



Development of a patient-reported outcome measure for psychotherapeutic interventions in people with seizures: A mixed methods study

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ABSTRACT

Background: Generic or even disease-specific quality of life measures are unlikely to be equally responsive to different epilepsy treatment modalities, such as pharmacotherapy, surgery, or psychotherapy. The purpose of the present study was to summarize the development of a patient-reported outcome measure (PROM) designed to be particularly sensitive to change mediated by psychotherapeutic interventions in people with seizures.

Methods: The development of this instrument involved seven steps: (1) Development of a candidate item set based on the outcome of previous qualitative research, (2) initial quantitative-descriptive study yielding an assessment of content validity by clinical experts, (3) qualitative-descriptive posttherapy cognitive debriefing interviews with patients with epileptic and/or nonepileptic seizures (NES), (4) English translation, (5) elicitation of qualitative feedback from international experts, (6) assessment of internal consistency and correlation with similar previously validated generic and epilepsy-specific measures in a pilot study, and (7) final expert content validity rating.

Results: (1) The candidate item set comprised 29 stem items; five of which were followed by a follow-up (FU) item that refers to the statement of the stem item. (2) Eight clinical experts assessed content validity. Informed by rating and experts' qualitative comments, 15 items remained unchanged, eleven underwent substantial revisions, three were excluded, and six added. (3) Cognitive debriefing interviews were conducted with 14 patients with epilepsy and/or NES. Based on the interviewees' feedback, 29 of 32 items remained unchanged, two were excluded, one reworded, and four added. (4) The forwards-backwards English translation prompted substantial revision of two items because the verbatim back translation of the corresponding English items was conceptually more convincing than the original German wording. (5) The international experts identified problems with item comprehensibility/clarity of four stem and three FU items that were subsequently reworded. Ten items were added to incorporate their qualitative feedback resulting in a total of 44 items. (6) Thirty-one patients with epilepsy participated in the pilot study. The overall internal consistency of the self-Efficacy, Assertiveness, Social support, self-awareness, and helpful thinking in people with seizures (EASE) was very good ($\alpha = 0.92$). Analysis at item-level revealed problems with inverted and self-evident items. Based on this analysis, three items were eliminated and two items were revised (one FU item was turned into a stem item) resulting in a total of 42 items. (7) The second content validity rating showed final item-content validity indices (I-CVIs) between 0.38 and 1 and an excellent mean CVI of 0.92 at scale level (S-CVI/ave). Fourteen stem items were substantially revised by incorporating the experts' qualitative feedback, three items with low I-CVIs were excluded, and one item was added. The final questionnaire consisted of 40 stem items; eight of which include at least one FU item.

Conclusion: Based on these results, the EASE is valid in terms of content, internally consistent, clear, and acceptable to patients with seizures. The measure has now been developed to the stage at which the validity and reliability as well as the psychometric properties and factorial structure of the new instrument can be assessed in larger patient groups in a prospective clinical study.

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1. Introduction

Generic health-related quality of life (HRQOL) measures (i.e., Short Form-36, EQ-5D) are often used for comparisons between different conditions [1]. Although it is unlikely that they are similarly sensitive to change across different disorders, they are sometimes employed to allocate limited healthcare resources on the basis of Cost per Quality-Adjusted Life Year (QALY) calculations [2]. Condition-specific HRQOL measures (such as the Quality of Life in Epilepsy (QOLIE) for epilepsy) are designed to be more sensitive to the particular symptomatology and health-related challenges of the targeted disorder while still capturing the same domains as generic measures [3]. However, neither generic nor disease-specific measures are likely to respond equally to different treatment modalities in patients with seizures, such as pharmacotherapy, surgery, or psychotherapy. In fact, some patients may show psychotherapy-related worsening of their QOLIE score even if they and others feel that they have benefited from treatment, for instance, when psychotherapy has successfully reduced alexithymic tendencies and allowed patients to gain a better understanding of their uncomfortable emotions [4].

In addition, psychological processes are often disregarded as long as they are not associated with clinically relevant symptoms of anxiety and depression. However, particularly in light of the biopsychosocial model [5], proactive resource-oriented psychological concepts should be taken into consideration. Such resources have been shown to have a significant influence on how people cope with chronic disorders [6]. In contrast, a predominant focus on pathology (such as anxiety or depression) may orient the self-perception of patients in a detrimental and illness-promoting way [7,8].

Therefore, the development of a seizure-related patient-reported outcome measure (PROM) that enables researchers to quantify the multilayered changes that are specifically targeted by psychological intervention seems warranted. This measure targets resources that have been shown to positively influence coping and resilience in people with epilepsy such as general and seizure-related self-efficacy, social support, assertiveness, and helpful thinking. To the knowledge of the authors, no PROM with this specific goal has been developed, so far.

This new instrument is not intended to replace HRQOL or other outcome scales (such as measures of distress or psychopathology) but to complement their use specifically in the context of psychotherapeutic interventions for patients with seizures. Therefore, we aimed to avoid item overlap with other existing outcome measures in the development of this new PROM. The new measure is designed to be transtheoretical and to capture psychotherapy outcomes that could be produced with a range of different psychotherapeutic approaches (e.g., cognitive behavioral therapy (CBT), and psychodynamic therapy).

2. Methods

The development sequence of this instrument consisted of seven steps: (1) development of the candidate item set, (2) assessment of content validity by expert rating, (3) cognitive debriefing interviews, (4) English translation, (5) feedback from English experts, (6) assessment of internal consistency and its correlation with similar constructs in a pilot study, and (7) second expert content validity rating.

2.1. Ethical considerations

The study was approved by the Ethics Committee of the Faculty Human Sciences Department of Psychology, University of Kassel, Germany. All participating subjects were fully informed about the study, and patients signed informed consent forms.

2.2. Development of candidate item set

A previous qualitative study had investigated the effects of a psychotherapeutic intervention in people with epilepsy [9]. A candidate item set was developed based on the outcome of this previous qualitative research (CS and RM). The following steps were taken to enhance the overall quality of the instrument:

2.3. Expert validity index

Determination of content validity is part of the item-developing and refinement process, as it aims to rate the relevance and appropriateness of a candidate item set [10,11]. Professional experts with clinical expertise and expertise related to the conceptual framework as well as patients themselves may act as raters [10]. The candidate item set, a short introduction to the background of the project and a content validation form were sent to experts: Experts were asked to state whether each item was comprehensible (yes: comprehensible/no: not comprehensible) and relevant (yes: relevant/no: not relevant). Additionally, experts were invited to comment on each item and the candidate item set as a whole. The content validity index (CVI) was determined at item (I-CVI) and mean scale level (S-CVI/ave). The I-CVI was calculated by adding up all “yes” ratings for an item’s relevance and dividing the resulting number by that of the total number of experts [12]. This procedure results in an I-CVI = 1.0 indicating complete agreement on an item’s relevance and an I-CVI = 0 for complete agreement on an item’s irrelevance. The I-CVI values of at least 0.78 are usually considered “excellent” [13]. The S-CVI/ave is the mean of all I-CVIs values. The S-CVI/ave scores ≥ 0.90 indicate “excellent” content validity [14]. CS and RM reviewed scores and qualitative feedback and discussed if an item should be removed or revised. Changes were made by consensus.

2.4. Cognitive debriefing interviews

Cognitive interviewing is a synthesis of social psychology and survey research methodology that has been increasingly utilized since the 1970s to determine content validity of surveys [15,16]. In the 1980s, cognitive interviewing methods were developed to pretest study materials, to identify potential sources of response error, and to ensure clarity and relevance [17–19]. When associated with other reliability and validity measures, cognitive interviews can lead to effective instruments [16]. Consistent with good research practice guidance [20,21], the following three techniques were utilized: thinking aloud/reading aloud, cognitive verbal probing, and observing. The interviews were conducted with consecutive patients from the Hephata Klinik Schwalmstadt-Treysa by a psychotherapist (CS). Purposive sampling was used with the intention to recruit a clinically and demographically heterogeneous but representative sample or patients receiving psychotherapy to help with seizure-related problems. To be eligible for inclusion, interested patients had to be at least 18 years of age and to be able to read and speak German. Prior to seeing the draft questionnaire, participants were trained to ensure that the “thinking aloud” process would elicit sufficiently detailed information. During the interview, participants were asked to verbalize their thoughts and understanding aloud as they read each survey question aloud and then attempted to answer the question as they understand it [15–17,21]. Then, the participants were asked to paraphrase the questions in their own words and to define the meanings of each word to explore their comprehension. Probing identified words that could be misinterpreted or misunderstood and provided an opportunity to ask the participant to rephrase the question in their own words. This technique can be used to understand how a participant goes about answering a question and recalling information [15–17]. Nonverbal behaviors of participants such as frowning can also identify problematic questions or words that might provoke confusion, embarrassment, or anxiety, thus risking collection of invalid

data [21]. Therefore, the interviewer observed the participants as they read the questions aloud and noted examples of skipping questions, omitting words in the question, putting answers in the wrong place, and hesitation or other nonverbal indicators of frustration or stress. The interviewer took detailed field notes, and findings were summarized on a question-by-question basis. For pragmatic reasons (i.e., there was no funding available for professional transcription, and time resources of all involved clinician-researchers were limited), the interviews were not audio-recorded. In such cases, Willis emphasized: “reliance on written outcome notes alone may be sufficient” [17]. The interviewer (CS) documented her impression of the participants' attention and concentration immediately after the interviews. CS and RM reviewed the feedback and discussed if an item should be revised, removed, or added. Changes were made by consensus.

2.5. English translation

The translations were undertaken by a native German-speaking professional expert with very good command of the English language (MR) for three main reasons: firstly, to ensure that its finalized version captured concepts that were not too closely tied to the German language but more widely relevant, secondly, to elicit feedback from international experts representing diverse schools of psychotherapy, and thirdly, to introduce this instrument to the international research community in an English publication. The German and English versions were contrasted in a table. If the verbatim back translation of an English item (RM, CS) differed from the original German item but seemed more convincing, the original German item was changed by consensus.

2.6. Qualitative feedback from English experts

The English instrument was sent to an entirely British psychotherapy team with extensive experience working with patients with seizure disorders (Academic Neurology Unit, University of Sheffield, Royal Hallamshire Hospital, Sheffield, UK), and their feedback was collected in person (MR) during an open discussion. Several additional international experts were asked to comment on the English version. Their qualitative feedback was discussed between the authors (CS, MR, and RM), and refinements of the instrument were made by consensus.

2.7. Pilot study

A pilot study was conducted to examine the reliability (internal consistency), content, and construct validity of the instrument. Content analysis of the items of the self-Efficacy, Assertiveness, Social support, self-awareness, and helpful thinking in people with seizures (EASE) was performed to allocate each item of the EASE to a relevant domain i.e., subscale (CS and RM): resilience/vulnerability, mastery, general self-efficacy, epilepsy-specific self-efficacy, and self-awareness/acceptance. All items were rated on a five-point Likert scale. The following measures were used to examine content and construct validity: the General Self-Efficacy Scale (GSES) by Schwarzer & Jerusalem [22] consists of ten items that are rated on a four-point Likert scale, the German translation (RM) of the Epilepsy Self-Efficacy Scale (ESES) [23] consists of 33 items that are rated on an 11-point Likert scale, the German version of the Mastery Scale by Pearlin et al. [24,25] consists of four items that are rated on a five-point Likert scale, the German Resilience Scale (Röhrig, Schleussner, Brix, Strauss) [26] comprises 11 items that are rated on a seven-point Likert scale, and the Revised Sense of Coherence Scale (SOC-R) [27] measures 13 items on three dimensions (manageability, reflection, and balance) that are rated on a seven-point Likert scale. Medical and demographic data were collected using the Performance, Sociodemographic aspects, and Subjective evaluation (PESOS) [28]. The introduction to the questionnaire set included a patient information sheet and consent form that participants had to sign (pen and paper) or accept (in the online-setting). The participants could either

complete this set of questionnaires online via the Sosci-Survey-Portal (www.sosci-survey.de/) or by using pen and paper. In-patients who had been diagnosed with epilepsy and who had previous experience of psychotherapy or indicated an active interest in psychotherapy were approached consecutively and offered participation in the study.

2.8. Second expert validity rating

As cognitive debriefing interviews had already been conducted with patients, only professionals were recruited to a second expert panel for a final determination of content validity. In this assessment, experts were asked to judge the relevance of the items on a 4-point Likert scale ranging from 1 = not at all relevant to 4 = highly relevant. To calculate the I-CVI, the rating scale was dichotomized to ratings categorized as “not relevant” (scores 1 and 2) and relevant (3 and 4) [12]. Subsequent data analysis followed the process described in Subsection 2.3.

3. Results

3.1. Candidate item set

The candidate item set comprised 29 stem items probing self-awareness, social support, assertiveness, general and seizure-related self-efficacy (open communication about seizures, coping with epilepsy-related limitations and uncomfortable postictal states, dealing with personal seizure triggers, seizure interruption strategies), and helpful thinking. Therefore, the acronym EASE (self-Efficacy, Assertiveness, Social support, self-awareness, helpful thinking) was chosen for this instrument. Five of the stem items were followed by a follow-up (FU) item that refers to the statement of the stem item: e.g., the stem item “I know at least one trigger for my seizures” is followed by the FU item “I can avoid this trigger/these triggers in my daily life”.

3.2. Expert validity index

Ten experts were contacted. This group of experts included five clinicians and five patients with epilepsy who had undergone psychotherapy. Eight of the ten experts responded (four patients and four clinicians including one adult neurologist with a special interest in psychotherapy for people with seizures, two neuropsychologists, and one psychological therapist; all of the latter three were working with people with seizures on a regular basis). Seven returned the content validation form including CVI ratings described in Section 2.3, the psychological therapist (Gerd Heinen) responded by providing an unpublished questionnaire that he had used to follow up his own patients. Computer-assisted data analysis was performed using Microsoft Office Excel 2013. The content validity rating revealed I-CVIs between 0.71 and 1 and an “excellent” S-CVI/ave of 0.91.

The experts' qualitative comments prompted substantial revision of eleven items. A “substantial revision” was defined as any change to an item that involved more than (a) addition, removal, or substitution of a word that did not change the meaning of the phrase or (b) a change to the order of the words in the item that did not change the meaning of the phrase. Common problems seen in items included issues with comprehensibility/clarity, inadequate word choice, and compound items: Problems with comprehensibility/clarity were identified with seven items, and these items were reworded. Word choice was criticized in four items as overblown or carrying an inappropriately judgmental and positivistic connotation. Therefore, the wording of these items was substantially revised in order to become more patient-oriented. In addition, three of these revised items were identified as problematic because they combined two different questions. These compound items were split into two items.

It has been recommended that items with an I-CVI of <0.78 should be excluded [13]: Three (i.e., half) of all six items with an I-CVI of 0.71

were removed. The remaining three items with an I-CVI of 0.71 related to sensitive topics such as self-acceptance, a seizure disorder's influence on one's perspective toward life, and a resource-oriented approach toward problems. These three items had been substantially revised because of issues with item comprehensibility/clarity and word choice. A total of six items were added inspired by the review of the unpublished questionnaire that was provided by the psychological therapist. The resulting questionnaire comprised 32 items. One of these items was an open request to add personal comments, seven of the items included a FU item.

3.3. Cognitive debriefing interviews

Cognitive debriefing interviews were conducted with 14 patients. The group was diverse in terms of seizure types, duration, and severity of seizure disorders as well as psychiatric comorbidity and cognitive functioning (for detailed medical and demographical characteristics see Table 1). Each participant responded to all items. Participants' feedback was used to assess the consistency with the intended meaning, ambiguity of item language, interpretability, and completeness of items as well as the appropriateness of response options. Most items were readily understood, even by individuals with self-reported cognitive dysfunction. Feedback from cognitive debriefing interviews identified substantial problems with three items. Two of these were subsequently excluded, and one was substantially revised. Interviewees identified a lack of items relating to a number of domains that they considered relevant to their life with seizures. Therefore, four items were added to survey assertiveness (one item), stigma/social support (two items), and mood (one item). The resulting questionnaire comprised 34 items.

When asked about the appropriateness of response options, most participants made statements such as "they made sense" or "I didn't have any problems". However, one participant noted that the addition of "I do not know" or "I do not remember" response options would be helpful. However, including these options increases scoring complexity, and previous research suggests that they do not enhance data quality [29]. For these reasons, these response options were not added.

3.4. English translation

The verbatim back translation of two items differed slightly from the original German wording but seemed conceptually more convincing; therefore, the original German items were modified. For example, when translating the item "Ich habe Angst, anderen zur Last zu fallen", the wording "I worry" ("I worry about being a burden for others") was used instead of the literally correct wording "I am afraid". Therefore, the German word "Angst" ("fear") was replaced by "Sorge" ("worry"). Revised items can be found in Supplementary Table 1s.

3.5. Qualitative feedback from English experts

The British psychotherapy team indicated that they found the instrument's items meaningful in terms of investigating outcomes that were susceptible to change targeted by psychotherapeutic interventions for patients with seizures, and no changes were recommended. The following psychotherapeutic approaches are employed by this team on an integrative basis: Acceptance and commitment therapy, compassion focused therapy, CBT, couple/relationship therapy, eye movement desensitization and reprocessing (EMDR) therapy, gestalt psychotherapy, integrative arts psychotherapy, integrative relational developmental psychotherapy, intensive short term dynamic psychotherapy (ISTDP), lifespan integration therapy, psychodynamic psychotherapy, and sensorimotor psychotherapy.

Four additional international experts (clinician-researchers, either native English speakers or experts with very good command of the English language) identified problems with the comprehensibility/clarity of five item stems and three FU items. These items were substantially reworded. Two FU items were added because of the compound nature of one stem and one FU item. While the German psychologists had all been trained in CBT, the international experts had expertise related to CBT ($n = 1$), psychoanalytic ($n = 1$), or mindfulness-based approaches ($n = 2$). Therefore, they added additional psychotherapeutic perspectives to the review of the instrument, and ten items were added to incorporate feedback from the psychoanalytic expert. These added items related to concepts such as alexithymia (one item), self-reliance (one item), self-care (one item), emotional self-management (two items), social support (two items), assertiveness (one item), and pacing, i.e., prevention of overdoing things (one item). Furthermore, one unintrusive trauma-related item was added ("I am still troubled by things that happened to me in the past."). The resulting questionnaire included 44 items. Five had one FU item, two had two FU items, and one three FU items. Revised and added items are summarized in Supplementary Table 1s.

3.6. Pilot study

Thirty-one patients with epilepsy participated in the pilot study. Sixteen of these patients (52%) had another disease or disability aside from epilepsy. For additional medical and demographical characteristics see Table 2.

In response to the open question about seizure triggers, almost half of the patients mentioned stress (15 patients, 48%) or sleep problems (14 patients, 45%) as a trigger for their epileptic seizures; almost one-third (9 patients, 29%) answered that they were not aware of any triggers or they left the response field blank. The most commonly reported strategies used to help participants feel better after a seizure were sleep (17 patients, 55%) and distraction (4 patients, 13%). Eleven patients (35%) answered that they did not know any strategies or they left the

Table 1
Medical and demographical characteristics of interviewees in cognitive debriefing interviews.

Seizure type	Gender N	Age Median [range]	Seizure frequency N	Comorbid psychiatric diagnosis N	Neuropsychological dysfunction N
Focal unaware epileptic seizures	4 females 4 males	40 [24–68]	2 daily 4 weekly 2 monthly	2 MDE	6 MCI
Myoclonic seizures	1 male	27	Daily	None	None
Nonepileptic seizures	2 females	47 [22–49]	2 weekly	2 MDE 1 PD 1 PTSD	2 MCI
Mixed seizures	2 females 1 male	26 [21–43]	1 daily 2 weekly	3 MDE 1 PTSD 1 BPD	1 MCI

BPD: borderline personality disorder, MCI: mild cognitive impairment, MDE: moderate depressive episode, PD: panic disorder, PTSD: posttraumatic stress disorder.

Table 5
Descriptive statistics of the included validated questionnaires.

Scale	Min	Max	Range	M	SD	Cronbach's α
General self-efficacy (10 items)	2.00	4.00	2.00	2.91	0.52	0.91
Epilepsy Self-Efficacy Scale (33 items)	4.94	11.00	6.06	8.27	1.60	0.93
Mastery Scale (4 items)	1.25	5.00	3.75	3.54	1.04	0.84
Resilience Scale (11 items)	1.27	7.00	5.73	5.07	1.24	0.91
Sense of Coherence Scale (13 items)	2.92	4.86	1.92	3.8	0.46	0.78
Manageability	2.40	4.80	2.40	3.72	0.66	0.76
Reflection	3.25	5.00	1.75	3.94	0.47	0.58
Balance	1.75	5.00	3.25	3.84	0.78	0.69

Max: maximum, Min: minimum, M: mean.

expectation, there were significant negative correlations of the EASE with the constructs to be validated (see Table 4). In light of the previously reported results of item analyses, this unexpected finding in particular raised the suspicion of vague item wording and ambiguity of the answering options in addition to a larger number of negatively phrased items on the EASE. As shown by Solis Salazar [30], this could be relevant because positively formulated items may achieve higher scores than the inverted scores of their negatively formulated counterparts. Informed by these results, two negatively phrased items were positively reworded in order to remove the inverted scoring. The rewording of one stem item turned one previously associated FU item into an additional stem item. Three self-evident items were eliminated. The resulting instrument consisted of 42 items. Response options were simplified for three stems and four FU items (i.e., 5-point Likert scales were collapsed to dichotomous yes/no answers). Revised and excluded items are summarized in Supplementary Table 1s.

3.7. Second expert validity rating

Eight of ten individuals approached for the second expert validity rating returned their form. These experts included seven psychological therapists and one adult neurologist with special expertise in the psychotherapeutic treatment of patients with seizure disorders. Four of the psychologists had additional neuropsychological training. All professionals were delivering and/or supervising psychotherapeutic interventions for people with seizures on a regular basis.

The rating yielded I-CVIs between 0.38 and 1 and an excellent mean S-CVI/ave of 0.92. A lack of comprehensibility/clarity was identified as a problem with 14 stems and three FU items. These items were substantially revised by incorporating the experts' qualitative feedback. As has been discussed above, questionnaire development experts have recommended excluding items with an I-CVI of <0.78 [13]: On this basis, three of seven items with an I-CVI of <0.78 were excluded. Two of the remaining four items with an I-CVI of <0.78 had been substantially revised because of issues with comprehensibility/clarity and word choice. The remaining two items with an I-CVI of <0.78 or less were retained because they had proven to be valued in cognitive debriefing interviews, and the authors decided to give preference to the patients' over clinical experts' feedback. One of these items was an invitation to add a personal comment ("Please feel free to add any personal comments to this questionnaire"), and the other item represented a resource-oriented perspective on problems ("I believe that problems are also an opportunity to develop new skills in life."). One new item was added at this late stage of development as it seemed to address a very important aspect of seizure-related self-efficacy that had not yet been captured: "I know what my seizures look like."

The final questionnaire consists of 40 items. Five stems had one FU item, two had two FU items, and one three FU items (Table 6). Revised, excluded, and added items are summarized in Supplementary Table 1s.

4. Discussion

Our study shows that the EASE questionnaire has content validity and reliability (or rather internal consistency) and is clear and acceptable to patients with seizures. The items of the questionnaire are now ready for validation in a large prospectively recruited clinical cohort of patients undergoing psychotherapy.

The original item set was derived from the qualitative analysis of data provided by patients with epilepsy describing psychotherapy outcomes. The preintervention application of the EASE could be used to identify and clarify treatment targets at the start of therapy, thereby serving therapist and client to reach a mutual understanding of what they would like to focus on in therapy. The optimum frequency to apply this measure still remains to be determined. If it is used to characterize treatment targets, it might also be useful during the psychotherapeutic process to monitor the realization of the identified treatment aims.

We set out to develop a transtheoretical measure that is applicable in diverse psychotherapy settings adhering to different schools of psychotherapy. Thus, the EASE is not intended to capture the successful application of specific therapeutic strategies but to gauge more generic therapeutic principles that have been shown to be essential in different schools of psychotherapy, e.g., an individual's capacity to realize self-awareness. In addition, the English translation led to some minor but meaningful changes of the German questions that are likely to have facilitated the more universal application of the questionnaire (not only among German and English speakers but – after appropriate validation of additional versions of the questionnaire – also those of other languages).

We specifically avoided overlap with other existing measures (such as those assessing depression, anxiety, and HRQOL measures including QOLIE and ESES). Depending on the research question, these measures should therefore be coadministered with the EASE.

A number of methodological shortcomings of this study need to be considered: The candidate item set was derived from qualitative research on patients with epilepsy who had participated in a psychotherapeutic intervention study. In terms of the goal of this study, to develop an item set sensitive to changes targeted and mediated by psychotherapeutic interventions in people with both epileptic and/or nonepileptic seizures (NES), some characteristics of this qualitative study limit the transferability of its results. Although the qualitative data represented diverse concepts relating to psychotherapeutic interventions, the qualitative research had focused particularly on the development of self-efficacy and mastery. In addition, the intervention patients had received was CBT-based, and no patients with NES were included in the qualitative study. Furthermore, the number of participants had been chosen for pragmatic reasons and not been based on content-related saturation. Additional steps taken in the course of the present study were intended to limit the effects of these limitations and to increase the content validity of the candidate item set, especially in regard to other concepts relevant to the broader effects of psychotherapy, patients with NES, and other schools of psychotherapy.

While the experts involved in the initial validity rating were provided with dichotomous response options to rate if an item was relevant, experts were asked to rate an item's relevance on a 4-point Likert scale during the second expert validity rating. Since the experts' answers were collapsed to a dichotomous format as well during the analysis of the second rating, the confounding effect of this methodological difference is probably negligible. However, we do not know with certainty if more answer options would have increased the sensitivity of the form that was used during the first expert rating.

Content analysis of cognitive debriefing interviews was performed based on field notes and not transcripts of audio-recorded interviews. Willis recommended this pragmatic solution for evaluation of a complex dataset [17]. Therefore, we consider that the detailed field notes that were taken by CS provided a sufficient basis for the incorporation

Table 6
Final questionnaire.

EASE
1. I am usually able to manage my daily tasks. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
2. I can manage limitations related to my seizures in my daily life. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
3. In difficult situations, I can do something that helps me. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
4. I talk openly about how I feel with people who are important to me. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
5. I am aware of my own needs and wishes. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
5.1. I am able to stand up firmly to others for my needs and wishes. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
6. I talk openly about my seizures with people who are important to me. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
7. I have informed people who I see regularly how to help me when I have a seizure. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
8. In some situations, I am confused about how I feel. <input type="radio"/> I strongly agree (1) <input type="radio"/> I slightly agree (2) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (4) <input type="radio"/> I strongly disagree (5)
9. I am able to express how I feel if it is important to me. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
10. I feel good about myself the way I am. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2)

Table 6 (continued)

EASE
<input type="radio"/> I strongly disagree (1)
11. I bottle up my feelings. <input type="radio"/> I strongly agree (1) <input type="radio"/> I slightly agree (2) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (4) <input type="radio"/> I strongly disagree (5)
12. I worry about being a burden to others. <input type="radio"/> I strongly agree (1) <input type="radio"/> I slightly agree (2) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (4) <input type="radio"/> I strongly disagree (5)
12.1 I was like that even before my first seizure. <input type="radio"/> More than now (3) <input type="radio"/> As much as now (2) <input type="radio"/> Less than now (1)
13. I am able to say "no" when others ask me to do things for them that I would rather not do. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
14. It is hard for me to ask others for help. <input type="radio"/> I strongly agree (1) <input type="radio"/> I slightly agree (2) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (4) <input type="radio"/> I strongly disagree (5)
14.1 I was like that even before my first seizure. <input type="radio"/> More than now (3) <input type="radio"/> As much as now (2) <input type="radio"/> Less than now (1)
15. I avoid open arguments. <input type="radio"/> I strongly agree (1) <input type="radio"/> I slightly agree (2) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (4) <input type="radio"/> I strongly disagree (5)
15.1 I was like that even before my first seizure. <input type="radio"/> More than now (3) <input type="radio"/> As much as now (2) <input type="radio"/> Less than now (1)
16. It is easy for me openly to disagree with others if I have a different opinion. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
17. I feel ashamed of my seizures. <input type="radio"/> I strongly agree (1) <input type="radio"/> I slightly agree (2) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (4) <input type="radio"/> I strongly disagree (5)
17.1 I easily felt ashamed before I ever had a seizure. <input type="radio"/> More than now (3) <input type="radio"/> As much as now (2) <input type="radio"/> Less than now (1)
18. I am capable of achieving the things that I would like to achieve. <input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3)

Table 6 (continued)

EASE
<input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
19. I accept the things that I cannot change.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
20. I look after my well-being in daily life.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
21. I accept that I make mistakes once in a while.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
22. I feel well-prepared for future challenges.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
23. I am still troubled by things that happened to me in the past.
<input type="radio"/> I strongly agree (1) <input type="radio"/> I slightly agree (2) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (4) <input type="radio"/> I strongly disagree (5)
24. I am confident when I deal with people I don't know.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
25. I find it easy to relax.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
26. I take on too much to the point of being exhausted.
<input type="radio"/> I strongly agree (1) <input type="radio"/> I slightly agree (2) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (4) <input type="radio"/> I strongly disagree (5)
27. It is realistic that my ability to cope with my seizures will improve.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
28. My seizures have changed my perspective on life.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
29. I believe that problems are also an opportunity to develop new skills in life.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4)

Table 6 (continued)

EASE
<input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
30. I am happy with the support that I receive.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
31. I am happy with the relationships that I have.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
32. There are people who I trust.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
33. I understand the causes of my seizure disorder.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
34. I experience exclusion and discrimination because of my seizures.
<input type="radio"/> I strongly agree (1) <input type="radio"/> I slightly agree (2) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (4) <input type="radio"/> I strongly disagree (5)
35. I am content with what I have achieved in my life despite seizures.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
36. I know what my seizures look like.
<input type="radio"/> I strongly agree (5) <input type="radio"/> I slightly agree (4) <input type="radio"/> I neither agree nor disagree (3) <input type="radio"/> I slightly disagree (2) <input type="radio"/> I strongly disagree (1)
37. I know at least one trigger for my seizures.
<input type="radio"/> Yes (1) <input type="radio"/> No (0)
37.1 If yes: please describe your trigger/s:
37.2 If yes: I can avoid this trigger/these triggers in my daily life.
<input type="radio"/> Yes (1) <input type="radio"/> No (0)
38. I know how I can help myself to feel better after a seizure.
<input type="radio"/> Yes (1) <input type="radio"/> No (0)
38.1 If yes: Please describe what helps you to feel better:
38.2 I am able to make use of this strategy/these strategies in my daily life.
<input type="radio"/> Yes (1) <input type="radio"/> No (0)
39. I have at least one strategy that I use at the first sign of a seizure.
<input type="radio"/> Yes (1) <input type="radio"/> No (0)

Table 6 (continued)

EASE
39.1 If yes: Please describe what you do:
39.2 If yes: I can shorten seizures by doing that. ○ Yes (1) ○ No (0)
39.3 If yes: I stop myself from losing consciousness by doing that. ○ Yes (1) ○ No (0)
40. Please feel free to add any personal comments to this questionnaire:

of the interviewees' feedback whenever an item did not function as intended.

The translator back translating the English version of the instrument into German was not blinded to the original German version. However, in this article, we focused on the development of the German questionnaire and how the comparison between the English translation, the German version, and the verbatim back translation of the English version served the refinement of the German questionnaire.

Our pilot study only included patients with epileptic seizures and no participants with NES, although the measure is intended to be used with patients with both seizure disorders. The new instrument's validity and sensitivity to psychotherapy-associated changes will need to be examined in prospective intervention studies with people with epileptic seizures and/or NES. The poor internal consistency of the domain epilepsy-specific self-efficacy and the absence of the expected positive correlations with other validated measures is the major weakness of the pilot study, especially since the study has not been repeated after the negatively phrased items had been reworded. Therefore, the construct validity of the final version of the EASE needs to be confirmed in future studies, preferably after a proper exploratory analysis of the instrument's factorial structure. The allocation of the final set of 40 items to subscales should be checked by exploratory factor analysis or confirmatory factor analysis in future studies based on larger sample size.

5. Conclusions

Despite these drawbacks, our findings suggest that the EASE questionnaire has content validity, is internally consistent, clear, and is acceptable to patients with seizures. Prior to its wider clinical or research application, the validity and reliability as well as the psychometric properties and factorial structure of the new instrument will need to be assessed in a prospective, longitudinal, clinical study in a patient cohort undergoing psychotherapeutic intervention in order to investigate its sensitivity to changes targeted and mediated by such treatments.

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Declaration of competing interest

The authors have no conflicts of interest to declare.

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