

## The Applicability of the International Classification of Functioning, Disability, and Health to Study Lifestyle and Quality of Life of Colorectal Cancer Survivors

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### Abstract

**Background:** Well-designed studies on lifestyle and health-related quality of life (HRQoL) in colorectal cancer survivors based on a biopsychosocial instead of a traditional biomedical approach are warranted. We report on the applicability of the International Classification of Functioning, Disability, and Health (ICF) as useful biopsychosocial framework to improve research on how lifestyle influences colorectal cancer survivors' HRQoL, using the *Energy* for life after ColoRectal cancer (EnCoRe) study as an example.

**Methods:** The ICF was used to develop a conceptual model for studying lifestyle and colorectal cancer survivors' HRQoL, by identifying relevant factors from literature and mapping them within the ICF. Subsequently, this model was used for selection of measurement instruments and biomarkers. By linking meaningful concepts within selected measures to the ICF, we could assess the ICF coverage of our developed conceptual model.

**Results:** Within selected measures, 450 meaningful concepts were identified, of which 88% were linked to the ICF. The linking process resulted in 132 distinctive ICF categories assigned (38% within "Body Functions," 2% within "Body Structures," 46% within "Activities and Participation," and 14% within "Environmental Factors").

**Conclusions:** The selected EnCoRe study measures broadly cover ICF domains relevant to colorectal cancer survivors, stressing the relevance of using a biopsychosocial approach for studying this population's HRQoL.

**Impact:** The developed conceptual model will guide data analyses and interpretation, and facilitate early transfer of results for development, evaluation, and implementation of personalized multidisciplinary lifestyle interventions. We recommend the ICF as an invaluable framework for improving the quality and scope of HRQoL studies. *Cancer Epidemiol Biomarkers Prev*; 23(7); 1394–405. ©2014 AACR.

### Introduction

Colorectal cancer is the second most prevalent cancer worldwide with an estimated number of 3.3 million survivors in 2008 diagnosed with colorectal cancer within

the previous 5 years (1). Both population ageing and increasing survival rates are causing a steady increase in the number of colorectal cancer survivors (2).

Increasing attention is given to the health-related quality of life (HRQoL) of this population (3). Although the overall HRQoL of colorectal cancer survivors generally improves after treatment up to a level equal to or even better than the general population (4–7), persisting physical and psychologic complaints related to the cancer and its treatment, such as fatigue, diarrhea, and depression, can negatively impact the HRQoL of colorectal cancer survivors up until 10 years postdiagnosis (4, 8). Importantly, colorectal cancer survivors with similar disease and treatment characteristics can show dissimilar HRQoL, suggesting that other factors like modifiable lifestyle factors, such as diet and physical activity, also directly or indirectly determine their HRQoL. Unraveling how these factors are related to HRQoL may provide novel leads for improving colorectal cancer survivors' HRQoL via personalized lifestyle interventions provided through client-centered counseling (9, 10).

Previous findings suggest that cancer survivors, including colorectal cancer survivors, are open to adopt lifestyle

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changes after diagnosis (a "teachable moment") to improve their health (11), and express a need for guidance in lifestyle choices (12, 13). Existing lifestyle guidelines for cancer survivors (14, 15) are nonspecific about cancer site and mostly based on findings from etiologic studies (16). Moreover, only a minority of cancer survivors seems to meet these recommendations (17), indicating a pressing need for appropriately timed personalized lifestyle interventions.

Well-designed studies on how specific lifestyle factors, such as diet and physical activity, affect the HRQoL of colorectal cancer survivors are scarce. Intervention studies have shown positive effects of physical activity and a healthy diet (high in fruits and vegetables, low in saturated fat) on HRQoL (18–20), but these studies were performed in a select group of colorectal cancer survivors (20), had a low number of participants (18), or a short follow-up (19). Similar findings have been observed in observational studies (17, 21–30), which nearly all had a cross-sectional design (17, 21–27, 30). The only 2 prospective studies found increased physical activity to be associated with improved HRQoL, but did not take dietary factors into account (28, 29).

Taken together, the above indicates that the influence of lifestyle behaviors on the health and well-being of colorectal cancer survivors remains understudied. HRQoL is a broad-ranging and multidimensional construct (31), which can be influenced by many factors at both an individual and environmental level (32). Therefore, prospective studies are needed that systematically examine short- and long-term influences of lifestyle factors on the HRQoL of colorectal cancer survivors. These studies should be based on a biopsychosocial paradigm, which incorporates biomedical and psychosocial models of health and health care, and allows medical, individual, social, and environmental influences on functioning and disability to be described and examined (33, 34). To fulfill this need, a new longitudinal study on lifestyle and HRQoL in colorectal cancer survivors was initiated in 2012: the *Energy for life after ColoRectal cancer* (EnCoRe) study.

The International Classification of Functioning, Disability and Health (ICF) was chosen to operationalize the biopsychosocial paradigm in order to strengthen the design of the EnCoRe study and to guide a broad and in-depth investigation of the interrelations between lifestyle and HRQoL. Developed in 2001 by the World Health Organization (WHO; ref. 35), the ICF is a biopsychosocial framework that comprehensively describes and classifies functioning of an individual in a certain health state by differentiating between body functions and structures (e.g., "mental functions" or "structures related to movement"), and activities and participation (e.g., "mobility" or "community, social, and civic life"), in the context of environmental (e.g., "support and relationships"), and personal barriers/facilitators (e.g., gender or genetic factors; Fig. 1; ref. 33). As a classification of health, the ICF is complementary to the Tenth Revision of the International Statistical Classification of Diseases and Related

Health Problems (ICD-10), which has its focus on morbidity and mortality (36). Importantly, the ICF represents a paradigm shift from a traditional biomedical approach with quantifiable biological health components to a more holistic concept of health and functioning, in which qualitative aspects such as psychosocial functioning and societal participation are also included (34). Moreover, the ICF provides a common language, which facilitates communication between professionals and patients, stimulating shared decision making important for providing personalized interventions within a client-centered and multidisciplinary approach (34).

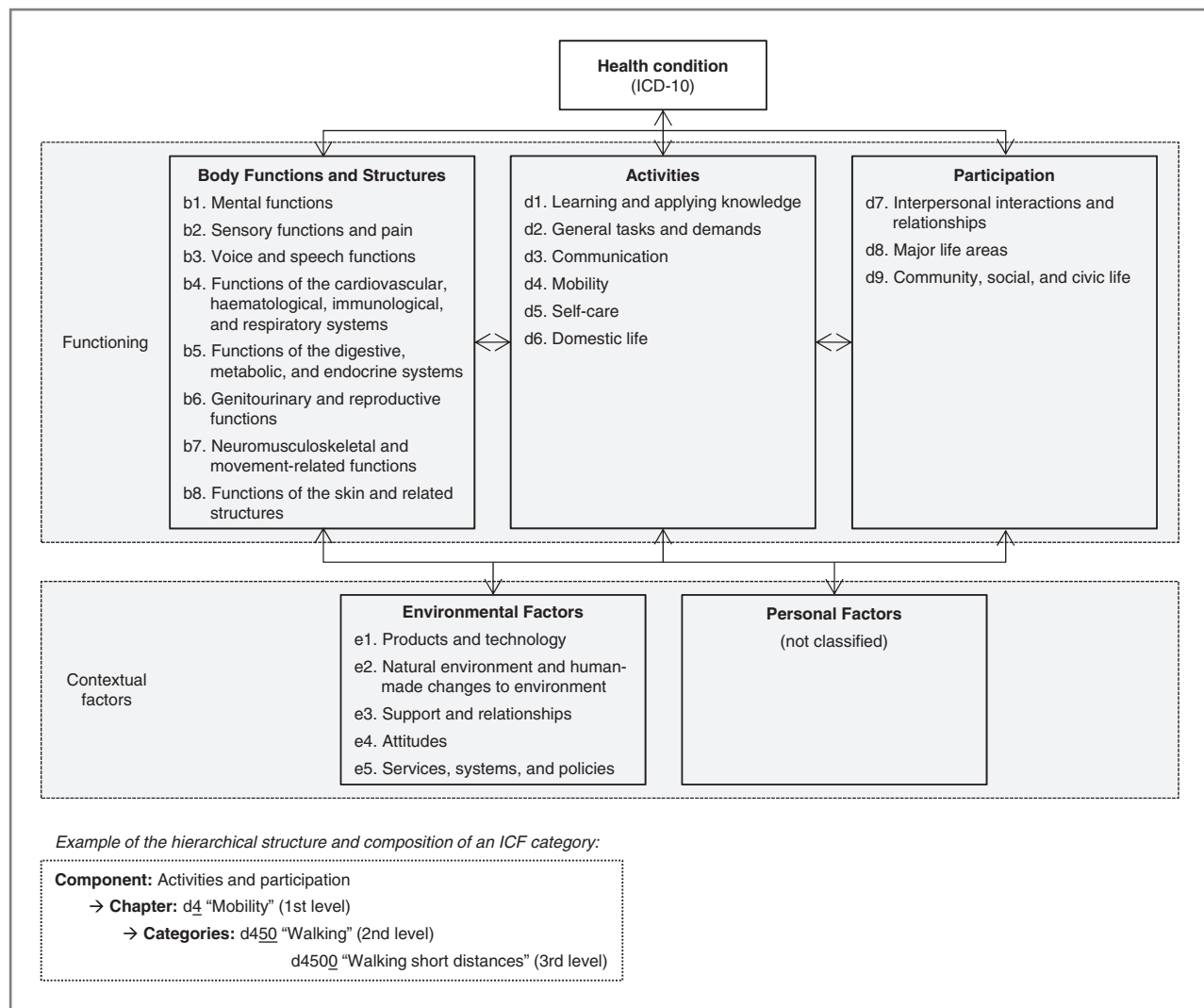
When designing the EnCoRe study, an ICF-based conceptual model for studying lifestyle and HRQoL in colorectal cancer survivors was developed by identifying relevant factors from literature and mapping these within the ICF framework (Fig. 2). In this conceptual model, HRQoL is regarded as a multidimensional construct underlying the functioning part of the ICF framework, because it is the subjective perception of an individual's level of functioning in different domains within the context of the individual's health state and specific environmental and personal barriers and facilitators (37, 38). Appropriate measurement instruments and biomarkers were selected based on the conceptual model.

The objective of this article is to report how we assessed the appropriateness of our ICF-based conceptual model when investigated with the instruments and markers selected, by identifying their meaningful concepts and linking these to the ICF. Thereby, we were able to determine whether relevant lifestyle and HRQoL domains and contextual factors are covered within the EnCoRe study and, moreover, to show that the ICF provides a framework and generic language, which can be applied to improve the design of and communication about a HRQoL study.

## Materials and Methods

### EnCoRe study design

The EnCoRe study is composed of a prospective cohort study, in which patients with stage I to III colorectal cancer from Maastricht University Medical Center+ (Maastricht UMC+) in the Netherlands are enrolled at diagnosis and followed up until 2 years after initial treatment (Fig. 3). To be able to study the 10-year colorectal cancer survivorship trajectory within a short time frame, a complementary cross-sectional study is conducted in patients treated for stage I to III colorectal cancer at Maastricht UMC+ between 2 and 10 years ago (2002–2010), who were selected via the Netherlands Cancer Registry (managed by Comprehensive Cancer Centre the Netherlands). Inclusion and exclusion criteria are depicted in Table 1. Patient recruitment started in April 2012 and is ongoing. The EnCoRe study has been approved by the Medical Ethics Committee of the University Hospital Maastricht and Maastricht University, the Netherlands, and informed consent is obtained from all participants.



**Figure 1.** The ICF biopsychosocial framework (WHO, 2001), which comprehensively describes and classifies the functioning of an individual with a certain health condition. The ICF consists of 2 parts, which are divided in different components denoted by letters: the "Functioning" part comprised of "Body Functions" (b), "Body Structures" (s), and "Activities and Participation" (d), and the "Contextual factors" part comprised of "Environmental Factors" (e) and "Personal Factors" (pf). All components are further divided in chapters, which in turn are subdivided into multilevel categories with specific codes (an example of the composition of a hierarchical ICF code is given below the framework). Within the figure, the components "Body Functions" and "Body Structures" are combined and only chapters of "Body Functions" are shown because they are most relevant for this article. In addition, for the purpose of this article, the component "Activities and Participation" was subdivided into "Activities" (Chapters d1 to d6) and "Participation" (Chapters d7 to d9).

## Data collection

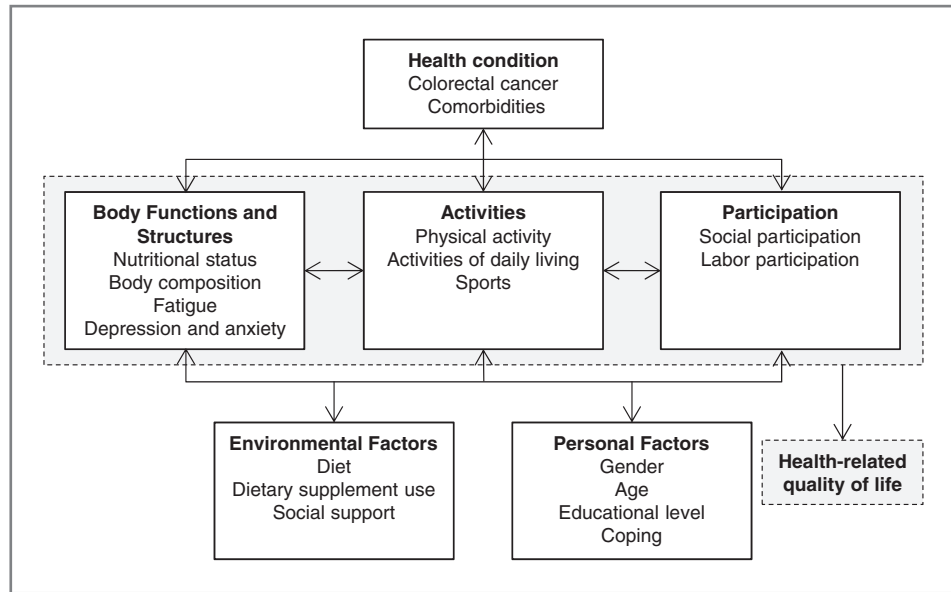
Study measurements are performed during visits to participants' homes. Timing of measurements within the prospective and cross-sectional study is shown in Table 2.

**Health outcomes.** Cancer-specific HRQoL is measured by the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30, version 3.0, ref. 39), complemented with the colorectal cancer-specific CR29 module (version 2.1; ref. 40). In addition, several generic HRQoL measures are used: the European Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L) questionnaire (41–44), the 12-item World Health Organization Disability Assessment Schedule II (WHODAS II; refs. 45 and 46), and the "General

Health," "Role-Emotional," "Role-Physical," and "Self-reported health transition" scales of the Short Form Health Survey (SF-36; refs. 47 and 48).

Furthermore, self-reported fatigue is measured by means of the Checklist Individual Strength (CIS; refs. 49 and 50), and the "Need for Recovery" subscale of the Dutch "Questionnaire on the Experience and Evaluation of Work" (Vragenlijst Beleving en Beoordeling van de Arbeid, VBBA; ref. 51). Levels of depression and anxiety are assessed by the Hospital Anxiety and Depression Scale (HADS; refs. 52 and 53) and fear of recurrence and psychological benefits of cancer with the subscales "Distress-recurrence" and "Benefits of cancer" of the Quality of Life in Adult Cancer Survivors (QLACS) questionnaire (54).

Figure 2. ICF-based conceptual model showing factors relevant to lifestyle and health-related quality of life of colorectal cancer survivors identified from the literature.



**Lifestyle exposures.** The Short QUestionnaire to ASsess Health-enhancing physical activity (SQUASH) is used to measure habitual activity level (55). Participants are also requested to wear a tri-axial accelerometer on the anterior upper leg for 7 consecutive days to determine intensity, frequency, and duration of daily activities like walking, standing, and lying, and thereby to capture both physical activity and sedentary behavior (56, 57).

In addition, participants are asked to fill out a 7-day dietary record, and dietary supplement use is registered by a dietician. Additional data are collected on specific dietary factors (e.g., vegetarianism), the influence of certain complaints on physical activity level, and advice

received on physical activity and diet since diagnosis. To assess dietary intake in the year preceding colorectal cancer diagnosis, a 101-item Food Frequency Questionnaire (FFQ) is applied at the pretreatment measurement of the prospective study.

**Other factors.** When developing our ICF-based conceptual model (Fig. 2), potential confounders, effect modifiers, and/or intermediate variables were identified from literature and selected for measurement. Body composition is assessed by measuring body weight and height; thickness of triceps, biceps, subscapular, and suprailiac skinfolds (58); mid-upper arm, waist, and hip circumference; and handgrip strength of the dominant hand (59).

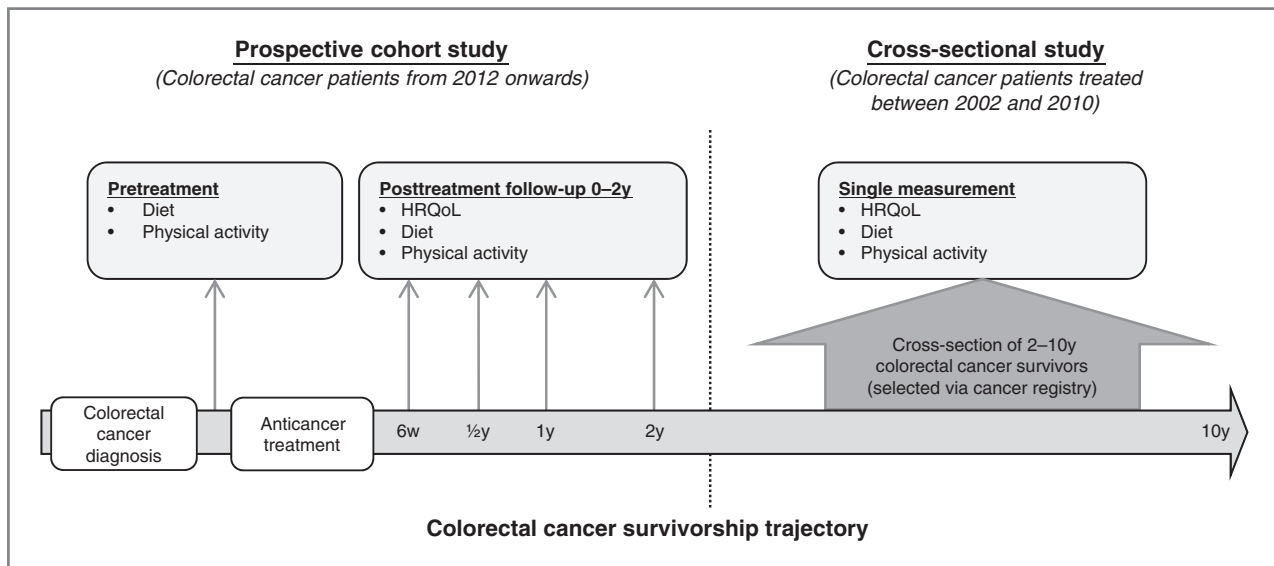


Figure 3. Design of the EnCoRe study showing the complementary prospective cohort study and cross-sectional study that together cover the colorectal cancer survivorship trajectory from diagnosis up until 10 years after treatment. w, week; y, year.

**Table 1.** Inclusion and exclusion criteria of the EnCoRe prospective cohort and cross-sectional study

	Prospective cohort study	Cross-sectional study
Inclusion criteria	<ul style="list-style-type: none"> <li>• Men and women, age <math>\geq 18</math> y;</li> <li>• Established diagnosis of stage I, II, or III colorectal cancer, including recurrent colorectal cancer, at Maastricht UMC+.</li> </ul>	<ul style="list-style-type: none"> <li>• Men and women, age <math>\geq 18</math> y;</li> <li>• History of stage I, II, or III colorectal cancer, including recurrent colorectal cancer, for which treatment was received at Maastricht UMC+ between 2002 and 2010.</li> </ul>
Exclusion criteria	<ul style="list-style-type: none"> <li>• Diagnosis of stage IV colorectal cancer<sup>a</sup>;</li> <li>• Current home address not in the Netherlands;</li> <li>• Inability to understand the Dutch language in speech as well as in writing (e.g., reading disorders or illiteracy);</li> <li>• Presence of comorbidities that may obstruct successful participation, including cognitive disorders such as Alzheimer disease, and severe visibility or hearing disorders such as complete blindness and/or deafness.</li> </ul>	<ul style="list-style-type: none"> <li>• Treatment for stage IV colorectal cancer at Maastricht UMC+ between 2002 and 2010<sup>a</sup>;</li> <li>• Not alive at present;</li> <li>• Current home address not in the Netherlands;</li> <li>• Inability to understand the Dutch language in speech as well as in writing (e.g., reading disorders or illiteracy);</li> <li>• Presence of comorbidities that may obstruct successful participation, including cognitive disorders such as Alzheimer disease, and severe visibility or hearing disorders such as complete blindness and/or deafness.</li> </ul>

<sup>a</sup>Patients with stage IV colorectal cancer are excluded, because their poor prognosis, and not lifestyle behavior, likely determines their HRQoL to the largest extent.

Clinical tumor characteristics are collected through the Netherlands Cancer Registry and further clinical information (e.g., on anticancer treatment) is retrieved from medical records. In addition, the presence of comorbidity at colorectal cancer diagnosis is collected using the Charlson Comorbidity Index (60–62), whereas the Self-Administered Comorbidity Questionnaire is used posttreatment (63). Social support is assessed by the 6-item Dutch Social Support List (SSL-6; ref. 64), and coping by the 21-item Coping Inventory for Stressful Situations (CISS; refs. 65–67). Finally, self-reported data are collected on health care utilization, family history of cancer, social/labor participation, smoking, and demographic factors.

**Biomarkers.** Repeated blood samples are collected from participants for analysis of biomarkers of energy balance and nutritional status, such as components of the insulin-like growth factor-I (IGF-I) axis and vitamin D. Participants have also approved the use of routinely collected tumor material or pathologic tissue samples for measurement of tumor-specific biomarkers, for example components of the mechanistic target of rapamycin (mTOR) pathway. In addition, as biomarkers of body composition, images from routinely collected abdominal computed tomography (CT) scans are used to determine cross-sectional area of skeletal muscle and of visceral, intramuscular, and subcutaneous fat at the landmark level of the third lumbar vertebra, which are valid measures of whole body muscle and fat mass and can be used to determine the presence of sarcopenia and sarcopenic obesity (i.e., muscle wasting masked by increased adiposity; refs. 68–70).

### ICF linking of measurement instruments

The ICF is a systematic classification of human functioning with a hierarchic structure. It consists of 2 parts, each divided in different components denoted by letters: "Body Functions" (b), "Body Structures" (s), and "Activities and Participation" (d) comprise the "Functioning" part, and "Environmental Factors" (e) and "Personal Factors" (pf) comprise the "Contextual Factors" part (Fig. 1). All components are divided in chapters, which are further divided into multilevel categories with specific codes. Every ICF code consists of the component letter followed by the first level (the chapter number, e.g., d4 "Mobility"), second level (e.g., d430 "Lifting and carrying objects"), third level (e.g., d4300 "Lifting"), and occasionally a fourth level. Personal Factors are currently not classified.

To retrospectively determine whether relevant lifestyle and HRQoL domains as well as contextual factors proposed in our ICF-based conceptual model (Fig. 2) are sufficiently covered within the EnCoRe study, all measurement instruments and biomarkers were linked to the ICF according to published linking rules (71). Meaningful concepts in instruments and represented by biomarkers were identified and subsequently linked to the most suitable ICF category. Briefly, the linking procedure occurred as follows. Meaningful concepts, defined as a separate meaningful entity distinct from other concepts (72), were identified first. For questionnaires, these concepts were identified from the separate questionnaire items, whereas for other study measures (such as hand-grip strength or skinfold measurements) the main purpose of the concerning measure was defined as the

**Table 2.** Timing of measurements in the EnCoRe prospective cohort study and cross-sectional study

	Prospective cohort study				Cross-sectional study
	Measurements at diagnosis (pretreatment)		Follow-up measurements (posttreatment)		Single measurement
	Before diagnosis <sup>a</sup>	At diagnosis	6 weeks (baseline <sup>b</sup> )	6, 12, and 24 months	2–10 years after treatment
Health outcomes					
Health-related quality of life			x	x	x
Fatigue			x	x	x
Emotional functions			x	x	x
Lifestyle exposures					
Physical activity questionnaire	x		x	x	x
Accelerometer			x	x	x
Food frequency questionnaire	x				
Seven-day dietary record			x	x	x
Dietary supplement use		x	x	x	x
Other factors					
Body composition <sup>c</sup>	x	x	x	x	x
Clinical tumor-related characteristics		x	x	x	x
Charlson comorbidity index		x			
Self-administered comorbidity questionnaire			x	x	x
Social support			x	x	x
Coping			x	x	x
Health care utilization		x	x	x	x
Family history of cancer		x	x	x	x
Social/labor participation		x	x	x	x
Smoking		x	x	x	x
Demographic factors		x	x	x	x
Biomarkers					
Blood-derived biomarkers		x	x	x	x
Tumor-specific biomarkers <sup>d</sup>		x			x
Biomarkers of body composition derived from CT images <sup>e</sup>		x	x	x	x

<sup>a</sup>Retrospectively (usual physical activity in the 4-week period before the first bowel symptoms/complaints, usual diet in the year before colorectal cancer diagnosis).

<sup>b</sup>As the goal is to investigate the effect of lifestyle on the HRQoL after treatment, the 6-week posttreatment time point is regarded as baseline; the pretreatment measurements are performed to adjust for prediagnosis levels of certain variables (e.g., the usual diet).

<sup>c</sup>Only self-reported body weight at birth and at age 18 in both the prospective and cross-sectional study, and at colorectal cancer diagnosis in the cross-sectional study is collected retrospectively.

<sup>d</sup>Measured in routinely collected tumor material or pathologic tissue samples collected around the time of diagnosis.

<sup>e</sup>Derived from images from abdominal CT scans routinely collected at diagnosis and during clinical follow-up.

meaningful concept. Subsequently, the meaningful concepts that had been identified were linked to one or more suitable ICF categories. For clarity, we provide an example of the linking procedure as applied to an item of the EORTC QLQ-C30. Item 6 of this cancer-specific quality of life questionnaire is, "Were you limited in doing either your work or other daily activities?" From this item, the meaningful concepts "doing your work" and "daily activ-

ities" were identified. Next, the concept "doing your work" was linked to the ICF categories d850 "Remunerative employment" and d855 "Non-remunerative employment," and the concept "daily activities" was linked to d230 "Carrying out daily routine." As an additional example of the linking procedure applied to an anthropometric measure, the meaningful concept of the handgrip strength measurement was defined as "total body muscle

strength," which this measure is aiming to represent. This meaningful concept was then linked to the ICF category b730 "Muscle power functions." Concepts could also be assigned as "Personal Factors" or "Health condition," both of which are part of the ICF framework but cannot be classified with a specific ICF code and, therefore, were encoded as "pf" and "hc," respectively. According to the published linking rules (71), when identified meaningful concepts were not precise enough to be linked to a specific ICF category, they were encoded as "not definable" (nd). If possible, further specification was provided by "not definable-quality of life" (nd-qol), "not definable-general health" (nd-gh), or "not-definable-physical health" (nd-ph). In case linking was not possible at all because the meaningful concept was not contained within the ICF, it was encoded as "not covered" (nc).

An iterative approach was undertaken, according to best current practices and recommendations about quality control methods (72). The linking procedure was first performed independently by 2 trained linkers with certified ICF knowledge (EvR and MB). Next, results of the independent linkers were compared and differences were discussed, after which consensus was reached about the definitive ICF code to be assigned. The entire process was supervised by a WHO Collaborating Centre ICF expert (HTN). The EQ-5D-5L and SF-36 had already been linked to the ICF and these results are reported (73, 74).

The number of meaningful concepts identified and the linkage of these concepts to separate ICF components was calculated, as well as the number of concepts that could not be linked and were therefore assigned either as "not definable" or "not covered." For the meaningful concepts being linked, we calculated both the total number of (partly overlapping) ICF categories assigned and the number of distinctive categories (i.e., separate, mutually exclusive categories) within each ICF component. [Note: Because identified meaningful concepts within the previously linked EQ-5D-5L questionnaire were not reported (73), the concepts of this measure were not incorporated in calculations of meaningful concepts, but only included in the results concerning ICF categories assigned.]

## Results

Within the EnCoRe study measures, a total number of 450 meaningful concepts were identified, of which 397 (88%) were linked to the ICF (Supplementary Table S1; Fig. 4). In total, 53 (12%) meaningful concepts could not be linked and were assigned as "not definable" ( $n = 22$ ), "not definable-general health" ( $n = 16$ ), "not definable-physical health" ( $n = 4$ ), "not definable-quality of life" ( $n = 1$ ), or "not covered" ( $n = 10$ ) (Supplementary Table S2). Of the 450 identified concepts, 132 (29%) were linked to categories within the "Body Functions" component, 2 (<1%) to the "Body Structures" component, 159 (35%) to "Activities and Participation," and 110 (24%) to "Environmental Factors." In addition, 18 (4%) meaningful concepts

were assigned as "Personal Factors" and 8 (2%) as "Health condition." The linking procedure resulted in a total number of 132 distinctive, mutually exclusive ICF categories assigned (within the total of 509 partly overlapping ICF categories linked), of which 50 (38%) were within "Body Functions," 2 (2%) within "Body Structures," 61 (46%) within "Activities and Participation," and 19 (14%) within "Environmental Factors."

## Health outcomes

Meaningful concepts within items of cancer-specific (EORTC QLQ-C30 with CR-29 module) and generic (EQ-5D-5L, WHODAS II, and SF-36 subscales) HRQoL instruments were linked to nearly all chapters of "Activities and Participation" (e.g., d510 "Washing oneself" and d9205 "Socializing" within the Chapters d5 "Self-care" and d9 "Community, social, and civic life," respectively), except for Chapters d3 "Communication" (both) and d6 "Domestic life" (cancer-specific measures). In addition, items within the cancer-specific measures were linked to nearly all chapters of "Body Functions" (e.g., categories b28012 "Pain in stomach or abdomen" and b6202 "Urinary continence" within the Chapters b2 "Sensory functions and pain" and b6 "Genitourinary and reproductive functions," respectively), except for Chapters b3 "Voice and speech functions" and b7 "Neuromusculoskeletal and movement-related functions." In contrast, the generic measures only covered categories within Chapters b1 "Mental functions" and b2 "Sensory functions and pain" (e.g., b152 "Emotional functions" and b280 "Sensation of pain"). Items concerning overall health and HRQoL were assigned as "not definable-general health" and "not definable-quality of life."

The fatigue measures (CIS and VBBA "Need for Recovery" subscale) were mainly linked to the "Body Functions" categories b1300 "Energy level" and b1301 "Motivation." Most items of both the HADS and QLACS subscales were linked to b152 "Emotional functions."

## Lifestyle exposures

The SQUASH and accelerometer were linked to several categories in chapters of "Activities and Participation," including Chapters d2 "General tasks and demands," d4 "Mobility," d5 "Self-care," d6 "Domestic life," d8 "Major life areas," and d9 "Community, social, and civic life" (e.g., d450 "Walking" and d9201 "Sports"). All dietary intake measures, including supplement use, were linked to the "Environmental Factors" category e1100 "Food." Items on specific dietary factors were linked to the "Body Functions" categories b530 "Weight maintenance functions" and b5153 "Tolerance to food," the "Activities and Participation" category d5701 "Managing diet and fitness," and "Personal Factors." Items on dietary and physical activity advice were mainly linked to Chapter e3 "Support and relationships" and category e5800 "Health services" of "Environmental Factors," and the "Activities and Participation" category d57020 "Managing medications and following health advice."

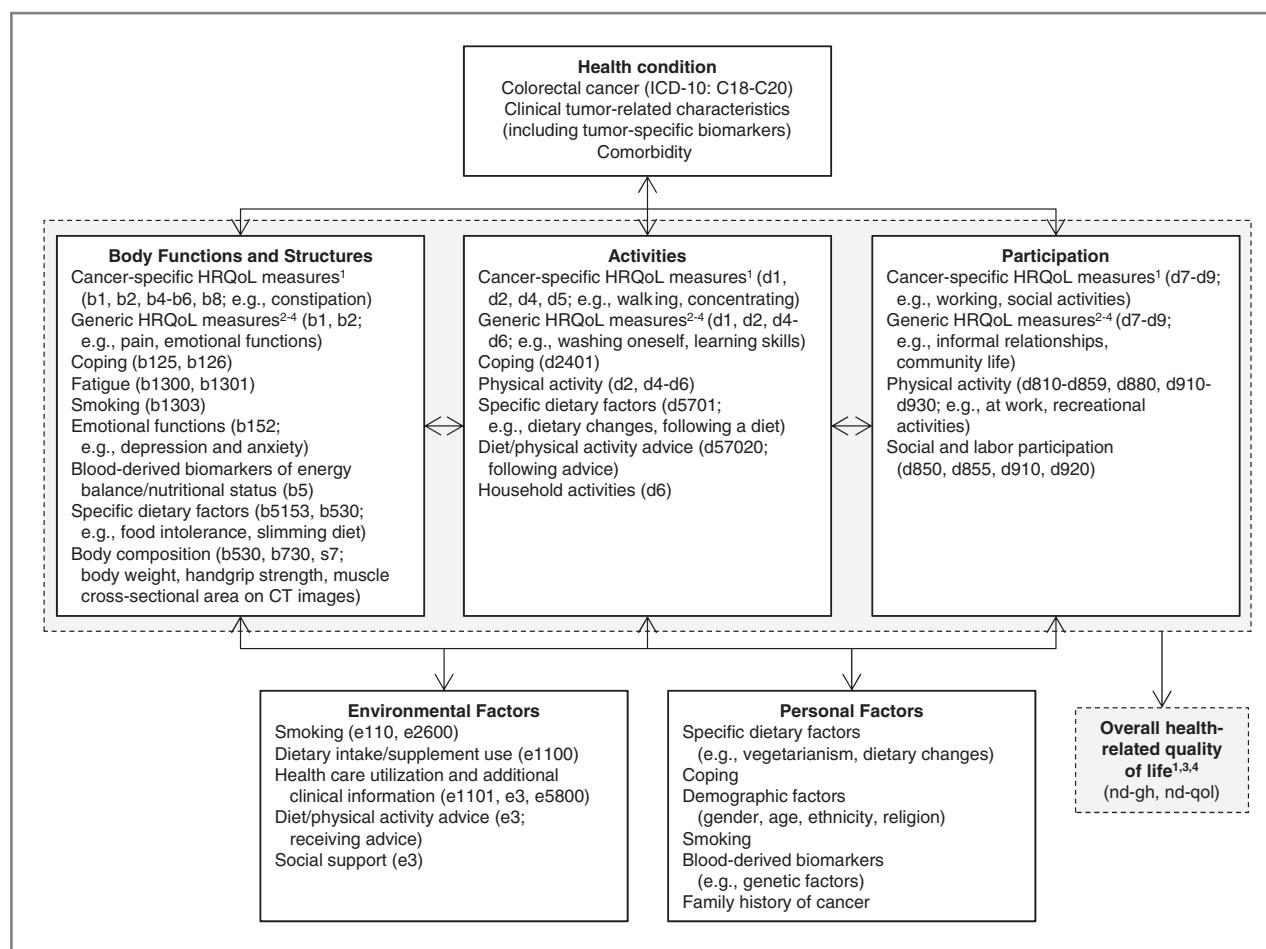


Figure 4. Summary of results of linking the EnCoRe study measures to the ICF (full description of linking results for separate measures can be found in Supplementary Tables S1 and S2). 1, European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) with CR29 module. 2, European Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L) questionnaire. 3, Short Form Health Survey (SF-36) subscales. 4, 12-item World Health Organization Disability Assessment Schedule II (WHODAS II).

### Other factors

Concerning body composition, we could only assign ICF categories to the measurement of body weight ("Body Functions": b530 "Weight maintenance functions"), handgrip strength ("Body Functions": b730 "Muscle power functions"), and muscle cross-sectional area on CT images ("Body Structures": Chapter s7 "Structures related to movement"). Clinical tumor-related characteristics (including tumor-specific biomarkers) and comorbidity were assigned as "Health condition," whereas data on health care utilization and additional clinical information were mainly linked to the "Environmental Factors" categories e1101 "Drugs" and e5800 "Health services," and several categories of Chapter e3 "Support and relationships" (e.g., e355 "Health professionals"). The social support questionnaire (SSL-6) was linked to Chapter e3 "Support and relationships" of "Environmental Factors," while coping (CISS) was linked to the "Body Functions" categories b125 "Dispositions and intra-personal functions" and b126 "Temperament and personality functions," the "Activities and Participation" category d2401 "Handling stress," and "Personal Factors."

Social and labor participation items were linked to Chapter d6 "Domestic life," and several categories within Chapters d8 "Major life areas" (e.g., d850 "Remunerative employment") and d9 "Community, social, and civic life" of "Activities and Participation" (e.g., d910 "Community life"). A family history of cancer, most demographic factors and smoking were assigned as "Personal Factors." In addition, (passive) smoking was linked to the "Environmental Factors" categories e110 "Products or substances for personal consumption" and e2600 "Indoor air quality," and the "Body Functions" category b1303 "Craving." Biomarkers of energy balance and nutritional status were linked to Chapter b5 "Functions of the digestive, metabolic, and endocrine systems" of "Body Functions," whereas other blood-derived biomarkers (e.g., genetic factors) were assigned as "Personal Factors."

### Discussion

This article describes how we applied the ICF as a biopsychosocial framework to design an observational



study on the influence of certain lifestyle behaviors on the HRQoL of colorectal cancer survivors (the EnCoRe study). By mapping relevant lifestyle and other variables related to and/or representing HRQoL within the ICF, an ICF-based conceptual model was developed that laid the foundation for the selection of measurement instruments and biomarkers. Subsequently, by linking all selected study measures to the ICF, we could retrospectively assess the content coverage of individual and the total combination of the selected measures. The results showed that the measures selected for use within the EnCoRe study have a broad coverage of different ICF domains and chapters relevant to lifestyle and HRQoL of colorectal cancer survivors, substantiating the relevance of using the ICF to operationalize the biopsychosocial paradigm, in order to pursue a holistic approach of health and functioning necessary for a HRQoL study.

The ICF has been used previously as frame of reference to determine the coverage of HRQoL instruments, including the EORTC QLQ-C30, SF-36, WHODAS II, and EQ-5D-5L, through the linking procedure (73, 75, 76). The results showed that the content differed between questionnaires (73, 75, 76), and that the coverage of categories from the component "Activities and Participation" by these instruments is generally limited (75). Therefore, careful selection of instruments according to the study questions and population of interest is important, and we have shown that the ICF can be useful for this purpose. As shown by our linking results, multiple complementary HRQoL measures as well as measures for relevant contextual factors are used within the EnCoRe study, to achieve a broad coverage of aspects relevant to every dimension of HRQoL, including societal participation.

The ICF linking rules provide a standardized way to identify meaningful concepts within instruments and assign a suitable ICF code (71). The validity of the procedure in our study was strengthened by using 2 independent coders with certified ICF knowledge, and a WHO Collaborating Centre ICF expert who supervised the process. However, we found it difficult to link certain lifestyle factors as precisely as possible, because some aspects could represent multiple ICF domains and categories. For example, all dietary measurement instruments were linked to the "Environmental Factors" category e1100 "Food," but items on specific dietary factors were also linked to the "Body Functions" category b530 "Weight maintenance functions" (e.g., following a slimming diet) and "Personal Factors" (e.g., vegetarianism), which could possibly limit the interpretability of these items. In addition, we identified some meaningful concepts that could not be assigned to a specific ICF category and were therefore assigned as "not definable" or "not covered," such as the measurement of skinfold thickness and body height, respectively.

The main strength of the ICF is that it is a comprehensive and well-structured biopsychosocial framework that promotes international and interdisciplinary communication by using a univocally defined terminology. It pro-

vides a common language that can facilitate the delivery of personalized lifestyle interventions through a multidisciplinary approach, which incorporates client-centered counseling and shared decision making (34). For oncology research, however, some suggestions for improvements were recently put forward (77). First, the term "Health condition" might be too narrow in the case of cancer survivorship, when the "Health condition" cancer is no longer present, but can still have a marked influence on (long-term) functioning, and when multiple health conditions (comorbidities) are often present. Therefore, the authors suggested to replace the term "Health condition" by "Health state" to permit a broader view on health (77). Second, HRQoL as the subjective perception of functioning is currently not part of the ICF (77). However, within our ICF-based conceptual model, we depicted overall HRQoL as an underlying concept for the subjective, personal perception of an individual's functioning within the context of environmental and personal factors, enabling us to successfully incorporate HRQoL's subjective nature into our conceptual model (37, 38).

Besides its usefulness during the design of our study, the developed ICF-based conceptual model will also guide future data analyses and aid in the interpretation and translation of study findings. During data analyses, it will guide the choice of relevant exposure as well as health outcome measures, and will also guide the selection of potential confounders, effect modifiers and/or mediating factors to be taken into account when analyzing separate research questions. For example, structural equation modeling likely is an appropriate statistical technique to unravel the direction and dynamics of interrelationships depicted within our proposed ICF-based conceptual model, enabling identification of moderation, mediation and confounding effects and latent constructs (78). During data interpretation, the developed conceptual model will help us to interpret our findings and deepen our understanding of complex interrelations between lifestyle and other factors associated with the multidimensional construct of HRQoL in colorectal cancer survivors. Increased understanding of complex lifestyle-HRQoL interrelations will facilitate the translation and promote the implementation of study findings within the practice of clinical and psychosocial oncology.

The EnCoRe study findings will provide new leads for the development of personalized lifestyle intervention programs within a multidisciplinary colorectal cancer survivorship care setting. The developed ICF-based conceptual model can be used for identification of important contextual facilitators or barriers (e.g., social support or the presence of a stoma, respectively), which can influence the effectiveness of these interventions and therefore need to be taken into account during implementation of these intervention programs. Based on this model, ICF-based patient-centered assessment tools that are already being used within the field of rehabilitation medicine, can be tailored and adjusted for use in the evaluation and implementation of such interventions to facilitate early transfer

of results from studies like ours to clinical oncology practice (79, 80).

In conclusion, we strongly believe the ICF is a versatile and invaluable framework for improving the quality and scope of HRQoL studies in colorectal cancer survivors, and likewise in populations with other health conditions. We recommend other researchers to follow a biopsychosocial rather than a biomedical approach based on the common language of the ICF throughout the design, conduct, and interpretation phase of an HRQoL study.

### Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

### Authors' Contributions

**Conception and design:** E.H. van Roekel, M.J.L. Bours, C.P.M. de Brouwer, I. Kant, M.P. Weijenberg

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**Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis):** E.H. van Roekel, M.J.L. Bours, C.P.M.

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