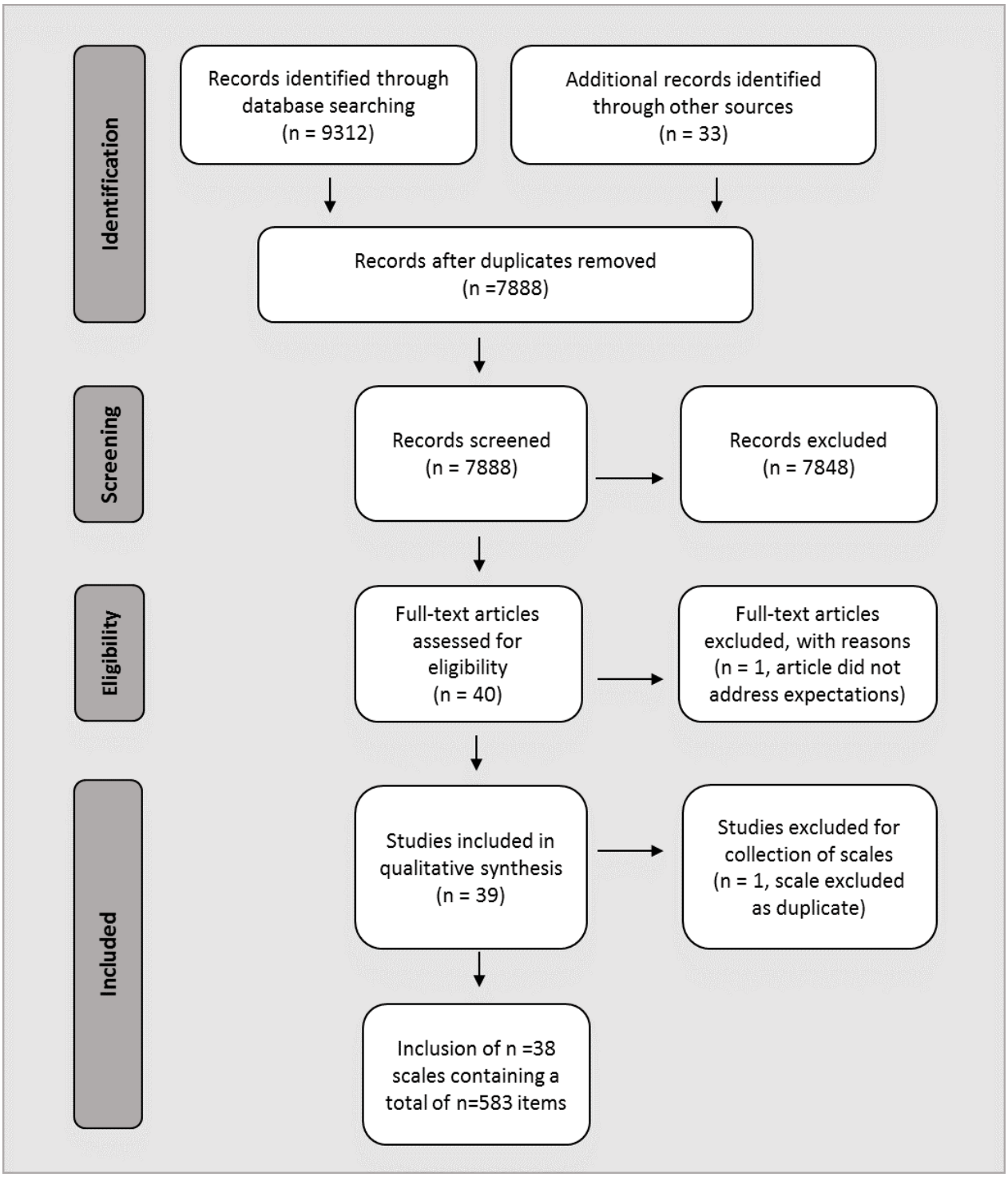

Figure 1: PRISMA flowchart of the literature search

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