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Functioning and disability in traumatic brain injury: the Italian patient perspective in developing ICF Core Sets

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Abstract

Objective. The purpose of the study was to explore the aspects of functioning and health relevant to patients with traumatic brain injury (TBI) and to the caregivers of TBI patients explicitly involved in the preliminary study for the Development of the ICF Core Set for TBI using a qualitative research method.

Method. The sampling of patients followed the maximum variation strategy. To respect this strategy, we involved patients with different degrees of impairment and so, for some people it was not possible to join the group because of their severe cognitive impairment, in this case we interviewed their caregivers. The focus groups were digitally recorded and transcribed verbatim. The meaning condensation procedure was used for the data analysis. After qualitative data analyses, the resulting concepts were linked to ICF categories according to established linking rules.

Results. Eighteen focus groups and five single interviews were performed. Forty-one patients participated in 10 focus groups. Thirty-three caregivers participated in eight focus group and six caregivers underwent a single interview. Saturation at 10% cutoff was reached. Based on 10 patient focus groups, we linked the concepts to 144 2nd level ICF different categories. In the eight focus group with caregiver we linked the concepts to129 2nd level categories. In the single interviews, we could link the concepts only to Environmental factors and we linked to 25 ICF different categories.

Conclusion. A broad range of aspects of functioning and health as well as several Environmental factors important to patients with TBI were explored and included in the preparatory phase of the development of ICF Core Sets for TBI. Whereas patients focused on problems in mobility, employment and recreation and leisure the caregivers highlighted several issues related to self-care as being important for the patients.

Keywords: *International Classification of Functioning, Disability and Health, ICF, traumatic brain injury (MeSH), qualitative research (MeSH), focus groups (MeSH), patient perspective*

Abbreviations: *ICF = International Classification of Functioning, Disability and Health; LCF = level of cognitive functioning; TBI = traumatic brain injury; WHO = World Health Organization; WHA = World Health Assembly*

Introduction

Functioning and disability is recognised as an important study outcome in traumatic brain injury (TBI). The number of clinical studies addressing functioning as a study endpoint in patients with TBI has steadily increased during the last decade [1].

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These investigations have predominantly been guided by the medical perspective, from which the measurement of functioning and health is required to evaluate the patient-relevant outcomes of an intervention and from which functioning and health are seen primarily as a consequence of the health condition [2]. Many of these investigations include patient-oriented instruments, e.g. patient and proxy (self-)reports on health status, quality of life and health preferences. In TBI, there is an extensive literature on outcome measures that have been used in clinical studies and in the evaluation of TBI but some of them have been developed for other health disorders and adapted for TBI [3].

These instruments have also been developed according to the medical perspective and in line with the current concept in outcomes and quality-of-life research of condition-specific measures [4], i.e. they are based on the assumption that different conditions are associated with salient patient problems in functioning. The individual influence of the environment and personal factors is, however, rarely taken into account [5,6]. However, the patients' experience of functioning and disability is determined by their interaction with the environment and their own personal characteristics and not only by the health condition [7–10]. TBI is also very much associated with the inability to continue working, ultimately leading to the experience of restriction in participation [11–14]. Thus, a very comprehensive approach is required when addressing TBI.

The bio-psycho-social perspective of functioning, disability and health of the World Health Organization (WHO) [15] establishes the basis for a more comprehensive description of the experience of patients suffering from determined health conditions. Based on this model, functioning with its components Body functions, Body structures and Activities and Participation is seen in relation to the health condition under consideration, as well as Personal and Environmental factors (Figure 1) [15]. Functioning denotes the positive aspects and disability the negative aspects of the interaction between an individual with a health condition and the contextual factors (Environmental factors and Personal factors) of that individual.

This bio-psycho-social view guided the development of the International Classification of Functioning, Disability and Health (ICF) [15], which was approved by the World Health Assembly (WHA) in May 2001. Since the ICF has been developed in a worldwide, comprehensive consensus process over the last few years and was endorsed by the WHA as a member of the WHO Family of International Classifications (FIC), it is likely to become the generally accepted framework to describe functioning and health. The ICF is intended for use in multiple sectors that include, besides health, education,

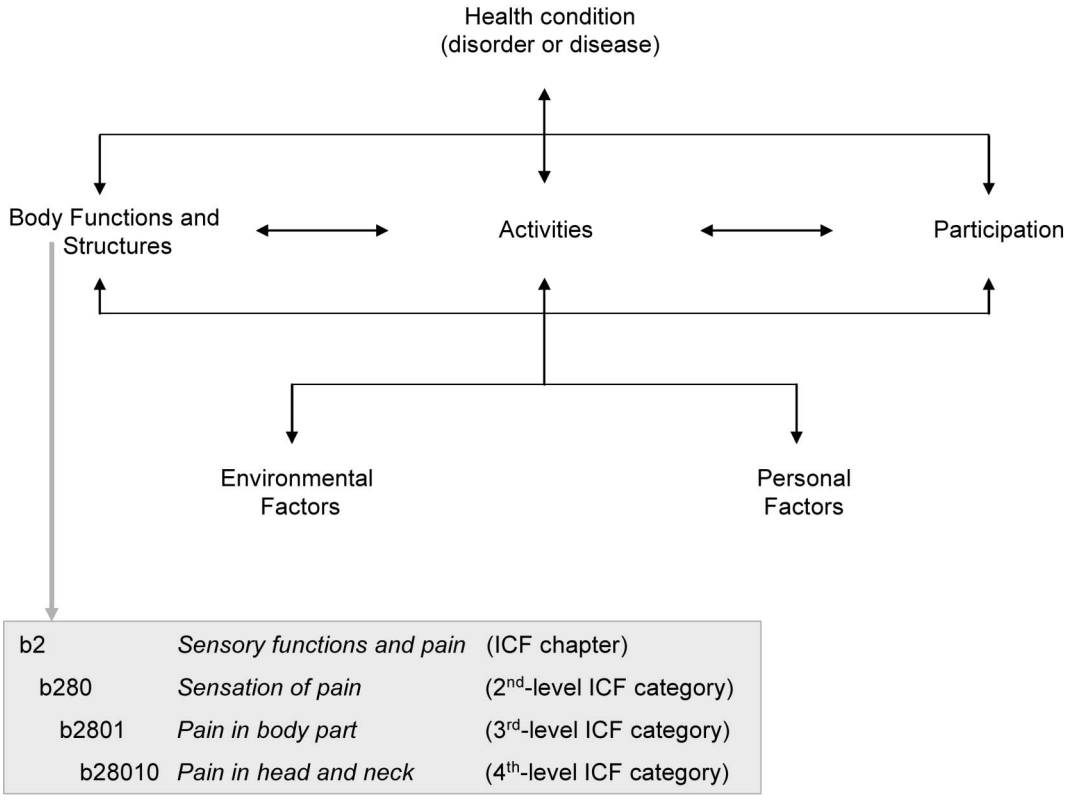

Figure 1. The bio-psycho-social model of Functioning, Disability and Health.

insurance, labour, health and disability policy, statistics, etc. In the clinical context, it is intended for use in needs assessment, matching interventions to specific health states, rehabilitation and outcome evaluation. With the ICF, not only an aetiologically neutral framework, but a globally-agreed-on language and a classification is available to describe functioning and disability both on the individual and the population levels and from both the patient perspective and that of the health professionals. The ICF contains more than 1400 so-called ICF categories, each allotted to the named components with the exception of the component Personal factors, which has not yet been classified. Each ICF category is denoted by a code composed by a letter that refers to the components of the classification (b: Body functions; s: Body structures; d: Activities and Participation and e: Environmental factors) and is followed by a numeric code starting with the chapter number (one digit), followed by the 2nd-level (two digits) and the 3rd- and 4th-levels (one digit each) (Figure 1).

All member states of the WHO are now called upon to implement the ICF in multiple sectors that include, besides health, education, insurance, labour, health-and-disability policy, statistics, etc. However, the ICF has to be tailored to suit these specific applications [16]. In the clinical context, the main challenge is the length of the classification with its over 1400 categories. Mainly to address the issue of feasibility regarding the number of categories, ICF Core Sets have been developed in a formal-decision-making and consensus-based process integrating evidence gathered from preparatory studies for a number of most burdensome, chronic health conditions. However, ICF Core Sets for TBI are not available so far.

The ICF Core Sets for TBI will be defined at an international Consensus Conference which will integrate evidence from different preparatory studies: (1) a systematic literature review on measures used in clinical trials and selected observational studies, (2) an expert survey with health professionals worldwide, (3) empirical cross-sectional study [17] and (4) a qualitative study [18]. In this article, we present the results regarding the fourth preparatory study – the qualitative study. This study was performed in Italy to describe functioning and health of individuals with TBI from the patient perspective.

The development of ICF Core Sets for TBI is a cooperative effort of the WHO, the Institute Guttmann (Barcelona, Spain), the ICF Research Branch in cooperation with the WHO Collaborating Centre for the Family of International Classifications in Germany (at DIMDI) and the International Society of Physical and Rehabilitation Medicine (ISPMR). The qualitative study was performed by the Italian Network group (coordinated by S. Maugeri Foundation IRCCS, Pavia). The patient perspective has been explicitly included in the preparatory phase of the development of ICF Core Sets for TBI to address the perspective of those who experience the disease. Qualitative methods are now widely used and increasingly accepted in health research and health-related sciences [19–21]. One of the most broadly used techniques in qualitative research is the focus group methodology [22–24]. Focus groups are discussions led by a moderator to obtain the individuals' view of interest in a permissive, non-threatening environment [25–27]. The idea behind this methodology is that group processes can help people to explore and clarify their views [28,29].

The objective of the study was to explore aspects of functioning and health as well as environmental factors from the perspective of individuals with TBI. To explore these aspects of TBI patients with severe cognitive impairment or vegetative state patients their caregivers were involved in this study. The specific aims of the study were (1) to explore the aspects of functioning and health as well as environmental factors important to patients with TBI using focus group methodology, (2) to explore the aspects of functioning and health as well as environmental factors important to vegetative state patients and TBI patients who could not participate in a group because of their low cognitive functioning performing focus groups and individual interviews with their caregivers and (3) to analyse these aspects of functioning and health as well as environmental factors using the ICF as a framework.

Materials and methods

Design

We conducted a multicentre qualitative study using the focus groups according to an established methodology for the identification of aspects of functioning [30]. The study was approved by the Ethics Commission of the Fondazione Maugeri, Pavia, Italy.

Participants

We enrolled patients with TBI diagnoses according to the diagnostic criteria of the definition of the TBI Model System [31,32] who had been treated in the departments and services of the members of the Italian Network at any time and we selected all patients with a Level of Cognitive Functioning (LCF) score [33] >6 at discharge ($n = 215$). We additionally listed caregivers ($n = 263$) of patients with mild and severe cognitive impairment and of patients in vegetative state [34,35], respectively.

We contacted from the lists 96 patients and 112 caregivers and asked whether they would like to participate in the study. Of these, 89 and 92% accepted, respectively. Participants were then selected from the list of all willing patients and caregivers by the maximum variation strategy [36] based on the criteria: time of onset (median = 696 days; 67–8390 days (min–max)) and age group (median = 34 years; 18–80 years (min–max)) and disease severity based on the LCF score. According to previous ICF-related studies with patients of other health conditions [30,37] the group size was set at a maximum of seven persons to represent different opinions and facilitate interactions. Patients and caregivers who participated in the focus groups gave written informed consent according to the Declaration of Helsinki 1996.

Materials

An established topic guide with guidelines describing how to prepare and perform the focus group sessions as well as open-ended questions asking for problems in Body functions, Body structures and Activities and Participation was applied (see Table I). Patients and caregivers were additionally asked about Environmental factors (barriers and facilitators) influencing their everyday life and the life of their relatives, respectively. As the questions were originally developed in English [38] a forward and backward translation procedure were used involving three bilingual Italian–English medical doctors to translate the questions into Italian language.

A case record form (CRF) was used to assess socio-demographic and clinical data of the patients.

Table I. Open-ended questions of the focus groups.

If you think about your body and mind, what does not work the way it is supposed to?
If you think about your body, in which parts are your problems?
If you think about your daily life, what are your problems?
If you think about your environment and your living conditions, what do you find helpful or supportive?
If you think about your environment and your living conditions, what barriers do you experience?

Data collection

Eleven Italian centres were involved in the data collection of this study (see Figure 2).

We collected data in three different ways according to the cognitive impairment of the included TBI patients relying on the score of the LCF scale: (1) patients focus groups with TBI patients who were able to join a group session, (2) caregiver focus groups with caregivers of TBI patients who cannot join a group session due to their cognitive impairment, (3) caregiver individual interviews with caregivers of TBI patients in vegetative state according to Jennett and Plum [39]. In the case of vegetative state, we decided to ask only about Environmental factors to confirm the already identified environmental factors retrieved from the focus groups performed with patients and caregivers, respectively. In addition, it is obvious that the caregivers of TBI patients in vegetative state could provide exclusively information on environmental factors.

Figure 2. Italian network: study centres involved in the data collection.

Each of the involved study centres did at least one focus group. According to their organisational structure they performed a focus group with patients or caregivers and an individual interview with a caregiver, respectively, or all these options. All focus groups and individual interviews of the respective study centres were conducted in a non-directive manner by the same moderator and in the case of focus groups by one group assistant using the topic guide. Moderators and group assistants were health professionals with expertise in the ICF and in conducting group processes.

At the beginning of each focus group and individual interview the procedure of the session was explained. The open-ended questions were presented visually to the participants by a Power-Point presentation. At the end of each focus group, a summary of the main results was given back to the participants to enable them to verify and amend emergent issues.

The focus groups and individual interviews were digitally recorded with the Olympus DSS-system and then transcribed verbatim facilitating the codification. The assistants who observed the process within the focus groups filled in field notes according to a standardised coding schema. After each focus group a debriefing with moderator and assistant took place to review the course of the session.

Data analysis

Qualitative analysis. The meaning condensation procedure [40] was used for the qualitative analysis of the verbatim transcripts of focus groups and individual interviews, respectively. In the first step, the transcripts of the focus groups were read through to get an overview over the collected data. In the second step, the data were divided into units of meaning, and the theme that dominated a meaning unit was determined. A meaning unit was defined as a specific unit of text either a few words or a few sentences with a common theme [41]. Therefore, a meaning unit division did not follow linguistic grammatical rules. Rather, the text was divided where the researcher discerned a shift in meaning [40]. In the third step, the concepts contained in the meaning units were identified. A meaning unit could contain more than one concept.

Linking to the ICF. The identified concepts were linked to ICF categories based on established linking rules [5,6] in a systematic and standardised way (see Table II). According to these linking rules health professionals trained in the ICF were advised to link each concept to the ICF category representing this concept most precisely. One concept could be linked to one or more ICF categories depending on the number of themes contained in the concept.

Table II. Qualitative data analysis and linking of the verbatim transcripts.

	Concept	ICF category
Transcription (Meaning unit)	Qualitative analysis	Linking procedure
Moderator: If you think about your daily life, what are your problems?		
A: Walking, the most severe (worst – hardest) is walking,	Problems in walking	d450
because my leg is powerless (I feel no power in my leg). I	Muscle power functions	b730
was a worker, now I don't get a job because I can not work more than 2 hours.	To get a job full time	d850
B: From my point of view, the greatest difficulties deal with	Problems in keeping a job	d845
the job because I am a worker, I had to quit my job, writing	Problems in writing	d 170
and speaking are really hard for me, and being unable to	Problems in speaking	d330
work makes me feel down	Emotional functions	b152

Saturation of data. We retrospectively analysed the saturation of data. Saturation of data refers to the point at which an investigator has obtained sufficient information from the field [25]. In this study, saturation of data was defined as the point during data collection and analysis in which the linking of the concepts of two consecutive focus groups each reveal less than 10% new 2nd level ICF categories in relation to the number of 2nd level ICF categories which were identified in the respective previous focus group (see Figure 3).

Accuracy of the analysis. To ensure the accuracy of data analysis, we followed the procedure of the so-called multiple coding: the qualitative analysis and the linking to the ICF of the first focus group and the first individual interview in each centre were done by two health professionals to achieve agreement regarding analysis and the implementation of the linking rules. Agreements, specifications and special cases of the linking rules occurred, when applying the rules, were documented.

Results

Participants

Eighteen focus group and five single interviews were performed. Forty-one patients participated in

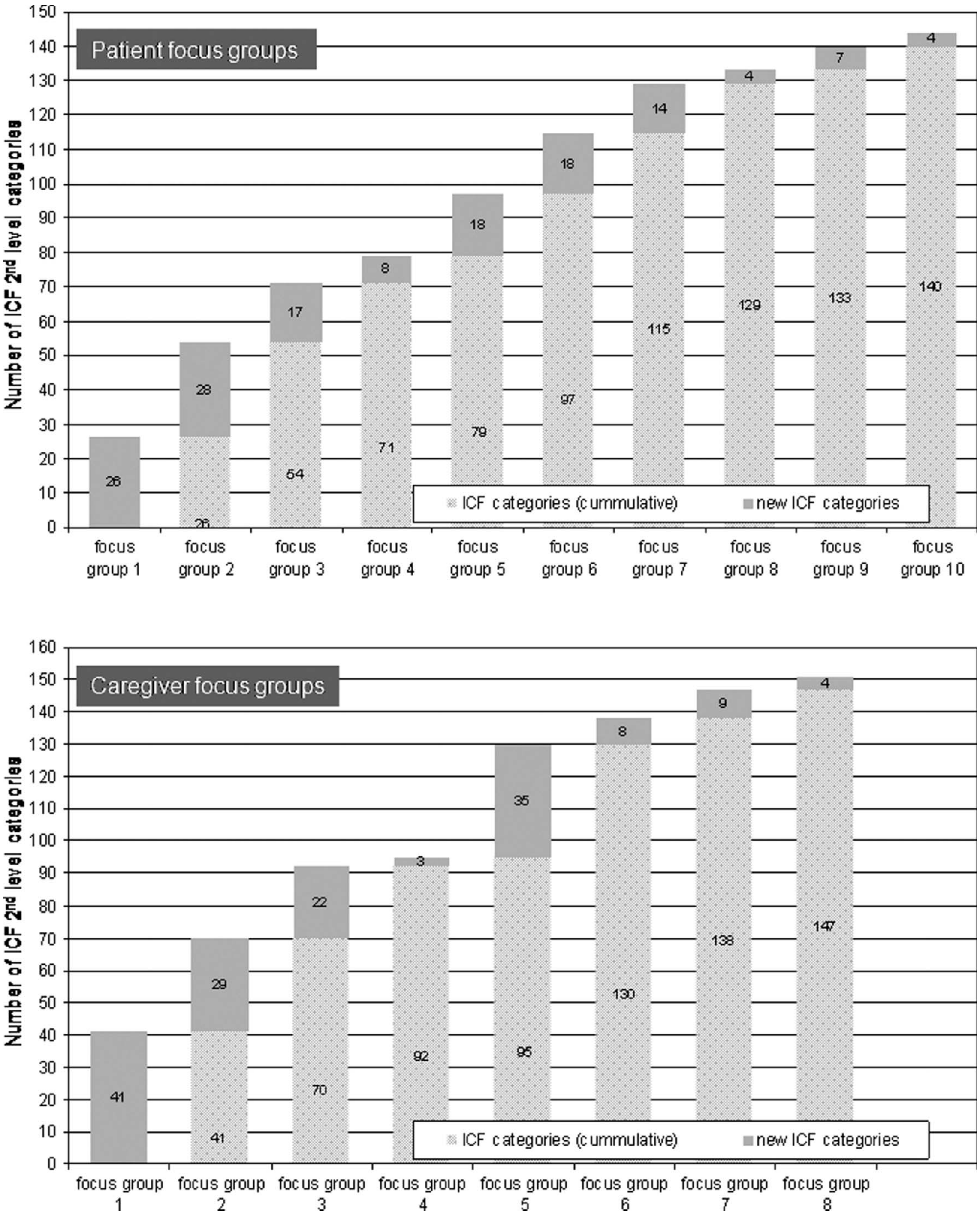

Figure 3. Saturation of the qualitative data in the focus groups.

ten patient focus groups. Thirty-three caregivers were included in eight caregiver focus groups. In addition, six caregivers underwent an individual interview. The focus group sessions lasted from about 50 min to 120 min including a short break. The individual interviews lasted from 20 to 35 min. Socio-demographic and clinical data of the participating patients are summarised in Table III.

Qualitative analysis and linking

Based on the patient focus groups the identified concepts were linked to 144 2nd-level ICF categories: 43 Body functions' categories, 7 Body structures' categories, 57 Activities and Participation's categories and 37 Environmental factors' categories. The concepts derived from the caregiver focus groups were linked to 129 2nd-level ICF

categories. These were in detail 34 Body functions' categories, 11 Body structures' categories, 54 Activities and Participation's categories and 30 Environmental factors' categories. As in the individual interviews only the question on Environmental factors' were asked 25 ICF categories of this ICF component were identified.

Saturation of data as defined in this study was reached for both, patient and caregiver focus groups (see Figure 3).

All chapters of the ICF components Body functions, Activities and participation and Environmental factors were identified based on the linking of the statements obtained in the patient focus groups as well as in the caregiver focus groups (see Tables IV–VII). Within the Body functions chapter b1 Mental functions the ICF category '*b144 Memory functions*' was identified in almost all focus groups performed (10 of 10 patient focus groups, 6 of 8 caregiver focus groups). Other frequently identified ICF categories from the same chapter were '*b126 Temperament and personality functions*' and '*b152 Emotional functions*' identified in nine and eight of ten patient focus groups, respectively, as well as seven of eight caregiver focus groups. The ICF category '*b280 Sensation of pain*' was identified in almost all caregiver focus groups, whereas slightly more than half of the patients addressed this category as an important issue in their life in the patient focus groups. ICF categories of the chapters b3 Voice and speech functions, b4 Functions of the cardiovascular, haematological, immunological and respiratory systems, b5 Functions of the digestive, metabolic and endocrine systems, b6 Genitourinary and reproductive functions and '*b8 Functions of the skin and related structures*' were identified only in some of the focus groups. Frequently linked were several ICF categories of the chapter b7 Neuromusculoskeletal and movement-related functions, especially '*b710 Mobility of joint functions*' and '*b730 Muscle power functions*' and '*b760 Control of voluntary movement functions*'.

As expected the following categories referring to the component *Body structures* were frequently identified within the patient and caregiver focus groups: '*s110 Structure of brain*', '*s730 Structure of upper extremity*' and '*s750 Structure of lower extremity*'.

From the component Activities and Participation the d5 Self care categories '*d510 Washing*', '*d540 Dressing*', '*d550 Eating*' as well as '*d560 Drinking*' were mentioned more frequently in the caregiver focus groups compared to the patient focus groups. In contrast '*d450 Walking*', '*d455 Moving around*', '*d460 Moving around in different locations*', '*d475 Driving*' were identified more frequently in the patient focus groups. A frequently addressed issue was the category '*d920 Recreation and leisure*' mentioned, respectively, in nine of ten and six of eight patients and caregiver focus groups.

Within the component Environmental factors the most frequently linked issues of the focus groups addressed to the chapter e3 Support and relationships, in particular the category '*e310 Immediate family*' mentioned in all patient focus groups and seven of eight caregiver focus groups followed by the category '*e320 Friends*'.

In addition, some issues mentioned in the individual interviews of caregivers of vegetative state patients were identified. In total, 24 ICF categories were identified (see marked categories in Table VII). Twenty-three of these categories were also identified in the focus groups and confirmed by the caregivers of patients in vegetative state. One category ('*e165 Assets*') only was brought up in the individual interviews.

Table III. Characteristics of TBI patients.

	Patient focus groups	Caregiver focus groups	Caregiver individual interviews
Gender [*n* (%)]			
Men	34 (82.9)	27 (81.8)	5 (83.3)
Women	7 (17.1)	6 (18.2)	1 (16.7)
Age [Mean (SD);	35.6 (12.1)	35.9 (13.5)	51.5 (20.0)
Range]	19–76	18–69	28–80
Years of education [Mean (SD);]	11.3 (3.3)	11.3 (2.9)	14 (5.6)
Range	5–18	8–18	8–20
Marital status [*n* (%)]			
Never married	25 (60.9)	23 (69.7)	2 (33.3)
Married/cohabiting	11 (26.8)	8 (24.3)	3 (50.0)
Separated/divorced	4 (9.9)	2 (6)	0
Widowed	1 (2.4)	0	1 (16.7)
Occupation [*n* (%)]			
Working	15 (36.6)	4 (12.2)	1 (16.7)
Student	1 (2.4)	2 (6)	0
Retired	3 (7.3)	0	2 (33.3)
Unemployed	22 (53.7)	27 (81.8)	3 (50.0)
Time since onset in months [Mean (SD)]	43.4 (560.6)	40.1 (51.4)	32.8 (45.9)
Range	2.2–279.0	2.3–228.0	4.3–121.0
Aetiology of trauma [*n* (%)]			
Traffic	34 (82.9)	26 (78.8)	4 (66.7)
Sports	1 (2.4)	2 (6.1)	0
Fall	5 (12.3)	3 (9.1)	1 (16.7)
Others	1 (2.4)	2 (6.1)	1 (16.7)
GCS grading [Mean (SD)]	6.7 (4.4)	6.7 (4.1)	5.8 (2.3)
Range	3–15	3–15	3–8
LCF level [Mean (SD)]	7.4 (0.6)	5.6 (1.7)	2.6 (0.5)
Range	6–8	3–8	2–3

Discussion

With this study a wide range of aspects of functioning and health as well as Environmental factors were

Table IV. Body Functions (b): reporting of ICF categories (2nd-level).

ICF code	ICF category title	Frequency of reporting in: Patient focus groups ($n = 10$)	Frequency of reporting in: Caregiver focus groups ($n = 8$)
b110	Consciousness functions	0	2
b114	Orientation functions	4	2
b117	Intellectual functions	0	2
b126	Temperament and personality functions	9	7
b130	Energy and drive functions	6	7
b134	Sleep functions	2	0
b140	Attention functions	4	6
b144	Memory functions	10	6
b147	Psychomotor functions	3	5
b152	Emotional functions	8	7
b156	Perceptual functions	2	1
b160	Thought functions	3	3
b164	Higher-level cognitive functions	6	6
b167	Mental functions of language	4	5
b172	Calculation functions	1	0
b176	Mental function of sequencing complex movements	2	1
b180	Experience of self and time functions	2	2
b199	Mental functions, unspecified	1	0
b210	Seeing functions	3	4
b230	Hearing functions	0	6
b235	Vestibular functions	4	1
b240	Sensations associated with hearing and vestibular function	3	0
b250	Taste function	1	0
b255	Smell function	0	1
b265	Touch function	1	1
b270	Sensory functions related to temperature and other stimuli	1	0
b280	Sensation of pain	6	2
b310	Voice functions	1	1
b320	Articulation functions	1	2
b330	Fluency and rhythm of speech functions	5	1
b410	Heart functions	0	1
b415	Blood vessel functions	0	1
b435	Immunological system functions	0	1
b440	Respiration functions	0	2
b445	Respiratory muscle functions	0	1
b450	Additional respiratory functions	2	2
b455	Exercise tolerance functions	3	1
b510	Ingestion functions	1	2
b525	Defecation functions	0	2
b530	Weight maintenance functions	2	2
b550	Thermoregulatory functions	1	1
b598	Functions of the digestive, metabolic and endocrine systems, other specified	1	0
b620	Urination functions	0	2
b640	Sexual functions	1	2
b698	Genitourinary and reproductive functions, other specified	1	0
b710	Mobility of joint functions	6	5
b720	Mobility of bone functions	1	0
b730	Muscle power functions	7	5
b735	Muscle tone functions	3	3
b740	Muscle endurance functions	2	1
b750	Motor reflex functions	0	1
b755	Involuntary movement reaction functions	0	1
b760	Control of voluntary movement functions	8	4
b765	Involuntary movement functions	1	3
b770	Gait pattern functions	4	3
b780	Sensations related to muscles and movement functions	2	2
b810	Protective functions of the skin	0	1

Table V. Body Structures (s): reporting of ICF categories (2nd-level).

ICF code	ICF category title	Frequency of reporting in: Patient focus groups ($n = 10$)	Frequency of reporting in: Caregiver focus groups ($n = 8$)
s110	Structure of brain	4	3
s220	Structure of eyeball	0	2
s320	Structure of mouth	1	1
s430	Structure of respiratory system	0	1
s610	Structure of urinary system	0	1
s710	Structure of head and neck region	4	2
s720	Structure of shoulder region	2	1
s730	Structure of upper extremity	8	5
s740	Structure of pelvic region	0	2
s750	Structure of lower extremity	6	4
s760	Structure of trunk	2	1
s810	Structure of areas of skin	0	2

identified from the patient perspective using the ICF as a reference. In order to describe functioning and health covering patients with a broad range of severity levels of TBI patient focus group as well as caregiver focus groups and individual interviews with caregivers were performed. For those patients who were cognitive impaired and could not join a focus group session their respective caregivers were enrolled in the focus group. To pay attention to Environmental factors relevant to vegetative state patients data were collected performing individual interviews with their caregivers.

The ICF categories identified in the focus groups were largely the same as in earlier studies with

Table VI. Activities and Participation (d): reporting of ICF categories (2nd-level).

ICF code	ICF category title	Frequency of reporting in: Patient focus groups ($n = 10$)	Frequency of reporting in: Caregiver focus groups ($n = 8$)
d110	Watching	1	1
d155	Acquiring skills	0	1
d160	Focusing attention	1	1
d163	Thinking	1	0
d166	Reading	2	2
d170	Writing	3	3
d177	Making decisions	0	2
d210	Undertaking a single task	2	3
d220	Undertaking multiple tasks	3	2
d230	Carrying out daily routine	5	8
d240	Handling stress and other psychological demands	2	1
d310	Communicating with – receiving – spoken messages	2	1
d315	Communicating with – receiving – nonverbal messages	0	2
d320	Communicating with – receiving – formal sign language messages	1	0
d330	Speaking	1	2
d335	Producing nonverbal messages	0	1
d340	Producing messages in formal sign language	0	1
d345	Writing messages	1	1
d350	Conversation	1	2
d355	Discussion	1	1
d360	Using communication devices and techniques	3	3
d410	Changing basic body position	4	4
d415	Maintaining a body position	1	1
d420	Transferring oneself	2	2
d430	Lifting and carrying objects	3	2
d435	Moving objects with lower extremities	0	1
d440	Fine hand use	6	4
d445	Hand and arm use	4	3
d450	Walking	10	5
d455	Moving around	7	2
d460	Moving around in different locations	5	1
d465	Moving around using equipment	4	2
d470	Using transportation	4	1
d475	Driving	8	5
d480	Riding animals for transportation	0	1
d510	Washing oneself	5	8
d520	Caring for body parts	5	3
d530	Toileting	2	2
d540	Dressing	6	6
d550	Eating	4	7
d560	Drinking	1	5
d570	Looking after one's health	3	2
d599	Self-care, unspecified	0	1
d620	Acquisition of goods and services	2	1
d630	Preparing meals	4	1
d640	Doing housework	3	1
d650	Caring for household objects	1	0
d660	Assisting others	1	1
d710	Basic interpersonal interactions	5	1
d720	Complex interpersonal interactions	2	3
d730	Relating with strangers	3	0
d740	Formal relationships	2	0
d750	Informal social relationships	4	2
d760	Family relationships	3	2
d770	Intimate relationships	4	2
d820	School education	1	0
d840	Apprenticeship (work preparation)	2	0
d845	Acquiring, keeping and terminating a job	6	3
d850	Remunerative employment	6	4
d855	Non-remunerative employment	0	1
d859	Work and employment, other specified and unspecified	2	0
d860	Basic economic transactions	0	1
d870	Economic self-sufficiency	2	1
d910	Community life	3	1
d920	Recreation and leisure	9	6
d930	Religion and spirituality	2	1
d940	Human rights	1	0
d950	Political life and citizenship	0	1

neurological patients in early post-acute rehabilitation and stroke patients respectively [42,43]. This study which is one of the preparatory studies for the development of ICF Core Sets for TBI confirmed almost entirely the results from one of the other preparatory studies – the empirical cross-sectional study focusing on functioning and health of TBI patients from the clinical perspective [17].

The most frequently identified categories were found in the components of Body functions and Activities and Participation both in the patients and the caregiver focus groups. As TBI can affect any part of the brain the large number of categories in these components considered as relevant from the patient perspective are not surprising. In particular, 24 out of the 43 2nd-level ICF categories of the Body functions' component were reported both by the patients and the caregivers. Most of them cover the chapters of Mental functions and Neuromusculoskeletal and movement related functions. Overall,

Table VII. Environmental Factors (e): reporting of ICF categories (2nd-level).

ICF code	ICF category title	Frequency of reporting in: Patient focus groups ($n = 10$)	Caregiver focus groups ($n = 8$)	Caregiver individual interviews ($n = 6$)
e110	Products or substances for personal consumption	4	3	0
e115	Products and technology for personal use in daily living	4	4	3
e120	Products and technology for personal indoor and outdoor mobility and transportation	6	4	1
e125	Products and technology for communication	3	1	0
e130	Products and technology for education	1	0	0
e135	Products and technology for employment	1	0	0
e150	Design, construction and building products and technology of buildings for public use	3	1	2
e155	Design, construction and building products and technology of buildings for private use	2	2	2
e160	Products and technology of land development	3	0	0
e165	Assets	0	0	1
e225	Climate	1	0	0
e310	Immediate family	8	8	6
e315	Extended family	2	4	3
e320	Friends	7	6	5
e325	Acquaintances, peers, colleagues, neighbours and community members	5	5	2
e340	Personal care providers and personal assistants	2	5	3
e345	Strangers	3	0	0
e350	Domesticated animals	1	0	0
e355	Health professionals	7	4	3
e360	Other professionals	3	1	0
e410	Individual attitudes of immediate family members	7	2	4
e415	Individual attitudes of extended family members	2	1	3
e420	Individual attitudes of friends	4	2	2
e425	Individual attitudes of acquaintances, peers, colleagues, neighbours and community members	0	2	1
e440	Individual attitudes of personal care providers and personal assistants	1	0	0
e450	Individual attitudes of health professionals	1	2	1
e455	Individual attitudes of health-related professionals	1	0	0
e460	Societal attitudes	2	2	0
e465	Social norms, practices and ideologies	1	0	0
e515	Architecture and construction services, systems and policies	1	2	1
e520	Open space planning services, systems and policies	0	2	0
e525	Housing services, systems and policies	0	1	1
e530	Utilities services, systems and policies	0	1	1
e540	Transportation services, systems and policies	2	4	1
e550	Legal services, systems and policies	3	0	0
e555	Associations and organizational services, systems and policies	2	1	0
e560	Media services, systems and policies	0	1	0
e565	Economic services, systems and policies	2	0	0
e570	Social security services, systems and policies	3	3	2
e575	General social support services, systems and policies	2	4	1
e580	Health services, systems and policies	4	6	5
e585	Education and training services, systems and policies	1	2	0
e590	Labour and employment services, systems and policies	2	1	1
e595	Political services, systems and policies	0	1	1

these categories address the typical symptoms and manifestation of TBI [14].

However, the patients and their caregivers mentioned some other issues in their life and the life of their relatives, respectively, which were identified as '*b310 Voice functions*', '*b320 Articulation functions*', '*b330 Fluency and rhythm of speech functions*' and '*b280 Sensation of pain*'. According to the literature all these functions have to be considered important in the assessment and in the rehabilitation process of TBI patients [44].

In particular, 45 out of the 54 2nd-level categories of the Activities and Participation's component were identified analysing patient as well as caregiver focus groups. This high number of ICF categories addressing limitations and restrictions in everyday activities and participation shows that TBI has a comprehensive effect on patient's life. Moreover, the issues from

patient and caregiver focus groups broadly covered the categories included in chapter d2 General tasks and demands (e.g. '*d210 Undertaking a single task*', '*d220 Undertaking multiple tasks*', '*d230 Carrying out daily routine*'). Comparing the identified categories of patient and caregiver focus groups it is interesting that in the patient focus groups issues referring to chapter d4 Mobility (e.g. '*d450 Walking*', '*d455 Moving around*', '*d460 Moving around in different locations*', '*d465 Moving around using equipment*', '*d470 Using transportation*' and '*d475 Driving*') were more often mentioned by the patients than by their relatives. In contrast, the caregivers reported more often categories of the chapter d5 Self care (e.g. '*d510 Washing*', '*d540 Dressing*', '*d550 Eating*', '*d560 Drinking*') as being important issues from the patient perspective.

The participants of this study often mentioned issues addressed to the categories '*d920 Recreation and leisure*', '*d845 Acquiring, keeping and terminating a job*', '*d850 Remunerative employment*' and '*d870 Economic self-sufficiency*'. Restrictions in these categories typically occur during social and working reintegration of patients after their return to community in the later stages of recovery.

These findings highlight the need to carefully consider these issues related to activity limitations and participation restrictions in extensive rehabilitation programmes as well as in outpatient rehabilitation settings. Additionally, the broad range of relevant Activities and Participation's categories suggests that our sample of patients may have a low quality of life because – as other works stated – restrictions in participation is a strong predictor of quality of life [9,45,46].

As expected only a few categories referring to the component Body structures were identified from the patient perspective, namely structure of brain and structures related to the movement (upper, lower extremity and trunk).

The broad range of identified ICF categories assigned to the component Environmental factors shows that individuals' environment is important to individuals with TBI. Here the results from the individual interviews performed the caregiver of vegetative state patients were added. In principal, Environmental factors' categories could be reported by the participants and caregivers as being a barrier or a facilitator. However, both – patients and caregivers – stated that all identified Environmental factors are predominantly facilitators except for the ICF categories '*e150 Design, construction and building products and technology of buildings for public use*' and '*e155 Design, construction and building products and technology of buildings for private use*'. The frequently named facilitators derive from the chapter e3 Support and relationship. In particular, the category '*e310 Immediate family*' is considered as an important facilitator of the majority of patients and caregivers. This finding could be explained with the fact that in Italy the burden of assistance is normally delegated to the family [47]. These results underline that Environmental factors play an important role beside 'good' and appropriate rehabilitation interventions with regard to the improvement of person's functioning and life satisfaction [48]. It could be very interesting to implement this aspect with studies in other countries in order to look on relevant Environmental factors in other cultural settings.

There are also some limitations of this study that should be mentioned. In qualitative research and studies with focus group methodology, sample sizes typically remain small [23,25]. According to Curtis et al. [49] the small samples in qualitative research are studied intensively and typically generate a large amount of information. By keeping the questions open-ended the moderator can stimulate useful trains of thought in the participants that were not anticipated [50]. The focus groups in our study were composed of four to six participants. We decided to perform groups with few participants because of the complexity of the topic and the expertise of the participants according to the literature [51]. With a small group size, each participant has a greater opportunity to talk, which is reported as an important aspect for the group dynamics in groups with elderly and ill participants [23,52].

Designing the study it was important to consider the perspective of all patients including those with severe cognitive impairments that cannot join a group as well as vegetative state patients. Therefore, we decided to include their caregivers in order to have a perspective from someone else than the health professionals treating the respective patients.

The sample of this qualitative study consists only of Italian participants. Our suggestion is that our methods could be used in similar studies in other countries to establish a cross-cultural perspective.

Finally, the linking process was performed by two health professionals according to established linking rules [5,6]. However, it remains unclear whether other health professionals would have decided differently. It is important to mention, that several strategies were used to improve and verify the trustworthiness of the qualitative data and the linking process: (1) triangulation: we included data triangulation by using two data analysts (investigator triangulation: multiple coding) [53,54]; (2) continuous data analysis according to Pope et al. [55]; (3) reflexivity: by filling in field notes during the group sessions and performing a debriefing after each session; (4) clear exposition: by using established guidelines for conducting the focus groups and individual interviews, verbatim transcription and linking rules [5,6].

Conclusions

A broad range of aspects of functioning and health as well as several Environmental factors important to patients with TBI were explored. Performing focus groups and individuals interviews with patients and caregivers the perspective of TBI patients of a broad range of severity levels according to the severity of TBI were enrolled in this study. Whereas patients focused on problems in mobility, employment and recreation and leisure the caregivers highlighted several issues related to self-care as being important for the patients.

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Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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