

# Patient-reported outcome measures for emotional functioning in cancer patients: Content comparison of the EORTC CAT Core, FACT-G, HADS, SF-36, PRO-CTCAE, and PROMIS instruments

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## Funding information

European Organisation for Research and Treatment of Cancer Quality of Life Group

## Abstract

**Background:** Cancer and its treatment can have substantial impact on patients' emotional functioning. Several patient-reported outcome measures (PROMs) assessing emotional functioning are available, but differences in content limit the comparability of results. To better understand conceptual (dis)similarities, we conducted a content comparison of commonly used PROMs.

**Methods:** We included emotional functioning items, scales, and item banks from the EORTC CAT Core, EORTC QLQ-C30, FACT-G, Hospital anxiety and depression scale (HADS), SF-36, PRO-CTCAE, and PROMIS (item banks for anxiety, depression, and anger). Item content was linked to the International Classification of Functioning, Disability, and Health (ICF) and a hierarchical framework established for PROMIS.

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Single items could be coded with more than one ICF category but were solely assigned to one facet within the PROMIS framework.

**Results:** The measures comprise 132 unique items covering the ICF components 'Body functions' (136/153 codings, 88.9%) and 'Activities and participation' (15/153, 9.8%). Most ICF codings (112/153, 73.2%) referred to the third-level category 'b1528 Emotional functions, other specified'. According to the PROMIS framework 48.5% of the items assessed depression (64/132 items), followed by anxiety (41/132, 31.1%) and anger (26/132, 19.7%). The EORTC measures covered depression, anxiety, and anger in a single measure, while the PROMIS inventory provides separate item banks for these concepts. The FACT-G, SF-36, PRO-CTCAE and HADS covered depression and anxiety, but not anger.

**Conclusion:** Our results provide an in-depth conceptual understanding of selected PROMs and important qualitative information going beyond psychometric evidence. Such information supports the identification of PROMs for which scores can be meaningfully linked with quantitative methods.

#### KEYWORDS

cancer, emotional functioning, FACT-G, HADS, oncology, patient-reported outcome measures, PRO-CTCAE, PROMIS, QLQ-C30, SF-36

## 1 | BACKGROUND

Patients diagnosed with and treated for cancer face a wide range of issues, which may impact their emotional functioning in many ways. The diagnosis of this life-threatening disease is accompanied by uncertainties and fears,<sup>1</sup> the patients may be confronted with severe disease symptoms and treatment side-effects, and the disruption of the patients' daily routines, social life and work life can result in further psychological burden.<sup>2</sup> While some patients cope well with these major changes and experience positive psychological effects as personal growth or benefit finding,<sup>3</sup> negative feelings like sadness, worries, or anger are common reactions in this situation. A substantial proportion of patients is known to be in need of professional interventions,<sup>4-6</sup> even though their psychological burden rarely meets diagnostic criteria for a mental disorder. This suggests that any assessment of emotional functioning should capture not only severe psychological conditions but also more subtle forms of emotional distress.

The World Health Organisation (WHO) defined health as not merely the absence of disease and infirmity but also a state of physical, mental and social well-being.<sup>7</sup> Mental health in particular has been defined as 'a state of mind characterized by emotional well-being, good behavioral adjustment, relative freedom from anxiety and disabling symptoms, and a capacity to establish constructive relationships and cope with the ordinary demands and stresses of life.'<sup>8</sup> Thus, mental health is an overarching concept comprising social functioning and emotional well-being or functioning. Lacking a generally agreed upon definition of emotional functioning and a consistent terminology for

emotional health aspects, labels and key aspects vary across assessment instruments. While some are labelled as well-being, others as functioning or distress scales, they frequently include anxiety, depression, or anger as central indicators.<sup>9,10</sup>

Since emotional states are not plainly observable, it is recommended to assess these issues via patient-reported outcome measures (PROMs).<sup>11,12</sup> PROMs, that is, well-validated, standardized questionnaires, are frequently used in clinical studies and increasingly also in clinical practice to assess several health-related quality of life (HRQOL) aspects. In cancer research, the most commonly used PROMs with a distinct emotional domain are the EORTC QLQ-C30,<sup>13</sup> the FACT-G,<sup>14</sup> and the SF-36.<sup>9,15</sup> In addition, novel instruments have recently been developed, such as the EORTC CAT Core,<sup>16,17</sup> PROMIS,<sup>10,18</sup> and the PRO-CTCAE.<sup>19</sup> Besides these instruments, the Hospital anxiety and depression scale (HADS) is probably the most widely used PROM for measuring anxiety and depression across all medical fields.<sup>20</sup>

While the availability of various well-validated PROMs for assessing emotional functioning allows to select the most suitable measure for a specific purpose, it also limits the comparability of study results and compromises the possibility of pooling data from different studies or conducting meta-analyses. Thus, increasing efforts have been made to establish common metrics or methods to enable crosswalks, that is, converting scores from a specific PROM to the metric of another measure.<sup>21,22</sup> Relying on complex statistical models, crosswalks allow to calculate what score obtained from a specific PROM corresponds best to a score from another PROM. Thus, such methods allow to pool data from individuals that completed different

PROMs and conduct a joint data analysis, or to directly compare results from studies using different PROMs. However, meaningful score conversion should not only rely on quantitative methods such as regression analyses, equipercentile equating, or Item Response Theory modelling but also evaluate the conceptual similarity of the PROMs.<sup>23</sup>

In an ongoing project, we are evaluating the possibilities to link scores from commonly used PROMs in cancer research to the EORTC CAT Core.<sup>16,17,24</sup> This comprises a qualitative content comparison of the measures, followed by quantitative analyses on the actual linking of scores. In this article, we present the results for the content analysis of the emotional functioning domains of selected PROMs to help developing an understanding of the linking possibilities. For our content comparison, we applied a standard method that was developed by Cieza et al.<sup>25–27</sup> and relies on the WHO International Classification of Functioning, Disability, and Health (ICF).<sup>28</sup> In addition, we conducted an analysis relying on the hierarchical framework provided by PROMIS,<sup>10,29</sup> to allow for a more detailed analysis of emotional states that goes beyond the level of granularity of the ICF framework. Our content analysis included the following measures:

- EORTC CAT Core Emotional Functioning item bank
- EORTC QLQ-C30 Emotional Functioning scale
- PROMIS Item Bank v1.1 Anger
- PROMIS Cancer Item Bank v1.0 Anxiety
- PROMIS Cancer Item Bank v1.0 Depression
- FACT-G Emotional Wellbeing scale
- SF-36 Mental Health scale
- HADS Anxiety scale
- HADS Depression scale
- PRO-CTCAE items describing emotional states

## 2 | METHODS

### 2.1 | Comparator measures

#### 2.1.1 | EORTC QLQ-C30 scale and EORTC CAT Core item bank for emotional functioning

The EORTC QLQ-C30 is a cancer-specific HRQOL questionnaire with 30 items. Besides nine symptom scales (e.g., fatigue, pain, nausea), it covers five functioning scales for physical, emotional, social, role, and cognitive functioning and a global HRQOL score. The emotional functioning scale consists of four items on worrying and feeling depressed, tense, and irritable. The EORTC CAT Core<sup>17,24</sup> consists of item banks covering the same domains as the EORTC QLQ-C30.<sup>13</sup> The EORTC CAT Core item bank for emotional functioning<sup>16</sup> contains 24 items. Both EORTC instruments use a 4-point-scale ranging from 'Not at all' to 'Very much' and refer to 'the past week' as recall period.

The EORTC CAT Core emotional functioning item bank includes all four emotional functioning items of the EORTC QLQ-C30 and

scores from the two measures are fully compatible.<sup>30</sup> They do not aim to reflect psychiatric diagnoses, but have been conceptualised as unidimensional measures covering only affective symptoms of anxiety, depression and general distress.<sup>16</sup>

### 2.1.2 | PROMIS item banks for anger, anxiety, and depression

The PROMIS inventory provides numerous item banks, three of which were included in the present analysis: The PROMIS Item Bank v1.1 Anger consists of 22 items assessing angry mood, negative social cognitions, and anger control.<sup>10</sup> The PROMIS Cancer Item Bank v1.0 Anxiety contains 22 items covering fear, anxious misery, hyperarousal, and related somatic symptoms.<sup>31</sup> The PROMIS Cancer Item Bank v1.0 Depression has 30 items addressing negative mood, self-perception, social cognition, as well as decreased positive affect and engagement.<sup>31</sup> Items of all three item banks refer to a recall period of 7 days and offer a 5-point Likert-scale ranging from 'Never' to 'Always'.

### 2.1.3 | FACT-G emotional wellbeing scale

The Functional Assessment of Cancer Therapy Scale—General (FACT-G; 14) consists of 27 items covering four domains: physical, functional, social/family, and emotional wellbeing. The emotional scale consists of six items that are rated on a 5-point-scale from 'Not at all' to 'Very much' and refer to a 7-day recall period. The items refer, for example, to worries, sadness, and satisfaction with coping.

### 2.1.4 | Short form 36 mental health scale

The SF-36<sup>9,15</sup> consists of 36 items covering eight domains: general health, bodily pain, physical functioning, physical role functioning, social role functioning, emotional role functioning, vitality, and mental health. The concept 'mental health' was defined as 'General mood or affect, including depression, anxiety, and psychological wellbeing during the past month'.<sup>15</sup> The subscale consists of five items with a 6-point-scale ranging from 'All of the time' to 'None of the time'.

### 2.1.5 | Hospital anxiety and depression scale

The HADS has been designed specifically for use in patients with somatic diseases in non-psychiatric hospital settings and, therefore, excludes somatic symptoms such as headaches and dizziness, but focuses on affective aspects of depression and anxiety.<sup>20</sup> The HADS consists of 14 items that form two 7-item scales for depression and anxiety, respectively. All items are scored on 4-point-scales and refer to 'the past week'.

## 2.1.6 | PRO-CTCAE items describing emotional states

The PRO-CTCAE aims to assess toxicity in cancer patients and was developed by the National Cancer Institute to complement the clinician-rated CTCAE with patient-reports.<sup>19</sup> The PRO-CTCAE comprises 124 items of which nine refer to emotional states. These emotional items that are considered in the present study cover the frequency, severity, and interference of feeling anxious, sad, or discouraged. The nine items refer to 'the last 7 days' and offer five response-options, ranging from 'Never' to 'Almost constantly', from 'None' to 'Very severe', or from 'Not at all' to 'Very much', respectively. This measure does not assign items to scales.

## 2.2 | Linking item content to the ICF framework

The ICF provides a comprehensive terminology to describe health in a standardised manner.<sup>28</sup> It covers body structures (s), body functions (b), as well as activities and participation (d). Furthermore, it takes environmental (e) and personal (p) factors into account. Sections (s), (b), (d) and (e) are further divided in several chapters (indicated by the first digit) consisting of several subchapters on a second (second and third digit) and third level (fourth digit). In this way, the ICF offers so-called 'codes' for various physical, psychological, and social health aspects. Table 1 gives an example of emotional health issues to illustrate the hierarchical structure of the ICF.

The standard methodology for ICF-based content analyses of PROMs has been developed and refined by Cieza et al.<sup>25–27</sup> The basic procedure is to identify meaningful concepts contained in items of a PROM and to assign these concepts to corresponding ICF codes. An item can be assigned to more than one code if it contains several concepts. If no suitable ICF category is available, items are coded as 'not covered' (nc) or 'not definable' (nd). Further codes are suggested

for items asking for overall ratings of specific health conditions (nc-hc) or quality of life (nc-qol).

For the present study, all items from the PROMs under investigation were linked to ICF categories by two independent reviewers out of a pool of reviewers [NE, MR, EL, CP, JG], a third reviewer was consulted if needed for reaching consensus.

## 2.3 | Linking item content to the PROMIS framework

While the ICF distinguishes between appropriateness (b1520), regulation (b1521), and range (b1522) of emotions, it offers no classification of different emotional states or functions (e.g., anger, sadness, or anxiety). Therefore, we additionally categorised all items into the three domains anxiety, anger, and depression of the hierarchical framework established by PROMIS.<sup>10</sup> Each domain is divided into subdomains, containing several factors, which are further described by facets. An example for the hierarchical structure is given in Table 1. The three domains used in this study were built during the development of the PROMIS emotional distress item banks.<sup>10</sup> Comparable domains of the framework were developed as the basis for the other PROMIS scales as well.<sup>29</sup>

In contrast to the ICF linking procedure, each item was solely assigned to one domain, subdomain, factor, and facet. Each item was categorised by two independent reviewers [MR, NE, EL, CP, JG] and conflicts were resolved by discussion or by consulting a third reviewer.

## 2.4 | Data analysis

The content analysis and comparison are summarised using descriptive statistics. Frequencies are reported as absolute numbers and percentages. For ICF linking, one item could be assigned to more than one ICF category. Thus, we provide the number of categories linked to each PROM as well as the number of codings representing these categories. The content evaluation based on the PROMIS framework is based on only one categorization per item. For the corresponding analysis, we provide the number of items per PROM covering the different domains, subdomains, and factors. Interrater agreement for both categorization systems is provided as total agreement (%) on the second level.

## 3 | RESULTS

### 3.1 | Content analysis based on the ICF framework

Combining all items of the investigated emotional functioning scales resulted in an overall item pool of 132 unique items. As some items were linked to more than one ICF domain, a total of 153 codings were derived from our analysis, most of which referred to the ICF components 'b – Body Functions' (136/153 codings, 88.9%) and 'd –

**TABLE 1** Examples of the hierarchical structure of the International Classification of Functioning, Disability and Health (ICF) categories (World Health Organisation (WHO), 2001) and the PROMIS framework (Pilkonis et al., 2011).

Example of the ICF framework		
Component	b	Body functions
First level (chapter)	b1	Mental functions
Second level	b152	Emotional functions
Third level	b1521	Regulation of emotions
Example of the hierarchical PROMIS framework		
Domain		Depression
Subdomain		Mood
Factor		Decreased positive affect
Facet		Loss of pleasure

Activities and Participation' (15/153 codings, 9.8%). Within component b, the only first level category was 'b1 Mental functions', while within component d, the following first-level categories were used, 'd7 Interpersonal interactions and relationships' (9/153 codings, 5.9%), 'd2 General tasks and demands' (4/153 codings, 2.6%), and 'd9 Community, social and civic life' (2/153 codings, 1.3%). Two items contained content not defined in the ICF framework, both relating to the health condition (nc-hc) (2/153 codings, 1.3%).

Notably, 112/153 codings (73.2%) referred to the third-level category 'b1528 Emotional functions, other specified'. For the individual PROMs, this category represented at least 50% of codings for the HADS depression scale and PRO-CTCAE items and 100% of codings for the EORTC QLQ-C30 emotional functioning scale and the SF-36 mental health scale.

Detailed information on the ICF codings for the individual PROMs are given in Figure 1 and the Supplementary Materials. When linking items to the ICF classification, the independent reviewers agreed at the second level for 84.7% (111/132) of all items.

### 3.2 | Content analysis based on the PROMIS framework

In the hierarchical framework provided by PROMIS, most items were assigned to the domain depression (64/132 items, 48.5%), followed

by anxiety (41/132 items, 31.1%), and anger (26/132 items, 19.7%). Only one item could not be assigned to one of the domains and was classified as 'other' (1/132 items, 0.8%). This item was from the FACT-G asking about patients' satisfaction about how they are coping with their illness.

The four EORTC QLQ-C30 items, which are also part of the EORTC CAT emotional functioning item bank, were categorised to assess the subdomains angry mood, anxious mood, somatic symptoms of anxiety and depressive mood (1/4, 25.0% each). In the EORTC CAT emotional functioning item bank, most items were categorised as depression-related items (16/24, 66.7%) assessing the subdomains depressive mood (9/24, 37.5%) and cognition (7/24, 29.2%). Six items were assigned to the anxiety domain (6/24, 25.0%), covering anxious cognition (1/24, 4.2%), mood (3/24, 12.5%), and somatic symptoms (2/24, 8.3%). Two items were linked to the anger domain, assessing angry mood (2/24, 8.3%).

All but one item of the PROMIS cancer anxiety item bank, were categorised as anxiety items (21/22, 95.5%), assessing anxious mood (14/22, 63.6%), somatic symptoms (5/22, 22.7%), and anxious cognition (2/22, 9.1%). One item, however, was assigned to rumination, a facet of depressive cognition (1/22, 4.5%). Within the PROMIS cancer depression item bank all but two items were assigned to the depression domain (28/30, 93.3%), covering cognition (16/30, 53.3%), mood (10/30, 33.3%), suicidality (1/30, 3.3%), and behaviour (1/30, 3.3%). However, two items of the depression item bank were

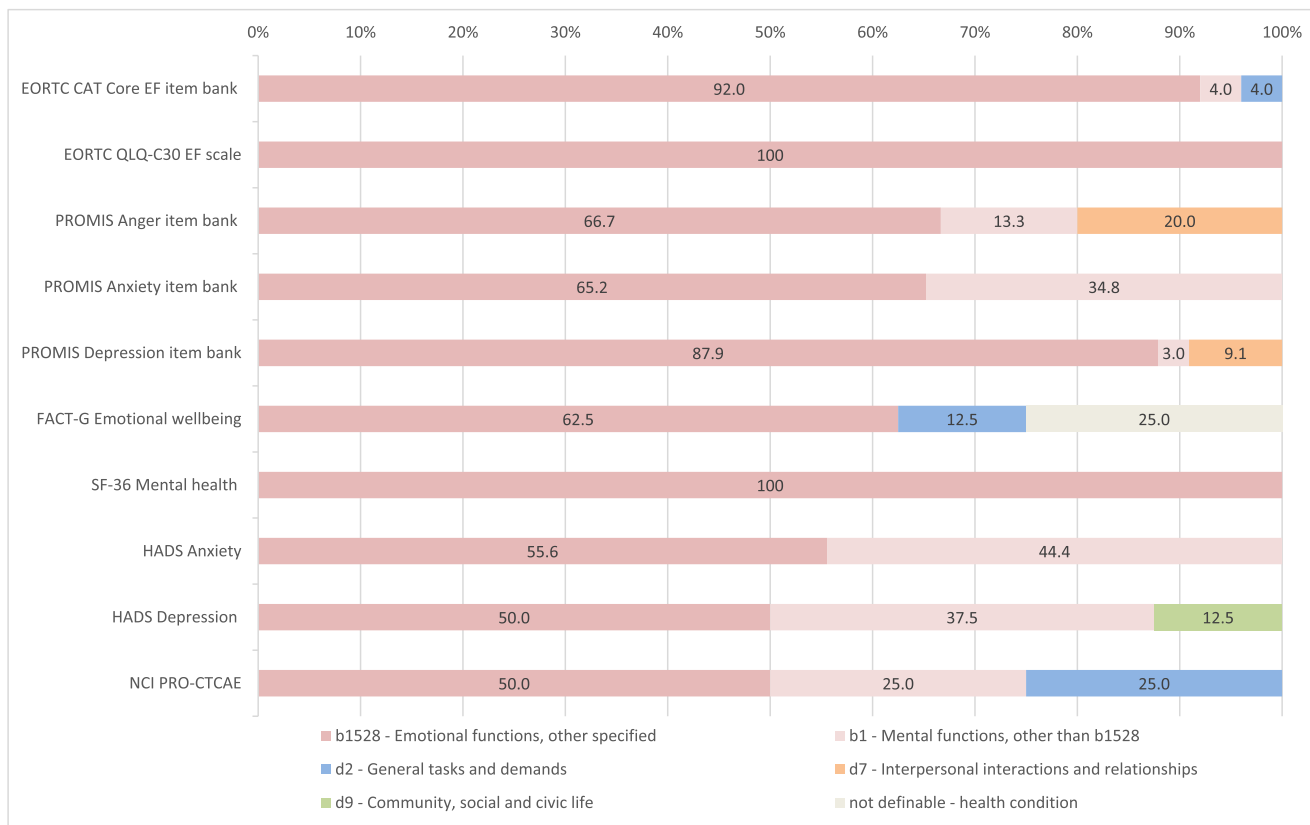


FIGURE 1 Relative frequency of meaningful concepts per scale or item bank assigned to ICF categories.

categorised as assessing angry mood (2/30, 6.7%). The whole PROMIS anger - item bank was categorised as assessing the anger domain (22/22, 100.0%), covering anger-related behaviour (8/22, 36.4%), mood (8/22, 36.4%), and cognition (6/22, 27.3%).

The FACT-G was categorised as covering the domains anxiety (3/6, 50.0%) and depression (2/6, 33.3%) as well as one item categorised as 'other' (1/6, 16.7%) asking for patients' satisfaction with their coping abilities.

Among the five SF-36 Mental Health items, three items were judged to cover depressive mood (3/5, 60.0%) and two were assigned to the domain anxiety, assessing somatic symptoms (2/5, 40.0%).

Within the HADS, all items of the depression scale were assigned to the depression domain of the PROMIS framework, assessing the subdomains depressive mood (6/7, 85.7%) and behaviour (1/7, 14.3%). Within the anxiety scale, 6 items were assigned to anxiety (6/7, 85.7%), covering somatic symptoms (4/7, 57.1%) and anxious mood (2/7, 28.6%). One item ('Worrying thoughts go through my mind') was classified as rumination and thus assigned to the depression domain (1/7, 14.3%).

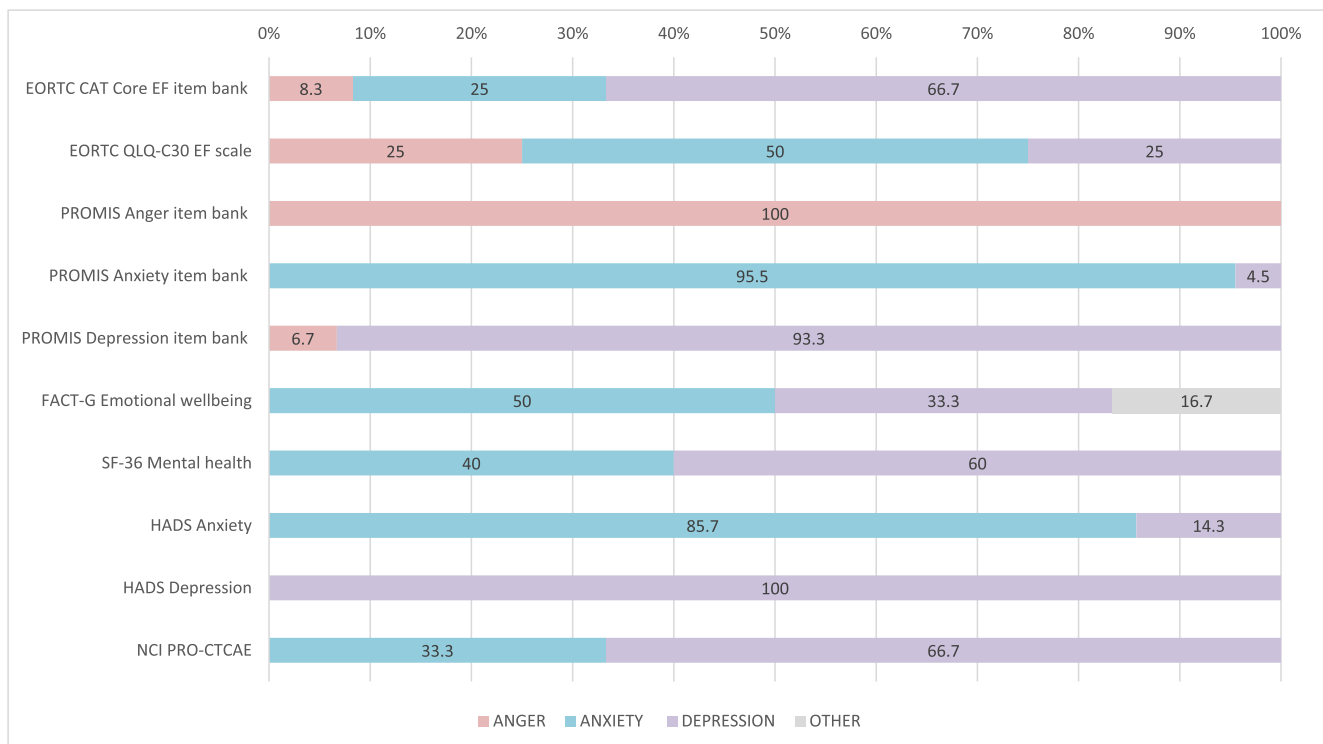
The PRO-CTCAE items were found to cover depression- and anxiety-related content. The three items on frequency, severity, and interference of anxiety were assigned to the anxiety domain, all assessing anxious mood (3/9, 33.3%). The items about sad or unhappy feelings and feeling depressed were assigned to the depression domain (6/9, 66.7%), assessing depressive behaviour (2/9, 22.2%) or mood (4/9, 44.4%).

Detailed results for all PROMs can be found in Figure 2 and Table 2. The total interrater agreement for the categorization of items into the hierarchical PROMIS framework was 86.3% (113/132 items) at the second level.

## 4 | DISCUSSION

We analysed the content of various PROMs that are commonly used to assess emotional functioning in cancer patients relying on the ICF and the PROMIS frameworks. While the ICF framework allows detailed coding of content related to physical health issues, it does not distinguish between emotional states in sufficient detail.<sup>29,32-35</sup> Therefore, the PROMIS framework was used to differentiate content related to depression, anxiety, and anger, acknowledging that this meant that the PROMIS items would not be assessed against an independent framework.

Within the ICF framework the category 'b1528 Emotional functions, other specified' accounted for at least 50.0% of codings assigned to each scale. Besides 'b1—Mental functions', some measures also contained content assigned to the component 'd—Activities and Participation': the FACT-G Emotional wellbeing scale and the PRO-CTCAE items covered 'd2—General tasks and demands', while the EORTC CAT Core emotional functioning item bank contained 'd9—Community, social and civil life'. The PROMIS depression and anger item banks related in part to 'd7—Interpersonal



**FIGURE 2** Relative frequency of items per scale or item bank representing the three domains of the PROMIS framework (anger, anxiety, and depression).

TABLE 2 Absolute and relative frequency of items assigned to the domains, subdomains, and factors of the PROMIS framework.

	EORTC CAT core EF item bank		EORTC QLQ C30 EF scale		PROMIS anger item bank		PROMIS anxiety item bank		PROMIS depression item bank		FACT-G emotional wellbeing		SF-36 mental health		HADS anxiety		HADS depression		PRO-CTCAE	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Total	24	100	4	100	22	100	22	100	30	100	6	100	5	100	7	100	7	100	9	100
ANGER	2	8.3	1	25.0	22	100			2	6.7										
Behavior					8	36.4														
General interpersonal conflicts					2	9.1														
Modes of expression or control					6	27.3														
Cognition					6	27.3														
General attitudes towards life					2	9.1														
Guilt about anger					1	4.5														
Social cognition					3	13.6														
Mood	2	8.3	1	25.0	8	36.4			2	6.7										
Angry mood	2	8.3	1	25.0	8	36.4			2	6.7										
ANXIETY	6	25.0	2	50.0			21	95.5	3	50.0	2	40.0	6	85.7	3	33.3				
Cognition	1	4.2			2	9.1														
Anxious cognition	1	4.2			2	9.1														
Mood	3	12.5	1	25.0	14	63.6			2	33.3	2	28.6	3	33.3						
Anxious misery	1	4.2	1	25.0	6	27.3			2	33.3	1	14.3								
Fear	2	8.3			8	36.4					1	14.3								
Somatic	2	8.3	1	25.0	5	22.7			1	16.7	2	57.1								
Hyperarousal	2	8.3	1	25.0	5	22.7			1	16.7	2	57.1								

TABLE 2 (Continued)

	EORTC CAT core EF item bank		EORTC QLQ C30 EF scale		PROMIS anger item bank		PROMIS anxiety item bank		PROMIS depression item bank		FACT-G emotional wellbeing		SF-36 mental health		HADS anxiety		HADS depression		PRO-CTCAE	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
DEPRESSION	16	66.7	1	25.0			1	4.5	28	93.3	2	33.3	3	60.0	1	14.3	7	100	6	66.7
Behavior									1	3.3							1	14.3	2	22.2
Decreased activity																				
Decreased energy/vitality																				
Interpersonal changes																				
Cognition	7	29.2					1	4.5	16	53.3	1	16.7			1	14.3				
Guilt/sense of punishment									1	3.3										
Helplessness/loss of mastery	3	12.5							2	6.7										
Hopelessness	1	4.2							1	3.3	1	16.7								
Impaired view of self	2	8.3							4	13.3										
Negative social cognition									5	16.7										
Unproductive information processing	1	4.2					1	4.5	3	10.0					1	14.3				
Mood	9	37.5	1	25.0					10	33.3	1	16.7	3	60.0			6	85.7	4	44.4
Decreased positive affect	5	20.8							3	10.0			1	20.0			6	85.7	2	22.2
Increased negative affect	4	16.7	1	25.0					7	23.3	1	16.7	2	40.0					2	22.2
Suicidality									1	3.3										
Suicidal ideation									1	3.3										
OTHER <sup>a</sup>											1	16.7								

Note: Bold values refers to the hierarchical structure of level one and two.

<sup>a</sup>This single item categorised as 'other' asks for satisfaction with coping with illness.



interactions and relationships'. The FACT-G also included item content not definable in the ICF framework.

According to the PROMIS framework, both the EORTC QLQ-C30 scale and the EORTC CAT Core item bank for emotional functioning included items across all three domains anxiety, depression, and anger, with more weight given to anxiety in the EORTC QLQ-C30 scale and more weight given to depression in the EORTC CAT Core item bank. This finding is in line with previous work on subdomains of emotional functioning,<sup>36</sup> that also considered depression and anxiety to be key concepts covered by the EORTC CAT Core item bank for emotional functioning. The FACT-G Emotional Well-being scale covered anxiety, depression, and other content (satisfaction with coping). The PRO-CTCAE items and the SF-36 Mental Health scale referred to anxiety and depression, with none of the items assessing anger. The HADS Depression scale consisted completely of depression-related items, whereas one item of the HADS Anxiety scale was not categorized as anxiety-related. Our categorizations of the three PROMIS item banks for anxiety, depression, and anger were largely but not perfectly consistent with the PROMIS framework. One rumination item in the anxiety item bank was categorized into the depression domain and two items on feeling angry and irritable were assigned to the anger-domain.

The minor discrepancies between scale names and our categorization do not necessarily indicate shortcomings in the conceptualisation or design of these PROMs. Instead, they reflect overlaps between symptoms, indicators, and diagnostic criteria of anxiety, depression, and anger. Rumination for example, is a well-known symptom of depression, even though it is also associated with anxiety.<sup>37</sup> The same is true for irritability, which is clearly a sign of anger, but can also occur in depression.<sup>38</sup>

In general, the content analysis based on the PROMIS framework revealed that depression-related aspects are most assessed, accounting for about half of the content across all measures. The depression domain was mostly covered by items referring to the subdomains mood and cognition (EORTC CAT Core and PROMIS depression item banks) or behaviour (HADS Depression scale and PRO-CTCAE items). Across all measures, items related to anger were rare, except for the dedicated PROMIS item bank. The FACT-G, the HADS, the PRO-CTCAE and the SF-36 did not include any anger items at all. The EORTC measures did assess anger with a focus on the mood subdomain, but no items referred to the anger subdomains behaviour or cognition. Regarding the domain anxiety, those measures assessing anxiety mostly referred to the mood and the somatic subdomain, except for the HADS (accurately reflecting the rationale underlying this measure). We could not find any consistent difference between measures labelled as emotional functioning (EORTC measures), wellbeing or health (FACT-G or SF-36) or scales on anxiety, depression, and/or anger (PROMIS, HADS, PRO-CTCAE).

As mentioned above, the ICF framework provides only limited possibilities to code item content related to emotional functioning. While physical states can be distinguished with a high level of granularity, little differentiation is possible for emotional states. For

example, 'b152 Emotional functions' is only divided into three further categories, namely 'b1520 Appropriateness of emotion', 'b1521 Regulation of emotion', or 'b1523 Range of emotions'. There are no unique codes for specific emotions. This reflects the intended use of the ICF in conjunction with the ICD-10 classification that allows for classification of psychological disorders and, thus, adequate classification of pathological emotional states.<sup>28</sup> However, it limits the use of the ICF for content analysis of psychological states such as in the current analysis. The use of the ICD-10 diagnoses for psychological disorders is not appropriate in this context as the PROMs under investigation are not diagnostic tools but provide a measurement of psychological states that also include normal, that is, non-pathological, states. The shortcoming of the ICF for this specific application has been highlighted previously.<sup>29,32-35</sup>

While our content analysis is largely consistent with the previous work by Tucker et al.<sup>33</sup> for the three PROMIS item banks, there is one notable difference. Unlike Tucker et al.,<sup>33</sup> we did not use the second-level ICF category 'b126 Temperament and personality functions'. This category contains third level categories such as 'b1263 Psychic stability', 'b1265 Optimism', or 'b1266 Confidence' that might seem useful to specify contents such as emotional instability (e.g., angry outbursts), positive feelings (e.g., hopefulness), or self-esteem. However, the category is explicitly defined as "General mental functions of constitutional disposition of the individual to react in a particular way to situations, including the set of mental characteristics that makes the individual distinct from others".<sup>28</sup> This clearly indicates that this relates to personality traits rather than psychological states. Since we investigated outcome measures intended for assessing change over time, we considered this category as not appropriate for our content analysis.

#### 4.1 | Study limitations

For our study we had to make a selection of PROMs for inclusion. This decision was guided by the frequency of their use in cancer patients and based on their expected conceptual overlap with the EORTC CAT Core. Doing so, we inevitably excluded other possibly relevant measures. Additionally, all included scales focused on emotional distress (depression, anxiety, and anger in particular). By selecting measures which are likely to have a large conceptual overlap, we excluded scales assessing positive aspects of emotional functioning.<sup>39</sup> This selection was made for practical reasons to allow for a detailed comparison and should not be considered a recommendation or core outcome set.

Lacking a single, widely accepted conceptual model for emotional functioning, we relied on two different frameworks for our classifications, both with their own benefits and shortcomings. The ICF framework was selected for being probably the most common framework for classifying health states, also in the context of the content analysis of PROMs. It is very comprehensive with its biopsychosocial approach to assessing health, but as discussed above

provides only low granularity for classifying emotional states. Among other emotion classifications,<sup>40,41</sup> the PROMIS framework has the advantage of being developed for the purpose of questionnaire development. It provides appropriate possibilities for distinguishing emotional states, which are well-suited for item categorization.<sup>29</sup> However, this framework is linked to a specific set of PROMs thus not providing an independent conceptual perspective on item content. We think the combination of two different frameworks with different foci allows for an in-depth understanding of the differences and similarities of the PROMs included in this study. Nonetheless, we would like to emphasise that any assessment of similarities and differences between PROMs depends on the framework used. For example, as discussed above, in the PROMIS framework rumination is a facet of depression,<sup>10</sup> even though it is also associated with anxiety.<sup>37</sup>

The content categorization and comparison of contents allows for a better understanding of concepts assessed by each PROM. However, this study is no evaluation of their content validity. Assessing the content validity of PROMs requires another methodology that goes beyond the description of contents and takes patients' and experts' perspectives of the relevance, comprehensiveness, and comprehensibility of these contents into account.<sup>42</sup>

## 4.2 | Clinical implications

In clinical practice, the included PROMs are commonly used for screening or monitoring emotional functioning of patients with cancer. The variety of labels for questionnaires and their subscales can obscure the specific concepts assessed within a PROM. Offering a detailed understanding of their content and the underlying concepts, our results can help to identify the most appropriate PROM for a specific clinical setting and application. Such information also supports the interpretation of scores from the included PROMs. This complements psychometric evidence for these measures and can inform the assessment of whether a measure is fit-for-purpose in the context of a particular application.

## 5 | CONCLUSION

In conclusion, the results from our analysis highlight conceptual differences between PROMs of emotional functioning, including the domains anxiety, depression, and anger. The EORTC emotional functioning scale and item bank covered all three domains, while the SF-36 Mental Health, the FACT-G Emotional Well-being scale and the PRO-CTCAE items referred to depression and anxiety only. The HADS Depression and Anxiety scale and the three PROMIS item banks included items that were mostly in line with the respective domains of the PROMIS framework. Our results allow a detailed understanding of what is measured by a specific PROM and provides important information that goes beyond the broad scale labels. For the EORTC CAT Core item bank, our analysis may provide valuable information to support content-balancing in the context of item

selection when creating static short-forms or conducting computer-adaptive assessments.<sup>24</sup> Future quantitative analysis on equating scores from these different PROMs will benefit from the qualitative information generated in our study. We expect crosswalks may work best between measures focusing on the same domain.

## ACKNOWLEDGEMENTS

This study has been funded by a grant from the EORTC Quality of life Group (#011 2016).

## CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

## DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

## ETHICS STATEMENT

Ethics approval was not required for this study since no patients were involved.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

**How to cite this article:** Rothmund M, Pilz MJ, Egeter N, et al. Patient-reported outcome measures for emotional functioning in cancer patients: content comparison of the EORTC CAT Core, FACT-G, HADS, SF-36, PRO-CTCAE, and PROMIS instruments. *Psychooncology*. 2023;32(4):628-639. <https://doi.org/10.1002/pon.6109>