

Generic rating scale for previous treatment experiences, treatment expectations, and treatment effects (GEEE)

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Aim:

We aimed to develop a screening tool that allows for the general assessment and quantification of patients' treatment expectations and their effects on clinical outcomes, irrespective of the clinical condition. In addition to patients' treatment related expectations, it assesses both prior treatment experiences and current experiences of treatment related effects as potentially relevant predictors of future expectations. Importantly, treatment expectations, as well as prior and current experiences are assessed on uniform scales including improvement as well as worsening and potential side effects.

Scope:

The GEEE screening allows for a compact assessment of treatment expectations in clinical as well as experimental settings. It enables the user to draw a comprehensive clinical picture about the treatment efficacy and tolerability, including expectations of and experiences with positive and negative treatment effects, as well as potential treatment side effects. This screening can be used in clinical research with patients, but it can be also adapted to the assessment of expectation effects in other settings (e.g., experiments with healthy volunteers).

Description:

Patients' expectations substantially contribute to treatment effects in most fields of medicine and health. This is not only an observation from randomized placebo-controlled clinical trials but has also been demonstrated in experimental settings and clinical proof-of-concept studies, where these effects have been systematically modulated.

According to contemporary models, patients' treatment expectations can be modulated in various ways: through verbal information (e.g., from health care professionals), through prior treatment experience or observational learning, and by characteristics of the therapeutic context or the therapeutic intervention itself.

Treatment expectations are not only considered the key determinant of placebo and nocebo effects but can also substantially modulate the efficacy and tolerability of active medical treatments (Barsky et al., 2002; Bingel et al., 2011; Bingel & for the Placebo Competence Group (U.Bingel P.Enck W.Rief M.Schedlowski), 2014; Petrie & Rief, 2019; Schedlowski et al., 2015)). This has been shown for analgesics, antidepressants, immune-modulating drugs, and even surgical procedures (Petrie & Rief, 2019).

Such modulatory effects of treatment expectations have been observed for subjective treatment outcomes (e.g., emotions, pain, and fatigue), behavioral measures, as well as for biological parameters (e.g., brain activity, cardiovascular parameters, and immune activity).

To systematically evaluate and quantify these effects, we need a generic screening tool that allows for the assessment of expectations and prior experiences with similar treatments before starting a new intervention. This screening should not only consider positive and negative expectations regarding the development of the patient's symptoms and complaints, but also expectations regarding the tolerability of the intervention in terms of side effects. When assessing pre-treatment experiences for very different treatments, it is helpful to offer a framework for assessing treatment intensity/treatment frequency in a similar way, independent of whether analgesics, hypertensives, or psychotherapy represent the focus of research.

Current measures of expectation have been solely developed for specific settings (such as orthopedic surgery, acupuncture, psychotherapy, or smoking abstinence expectations), thereby restricting the assessment and comparability across different clinical conditions and settings (for an overview on clinical expectation measures see: (Alberts et al., 2020)). The G-EEE is the first screening of treatment expectations and relevant treatment experiences that allows for a generic assessment of these variables.

Further research has shown that positive expectations and positive treatment related events are not just the opposite of negative expectations and negative treatment related events. This parallels findings on affect, showing that negative affect and (lack of) positive affect play different roles in mental disorders (Watson et al., 2011) and need to be considered separately. Similarly, people can have both positive and negative expectations about the same intervention. Therefore, a screening for expectations needs to address both dimensions.

Treatment expectations are not static but represent a dynamic process that adapts to new treatment-related experiences and information. Hence, today's treatment effects determine tomorrow's treatment expectations. Within this concept of dynamically fluctuating expectations and experiences, the G-EEE assesses the three relevant features of patients' treatment expectations in a comprehensive, yet condensed fashion, allowing for repeated assessments over the course of clinical and experimental trials.

To promote comparability of expectation effects in different clinical fields, intervention outcomes need to be assessed in a similar way, even if different biological or psychological systems are investigated. Therefore, we also designed a generic outcome screening of current treatment effects that can be used for all types of medical and psychological interventions.

For most variables, we used a Numeric Rating Scale (NRS) with a 0 – 10 scaling. This kind of scaling has been frequently used especially in pain research and it has shown to be easy to understand, practical in use, highly sensitive, and suitable for repeated measurements.

Evaluation:

The G-EEE is currently under further evaluation in a series of different studies. However, since its scaling format is frequently used in clinical research, we expect a positive evaluation of its reliability and validity. Its proximity to the TEX-Q gives another reason to expect good psychometric quality criteria: we use the same scaling as the longer, theoretically founded Treatment Expectation Questionnaire TEX-Q, (Alberts et al., 2020), and we use comparable items in the expectation part. While the G-EEE assess expectations with less items, it also addresses prior experiences and current intervention effects in a generic way. Further evaluation results will be reported as soon as they become available.

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English version:

Expectations

The following section refers to what expectations you have for the treatment:												
1. How much improvement ([insert: primary outcome]) do you expect from the treatment (optional: add name of treatment)?												
no improvement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	greatest improvement imaginable
	0	1	2	3	4	5	6	7	8	9	10	
2. How much worsening of ([insert: primary outcome]) do you expect from the treatment (optional: add name of treatment)?												
no worsening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	greatest worsening imaginable
	0	1	2	3	4	5	6	7	8	9	10	
3. How many complaints/side effects do you expect from the treatment (optional: add name of treatment)?												
no complaints	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	greatest complaints imaginable
	0	1	2	3	4	5	6	7	8	9	10	

Previous treatment experiences

4. The following section is about previous treatment experiences you had with (specify treatment):												
I have never experienced this treatment. (continue with question 8)												<input type="checkbox"/>
I have experienced this treatment during the last 12 months (nearly) daily.												<input type="checkbox"/>
I have experienced this treatment during the last 12 months on more than 10 days.												<input type="checkbox"/>
I have experienced this treatment during the last 12 months on about 5 to 10 days.												<input type="checkbox"/>
I have experienced this treatment during the last 12 months on about 1 to 4 days.												<input type="checkbox"/>
I have not experienced this treatment during the last 12 months, but I have experienced it before.												<input type="checkbox"/>
5. How much improvement of ([insert: primary outcome]) have you experienced with the treatment (optional: add name of treatment) in the past?												
no improvement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	greatest improvement imaginable
	0	1	2	3	4	5	6	7	8	9	10	

6. How much worsening of ([insert: primary outcome]) have you experienced with the treatment (optional: add name of treatment) in the past?												
no worsening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	greatest worsening imaginable
	0	1	2	3	4	5	6	7	8	9	10	
7. How many complaints/side effects have you experienced with the treatment (optional: add name of treatment) in the past?												
no complaints	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	greatest complaints imaginable
	0	1	2	3	4	5	6	7	8	9	10	

Current treatment effects

The following section is about what changes you have experienced since your participation in this study:												
8. How much improvement of ([insert: primary outcome]) have you experienced since?												
no improvement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	greatest improvement imaginable
	0	1	2	3	4	5	6	7	8	9	10	
9. How much worsening of ([insert: primary outcome]) have you experienced since?												
no worsening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Greatest worsening imaginable
	0	1	2	3	4	5	6	7	8	9	10	
10. How many complaints/side effects have you experienced since your participation/treatment with (insert: name of treatment)?												
no complaints	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	greatest complaints imaginable
	0	1	2	3	4	5	6	7	8	9	10	

Completion of study (this is an optional question if you want to evaluate the assumptions of the patient).

Thank you for your participation. In this study, you received a specific treatment (pill, cream, or similar). Regardless of the information provided by the study investigator, what do you believe regarding your treatment?

I believe this treatment (pill, cream) contained a real active ingredient.

☐

I believe this treatment (pill, cream) did not contain a real active ingredient.

☐

German version:

Erwartungen

Im folgenden Abschnitt geht es darum, welche Erwartungen Sie an die Behandlung haben:												
1. Wie viel Verbesserung der ([hier einsetzen: Primäres Outcome]) erwarten Sie durch die Behandlung (optional Name der Behandlung hinzufügen)?												
Keine Verbesserung	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	größte vorstellbare Verbesserung
	0	1	2	3	4	5	6	7	8	9	10	
2. Wie viel Verschlechterung der ([hier einsetzen: Primäres Outcome]) erwarten Sie durch die Behandlung (optional Name der Behandlung hinzufügen)?												
keine Verschlechterung	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	größte vorstellbare Verschlechterung
	0	1	2	3	4	5	6	7	8	9	10	
3. Wie viel Beschwerden/Nebenwirkungen erwarten Sie durch die Behandlung (optional Name der Behandlung hinzufügen)?												
keine Beschwerden	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	größte vorstellbare Beschwerden
	0	1	2	3	4	5	6	7	8	9	10	

Vorerfahrungen

4. Im folgenden Abschnitt geht es darum, welche früheren Behandlungserfahrungen Sie mit (Name der Behandlung hinzufügen) haben:												
Ich habe diese Behandlung noch nie erfahren. (weiter mit Frage 8)												<input type="checkbox"/>
Ich habe diese Behandlung in den letzten 12 Monaten (fast) täglich erfahren.												<input type="checkbox"/>
Ich habe diese Behandlung in den letzten 12 Monaten an mehr als 10 Tagen erfahren.												<input type="checkbox"/>
Ich habe diese Behandlung in den letzten 12 Monaten an ca. 5-10 Tagen erfahren.												<input type="checkbox"/>
Ich habe diese Behandlung in den letzten 12 Monaten an ca. 1 - 4 Tagen erfahren.												<input type="checkbox"/>
Ich habe diese Behandlung in den letzten 12 Monaten nicht erfahren, aber früher schon mal.												<input type="checkbox"/>
5. Wie viel Verbesserung der ([hier einsetzen: Primäres Outcome]) haben Sie durch die Behandlung mit (optional Name der Behandlung hinzufügen) in der Vergangenheit erfahren?												
keine Verbesserung	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	größte vorstellbare Verbesserung
	0	1	2	3	4	5	6	7	8	9	10	
6. Wie viel Verschlechterung der ([hier einsetzen: Primäres Outcome]) haben Sie durch die Behandlung mit (optional Name der Behandlung hinzufügen) in der Vergangenheit erfahren?												
keine Verschlechterung	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	größte vorstellbare Verschlechterung
	0	1	2	3	4	5	6	7	8	9	10	

7. Wie viel Beschwerden/Nebenwirkungen haben Sie durch die Behandlung mit (Name der Behandlung hinzufügen) in der Vergangenheit erfahren?

keine ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ größte vorstellbare
Beschwerden 0 1 2 3 4 5 6 7 8 9 10 Beschwerden

Aktuelle Effekte

Im folgenden Abschnitt geht es darum, welche **Veränderungen Sie seit Ihrer Teilnahme an dieser Studie** erfahren haben:

8. Wie viel Verbesserung der ([hier einsetzen: Primäres Outcome]) haben Sie seither erfahren?

keine ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ größte vorstellbare
Verbesserung 0 1 2 3 4 5 6 7 8 9 10 Verbesserung

9. Wie viel Verschlechterung der ([hier einsetzen: Primäres Outcome]) haben Sie seither erfahren?

keine Ver- ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ größte vorstellbare
schlechterung 0 1 2 3 4 5 6 7 8 9 10 Verschlechterung

10. Wie viel Beschwerden/Nebenwirkungen haben Sie seither (hier einsetzen: Behandlung) erfahren?

keine ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ größte vorstellbare
Beschwerden 0 1 2 3 4 5 6 7 8 9 10 Beschwerden

Abschluss der Studie (Dies ist eine optionale Frage, wenn Sie die Annahmen der Patienten evaluieren möchten)

Vielen Dank, dass Sie an der Studie teilgenommen haben. In der Studie haben Sie auch eine Behandlung bekommen (Pille, Creme, oder ähnliches).

Unabhängig von den Informationen der Studienleitung: Was glauben Sie bezüglich der verabreichten Behandlung?

Ich glaube, die Behandlung (Pille, Creme) enthielt einen echten Wirkstoff.

☐

Ich glaube, die Behandlung (Pille, Creme) enthielt keinen echten Wirkstoff.

☐

Literature

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