Functioning and disability after stroke:
The patient and the health professional perspective

Dissertation

zum Erwerb des Doktorgrades der Humanbiologie

an der Medizinischen Fakultät der

Ludwig-Maximilians-Universität zu München

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vorgelegt von
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Abbreviations

ADL	Activities of daily living
BAR	Bundesarbeitsgemeinschaft für Rehabilitation
CAS	Classification, Assessment and Surveys
DIMDI	Deutsches Institut für Medizinische Dokumentation und Information
EGNR	European Federation of Neuro-Rehabilitation
ENPHE	European Network of Physiotherapy in Higher Education
FHS	Framingham Study
ICD-10	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
IHRS	Institute for Health and Rehabilitation Sciences
ISPMR	International Society of Physical and Rehabilitation Medicine
LMU	Ludwig-Maximilians-Universität
OT	Occupations Therapists
PT	Physical Therapists
SGB IX	Social Security Code / Sozialgesetzbuch Neun
SPF	Swiss Paraplegic Research
WCPT	World Confederation for Physical Therapy
WHO	World Health Organisation

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Content

"Functioning and disability after stroke: The patient and the health professional perspective"

Zusammenfassung

Diese kumulative Dissertation stellt die Untersuchungen und Ergebnisse aus drei Originalarbeiten vor, die von der Doktorandin eigenverantwortlich durchgeführt und als Erstautorin in den medizinischen Fachzeitschriften „Disability and Rehabilitation", „European Journal of Physical Medicine and Rehabilitation" und „Physical Therapy" publiziert wurden.

Das übergeordnete Ziel dieses wissenschaftlichen Projektes war es, die Inhaltsvalidität der erweiterten Version des neu entwickelten *ICF Core Sets* der *Internationalen Klassifikation der Funktionsfähigkeit, Behinderung und Gesundheit (ICF)* für Schlaganfall zu untersuchen.

Auf der Grundlage der Familie der internationalen Klassifikationen der Weltgesundheitsorganisation (WHO) wird die Beschreibung und der Vergleich der Gesundheit und Krankheit in der Bevölkerung im internationalen Kontext möglich. Die International Classification of Diseases (ICD-10) liefert dazu die Informationen über Diagnose und Mortalität. Die ICF hingegen gibt Auskunft über die gesundheitlichen Auswirkungen und Folgen einer Erkrankung oder Verletzung. Dabei bildet die Erfassung der funktionalen Gesundheit/Funktionsfähigkeit einer Person anhand der ICF die Basis für die klinische Diagnostik, Versorgung, Intervention und Evaluation. Die ICF umfasst insgesamt 1424 Kategorien. Um die Anwendung der ICF in der klinischen Praxis zu erleichtern, wurden diagnosespezifische Core Sets entwickelt. Diese stellen eine Auswahl von Kategorien dar, die für die Mehrheit von Personen mit einem bestimmten Gesundheitszustand, wie zum Beispiel nach Schlaganfall, relevant sind. In Zukunft wird es damit möglich sein, eine international einheitliche Beschreibung der gesundheitlichen Probleme nach Schlaganfall vorzunehmen.

Die Ziele der spezifischen Studien bestanden darin, die Inhaltsvalidität der *erweiterten Version des umfassenden ICF Core Sets für Schlaganfall* aus folgenden Perspektiven zu überprüfen:

1) der Perspektive der Patienten nach Schlaganfall im Allgemeinen
2) der Perspektive der Patienten nach Schlaganfall unter Berücksichtigung gender-spezifischer Unterschiede und

3.) der Perspektive der Physiotherapeuten, die Patienten nach Schlaganfall behandeln.

Um die Ziele 1 und 2 zu erreichen wurden zwei multizentrische qualitative Studien mit Fokusgruppen bzw. mit Einzelinterviews bei Patienten nach Schlaganfall durchgeführt. Um Studienziel 3 zu erreichen wurde eine weltweite Delphi-Befragung von PhysiotherapeutInnen durchgeführt.

Die Ergebnisse dieser kumulativen Dissertation bestätigen die Inhaltsvalidität der *erweiterten Version des ICF Core Sets* für Schlaganfall nahezu vollständig. Zukünftiger Forschungsbedarf besteht bezüglich der ICF-Kategorien, die in diesen Studien identifiziert wurden, aber bisher nicht in der *erweiterten Fassung des ICF-Core Sets für Schlaganfall* enthalten sind. Darüber hinaus unterstreichen die Ergebnisse aus allen drei Studien die Notwendigkeit der Entwicklung der ICF-Komponente der „Personenbezogenen Faktoren", um die relevanten Aspekte der Funktionsfähigkeit und Gesundheit von Personen nach Schlaganfall systematisch beschreiben zu können.

"Functioning and disability after stroke: The patient and the health professional perspective"

Summary

This doctoral thesis comprises the research and results of three original studies published in the medical journals "Disability and Rehabilitation", "European Journal of Physical Medicine and Rehabilitation" and "Physical Therapy", of which the doctoral candidate was first author.

The overall objective of this research project was to investigate the content validity of the extended version of the newly developed *ICF Core Set* of the *International Classification of Functioning, Disability and Health (ICF) for stroke*.

The WHO family of international classifications provides a tool to describe and compare the health of populations in an international context. The information on diagnosis and mortality is provided by the International Classification of Diseases (ICD-10). The information on health outcomes is provided by the ICF. The recording of the functional health according to the ICF constitutes the basis of clinical diagnostics, health care, intervention and evaluation. The ICF comprises 1424 categories. To facilitate the application of the ICF in clinical practice, disease-specific Core Sets were developed. These are selections of categories relevant for the majority of persons with a certain health condition, in this case persons after stroke. In future, it will be possible to carry out an internationally uniform description of health-related problems associated with stroke.

The objectives of the specific studies were to investigate the content validity of the *extended version of the ICF Core Set for stroke* from:

1) the patient's perspective in general,
2) the patient's perspective taking into account gender differences, and
3) the perspective of physical therapists (PTs) treating patients with stroke, respectively.

To achieve objectives 1 and 2, two qualitative multi-centre studies using focus groups and individual interviews with patients after stroke, respectively, were conducted. To achieve objective 3, a worldwide Delphi survey with physical therapists was conducted. The findings of this doctoral thesis confirmed almost entirely the content validity of the *extended version of the ICF Core Set for stroke*. Further research is necessary with respect to the ICF categories which were identified in these studies but are not yet included in the current version of the *extended ICF Core Set for stroke*. Furthermore, the results of all three studies underline the need to develop the ICF component personal factors to describe systematically the relevant aspects of functioning and health in persons after stroke.

I. Introduction

I. Introduction

Background

Stroke is the second leading cause of death worldwide. Each year, 15 million people suffer a stroke and nearly six million people die from stroke. Projections indicate that stroke will remain one of the leading causes of long-term disability in industrialised countries until 2020, irrespective of age, ethnicity or gender [1,2]. The consequences of stroke are strongly associated with inability to maintain independence in everyday life, self-care, mobility and work, ultimately leading to restricted ability to participate in several life areas [3-6].

For the World Health Organization (WHO), impaired functioning and impaired ability to participate in everyday life can be understood not only as a consequence of disease and its treatment, but should also be considered on an individual basis as they may differ greatly depending on the private and societal background of women and men [7]. This would imply that the biological, psychological, social and environmental aspects of everyday life must be taken into account in order to achieve a comprehensive perspective on the health or health-related problems in women and men who suffer a stroke [8-10]. Disability after stroke appears in the form of neurological dysfunction (e.g. motor, sensory, visual), limited ability to perform activities of daily living (ADL), as well as neuropsychological deficits (memory, attention, language) [11].

In the Framingham Study (FHS) cohort and in many other studies, gender-specific neurological deficits and gender-specific aspects of disability in post-stroke persons have been identified and documented during the last few decades [12,13,14]. Gender-specific results showed that strokes are more severe in women and that gender differences go beyond incidence, lifetime risk of stroke, age at first stroke and institutionalisation rates in post-stroke disability [13]. In addition, over their lifetime 16% of women are at risk of dying from stroke compared to only 8% of men [15,16]. Accordingly, the growing recognition of the clinical and public health importance of stroke in women [8] has led to a knowledge and awareness of the importance of gender differences in stroke and of its potential relevance for improving prevention and rehabilitation strategies and in-hospital management of persons with stroke [2].

Irrespective of gender differences, stroke is always associated with a large variety of consequences, which can only be treated and managed with an interdisciplinary approach. Rehabilitation after stroke requires an interdisciplinary team including physicians, psychologists, occupational therapists, nurses, social workers and physical therapists [17,18]. Physical therapists are described as one of the key components of the interdisciplinary team in stroke rehabilitation [19-21]. To optimize interventions aimed at improving function and minimizing disability, a comprehensive understanding of the individuals' situation and health status after stroke is needed [17] taking into account different perspectives. Only based on such a comprehensive approach can intervention goals be established, taking into account the needs and problems of patients along with gender differences.

The International Classification of Functioning, Disability and Health (ICF) can contribute to this comprehensive understanding. This classification is based on an integrative model of health that provides a holistic, multidimensional and interdisciplinary understanding of health and health-related conditions [22]. The ICF provides a globally agreed language and classification to describe functioning both on an individual and population level. The ICF language consists of so-called ICF categories, which refer to specific *Body Functions*, *Body Structures* and *Activities and Participation* areas of life.

Here are some examples of ICF categories:

b735 *Muscle tone functions*

s720 *Structure of shoulder regions*

d450 *Walking*

Environmental Factors are also classified since they influence the level of impairment in Body Functions and Structures and the level of a problem in Activities and Participation areas of life. Examples of Environmental Factors are:

e1101 *Drugs (medication)*

e120 *Products and technology for personal indoor and outdoor mobility and transportation*

e310 *Immediate family*

e455 *Individual attitudes of healthcare professionals*

Personal Factors, such as gender, age and coping styles are also recognized as important influencing factors. They have not, however, been classified so far [22].

The ICF comprises 1424 ICF categories, which ensure its value as a standard comprehensive tool to classify functioning and disability independently of the health condition. It contains almost everything that is potentially relevant to any person with any health condition at any stage of the disease. This is also why the ICF is an attractive classification for use in any health care setting. At the same time, however, the ICF represents a challenge in routine clinical use. It has often been acknowledged that it is not feasible for clinical practice because of its comprehensiveness.

To address this challenge and to facilitate clinical practicability, ICF Core Sets have been developed for 22 health conditions. The selection criteria for these 22 health conditions included the associated burden. Thus, the *ICF Core Sets for stroke* were among the first to be developed. [23,24]

As for any other health condition, there is a *Brief ICF Core Set* and a *Comprehensive ICF Core Set for stroke*. The *Brief ICF Core Set for stroke* contains 18 ICF categories. The *Comprehensive ICF Core Set for stroke* contains 130 ICF categories. It covers the typical spectrum of problems in functioning in persons with chronic stroke [25] and should serve as standard for multidisciplinary, comprehensive assessment. In 2005, the *Comprehensive ICF Core Set for stroke* was extended by 36 ICF categories from the ICF Core Sets for persons with neurological conditions in the acute and early post-acute phases to enable its use in all clinical situations [26-29]. The *extended version of the Comprehensive ICF Core Set for stroke* includes 166 categories, 59 *Body Functions* categories, 11 *Body Structures* categories, 59 A*ctivities and Participation* categories and 37 *Environmental Factors*.

The focus of this doctoral thesis is this *extended version of the Comprehensive ICF Core Set for stroke.* This *ICF Core Set* is now undergoing worldwide testing and validation using a number of approaches including: 1) statistical validation based on the data collected in an international multicentre validation study, 2) the patient's perspective to find out whether all aspects of functioning relevant to patients are included in this *version of the ICF Core Set for stroke* and 3) the perspective of the different health professions involved in the treatment of stroke [29-33], i.e. analyse the extent to which this *ICF Core Set for stroke* contains the interventions goals of all health professionals involved in the treatment of persons after stroke.

One key issue in the validation from the patient's perspective is the gender differences. From a gender perspective it is important to identify whether the *extended version of the Comprehensive ICF Core Set for stroke* includes the specific problems of both men and women. Regarding the health professional perspective, this doctoral thesis will concentrate on physical therapists.

Rationale of the doctoral thesis

The objective of this doctoral thesis was to answer the question whether the content of the extended version of the *Comprehensive ICF Core Set for stroke* is valid from three perspectives, namely 1) the patient's perspective in general, 2) the patient's perspective taking particular gender differences into account and 3) the perspective of physical therapists.

I have performed three qualitative studies to achieve this objective, one study for each of the perspectives mentioned. For the first study, addressing the patient's perspective in general, I used the focus group technique involving 60 patients. For the second study to analyse the gender differences, I conducted individual interviews with 24 patients. For the third study, I used the Delphi technique involving 125 physical therapists specialized in the treatment of stroke from 24 countries.

In both studies addressing the patient's perspective:

(1) Patients were selected by the maximum variation strategy [34] based on the criteria of type of stroke, affected hemiplegic side, date of diagnosis, age and gender.

(2) Saturation was used as criterion to determine the sample size. Saturation is the point during data collection where no new information can be gathered [34,35,36].

In all three studies:

(3) The open-ended questions were formulated along with the ICF components: Body Functions, Body Structures, Activities and Participation, Environmental Factors, Personal Factors;

(4) Established linking rules [37,38] were used to translate the responses of the participants (patients and health professionals, respectively) into ICF language.

(5) The kappa coefficient was calculated as a statistical measure of agreement with bootstrapped interval for the linking process.

(6) Descriptive statistics characterized the samples and frequencies with which the ICF categories were selected in the linking process.

(7) The following procedures were used for quality assurance of the data material: peer review and multiple coding.

(8) The ICF categories resulting from the linking process were compared to those included in the *extended version of the ICF Core Set for stroke* to study its content validity. The results are presented as follows:

   a. Confirmed ICF Categories: ICF categories included in the *extended ICF Core Set for stroke*.
   b. Non-confirmed ICF categories: ICF categories included in the *extended ICF Core Set for stroke* but the content of which was not mentioned by the patients or the physical therapists and therefore was not identified in the linking process.
   c. Additional ICF categories: ICF categories not included in the *extended ICF Core Set for stroke* but which are part of the ICF, i.e. they are only "additional" with respect to the content of the ICF Core Set but not with respect to the ICF – they are part of the 1424 ICF categories.

Summary of study 1

The results of the first study were published as: **Glässel A,** Coenen M, Kollerits B, Cieza A. **Validation of the Extended ICF Core Set for stroke from patient perspective by using focus groups**: Disabil Rehabil. 2012;34(2):157-66. Epub 2011 Oct 4.

The objective of the study was to investigate the **content validity** of the *extended version of the ICF Core Set for stroke* **from the patient's perspective**. The specific aims were: (1) to explore the aspects of functioning and health important to persons after stroke and (2) to examine the extent to which these aspects are represented by the *extended version of the ICF Core Set for stroke*.

To achieve these aims, a qualitative study using focus groups was conducted. I selected this methodology because qualitative methods provide the possibility to explore the perspective of those who experience a health problem, i.e. the so-called patient perspective [39-42]. Compared to quantitative methodology, the qualitative approach promises greater openness to unexplored concepts or phenomena [43] and focuses on how people understand and interpret their social world [48].

To be included in the study, the participants had to have been diagnosed according to the WHO 2006 stroke criteria [1] and treated in one of seven study centres for neurological rehabilitation in Germany. I followed the maximum variation strategy to select the patients based on type of stroke, affected hemiplegic side, and date of diagnosis, age and gender. The sample size was determined by saturation [34,35,36], which was reached after 15 focus groups involving a total of 60 patients (30 female, 30 male) with a median age of 57 years. The focus groups were conducted during 2008 and 2009.

I conducted 6 of the 15 focus groups. The rest were conducted by two psychologists from the Chair for Public Health and Health Services Research. All three of us used the same methodology for collecting information: we asked open-ended questions addressing the components of the ICF, Body Functions, Body Structures, Activities and Participation, as well as relevant Environmental Factors and Personal Factors as barriers or facilitators influencing the patients' everyday life after stroke. The focus group interviews were audio recorded and transcribed verbatim by one typist and myself.

I performed the qualitative analysis of all 15 focus groups using the meaning condensation procedure [42] in three steps: in the first step, I read the transcripts of the interviews in order to get an overview of the collected data. In the second step, I divided the data into meaning units and themes. A meaning unit was defined as a specific unit of text, either a few words or a few sentences with a common theme [42,44]. In the third step, I identified the concepts contained in the meaning units.

The resulting 3907 concepts were linked to 158 ICF categories and compared to the categories included in the *extended version of the ICF Core Set for stroke*. Two researchers were involved in the linking process, the author, who linked the concepts identified in the transcripts of all 15 focus groups, and a psychologist, who linked the concepts from 5 focus groups. The kappa coefficient for the linking agreement of the 5 focus groups linked by both of us was 0.73 (95% bootstrapped confidence interval 0.68–0.76).

In total, 127 of the 166 categories included in the *extended ICF Core Set for stroke* were **confirmed** by the participants: 47 of 59 Body Functions categories, 6 of 11 Body Structures categories, 47 of 59 Activities and Participation categories and 28 of 37 Environmental Factors categories.

39 ICF categories from the *extended version of the ICF Core Set for stroke* were **not confirmed** from the patient perspective. Most of the categories belong to the *Body functions* and *Activities and Participation* components such as b172 Calculation functions, b435 Immunological system functions, b450 Additional respiratory functions or b515 Digestive functions, which were not identified in the focus groups. ICF categories from the *Activities and Participation* component, which were not confirmed, were d110 Watching, d115 Listening, d120 Other purposeful sensing, d130 Copying, d310 Communicating with - receiving - spoken messages, d315 Communicating with - receiving - nonverbal messages, d335 Producing nonverbal messages, d420 Transferring oneself, d710 Basic interpersonal relationships, d910 Community life and d940 Human rights. Thirty one "**additional** ICF categories" that are not included in the *extended ICF Core Set for stroke* were identified in the focus groups. Most of these additional categories derive from the *Environmental Factors* component (n=11) followed by *Activities and Participation* (n=9). Seven and 4 additional categories from the component *Body Functions* and *Body Structures* were reported by the participants, respectively.

To summarize, the *extended version of the ICF Core Set for stroke* was confirmed almost entirely from the patient perspective.

The high percentage (70%) of ICF categories resulting from the focus groups of patients with stroke represented in the ICF Core Set for stroke indicates good content validity from the patient's perspective. This study also underlines the need for a comprehensive perspective on functioning and disability in stroke to capture the problems patients experience during rehabilitation.

The doctoral candidate carried out the study independently (writing of study protocol, application to the ethics committee, recruitment of participants and organization of the interviews, conducting the interviews, data collection, qualitative and quantitative analyses and reporting of the results). She was assisted by colleagues in the study team only in interviewing 9 focus groups.

Summary of study 2

The results of the second study were published as: **Glässel A**, Coenen M, Kollerits B, Cieza A**. Content validation of the International Classification of Functioning, Disability and Health (ICF) Core Set for stroke from gender perspective using a qualitative approach.** European Journal of Physical & Rehabilitation Medicine (accepted July 10th 2012)

The objective of the study was to investigate the **content validity** of the *extended version of the ICF Core Set for stroke* from the perspective of clients after stroke considering the **gender perspective**. The specific aims of the study were: (1) to determine whether women and men report different problems in functioning after stroke and (2) to examine whether both gender perspectives are represented by the current version of the *extended ICF Core Set for stroke*.

To achieve these aims a qualitative study using individual interviews was performed. Participants were women and men diagnosed with stroke according to ICD-10 and the WHO stroke criteria 2006 [1] and who had been treated in one of three study centres in Germany (Reha clinic Nittenau, Mutabor day clinic Munich, private practice Regensburg) at any time in 2008 and 2010.

I followed the maximum variation strategy to select the participants [34] based on the type of stroke, affected hemiplegic side, date of diagnosis, age and gender. Clients with aphasia were also included. However, in this case proxies answered the questions during the interview. Sample size was determined for women and men separately by saturation of data [34-36], which was reached after 24 individual interviews (12 women and 12 men) with a median age of women 65 [36;85] and men 53 [40;85].

The individual interviews followed an established protocol and were conducted according to guidelines including open-ended questions and further instructions (e.g. introduction, procedure of the session, technical aspects) [45]. I asked interview participants to report their problems in functioning after stroke by using open-ended questions addressing the components of the ICF, *Body Functions, Body Structures, Activities and Participation*, as well as relevant *Environmental Factors and Personal Factors* as barriers or facilitators influencing their everyday life after stroke. These kinds of questions were developed and tested in previous studies [45-47]. The individual interviews

were audio recorded and transcribed verbatim by one typist and myself. I performed the qualitative analysis of all 24 individual interviews using the meaning condensation procedure [42] in three steps:

In the first step, I read the transcripts of the individual interviews in order to get an overview of the collected data. In the second step, I divided the data into meaning units and themes. A meaning unit was defined as a specific unit of text, either a few words or a few sentences with a common theme [42,44]. In the third step, I identified the concepts contained in the meaning units.

In the qualitative analysis, 5346 concepts were identified in the interviews (women: n= 2530; men: n= 2816). The identified concepts were linked to the ICF and compared to the ICF categories of the *extended version of the ICF Core Set for stroke*.

Two researchers were involved in the linking process, the author, who linked the concepts identified in the transcripts of all 24 individual interviews and a psychologist, who linked the concepts from 8 individual interviews. The kappa coefficient for the linking agreement of the 8 interviews linked by both of us calculated according to gender was 0.65 [0.60; 0.69] for women and 0.65 [0.62; 0.69] for men.

The identified concepts were linked to 181 ICF categories. 129 ICF categories were identified in both genders, 19 were identified only in women and 33 only in men. The main differences between genders show that while only women reported problems in ingestion and sensations of digestion, endurance functions and undertaking multiple tasks, men mentioned the following problems that had not been mentioned by the woman: mental functions of sequencing movements or calculation, protective functions of skin, producing messages, economic self-sufficiency, and societal attitudes.

Women and men **confirmed** 143 of the 166 categories included in the *extended version of the ICF Core Set for stroke* (women: n=13; men: n=17 both: n=113). Of the 129 categories identified in both genders, 113 were included in the *extended ICF Core Set for stroke*. 13 of the 19 specific to women were included and 17 of the 33 specific to men. Twenty-three ICF categories from the *extended ICF Core Set for stroke* were **not confirmed**. However, the participants mentioned 38 **additional categories** (women: n=22; men: n=32) which are not included in the current *version of the extended ICF Core Set for stroke*.

To summarize, differences in the experience of disability were found between women and men. In general, women reported fewer problems than men and seem to attach more importance to complex interpersonal interactions or multiple tasking. Men see more problems in activities of daily living including discussions and formal relationships, but also with people in authority or in economic self-sufficiency. In addition, the *extended version of the ICF Core Set for stroke* was confirmed almost entirely with regard to the gender perspective.

The doctoral candidate carried out this study independently also (writing of study protocol, application to the ethical committee, recruitment of participants and organization of the interviews, conducting the interviews, data collection, qualitative and quantitative analyses and reporting of the results).

Summary of study 3

The results of the third study were published as: **Glässel A**, Kirchberger K, Kollerits B, Amann B, Cieza A. **Validation of the Extended ICF Core Set for stroke from the perspective of physical therapists – a Delphi survey.** Physical Therapy. 2011;91(8):1211-22.

The objective of the study was to investigate the **content validity** of the *extended version of the ICF Core Set for stroke* from the **perspective of physical therapists** (PT) by using the Delphi technique. The specific aims of the study were (1) to identify the patient's problems and resources and aspects of their environment treated by PTs; (2) to analyse whether these issues are represented by the current version of the *extended ICF Core Set for stroke*.

To achieve these aims a Delphi study was conducted as a worldwide email survey in three rounds. The Delphi technique was used because it is the most appropriate procedure to gain consensus from a panel of individuals who are experts in the topic being investigated.

I recruited PT experts in the treatment of stroke patients worldwide. A snowball sampling approach was initiated in 2006 to recruit PTs. In addition, I had undertaken Internet searches and contacted specialist groups and authors of published investigations as well as universities, hospitals and professional groups.

In the first Delphi round, PTs were requested to provide a list of problems, resources and aspects of the environment that are relevant in practice when treating patients after stroke. Responses were listed in an open-ended questionnaire (see Annex p. 145). The responses were linked to the ICF to enable comparison with the *extended ICF Core Set for stroke*. Information on demographics and professional experience was obtained. In the second Delphi round, the experts received the list of ICF categories resulting from the first round and had to decide whether the respective ICF categories represent relevant patient problems, resources and aspects of the environment when treated by PTs (see Annex p. 146). Categories with insufficient endorsement obtained by a scree test [48] were included in the third Delphi round. The endorsement frequencies from the previous round as well as their own answers were provided to the experts in this final third round. They had to decide again, taking the frequencies and their own answers into account, whether the listed ICF categories – patient's problems, resources and aspects of the environment when treated by PTs – were relevant.

146 PTs from 24 countries agreed to participate. 125 filled in the first-round questionnaire. In the first Delphi round, 4,793 patients' problems, patients' resources or aspects of the environment treated by physical therapists in patients with stroke were named. The second-round questionnaire was filled in by 111 out of 125 participants. 101 PTs completed the third-round questionnaire. ICF categories, which reached an agreement of more than 75% among the experts in the third round, were considered for comparison with the *extended version of the ICF Core Set for stroke*. Besides myself, who linked all 4,793 responses of the PTs, two further researchers were involved (each 50%) in the linking process. The kappa coefficient for the linking agreement was 0.39 (95% bootstrapped confidence interval 0.34–0.41).

In total, of the 376 ICF categories linked to the participants' responses 185 reached an agreement of at least 75% in the final round and were considered for comparison with the *extended ICF Core Set for stroke*. The PTs **confirmed** 63 ICF categories of the *extended version of the ICF Core Set for stroke*. Most of the categories which were **not confirmed** belong to the ICF component Activities and Participation (such as *d110 Watching, d115 Listening, d166 Reading, d170 Writing, d172 Calculating*). PTs identified ten **additional** ICF categories which are currently not included in the *extended version ICF Core Set for stroke*.

To summarize, the *extended version of the ICF Core Set for stroke* was confirmed almost entirely from the PT's perspective. More than one third of the included ICF Core Set categories are confirmed by the PTs. These categories represent typical fields of PT treatment. This study demonstrates that the ICF and more specifically the *extended version ICF Core Set for stroke* can be a useful tool for PTs when working with stroke patients. The ICF categories derived from this investigation can be used to describe the patients' problems and as a guide for planning interventions.

The doctoral candidate carried out this study independently also (writing of study protocol, recruitment of participants and organization of the interviews by email, data collection and development of questionnaire, qualitative and quantitative analyses and reporting of the results).

General discussion

The results of this doctoral thesis illustrate that the content of the *extended version ICF Core Set for stroke* was almost entirely confirmed from three perspectives investigated in three studies, 1) the patient's perspective in general, 2) the patient's perspective taking into account particular gender differences and 3) the perspective of physical therapists. In concrete terms this means that 155 categories out of 166 ICF categories of the *extended version of the ICF Core Set for stroke* were considered relevant for a comprehensive description of the functioning, disability and health of stroke patients.

In general, the results illustrate that PTs **confirmed** the least number of ICF categories in all ICF components. However, all ICF categories confirmed by PTs are also confirmed from the patient and gender perspective. These results make it clear that the perspective of other health professionals and not only PTs has to be taken into account to address the whole spectrum of patients' needs and problems after stroke. This has also been shown in other publications in which the doctoral candidate was involved [29;32].

Regarding ICF categories that are not included in the ICF Core Sets, this doctoral thesis shows that among body functions only 3 from the extended version of the ICF Core Set for stroke were not confirmed: b117 Intellectual functions, b550 Thermoregulatory functions and b630 Sensations associated with urinary functions. Again, all three categories have been confirmed in another validation study reflecting the perspective of physicians [29]. In the Activities and

Participation component, the ICF categories *d315 Communicating with – receiving – nonverbal messages and d940 Human rights* were **not confirmed** neither from the patients nor from the PTs.

In the Environmental Factors 37 of the identified ICF categories were included in the *extended version of the ICF Core Set for stroke*. Only the following four categories, *e240 Light, e455 Individual attitudes of health related professionals, e465 Social norms, practices and ideologies*, *e535 Communication services, systems and policies* were not confirmed from any of the perspectives. In contrast to the ICF categories mentioned by PTs, patients mentioned a large number of Environmental Factors. This is not surprising since PTs usually concentrate on aspects directly related to the body more than on the environment when treating persons with stroke.

There are six ICF categories, which were identified in all three studies but are not part of the current version of the *extended ICF Core Set for stroke*: *s760 Structure of trunk, s770 Additional musculoskeletal structures related to movement, b765 Involuntary movement functions, b780 Sensations related to muscles and movement functions, d435 Moving objects with lower extremities, d650 Caring for household objects* (see, Appendix p.21). These six **additional** categories should be intensively discussed for inclusion in a final version of the *extended ICF Core Set for stroke*. These six categories were also confirmed in two further Delphi studies to validate the ICF Core Sets from the perspective of physicians [29] and occupational therapists (OTs) [32].

All 84 participants named aspects related to personal factors such as self-perception, knowledge about disease, interests, habits and handedness, which are not yet classified but require further investigation.

Outlook

This doctoral thesis contributes new insights to the existing stroke research by studying the content validity of the *extended version of the Comprehensive ICF Core Sets for stroke*. The content validity was confirmed by this doctoral thesis by three different perspectives. Nevertheless, more research is necessary regarding the relevance of some responses by the participants of the studies, which are not yet included in the *extended version of the ICF Core Set for stroke* to describe systematically the relevant aspects of functioning and health in persons with stroke. Furthermore, it will be necessary to develop the ICF component of personal factors. The *extended version of the ICF Core Sets for stroke* was found to provide a useful basis for clinical practice to describe and classify functioning, health and disability using a common framework and unifying language.

The three studies focused on different questions and their results are complementary. All three studies underline the most relevant aspects of functioning in persons after stroke from different perspectives. By using qualitative methods, it was possible to identify areas of functioning which are relevant to persons after stroke but are not yet included in the ICF. From now on these areas can be integrated into the ICF update process, in which German physicians are participating also [49].

For future use in daily practice, the *extended version of the ICF Core Set for stroke* is included in the revision process of the ICD-11 and is not being used only for research. Through a list of so called 'functioning properties' the joint use of the two classifications, the ICD and the ICF, will be facilitated, contributing to a valuable synergy. The aim of this joint use is to enhance patient management, the design of interventions and the reporting of the health of persons with health conditions such as stroke [50].

Furthermore, in quality management systems for certification of rehabilitation clinics by a program like 'IQMP Reha', compliance with a participation-orientated concept (Teilhabeorientiertes Leitbild) is being requested more and more, based on § 20 section 2a clause 1 of the Social Security Code (SGB) IX [51;52]. ICF-based tools are needed to implement participation in daily practice. The validated *ICF Core Set for stroke* can be used to implement participation-orientated concepts.

The ICF is also becoming an essential tool in the health professionals' curriculum. For example, the curriculum of physical therapists focuses more and more on interdisciplinary education, in which the comprehensive perspective of the ICF plays an essential role. To facilitate the implementation of this comprehensive perspective in education, the ICF Core Sets can be used as a learning tool to build an understanding of that comprehensive perspective. To develop a comprehendsive perspective on rehabilitation, ICF Core Sets are still part of the ICF teaching material from the Bundesarbeitsgemeinschaft für Rehabilitation (BAR) [Federal Rehabilitation Council] and the ICF guideline ("ICF-Leitfaden 2") is an example of ICF-orientated documentation [53]. This follows the recommendation of the International Society of Physical and Rehabilitation Medicine (ISPMR) addressing functioning and disability in clinical practice by using ICF Core Sets. This validation of the *ICF Core Sets for stroke* contributes to aspects of the patient-centred rehabilitation management of persons after stroke, implementation into clinical practice, health service research and policy, as well as decision-making by and especially education of health professionals.

Implications for rehabilitation and research

- The content validity of the *extended version of the ICF Core Set for stroke* was by and large confirmed from the three perspectives reflected in the validation studies that are part of this doctoral thesis: the patient's, the gender and the health professional perspective.
- The *extended version of the ICF Core Set for stroke* contains those areas of functioning and disability that are relevant to patients with stroke in general but also those that are exclusively relevant to women and men. It can, therefore, be a useful tool to describe gender differences in functioning and disability in clinical practice.
- Additional categories from the whole ICF classification can be added to the *extended ICF Core Set for stroke* to follow a client-centred approach taking into account the gender perspective.

- Since the *extended ICF Core Set for stroke* also contains those areas of functioning and disability considered relevant by physical therapists, it can be used as a basis for a client-centred approach in physical therapy practice and education and can be integrated as a clinical tool for the treatment of women and men after stroke.
- The differences in functioning and disability in women and men after stroke identified in this doctoral thesis, such as 'functions of skin', or 'urination functions', or 'formal relationships', can help to strengthen the client-centred approach when taken into account by health professionals in clinical practice.
- These studies provide a basis for the further development of the ICF, especially with regard to up-dating it in relevant aspects such as personal factors from the patient's perspective after stroke.

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Appendix of the summary of the dissertation

Table 1 Comparison of perspectives of patients, gender and the perspective of physical therapists of *additional categories* of the extended version of ICF Core Set for stroke

ICF Code	Activities and Participation: Title ICF Category	FG	Open A	ICF-b	women	men	both	PTs
d145	Learning to write	x	x	x	x			
d163	Thinking	x	x				x	
d355	Discussion	x	x	x		x		
d435	Moving objects with lower extremities	x	x	x			x	x
d480	Riding animals for transportation	x						
d610	Acquiring a place to live		x	x		x		
d650	Caring for household objects	x	x	x			x	x
d660	Assisting others	x	x	x			x	
d720	Complex interpersonal interactions	x		x	x			
d730	Relating with strangers		x	x			x	
d740	Formal relationships		x			x		
d840	Apprenticeship (work preparation)		x			x		
d865	Complex economic transaction	x	x	x		x		
d950	Political life and citizenship			x		x		
ICF Code	**Environmental factors: Title ICF Category**	**FG**	**Open A**	**ICF-b**	**women**	**men**	**both**	**PTs**
e130	Products and technology for education		x	x		x		
e140	Products and technology for culture, recreation and sport		x			x		x
e160	Products and technology of land development	x						
e215	Population	x		x	x			
e220	Flora und fauna	x		x			x	
e225	Climate	x	x	x			x	
e330	People in positions of authority	x	x			x		
e345	Strangers	x	x	x			x	
e350	Domesticated animals	x	x	x			x	
e430	Individual attitudes of people in positions of authority	x	x				x	
e445	Individual attitudes of strangers	x						
e520	Open space planning services, systems and policies			x		x		
e530	Utilities services, systems and policies	x						
e545	Civil protection services, systems and policies	x						
e565	Economic services, systems and policies			x	x			
ICF Code	**Body functions: Title ICF Category**	**FG**	**Open A**	**ICF-b**	**women**	**men**	**both**	**PTs**
b220	Sensations associated with the eye and adjoining structures	x		x	x			
b250	Taste function	x		x			x	
b255	Smell function	x						
b445	Respiratory muscle functions							x
b555	Endocrine gland functions		x	x		x		
b720	Mobility of bone functions			x			x	x
b765	Involuntary movement functions	x	x	x			x	x
b780	Sensations related to muscles and movement functions	x	x	x			x	x
b830	Other functions of skin	x						
b840	Sensation related to the skin	x						
b850	Functions of hair		x			x		
b860	Functions of nail		x			x		
ICF Code	**Body structures: Title ICF Category**	**FG**	**Open A**	**ICF-b**	**women**	**men**	**both**	**PTs**
s220	Structure of eyeball	x		x	x			
s320	Structure of mouth	x		x			x	
s740	Structure of pelvis region							x
s760	Structure of trunk	x	x	x		x		x
s770	Additional musculoskeletal structures related to movement	x	x	x			x	x
s830	Structure of nails		x			x		
s840	Structure of hair		x			x		

II. Research article 1:

Validation of the extended ICF core set for stroke from the patient perspective using focus groups

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Abstract

Purpose. The *extended ICF Core Set for stroke* is an application of the International Classification of Functioning, Disability and Health (ICF) of the World Health Organisation (WHO) with the purpose to represent the typical spectrum of functioning of persons with stroke. The objective of the study was to add evidence to the validation of the *extended ICF Core Set for stroke* from the perspective of patients using focus groups to explore the aspects of functioning and health important to persons with stroke.

Methods. The sampling of patients followed the maximum variation strategy. Sample size was determined by saturation. The focus groups were digitally recorded and transcribed verbatim. After qualitative data analysis the resulting concepts were linked to ICF categories and compared to the categories included in the *extended ICF Core Set for stroke*.

Results. Sixty patients participated in 15 focus groups. The content of 127 out of 166 ICF categories contained in the *extended ICF Core Set for stroke* was reported by the persons with stroke. The content of 31 additional categories that are not covered in the *extended ICF Core Set for stroke* was raised.

Conclusions. The existing version of the *extended ICF Core Set for stroke* could be confirmed almost entirely from patient perspective.

Keywords: Stroke, ICF, ICF core set, patient perspective, focus group, qualitative method

Introduction

Stroke is the second leading cause of death for people above the age of 60 and the fifth leading cause in people aged 15 to 59. Each year, there are 15 million people suffering a stroke and nearly six million people dying from stroke. Stroke is also the leading cause of long-term disability irrespective of age, gender, ethnicity or country [1]. It is strongly associated with the inability to continue independence in everyday life, self-care, mobility, working, ultimately leading to the experience of restrictions in participation in several life areas [2-5].

For the World Health Organization (WHO) functioning and the ability to participate in everyday life can be understood not only as a mere consequence of disease and its treatment, but also within the context of the person that may differ greatly depending on that person's private and societal background [6]. This would imply that the biological, psychological, social and environmental aspects of everyday life must be taken into account in order to achieve a comprehensive perspective of health or health-related problems in persons suffering a stroke [7].

With the International Classification of Functioning, Disability and Health (ICF) a globally agreed-on language and classification is available to describe functioning both on individual and population levels and from both patient perspective and that of the health professionals. To improve clinical practicability of ICF the *Comprehensive ICF Core Set for stroke* was developed in 2004 including 130 ICF categories from the second level of the ICF classification. It covers the typical spectrum of problems in functioning in persons with chronic stroke [8] and should serve as standard for multi-professional, comprehensive assessment. In 2005, the *Comprehensive ICF Core Set for stroke* was extended by 36 ICF categories from the ICF Core Sets for persons with neurological conditions in the acute and early post-acute phases to enable its use in all clinical situations [9-11]. The current version of this *extended ICF Core Set for stroke* includes 166 categories at the second level of the classification, 59 *body functions* categories, 11 *body structures* categories, 59 a*ctivities and participation* categories and 37 *environmental factors*. Since the *extended ICF Core Set for*

stroke addresses aspects within all the components of the ICF it presents a broad, condition-specific perspective that reflects the whole health experience of persons suffering from the effects of a stroke.

The *extended ICF Core Set for stroke* is now undergoing worldwide testing and validation using a number of approaches including an international multicentre validation study and validation from the perspective of health professionals [12-16]. Another key aspect is the validation from the patient perspective. While the patient perspective has been implicitly included in the development of the *extended ICF Core Set for stroke* [17], the patients will now be explicitly involved in the process of the validation of this ICF Core Set.

Studies aimed at the exploration of this 'patient perspective' frequently apply to qualitative methods, which are increasingly accepted in health research and health-related sciences [18-23]. Qualitative methods provide the possibility to explore the perspective of those who experience a health problem, i.e. the so-called patient perspective [24-27]. Compared to quantitative methodology the qualitative approach promises a greater openness to unexplored concepts or phenomena [28] and focuses on how people understand and interpret their social world [29].

The objective of the present study was to add evidence to the validation of the *extended ICF Core Set for stroke* from the perspective of persons with stroke. The specific aims were 1) to explore the aspects of functioning and health important to persons with stroke using focus groups and 2) to examine to what extent these aspects are represented by the current version of the *extended ICF Core Set for stroke*.

Methods and materials

Design

A qualitative study with persons with stroke was performed using focus groups and an established methodology for the validation of ICF Core Sets from the patient perspective, which was applied in previous studies [30, 31].

The study was approved by the Ethics Commission of the Ludwig Maximilians-Universität of Munich project-number 326-07, Germany and was performed in accordance with the Declaration of Helsinki.

Participants

Persons with stroke, who had been diagnosed according to the stroke criteria of WHO 2006 [1] and had been treated in one of seven study centres for neurological rehabilitation in Germany (rehabilitation centre Nittenau, rehabilitation centre Bad Neustadt, rehabilitation centre Europakanal in Erlangen, rehabilitation centre Herzogenaurach, rehabilitation centre Passauer Wolf in Bad Griesbach, rehabilitation centre Loipl, outpatient department Mutabor in Munich) at any time since 2008 to 2009 were included in the study. The inclusion criteria were: stroke as main diagnosis, age of at least 18 years, ability to concentrate 30 minutes at minimum and sufficient knowledge of the language of the country to understand all aspects of the study for purposes of consent. Patients were excluded from the study, if they have had surgery and not completed wound healing, or were diagnosed with psychiatric disorders (e.g. acute major depression, personality disorders).

Trained health professionals in each study centre asked persons with stroke to participate after having checked the inclusion criteria. Participants were then selected from a list of willing and suitable patients by the maximum variation strategy [32] based on the following criteria: kind of stroke, affected hemiplegic side, time after stroke, age and gender.

According to previous studies [30] the group size for the focus group sessions was set at a maximum of five persons to represent different opinions and facilitate interactions. Overall sample size was determined by saturation [32, 33]. Saturation refers to the point at which an investigator has obtained sufficient information from the field [33, 34] (see data analysis: saturation of data).

Data collection

All groups were performed in a non-directive manner by three moderators, who were health professionals experienced in the ICF, the treatment of persons with stroke and in conducting group processes.

Focus groups were performed according to focus group guidelines using open-ended questions and providing further instructions (e.g. introduction, procedure of the session, technical aspects). At the beginning of each focus group in addition to introducing the procedures during the session, the concept of the ICF was presented in layman terms to all participants.

Six open-ended questions were asked addressing the components of the ICF related to problems in *Body functions*, *Body structures*, *Activities and participation* as well as relevant *Environmental factors* and *Personal factors* as barriers or facilitators influencing their everyday life after stroke. The following open-ended questions were used (Table 1):

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 group to enable the participants to verify and amend emergent issues.

The focus groups were audio recorded and transcribed verbatim with the Olympus DSS-system. An assistant observed the process within the groups filling in field notes according to a standardized coding schema. After each focus group a debriefing with the moderator and assistant took place to review the course of the focus group.

Table 1 Open-ended questions given to the focus group participants. The ICF component indicated within the brackets was not seen by the participants.

Open-ended questions
1. If you think about your body and mind, what does not work the way it is supposed to? [Body functions]
2. If you think about your body, in which parts are your problems? [Body structures]
3. If you think about your daily life, what are your problems? [Activities & Participation]
4. If you think about your-self, what is important to handle your situation after stroke? [Personal factors]
5. If you think about your environment and your living conditions, what barriers do you experience? [Environmental factors as barriers]
6. If you think about your environment and your living conditions, what do you find helpful or supportive? [Environmental factors as facilitator]

Data analysis

Qualitative analysis

The meaning condensation procedure [27] was used for the qualitative analysis of data following a three-step procedure: In the first step, the transcripts of the focus groups were read in order to get an overview over the collected data. In the second step, 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 [35]. Therefore, a meaning unit division did not follow linguistic grammatical rules. Rather, the text was divided where the researcher discerned a shift in meaning [27]. 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 categories of the ICF based on established linking rules [36, 37], which enable the linking of concepts to ICF categories in a systematic and standardized way (Table 2). According to these linking rules health professionals trained in the ICF linked 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 2 Scheme of the data analysis: qualitative analysis and linking to the ICF: an example.

Transcription → *Qualitative analysis*		Concept → *Linking*	ICF category
Moderator:	*Let's go on to the next question. Next question is, if you think about your daily life what are your problems?*		
Patient A:	Firstly, to be employed at this stage is impossible, because you've got so many distractions and malfunctions, you wouldn't be able to do your job properly.	Employment is impossible	d850 Remunerative employment
Moderator:	*At this stage it's impossible….* *There are further experiences or problems in daily life*		
Patient B:	Yes, because I don't sleep at night because I have pain in my right shoulder and neck.	Problems sleeping at night Pain in shoulder Pain in neck	b134 Sleep functions b28016 Pain in joints b28010 Pain in head and neck
	At the morning I have problems to dress myself	Dressing is a problem	d540 Dressing
Patient C:	To concentrate on a discussion with more than one person becomes a problem in daily life…..	Concentrate on discussion	b140 Attention functions d160 Focusing attention d350 Conversation

Saturation of data

Saturation of data was defined as the point during data collection and analysis when the linking of the concepts of two consecutive focus groups revealed no additional second-level categories from the *extended ICF Core Set for stroke* [33, 38].

Confirmation of the ICF categories of the Extended ICF Core Set for stroke

An ICF category of the *extended ICF Core Set for stroke* was regarded as confirmed when the identical or a similar category emerged from the focus groups (*example* e.g. 'b7359 *functions of muscle tone,* unspecified' confirmed by 'b735 *functions of muscle tone'*). Since the ICF categories are arranged in a hierarchical code system the second-level categories of the *extended ICF Core Set for stroke* were considered confirmed when the corresponding third- or fourth-level category they belong to had been identified from the patient perspective.

Additional categories

An ICF category was regarded as an additional category when the category emerged from the focus groups and was not included in the current version of the *extended ICF Core Set for stroke*.

Accuracy of the analysis

To ensure the accuracy of data analysis the following two strategies were adopted:

Multiple coding: Qualitative analysis and linking to the ICF of the first focus group was done by two health professionals (BK and AG) in order to achieve agreement concerning the implementation of the linking rules. Agreements, specifications and special cases of the linking rules that occurred when applying the rules were documented.

Peer review: After completing the multiple coding of the first focus group a peer review was performed. Random samples of 20% of the transcribed text and 20% of the identified concepts (of the first health professional) were analysed and linked additionally by a second health professional. The degree of agreement between the two health professionals regarding linked ICF categories was calculated by kappa statistics with 95%-bootstrapped confidence intervals [39, 40], respectively. The values of the kappa coefficient generally range from 0 to 1 where 1 indicates perfect agreement and 0 indicates no additional agreement beyond what is expected by chance only. The data analysis was performed with SAS for windows V9.1 (Copyright © 2002–2003 by SAS Institute Inc., Cary, NC, USA).

Results

Description of the focus groups

A total of 60 German speaking persons with stroke (30 female, 30 male) with a median age of 57 years (31 to 79 years) participated in the study. The mean disease duration was 3.7 month and ranged from 1 to 29 month. The focus group sessions lasted from about 45 minutes to 110 minutes. Saturation of data was reached after performing 15 focus groups (Figure 1).

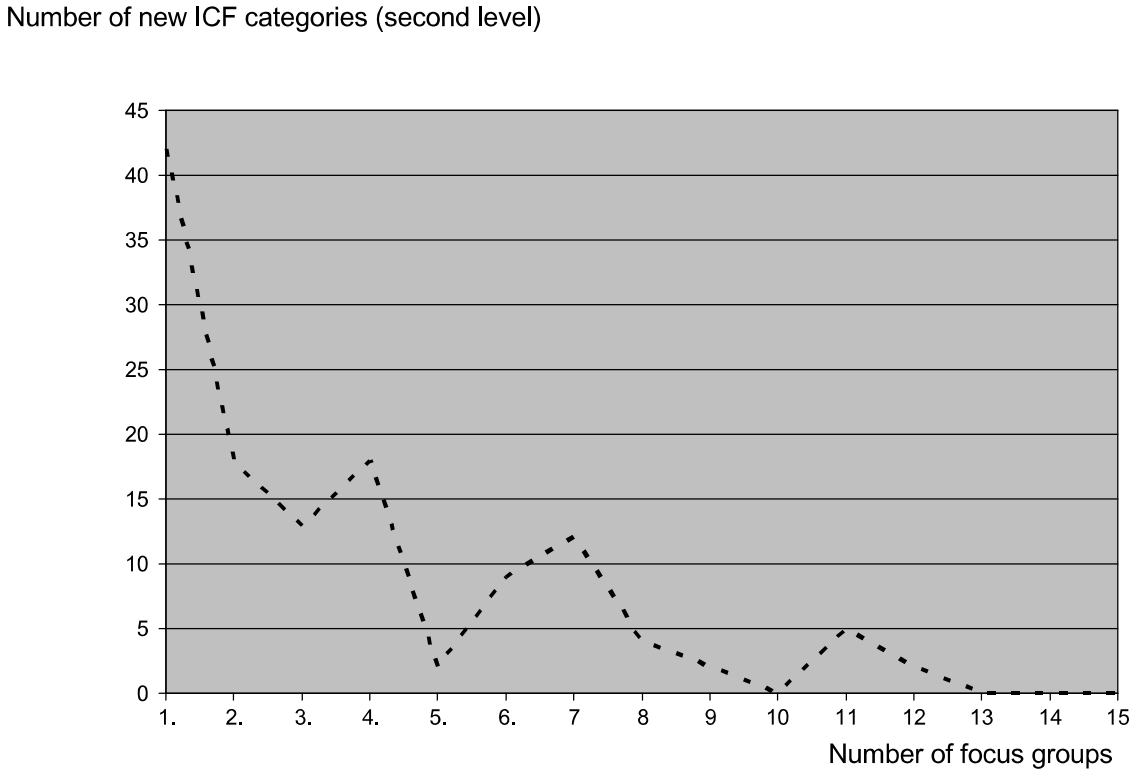

Figure 1 Saturation of data in the focus groups: identification of new second-level categories

Qualitative analysis and linking to the ICF

In total, 3907 concepts were identified in the qualitative analysis of the transcribed focus group sessions. These concepts were linked to 329 different ICF categories from first to fourth level of the classification. Thus, the concepts were linked to a total of 158 second-level categories. Three hundred and eighty-five concepts could not be linked to ICF categories (e.g. quality of life in general, aspects of coping, disease management, time-related aspects, and variability of functioning). Two hundred and sixty-eight concepts were allotted to the component *personal factors* which has not yet been classified.

Confirmation of the ICF categories of the extended ICF Core Set for stroke

In total, 127 out of the 166 second-level categories included in the *extended ICF Core Set for stroke* were confirmed by the participants. Forty-seven out of 59 second-level categories of the component *body functions*, 6 out of 11 second-level categories of the component *body structures,* 47 out of 59 categories of *activities and participation* and 28 out of 37 categories of *environmental factors* included in the *extended ICF Core Set for stroke* were reported by the participants (Tables 3 – 6; categories in bold typeface specified as 'confirmed categories').

Nine ICF categories of the *extended ICF Core Set for stroke* were identified in at least 14 of the 15 focus group sessions (Tables 3 – 6; categories marked with**).

Additional categories

Thirty-one second-level additional categories which are not included in the current version of the *extended ICF Core Set for stroke* were identified in the focus groups. Most of the additional categories derive from the component *environmental factors* (n=11) followed by *activities and participation* (n=9). Seven and 4 additional categories from the component *body functions* and *body structures* were reported by the participants, respectively (Tables 3 – 6; categories in *italic* typeface).

In addition to these categories, some issues emerged from the patient perspective which have not yet been covered by the *extended ICF Core Set for stroke* or even by the ICF classification like coping, expectations, gender, comorbidities, right half and left half of the body, risk to fall, need of time and breaks, reaction rate and others.

Accuracy of the analysis

The kappa coefficient for the agreement between the two health professionals (peer review) was 0.73. The 95%-bootstrapped confidence interval which indicates the precision of the estimated kappa coefficient was 0.68 to 0.76.

Table 3 *Body functions* (b) part 1: Patients' reporting of ICF categories (second-level). ICF categories of the extended *ICF Core Set for stroke* are shown in **bold typeface**. Additional ICF categories are shown in *italic typeface*.

ICF categories		confirmed categories	additional categories
ICF code	**ICF category title**		
Chapter 1	***Mental functions***		
b110	**Consciousness functions**	**yes**	
b114	**Orientation functions**	**yes**	
b117	Intellectual functions		
b126	**Temperament and personality functions**	**yes**	
b130	**Energy and drive functions**	**yes**	
b134	**Sleep functions**	**yes**	
b140	**Attention functions**	**yes**	
b144	**Memory functions**	**yes**	
b147	**Psychomotor functions**	**yes**	
b152	**Emotional functions**	**yes**	
b156	**Perceptual functions**	**yes**	
b160	**Thought functions**	**yes**	
b164	**Higher-level cognitive functions**	**yes**	
b167	**Mental functions of language**	**yes**	
b172	**Calculation functions**		
b176	**Mental Functions of sequencing complex movements**	**yes**	
b180	**Experience of self and time functions**	**yes**	
Chapter 2	***Sensory functions and pain***		
b210	**Seeing functions**	**yes**	
b215	**Functions of structures adjoining the eye**	**yes**	
b220	*Sensations associated with the eye and adjoining structures*		*yes*
b230	**Hearing functions**	**yes**	
b235	**Vestibular functions**	**yes**	
b240	**Sensations associated with hearing and vestibular function**	**yes**	
b250	*Taste function*		*yes*
b255	*Smell function*		*yes*
b260	**Proprioceptive functions**	**yes**	
b265	**Touch function**	**yes**	
b270	**Sensory functions related to temperature and other stimuli**	**yes**	
b280	**Sensation of pain**	**yes**	
Chapter 3:	***Voice and speech functions***		
b310	**Voice functions**	**yes**	
b320	**Articulation functions**	**yes**	
b330	**Fluency and rhythm of speech functions**	**yes**	
b340	Alternative vocalization functions		

Table 3 *Body functions* (b) part 2: Patients' reporting of ICF categories (second-level). ICF categories of the extended *ICF Core Set for stroke* are shown in **bold typeface**. Additional ICF categories are shown in *italic typeface*.

ICF categories		confirmed categories	additional categories
ICF code	**ICF category title**		
Chapter 4:	***Functions of the cardiovascular, haematological, immunological and respiratory systems***		
b410	**Heart functions**	**yes**	
b415	**Blood vessel functions**	**yes**	
b420	**Blood pressure functions**	**yes**	
b430	**Haematological system functions**	**yes**	
b435	Immunological system functions		
b440	**Respiration functions**	**yes**	
b450	Additional respiratory functions		
b455	**Exercise tolerance functions**	**yes**	
Chapter 5:	***Functions of the digestive, metabolic and endocrine systems***		
b510	**Ingestion functions**	**yes**	
b515	Digestive functions		
b525	**Defecation functions**	**yes**	
b530	**Weight maintenance functions**	**yes**	
b535	**Sensations associated with the digestive system**	**yes**	
b540	General metabolic functions		
b545	**Water, mineral and electrolyte balance functions**	**yes**	
b550	Thermoregulatory functions		
Chapter 6:	***Genitourinary and reproductive functions***		
b620	**Urination functions**	**yes**	
b630	Sensations associated with urinary functions		
b640	Sexual functions		
Chapter 7:	***Neuromusculoskeletal and movement-related functions***		
b710	**Mobility of joint functions**	**yes**	
b715	**Stability of joint functions**	**yes**	
b730	**Muscle power functions**	**yes****	
b735	**Muscle tone functions**	**yes**	
b740	Muscle endurance functions		
b750	**Motor reflex functions**	**yes**	
b755	**Involuntary movement reactions**	**yes**	
b760	**Control of voluntary movement functions**	**yes**	
b765	*Involuntary movement functions*		*yes*
b770	**Gait pattern functions**	**yes**	
b780	*Sensations related to muscles and movement functions*		*yes*
Chapter 8:	***Functions of the skin and related structures***		
b810	Protective functions of the skin		
b830	*Other functions of skin*		*yes*
b840	*Sensation related to the skin*		*yes*

** ICF categories confirmed in at least 14 of 15 focus groups

Table 4 *Body structures* (s): Patients' reporting of ICF categories (second-level). ICF categories of the extended *ICF Core Set for stroke* are shown in **bold typeface**. Additional ICF categories are shown in *italic typeface.*

ICF categories		confirmed categories	additional categories
ICF code	**ICF category title**		
Chapter 1:	***Structures of the nervous system***		
s110	**Structure of brain**	**yes**	
s120	Spinal cord and related structure		
s130	Structure of meninges		
Chapter 2:	***The eye, ear and related structures***		
s210	*Structure of eyeball*		*yes*
Chapter 3	***Structures involved in voice and speech***		
s320	*Structure of mouth*		*yes*
Chapter 4:	***Structures of the cardiovascular, immunological and respiratory systems***		
s410	**Structure of cardiovascular system**	**yes**	
s430	Structure of respiratory structure		
Chapter 5:	***Structures related to the digestive, metabolic and endocrine systems***		
s530	**Structure of stomach**		
Chapter 7:	***Structures related to movement***		
s710	**Structure of head and neck region**	**yes**	
s720	**Structure of shoulder region**	**yes**	
s730	**Structure of upper extremity**	**yes****	
s750	**Structure of lower extremity**	**yes**	
s760	*Structure of trunk*		*yes*
s770	*Additional musculoskeletal structures related to movement*		*yes*
Chapter 8:	***Structures of skin***		
s810	Structure of areas of skin		

** ICF categories confirmed in at least 14 of 15 focus groups

Table 5 *Activities and participation* (d) part 1: Patients' reporting of ICF categories (second-level). ICF categories of the *extended ICF Core Set for stroke* are shown in **bold typeface**. Additional ICF categories are shown in *italic typeface*.

ICF categories		confirmed categories	additional categories
ICF code	**ICF category title**		
Chapter 1:	***Learning and applying knowledge***		
d110	Watching		
d115	Listening		
d120	Other purposeful sensing		
d130	Copying		
d135	**Rehearsing**	**yes**	
d145	*Learning to write*		*yes*
d155	**Acquiring skills**	**yes**	
d160	**Focusing attention**	**yes**	
d163	*Thinking*		*yes*
d166	**Reading**	**yes**	
d170	**Writing**	**yes**	
d172	Calculating		
d175	**Solving problems**	**yes**	
d177	**Making decisions**	**yes**	
Chapter 2:	***General tasks and demands***		
d210	**Undertaking a single task**	**yes**	
d220	**Undertaking a multiple task**	**yes**	
d230	**Carrying out daily routine**	**yes**	
d240	**Handling stress and other psychological demands**	**yes****	
Chapter 3:	***Communication***		
d310	Communication with receiving spoken messages		
d315	Communication with receiving nonverbal messages		
d325	**Communication with receiving written messages**	**yes**	
d330	**Speaking**	**yes**	
d335	Producing nonverbal messages		
d345	**Producing messages in formal sign messages**	**yes**	
d350	**Conversation**	**yes**	
d355	*Discussion*		*yes*
d360	**Using communication devices and techniques**	**yes**	
Chapter 4:	***Mobility***		
d410	**Changing basic body position**	**yes**	
d415	**Maintaining a body position**	**yes**	
d420	Transferring oneself		
d430	**Lifting and carrying objects**	**yes**	
d435	*Moving objects with lower extremities*		*yes*
d440	**Fine hand use**	**yes**	
d445	**Hand and arm use**	**yes**	
d450	**Walking**	**yes****	
d455	**Moving around**	**yes**	
d460	**Moving around in different locations (d455)***	**yes**	

Table 5 *Activities and participation* (d) part 2: Patients' reporting of ICF categories (second-level). ICF categories of the *extended ICF Core Set for stroke* are shown in **bold typeface**. Additional ICF categories are shown in *italic typeface*.

ICF categories		confirmed categories	additional categories
ICF code	**ICF category title**		
d465	**Moving around using equipment**	**yes**	
d470	**Using transportation**	**yes**	
d475	**Driving**	**yes**	
d480	*Riding animals for transportation*		*yes*
Chapter 5:	***Self-care***		
d510	**Washing oneself**	**yes**	
d520	**Caring for body parts**	**yes**	
d530	**Toileting**	**yes**	
d540	**Dressing**	**yes**	
d550	**Eating**	**yes**	
d560	**Drinking**	**yes**	
d570	**Looking after one's health**	**yes****	
Chapter 6:	***Domestic life***		
d620	**Acquisition of goods and services**	**yes**	
d630	**Preparing meals**	**yes**	
d640	**Doing housework**	**yes**	
d650	*Caring for household objects*		*yes*
d660	*Assisting others*		*yes*
Chapter 7:	***Interpersonal interactions and relationships***		
d710	Basic interpersonal interactions		
d720	*Complex interpersonal interactions*		*yes*
d750	**Informal social relationships**	**yes**	
d760	**Family relationships**	**yes**	
d770	**Intimate relationships**	**yes**	
Chapter 8:	***Major life areas***		
d845	**Acquiring, keeping and terminating a job**	**yes**	
d850	**Remunerative employment**	**yes****	
d855	**Non-remunerative employment**	**yes**	
d860	**Basic economic transactions**	**yes**	
d865	*Complex economic transaction*		*yes*
d870	**Economic self-sufficiency**	**yes**	
Chapter 9:	***Community, social and civic life***		
d910	Community life		
d920	**Recreation and leisure**	**yes**	
d930	**Religion and Spirituality**	**yes**	
d940	Human rights		

* confirmation according to similar ICF categories

** ICF categories confirmed in at least 14 of 15 focus groups

Table 6 *Environmental factors* (e) part 1: Patients' reporting of ICF categories (second-level). ICF categories of the *extended ICF Core Set for stroke* are shown in **bold typeface**. Additional ICF categories are shown in *italic typeface*.

ICF categories		confirmed categories	additional categories
ICF code	**ICF category title**		
Chapter 1:	***Products and Technology***		
e110	**Products or substances for personal consumption**	**yes**	
e115	**Products and technology for personal use in daily living**	**yes**	
e120	**Products and technology for personal indoor and outdoor mobility and transportation**	**yes**	
e125	**Products and technology for communication**	**yes**	
e135	Products and technology for employment		
e150	**Design, construction and building products and technology of buildings for public use**	**yes**	
e155	**Design, construction and building products and technology of buildings for private use**	**yes**	
e160	*Products and technology of land development*		*yes*
e165	**Assets**	**yes**	
Chapter 2:	***Natural environment and human-made changes to environment***		
e210	**Physical geography**	**yes**	
e215	*Population*		*yes*
e220	*Flora and fauna*		*yes*
e225	*Climate*		*yes*
e240	Light		
e250	**Sound**	**yes**	
Chapter 3:	***Support and relationships***		
e310	**Immediate family**	**yes****	
e315	**Extended family**	**yes**	
e320	**Friends**	**yes**	
e325	**Acquaintances, peers, colleagues, neighbours and community members**	**yes**	
e330	*People in positions of authority*		*yes*
e340	**Personal care providers and personal assistants**	**yes**	
e345	*Strangers*		*yes*
e350	*Domesticated animals*		*yes*
e355	**Health professionals**	**yes****	
e360	**Other professionals**	**yes**	
Chapter 4:	***Attitudes***		
e410	**Individual attitudes of immediate family members**	**yes**	
e415	Individual attitudes of extended family members		
e420	**Individual attitudes of friends**	**yes**	
e425	**Individual attitudes of acquaintances, peers, colleagues, neighbours and community members**	**yes**	

Table 6 *Environmental factors* (e) part 2: Patients' reporting of ICF categories (second-level). ICF categories of the *extended ICF Core Set for stroke* are shown in **bold typeface**. Additional ICF categories are shown in *italic typeface*.

ICF categories		confirmed categories	additional categories
ICF code	**ICF category title**		
e430	*Individual attitudes of people in positions of authority*		*yes*
e440	Individual attitudes of care providers and personal assistance		
e445	*Individual attitudes of strangers*		*yes*
e450	**Individual attitudes of health professionals**	**yes**	
e455	Individual attitudes of health-related professionals		
e460	**Societal attitudes**	**yes**	
e465	Social norms, practices and ideologies		
e515	Architecture and construction services, systems and policies		
e525	**Housing services, systems and policies**	**yes**	
Chapter 5: Services, systems and policies			
e530	*Utilities services, systems and policies*		*yes*
e535	Communication services, systems and policies		
e540	**Transportation services, systems and policies**	**yes**	
e545	*Civil protection services, systems and policies*		*yes*
e550	Legal services, systems and policies		
e555	Associations and organizational services, systems and policies		
e570	**Social security services, systems and policies**	**yes**	
e575	**General social support services, systems and policies**	**yes**	
e580	**Health services, systems and policies**	**yes****	
e590	**Labour and employment services, systems and policies**	**yes**	

** ICF categories confirmed in at least 14 of 15 focus groups

Discussion

This study shows that the current version of the *extended ICF Core Set for stroke* was almost entirely confirmed from the patient perspective. A broad range of aspects related to everyday life were identified from the perspective of persons with stroke e.g. having problems in all fields of daily living like grasping, eating, washing, dressing, toileting, but also memory and aspects of personality. In addition, the content of several categories not contained in the *extended ICF Core Set for Stroke* were named by the participants. These ICF categories need special clarification and will be discussed in the following paragraphs.

Thirty-one additional second-level categories not included in the current version of the *extended ICF Core Set for stroke* are mainly from the components *environmental factors* and *activities and participation*. In addition, the participants of the study named the content of several *body functions*' and *body structures'* categories. It is important to note that the participants often reported impairments in body structures by describing them in terms of impaired body functions. In line with this, categories like b220 *Sensations associated with the eye and adjoining structures* and the corresponding body structures s210 *Structure of eyeball* or s320 *Structure of mouth* and b250 *Taste* as well b255 *Smell functions* which are corresponding to these body structures were identified from the patient perspective. It also needs to be mentioned that in persons with stroke s320 *Structure of mouth* can be injured. Therefore, they have a risk to get wounds on lips as a consequence of reduced sensory in the face and mouth. Also eating with numbness around the mouth is difficult to control [41].

Structures related to movement such as s760 *Structures of trunk* and s770 *Additional musculoskeletal structures related to movement* were identified as being important from the patient perspective. These are typical categories which are affected after a stroke attack in combination with muscle tone and movement control or pain [42, 43]. Movement-related categories of the component body functions which are currently not included in the *extended ICF Core Set for stroke* were b765 *Involuntary movement functions* and b780 *Sensations related to muscles and movement functions*. These are categories which focus on the subjective perception of movement-related function. To assess muscle sensations one has to rely on the self-report of persons suffering a disease because it is impossible to measure functions related to sensations objectively by a scale or an instrument. This is comparable to measuring pain or other sensations which are driven by feelings and depend from individual experiences and self-perceptions.

The ICF categories d163 *Thinking* and d355 *Discussion* are basic skills and core competencies for communication and were intensively discussed by the participants of this study. To learn to speak again is a profound experience after stroke [44]. Not being able to say what one wants, struggling for words, knowing what is meant but not being able to tell it can lead to depressive phases of life for the patients [45, 46]. This experience was often reported as connected to the inability to write, which is indicated by the ICF category d145 *Learning to write*. Limitations in speaking and writing have an important influence on keeping or losing autonomy and requiring help from other people [29, 46, 47].

Autonomy in movement was one of the most important topics of the focus group sessions reported by the participants and are represented by the not included ICF categories d480 *Riding animals for transportation* and d435 *Moving objects with lower extremities*. In almost all focus groups the participants intensively discussed issues referring to car driving and its corresponding abilities [48]. This also reflects expectations regarding the recovery of the movement ability of the lower extremities like pedalling the accelerator or the brakes of a car. It also includes cognitive functions such as reaction rate which was also identified from the patient perspective. Patients

from rural areas are dependent on driving a car, especially as e530 *Utility services and system*s are not as well equipped as in the cities [49]. Persons with stroke exchanged their concerns regarding decreased mobility and independence, a fact that was also supported in further validation studies of the *extended ICF Core Set for stroke* from the perspective of health professionals [12, 13].

Losing autonomy means becoming more and more dependent and needing support from other people like family, partner, or health professionals and animals in everyday life described by the ICF categories d650 *Caring for household objects*, d660 *Assisting others,* d865 *Complex economic transactions* or caring for e350 *Domestic animals.* These activities are no longer possible to the same extent as before [50-52]. In line with this, the participants of the focus groups exchanged worries and concerns, such as:

'…in the past I have done everything alone, I was responsible and did take care of my family and now, I need help in nearly each part of daily living. I do want to be independent from other people'.

Staying at home and living independently are environmental factors that are crucial for persons with stroke. The ICF category e545 *Civil protection services, systems and policies* is reported by participants of the focus groups in the context of feeling unsecure at home and needing help from emergency services using special emergency systems. The identified *environmental factors* have an impact on nearly all fields of everyday life and therefore, this component covers aspects which range from interventions (e.g. medication) and devices in different forms to climate, flora and fauna and also includes social systems. In our study the statements of the participants were mostly related to categories of chapter 3 *Support and relationships (*e.g. e330 *People in authority* or e345 *Strangers)* and chapter 4 *Attitudes* of their surrounding people (e.g. e430 *Individual attitudes of people in authority* or e445 *Individual attitudes of strangers)*. Attitudes of people in authority are important for persons with stroke because long-term (chronic) illness and their consequences are strongly associated with unsecure return-to-work [44, 53-57]. In most cases successful vocational rehabilitation needs constructive collaborations between employees and their persons in authority [58, 59]. These additional categories may be considered if an updated version of the *extended ICF Core Set for stroke* is developed.

Regarding the ICF categories from the *extended ICF Core Set for Stroke which* were not confirmed from the patient perspective, it is important to mention that those of the component *activities and participation* are strongly associated with *body functions'* categories which were confirmed, such as b210 *Seeing functions*, b230 *Hearing functions*, b310 *Voice functions* and b320 *Articulation functions*. ICF categories from the component *activities and participation* which were not confirmed were d110 *Watching*, d115 *Listening*, d120 *Other purposeful sensing*, d130 *Copying*, d310 *Communicating with - receiving - spoken messages*, d315 *Communicating with - receiving - nonverbal messages,* d335 *Producing nonverbal messages*, d420 *Transferring*

oneself, d710 *Basic interpersonal relationships*, d910 *Community life* and d940 *Human rights*. In addition, b*ody functions'* categories as b172 *Calculation functions*, b435 *Immunological system functions*, b450 *Additional respiratory functions*, or b515 *Digestive functions* and *body structures*' categories as s120 *Spinal cord and related structures*, s130 *Structure of meninges*, s430 *Structure of respiratory system* and s530 *Structure of stomach* were not identified in the focus groups. Several concepts identified from the patient perspective were labelled as 'not covered' by the ICF. It is important to emphasize that the majority of these concepts does not refer to aspects of functioning and disability as defined by the ICF classification. These concepts mainly cover time-related or disease specific aspects (e.g. "needing more time and breaks to accomplish daily activities" and "right half and left half of the body") and general quality of life or satisfaction with life, respectively. Since the ICF does not cover these aspects nor quality of life in the sense of subjective wellbeing [60], these issues could not be linked to the ICF. However, other 'not covered' concepts identified in this study are clearly related to functioning and disability as defined by the ICF (e.g. "reaction rate"). These issues should be included in the update process of the ICF, which has already been initiated by WHO.

There are some methodological issues that should be mentioned in detail. The focus groups in our study were composed of 3 to 5 participants which is a small group size compared to other qualitative studies. We decided to perform focus group sessions with few participants because of the complexity of the topic and the expertise of the participants according to the literature [61]. With a small group size each participant has a greater opportunity to talk which is reported to be an important aspect for group dynamics in groups with elderly and ill participants [62, 63].

It is important to mention that several strategies were used to improve and verify the trustworthiness of the qualitative data. *(1) Triangulation* to ensure the comprehensiveness of data. We included data triangulation by using two data analysts (investigator triangulation: multiple coding) [64, 65]. *(2) Continuous data analysis* was used according to Pope et al. [22]. *(3) Reflexivity* was assured by conducting a research diary for the documentation of memos concerning the design, data collection and analysis of the study. *(4) Clear exposition* was used establishing guidelines for conducting the focus groups (including open-ended questions), verbatim transcription, and linking rules [36, 37]. Thus, a clear account of methods of data collection and analysis was assured. *(5)* Finally, a *peer review* was performed. The kappa coefficient of 0.73 for the accuracy of the peer review is comparable to other studies reporting kappa statistics about the linking of categories and can be regarded as ‘substantial agreement’ [38, 66-68].

There are also some limitations of this study that need special mentioning. The sample consists only of German speaking participants from Austria, Bulgaria, and Germany. Our suggestion is that our methods could be used in similar studies in other countries to establish a cross-cultural perspective. Secondly, the linking process was performed by two health professionals according to established linking rules [36, 37]. However, it remains unclear whether other health professionals would have decided differently. Finally, we followed the strategy of saturation during data analyses with the criteria of two consecutive focus groups revealing no additional second-level categories in the *extended ICF Core Set for stroke*. Participants in a 16th focus group still might report new themes and concepts not yet reported.

Conclusions

The current version of the *extended ICF Core Set for stroke* with its selected categories was confirmed almost entirely from the patient perspective. Several additional categories not represented in the *extended ICF Core Set for stroke* emerged from the focus groups. Further research specifically on the additional ICF categories that are not yet included in the *extended ICF Core Set for stroke* is needed. The results of this study will be taken into account when the final version of the *extended ICF Core Set for stroke* is agreed. Further research is needed to implement the ICF Core Sets for stroke in clinical practice and to develop i.e. patient reported outcome measures based on the ICF Core Set as it was already done in other diseases [69].

Implications for Rehabilitation

- The *extended ICF Core Set for stroke* can be used to create a functioning profile for persons after stroke to identify problems and resources considering a client-centred approach.
- This study shows which aspects of the environment of persons after stroke are relevant from the clients' perspective and should be integrated in the rehabilitation process.
- This study provides a basis for the further development of the ICF, especially with regard to its update in relevant aspects from clients' perspective after stroke.

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Declaration of interest

The authors report no declarations of interest. This study forms part of the doctoral thesis of the first author at the Faculty of Medicine, Ludwig-Maximilians-University Munich, Germany.

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III. Research article 2:

Content validation of the International Classification of Functioning, Disability and Health (ICF) Core Set for stroke from gender perspective using a qualitative approach

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Abstract

Background. The *extended ICF Core Set for stroke* is an application of the International Classification of Functioning, Disability and Health (ICF) of the World Health Organisation (WHO) with the purpose to represent the typical spectrum of functioning of persons with stroke.

Aim: The objective of the study is to add evidence to the content validity of the *extended ICF Core Set for stroke* from persons after stroke taking into account gender perspective.
A qualitative study design was conducted by using individual interviews with women and men after stroke in an in- and outpatient rehabilitation setting.

Methods: The sampling followed the maximum variation strategy. Sample size was determined by saturation. Concepts from qualitative data analysis were linked to ICF categories and compared to the *extended ICF Core Set for stroke*.

Results. Twelve women and 12 men participated in 24 individual interviews. In total, 143 out of 166 ICF categories included in the *extended ICF Core Set for stroke* were confirmed (women: n=13; men: n=17; both genders: n=113). Thirty-eight additional categories that are not yet included in the *extended ICF Core Set for stroke* were raised by women and men.

Conclusions. This study confirms that the experience of functioning and disability after stroke shows communalities and differences for women and men. The validity of the *extended ICF Core Set for stroke* could be mostly confirmed, since it does not only include those areas of functioning and disability relevant to both genders but also those exclusively relevant to either women or men. Further research is needed on ICF categories not yet included in the *extended ICF Core Set for stroke*.

Keywords: Stroke, rehabilitation, gender, qualitative research

Introduction

Stroke is the second leading cause of death of people worldwide. Projections indicate that until 2020 stroke will remain one of the leading causes of disability in industrialised countries.[1] There is a growing recognition of gender differences with implications at the clinical and public health level.[2,3] Over their lifetime, 16% of women are at risk to die from stroke compared to only 8% of men.[4,5]

In the Framingham Study (FHS) cohort, gender-specific neurological deficits and aspects of disability in post-stroke people were documented longitudinally in the cohort initiated in 1948 with 5209 participants.[6-8] Gender-specific results showed differences in women and men with respect to incidence, lifetime risk of stroke, age at first stroke, institutionalisation rates and post-stroke disability.[3,6,9] In acute phase and three months after stroke, women are more disabled in every-day activities (e.g. eating, dressing, grooming, transfer from bed to chair) than men.[1,6] Men are also almost three times more likely to be married at the time of their stroke as opposed to women, who are more likely to be widowed or unmarried and to be living alone.[6,10] These results are concordant with other disability studies.[6,8,11,12] Thus, gender perspective has been increasingly taken into account in health-related research since 1980.[13]

Although functioning is recognized as an important study outcome in men and women after stroke, gender-specific studies are still rare. Based on a biopsychosocial perspective, functioning and the ability to participate in everyday life can be understood not only as a mere consequence of disease and its treatment in contrast to a biomedical perspective. Furthermore, it differs on the level of functioning depending on who the person is and the environmental factors that support or hindrance his or her level of functioning.[2,14,15] This is the perspective of the International Classification of Functioning, Disability and Health (ICF) based on which functioning and disability both on individual and population levels can be described. Cerniauskaite and colleagues show in their systematic literature review that the ICF classification has already been implemented in a wide range of (health) sectors.[16] In addition, they present an overview on the development and application of ICF-based tools such as ICF Core Sets. An ICF Core Set is a selection of categories from the full ICF classification that provides a user-friendly tool for describing functioning and disability in various health care contexts (acute, post-acute und long-term) and for various health conditions like stroke.[17] The *Comprehensive ICF Core Set for stroke* covers the typical spectrum of problems of functioning in persons after stroke and should serve as a standard for multi-professional, comprehensive assessment.[18] In 2005, the *Comprehensive ICF Core Set for stroke* was extended by 36 ICF categories from the ICF Core Sets for persons with neurological conditions in acute and early post-acute phases to enable its use in different clinical situations.[19-21] The current version of this *extended ICF Core Set for stroke* includes 166 categories at the second level of the classification, 59 *Body functions'* categories, 11 *Body structures'* categories, 59 *Activities and participation's* categories and 37 *Environmental factors*. This *extended ICF Core Set*

for stroke can be used to guide the process of assessment, assignment, intervention and evaluation in multi-professional patient care and rehabilitation. Thus, the care and rehabilitation of clients with stroke can be tailored according to their specific needs.[22] There are first efforts for implementing the *ICF Core Set for stroke* in clinical settings.[23,24.]

The *extended ICF Core Set for stroke* is now undergoing worldwide testing and validation using a number of approaches including an international multi-centre validation study and validation from the perspective of health professionals.[25-28] One key aspect is the validation from the patient perspective. While the patient perspective has been implicitly included in the development of the *ICF Core Set for stroke*[29], patients now will be explicitly involved in the process of its validation. An additional aspect of the validation that has not been yet considered is the gender perspective. It is important to identify ICF categories which are common in women and men as well as categories exclusively relevant for either women or men. If the *ICF Core Set for stroke* is to be used in the context of patient-centred care, this information of commonalities and differences between genders is important to explore.

The objective of the study is therefore to add evidence to the content validity of the *extended ICF Core Set for stroke* from persons after stroke, taking into account the gender perspective. The specific aims are 1) to identify areas of functioning and health relevant to women and men after stroke to explore communalities and differences in functioning and health and 2) to explore the content validity of the current version of the *extended ICF Core Set for stroke* taking into account the gender perspective.

Methods and materials

Design

We performed a qualitative study with male and female clients after stroke using individual interviews from 2008 to 2010. Qualitative studies are increasingly accepted in health research and health-related sciences.[13,14,28] They provide the possibility to explore the perspective of those who experience a health problem.[30,31] Compared to quantitative methodology, the qualitative approach promises a greater openness to unexplored concepts or phenomena[32] and focuses on how people understand and interpret their social world from their own perspective.[30]

In addition to an already published ICF Core Set validation study using focus groups with persons after stroke[28], we performed a further study using individual interviews to include a broader spectrum of persons after stroke who were not able to follow a focus-group discussion because of stroke-related impairments. Two different individual interview approaches were conducted: an open approach and an ICF-based approach; both were developed and tested in previous studies.[30]

The study was approved by the Ethics Commission of the Ludwig-Maximilians-University of Munich, Germany (project-number 326-07). It was performed in accordance with the Declaration of Helsinki. All participants of the study signed a written informed consent.

Participants

Participants were women and men diagnosed with stroke according to ICD-10 and the WHO stroke criteria 2006[32] who had been treated in one of three study centres in Germany at any time from 2008 to 2010: rehabilitation centre Nittenau, outpatient department Mutabor Munich and a physiotherapy outpatient department in Regensburg. The inclusion criteria were: stroke as main diagnosis, age of at least 18 years, ability to concentrate 30 minutes at minimum and sufficient knowledge of the language of the country to understand all aspects of the study for purposes of consent. Patients were excluded from the study if they have had surgery and incomplete wound healing, or were diagnosed with psychiatric disorders (e.g. acute major depression, personality disorders).

After having checked the inclusion criteria, trained health professionals in each study centre asked persons diagnosed with stroke to participate. Participants were selected by the maximum variation strategy[33] based on the following criteria: type of stroke, affected hemiplegic side, date of diagnosis, age and gender. Clients with aphasia were included in the study, and the individual interview was performed involving the client and a proxy.

Overall sample size was determined by saturation.[33,34] Saturation refers to the point at which an investigator has obtained sufficient information from the field[34] (see data analysis: saturation of data).

Data collection

All individual interviews were performed in a non-directive manner by the same interviewer (AG). The interviewer was a physiotherapist with expertise in treatment of persons after stroke, ICF and interview procedures. The individual interviews followed an established protocol and were performed according to guidelines including open-ended questions and further instructions (e.g. introduction, procedure of the session, technical aspects).[31] At the beginning of each individual interview, the procedure of the session was explained, and the concept of the ICF was presented to the interviewee in lay terms. Women and men after stroke were asked to report about their experiences of functioning and health after the stroke by using open-ended questions. One of two different individual interview approaches was performed (‘open approach’ or ‘ICF-based approach’).

To apply the *open approach* women and men after stroke were asked in the following open-ended questions to name their problems relating to *body functions and structures*, *activities and participation, personal and environmental factors* (barriers and facilitators) that influenced their everyday life:

'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 yourself, what is important for handling your situation after stroke?
If you think about your environment and your living conditions, what barriers do you experience?
If you think about your environment and your living conditions, what do you find helpful or supportive?'

To apply the *ICF-based approach,* the open-ended questions listed above were presented and additionally ICF chapters of the ICF categories contained in the *extended ICF Core Set for stroke* were included. The following example illustrates an ICF-based question concerning ICF chapter *d4 Self-care*:

'If you think about your daily life, what are your problems, do you have problems in self-care?'

The interviewer presented the questions verbally and visually with help of printed cards. At the end of each individual interview, a summary of the main results was given back to the participant to enable them to verify and amend emergent issues. The individual interviews were audio-recorded and transcribed verbatim using the Olympus DSS-system. The interviewer made debriefing notes to review the course of each individual interview. The two individual interview approaches were performed alternately.

Data analysis

Data analyses were performed following a three-step procedure.

Qualitative analysis

The meaning condensation method[35] was used for qualitative data analysis following a three-step procedure: (1) Transcripts of the individual interviews were read in order to get an overview over the collected data. Data were divided into units of meaning. (2) 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.[36] Therefore, a meaning-unit division

did not follow linguistic grammatical rules. Rather, the text was divided where the researcher discerned a shift in meaning.[35] (3) Concepts contained in the meaning units were identified. A meaning unit could contain more than one concept.

Identification of aspects of functioning and health important to women and men after stroke

The identified concepts were linked to ICF categories based on established linking rules[37], which enable the linking of concepts to ICF categories in a systematic and standardised way. According to these linking rules, two ICF-trained health professionals (AG, BK) linked each concept to the ICF category representing this concept most precisely (Table 1). One concept could be linked to one or more ICF categories depending on the number of themes contained in the concept. Consensus between the two health professionals was used to decide which ICF category should be linked to each meaning unit. In case of disagreement between the two health professionals, the suggested categories were discussed by a team consisting of three health professionals (AG, BK, MC). Based on this discussion a joint decision was made.

Saturation of data

Saturation was defined as the point during data collection and analysis when the linking of the concepts of two consecutive individual interviews revealed no additional second-level categories from the *extended ICF Core Set for stroke*. This operationalization of saturation was established in several qualitative studies aiming to validate ICF Core Sets from the patient perspective.[28,30] Saturation was calculated separately according to women and men, as well as according to interview approach (open-ended, ICF-based approach).

Table 1 Scheme of the qualitative data analysis: Linking process: an example

Transcript with **meaning units**		Concept	ICF category
	Qualitative analysis	*Linking*	
Examples for open questions			
Interviewer:	*Let's go on to the next question. If you think about your daily life what are your problems?*		
Interview 1:	Firstly, **to be employed at this stage is impossible**, because you've got so many distractions and malfunctions, you wouldn't be able to do your job properly.	Employment is impossible	d850 Remunerative employment
Interviewer:	*Do you have further experiences or problems in daily life ….*		
Interview 16:	**To concentrate on a discussion with more than one person** becomes a problem in daily life.….	Concentrate on discussion with more than person	b140 Attention functions d160 Focusing attention d3551 Discussion with many people
Examples for ICF-based questions			
Interviewer:	*Now, I want to ask you, if you think about your daily life do you have problems in self-care?*		
Interview 11*:*	Yes, I **need help to go to the toilet**. In the morning I have **problems to dress myself**.	Problems with toileting Problems with dressing	d530 Toileting d540 Dressing
Interviewer:	*Now, the next question: If you think about your daily life do you have problems in domestic life?*		
Interview 19:	Without my arm **I tried to cook but it is not possible** at the moment	Problems in cooking	d630 Preparing meals

Comparison of identified ICF categories with the extended ICF Core Set for stroke

The identified categories for women, men and both genders were compared to the categories of the *extended ICF Core Set for stroke* taking into account the interview approach. Since the ICF categories are arranged in a hierarchical code system, the second-level categories of the *ICF Core Set* were considered confirmed when the corresponding third- or fourth-level category to which they belong had been identified (e.g., 'd470 *Using transportation*' confirmed by 'd4702 *Using public motorized transportation'*).

An ICF category was regarded as an additional category if it emerged from the individual interviews and had not been included in the current version of the *extended ICF Core Set for stroke*.

Accuracy of the analysis

To ensure the accuracy of data analysis, the following two strategies were adopted:
(1) Multiple coding: qualitative analysis and linking to the ICF of the first individual interview of the open and ICF-based approach was carried out by two health professionals (AG and BK) in order to achieve agreement concerning the implementation of the linking rules. Agreements and specifications when applying the rules were documented. *(2)* Peer review: after completing the multiple coding of the first individual interview in both approaches, a peer review was performed. One interview of each interview approach (in total 6 out of 24 interviews) was randomly selected and the concepts were identified by a second health professional. Three interviews of each interview approach were randomly selected and linked by a second health professional.

The degree of agreement between the two health professionals regarding linked ICF categories was calculated by kappa statistics with 95%-bootstrapped confidence intervals.[38,39] The values of the kappa coefficient generally range from 0 to 1 whereas 1 indicates perfect agreement and 0 indicates no additional agreement beyond what is expected randomly. The data analysis was performed with SAS for windows V9.1 (Copyright © 2002–2003 by SAS Institute Inc., Cary, NC, USA).

Results

A total of 12 German-speaking women and 12 men were involved in this study. Participants' characteristics are summarized in table 2. Saturation of data was reached after having performed 12 individual interviews stratified by gender and interview approach respectively. The interview sessions lasted from 52 minutes to 126 minutes.

Table 2 Characteristics of participants

Characteristics of participants	women	men	Total
Number of participants after stroke, n	12	12	24
Interviews with persons with stroke, n	10	10	20
Interviews with proxies of persons with stroke-related aphasia, n	1*	3**	5
Age [range]	65 [36;85]	53 [40;85]	59 [36;85]
Hemiplegic side of body (right), n	5	13	18
Retired, n	10	10	20
Disease duration (months), mean [range]	6.7 [1-24]	15.5 [1-45]	12.6 [1-45]
Interview approach, n (open approach/ICF-based approach)	5/7	7/5	12/12

* In the individual interview with a woman with stroke-related aphasia her husband answered the questions.

** In the individual interviews with the men with stroke-related aphasia the daughter, the female cohabitant and the sister and his brother-in-law answered the questions, respectively. In all interviews with proxies the person with stroke-related aphasia joined the interview.

Identification of aspects of functioning and health important to women and men after stroke

In total, 5346 concepts were identified in the qualitative analysis of the transcribed interviews of women and men (women: n= 2530; men: n= 2816).

The concepts identified in the qualitative analysis were linked to 342 ICF categories from first to fourth level of the classification. According to the ICF structure, this corresponds to 181 second-level categories. With respect to the 181 second-level ICF categories, there were 129 ICF categories commonly identified for both genders, 19 identified only in the group of women and 33 only in the group of men (Figure 1).

In addition to the identified ICF categories, some concepts emerged which are not included in the ICF such as volition, walking barefoot, need of time and breaks, time for compensation, reaction rate, and career perspective. A total of 62 concepts could not be linked to ICF categories such as quality of life in general, disease management, time-related aspects, and variability of functioning. Thirty-four concepts were allotted to the component *Personal factors* which has not yet been classified,

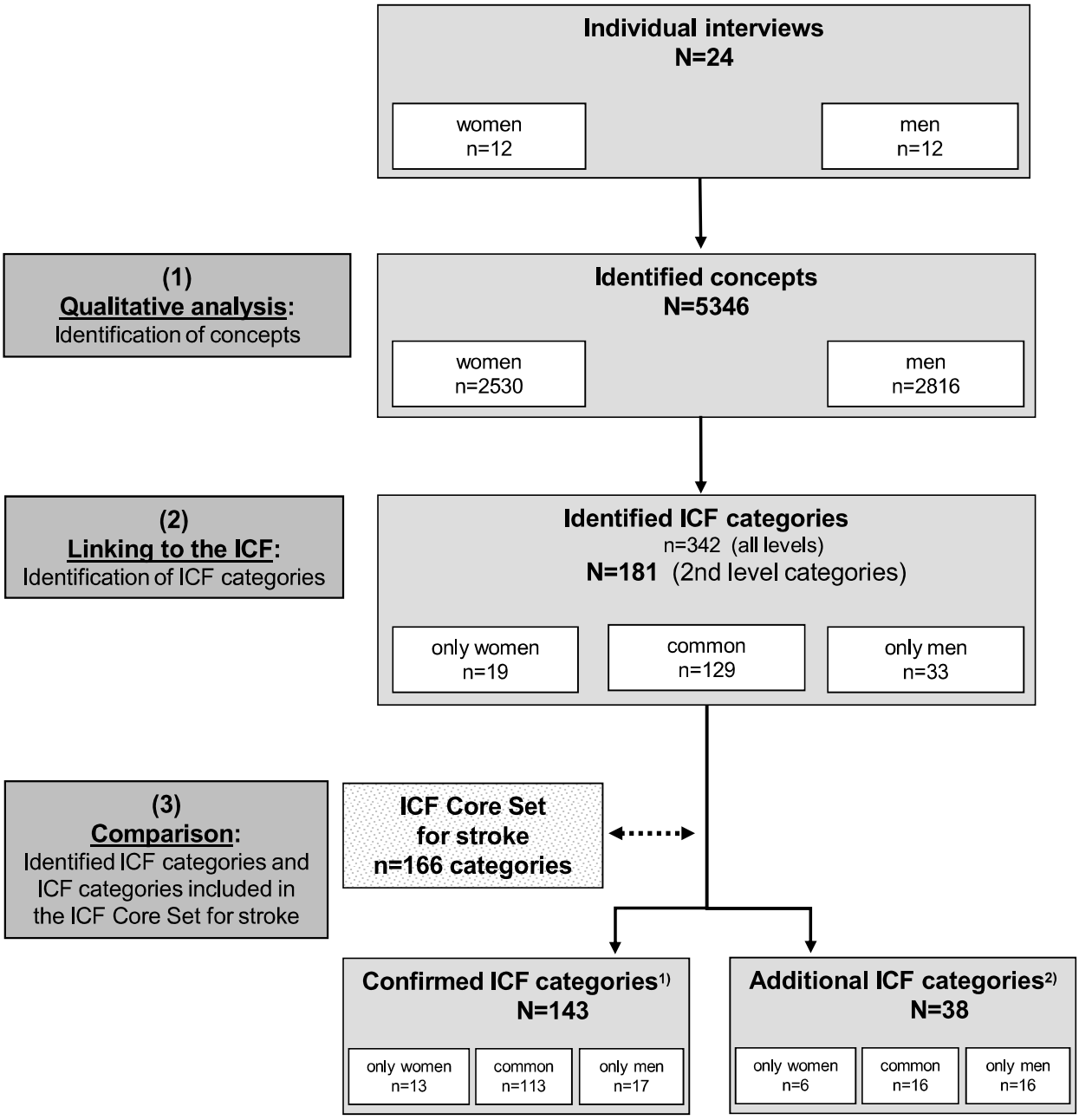
Comparison of identified ICF categories with the extended ICF Core Set for stroke

One-hundred forty three of 166 categories included in the *extended ICF Core Set for stroke* were confirmed (women: n=13; men: n=17; both genders: n=113). An overview of the results of this study is shown in Figure 1 taking into account the gender of the participants.

The exact distribution according to the ICF components is summarized in tables 3-6 representing ICF categories of the *extended ICF Core Set for stroke* that were confirmed in women, men and in both genders. Table 7 displays 38 additional ICF categories identified from the participants of this study but not included in the *extended ICF Core Set for stroke*. Of these, 6 categories were identified only in women, 16 only in men and 16 in both genders.

Accuracy of the analysis

The kappa coefficients and 95%-bootstrapped confidence intervals for interviews performed with women and men were 0.65 [0.60; 0.69] and 0.65 [0.62; 0.69], respectively. The coefficients for the open approach and the ICF-based approach were 0.68 [0.64; 0.71] and 0.76 [0.73; 0.78], respectively.



1) ICF categories included in the ICF Core Set for stroke
2) ICF categories not included in the ICF Core Set for stroke

Figure 1: Identification of aspects of functioning and health important to women and men after stroke

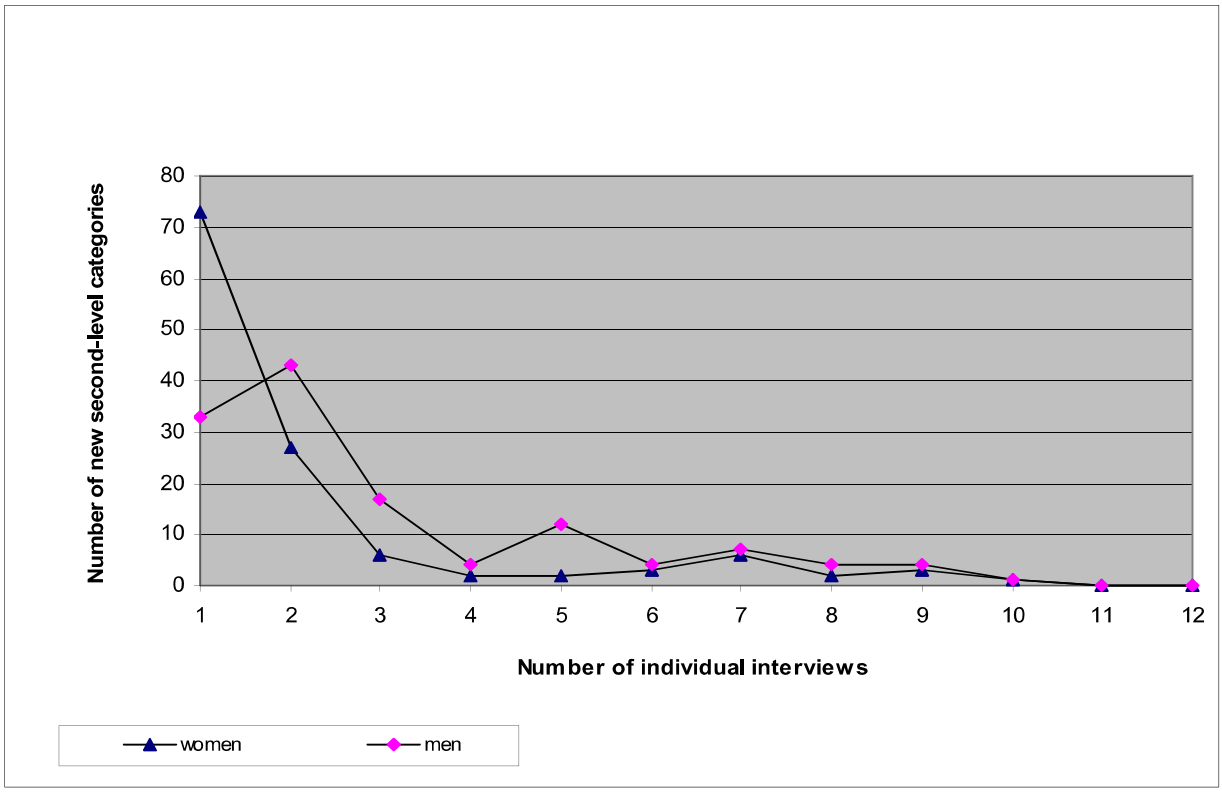


Figure 2 Saturation of the qualitative data in the individual interviews taking into account the gender perspective: identification of new second-level categories

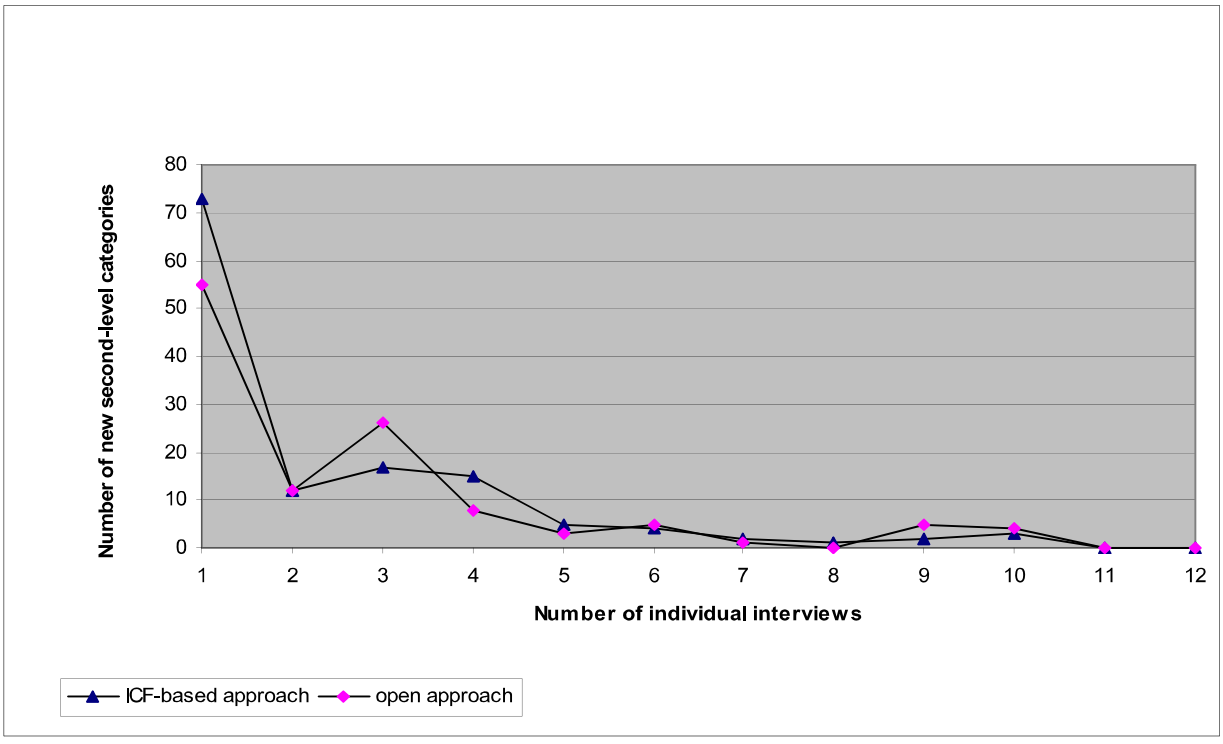


Figure 3 Saturation of the qualitative data in the individual interviews taking into account the interview approach: identification of new second-level categories

Table 3 *Body functions* (b) part 1: Reported ICF categories (second-level) by women and men. ICF categories shown in **bold typeface** are categories included in the *extended ICF Core Set for stroke* and confirmed from the women or men only. Confirmed ICF categories of the *extended ICF Core Set for stroke* are shown in normal typeface. **o= open approach / i= ICF-based approach**

ICF code	ICF Title	women	men
Chapter 1 Mental functions			
b110	Consciousness functions	o	oi
b114	Orientation functions		
b117	Intellectual functions		
b126	Temperament and personality functions	oi	oi
b130	Energy and drive functions	oi	oi
b134	Sleep functions	oi	oi
b140	Attention functions	oi	oi
b144	Memory functions	oi	oi
b147	Psychomotor functions		
b152	Emotional functions	oi	oi
b156	Perceptual functions	oi	oi
b160	Thought functions	oi	oi
b164	Higher-level cognitive functions	oi	oi
b167	Mental functions of language	oi	oi
b172	**Calculation functions**		**i**
b176	**Mental Functions of sequencing complex movements**		**o**
b180	Experience of self and time functions	oi	oi
Chapter 2 Sensory functions and pain			
b210	Seeing functions	oi	oi
b215	**Functions of structures adjoining the eye**		**oi**
b230	**Hearing functions**		**i**
b235	Vestibular functions	oi	oi
b240	Sensations associated with hearing and vestibular function	oi	oi
b260	Proprioceptive functions	o	i
b265	Touch function	oi	oi
b270	Sensory functions related to temperature and other stimuli	oi	oi
b280	Sensation of pain	oi	oi
Chapter 3: Voice and speech functions			
b310	Voice functions	i	i
b320	Articulation functions	i	oi
b330	Fluency and rhythm of speech functions	oi	oi
b340	Alternative vocalization functions	o	o

Table 3 *Body functions* (b) part 2: Reported ICF categories (second-level) by women and men. ICF categories shown in **bold typeface** are categories included in the *extended ICF Core Set for stroke* and confirmed from the women or men only. Confirmed ICF categories of the *extended ICF Core Set for stroke* are shown in normal typeface. **o= open approach / i= ICF-based approach**

ICF code	ICF Title	women	men
Chapter 4: Functions of the cardiovascular, haematological, immunological and respiratory systems			
b410	Heart functions	oi	i
b415	Blood vessel functions	oi	oi
b420	Blood pressure functions	oi	i
b430	Haematological system functions	oi	o
b435	**Immunological system functions**	**oi**	
b440	Respiration functions	i	i
b450	Additional respiratory functions	oi	i
b455	Exercise tolerance functions	oi	oi
Chapter 5: Functions of the digestive, metabolic and endocrine systems			
b510	**Ingestion functions**	**oi**	
b515	Digestive functions	i	o
b525	Defecation functions	i	o
b530	**Weight maintenance functions**		**i**
b535	**Sensations associated with the digestive system**	**oi**	
b540	**General metabolic functions**		**oi**
b545	Water, mineral and electrolyte balance functions		
b550	Thermoregulatory functions		
Chapter 6: Genitourinary and reproductive functions			
b620	**Urination functions**	**i**	
b630	Sensations associated with urinary functions		
b640	Sexual functions	i	o
Chapter 7: Neuromusculoskeletal and movement-related functions			
b710	Mobility of joint functions	i	oi
b715	Stability of joint functions	i	i
b730	Muscle power functions	oi	oi
b735	Muscle tone functions	oi	oi
b740	**Muscle endurance functions**	**i**	
b750	Motor reflex functions	i	i
b755	Involuntary movement reactions	oi	oi
b760	Control of voluntary movement functions	oi	oi
b770	Gait pattern functions	oi	oi
Chapter 8: Functions of the skin and related structures			
b810	**Protective functions of the skin**		**oi**

Table 4 *Body structures* (s): Reported ICF categories (second-level) by women and men. ICF categories shown in **bold typeface** are categories included in the *extended ICF Core Set for stroke* and confirmed from the women or men only. Confirmed ICF categories of the *extended ICF Core Set for stroke* are shown in normal typeface. **o= open approach / i= ICF-based approach**

ICF code	ICF Title	women	men
Chapter 1: Structures of the nervous system			
s110	Structure of brain	oi	i
s120	Spinal cord and related structure		
s130	Structure of meninges		
Chapter 2: The eye, ear and related structures			
Chapter 3: Structures involved in voice and speech			
Chapter 4: Structures of the cardiovascular, immunological and respiratory systems			
s410	**Structure of cardiovascular system**	**oi**	
s430	**Structure of respiratory structure**		**i**
Chapter 5: Structures related to the digestive, metabolic and endocrine systems			
s530	Structure of stomach		
Chapter 7: Structures related to movement			
s710	**Structure of head and neck region**		**oi**
s720	Structure of shoulder region	i	i
s730	Structure of upper extremity	oi	oi
s750	Structure of lower extremity	oi	oi
Chapter 8: Skin and related structures			
s810	Structure of areas of skin		

Table 5 *Activities and participation* (d) part 1: Reported ICF categories (second-level) by women and men. ICF categories shown in **bold typeface** are categories included in the *extended ICF Core Set for stroke* and confirmed from the women or men only. Confirmed ICF categories of the *extended ICF Core Set for stroke* are shown in normal typeface. **o= open approach / i= ICF-based approach**

ICF code	ICF Title	women	men
Chapter 1: Learning and applying knowledge			
d110	Watching	i	oi
d115	**Listening**	**o**	
d120	**Other purposeful sensing**		**o**
d130	**Copying**		**oi**
d135	Rehearsing	oi	oi
d155	Acquiring skills	oi	oi
d160	Focusing attention	oi	o
d166	Reading	oi	oi
d170	Writing	i	oi
d172	Calculating	o	o
d175	Solving problems		
d177	Making decisions	o	o
Chapter 2: General tasks and demands			
d210	Undertaking a single task		
d220	**Undertaking a multiple task**	**oi**	
d230	Carrying out daily routine	oi	oi
d240	Handling stress and other psychological demands	oi	oi
Chapter 3: Communication			
d310	**Communication with receiving spoken messages**	**i**	
d315	Communication with receiving nonverbal messages		
d325	Communication with receiving written messages		
d330	Speaking	oi	oi
d335	Producing nonverbal messages	i	oi
d345	**Producing messages in formal sign messages**		**o**
d350	Conversation	oi	oi
d360	Using communication devices and techniques	i	oi
Chapter 4: Mobility			
d410	Changing basic body position	oi	oi
d415	Maintaining a body position	oi	oi
d420	Transferring oneself	i	oi
d430	Lifting and carrying objects	oi	oi
d440	Fine hand use	oi	oi
d445	Hand and arm use	oi	oi
d450	Walking	oi	oi
d455	Moving around	oi	oi
d460	Moving around in different locations (d455)**	oi	oi
d465	Moving around using equipment	oi	oi
d470	Using transportation	oi	oi
d475	Driving	oi	oi

Table 5 *Activities and participation* (d) part 2: Reported ICF categories (second-level) by women and men. ICF categories shown in **bold typeface** are categories included in the *extended ICF Core Set for stroke* and confirmed from the women or men only. Confirmed ICF categories of the *extended ICF Core Set for stroke* are shown in normal typeface. **o= open approach / i= ICF-based approach**

ICF code	ICF Title	women	men
Chapter 5: Self-care			
d510	Washing oneself	oi	oi
d520	Caring for body parts	oi	i
d530	Toileting	i	oi
d540	Dressing	i	oi
d550	Eating	oi	i
d560	**Drinking**	**oi**	
d570	Looking after one's health	oi	oi
Chapter 6: Domestic life			
d620	Acquisition of goods and services	oi	oi
d630	Preparing meals	oi	oi
d640	Doing housework	oi	oi
Chapter 7: Interpersonal interactions and relationships			
d710	**Basic interpersonal interactions**	**oi**	
d750	Informal social relationships	oi	oi
d760	Family relationships	oi	oi
d770	Intimate relationships	oi	oi
Chapter 8: Major life areas			
d845	Acquiring, keeping and terminating a job	i	i
d850	Remunerative employment	oi	oi
d855	Non-remunerative employment	i	i
d860	**Basic economic transactions**		**o**
d870	**Economic self-sufficiency**		**oi**
Chapter 9: Community, social and civic life			
d910	Community life	i	o
d920	Recreation and leisure	oi	oi
d930	Religion and Spirituality		
d940	Human rights		

Table 6 *Environmental factors* (e): Reported ICF categories (second-level) by women and men. ICF categories shown in **bold typeface** are categories included in the *extended ICF Core Set for stroke* and confirmed from the women or men only. Confirmed ICF categories of the *extended ICF Core Set for stroke* are shown in normal typeface. **o= open approach / i= ICF-based approach**

ICF code	ICF Title	women	men
Chapter 1:	***Products and Technology***		
e110	Products or substances for personal consumption	oi	oi
e115	Products and technology for personal use in daily living	oi	oi
e120	Products and technology for personal indoor and outdoor mobility and transportation	oi	oi
e125	Products and technology for communication	oi	oi
e135	Products and technology for employment		
e150	Design, construction and building products and technology of buildings for public use	i	oi
e155	Design, construction and building products and technology of buildings for private use	oi	oi
e165	Assets	i	oi
Chapter 2:	***Natural environment and human-made changes to environment***		
e210	**Physical geography**	**i**	
e240	Light		
e250	Sound		
Chapter 3:	***Support and relationships***		
e310	Immediate family	oi	oi
e315	Extended family	oi	i
e320	Friends	oi	i
e325	Acquaintances, peers, colleagues, neighbours and community members	oi	oi
e340	**Personal care providers and personal assistants**	**i**	
e355	Health professionals	oi	oi
e360	Other professionals	i	o
Chapter 4:	***Attitudes***		
e410	Individual attitudes of immediate family members	oi	oi
e415	Individual attitudes of extended family members	i	oi
e420	Individual attitudes of friends	oi	oi
e425	Individual attitudes of acquaintances, peers, colleagues, neighbours and community members	oi	oi
e440	Individual attitudes of care providers and personal assistance		
e450	Individual attitudes of health professionals	oi	o
e455	Individual attitudes of health-related professionals		
e460	**Societal attitudes**		**o**
e465	Social norms, practices and ideologies		
Chapter 5: Services, systems and policies			
e515	**Architecture and construction services, systems and policies**		**o**
e525	**Housing services, systems and policies**		**o**
e535	Communication services, systems and policies		
e540	Transportation services, systems and policies	oi	oi
e550	Legal services, systems and policies	i	i
e555	Associations and organizational services, systems and policies	i	oi
e570	Social security services, systems and policies	i	oi
e575	General social support services, systems and policies	oi	o
e580	Health services, systems and policies	oi	oi
e590	Labour and employment services, systems and policies	i	o

Table 7 Additional ICF categories: ICF categories (second-level) identified by women and men which are not included in the *extended ICF Core Set for stroke*. ICF categories shown in **bold typeface** are categories reported from women or men only. Additional ICF categories of the *extended ICF Core Set for stroke* are shown in normal typeface. **o= open approach / i= ICF-based approach**

ICF code	ICF Title	women	men
	BODY FUNCTIONS		
b220	**Sensations associated with the eye and adjoining structures**	**i**	
b250	Taste function	oi	i
b555	**Endocrine gland functions**		**oi**
b720	Mobility of bone functions	i	i
b765	Involuntary movement functions	i	o
b780	Sensations related to muscles and movement functions	i	oi
b850	**Functions of hair**		**o**
b860	**Functions of nail**		**o**
	BODY STRUCTURES		
s220	**Structure of eyeball**	**i**	
s320	Structure of mouth	i	i
s760	**Structure of trunk**		**oi**
s770	Additional musculoskeletal structures related to movement	i	oi
s830	**Structure of nails**		**o**
s840	**Structure of hair**		**o**
	ACTIVITIES AND PARTICIPATION		
d145	**Learning to write**	**oi**	
d163	Thinking	o	o
d355	**Discussion**		**oi**
d435	Moving objects with lower extremities	oi	oi
d610	**Acquiring a place to live**		**o**
d650	Caring for household objects	i	oi
d660	Assisting others	oi	o
d720	**Complex interpersonal interactions**	**i**	
d730	Relating with strangers	i	o
d740	**Formal relationships**		**o**
d840	**Apprenticeship (work preparation)**		**o**
d865	**Complex economic transaction**		**oi**
d950	**Political life and citizenship**		**i**
	ENVIRONMENTAL FACTORS		
e130	**Products and technology for education**		**oi**
e140	**Products and technology for culture, recreation and sport**		**o**
e215	**Population**	**i**	
e220	Flora and fauna	i	i
e225	Climate	i	oi
e330	**People in positions of authority**		**o**
e345	Strangers	i	oi
e350	Domesticated animals	i	oi
e430	Individual attitudes of people in positions of authority	o	o
e520	**Open space planning services, systems and policies**		**i**
e565	**Economic services, systems and policies**	**i**	

Discussion

With this qualitative study we add evidence to the content validity of the *extended ICF Core Set for stroke* from persons after stroke. It was the first ICF Core Set validation study from the patient perspective taking into account the gender perspective to explore communalities and differences of women and men in functioning and health. Although most of the areas of functioning and health are common in both genders, we still identified some gender differences in our study. In line with this, most of the categories of the *extended version of the ICF Core Set for stroke* were confirmed by women and men. Only a small number of categories were not common in both.

The ICF categories of the *extended ICF Core Set for stroke* that were only named by women, such as '*b535 Sensations associated with the digestive system', 'b620 Urination functions', or 'd710 Basic interpersonal interactions', 'e340 Personal care providers and personal assistants'*, and others only by men, such as '*b172 Calculation functions', 'b540 General metabolic functions', 'd860 Basic economic transactions', 'd870 Economic self-sufficiency' or 'e525 Housing services, systems and policies'* and others showed the different perspectives of women and men with regard to functioning and disability from their respective perspectives. In addition, 38 ICF categories not included in the *extended ICF Core Set for stroke* covering all ICF components were named by women, men or common to both genders. Some of these additional ICF categories need special clarification and will be discussed in the following paragraphs.

Firstly, we want to discuss **additional** categories not included in the *extended ICF Core Set for stroke* and identified in the individual interviews of both genders. From the *Body structures'* component the ICF category 's770 *Additional musculoskeletal structure related to movement'* was reported by women and men. This is a typical category which is affected after stroke in combination with non-physiological muscle tone and impaired movement control or shoulder pain.[40,41] In addition, other movement-related *Body functions'* categories which are not currently included in the *extended ICF Core Set for stroke* were identified, namely 'b765 *Involuntary movement functions'* and 'b780 *Sensations related to muscles and movement functions'*.

To assess muscle sensations, such as pain and other sensations, one has to rely on self-reporting of persons suffering a disease. Therefore, it is not surprising that this category is identified in this study, in which participants are asked explicitly about their problems.[28] This means for the use of ICF Core Sets in daily clinical routine, a Core Set offers a list of the most important ICF categories for assessing clients with a specific health condition, such as stroke. Moreover, if it is necessary for the user's purposes, additional ICF categories from the whole ICF classification could be added individually.[17]

The category 'd435 *Moving objects with lower extremities'* was an important additional ICF category consequently identified in all interviews with women and men. Clients discussed driving a car and its corresponding abilities intensively in almost all individual interviews.[28,42] This reflects the importance of the recovery of movement abilities of lower extremities like pressing a gas pedal or

the brakes in a car. From the *Activities and participation's* chapter 6 *Domestic life* women and men addressed two additional ICF categories, namely 'd650 *Caring for household objects'* and 'd660 *Assisting others'.* Despite the fact, that stroke is often connected with requiring support from other people such as family, partner, or health care professionals in daily living[3,12,43] the participants of this study reported about their changed life-situation. After having a stroke they need support in simple every-day tasks, such as repairing equipment, preparing a meal, or grasping and holding a glass. Furthermore, they are dependent on others and they need help. Moreover, their social role as grandparents for example has changed and they are no longer able to care for their grandchildren.

Women and men after stroke also identified a large number of *Environmental factors'* categories which have an impact on nearly all aspects of everyday life. Not included in the ICF Core Set yet are 'e225 *Climate'* to 'e345 *Strangers*' and 'e350 *Domesticated animals'*, as well as 'e430 *Individual attitudes of people in positions of authority*'.

In the following two paragraphs we discuss some additional categories identified only in women and men, respectively. Women's additional categories focus on activities like 'd145 *Learning to write'* and 'd720 *Complex interpersonal interactions'.* In line with the second mentioned category, Reeves and colleagues point out that the societal impact of poor stroke outcomes in women is compounded by the fact that elderly women are more likely to live alone and are socially isolated.[3]

The additional categories only identified in the interviews with men were for example: 's760 *Structures of trunk'*, 'd355 *Discussion'*, 'd610 *Acquiring a place to live'*, 'd740 *Formal relationships'*, 'd840 *Apprenticeship (work preparation)'*, 'd865 *Complex economic transaction'*, 'd950 *Political life and citizenship'*. The category 'd865 *Complex economic transactions'* was an emphasised topic reported by men. Men were also concerned about the support and relationship to persons at their workplace, especially to their managers as addressed by ICF category 'e330 People in positions of authority'. This environmental factor can be a facilitator or barrier important for persons after stroke because long-term (chronic) illness such as stroke and its consequences are strongly associated with an insecure return-to-work.[44-46]

In this study, differences but also commonalities in functioning and disability of women and men after stroke were explicitly investigated. This result is underlined by different studies[3,14,47] and can be seen as a hint for health professionals for taking the gender perspective into account in their daily practice. Consequently, in every day clinical practice providers of rehabilitation and health professionals are aware of differences but also commonalities in functioning and disability of women and men after stroke and have specific knowledge about including gender-specific aspects in their clinical routine.[3,14] However, Andersson and colleagues[15] state that there is a lack of awareness and knowledge of gender differences up to now and that they have to be taken into account in every day clinic, for example in goal setting.

From the responses of women and men we also identified some issues which were coded as 'not covered' by the ICF classification. The majority of these issues do not refer to aspects of functioning and health as defined by the ICF classification. These issues mainly cover time-related issues (e.g., 'need of time and breaks', 'time for compensation'). Since the ICF does not cover time-related issues, such issues could not be linked to the ICF. However, other 'not covered' issues identified in this study are clearly related to functioning and health as defined by the ICF (e.g., 'reaction rate', 'volition', 'walking barefoot'). Most aspects came up in both genders. Some of these aspects that are not covered by the ICF classification should be included in the updated process of the ICF, which has already been initiated by WHO.[48]

Minor differences were seen in personal factors in women concerning religion or the influence of their faith. In contrast, men were talking about 'soul' in context of spirituality. Women made statements referring to early stroke warning signs that are not covered by the ICF classification; this issue was not reported by men.

It is worthwhile discussing some methodological aspects of our study. When starting our study in 2008, we followed the established methods for the validation of ICF Core Sets and used the two approaches – the open approach and the ICF-based approach to address functioning and health as broadly as possible.[28,30,31] Coenen et al. have recently published a methodological paper on the comparison of these two approaches and recommend the ICF-based approach as the most appropriate approach in validating ICF Core Sets from the patient perspective.[30] Our results support this recommendation. The questions of the ICF-based approach are formulated in line with the ICF chapters of categories included in the ICF Core Set, motivate the participants of the qualitative study to provide more information and consequently a larger number of ICF categories can be confirmed based on it. Furthermore, having the wording of respective ICF chapters in mind, the participants' statements in the ICF-based approach are more precise compared to statements from the open approach. This facilitates the linking of the statements of the ICF-based approach and results in a higher kappa coefficient for the linking procedure.

It is important to mention that several strategies were used to improve and verify the trustworthiness of the qualitative data: *(1) Triangulation* to ensure the comprehensiveness of data. We included triangulation by using two data analysts (investigator triangulation: multiple coding).[49,50] *(2) Continuous data analysis* was used according to Pope et al.[51] *(3) Reflexivity* was assured by conducting a research diary for the documentation of memos concerning the design, data collection and analysis of the study. *(4) Clear exposition* was assured by using established guidelines for data collection and analysis. *(5)* Finally, a *peer review* was performed. The kappa coefficients of both approaches for the accuracy of the peer review are comparable to other studies[28,30] and can be regarded as 'substantial agreement'.[52]

There are also some **limitations** of this study that require special mentioning. In our study, a small sample size of 12 women and 12 men was used to obtain the required level of rich and meaningful data. In qualitative research, sample sizes are typically small because intensive data analysis is required.[53] In addition, qualitative studies focus on the generation of hypotheses rather than on testing of research questions. We recommend investigating larger samples with persons after stroke using quantitative studies to examine gender differences in functioning and health and to control the outcome for confounders like age, employment status and cultural background. Furthermore, our sample consists of participants from Germany, Austria, Argentina, Czech Republic and Russia living in Germany. We suggest that our methods could be used in similar studies in other countries to establish a cross-cultural perspective. In our case, the linking process was performed by two health professionals according to established linking rules.[37] However, it remains unclear whether other health professionals would have decided differently. Finally, we followed the strategy of saturation during data analyses with the criteria of two consecutive individual interviews revealing no new second-level categories included in the *extended ICF Core Set for stroke* with respect to previous individual interviews. Participants in a 25th individual interview might still report new themes and concepts not yet reported.

This study confirms that the experience of functioning and disability after stroke is different for women and men. The validity of the *extended ICF Core Set for stroke* could be almost entirely confirmed, since it does not only include those areas of functioning and disability relevant to both genders, but also of those exclusively relevant to women and men. However, several additional categories that are not represented in the current version of the ICF Core Set arose either from women or men.

Conclusions

This study confirms that the experience of functioning and disability after stroke is slightly different for women and men. Based on the ICF conceptualisation of functioning and disability, functioning can substantially differ in subjects with the same health condition, since the interaction with environmental factors is unique and varies from case to case.

The validity of the *extended ICF Core Set for stroke* could be confirmed, since it does not only include those areas of functioning and disability relevant to both genders, but also of those exclusively relevant to women and men. However, several additional categories which are not represented in the current version of the ICF Core Set arose either from women or men. Further research on additional ICF categories not yet included in the *extended ICF Core Set for stroke* is needed. The results of this study will be considered when the final version of the *extended ICF Core Set for stroke* is agreed on.

1) The content validity of the *extended ICF Core Set for stroke* is confirmed by the perspective of women and men after stroke showing a broad spectrum of communalities; only minor gender differences regarding the categories included in the *extended ICF Core Set for stroke* were identified.

2) Additional categories from the whole ICF classification can be added to the *extended ICF Core Set for stroke* to follow a client-centred approach taking into account the gender perspective.

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Declaration of interest

The authors report no declarations of interests. This study forms part of the doctoral thesis of the first author at the Faculty of Medicine, Ludwig-Maximilians-University of Munich, Germany.

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IV. Research article 3:

Content validity of the Extended ICF Core Set for stroke: an international Delphi survey of physical therapists

Glässel A, Kirchberger I, Kollerits B, Amann E, Cieza A.

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Abstract

Background and Purpose: The ”Extended ICF Core Set for stroke” is an application of the International Classification of Functioning, Disability and Health (ICF) and represents the typical spectrum of problems in functioning of persons with stroke. The objective of this study was to validate this ICF Core Set from the perspective of physical therapists.

Methods: Physical therapists experienced in stroke intervention were asked about the patients' problems, patients' resources and aspects of environment that physical therapists treat in persons with stroke in a three-round electronic mail survey using the Delphi technique. The responses were linked to the ICF by two persons. The degree of agreement was calculated using Kappa statistic.

Results: One hundred and twenty-five physical therapists from 24 countries named 4.793 problems treated by physical therapists in persons with stroke. They identified ten second-level ICF categories which are currently not represented in the Extended ICF Core Set for stroke. Twelve responses of the participants were linked to the ICF component Personal Factors and 15 responses were not covered by the current version of the classification. The Kappa coefficient for the linking agreement between the two persons was 0.39 (95% bootstrapped CI 0.34 - 0.41).

Discussion and Conclusion: The current version of Extended ICF Core Set for stroke largely covers what the physical therapists agreed upon to take care of in their interventions. However, some aspects of functioning emerged which are not yet covered and may need further investigation.

Introduction

Worldwide about 15 million people experience a stroke each year 1. Although stroke is one of the leading causes of mortality, 40-77% of the affected persons are still alive one year after the event [2]. One third of the survivors face long-term disability. Disability after stroke appears in form of neurological dysfunctions (e.g. motor, sensory, visual), limited ability to perform activities of daily living (ADL), as well as neuropsychological deficits (memory, attention, language) [3]. Taking the diversity and complexity of consequences of a stroke into account, an inter-disciplinary approach is most appropriate. Rehabilitation after stroke requires an inter-professional team including physicians, psychologists, occupational therapists, nurses, social workers and physical therapists [4, 5].

Physical therapists are described as one of the key components of the inter-disciplinary team in stroke rehabilitation [6, 7, 8]. Particularly, physical therapy aims at restoring motor control in locomotion, improving upper limb function, enhancing the ability of persons with stroke to cope with existing deficits in ADL and achieving the best possible participation in community. In order to reach these rehabilitation goals, physical therapists use different neurological intervention approaches and instruct and advise the persons with stroke and their families regarding prevention of complications, such as falls and shoulder pain [9,10].

To optimize interventions aimed at improving function and minimizing disability, a proper understanding of an individuals' functioning and health status is needed [4]. The International Classification of Functioning, Disability and Health (ICF) is based on an integrative model of health that provides a holistic, multidimensional and interdisciplinary understanding of health and health-related conditions [11]. According to the ICF, the problems associated with a disease may concern *Body Functions* and *Body Structures* and the performance of *Activities and Participation* in life situations. Health states and the development of disability are modified by contextual factors which include environmental factors and personal factors [11]. The ICF comprises 1454 ICF categories from the components *Body Functions*, *Body Structures, Activities and Participation* and *Environmental factors* which are organized in a hierarchical structure (see Figure 1). Categories are divided into chapters, which constitute the first level of specification. Higher-levels categories (e.g. second, third **or** fourth level) are more detailed.

Both the content and the structure of the ICF point out their potential value for rehabilitation professions, especially physical therapists [5]. The ICF is increasingly applied in physiotherapy and rehabilitation especially in the field of neurorehabilitation, to facilitate interdisciplinary team communication, to structure the rehabilitation process, for goal setting and assessment, as well as for documentation and reporting [12, 13]. Recently, ICF-based documentation tools have been developed to be used in interdisciplinary rehabilitation management [14].

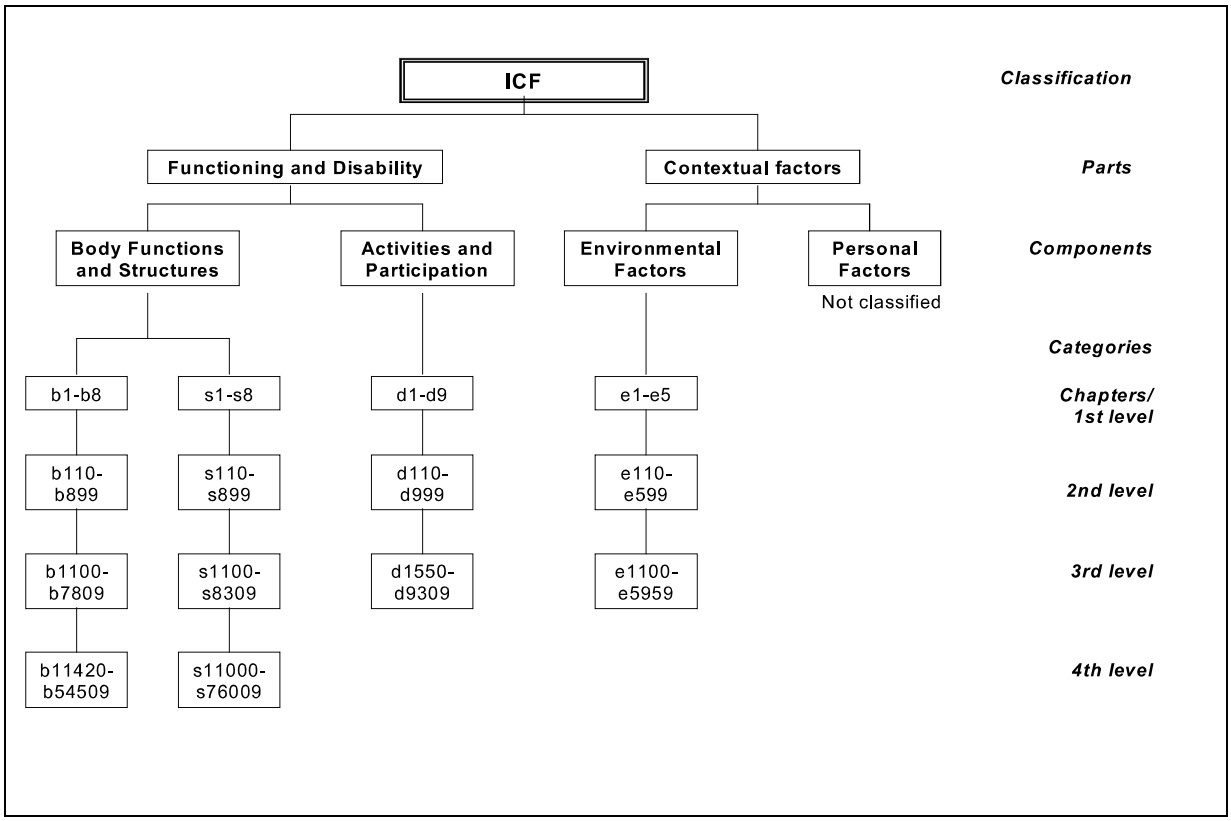

Figure 1: Structure of the WHO International Classification of Functioning, Disability and Health (ICF) (with permission of the World Health Organization (WHO). All rights are reserved by the WHO)

However, the ICF as a whole is not feasible for use in clinical routine application. To facilitate the implementation of the ICF into clinical practice, so-called 'ICF Core Sets' have been developed [15, 16]. ICF Core Sets include a selection of ICF categories relevant for persons with a specific health condition or a specific intervention phase, e.g. acute or post-acute care [15]. The development of the ICF Core Set followed a standard approach that includes a formal-decision-making and consensus process integrating evidence gathered from preparatory studies by experts consisting of neurologic health professionals. Preparatory studies included a worldwide Delphi study with 36 experts including seven physical therapists, a systematic review on outcome measures used in 160 stroke clinical trials, and an empiric data collection on 93 German patients with stroke. [17, 18, 19].

Based on the results of these studies a panel of 36 stroke experts (25 physicians, seven physical therapists, two psychologists, one social worker, and one sociologist) from 12 different countries decided on the composition of the "Comprehensive ICF Core Set for stroke" in a formal consensus process. The Comprehensive ICF Core Set for stroke includes a set of 130 ICF categories which cover the typical spectrum of problems in functioning in persons with chronic stroke [20]. It was extended by 36 ICF categories from the ICF Core Sets for persons with

neurological conditions in the acute and early post-acute phases to enable its use in all clinical situations [20, 21].

Based on this extended ICF Core Set for stroke, physical therapists can comprehensively describe the impairments, limitations in activities, restriction in participation and the influential environmental factors of a determined person with stroke and can create a functioning profile. The Extended ICF Core Set for stroke can facilitate assessment and offers the opportunity to clarify responsibilities among the team members by distributing the information gathered from specific ICF categories to the appropriate team members [13, 22].

The extended ICF Core Set for stroke is now undergoing worldwide testing using a number of approaches including international multi-center field studies, reliability studies [23], and content validation from the health professional perspective. Content validity from the health professional perspective means that at least those problems in functioning which are substantial targets of the specific interventions applied by health professionals are represented in the ICF Core Set for stroke. This is a prerequisite for the implementation of the ICF Core Set for stroke in clinical practice. To give an example, if joint mobility is a main intervention target of physical therapists, it is essential that physical therapists are able to document the extent and the change of joint mobility problems in a determined patient during the treatment course using the ICF Core Set for stroke. Consequently, if the corresponding ICF category for joint mobility is not included in the current version of the Core Set for stroke, the Core Set is lacking content validity from the perspective of physical therapists.

The purpose of this study was to examine the content validity from the perspective of physical therapists. It firstly intends to identify the patient's problems, resources and aspects of environment treated by physical therapists; secondly, to analyze whether these issues are represented by the current version of the extended ICF Core Set for stroke.

Methods and material

A three-round electronic-mail survey of physical therapists using the Delphi technique was conducted [24,25,26,27]. The purpose of the Delphi technique is to gain consensus from a panel of individuals who have knowledge of a topic being investigated [28]. These informed persons are commonly called ‘experts’ [29]. The Delphi method is a multi-stage process with each stage building on the results of the previous one and a series of rounds are used to both gather and provide information about a particular subject. The technique is characterized by its anonymity to avoid the dominance of single individuals in a group; iteration, which allows panel members to change their opinions in subsequent rounds; and controlled feedback, which shows the distribution of the group’s responses as well as each individual’s previous responses [30].

Recruitment of participants

In the preparatory phase of the study, international associations of physical therapists such as the World Confederation for Physical Therapy (WCPT) and members of the European Region of WCPT, as well as universities with health professional programs and members of the Association of Higher Education of Physical Therapy (ENPHE) were contacted. Associations with a focus on neuro-rehabilitation and certified physical therapists in neurological intervention from United States of America (USA) received an invitation to participate. A literature search and personal recommendations were used to identify experts.

The sample was selected using a purposive sampling approach which is commonly applied in Delphi studies [25, 31, 32]. Purposive sampling is based on the assumption that a researcher's knowledge about the population can be used to handpick the cases to be included in the sample [33]. In contrast to random sampling, purposive sampling does not assure representativeness. Since no database of the target population of physical therapists worldwide who are experienced in the treatment of patients with stroke was available, random sampling was not possible in our study.

To assure that the participants were experienced in the management of people post-stroke, the initial letter specified that participants should be "physical therapy experts in the treatment of post- stroke individuals". The first contact included an invitation to participate and a detailed description of the project's targets, the Delphi process and the timeline. The study was conducted from January to August 2005.

Delphi Process

The process and verbatim questions of the electronic-mail survey using the Delphi technique is displayed in Figure 2. The participants had three weeks to mail their responses for each round. Reminders were sent one week and two days before and one week after deadline. The study was conducted in English language.

In the **first** round of the Delphi procedure, an information letter including instructions and an Excel file containing an open-ended questionnaire was sent to all participants. The participants were requested to list all the "patient's problems, patient's resources and aspects of environment treated by physical therapists in patients with stroke". The phrasing of this question aimed at encouraging the participants to consider not only problems but also resources and environmental factors which are covered by the ICF model. The responses were collected and linked to the ICF. Additionally, the participants were asked to complete questions on demographic characteristics and professional experience.

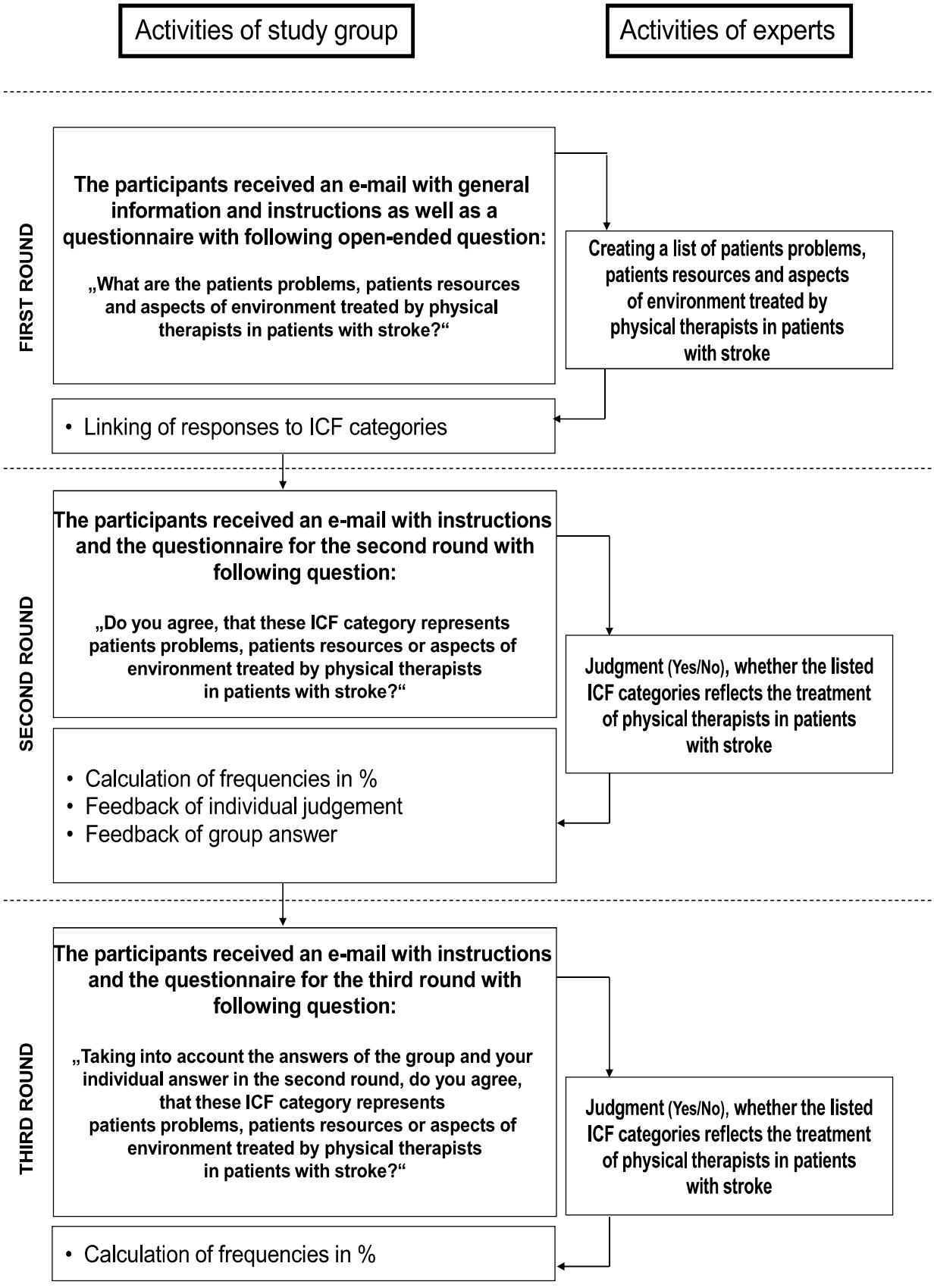

Figure 2: Description of the Delphi-exercise

In the **second** Delphi round, the participants received a list of the ICF categories linked to the responses of the first round. The participants were requested to agree or disagree that the respective ICF category represents patient's problems, patient's resources or aspects of environment treated by physical therapists in patients with stroke. Again, the number of participants considering the listed ICF categories as relevant was calculated.

In order to maintain the participants' motivation and increase the response rates the participants of the third Delphi round received only a selection of ICF categories included in the second round. Scree test was used to identify the categories which did not reach an adequate consensus [34, 35]. The Scree test includes an examination of a graph of the percentage of agreement among the participants plotted along the vertical axis against the ICF categories plotted along the horizontal axis. A straight edge is placed along the points to see where they form an approximately straight line, the scree line. Points close to the Scree line indicated an insufficient endorsement (see Figure 3). The participants received a list of the selected ICF categories including the proportion and the identification numbers of the participants who have agreed that the categories represent patient's problems, patient's resources or aspects of environment treated by physical therapists in individuals after stroke. The participants were requested to answer the same question taking into account the answers of the group, as well as their previous response.

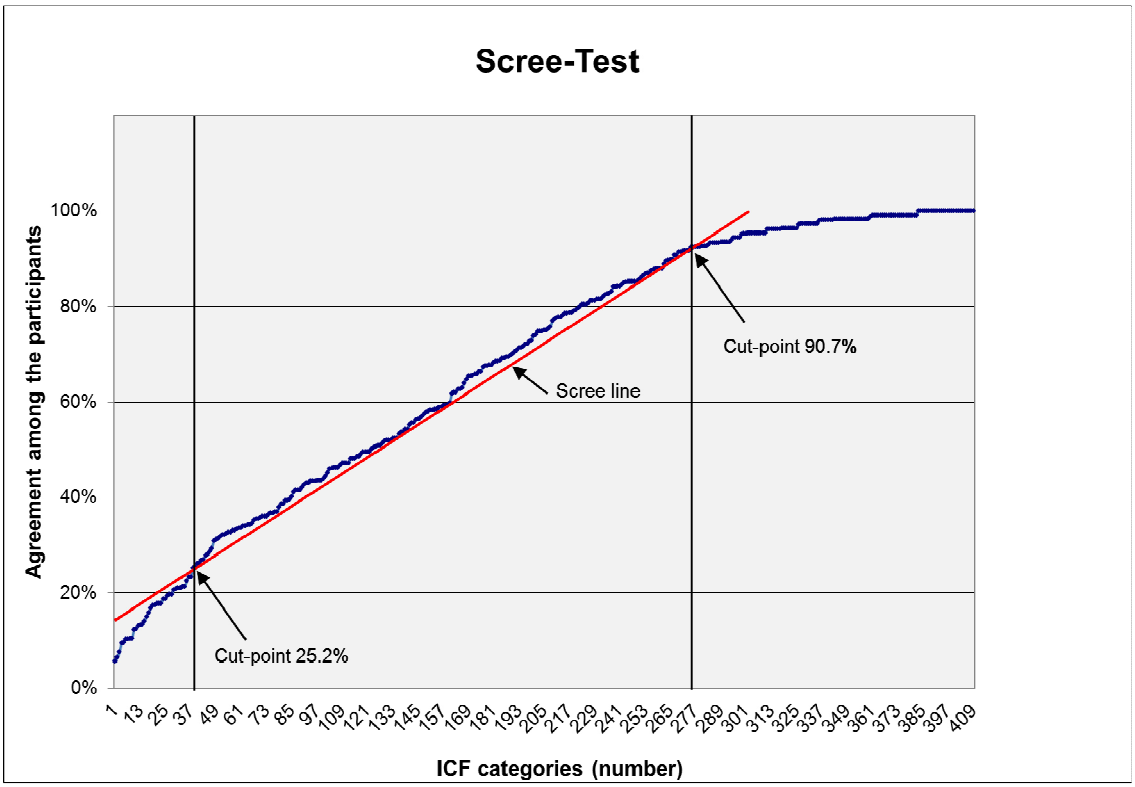

Figure 3: Scree Test Delphi round 2 PT stroke

Selection of ICF categories without clear consensus using the modified Scree Test. ICF categories of the second Delphi round were ordered by percentage of expert agreement and plotted. The scree line was placed onto the slope, along the points to see where they approximately form a straight line. Points close to the scree line indicate an inadequate endorsement. Cut-points were defined as the points **where** the slope **markedly** deviates from the scree line. ICF categories with an agreement >25.2% and <90.7% were included in the third Delphi round.

Linking

An ICF category is coded by the component letter and a suffix of one to five digits. The letters b, s, d and e refer to the components *Body Functions* (b), *Body Structures* (s), A*ctivities and Participation* (d) and *Environmental Factors* (e) (see Figure 1). This letter is followed by a one digit number indicating the chapter, the code for the second level (two digits) and the third and forth levels (one digit each). The component letter with the suffixes of 1, 3, 4, or five digits corresponds with the code of the so-called ICF categories. Within each component, the categories are arranged in a stem/branch/leaf scheme. This indicates that a more detailed higher-leveled category covers all the aspects applicable for the lower-leveled category, of which it is a member, but not vice versa.

Each response of the first Delphi round was linked to the most precise ICF category based on ten linking rules established in former studies [36]. If an answer contained more than one concept, several ICF categories could be linked. Answers related to Personal Factors were assigned the code “pf”. If the content of an answer was not included in the ICF classification, this answer was coded “Not covered”.

The linking was performed by a physical therapist (AG) specialized in stroke intervention. In addition, responses from 46 participants (36.8%) out of the 125 participants were linked independently by a psychologist (EA, BK). All persons involved in the linking process had some years of experience regarding the ICF. Since the linking process is extremely time-consuming and the linking of a sample of the 4.793 responses was expected to provide a good estimation of the true agreement, we refrained from linking all responses. Consensus between the physical therapist and the psychologist was used to decide which ICF category should be linked to each response. In cases of disagreement between the two health professionals, the suggested categories were discussed by a team consisting of three psychologists (EA, BK, IK) and one physical therapist (AG) aimed at a joint decision.

Statistical methods

Statistical analysis was performed using SAS for Windows V6*. Descriptive statistics were used to characterize the sample and frequencies of responses**.** The agreement between the two persons who performed the linking was described using the percent agreement and Kappa statistics with bootstrapped confidence intervals [37, 38]. The values of the Kappa coefficient generally range from 0 to 1, where 1 indicates perfect agreement and 0 indicates no additional agreement beyond what is expected by chance only.

The percentage of participants who agreed with the question of the second and third Delphi round was calculated. Only ICF categories which reached “consensus” among the participants in the third round were considered for comparison with the Extended ICF Core Set for stroke. Lacking a universally accepted definition of “consensus” [31], an agreement of at least 75% among the participants was considered sufficiently high based on experiences from former studies [16, 31].

Results

Recruitment and participants

Seventy-eight national physical therapy associations and 54 European associations named 23 participants. Three participants were named by the European Federation of Neuro-Rehabilitation (EGNR). Seventeen certified experts in neurology from USA agreed to participate. Nine universities with specialization in neurology named 11 participants, and six Bobath instructors agreed to participate. Two participants were identified by literature searches. Thirty-two international and eight national partners from the ICF Network for stroke were contacted. Five of them agreed to participate. The remaining 80 physical therapists who participated in this study were contacted on basis of personal recommendations of other participants (“snowball sampling”). In total, 146 physical therapists from 24 countries agreed to participate.

One hundred twenty-five (85.6%) out of 146 physical therapists, who agreed to participate in the study filled in the first round questionnaire. The demographic and professional characteristics of these participants are shown in Table 1.

Delphi process

In the first Delphi round, 4.793 patients’ problems, patients’ resources or aspects of environment treated by physical therapists in patients with stroke were named. One hundred eleven out of 125 participants (88.8%) filled in the second round questionnaire. One hundred one out of 111 (90.9%) physical therapists completed the third round questionnaire.

Table1: Distribution of the participants about three Delphi rounds, demographic and professional experience of the participants from round 1

WHO Region	Round 1 (n)	Round 2 (n)	Round 3 (n)	Female %	Age [years] Median (Min-Max)	Professional experience [years] Median (Min-Max)	Practical experience with stroke patients [years] Median (Min-Max)	Self-rating stroke Treatment expertise* [years] Median (Min-Max)
Regions of the Americas	**28**	**25**	**23**	85.10	39.0 (31.0-51.0)	15.0 (6.0-30.0)	13.0 (5.0-28.0)	4.0 (3.0-5.0)
European Region	**91**	**81**	**73**	80.20	42.0 (22.0-67.0)	16.0 (1.0-40.0)	13.0 (1.0-35.0)	4.0 (3.0-5.0)
Western-Pacific Region	**4**	**3**	**3**	100.00	43.5 (28.0-47.0)	21.5 (6.0-25.0)	16.5 (3.0-25.0)	4.0 (3.0-4.0)
African Region	**2**	**2**	**2**	50.00	51.5 (35.0-68.0)	26.5 (11.0-42.0)	26.5 (13.0-40-0)	4.25 (4.0-4.5)
Total	**125 (87.4%)**	**111 (88.8%)**	**101 (90.9%)**	**77.9%**	**40.0 (22-68)**	**16.0 (1-42)**	**13.0 (1-40)**	**4.0 (3-5)**

* 1= low 5=excellent

Region of Americas	Brazil, Canada, Jamaica, USA;
European Region	Austria, Belgium, Czech Republic, Finland, Germany, Hungary, Israel, Italy, Netherlands, Norwegian, Spain, Sweden, Switzerland, Turkey, UK;
African Region	Nigeria, South Africa;
Western Pacific Region	Australia, Japan, New Zealand;
Eastern Mediterranean Region	Not represented
South East Asia Region	Not represented

Linking of the responses to the ICF

All components of the ICF were represented by 376 identified ICF categories. Seven fourth-level categories, 80 third-level categories, and 59 second-level categories were linked to the component *Body Functions*. Two fourth-level categories, twelve third-level categories, and ten second-level categories were linked to the component *Body Structures*. Sixty-seven third-level categories and 53 second-level categories were linked to the component Activities *and Participation* whereas 27 third-level categories and 37 second-level categories were linked to the component *Environmental Factors*. Fifteen aspects were named that could be attributed to the not-yet-developed ICF component *Personal Factors*. Fifteen responses were not covered by the current version of the ICF. Agreement between the two persons who performed the linking was reached in 42% of the responses. The Kappa statistics for the linking was 0.39 with a 95% bootstrapped confidence interval of 0.34 - 0.41.

Representation of the physical therapists' responses in the ICF Core Set for stroke

In total, from the 376 ICF categories linked to the participants' responses 185 reached an agreement of at least 75% in the final round and were considered for comparison with the extended ICF Core Set for stroke.

Of the 83 ICF categories linked to *Body Functions*, 26 are included on the same level of classification and 48 are more detailed third- and fourth-level categories, which are represented by the corresponding second-level categories, e.g. *b1300 Energy level,* which is represented in the Extended ICF Core Set for stroke by the second-level category *b130 Energy and drive functions* (see Table 2). Ten ICF categories which correspond to the four second-level ICF categories, *b445 Respiratory muscle function, b720 Mobility of joint functions, b765 Involuntary movement functions,*

and b780 Sensations related to muscles and movement functions, are not represented in the extended ICF Core Set for stroke (see Table 2).

Of the component *Body Structures* 23 ICF categories reached an agreement ≥ 75%. Among these, six categories are included in the extended ICF Core Set for stroke at the same level of classification whereas nine were represented at a different level of the classification. Three second-level ICF categories and five corresponding third level categories are not represented in the extended ICF Core Set for stroke (see Table 2).

Of the 67 ICF categories from the ICF component *Activities and Participation* which reached an agreement ≥ 75%, 23 are included at the same level of the classification and 42 more detailed, third-level categories are represented in the extended ICF Core Set for stroke by their corresponding second-level categories. Two ICF categories, namely *d435 Moving objects with lower extremities* and *d6504 Maintaining assistive devices* are not represented in the extended ICF Core Set for stroke (see Table 2).

Of the component *Environmental factors* nine categories reached an agreement ≥ 75%. Of these, five categories are included at the same level of classification in the extended ICF Core Set for stroke, whereas three categories were represented at a different level of the classification. The ICF category *e1401 Assistive products and technology for culture, recreation and sport* is not represented in the extended ICF Core Set for stroke (see Table 2).

Twelve responses were assigned to the not-yet-developed ICF component *Personal factors* and reached an agreement surpassing 75%. Most of them addressed attitudes supporting the independence of a person with stroke in managing his/her disease, e.g. self-management, compliance, autonomy / independence. Autonomy, compliance, self-concept and self-management, illness knowledge and also coping were considered to comprise personal factors according to the ICF language. In addition, “brain plasticity” and “recovery” were identified as personal factors representing relevant aspects of stroke intervention by physical therapists (see Table 3).

Fifteen responses of the participants were not covered by any ICF component or specific ICF category out of the classification (see Table 3).

Table 2: ICF categories that are not represented in the current version of the ICF Core Set for stroke. Only categories with agreement ≥ 75% are shown. Percentage of participants who considered the respective ICF category as relevant in the final round

ICF Code Level 2	ICF Code Level 3	Title of ICF Category	Final Round 3 n = 101 %
Body functions			
b445		Respiratory muscle functions	**100.0**
b720		Mobility of bone functions	**98.2**
b765		Involuntary movement functions	**93.6**
	b7650	Involuntary contractions of muscles	**86.8**
	b7651	Tremor	**92.9**
b780		Sensations related to muscles and movement functions	**99.1**
	b7800	Sensation of muscle stiffness	**98.1**
	b7801	Sensation of muscle spasm	**95.5**
Body structures			
s740		Structure of pelvic region	**90.7**
	s7402	Muscles of pelvic region	**96.3**
s760		Structure of trunk	**92.5**
s770		Additional musculoskeletal structures related to movement	**94.0**
	s7700	Bones	**89.5**
	s7701	Joints	**96.3**
	s7702	Muscles	**96.2**
	s7703	Extraarticular ligaments, fasciae, extramuscular aponeuroses, retinacula, septa, bursae, unspecified	**90.7**
Activities and participation			
d435		Moving objects with lower extremities	**98.2**
	d6504	Maintaining assistive devices	**83.0**
Environmental factors			
	e1401	Assistive products and technology for culture, recreation and sport	**77.7**

Table 3: Responses that were linked to the ICF component **Personal factors and 'Not classified'** terms. Percentage of participants who considered the respective concepts as relevant in the final round (only concepts with agreement ≥ 75% are shown).

Personal factors

Linking	**Final Round n=101 %**
Autonomy, independence	**97.3**
Brain plasticity / recovery	**97.2**
Self-concept, self-perception	**95.9**
Endurance/discipline, hardiness	**93.8**
Coping	**92.8**
Optimistic/positive attitude	**92.8**
Compliance	**92.7**
Self-management	**91.8**
Illness knowledge	**91.8**
Problems/worries/uncertainty about future	**88.6**
Sense of mastery	**88.5**
Life values, life goals, life style	**87.6**

Not classified

Linking	**Final Round n=101 %**
Posture/ postural alignment	**99.1**
Adaptation to bodily changes/ Compensation strategies	**98.1**
Secondary complications	**98.1**
Multi-professional- and interdisciplinary treatment	**97.2**
Therapeutic positioning	**97.2**
Assessment of the patient and evaluation	**96.3**
Impairment of body symmetry	**96.3**
Positive model for living with a handicap	**95.8**
Education of self and family about Stroke	**95.4**
PT Intervention	**95.2**
Perspective of life (living at home, profession)	**92.7**
Learning experience in dealing with limitations	**92.7**
Conveying problem to others and their understanding	**91.8**
Competence in self-relaxation	**91.8**
Self-observation	**91.8**

Discussion

This study examined the content validity of the extended ICF Core Set for stroke from the perspective of physical therapists. In this study, content validity refers to the extent to which the patients' problems, resources and environmental factors identified by physical therapists as relevant to their management of persons with stroke are represented in the extended ICF Core Set for stroke. An agreement of at least 75% among the participants in the final Delphi round was regarded as sufficient consensus. Consequently, ICF categories with an agreement of at least 75%, which are not represented in the extended ICF Core Set for stroke may indicate missing content validity and will be the main focus of the following discussion.

A 100% agreement among the participants was found regarding the category *b445 Respiratory muscle function*. However, this ICF category is not included in the extended ICF Core Set for stroke. Several studies have demonstrated that problems associated with strength and endurance of respiratory muscles as well as with muscles of the trunk and the position of the diaphragm are important risk factors for secondary complications after stroke such as pneumonia [39]. In order to minimize these risks, physical therapists use respiratory exercises including training of respiration and specific intervention techniques to activate or relax respiratory muscles [40].

The participants addressed nearly all of the different categories from the chapter *Neuro-musculosceletal and movement related functions,* which covers functions of joints, bones, reflexes and muscles [11]. These aspects clearly represent one main focus of the physical therapists' work in stroke rehabilitation. However, although the ICF category *b720 Mobility of bone functions* reached an agreement of 98.2% among the participants it is not included in the ICF Core Set for stroke. Bone mobility is a prerequisite for activities such as grasping a glass. Bone mobility is treated by physical therapists using different manual techniques, e.g. mobilization of the scapulae in shoulder pain after stroke [41].

Furthermore, over *90 %* of the participants agreed that *b765 Involuntary movement functions* is a problem treated by physical therapists which is not included in the ICF Core Set for stroke. This finding is clearly supported by literature, which reports a close relationship between stroke and spasticity and the incidence of clonus or tremor [42, 43]. In addition, validation studies have also identified this ICF category as being relevant for occupational therapists [44] and physicians [45].

Regarding the ICF category *b780 Sensations related to muscles and movement functions* which is not represented in the ICF Core Set for stroke, again a high consensus among the participants was found. It is quite obvious that persons with stroke experience stiffness and tightness of muscles. Muscle spasms and heaviness of muscles are commonly treated by physical therapists [40].

With regard to the ICF component *Body structures*, three ICF categories were found not to be included in the current version of the ICF Core Set for stroke. Spasticity and muscle imbalance in lower limbs, one of the major problems after stroke, are associated with walking problems.

Improvement of multi-joint coordination and muscle activity in lower limbs including the pelvis are relevant intervention goals for physical therapists. However, the ICF category *s740 Structure of pelvic* is currently not included.

The ICF category *s760 Structure of trunk* including bones, muscles and ligaments of the trunk represents a main intervention area of physical therapy after stroke since hemiplegia not merely results in diverse problems in upper and lower extremities but also affects the trunk and its corresponding structures [46, 47]. Finally, the ICF category *s770 Additional musculoskeletal structures related to movement* addresses structures which are still not sufficiently mapped in the ICF. For instance, muscles of the neck are frequently affected in neglect [48].

Regarding the ICF component *Activities and Participation* the ICF category *d435 Moving objects with lower extremities* was regarded as relevant by the participants but this is not included in the ICF Core Set for stroke. Indeed, persons with stroke have impairments in structure and functioning of the feet, such as decreased muscle power or problems with spasticity or flaccid muscles, which can lead to difficulties with pushing pedals on a bicycle or difficulty pressing the gas pedal of a car [49, 50]. On the other hand, problems with riding a bicycle or driving a car are covered by the ICF category *d475 Driving* which is already part of the extended ICF Core Set for stroke.

The high agreement among the participants regarding the ICF categories related to assistive devices such as *e115 Products and technology for personal use in daily living* highlights the relevance of a restoratory and compensatory rehabilitation strategy. The education and training on the use and maintenance of assistive devices is an inherent part of physical therapy. However, the ICF categories *e1401 Assistive products and technology for culture, recreation and sport* and *d6504 Maintaining assistive devices* are not yet included in the extended ICF Core Set for stroke.

Twelve aspects were linked to the not-yet-developed ICF component *Personal Factors*. *Patients' self-management, illness knowledge and abilities to cope with the disease* are relevant for patient education provided by physical therapists [51]. Various studies and systematic reviews support the positive effects of patient education regarding self-management [51] and coping with disease [52]. These results indicate that *Personal Factors* are also considered by physical therapists. Therefore it could be most helpful for physical therapists, if the ICF would provide a classification of the *Personal Factors* in the future. This will enable health professionals to identify systematically all personal factors influencing the functioning of a certain person.

"Posture/ postural alignment" was regarded as a relevant aspect by almost all of the participants; however, this is not covered by the ICF. Although the ICF category *d415 Maintaining a body position* covers the static aspects of posture, the dynamic aspects of posture are missing.

Thus, it could be useful to develop an ICF category addressing "Posture/ postural alignment" more specifically. However, when increasing the specificity of such an ICF category it should be kept in mind that the ICF should be used by all health professions and therefore physical therapy specific terminology should be avoided.

In general, the participants named a high amount of detailed aspects, represented by third- and fourth-level ICF categories which are relevant for stroke intervention. This detailed information is necessary for assessment, therapy planning and intervention in physical therapy. As the ICF Core Set only includes less specific second-level categories this might be unfavourable for physical therapy practice on the one hand. On the other hand, the current version of the extended ICF Core Set for stroke already includes 166 second-level ICF categories and any further extension could compromise its feasibility in clinical practice.

The Delphi technique proved to be an appropriate method for this study objective. With response rates exceeding 87% in the present study, previously reported response rates of approximately 50% [30, 33, 53] were clearly surpassed. However, there are some limitations regarding the reliability and external validity of this study.

The agreement between the persons who performed the linking was lower than in other studies that used comparable methods [54, 55, 56]. This may be related to the fact that the answers of the participants were longer and therefore the extraction of the meaningful concepts was more difficult than in similar studies regarding other health conditions. Consequently, the instructions for the first round were revised for their use in future studies. Furthermore, as we have only linked a sample of the responses, we cannot exclude that the agreement would have been different in another sample of responses.

Although the authors were successful in recruiting physical therapists from 24 countries, the African and the Eastern Mediterranean world region are not represented in the sample. Health care systems in these world regions may differ from other world regions and it cannot be excluded that this also affects the intervention targets of physical therapists in stroke treatment. Thus, the sample is not representative of all physical therapists experienced in the intervention of persons with stroke worldwide. Language barriers could have influenced the participation in some world regions since the Delphi survey was conducted in English language only.

Although some restrictions of the current version of the extended ICF Core Set for stroke were detected in this study, we found the categories of the current version of extended ICF Core Set for stroke were largely representing what the physical therapists in our study agreed upon to take care of in their interventions.

The results of finalized or ongoing studies involving both health professionals [44, 45] and patients will further elucidate the validity of the extended ICF Core Set for stroke from the different perspectives. A number of ICF categories identified as missing in the current version of the extended ICF Core Set for stroke by occupational therapists [44], were also mentioned by the participants in our studies. These ICF categories included the categories *b720 Mobility of bone functions* and *b765 Involuntary movement functions* from the component *Body Functions, s760 Structure of trunk* and *s770 Additional musculoskeletal structures related to movement* from the component *Body Structures*, *d435 Moving objects with lower extremities* and *d650 Caring for household objects* from the component *Activities and Participation*, and *e140 Products and technology for culture, recreation and*

sport from the component *Environmental Factors*. In contrast to physical and occupational therapists, the physicians have only found four ICF categories which are relevant for their treatment but not yet part of the current version of the extended ICF Core Set for stroke [45]. Of interest, the ICF category *b765 Involuntary movement functions* was mentioned as relevant by all three health professions. Thus, this category would be a good candidate for being included in the Extended ICF Core Set for stroke.

The validation from the perspective of three different health professions has shown that it might be useful to add relevant ICF categories to the extended ICF Core Set for stroke [44, 45]. On the other hand, studies that have applied the extended ICF Core Set for stroke in a sample of persons with stroke, have identified ICF categories which are less relevant and might be excluded [57,58].

However, the validation from the patient perspective is not yet completed. It seems reasonable that a final decision on the content of a revised version of the extended ICF Core Set for stroke should be postponed until the results from the patient perspective are available and can be included in the discussion.

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Appendix

Appendix 108

Appendix 1 The extended version of the ICF Core Set for stroke comparison of perspectives from the validation studies

ICF	Title	perspectives				
code	Body functions (59)	pa-tient	women	men	both gender	PT
b110	Consciousness functions	x	x	x	x	x
b114	Orientation functions	x				x
b117	Intellectual functions					
b126	Temperament and personality functions	x	x	x	x	
b130	Energy and drive functions	x	x	x	x	x
b134	Sleep functions	x	x	x	x	
b140	Attention functions	x	x	x	x	x
b144	Memory functions	x	x	x	x	x
b147	Psychomotor functions	x				x
b152	Emotional functions	x	x	x	x	
b156	Perceptual functions	x	x	x	x	x
b160	Thought functions	x	x	x	x	
b164	Higher-level cognitive functions	x	x	x	x	
b167	Mental functions of language	x	x	x	x	
b172	Calculation functions			x		
b176	Mental function of sequencing complex movements	x	x			x
b180	Experience of self and time functions	x	x	x	x	
b210	Seeing functions	x	x	x	x	
b215	Functions of structures adjoining the eye	x		x		
b230	Hearing functions	x		x		
b235	Vestibular functions	x	x	x	x	x
b240	Sensations associated with hearing and vestibular function	x	x	x	x	x
b260	Proprioceptive function	x	x	x	x	x
b265	Touch function	x	x	x	x	x
b270	Sensory functions related to temperature and other stimuli	x	x	x	x	x
b280	Sensation of pain	x	x	x	x	x
b310	Voice functions	x	x	x	x	
b320	Articulation functions	x	x	x	x	
b330	Fluency and rhythm of speech functions	x	x	x	x	
b340	Alternative vocalization functions		x	x	x	
b410	Heart functions	x	x	x	x	
b415	Blood vessel functions	x	x	x	x	
b420	Blood pressure functions	x	x	x	x	
b430	Haematological system functions	x	x	x	x	
b435	Immunological system functions		x			x
b440	Respiration functions	x	x	x	x	x
b450	Additional respiratory functions		x	x	x	x
b455	Exercise tolerance functions	x	x	x	x	x

b510	Ingestion functions	x	x			
b515	Digestive functions		x	x	x	
b525	Defecation functions	x	x	x	x	
b530	Weight maintenance functions	x		x		
b535	Sensations associated with the digestive system	x	x			
b540	General metabolic functions			x		
b545	Water, mineral and electrolyte balance functions	x				
b550	Thermoregulatory functions					
b620	Urination functions	x	x			
b630	Sensations associated with urinary functions					
b640	Sexual functions		x	x	x	
b710	Mobility of joint functions	x	x	x	x	x
b715	Stability of joint functions	x	x	x	x	x
b730	Muscle power functions	x	x	x	x	x
b735	Muscle tone functions	x	x	x	x	x
b740	Muscle endurance functions		x			x
b750	Motor reflex functions	x	x	x	x	x
b755	Involuntary movement reaction functions	x	x	x	x	x
b760	Control of voluntary movement functions	x	x	x	x	x
b770	Gait pattern functions	x	x	x	x	x
b810	Protective functions of the skin			x		
	Activities and Participation (59)	**pa-tient**	**women**	**men**	**both gender**	**PT**
d110	Watching		x	x	x	
d115	Listening		x			
d120	Other purposeful sensing			x		x
d130	Copying			x		x
d135	Rehearsing	x	x	x	x	
d155	Acquiring skills	x	x	x	x	x
d160	Focusing attention	x	x	x	x	x
d166	Reading	x	x	x	x	
d170	Writing	x	x	x	x	
d172	Calculating		x	x	x	
d175	Solving problems	x				
d177	Making decisions	x	x	x	x	x
d210	Undertaking a single task	x				x
d220	Undertaking multiple tasks	x	x			x
d230	Carrying out daily routine	x	x	x	x	x
d240	Handling stress and other psychological demands	x	x	x	x	
d310	Communicating with - receiving - spoken messages		x			
d315	Communicating with - receiving - nonverbal messages					
d325	Communicating with - receiving - written messages	x				
d330	Speaking	x	x	x	x	
d335	Producing nonverbal messages		x	x	x	
d345	Producing messages in formal sign messages	x		x		

d350	Conversation	x	x	x	x	
d360	Using communication devices and techniques	x	x	x	x	
d410	Changing basic body position	x	x	x	x	x
d415	Maintaining a body position	x	x	x	x	x
d420	Transferring oneself		x	x	x	x
d430	Lifting and carrying objects	x	x	x	x	x
d440	Fine hand use	x	x	x	x	x
d445	Hand and arm use	x	x	x	x	x
d450	Walking	x	x	x	x	x
d455	Moving around	x	x	x	x	x
d460	Moving around in different locations	x	x	x	x	x
d465	Moving around using equipment	x	x	x	x	x
d470	Using transportation	x	x	x	x	x
d475	Driving	x	x	x	x	
d510	Washing oneself	x	x	x	x	
d520	Caring for body parts	x	x	x	x	
d530	Toileting	x	x	x	x	
d540	Dressing	x	x	x	x	x
d550	Eating	x	x	x	x	x
d560	Drinking	x	x			x
d570	Looking after one's health	x	x	x	x	
d620	Acquisition of goods and services	x	x	x	x	
d630	Preparing meals	x	x	x	x	
d640	Doing housework	x	x	x	x	
d710	Basic interpersonal interactions		x			
d750	Informal social relationships	x	x	x	x	
d760	Family relationships	x	x	x	x	
d770	Intimate relationships	x	x	x	x	
d845	Acquiring, keeping and terminating a job	x	x	x	x	
d850	Remunerative employment	x	x	x	x	
d855	Non-remunerative employment	x	x	x	x	
d860	Basic economic transactions	x		x		
d870	Economic self-sufficiency	x		x		
d910	Community life		x	x	x	
d920	Recreation and leisure	x	x	x	x	x
d930	Religion and spirituality	x				
d940	Human rights					

	Environmental factors (37)	**pa-tient**	**women**	**men**	**both gender**	**PT**
e110	Products or substances for personal consumption	x	x	x	x	
e115	Products and technology for personal use in daily living	x	x	x	x	x
e120	Products and technology for personal indoor and outdoor mobility and transportation	x	x	x	x	x
e125	Products and technology for communication	x	x	x	x	
e135	Products and technology for employment					
e150	Design, construction and building products and technology of buildings for public use	x	x	x	x	

e155	Design, construction and building products and technology of buildings for private use	x	x	x	x	
e165	Assets	x	x	x	x	
e210	Physical geography	x	x			
e240	Light					
e250	Sound	x				
e310	Immediate family	x	x	x	x	
e315	Extended family	x	x	x	x	
e320	Friends	x	x	x	x	
e325	Acquaintances, peers, colleagues, neighbours and community members	x	x	x	x	
e340	Personal care providers and personal assistants	x	x			x
e355	Health professionals	x	x	x	x	x
e360	Other professionals	x	x	x	x	
e410	Individual attitudes of immediate family members	x	x	x	x	
e415	Individual attitudes of extended family members		x	x	x	
e420	Individual attitudes of friends	x	x	x	x	
e425	Individual attitudes of acquaintances, peers, colleagues, neighbours & community members	x	x	x	x	
e440	Individual attitudes of personal care providers and personal assistants	x				
e450	Individual attitudes of health professionals	x	x	x	x	x
e455	Individual attitudes of health-related professionals					
e460	Societal attitudes	x		x		
e465	Social norms, practices and ideologies					
e515	Architecture and construction services, systems and policies	x		x		
e525	Housing services, systems and policies	x		x		
e535	Communication services, systems and policies					
e540	Transportation services, systems and policies	x	x	x	x	
e550	Legal services, systems and policies		x	x	x	
e555	Associations and organizational services, systems and policies		x	x	x	
e570	Social security services, systems and policies	x	x	x	x	
e575	General social support services, systems and policies	x	x	x	x	
e580	Health services, systems and policies	x	x	x	x	
e590	Labour and employment services, systems and policies	x	x	x	x	
	Body structures (11)	**pa-tient**	**women**	**men**	**both gender**	**PT**
s110	Structure of brain	x	x	x	x	x
s120	Spinal cord and related structures					x
s130	Structure of meninges					
s410	Structure of cardiovascular system	x	x			x
s430	Structure of respiratory system			x		x
s530	Structure of stomach					
s710	Structure of head and neck region	x		x		x
s720	Structure of shoulder region	x	x	x	x	x
s730	Structure of upper extremity	x	x	x	x	x
s750	Structure of lower extremity	x	x	x	x	x
s810	Structure of areas of skin					

Appendix 2 Comparison of additional ICF categories of the patients & PTs

ICF Code	Activities and Participation: Title ICF Category	FG	Open A	ICF-b	women	men	both	PTs
d145	Learning to write	x	x	x	x			
d163	Thinking	x	x				x	
d355	Discussion	x	x	x		x		
d435	Moving objects with lower extremities	x	x	x			x	x
d480	Riding animals for transportation	x						
d610	Acquiring a place to live		x	x		x		
d650	Caring for household objects	x	x	x			x	x
d660	Assisting others	x	x	x			x	
d720	Complex interpersonal interactions	x		x	x			
d730	Relating with strangers		x	x			x	
d740	Formal relationships		x			x		
d840	Apprenticeship (work preparation)		x			x		
d865	Complex economic transaction	x	x	x		x		
d950	Political life and citizenship			x		x		
ICF Code	**Environmental factors: Title ICF Category**	**FG**	**Open A**	**ICF-b**	**women**	**men**	**both**	**PTs**
e130	Products and technology for education		x	x		x		
e140	Products and technology for culture, recreation and sport		x			x		x
e160	Products and technology of land development	x						
e215	Population	x		x	x			
e220	Flora und fauna	x		x			x	
e225	Climate	x	x	x			x	
e330	People in positions of authority	x	x			x		
e345	Strangers	x	x	x			x	
e350	Domesticated animals	x	x	x			x	
e430	Individual attitudes of people in positions of authority	x	x				x	
e445	Individual attitudes of strangers	x						
e520	Open space planning services, systems and policies			x		x		
e530	Utilities services, systems and policies	x						
e545	Civil protection services, systems and policies	x						
e565	Economic services, systems and policies			x	x			
ICF Code	**Body functions: Title ICF Category**	**FG**	**Open A**	**ICF-b**	**women**	**men**	**both**	**PTs**
b220	Sensations associated with the eye and adjoining structures	x		x	x			
b250	Taste function	x		x			x	
b255	Smell function	x						
b445	Respiratory muscle functions							x
b555	Endocrine gland functions		x	x		x		
b720	Mobility of bone functions			x			x	x
b765	Involuntary movement functions	x	x	x			x	x
b780	Sensations related to muscles and movement functions	x	x	x			x	x
b830	Other functions of skin	x						
b840	Sensation related to the skin	x						
b850	Functions of hair		x			x		
b860	Functions of nail		x			x		
ICF Code	**Body structures: Title ICF Category**	**FG**	**Open A**	**ICF-b**	**women**	**men**	**both**	**PTs**
s220	Structure of eyeball	x		x	x			
s320	Structure of mouth	x		x			x	
s740	Structure of pelvis region							x
s760	Structure of trunk	x	x	x		x		x
s770	Additional musculoskeletal structures related to movement	x	x	x			x	x
s830	Structure of nails		x			x		
s840	Structure of hair		x			x		

Appendix 3 Comparison of additional ICF categories from validation studies

- the perspectives of patients, women, men, both gender, PTs, OTs, Physicians-

	Comparison of additional ICF categories from the validation studies including 7 perspectives											
ICF Code	**Activities and Participation: Title ICF Category**	**%**	**FG**	**II_Open A**	**II_ICF-b**	**women**	**men**	**both**	**PTs**	**OTs**	**Physician**
d145	Learning to write	57	x	x	x	x					
d163	Thinking	43	x	x				x			
d355	Discussion	57	x	x	x		x				
d435	Moving objects with lower extremities	86	x	x	x			x	x	x	
d480	Riding animals for transportation	14	x								
d610	Acquiring a place to live	57		x	x		x			x*	
d650	Caring for household objects	86	x	x	x			x	x	x	
d660	Assisting others	71	x	x	x			x		x	
d720	Complex interpersonal interactions	43	x		x	x					
d730	Relating with strangers	43		x	x			x			
d740	Formal relationships	28		x			x				
d825	Vocational training	14								x	
d840	Apprenticeship (work preparation)	43		x			x			x	
d865	Complex economic transaction	57	x	x	x		x				
d950	Political life and citizenship	28			x		x				
ICF Code	**Environmental factors: Title ICF Category**	**%**	**FG**	**II_Open A**	**II_ICF-b**	**women**	**men**	**both**	**PTs**	**OTs**	**Physician**
e130	Products and technology for education	57		x	x		x			x	
e140	Products and technology for culture, recreation and sport	57		x			x		x	x	
e160	Products and technology of land development	14	x								
e215	Population	43	x		x	x					
e220	Flora und fauna	43	x		x			x			
e225	Climate	57	x	x	x			x			
e330	People in positions of authority	43	x	x			x				
e345	Strangers	57	x	x	x			x			
e350	Domesticated animals	57	x	x	x			x			
e430	Individual attitudes of people in positions of authority	43	x	x				x			
e445	Individual attitudes of strangers	14	x								
e520	Open space planning services, systems and policies	28			x		x				
e530	Utilities services, systems and policies	14	x								
e545	Civil protection services, systems and policies	14	x								
e565	Economic services, systems and policies	28			x	x					
e575	General social support servicies, systems and policies	14								x	
ICF Code	**Body functions: Title ICF Category**	**%**	**FG**	**II_Open A**	**II_ICF-b**	**women**	**men**	**both**	**PTs**	**OTs**	**Physician**
b122	Global psychosocial functions	14								x	
b220	Sensations associated with the eye and adjoining structures	43	x		x	x					
b250	Taste function	43	x		x			x			
b255	Smell function	14	x								
b445	Respiratory muscle functions	14							x		
b460	Sensations associated with cardiovascular and respiratory functions	14									x
b555	Endocrine gland functions	43		x	x		x				
b610	Urinary excretory functions	14									x
b720	Mobility of bone functions	57			x			x	x	x	
b765	Involuntary movement functions	100	x	x	x			x	x	x	x
b780	Sensations related to muscles and movement functions	86	x	x	x			x	x		x
b830	Other functions of skin	14	x								
b840	Sensation related to the skin	14	x								
b850	Functions of hair	28		x			x				
b860	Functions of nail	28		x			x				
ICF Code	**Body structures: Title ICF Category**	**%**	**FG**	**II_Open A**	**II_ICF-b**	**women**	**men**	**both**	**PTs**	**OTs**	**Physician**
s220	Structure of eyeball	43	x		x	x					
s320	Structure of mouth	43	x		x			x			
s740	Structure of pelvis region	14							x		
s760	Structure of trunk	86	x	x	x		x		x	x	
s770	Additional musculoskeletal structures related to movement	86	x	x	x			x	x	x*	
s830	Structure of nails	28		x			x				
s840	Structure of hair	28		x			x				

Appendix 4 Study 1 - copy of the original publication - patient perspective -

Validation of the extended ICF core set for stroke from the patient perspective using focus groups

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RESEARCH PAPER

Validation of the extended ICF core set for stroke from the patient perspective using focus groups

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Purpose: **The extended international classification of functioning, disability and health (ICF) core set for stroke is an application of the ICF of the World Health Organisation (WHO) with the purpose to represent the typical spectrum of functioning of persons with stroke. The objective of the study was to add evidence to the validation of the extended ICF core set for stroke from the perspective of patients using focus groups to explore the aspects of functioning and health important to persons with stroke.** ***Method:*** **The sampling of patients followed the maximum variation strategy. Sample size was determined by saturation. The focus groups were digitally recorded and transcribed verbatim. After qualitative data analysis, the resulting concepts were linked to ICF categories and compared to the categories included in the extended ICF core set for stroke.** ***Results*****: Sixty patients participated in 7 focus groups. The content of 131 out of 166 ICF categories contained in the extended ICF core set for stroke was reported by the persons with stroke. The content of 31 additional categories that are not covered in the extended ICF core set for stroke was raised.** ***Conclusions:*** **The existing version of the extended ICF core set for stroke could be confirmed almost entirely from patient perspective.**

Keywords: ICF core set, ICF, patient perspective, stroke

Implications for Rehabilitation:

- The extended ICF Core Set for stroke can be used to create a functioning profile for persons after stroke to identify problems and resources considering a client-centred approach.
- This study shows which aspects of the environment of persons after stroke are relevant from the clients' perspective and should be integrated in the rehabilitation process.
- This study provides a basis for the further development of the ICF, especially with regard to its update via relevant aspects from clients' perspective after stroke.

Introduction

Stroke is the second leading cause of death for people above the age of 60 and the fifth leading cause in people aged 15–59. Each year, there are 15 million people suffering a stroke and nearly six million people dying from stroke. Stroke is also the leading cause of long-term disability irrespective of age, gender, ethnicity or country [1]. It is strongly associated with the inability to continue independence in everyday life, self-care, mobility, and working, ultimately leading to the experience of restrictions in participation in several life areas [2–5].

For the World Health Organization (WHO) functioning and the ability to participate in everyday life can be understood not only as a mere consequence of disease and its treatment, but also within the context of the person that may differ greatly depending on that person's private and societal background [6]. This would imply that the biological, psychological, social and environmental aspects of everyday life must be taken into account in order to achieve a comprehensive perspective of health or health-related problems in persons suffering a stroke [7].

With the International Classification of Functioning, Disability and Health (ICF), a globally agreed-on language and classification is available to describe functioning both on individual and population levels and from both patient perspective and that of the health professionals. To improve clinical practicability of ICF, the comprehensive ICF core set for stroke was developed in 2004 including 130 ICF categories from the second-level of the ICF classification. It covers the typical spectrum of problems in functioning in persons with

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chronic stroke [8] and should serve as standard for multiprofessional, comprehensive assessment. In 2005, the comprehensive ICF core set for stroke was extended by 36 ICF categories from the ICF Core Sets for persons with neurological conditions in the acute and early post-acute phases to enable its use in all clinical situations [9–11]. The current version of this extended ICF core set for stroke includes 166 categories at the second-level of the classification, 59 categories of body functions, 11 categories of body structures, 59 activities and participation categories and 37 environmental factors. Since the extended ICF core set for stroke addresses aspects within all the components of the ICF, it presents a broad, condition-specific perspective that reflects the whole health experience of persons suffering from the effects of a stroke.

The extended ICF core set for stroke is now undergoing worldwide testing and validation using a number of approaches including an international multicentre validation study and validation from the perspective of health professionals [12–16]. Another key aspect is the validation from the patient perspective. While the patient perspective has been implicitly included in the development of the extended ICF core set for stroke [17], the patients will now be explicitly involved in the process of the validation of this ICF Core Set.

Studies aimed at the exploration of this "patient perspective" frequently apply to qualitative methods, which are increasingly accepted in health research and health-related sciences [18–23]. Qualitative methods provide the possibility to explore the perspective of those who experience a health problem, i.e. the so-called patient perspective [24–27]. Compared to quantitative methodology, the qualitative approach promises a greater openness to unexplored concepts or phenomena [28] and focuses on how people understand and interpret their social world [29].

The objective of the present study was to add evidence to the validation of the extended ICF core set for stroke from the perspective of persons with stroke. The specific aims were 1) to explore the aspects of functioning and health important to persons with stroke using focus groups and 2) to examine to what extent these aspects are represented by the current version of the extended ICF core set for stroke.

Methods and materials

Design

A qualitative study with persons with stroke was performed using focus groups and an established methodology for the validation of ICF Core Sets from the patient perspective, which was applied in previous studies [30,31].

The study was approved by the Ethics Commission of the Ludwig-Maximilians-Universität of Munich project number 326-07, Germany and was performed in accordance with the Declaration of Helsinki.

Participants

Persons with stroke, who had been diagnosed according to the stroke criteria of WHO 2006 [1] and had been treated in one of seven study centres for neurological rehabilitation in Germany (rehabilitation centre Nittenau, rehabilitation centre Bad Neustadt, rehabilitation centre Europakanal in Erlangen, rehabilitation centre Herzogenaurach, rehabilitation centre Passauer Wolf in Bad Griesbach, rehabilitation centre Loipl, outpatient department Mutabor in Munich) at any time since 2008 to 2009 were included in the study. The inclusion criteria were: stroke as main diagnosis, age of at least 18 years, ability to concentrate 30 minutes at minimum and sufficient knowledge of the language of the country to understand all aspects of the study for purposes of consent. Patients were excluded from the study, if they have had surgery and not completed wound healing, or were diagnosed with psychiatric disorders (e.g. acute major depression and personality disorders).

Trained health professionals in each study centre asked persons with stroke to participate after having checked the inclusion criteria. Participants were then selected from a list of willing and suitable patients by the maximum variation strategy [32] based on the following criteria: kind of stroke, affected hemiplegic side, time after stroke, age and gender.

According to previous studies [30], the group size for the focus group sessions was set at a maximum of five persons to represent different opinions and facilitate interactions. Overall sample size was determined by saturation [32,33]. Saturation refers to the point at which an investigator has obtained sufficient information from the field [33,34] (see data analysis: Saturation of data).

Data collection

All groups were performed in a non-directive manner by three moderators, who were health professionals experienced in the ICF, the treatment of persons with stroke and in conducting group processes.

Focus groups were performed according to focus group guidelines using open-ended questions and providing further instructions (e.g. introduction, procedure of the session and technical aspects). At the beginning of each focus group, in addition to introducing the procedures during the session, the concept of the ICF was presented in layman terms to all participants.

Six open-ended questions were asked addressing the components of the ICF addressing problems in Body functions, Body structures, Activities and participation as well as relevant Environmental factors and Personal factors as barriers or facilitators in layman terms (Table I). These questions have been used and validated through previous ICF Core Set validation studies [30,35].

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 group to enable the participants to verify and amend emergent issues.

The focus groups were audio recorded and transcribed verbatim with the Olympus DSS system. An assistant observed the process within the groups filling in field notes according to a standardized coding schema. After each focus group, a debriefing with the moderator and assistant took place to review the course of the focus group.

Table I. Open-ended questions given to the focus group participants.

	Open-ended questions
1.	If you think about your body and mind, what does not work the way it is supposed to? [body functions]
2.	If you think about your body, in which parts are your problems? [body structures]
3.	If you think about your daily life, what are your problems? [activities & participation]
4.	If you think about yourself, what is important to handle your situation after stroke? [personal factors]
5.	If you think about your environment and your living conditions, what barriers do you experience? [environmental factors as barriers]
6.	If you think about your environment and your living conditions, what do you find helpful or supportive? [environmental factors as facilitator]

Note: The ICF components indicated within the brackets were not presented to the participants.

Table II. Scheme of the data analysis: Qualitative analysis and linking to the ICF: An example.

Transcription		Concept	ICF category
	Qualitative analysis		*Linking*
Moderator	Let's go on to the next question. Next question is, if you think about your daily life, what are your problems?		
Patient A	Firstly, to be employed at this stage is impossible, because you've got so many distractions and malfunctions, you wouldn't be able to do your job properly.	Employment is impossible	d850 Remunerative employment
Moderator	At this stage, it's impossible…. There are further experiences or problems in daily life.		
Patient B	Yes, because I don't sleep at night because I have pain in my right shoulder and neck.	Problems sleeping at night Pain in shoulder Pain in neck	b134 Sleep functions b28016 Pain in joints b28010 Pain in head and neck
	At the morning, I have problems to dress myself.	Dressing is a problem	d540 Dressing
Patient C	To concentrate on a discussion with more than one person becomes a problem in daily life.….	Concentrate on discussion	b140 Attention functions d160 Focusing attention

Data analysis

Qualitative analysis

The meaning condensation procedure [27] was used for the qualitative analysis of data following a three-step procedure: In the first step, the transcripts of the focus groups were read in order to get an overview over the collected data. In the second step, 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 [36]. Therefore, a meaning unit division did not follow linguistic grammatical rules. Rather, the text was divided where the researcher discerned a shift in meaning [27]. 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 categories of the ICF based on established linking rules [37,38], which enable the linking of concepts to ICF categories in a systematic and standardized way (Table II). According to these linking rules, health professionals trained in the ICF linked 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.

Saturation of data

Saturation of data was defined as the point during data collection and analysis when the linking of the concepts of two consecutive focus groups revealed no additional second-level categories from the extended ICF core set for stroke [33,35].

Confirmation of the ICF categories of the extended ICF core set for stroke

An ICF category of the extended ICF core set for stroke was regarded as confirmed when the identical or a similar category emerged from the focus groups (e.g. "b7359 Functions of muscle tone, unspecified" confirmed by "b735 Functions of muscle tone"). Since the ICF categories are arranged in a hierarchical code system, the second-level categories of the extended ICF core set for stroke were considered confirmed when the corresponding third- or fourth-level category they belong to had been identified from the patient perspective.

Additional categories

An ICF category was regarded as an additional category when the category emerged from the focus groups and was not included in the current version of the extended ICF core set for stroke.

Accuracy of the analysis

To ensure the accuracy of data analysis, the following two strategies were adopted:

Multiple coding: Qualitative analysis and linking to the ICF of the first focus group was done by two health professionals (BK and AG) in order to achieve agreement concerning the implementation of the linking rules. Agreements, specifications and special cases of the linking rules that occurred when applying the rules were documented.

Peer review: After completing the multiple coding of the first focus group, a peer review was performed. Random samples of 20% of the transcribed text and 20% of the identified concepts (of the first health professional) were analysed and linked additionally by a second health professional. The

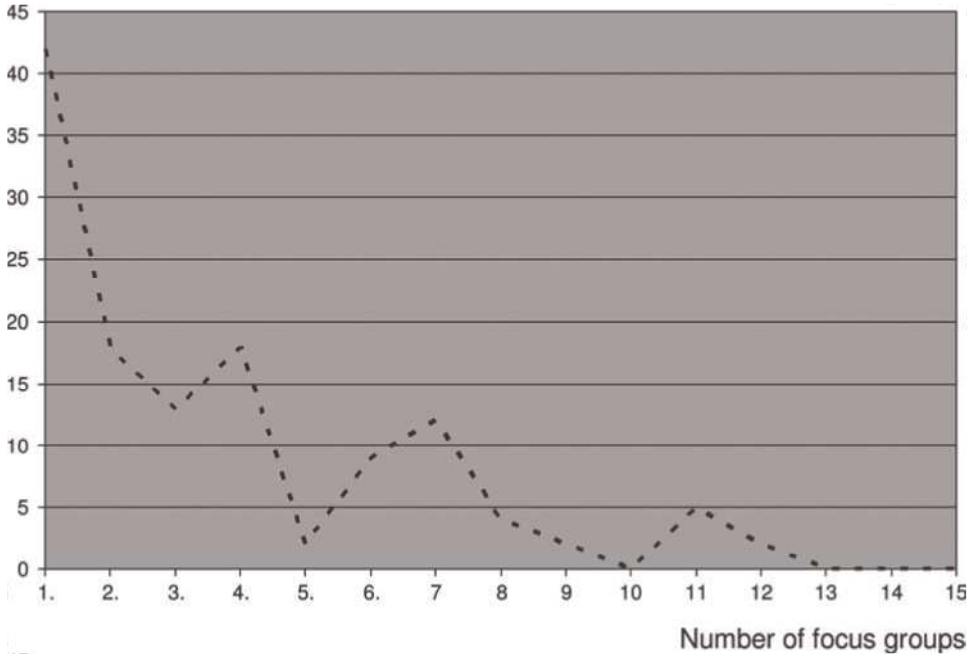

Figure 1. Saturation of data in the focus groups: Identification of new second-level categories.

degree of agreement between the two health professionals regarding linked ICF categories was calculated by κ statistics with 95%-bootstrapped confidence intervals [39,40], respectively. The values of the κ coefficient generally range from 0 to 1 where 1 indicates perfect agreement and 0 indicates no additional agreement beyond what is expected by chance only. The data analysis was performed with Statistical Analysis System (SAS) for windows V9.1 (SAS Institute Inc., Cary, NC, USA).

Results

Description of the focus groups

A total of 60 German speaking persons with stroke (30 female and 30 male) with a median age of 57 years (31–79 years) participated in the study. The mean disease duration was 3.7 month and ranged from 1 to 29 months. The focus group sessions lasted from about 45 minutes to 110 minutes. Saturation of data was reached after performing 15 focus groups (Figure 1).

Qualitative analysis and linking to the ICF

In total, 3907 concepts were identified in the qualitative analysis of the transcribed focus group sessions. These concepts were linked to 329 different ICF categories from first to fourth-level of the classification. Thus, the concepts were linked to a total of 158 second-level categories. Three hundred and eighty-five concepts could not be linked to ICF categories (e.g. quality of life in general, aspects of coping, disease management, time-related aspects, and variability of functioning). Two hundred and sixty-eight concepts were allotted to the component Personal factors which has not yet been classified.

Confirmation of the ICF categories of the extended ICF core set for stroke

In total, 127 out of the 166 second-level categories included in the extended ICF core set for stroke were confirmed by the participants. Forty-seven out of 59 second-level categories of the component Body functions, six out of 11 second-level categories of the component body structures, 47 out of 59 categories of Activities and participation and 28 out of 37 categories of Environmental factors included in the extended ICF core set for stroke were reported by the participants (Tables III–VI; categories in bold typeface specified as "confirmed categories").

Nine ICF categories of the extended ICF core set for stroke were identified in at least 14 of the 15 focus group sessions (Tables III–VI; categories marked with **).

Additional categories

Thirty-one second-level additional categories which are not included in the current version of the extended ICF core set for stroke were identified in the focus groups. Most of the additional categories derive from the component Environmental factors (n = 11) followed by Activities and participation (n = 9). Seven and four additional categories from the component Body functions and Body structures were reported by the participants, respectively (Tables III–VI; categories in italic typeface).

In addition to these categories, some issues emerged from the patient perspective which have not yet been covered by the extended ICF core set for stroke or even by the ICF classification like coping, expectations, gender, comorbidities, right half and left half of the body, risk to fall, need of time and breaks, reaction rate and others.

Accuracy of the analysis

The κ coefficient for the agreement between the two health professionals (peer review) was 0.73. The 95%-bootstrapped

Table III. Body functions (b): Patients' reporting of ICF categories (second-level).

ICF categories			
ICF code	ICF category title	Confirmed categories	Additional categories
Chapter 1: Mental functions			
b110	**Consciousness functions**	yes	
b114	**Orientation functions**	yes	
b117	**Intellectual functions**		
b126	**Temperament and personality functions**	yes	
b130	**Energy and drive functions**	yes	
b134	**Sleep functions**	yes	
b140	**Attention functions**	yes	
b144	**Memory functions**	yes	
b147	**Psychomotor functions**	yes	
b152	**Emotional functions**	yes	
b156	**Perceptual functions**	yes	
b160	**Thought functions**	yes	
b164	**Higher-level cognitive functions**	yes	
b167	**Mental functions of language**	yes	
b172	**Calculation functions**		
b176	**Mental Functions of sequencing complex movements**	yes	
b180	**Experience of self and time functions**	yes	
Chapter 2: Sensory functions and pain			
b210	**Seeing functions**	yes	
b215	**Functions of structures adjoining the eye**	yes	
b220	*Sensations associated with the eye and adjoining structures*		*yes*
b230	**Hearing functions**	yes	
b235	**Vestibular functions**	yes	
b240	**Sensations associated with hearing and vestibular function**	yes	
b250	*Taste function*		*yes*
b255	*Smell function*		*yes*
b260	**Proprioceptive functions**	yes	
b265	**Touch function**	yes	
b270	**Sensory functions related to temperature and other stimuli**	yes	
b280	**Sensation of pain**	yes	
Chapter 3: Voice and speech functions			
b310	**Voice functions**	yes	
b320	**Articulation functions**	yes	
b330	**Fluency and rhythm of speech functions**	yes	
b340	**Alternative vocalization functions**		
Chapter 4: Functions of the cardiovascular, haematological, immunological and respiratory systems			
b410	**Heart functions**	yes	
b415	**Blood vessel functions**	yes	
b420	**Blood pressure functions**	yes	
b430	**Haematological system functions**	yes	
b435	**Immunological system functions**		
b440	**Respiration functions**	yes	
b450	**Additional respiratory functions**		
b455	**Exercise tolerance functions**	yes	
Chapter 5: Functions of the digestive, metabolic and endocrine systems			
b510	**Ingestion functions**	yes	
b515	**Digestive functions**		
b525	**Defecation functions**	yes	
b530	**Weight maintenance functions**	yes	
b535	**Sensations associated with the digestive system**	yes	
b540	**General metabolic functions**		
b545	**Water, mineral and electrolyte balance functions**	yes	
b550	**Thermoregulatory functions**		
Chapter 6: Genitourinary and reproductive functions			
b620	**Urination functions**	yes	
b630	**Sensations associated with urinary functions**		
b640	**Sexual functions**		
Chapter 7: Neuromusculoskeletal and movement-related functions			
b710	**Mobility of joint functions**	yes	
b715	**Stability of joint functions**	yes	
b730	**Muscle power functions**	yes**	
b735	**Muscle tone functions**	yes	
b740	**Muscle endurance functions**		
b750	**Motor reflex functions**	yes	
b755	**Involuntary movement reactions**	yes	
b760	**Control of voluntary movement functions**	yes	
b765	*Involuntary movement functions*		*yes*
b770	**Gait pattern functions**	yes	
b780	*Sensations related to muscles and movement functions*		*yes*
Chapter 8: Functions of the skin and related structures			
b810	**Protective functions of the skin**		
b830	*Other functions of skin*		*yes*
b840	*Sensation related to the skin*		*yes*

Continued

**ICF categories confirmed in at least 14 of 15 focus groups. ICF categories of the extended ICF core set for stroke are shown in bold typeface. Additional ICF categories are shown in italic typeface.

confidence interval which indicates the precision of the estimated κ coefficient was 0.68–0.76.

Discussion

This study shows that the current version of the extended ICF core set for stroke was almost entirely confirmed from the patient perspective. A broad range of aspects related to everyday life were identified from the perspective of persons with stroke e.g. having problems in all fields of daily living like grasping, eating, washing, dressing, toileting, but also memory and aspects of personality. In addition, the content of several categories not contained in the extended ICF core set for stroke were named by the participants. These ICF categories need special clarification and will be discussed in the following paragraphs.

Thirty-one additional second-level categories not included in the current version of the extended ICF core set for stroke are mainly from the components environmental factors and activities and participation. In addition, the participants of the study named the content of several body functions' and body structures' categories. It is important to note that the

Table IV. Body structures (c): Patients' reporting of ICF categories (second-level).

ICF categories			
ICF code	**ICF category title**	**Confirmed categories**	**Additional categories**
Chapter 1: Structures of the nervous system			
s110	**Structure of brain**	**yes**	
s120	**Spinal cord and related structure**		
s130	**Structure of meninges**		
Chapter 2: The eye, ear and related structures			
s210	*Structure of eyeball*		*yes*
Chapter 3 Structures involved in voice and speech			
s320	*Structure of mouth*		*yes*
Chapter 4: Structures of the cardiovascular, immunological and respiratory systems			
s410	**Structure of cardiovascular system**	**yes**	
s430	**Structure of respiratory structure**		
Chapter 5: Structures related to the digestive, metabolic and endocrine systems			
s530	**Structure of stomach**		
Chapter 7: Structures related to movement			
s710	**Structure of head and neck region**	**yes**	
s720	**Structure of shoulder region**	**yes**	
s730	**Structure of upper extremity**	**yes****	
s750	**Structure of lower extremity**	**yes**	
s760	*Structure of trunk*		*yes*
s770	*Additional musculoskeletal structures related to movement*	*yes*	
Chapter 8: Structures of skin			
s810	**Structure of areas of skin**		

**ICF categories confirmed in at least 14 of 15 focus groups. ICF categories of the extended ICF core set for stroke are shown in bold typeface. Additional ICF categories are shown in italic typeface.

Table V. Activities and participation (d): Patients' reporting of ICF categories (second-level).

ICF categories			
ICF code	**ICF category title**	**Confirmed categories**	**Additional categories**
Chapter 1: Learning and applying knowledge			
d110	**Watching**		
d115	**Listening**		
d120	**Other purposeful sensing**		
d130	**Copying**		
d135	**Rehearsing**	**yes**	
d145	*Learning to write*		*yes*
d155	**Acquiring skills**	**yes**	
d160	**Focusing attention**	**yes**	
d163	*Thinking*		*yes*
d166	**Reading**	**yes**	
d170	**Writing**	**yes**	
d172	**Calculating**		
d175	**Solving problems**	**yes**	
d177	**Making decisions**	**yes**	
Chapter 2: General tasks and demands			
d210	**Undertaking a single task**	**yes**	
d220	**Undertaking a multiple task**	**yes**	
d230	**Carrying out daily routine**	**yes**	
d240	**Handling stress and other psychological demands**	**yes****	
Chapter 3: Communication			
d310	**Communication with receiving spoken messages**		
d315	**Communication with receiving nonverbal messages**		
d325	**Communication with receiving written messages**	**yes**	
d330	**Speaking**	**yes**	
d335	**Producing nonverbal messages**		
d345	**Producing messages in formal sign messages**	**yes**	
d350	**Conversation**	**yes**	
d355	*Discussion*		*yes*
d360	**Using communication devices and techniques**	**yes**	
Chapter 4: Mobility			
d410	**Changing basic body position**	**yes**	
d415	**Maintaining a body position**	**yes**	
d420	**Transferring oneself**		
d430	**Lifting and carrying objects**	**yes**	
d435	*Moving objects with lower extremities*		*yes*
d440	**Fine hand use**	**yes**	
d445	**Hand and arm use**	**yes**	
d450	**Walking**	**yes****	
d455	**Moving around**	**yes**	
d460	**Moving around in different locations *(d455)****	**yes**	
d465	**Moving around using equipment**	**yes**	
d470	**Using transportation**	**yes**	
d475	**Driving**	**yes**	
d480	*Riding animals for transportation*		*yes*
Chapter 5: Self-care			
d510	**Washing oneself**	**yes**	
d520	**Caring for body parts**	**yes**	
d530	**Toileting**	**yes**	
d540	**Dressing**	**yes**	
d550	**Eating**	**yes**	
d560	**Drinking**	**yes**	
d570	**Looking after one's health**	**yes****	
Chapter 6: Domestic life			
d620	**Acquisition of goods and services**	**yes**	
d630	**Preparing meals**	**yes**	
d640	**Doing housework**	**yes**	
d650	*Caring for household objects*		*yes*
d660	*Assisting others*		*yes*
Chapter 7: Interpersonal interactions and relationships			
d710	**Basic interpersonal interactions**		
d720	*Complex interpersonal interactions*		*yes*
d750	**Informal social relationships**	**yes**	
d760	**Family relationships**	**yes**	
d770	**Intimate relationships**	**yes**	
Chapter 8: Major life areas			
d845	**Acquiring, keeping and terminating a job**	**yes**	
d850	**Remunerative employment**	**yes****	
d855	**Non-remunerative employment**	**yes**	
d860	**Basic economic transactions**	**yes**	
d865	*Complex economic transaction*		*yes*
d870	**Economic self-sufficiency**	**yes**	

Continued

Chapter 9: Community, social and civic life			
d910	**Community life**		
d920	**Recreation and leisure**	**yes**	
d930	**Religion and Spirituality**	**yes**	
d940	**Human rights**		

*Confirmation according to similar ICF categories; **ICF categories confirmed in at least 14 of 15 focus groups. ICF categories of the extended ICF core set for stroke are shown in bold typeface. Additional ICF categories are shown in italic typeface.

Table VI. Environmental factors (e): Patients' reporting of ICF categories (second-level).

ICF categories			
ICF code	**ICF category title**	**Confirmed categories**	**Additional categories**
Chapter 1: Products and technology			
e110	**Products or substances for personal consumption**	**yes**	
e115	**Products and technology for personal use in daily living**	**yes**	
e120	**Products and technology for personal indoor and outdoor mobility and transportation**	**yes**	
e125	**Products and technology for communication**	**yes**	
e135	**Products and technology for employment**		
e150	**Design, construction and building products and technology of buildings for public use**	**yes**	
e155	**Design, construction and building products and technology of buildings for private use**	**yes**	
e160	*Products and technology of land development*		*yes*
e165	**Assets**	**yes**	
Chapter 2: Natural environment and human-made changes to environment			
e210	**Physical geography**	**yes**	
e215	*Population*		*yes*
e220	*Flora and fauna*		*Yes*
e225	*Climate*		*Yes*
e240	**Light**		
e250	**Sound**	**yes**	
Chapter 3: Support and relationships			
e310	**Immediate family**	**yes****	
e315	**Extended family**	**yes**	
e320	**Friends**	**yes**	
e325	**Acquaintances, peers, colleagues, neighbours and community members**	**yes**	
e330	*People in positions of authority*		*yes*
e340	**Personal care providers and personal assistants**	**yes**	
e345	*Strangers*		*yes*
e350	*Domesticated animals*		*yes*
e355	**Health professionals**	**yes****	
e360	**Other professionals**	**yes**	
Chapter 4: Attitudes			
e410	**Individual attitudes of immediate family members**	**yes**	
e415	*Individual attitudes of extended family members*		
e420	**Individual attitudes of friends**	**yes**	
e425	**Individual attitudes of acquaintances, peers, colleagues, neighbours and community members**	**yes**	
e430	*Individual attitudes of people in positions of authority*		*yes*
e440	**Individual attitudes of care providers and personal assistance**		
e445	*Individual attitudes of strangers*		*yes*
e450	**Individual attitudes of health professionals**	**yes**	
e455	**Individual attitudes of health-related professionals**		
e460	**Societal attitudes**	**yes**	
e465	**Social norms, practices and ideologies**		
e515	**Architecture and construction services, systems and policies**	**yes**	
e525	**Housing services, systems and policies**	**yes**	
Chapter 5: Services, systems and policies			
e530	**Utilities services, systems and policies**		*yes*
e535	*Communication services, systems and policies*		
e540	**Transportation services, systems and policies**	**yes**	
e545	*Civil protection services, systems and policies*		*yes*
e550	**Legal services, systems and policies**		
e555	**Associations and organizational services, systems and policies**		
e570	**Social security services, systems and policies**	**yes**	
e575	**General social support services, systems and policies**	**yes**	
e580	**Health services, systems and policies**	**yes****	
e590	**Labour and employment services, systems and policies**	**yes**	

**ICF categories confirmed in at least 14 of 15 focus groups. ICF categories of the extended ICF core set for stroke are shown in bold typeface. Additional ICF categories are shown in italic typeface.

participants often reported impairments in body structures by describing them in terms of impaired body functions. In-line with this, categories like b220 Sensations associated with the eye and adjoining structures and the corresponding body structures s210 Structure of eyeball or s320 Structure of mouth and b250 Taste as well b255 Smell functions which are corresponding to these body structures were identified from the patient perspective. It also needs to be mentioned that in persons with stroke s320 Structure of mouth can be injured. Therefore, they have a risk to get wounds on lips as a consequence of reduced sensory in the face and mouth. Also eating with numbness around the mouth is difficult to control [41].

Structures related to movement such as s760 Structures of trunk and s770 Additional musculoskeletal structures related to movement were identified as being important from the patient perspective. These are typical categories which are affected after a stroke attack in combination with muscle tone and movement control or pain [42,43]. Movement-related categories of the component Body functions which are currently

not included in the extended ICF core set for stroke were b765 Involuntary movement functions and b780 Sensations related to muscles and movement functions. These are categories which focus on the subjective perception of movement-related function. To assess muscle sensations, one has to rely on the self-report of persons suffering a disease because it is impossible to measure functions related to sensations objectively by a scale or an instrument. This is comparable to measuring pain or other sensations which are driven by feelings and depend from individual experiences and self-perceptions.

The ICF categories d163 Thinking and d355 Discussion are basic skills and core competencies for communication and were intensively discussed by the participants of this study. To learn to speak again is a profound experience after stroke [44]. Not being able to say what one wants, struggling for words, knowing what is meant but not being able to tell it can lead to depressive phases of life for the patients [45,46]. This experience was often reported as connected to the inability to write, which is indicated by the ICF category d145 Learning to write. Limitations in speaking and writing have an important influence on keeping or losing autonomy and requiring help from other people [29,46,47].

Autonomy in movement was one of the most important topics of the focus group sessions reported by the participants and are represented by the not included ICF categories d480 Riding animals for transportation and d435 Moving objects with lower extremities. In almost all focus groups, the participants intensively discussed issues referring to car driving and its corresponding abilities [48]. This also reflects expectations regarding the recovery of the movement ability of the lower extremities like pedalling the accelerator or the brakes of a car. It also includes cognitive functions such as reaction rate which was also identified from the patient perspective. Patients from rural areas are dependent on driving a car, especially as e530 utility services and systems are not as well equipped as in the cities [49]. Persons with stroke exchanged their concerns regarding decreased mobility and independence, a fact that was also supported in further validation studies of the extended ICF core set for stroke from the perspective of health professionals [12,13].

Losing autonomy means becoming more and more dependent and needing support from other people like family, partner, or health professionals and animals in everyday life described by the ICF categories d650 Caring for household objects, d660 Assisting others, d85 Complex economic transactions or caring for e350 Domestic animals. These activities are no longer possible to the same extent as before [50–52]. In-line with this, the participants of the focus groups exchanged worries and concerns, such as: "…in the past I have done everything alone, I was responsible and did take care of my family and now, I need help in nearly each part of daily living. I do want to be independent from other people".

Staying at home and living independently are environmental factors that are crucial for persons with stroke. The ICF category d545 Civil protection services, systems and policies is reported by participants of the focus groups in the context of feeling unsecure at home and needing help from emergency services using special emergency systems. The identified environmental factors have an impact on nearly all fields of everyday life and therefore, this component covers aspects which range from interventions (e.g. medication) and devices in different forms to climate, flora and fauna and also includes social systems. In our study, the statements of the participants were mostly related to categories of chapter 3 support and relationships (e.g. e330 People in authority or e345 Strangers) and chapter 4 attitudes of their surrounding people (e.g. e445 Individual attitudes of people in authority or e445 individual attitudes of strangers). Attitudes of people in authority are important for persons with stroke because long-term (chronic) illness and their consequences are strongly associated with unsecure return-to-work [44,53–57]. In most cases, successful vocational rehabilitation needs constructive collaborations between employees and their persons in authority [58,59]. These additional categories may be considered if an updated version of the extended ICF core set for stroke is developed.

Regarding the ICF categories from the extended ICF core set for stroke which were not confirmed from the patient perspective, it is important to mention that those of the component Activities and participation are strongly associated with Body functions' categories which were confirmed, such as b210 Seeing functions, b230 Hearing functions, b310 Voice functions and b320 Articulation functions. ICF categories from the component Activities and participation which were not confirmed were d110 Watching, d115 Listening, d120 Other purposeful sensing, d130 Copying, d310 Communicating with—receiving—spoken messages, d315 Communicating with—receiving—nonverbal messages, d335 Producing nonverbal messages, d420 Transferring oneself, d710 Basic interpersonal relationships, d910 Community life and d940 Human rights. In addition, body functions' categories as b172 Calculation functions, b435 Immunological system functions, b450 Additional respiratory functions, or b515 Digestive functions and body structures' categories as s120 Spinal cord and related structures, s130 Structure of meninges, s430 Structure of respiratory system and s530 Structure of stomach were not identified in the focus groups. Several concepts identified from the patient perspective were labelled as "not covered" by the ICF. It is important to emphasize that the majority of these concepts does not refer to aspects of functioning and disability as defined by the ICF classification. These concepts mainly cover time-related or disease specific aspects (e.g. "needing more time and breaks to accomplish daily activities" and "right half and left half of the body") and general quality of life or satisfaction with life, respectively. Since the ICF does not cover these aspects nor quality of life in the sense of subjective wellbeing [60], these issues could not be linked to the ICF. However, other "not covered" concepts identified in this study are clearly related to functioning and disability as defined by the ICF (e.g. "reaction rate"). These issues should be included in the update process of the ICF, which has already been initiated by WHO.

There are some methodological issues that should be mentioned in detail. The focus groups in our study were composed of 3–5 participants which is a small group size compared to other qualitative studies. We decided to perform focus group sessions with few participants because of the complexity of

the topic and the expertise of the participants according to the literature [61]. With a small group size, each participant has a greater opportunity to talk which is reported to be an important aspect for group dynamics in groups with elderly and ill participants [62,63].

It is important to mention that several strategies were used to improve and verify the trustworthiness of the qualitative data. (1) Triangulation to ensure the comprehensiveness of data. We included data triangulation by using two data analysts (investigator triangulation: multiple coding) [64,65]. (2) Continuous data analysis was used according to Pope *et al.* [22]. (3) Reflexivity was assured by conducting a research diary for the documentation of memos concerning the design, data collection and analysis of the study. (4) Clear exposition was used establishing guidelines for conducting the focus groups (including open-ended questions), verbatim transcription, and linking rules [37,38]. Thus, a clear account of methods of data collection and analysis was assured. (5) Finally, a peer review was performed. The κ coefficient of 0.73 for the accuracy of the peer review is comparable to other studies reporting κ statistics about the linking of categories and can be regarded as "substantial agreement" [30,35,66,67].

There are also some limitations of this study that need special mentioning. The sample consists only of German speaking participants from Austria, Bulgaria, and Germany. Our suggestion is that our methods could be used in similar studies in other countries to establish a cross-cultural perspective. Secondly, the linking process was performed by two health professionals according to established linking rules [37,38]. However, it remains unclear whether other health professionals would have decided differently. Finally, we followed the strategy of saturation during data analyses with the criteria of two consecutive focus groups revealing no additional second-level categories in the Extended ICF Core Set for stroke. Participants in a 16th focus group still might report new themes and concepts not yet reported.

Conclusions

The current version of the extended ICF core set for stroke with its selected categories was confirmed almost entirely from the patient perspective. Several additional categories not represented in the extended ICF core set for stroke emerged from the focus groups. Further research specifically on the additional ICF categories that are not yet included in the extended ICF core set for stroke is needed. The results of this study will be taken into account when the final version of the extended ICF core set for stroke is agreed. Further research is needed to implement the Extended ICF Core Set for stroke in clinical practice and to develop, for example, patient-oriented outcome measures based on this ICF Core Set as it was already done in other diseases [68].

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Appendix 5 Study 1 - short description of the project

- patient perspective -

Kurzdarstellung des Projektes

Die im Jahr 2001 durch die World Health Assembly (WHO) verabschiedete Internationale Klassifikation der Funktionsfähigkeit, Behinderung und Gesundheit (ICF) [1] bietet ein anerkanntes Rahmenkonzept für die Beschreibung der funktionalen Gesundheit von Personen mit einer bestimmten Gesundheitsstörung, wie z.B. nach Schlaganfall. Die ICF basiert auf dem bio-psycho-sozialen Modell, das die funktionale Gesundheit und Behinderung über die Komponenten *Körperstrukturen* und *–funktionen*, *Aktivitäten und Partizipation* als auch *Personbezogene Faktoren* und *Umweltfaktoren* abbildet. Die ICF-Klassifikation mit ihren über 1.400 Kategorien kann als Referenz gesehen werden, ist aber in der klinischen Praxis nicht anwendbar. Um die ICF praktikabel für den Einsatz in der Medizin zu machen [2], wurden so genannte ICF Core Sets entwickelt [3]. Bisher wurden ICF Core Sets für 12 chronische Erkrankungen, darunter für Schlaganfall [4,5,6,] für den Einsatz im Akutbereich und in der Rehabilitation [7,8,9], entwickelt.

Da die Funktionsfähigkeit ein bedeutendes Outcome für Personen nach Schlaganfall ist, wurden in mehreren Projektphasen das *ICF Core Set für Schlaganfall* entwickelt und dabei für diese Gesundheitsstörung relevante ICF-Kategorien von Funktionsfähigkeit identifiziert.

Ziel des geplanten Forschungsvorhabens ist es nun, das *ICF Core Set für Schlaganfall* aus der Perspektive der Patienten zu validieren. Es handelt sich dabei um ein Kooperationsprojekt der ICF Research Branch an der Ludwig-Maximilians-Universität München (Deutschland) mit verschiedenen klinischen Kooperationspartnern und dem Team der WHO für Classification, Assessment and Surveys (CAS). Die vorliegende und bisher vorläufige Version des *ICF Core Sets für Schlaganfall* wurde evidenzbasiert entwickelt und auf einer ICF Core Set Konsensus-Konferenz 2004 verabschiedet [10].

Die vorgesehene Validierung des *ICF Core Sets für Schlaganfall* erfolgt nach folgenden drei Forschungsansätzen:

(a) Im Rahmen einer qualitativen Studie soll das vorliegende *ICF Core Set für Schlaganfall* validiert werden. Mithilfe qualitativer Forschungsmethodik soll anhand von Fokusgruppen (qualitative Gruppeninterviews mit 4-6 Patienten) und Einzelinterviews

(1) die Sichtweise von Patienten nach Schlaganfall hinsichtlich ihrer funktionalen Gesundheit untersucht und verstanden werden. Darüber hinaus

(2) Konzepte der funktionalen Gesundheit, die für Patienten nach Schlaganfall wichtig sind, identifiziert und mit der ICF und deren Kategorien in Beziehung gesetzt werden.

Für diesen Teil des Projektes suchen wir aktuell nach **Kooperationspartnern,** die es uns ermöglichen Patienten/Patientinnen ihrer Einrichtung in Form von Fokusgruppen oder Einzelinterviews befragen zu dürfen. Wesentlich dabei ist der Zugang zum Patienten/Patientin. Die Datenerhebung selbst erfolgt durch das Team der ICF Forschungsstelle aus München.

Die beiden folgenden Validierungsansätze sind für das *ICF Core Set für Schlaganfall* bereits abgeschlossen.

(b) Expertenbefragung: Mit der Expertenbefragung wurden die relevantesten Aspekte der funktionalen Gesundheit von Patienten mit Schlaganfall exploriert. An dieser Expertenbefragung nahmen weltweit Experten unterschiedlicher Berufsgruppen (Neurologie, Pflege, Ergotherapie, Neuropsychologie, Physiotherapie, Logopädie, Sozialarbeit) teil.

(c) Empirische Querschnittstudie: Mit dem vorliegenden *ICF Core Set für Schlaganfall* wurden weltweit in einer Querschnittsstudie Daten von Patienten mit Schlaganfall erhoben, um die funktionale Gesundheit der Patienten aus klinischer Sicht zu beschreiben. Zusätzlich wurden Daten mittels der Stroke Impact Scale (SIS) [11], dem Komorbiditätsfragebogen (SCQ) [12] und fünf Fragen zur Zufriedenheit mit verschiedenen Lebensbereichen aus dem World Health Organization Quality of Life Questionnaire (WHOQoL) [13] und der Short-Form Health Survey (SF-36) [14] erhoben, um die subjektive Einschätzung der Patienten hinsichtlich Gesundheit und Wohlbefinden zu erfassen.

Die Studienergebnisse dieser drei Validierungsansätze werden im Herbst 2009 auf der ICF Core Set Konsensus-Konferenz einem internationalen Expertenpanel vorgestellt, um in einem mehrstufigen Verfahren die ICF Core Sets für Schlaganfall endgültig zu verabschieden.

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Andrea Gläßel 16.10.08

Appendix 6 Study 1 - patient information and informed consent -

- patient perspective -

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Ihr Zeichen	Unser Zeichen	Ansprechpartner	Telefon	Telefax	E Mail
		Prof. Gerold Stucki	089/7095 4051	089/7095 8836	gerold.stucki@.med.uni-muenchen.de

Patienteninformation und Einverständniserklärung zur Studie

„Validierung der *ICF Core Sets für Schlaganfall* aus der Patientenperspektive“

Sehr geehrte Patientin, sehr geehrter Patient,

wir möchten Sie einladen, an einer Gruppeninterview-Studie (‚Fokusgruppen-Studie') teilzunehmen, die die Auswirkungen eines Schlaganfall auf den Alltag untersucht. Die Studie wird von der Klinik für Physikalische Medizin und Rehabilitation des Klinikums Großhadern durchgeführt. Im Folgenden werden die genauen Ziele der Studie sowie weitere wichtige Informationen erläutert, die Ihnen dabei helfen sollen, eine Entscheidung bezüglich Ihrer Teilnahme an der Studie zu treffen.

Ziel der Studie

Der Schlaganfall und seine Behandlung verursachen Beschwerden, die nicht nur den Körper, sondern auch die Funktionsfähigkeit und das Alltagsleben der PatientInnen beeinflussen. Damit diese Probleme im klinischen Alltag dokumentiert werden können, wurden für Ärzte/Ärztinnen und Fachleute der Gesundheitsberufe sogenannte ICF Core Sets wissenschaftlich entwickelt (ICF = Internationale Klassifikation für Funktionsfähigkeit, Behinderung und Gesundheit). Somit können ausgehend von der Diagnose alle Bereiche des Patientenlebens mit dieser Klassifikation dokumentiert werden. Zu klären ist noch die Frage, ob die von den Fachleuten entwickelten Core Sets für Schlaganfall aus Ihrer Sicht den Alltag und die Probleme für Sie adäquat abbilden. Hierfür möchten wir Sie als Experten/Expertin Ihrer Erkrankung befragen. Wir werden verschiedene Gruppendiskussionen („Fokusgruppen“) durchführen und die Ergebnisse dieser Gruppendiskussionen zu einer neuen Version der Core Sets aus Patientensicht zusammenstellen. Diese Ergebnisse werden wir später mit den von den Fachleuten entwickelten Core Sets für Schlaganfall vergleichen.

Die Studie ist für Sie mit keinerlei Risiko verbunden. In dieser Studie wird es Ihre Aufgabe sein, an einer Gruppendiskussion mit anderen PatientInnen teilzunehmen sowie einen Fragebogen auszufüllen. Eine Wegeversicherung wurde nicht abgeschlossen.

Zeitaufwand für diese Studie

Das Gruppeninterview wird etwa eineinhalb Stunden dauern. Zusätzlich ist ein kurzer Fragebogen auszufüllen. Es werden keine sonstigen Untersuchungen durchgeführt.

Freiwilligkeit der Teilnahme

Ihre Teilnahme an dieser Studie ist vollkommen freiwillig. Sie können Sie ablehnen, Ihr Einverständnis jederzeit ohne Angabe von Gründen widerrufen, ohne dass Ihnen dadurch Nachteile entstehen. Ein Widerruf Ihres Einverständnisses berührt nicht Ihren Anspruch auf weitere und fortlaufende medizinische Behandlung.

Durchführung der Studie

Falls Sie sich für eine Teilnahme an der Studie entscheiden sollten und die beiliegende Einverständniserklärung unterschreiben, wird Frau Andrea Gläßel mit Ihnen Kontakt aufnehmen, um mit Ihnen einen Termin zur Teilnahme an dem Gruppeninterview zu vereinbaren. Dabei werden verschiedene Termine zur Auswahl stehen. Das Interview wird in einem ruhigen Raum im Klinikum Großhadern durchgeführt. Die im Rahmen des Gruppeninterviews angesprochenen Themen unterliegen selbstverständlich der Schweigepflicht. Das Gruppeninterview wird digital aufgezeichnet und wörtlich abgeschrieben. Ihr Name wird bei der Abschrift der Aufzeichnung durch eine Codenummer ersetzt, so dass Ihr Name in der Abschrift nicht erscheint. Das bedeutet, dass ab der Aufnahme alle Daten und weiteren Auswertungen in pseudonomysierter Form gespeichert und bearbeitet werden. Die digitalen Aufzeichnungen werden nach Auswertung der Daten vernichtet.
Diese Studie soll als wissenschaftliche Arbeit publiziert werden. In dieser wissenschaftlichen Arbeit wird, ebenfalls in pseudonymisierter Form, aus den Interviews zitiert werden. Auf Wunsch informieren wir Sie gerne über die Ergebnisse der Studie.
Die Studie ist für Sie mit keinerlei Risiko verbunden. In dieser Studie wird es Ihre Aufgabe sein, an einem Gruppeninterview mit anderen Patientinnen und Patienten teilzunehmen.

Einverständnis und Datenschutz

Alle Patienteninformationen, die durch diese wissenschaftliche Studie erhalten werden, werden als bevorzugte Informationen behandelt und pseudonomysiert dokumentiert. Die Patientenidentität sowie jede Information, die mit dieser Person in Bezug gebracht werden könnten, dürfen nicht offenbart werden.

Für diesen Zweck werden Sie innerhalb dieser Studie eine Codenummer erhalten, und alle erhobenen Daten werden pseudonomysiert und unter einem wissenschaftlichen ethischen Standard ausgewertet. Die Weitergabe der Daten im In- und Ausland erfolgt ausschließlich zu wissenschaftlichen Zweck und Ihre Angaben zur Person werden streng vertraulich behandelt und Sie werden ausnahmslos darin nicht namentlich genannt.

Patientendaten, die im Rahmen der Studie verwendet werden, werden nur verschlüsselt weitergegeben. Alle Daten (Transkripte und die digitalen Aufzeichnungen) werden auf dem Computer gespeichert. Diese Dateien sind nur über ein Kennwort zugänglich, das ausschließlich der Studienkoordinatorin bekannt ist. Die Originalfragebögen werden in einem verschließbaren Schrank aufbewahrt.

Um eine Pseudonymisierung gewährleisten zu können, werden bei der Transkription die Patienten nicht namentlich erwähnt, sondern deren Namen durch eine sechsstellige Codenummer ersetzt. Diese Codenummern werden ebenfalls für die Identifikation der Patienten-Fragebögen verwendet, d.h. auf allen Fragebögen sind nur die entsprechenden Codenummern vermerkt. Die Codenummern enthalten keine Zusätze, die aus personenbezogenen Merkmalen oder Teilen davon gewonnen werden können; sie enthalten ausschließlich Zahlen, die fortlaufend vergeben werden.

Die Auswertung der Daten an sich erfolgt in pseudonymisierter Form. Die digitalen Aufzeichnungen, Transkripte und Fragebögen werden nach Abschluss der Auswertungen vernichtet. Eine Entschlüsselung aller Daten ist grundsätzlich nicht vorgesehen. Sollte ein Patient sein Einverständnis zur Teilnahme widerrufen, werden die Daten entschlüsselt und alle personenbezogenen Daten vernichtet. Die bis dahin erhobenen und gespeicherten Daten werden jedoch bei der Auswertung verwendet.

Sollten sich nach Durchsicht dieser Information noch Fragen ergeben oder Unklarheiten bestehen, so wenden Sie sich bitte an:

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und Rehabilitation • Marchioninistraße 15 • D-81377 München

Einverständniserklärung zur Teilnahme an der Studie

„Validierung der *ICF Core Sets für Schlaganfall* aus der Patientenperspektive - eine qualitative Studie“

Ich, Frau / Herr _____ geboren am _____, wurde von

_____(Name des Arztes oder der Gesundheitsfachperson) über Art, Zielsetzung und zeitlichen Aufwand der wissenschaftlichen Studie “Die Auswirkungen eines Schlaganfalls auf den Gesundheitszustand und auf den Alltag aus der Sicht der Patienten - eine qualitative Studie“ aufgeklärt und informiert. Die schriftliche Patienteninformation und eine Kopie der Einverständniserklärung wurden mir ausgehändigt. Ich hatte ausreichend Zeit, diese zu lesen und mich für oder gegen eine Teilnahme zu entscheiden. Ich habe den Inhalt verstanden, bestehende Fragen wurden besprochen und beantwortet.
Ich erkläre mich einverstanden, an der genannten Studie teilzunehmen, behalte mir jedoch vor, diese ohne Angabe von Gründen jederzeit abzubrechen, ohne dass dadurch Nachteile für mich entstehen. Ich erkläre mich mit der pseudonomysierten Aufzeichnung von Daten und deren Weitergabe für wissenschaftliche Zwecke einverstanden.

_____ _____
Unterschrift der Patientin/des Patienten Datum, Ort

Ich habe heute Frau / Herrn _____bestmöglich und verständlich über die Teilnahmebedingungen der wissenschaftlichen Studie „Die Auswirkungen eines Schlaganfall auf den Gesundheitszustand und auf den Alltag aus der Sicht der Patienten - eine qualitative Studie“ im obigen Sinne aufgeklärt.

_____ _____
Unterschrift des aufklärenden Arztes oder einer Gesundheitsfachperson Datum, Ort

Bitte der Patientin/dem Patienten eine Kopie nach Unterschrift aushändigen!

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Erklärung zur Erhebung und Verwendung der Daten nach Maßgabe der Information

„Validierung der *ICF Core Sets für Schlaganfall* aus der Patientenperspektive - eine qualitative Studie“

Ich, Frau / Herr _____ geboren am _____, wurde von _____ (Name des Arztes oder der Gesundheitsfachperson) über die datenschutzrechtlichen Belange der wissenschaftlichen Studie “Die Auswirkungen von Fingerpolyarthrose auf den Gesundheitszustand und auf den Alltag aus der Sicht der Patienten - eine qualitative Studie“ aufgeklärt und informiert. Ich erkläre mich mit der pseudonomysierten Aufzeichnung von Daten und deren Weitergabe für wissenschaftliche Zwecke einverstanden.
Mit ist bekannt, dass

- alle Patienteninformationen, die durch diese wissenschaftliche Studie erhalten werden, als bevorzugte Informationen behandelt und pseudonomysiert dokumentiert werden.
- die Patientenidentität sowie jede Information, die mit einer Person in Bezug gebracht werden könnte, nicht offenbart werden dürfen und alle erhobenen Daten pseudonomysiert und unter einem wissenschaftlichen ethischen Standard ausgewertet werden.
- die Weitergabe der Daten im In- und Ausland ausschließlich zu wissenschaftlichen Zweck und nur verschlüsselt erfolgt und die Angaben zur Person streng vertraulich behandelt werden.
- Patientendaten, die im Rahmen der Studie erhoben wurden, unter Verschluss gehalten werden.
- zur Pseudonymisierung bei der Transkription die Patienten nicht namentlich erwähnt werden, sondern deren Namen durch eine sechsstellige Codenummer ersetzt werden. Die Codenummern enthalten keine Zusätze, die aus personenbezogenen Merkmalen oder Teilen davon gewonnen werden können; sie enthalten ausschließlich Zahlen, die fortlaufend vergeben werden.
- die Auswertung der Daten in pseudonymisierter Form erfolgt. Die digitalen Aufzeichnungen, Transkripte und Fragebögen werden nach Abschluss der Auswertungen vernichtet.
- sollte ein Patient sein Einverständnis zur Teilnahme widerrufen, die Daten entschlüsselt und alle personenbezogenen Daten vernichtet werden. Die bis dahin erhobenen und gespeicherten Daten werden jedoch bei der Auswertung verwendet.

Unterschrift der Patientin/des Patienten _____ Datum, Ort _____

Vorlage KUM/OC – fe (00-03-13)

Ich habe heute Frau / Herrn _____ bestmöglich und verständlich über die datenschutzrechtlichen Belange der wissenschaftlichen Studie „Validierung der *ICF Core Sets für Schlaganfall* aus der Patientenperspektive - eine qualitative Studie“ im obigen Sinne aufgeklärt.

Unterschrift des aufklärenden Arztes oder einer Gesundheitsfachperson	Datum, Ort

Bitte dem Patienten eine Kopie nach Unterschrift aushändigen!

Appendix 7 Study 2 - copy of the original publication - gender perspective -

Content validation of the International Classification of Functioning, Disability and Health (ICF) Core Set for stroke from gender perspective using a qualitative approach

Authors: **Glässel A**, Coenen M, Kollerits B, Cieza A.

Reference: European Journal of Physical and Rehabilitation Medicine (accepted for publication July 10th 2012) proof version

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EUR J PHYS REHABIL MED 2012;48:1-2

Content validation of the International Classification of Functioning, Disability and Health Core Set for stroke from gender perspective using a qualitative approach

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Background. **The extended ICF Core Set for stroke is an application of the International Classification of Functioning, Disability and Health (ICF) of the World Health Organisation (WHO) with the purpose to represent the typical spectrum of functioning in persons with stroke.**

Aim. **The objective of the study is to provide evidence for the content validity of the extended ICF Core Set for stroke from persons after stroke taking into account gender perspective.**

Design and setting. **A qualitative design was conducted by using individual interviews with women and men after stroke in an outpatient rehabilitation setting.**

Methods. **The sample for the maximum variation strategy. Saturation was determined by consideration. Concepts from qualitative data analysis were linked to ICF categories and compared to the extended ICF Core Set for stroke.**

Results. **Twelve women and 12 men participated in 24 individual interviews. In total, 143 of 166 ICF categories included in the extended ICF Core Set for stroke were confirmed (women's version: N.=17; both genders: N.=113). Thirty-six additional categories that are not yet included in the extended ICF Core Set for stroke were raised by women and men.**

Conclusion. **This study confirms that the experience of functioning and disability of stroke shows communalities and differences between women and men. The validity of the extended ICF Core Set for stroke could be only confirmed, since it does not only include the areas of functioning and disability relevant to both genders but also those exclusively relevant to either women or men.**

Clinical Rehabilitation Impact. **Further research is needed on ICF categories not yet included in the extended ICF Core Set for stroke.**

KEY WORDS: Stroke - Rehabilitation - Qualitative research.

Stroke is the second leading cause of death of people worldwide. Projections indicate that until 2020 stroke will remain one of the leading causes of disability in industrialised countries.[1] There is a growing recognition of gender differences with implications at the clinical and public health level.[2, 3] Over their lifetime, 16% of women are at risk to die from stroke compared to only 8% of men.[4, 5]

In the Framingham Study (FHS) cohort, gender-specific neurological deficits and aspects of disability in post-stroke people were documented longitudinally in the cohort initiated in 1948 with 5209 participants.[6-8] Gender-specific results showed differences in women and men with respect to inci-

*The responsibility for the content of this publication lies with the ICF Research Branch

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dence, lifetime risk of stroke, age at first stroke, institutionalisation rates and post-stroke disability.[3, 6, 9] In acute phase and three months after stroke, women are more disabled in every-day activities (*e.g.* eating, dressing, grooming, transfer from bed to chair) than men.[1,6] Men are also almost three times more likely to be married at the time of their stroke as opposed to women, who are more likely to be widowed or unmarried and to be living alone.[6, 10] These results are concordant with other disability studies.[6, 8, 11, 12] Thus, gender perspective has been increasingly taken into account in health-related research since 1980.[13]

Although functioning is recognized as an important study outcome in men and women after stroke, gender-specific studies are still rare. Based on a biopsychosocial perspective, functioning and the ability to participate in everyday life can be understood not only as a mere consequence of disease and its treatment in contrast to a biomedical perspective. Furthermore, it differs on the level of functioning depending on who the person is and the environmental factors that support or hindrance its or level of functioning.[2, 14, 15] This is the perspective the International Classification of Functioning, Disability and Health (ICF) based on which functioning and disability both on individual and population levels can be described. Cerniauskaite and colleagues show in their systematic review that the ICF classification has already been implemented in a wide range of (health) [illegible].[16] In addition, they present an overview of the development and application of ICF-based tools such as ICF Core Sets. An ICF Core Set is a selection of categories from the full ICF classification that provides a user-friendly tool for describing functioning and disability in various health care contexts (acute, post-acute und long-term) and for various health conditions like stroke.[17] The *Comprehensive ICF Core Set for stroke* covers the typical spectrum of problems of functioning in persons after stroke and should serve as a standard for multiprofessional comprehensive assessment.[18] In 2005, the Comprehensive ICF Core Set for stroke was extended by 36 ICF categories from the ICF Core Sets for persons with neurological conditions in acute and early post-acute phases to enable its use in different clinical situations.[19-21] The current version of this extended ICF Core Set for stroke includes 166 categories at the second level of the classification, 59 Body functions' categories, 11 *Body structures'* categories, 59 *Activities and participation's* categories and 37 *Environmental factors*. This *extended ICF Core Set for stroke* can be used to guide the process of assessment, assignment, intervention and evaluation in multi-professional patient care and rehabilitation. Thus, the care and rehabilitation of clients with stroke can be tailored according to their specific needs.[22] There are first efforts for implementing the *ICF Core Set for stroke* in clinical settings.[23,24]

The *extended ICF Core Set for stroke* is now undergoing worldwide testing and validation using a number of approaches including an international multi-centre validation study and validation from the perspective of health professionals.[25-28] One key aspect is the validation from the patient perspective. The patient perspective was implicitly included in the development of the ICF Core Set for stroke as patients now were explicitly involved in the process of its validation. An additional aspect of validation that has not been yet considered is the gender perspective. It is important to identify ICF categories which are common in women and men as well as categories exclusively relevant for either women or men. If the ICF Core Set for stroke is to be used in the context of patient-centred care, this information of commonalities and differences between genders is important to explore.

The objective of the study is therefore to add evidence to the content validity of the extended ICF Core Set for stroke from persons after stroke, taking into account the gender perspective. The specific aims are 1) to identify areas of functioning and health relevant to women and men after stroke to explore communalities and differences in functioning and health; and 2) to explore the content validity of the current version of the extended ICF Core Set for stroke taking into account the gender perspective.

Materials and methods

Design

We performed a qualitative study with male and female clients after stroke using individual interviews from 2008 to 2010. Qualitative studies are increasingly accepted in health research and health-related sciences.[13, 14, 28] They provide the possibility to explore the perspective of those who experience a

health problem.[30, 31] Compared to quantitative methodology, the qualitative approach promises a greater openness to unexplored concepts or phenomena [32] and focuses on how people understand and interpret their social world from their own perspective.[30]

In addition to an already published ICF Core Set validation study using focus groups with persons after stroke,[28] we performed a further study using individual interviews to include a broader spectrum of persons after stroke who were not able to follow a focus-group discussion because of stroke-related impairments. Two different individual interview approaches were conducted: an open approach and an ICF-based approach; both were developed and tested in previous studies.[30]

The study was approved by the Ethics Commission of the Ludwig-Maximilians-University of Munich, Germany (project-number 326-07). It was performed in accordance with the Declaration of Helsinki. All participants of the study signed written informed consent.

Participants

Participants were women and men diagnosed with stroke according to ICD-10 [illegible] stroke criteria 2006[32] who had been treated in one of three study centres in Germany [illegible] time from 2008 to 2009: rehabilitation centre [illegible]u, outpatient department Mutaborn [illegible] and physiotherapy patient department [illegible]ensburg. The inclusion criteria were: [illegible] diagnosis, age [illegible] 18 years, ability to concentrate 30 minutes [illegible] minimum and sufficient knowledge of the language of the country to understand all aspects [illegible]dy for purposes of consent. Patients were excluded from the study if they have had surgery, incomplete wound healing, or were diagnosed with psychiatric disorders (e.g. acute manic depression, personality disorders).

After having checked the inclusion criteria, trained health professionals in each study centre asked persons diagnosed with stroke to participate. Participants were selected by the maximum variation strategy [33] based on the following criteria: type of stroke, affected hemiplegic side, date of diagnosis, age and gender. Clients with aphasia were included in the study, and the individual interview was performed involving the client and a proxy.

Overall sample size was determined by saturation.[33, 34] Saturation refers to the point at which an investigator has obtained sufficient information from the field (see data analysis: saturation of data).[34]

Data collection

All individual interviews were performed in a non-directive manner by the same interviewer (AG). The interviewer was a physiotherapist with expertise in treatment [illegible] after stroke, ICF and interview procedure [illegible] individual interviews followed an established [illegible] and were performed according to [illegible]s including open-ended questions and [illegible]uctions (*e.g.* introduction procedure of the session, technical aspects).[31] At the beginning of each individual interview [illegible]edure of the session was explained, and the concept of the ICF was [illegible]ted to the interview in lay terms. Women and men after stroke were asked to report about their experiences [illegible]tioning and health after the stroke by using open-ended questions. One of two different individual interview approaches was performed ("open approach" or "ICF-based approach").

To apply the open approach women and men after stroke were asked in the following open-ended questions to name their problems relating to body functions and structures, activities and participation, personal and environmental factors (barriers and facilitators) that influenced their everyday life:

"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 yourself, what is important for handling your situation after stroke?

If you think about your environment and your living conditions, what barriers do you experience?

If you think about your environment and your living conditions, what do you find helpful or supportive?"

To apply the *ICF-based approach,* the open-ended questions listed above were presented and additionally ICF chapters of the ICF categories contained in the *extended ICF Core Set for stroke* were included. The following example illustrates an ICF-based question concerning ICF chapter *d4 Self-care*:

"If you think about your daily life, what are your problems, do you have problems in self-care?"

The interviewer presented the questions verbally and visually with help of printed cards. At the end of each individual interview, a summary of the main results was given back to the participant to enable them to verify and amend emergent issues. The individual interviews were audio-recorded and transcribed verbatim using the Olympus DSS-system. The interviewer made debriefing notes to review the course of each individual interview. The two individual interview approaches were performed alternately.

Data analysis

Data analyses were performed following a three step procedure.

Qualitative analysis

The meaning condensation method was used for qualitative data analysis following a three step procedure: 1) transcripts of the individual interviews were read in order to get an overview over the collected data. Data were divided into units of meaning; 2) The theme addressed in 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.[36] Therefore, a meaning-unit division did not follow linguistic grammatical rules. Rather, the text was divided where the researcher discerned a shift in meaning.[35] 3) Concepts contained in the meaning units were identified. A meaning unit could contain more than one concept.

Identification of aspects of functioning and health important for women and men after stroke

The identified concepts were linked to ICF categories based on established linking rules,[37] which ensure linking of concepts to ICF categories in a consistent and standardised way. According to these linking rules, two ICF-trained health professionals (G. P.) linked each concept to the ICF category describing this concept most precisely (Table I). If a concept could be linked to one or more ICF categories depending on the number of themes contained in the concept, consensus between the two health professionals was used to decide which ICF category should be linked to each meaning unit. In case of disagreement between the two health professionals, the suggested categories were discussed by a team consisting of three health professionals (BK, MC). Based on this discussion a joint decision was made.

TABLE I.—*Scheme of the qualitative data analysis: Linking process an example*

Transcript with meaning units	Concept	ICF category
Qualitative analysis		
Examples for open questions		
Interviewer: Let's go on to the next question. If you think about your daily life what are your problems?		
Interview 1: Firstly, to be employed at the moment impossible, because you've got so many distractions and you wouldn't be able to do your job properly.	Employment is impossible	d850 Remunerative employment
Interviewer: Do you have further problems in daily life....		
Interview 16: To concentrate when with more than one person becomes a problem in daily life	Concentrate on discussion with more than person	b140 Attention functions d160 Focusing attention d3551 Discussion with many people
Examples for ICF-based questions		
Interviewer: Now, I want to ask you, if you think about your daily life do you have problems in self-care?		
Interview 11: Yes, I need help to go to the toilet. In the morning I have problems to dress myself.	Problems with toileting Problems with dressing	d530 Toileting d540 Dressing
Interviewer: Now, the next question: If you think about your daily life do you have problems in domestic life?		
Interview 19: Without my arm I tried to cook but it is not possible at the moment	Problems in cooking	d630 Preparing meals

Saturation of data

Saturation was defined as the point during data collection and analysis when the linking of the concepts of two consecutive individual interviews revealed no additional second-level categories from the extended ICF Core Set for stroke. This operationalization of saturation was established in several qualitative studies aiming to validate ICF Core Sets from the patient perspective.[28, 30] Saturation was calculated separately according to women and men, as well as according to interview approach (open-ended, ICF-based approach).

Comparison of identified ICF categories with the extended ICF Core Set for stroke

The identified categories for women, men and both genders were compared to the categories of the extended ICF Core Set for stroke taking into account the interview approach. Since the ICF categories are arranged in a hierarchical code system, second-level categories of the ICF Core Set were considered confirmed when the corresponding third- or fourth-level category to which they belong had been identified (*e.g.*, "d470 Using transportation" confirmed by "d4702 Using public motorized transportation").

An ICF category was considered as additional category if it emerged from individual interviews and had not been included in the current version of the extended ICF Core Set for stroke.

Accuracy of data analysis

To ensure the accuracy of data analysis the following two strategies were adopted:

(1) multiple coding: qualitative analysis and linking to the ICF of the first individual interview of the open and ICF-based approach was carried out by two health professionals (AG and BK) in order to achieve agreement concerning the implementation of the linking rules. Agreements and specifications when applying the rules were documented; 2) peer review: after completing the multiple coding of the first individual interview in both approaches, a peer review was performed. One interview of each interview approach (in total 2 out of 24 interviews) was randomly selected and the concepts were identified by a second health professional. Three interviews of each interview approach were randomly selected and linked by a second health professional. The degree of agreement between the two health professionals regarding the linked categories was calculated as kappa statistics with 95%-bootstrapped confidence intervals.[38,39] The values of the kappa statistic generally range between 0 and 1 whereas 1 indicates perfect agreement and 0 indicates no additional agreement beyond what is expected randomly. Data analysis was performed with SAS for Windows 9.1 (Copyright © 2002–2003 by SAS Institute Inc., Cary, NC, USA).

Results

A sample of 12 German-speaking women and 12 men were involved in this study. Participants' characteristics are summarized in Table II. Saturation of data was reached after having performed 12 individual interviews stratified by gender and interview approach respectively. The interview sessions lasted from 52 minutes to 126 minutes.

Identification of aspects of functioning and health important to women and men after stroke.

TABLE II.—*Characteristics of participants.*

Characteristics of participants	Women	Men	Total
Number of participants after	12	12	24
Interviews with persons with	10	10	20
Interviews with proxies of person with stroke-related aphasia, N.	1*	3**	5
Age [range]	65 [36;85]	53 [40;85]	59 [36;85]
Hemiplegic side of body (right), N.	5	13	18
Retired, n	10	10	20
Disease duration (months), mean [range]	6.7 [1-24]	15.5 [1-45]	12.6 [1-45]
Interview approach, n (open approach/ICF-based approach)	5/7	7/5	12/12

*In the individual interview with a woman with stroke-related aphasia her husband answered the questions.
**In the individual interviews with the men with stroke-related aphasia the daughter, the female cohabitant and the sister and his brother-in-law answered the questions, respectively. In all interviews with proxies the person with stroke-related aphasia joined the interview.

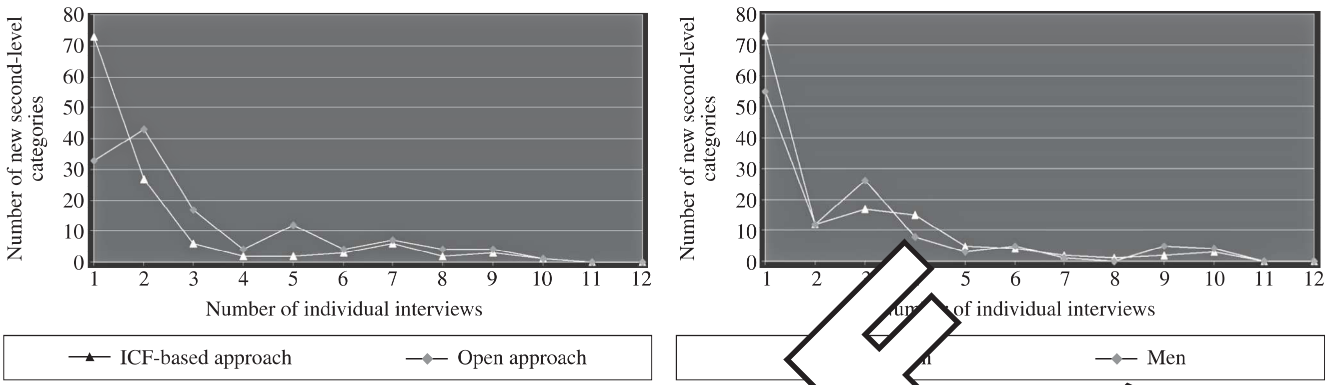

Figure 1.—Identification of aspects of functioning and health important to wo[illegible] stroke.

In total, 5346 concepts were identified in the qualitative analysis of the transcribed interviews of women and men (women: N.=2530; men: N.=2816).

The concepts identified in the qualitative analysis were linked to 342 ICF categories from first t[illegible] level of the classification. According to th[illegible] ture, this corresponds to 181 second-lev[illegible] With respect to the 181 second-level I[illegible] there were 129 ICF categories comm[illegible] for both genders, 19 identified [illegible] women and 33 only in the gr[illegible]men (Figure 1).

In addition to the identif[illegible] some concepts emerged whic[illegible] in the ICF such as volition, walking[illegible], need of time and breaks, time for co[illegible]eaction rate, and career perspectiv[illegible] concepts could be linked to IC[illegible] such as quality [illegible] in general, dis[illegible]ement, time-relate[illegible] and variabi[illegible]ctioning. Thirty-f[illegible] were allotted [illegible] component [illegible] which has not ye[illegible]en classified.

Comparison of identified IC[illegible] with the extended ICF Core Set for[illegible]

One-hundred forty[illegible] categories included in the *extended ICF* [illegible] *for stroke* were confirmed (women: N.=13; [illegible]: N.=17; both genders: N.=113). An overview of the results of this study is shown in Figure 1 taking into account the gender of the participants.

The exact distribution according to the ICF components is summarized in Tables III-VI representing ICF categories of the extended ICF Core Set for stroke that were confirmed in women, men and in [illegible]s. Table VII dis[illegible]dditional ICF categor[illegible]dentified from [illegible] participants of this [illegible]dy [illegible]not included [illegible]ended ICF Core [illegible]troke. Of the[illegible]tegories were identi[illegible]only in wome[illegible] men and 16 in both genders.

Accuracy [illegible]sis

The [illegible]efficients and 95%-bootstrapped confide[illegible]rvals for interviews performed with women a[illegible] men were 0.65 (0.60; 0.69) and 0.65 ([illegible]0.69), respectively. The coefficients for the o[illegible]pproach and the ICF-based approach were 0.[illegible] (0.64; 0.71) and 0.76 (0.73; 0.78), respectively.

Discussion

With this qualitative study we add evidence to the content validity of the extended ICF Core Set for stroke from persons after stroke. It was the first ICF Core Set validation study from the patient perspective taking into account the gender perspective to explore communalities and differences of women and men in functioning and health. Although most of the areas of functioning and health are common in both genders, we still identified some gender differences in our study. In line with this, most of the categories of the extended version of the ICF Core Set for stroke were confirmed by women and men. Only a small number of categories were not common in both.

The ICF categories of the extended ICF Core Set for stroke that were only named by women, such

TABLE III.—*Body functions (b): Reported ICF categories (second-level) by women and men. ICF categories shown in bold typeface are categories included in the extended ICF Core Set for stroke and confirmed from the women or men only. Confirmed ICF categories of the extended ICF Core Set for stroke are shown in normal typeface.*

ICF code	ICF Title	Woman	Men
Chapter 1 Mental functions			
b110	Consciousness functions	o	oi
b114	Orientation functions		
b117	Intellectual functions		
b126	Temperament and personality functions	oi	oi
b130	Energy and drive functions	oi	oi
b134	Sleep functions	oi	oi
b140	Attention functions	oi	oi
b144	Memory functions	oi	oi
b147	Psychomotor functions		
b152	Emotional functions	oi	oi
b156	Perceptual functions	oi	oi
b160	Thought functions	oi	oi
b164	Higher-level cognitive functions	oi	oi
b167	Mental functions of language		oi
b172	**Calculation functions**		**i**
b176	**Mental Functions of sequencing complex movements**		**o**
b180	Experience of self and time functions	oi	oi
Chapter 2 Sensory functions and pain			
b210	Seeing functions	oi	oi
b215	**Functions of structures adjoining the eye**		**oi**
b230	**Hearing functions**		**i**
b235	Vestibular functions	oi	oi
b240	Sensations associated with hearing and vestibul	oi	oi
b260	Proprioceptive functions	o	i
b265	Touch function	oi	oi
b270	Sensory functions related to temperature ner stim	oi	oi
b280	Sensation of pain	oi	oi
Chapter 3: Voice and speech functions			
b310	Voice functions	i	i
b320	Articulation functions	i	oi
b330	Fluency and rhythm of speech ns	oi	oi
b340	Alternative vocalization fun	o	o
Chapter 4: Functions of the cardiov logical, immunological and re tory systems			
b410	Heart functions	oi	i
b415	Blood vessel functio	oi	oi
b420	Blood pressure fu	oi	i
b430	Haematological syste	oi	o
b435	**Immunologi e**	**oi**	
b440	Respiration	i	i
b450	Addition funct	oi	i
b455	Exerci ctions	oi	oi
Chapter 5: Funct f th estive, metabolic and e ems			
b510	**I ons**	**oi**	
b515	Di ons	i	o
b525	Defec ns	i	o
b530	**Weight nce functions**		**i**
b535	**Sensation ociated with the m**	**oi**	
b540	**General metabolic functions**		**oi**
b545	Water, mineral and electrolyte ns		
b550	Thermoregulatory function		
Chapter 6: Genitourinary and repro ions			
b620	**Urination functions**	**i**	
b630	Sensations associated nctions		
b640	Sexual functions	i	o
Chapter 7: Neuromusculosk ement-related functions			
b710	Mobility of joint f	i	oi
b715	Stability of joint fun	i	i
b730	Muscle power functio	oi	oi
b735	Muscle tone functions	oi	oi
b740	**Muscle endurance functions**	**i**	
b750	Motor reflex functions	i	i
b755	Involuntary movement reactions	oi	oi
b760	Control of voluntary movement functions	oi	oi
b770	Gait pattern functions	oi	oi
Chapter 8: Functions of the skin and related structures			
b810	**Protective functions of the skin oi**		

o: open approach; i: ICF-based approach

TABLE IV.—*Body structures (s): Reported ICF categories (second-level) by women and men. ICF categories shown in bold typeface are categories included in the extended ICF Core Set for stroke and confirmed from the women or men only. Confirmed ICF categories of the extended ICF Core Set for stroke are shown in normal typeface.*

ICF code	ICF Title	woman	men
Chapter 1: Structures of the nervous system			
s110	Structure of brain	oi	i
s120	Spinal cord and related structure		
s130	Structure of meninges		
Chapter 2: The eye, ear and related structures			
Chapter 3: Structures involved in voice and speech			
Chapter 4: Structures of the cardiovascular, immunological and respiratory systems			
s410	**Structure of cardiovascular system**	**oi**	
s430	**Structure of respiratory structure**		**i**
Chapter 5: Structures related to the digestive, metabolic and endocrine systems			
s530	Structure of stomach		
Chapter 7: Structures related to movement			
s710	**Structure of head and neck region**		**oi**
s720	Structure of shoulder region		i
s730	Structure of upper extremity	oi	oi
s750	Structure of lower extremity	oi	oi
Chapter 8: Skin and related structures			
s810	Structure of areas of skin		

o: open approach; i: ICF-based approach

as "b535 Sensations associated with the digestive system", "b620 Urination functions", "d710 Basic interpersonal interactions", "e340 [illegible] providers and personal assistants" and [illegible] only by men, such as "b172 Calculation functions", "b540 General metabolic functions", "d8[illegible] economic transactions", "d870 Economic self-sufficiency" or "e525 Housing services, [illegible] and policies" and others showed the [illegible] perspectives of women and men with [illegible] functioning and disability from their respective perspectives. In addition, [illegible] ICF categories [illegible] included in the extended [illegible] Core Set for [illegible] covering all ICF components were named by women, men or [illegible] both genders. Some of these additional ICF categories need special clarification and [illegible] discussed in the following paragraphs.

Firstly, we want to discuss additional categories not included in the extended ICF Core Set for stroke and identified in the [illegible] interviews of both genders. From the Body Structures' component the ICF category 's770 Additional musculoskeletal structure related to movement' was reported by women and men. This is a typical category which is affected after stroke in combination with non-physiological muscle tone and impaired movement control or shoulder pain.[40, 41] In addition, other movement-related Body functions' categories which are not currently included in the extended ICF Core Set for stroke were [illegible], namely "b765 Involuntary movement functions" and "b780 Sensations related to muscles and movement functions".

To assess muscle sensations, such as pain and other sensations, one has to rely on self-reporting of [illegible] suffering a disease. Therefore, it is not surprising that this category is identified in this study, in which participants are asked explicitly about their problems.[28] This means for the use of ICF Core Sets in daily clinical routine, a Core Set offers a list of the most important ICF categories for assessing clients with a specific health condition, such as stroke. Moreover, if it is necessary for the user's purposes, additional ICF categories from the whole ICF classification could be added individually.[17]

The category "d435 Moving objects with lower extremities" was an important additional ICF category consequently identified in all interviews with women and men. Clients discussed driving a car and its corresponding abilities intensively in almost all individual interviews.[28, 42] This reflects the importance of the recovery of movement abilities of lower extremities like pressing a gas pedal or the brakes in a car. From the *Activities and* participation's chapter 6 Domestic life women and men addressed two additional ICF categories, namely "d650 Caring for household objects" and "d660 Assisting others". Despite the fact,

TABLE V.—*Activities and participation (d): Reported ICF categories (second-level) by women and men. ICF categories shown in bold typeface are categories included in the extended ICF Core Set for stroke and confirmed from the women or men only. Confirmed ICF categories of the extended ICF Core Set for stroke are shown in normal typeface.*

ICF code	ICF Title	women	men
Chapter 1: Learning and applying knowledge			
d110	Watching	i	oi
d115	**Listening**	**o**	
d120	**Other purposeful sensing**		**o**
d130	**Copying**		**oi**
d135	Rehearsing	oi	oi
d155	Acquiring skills	oi	oi
d160	Focusing attention	oi	o
d166	Reading	oi	oi
d170	Writing	i	oi
d172	Calculating	o	o
d175	Solving problems		
d177	Making decisions	o	o
Chapter 2: General tasks and demands			
d210	Undertaking a single task		
d220	**Undertaking a multiple task**		
d230	Carrying out daily routine		oi
d240	Handling stress and other psychological demands		oi
Chapter 3: Communication			
d310	**Communication with receiving spoken messages**	**i**	
d315	Communication with receiving nonverbal messages		
d325	Communication with receiving written messages		
d330	Speaking	oi	oi
d335	Producing nonverbal messages	i	oi
d345	**Producing messages in formal sign messag**		**o**
d350	Conversation	oi	oi
d360	Using communication devices and techniqu	i	oi
Chapter 4: Mobility			
d410	Changing basic body position	oi	oi
d415	Maintaining a body position	oi	oi
d420	Transferring oneself	i	oi
d430	Lifting and carrying objects	oi	oi
d440	Fine hand use	oi	oi
d445	Hand and arm use	oi	oi
d450	Walking	oi	oi
d455	Moving around	oi	oi
d460	Moving around in dif	oi	oi
d465	Moving around using	oi	oi
d470	Using transportation	oi	oi
d475	Driving	oi	oi
Chapter 5: Self-care			
d510	Washing	oi	oi
d520	Caring	oi	i
d530	Toile	i	oi
d540	Dre	i	oi
d550	Eating	oi	i
d560	**Drinkin**	**oi**	
d570	Looking a health	oi	oi
Chapter 6: Domestic li			
d620	Acquisition of goods and services	oi	oi
d630	Preparing meals	oi	oi
d640	Doing housework	oi	oi
Chapter 7: Interpersonal interactio nships			
d710	**Basic interpersonal in**	**oi**	
d750	Informal social relations	oi	oi
d760	Family relationship	oi	oi
d770	Intimate relationsh	oi	oi
Chapter 8: Major life areas			
d845	Acquiring, keeping an minating a job	i	i
d850	Remunerative employm	oi	oi
d855	Non-remunerative employment	i	i
d860	**Basic economic transactions**		**o**
d870	**Economic self-sufficiency**		**oi**
Chapter 9: Community, social and civic life			
d910	Community life	i	o
d920	Recreation and leisure	oi	oi
d930	Religion and Spirituality		
d940	Human rights		

o: open approach; i: ICF-based approach

TABLE VI.—*Environmental factors (e): Reported ICF categories (second-level) by women and men. ICF categories shown in bold typeface are categories included in the extended ICF Core Set for stroke and confirmed from the women or men only. Confirmed ICF categories of the extended ICF Core Set for stroke are shown in normal typeface.*

ICF code	ICF Title	women	men
Chapter 1: Products and Technology			
e110	Products or substances for personal consumption	oi	oi
e115	Products and technology for personal use in daily living	oi	oi
e120	Products and technology for personal indoor and outdoor mobility and transportation	oi	oi
e125	Products and technology for communication	oi	oi
e135	Products and technology for employment		
e150	Design, construction and building products and technology of buildings for public u	i	oi
e155	Design, construction and building products and technology of buildings for priva	oi	oi
e165	Assets	i	oi
Chapter 2: Natural environment and human-made changes to environment			
e210	**Physical geography**	**i**	
e240	Light		
e250	Sound		
Chapter 3: Support and relationships			
e310	Immediate family		oi
e315	Extended family		i
e320	Friends		i
e325	Acquaintances, peers, colleagues, neighbours and commu members	oi	oi
e340	**Personal care providers and personal assis**	**i**	
e355	Health professionals	oi	oi
e360	Other professionals	i	o
Chapter 4: Attitudes			
e410	Individual attitudes of immediate fami bers	oi	oi
e415	Individual attitudes of extended family	i	oi
e420	Individual attitudes of friends	oi	oi
e425	Individual attitudes of acqu peers, ague, neighbours and members	oi	oi
e440	Individual attitudes of c personal assistance		
e450	Individual attitudes of h	oi	o
e455	Individual attitude ssionals		
e460	**Societal attitude**		**o**
e465	Social norms, practic ogies		
Chapter 5: Services, sys bo			
e515	**Archit onstr on services, syste s**		**o**
e525	**Hou ery systems and policies**		**o**
e535	C rvices, systems and polici		
e540	services, systems and poli	oi	oi
e550	Leg ystems and policies	i	i
e555	Associ organizational ser d policies	i	oi
e570	Social se services, systems a olicies	i	oi
e575	General social support service olicies	oi	o
e580	Health services, systems and	oi	oi
e590	Labour and employment ms and policies	i	o

o: open approach; i: ICF-based app

that stroke is often connected with requiring support from other people such as family, partner, or health care professionals in daily living [3, 12, 43] the participants of this study reported about their changed life-situation. After having a stroke they need support in simple every-day tasks, such as repairing equipment, preparing a meal, or grasping and holding a glass. Furthermore, they are dependent on others and they need help. Moreover, their social role as grandparents for example has changed and they are no longer able to care for their grandchildren.

Women and men after stroke also identified a large number of Environmental factors' categories which have an impact on nearly all aspects of everyday life. Not included in the ICF Core Set yet are "e225 Climate" to "e345 Strangers" and "e350 Do-

TABLE VII.—*Additional ICF categories: ICF categories (second-level) identified by women and men which are not included in the extended ICF Core Set for stroke. ICF categories shown in bold typeface are categories reported from women or men only. Additional ICF categories of the extended ICF Core Set for stroke are shown in normal typeface.*

ICF code	ICF Title	woman	men
BODY FUNCTIONS			
b220	**Sensations associated with the eye and adjoining structures**	**i**	
b250	Taste function	oi	i
b555	**Endocrine gland functions**		**oi**
b720	Mobility of bone functions	i	i
b765	Involuntary movement functions	i	o
b780	Sensations related to muscles and movement functions	i	oi
b850	**Functions of hair**		**o**
b860	**Functions of nail**		**o**
BODY STRUCTURES			
s220	**Structure of eyeball**	**i**	
s320	Structure of mouth	i	i
s760	**Structure of trunk**		**oi**
s770	Additional musculoskeletal structures related to movement		oi
s830	**Structure of nails**		**o**
s840	**Structure of hair**		**o**
ACTIVITIES AND PARTICIPATION			
d145	**Learning to write**		
d163	Thinking	o	o
d355	**Discussion**		**oi**
d435	Moving objects with lower extremities	oi	oi
d610	**Acquiring a place to live**		**o**
d650	Caring for household objects	i	oi
d660	Assisting others	oi	o
d720	**Complex interpersonal interactions**	**i**	
d730	Relating with strangers	i	o
d740	**Formal relationships**		**o**
d840	**Apprenticeship (work p**		**o**
d865	**Complex economic tr ion**		**oi**
d950	**Political life and ci**		**i**
ENVIRONMENTAL FACTORS			
e130	**Products and techno ucation**		**oi**
e140	**Products a og ure, recreation a**		**o**
e215	**Populati**	**i**	
e220	Flora a ma	i	i
e225	Clim	i	oi
e330	**Pe ons of authority**		**o**
e345	Strang	i	oi
e350	Domesti als	i	oi
e430	Individual a des of people in po ity	o	o
e520	**Open space planning service policies**		**i**
e565	**Economic services, system**	i	

o: open approach; i: ICF-based approach

mesticated animals", a "e430 Individual attitudes of people in positions of authority".

In the following two paragraphs we discuss some additional categories identified only in women and men, respectively. Women's additional categories focus on activities like "d145 Learning to write" and "d720 Complex interpersonal interactions". In line with the second mentioned category, Reeves and colleagues point out that the societal impact of poor stroke outcomes in women is compounded by the fact that elderly women are more likely to live alone and are socially isolated.[3]

The additional categories only identified in the interviews with men were for example: "s760 Structures of trunk", "d355 Discussion", "d610 Acquiring a place to live", "d740 Formal relationships", "d840 Apprenticeship (work preparation)", "d865 Complex economic transaction", "d950 Political life and citi-

zenship". The category "d865 Complex economic transactions" was an emphasised topic reported by men. Men were also concerned about the support and relationship to persons at their workplace, especially to their managers as addressed by ICF category "e330 People in positions of authority". This environmental factor can be a facilitator or barrier important for persons after stroke because long-term (chronic) illness such as stroke and its consequences are strongly associated with an insecure return-to-work.[44-46]

In this study, differences but also commonalities in functioning and disability of women and men after stroke were explicitly investigated. This result is underlined by different studies [3, 14, 47] and can be seen as a hint for health professionals for taking the gender perspective into account in their daily practice. Consequently, in every day clinical practice providers of rehabilitation and health professionals are aware of differences but also commonal[illegible] functioning and disability of women and [illegible] stroke and have specific knowledge ab[illegible] inclu[illegible] gender-specific aspects in their clinic[illegible] routine. However, Andersson *et al.*[15] state that [illegible] of awareness and knowledge of [illegible] up to now and that they hav[illegible] taken into account in every day clinic, fo[illegible] goal setting.

From the responses of [illegible] we also identified some issues [illegible] were coded as "not covered" by the ICF [illegible]. The majority of these issues do [illegible] to aspects of functioning and health as [illegible] the ICF classification [illegible] issues mainly [illegible]-related issues (*e.g.* [illegible] time and bre[illegible] for compensation [illegible] the ICF does not [illegible]-related issu[illegible] issues could not be link[illegible] to the ICF. Ho[illegible] "not covered" issues identified in this [illegible] clearly related to functioning and health [illegible] by the ICF (*e.g.*, "reaction rate", "voliti[illegible] barefoot"). Most aspects came up in [illegible]. Some of these aspects that are not co[illegible] the ICF classification should be included in t[illegible] process of the ICF, which has already been i[illegible] by WHO.[48]

Minor differences were seen in personal factors in women concerning religion or the influence of their faith. In contrast, men were talking about "soul" in context of spirituality. Women made statements referring to early stroke warning signs that are not covered by the ICF classification; this issue was not reported by men.

It is worthwhile discussing some methodological aspects of our study. When starting our study in 2008, we followed the established methods for the validation of ICF Core Sets and used the two approaches – the open approach and the ICF-based approach to address functioning and health as broadly as possible.[28, 30, 31] Coenen et al. have recently published a methodological paper on the comparison of these two approaches [illegible] recommend the ICF-based approach as the [illegible] appropriate approach in validating ICF [illegible] from the patient perspective.[30] Our resul[illegible] this recommendation. The questions of t[illegible] based approach are formulated in line with the [illegible] chapters of cate[illegible] included in th[illegible] motivate the pa[illegible] of the [illegible] study to provide [illegible] information and consequ[illegible] a larger numb[illegible] of [illegible] categories can [illegible] based on [illegible] more, having the [illegible] of respective [illegible] in mind, the par[illegible] statement[illegible] -based approach are more precise co[illegible] statements from the open approach. Thi[illegible] the linking of the statements of th[illegible] approach and results in a higher kap[illegible] for the linking procedure.

It is [illegible] to mention that several strategies were us[illegible] improve and verify the trustworthiness of the qua[illegible] data: 1) triangulation to ensure the [illegible] hensiveness of data. We included triangulat[illegible] using two data analysts (investigator trian[illegible] on: multiple coding).[49, 50] 2) Continuous data analysis was used according to Pope *et al.*;[51] 3) reflexivity was assured by conducting a research diary for the documentation of memos concerning the design, data collection and analysis of the study; 4) clear exposition was assured by using established guidelines for data collection and analysis; 5) finally, a peer review was performed. The kappa coefficients of both approaches for the accuracy of the peer review are comparable to other studies [28, 30] and can be regarded as "substantial agreement".[52]

There are also some limitations of this study that require special mentioning. In our study, a small sample size of 12 women and 12 men was used to obtain the required level of rich and meaningful data. In qualitative research, sample sizes are typically small because intensive data analysis is required.[53] In addition, qualitative studies focus on the generation of hypotheses rather than on testing of research questions. We recommend investigating larger samples with persons after stroke using

quantitative studies to examine gender differences in functioning and health and to control the outcome for confounders like age, employment status and cultural background. Furthermore, our sample consists of participants from Germany, Austria, Argentina, Czech Republic and Russia living in Germany. We suggest that our methods could be used in similar studies in other countries to establish a cross-cultural perspective. In our case, the linking process was performed by two health professionals according to established linking rules.[37] However, it remains unclear whether other health professionals would have decided differently. Finally, we followed the strategy of saturation during data analyses with the criteria of two consecutive individual interviews revealing no new second-level categories included in the extended ICF Core Set for stroke with respect to previous individual interviews. Participants in a 25th individual interview might still report new themes and concepts not yet reported.

This study confirms that the experience of functioning and disability after stroke is different for women and men. The validity of the extended ICF Core Set for stroke could be almost entirely confirmed, since it does not only include those areas of functioning and disability relevant to both genders, but also of those exclusively relevant to women and men. However, several additional categories that are not represented in the current version of the ICF Core Set arose either from women or men. Further research on additional ICF categories not yet included in the extended ICF Core Set for stroke is needed. The results of this study will be considered when the final version of the extended ICF Core Set for stroke is agreed on.

Conclusions

This study confirms that the experience of functioning and disability after stroke is slightly different for women and men. Based on the ICF conceptualisation of functioning and disability, functioning can substantially differ in subjects with the same health condition, since the interaction with environmental factors is unique and varies from case to case.

The validity of the extended ICF Core Set for stroke could be confirmed, since it does not only include those areas of functioning and disability relevant to both genders, but also of those exclusively relevant to women and men. However, several additional categories which are not represented in the current version of the ICF Core Set arose either from women or men. Further research on additional ICF categories not yet included in the extended ICF Core Set for stroke is needed. The results of this study will be considered when the final version of the extended ICF Core Set for stroke is agreed on.

1) The content validity of the extended ICF Core Set for stroke is confirmed by the perspective of women and men after stroke showing a broad spectrum of categories; only minor gender differences regarding the categories included in the extended ICF Core Set for stroke were identified.

2) Additional categories from the ICF classification should be added to the extended ICF Core Set for stroke to follow a client-centred approach taking into account the gender perspective.

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Appendix 8 Study 2 - patient information and informed consent - gender perspective -

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Patienteninformation und Einverständniserklärung zur Studie

„Validierung der *ICF Core Sets für Schlaganfall* aus der Patientenperspektive“

Sehr geehrte Patientin, sehr geehrter Patient,

wir möchten Sie einladen, an einer Einzelinterview-Studie (‚Einzelbefragungsstudie’) teilzunehmen, die die Auswirkungen eines Schlaganfall auf den Alltag untersucht. Die Studie wird von der Klinik für Physikalische Medizin und Rehabilitation des Klinikums Großhadern durchgeführt. Im Folgenden werden die genauen Ziele der Studie sowie weitere wichtige Informationen erläutert, die Ihnen dabei helfen sollen, eine Entscheidung bezüglich Ihrer Teilnahme an der Studie zu treffen.

Ziel der Studie

Der Schlaganfall und seine Behandlung verursachen Beschwerden, die nicht nur den Körper, sondern auch die Funktionsfähigkeit und das Alltagsleben der PatientInnen beeinflussen. Damit diese Probleme im klinischen Alltag dokumentiert werden können, wurden für Ärzte/Ärztinnen und Fachleute der Gesundheitsberufe sogenannte ICF Core Sets wissenschaftlich entwickelt (ICF = Internationale Klassifikation für Funktionsfähigkeit, Behinderung und Gesundheit). Somit können ausgehend von der Diagnose alle Bereiche des Patientenlebens mit dieser Klassifikation dokumentiert werden. Zu klären ist noch die Frage, ob die von den Fachleuten entwickelten Core Sets für Schlaganfall aus Ihrer Sicht den Alltag und die Probleme für Sie adäquat abbilden. Hierfür möchten wir Sie als Experten/Expertin Ihrer Erkrankung befragen. Wir werden verschiedene Einzelinterviews durchführen und die Ergebnisse dieser Einzelinterviews zu einer neuen Version der Core Sets aus Patientensicht zusammenstellen. Diese Ergebnisse werden wir später mit den von den Fachleuten entwickelten Core Sets für Schlaganfall vergleichen.

Die Studie ist für Sie mit keinerlei Risiko verbunden. In dieser Studie wird es Ihre Aufgabe sein, an einer Gruppendiskussion mit anderen PatientInnen teilzunehmen sowie einen Fragebogen auszufüllen. Eine Wegeversicherung wurde nicht abgeschlossen.

Zeitaufwand für diese Studie

Das Einzelinterview wird etwa 30 bis 60 Minuten dauern. Zusätzlich ist ein kurzer Fragebogen auszufüllen. Es werden keine sonstigen Untersuchungen durchgeführt.

Freiwilligkeit der Teilnahme

Ihre Teilnahme an dieser Studie ist vollkommen freiwillig. Sie können Sie ablehnen, Ihr Einverständnis jederzeit ohne Angabe von Gründen widerrufen, ohne dass Ihnen dadurch Nachteile entstehen. Ein Widerruf Ihres Einverständnisses berührt nicht Ihren Anspruch auf weitere und fortlaufende medizinische Behandlung.

Durchführung der Studie

Falls Sie sich für eine Teilnahme an der Studie entscheiden sollten und die beiliegende Einverständniserklärung unterschreiben, wird Frau Andrea Gläßel mit Ihnen Kontakt aufnehmen, um mit Ihnen einen Termin zur Teilnahme an dem Einzelinterview zu vereinbaren. Dabei werden verschiedene Termine zur Auswahl stehen. Das Interview wird in einem ruhigen Raum im Klinikum Großhadern durchgeführt. Die im Rahmen des Einzelinterviews angesprochenen Themen unterliegen selbstverständlich der Schweigepflicht. Das Einzelinterview wird digital aufgezeichnet und wörtlich abgeschrieben. Ihr Name wird bei der Abschrift der Aufzeichnung durch eine Codenummer ersetzt, so dass Ihr Name in der Abschrift nicht erscheint. Das bedeutet, dass ab der Aufnahme alle Daten und weiteren Auswertungen in pseudonomysierter Form gespeichert und bearbeitet werden. Die digitalen Aufzeichnungen werden nach Auswertung der Daten vernichtet.
Diese Studie soll als wissenschaftliche Arbeit publiziert werden. In dieser wissenschaftlichen Arbeit wird, ebenfalls in pseudonymisierter Form, aus den Interviews zitiert werden. Auf Wunsch informieren wir Sie gerne über die Ergebnisse der Studie.
Die Studie ist für Sie mit keinerlei Risiko verbunden. In dieser Studie wird es Ihre Aufgabe sein, an einem Gruppeninterview mit anderen Patientinnen und Patienten teilzunehmen.

Einverständnis und Datenschutz

Alle Patienteninformationen, die durch diese wissenschaftliche Studie erhalten werden, werden als bevorzugte Informationen behandelt und pseudonomysiert dokumentiert. Die Patientenidentität sowie jede Information, die mit dieser Person in Bezug gebracht werden könnten, dürfen nicht offenbart werden.

Für diesen Zweck werden Sie innerhalb dieser Studie eine Codenummer erhalten, und alle erhobenen Daten werden pseudonomysiert und unter einem wissenschaftlichen ethischen Standard ausgewertet. Die Weitergabe der Daten im In- und Ausland erfolgt ausschließlich zu wissenschaftlichen Zweck und Ihre Angaben zur Person werden streng vertraulich behandelt und Sie werden ausnahmslos darin nicht namentlich genannt.

Patientendaten, die im Rahmen der Studie verwendet werden, werden nur verschlüsselt weitergegeben. Alle Daten (Transkripte und die digitalen Aufzeichnungen) werden auf dem Computer gespeichert. Diese Dateien sind nur über ein Kennwort zugänglich, das ausschließlich der Studienkoordinatorin bekannt ist. Die Originalfragebögen werden in einem verschließbaren Schrank aufbewahrt.

Um eine Pseudonymisierung gewährleisten zu können, werden bei der Transkription die Patienten nicht namentlich erwähnt, sondern deren Namen durch eine sechsstellige Codenummer ersetzt. Diese Codenummern werden ebenfalls für die Identifikation der Patienten-Fragebögen verwendet, d.h. auf allen Fragebögen sind nur die entsprechenden Codenummern vermerkt. Die Codenummern enthalten keine Zusätze, die aus personenbezogenen Merkmalen oder Teilen davon gewonnen werden können; sie enthalten ausschließlich Zahlen, die fortlaufend vergeben werden.

Die Auswertung der Daten an sich erfolgt in pseudonymisierter Form. Die digitalen Aufzeichnungen, Transkripte und Fragebögen werden nach Abschluss der Auswertungen vernichtet. Eine Entschlüsselung aller Daten ist grundsätzlich nicht vorgesehen. Sollte ein Patient sein Einverständnis zur Teilnahme widerrufen, werden die Daten entschlüsselt und alle personenbezogenen Daten vernichtet. Die bis dahin erhobenen und gespeicherten Daten werden jedoch bei der Auswertung verwendet.

Sollten sich nach Durchsicht dieser Information noch Fragen ergeben oder Unklarheiten bestehen, so wenden Sie sich bitte an:

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Einverständniserklärung zur Teilnahme an der Studie

„Validierung der *ICF Core Sets für Schlaganfall* aus der Patientenperspektive - eine qualitative Studie“

Ich, Frau / Herr _____ geboren am _____, wurde von

_____(Name des Arztes oder der Gesundheitsfachperson) über Art, Zielsetzung und zeitlichen Aufwand der wissenschaftlichen Studie “Die Auswirkungen eines Schlaganfalls auf den Gesundheitszustand und auf den Alltag aus der Sicht der Patienten - eine qualitative Studie“ aufgeklärt und informiert. Die schriftliche Patienteninformation und eine Kopie der Einverständniserklärung wurden mir ausgehändigt. Ich hatte ausreichend Zeit, diese zu lesen und mich für oder gegen eine Teilnahme zu entscheiden. Ich habe den Inhalt verstanden, bestehende Fragen wurden besprochen und beantwortet.
Ich erkläre mich einverstanden, an der genannten Studie teilzunehmen, behalte mir jedoch vor, diese ohne Angabe von Gründen jederzeit abzubrechen, ohne dass dadurch Nachteile für mich entstehen. Ich erkläre mich mit der pseudonomysierten Aufzeichnung von Daten und deren Weitergabe für wissenschaftliche Zwecke einverstanden.

_____ _____
Unterschrift der Patientin/des Patienten Datum, Ort

Ich habe heute Frau / Herrn _____ bestmöglich und verständlich über die Teilnahmebedingungen der wissenschaftlichen Studie „Die Auswirkungen eines Schlaganfall auf den Gesundheitszustand und auf den Alltag aus der Sicht der Patienten - eine qualitative Studie“ im obigen Sinne aufgeklärt.

_____ _____
Unterschrift des aufklärenden Arztes oder einer Gesundheitsfachperson Datum, Ort

Bitte der Patientin/dem Patienten eine Kopie nach Unterschrift aushändigen!

Klinikum der Universität München
Klinik und Poliklinik für
Physikalische Medizin und Rehabilitation
Großhadern
Direktor: Prof. Dr. med. Gerold Stucki

Klinikum der Universität München • Klinik und Poliklinik für Physikalische Medizin und Rehabilitation • Marchioninistraße 15 • D-81377 München

Erklärung zur Erhebung und Verwendung der Daten nach Maßgabe der Information

„Validierung der *ICF Core Sets für Schlaganfall* aus der Patientenperspektive - eine qualitative Studie“

Ich, Frau / Herr _____ geboren am _____, wurde von _____ (Name des Arztes oder der Gesundheitsfachperson) über die datenschutzrechtlichen Belange der wissenschaftlichen Studie “Die Auswirkungen von Fingerpolyarthrose auf den Gesundheitszustand und auf den Alltag aus der Sicht der Patienten - eine qualitative Studie“ aufgeklärt und informiert. Ich erkläre mich mit der pseudonomysierten Aufzeichnung von Daten und deren Weitergabe für wissenschaftliche Zwecke einverstanden.

Mit ist bekannt, dass

- alle Patienteninformationen, die durch diese wissenschaftliche Studie erhalten werden, als bevorzugte Informationen behandelt und pseudonomysiert dokumentiert werden.
- die Patientenidentität sowie jede Information, die mit einer Person in Bezug gebracht werden könnte, nicht offenbart werden dürfen und alle erhobenen Daten pseudonomysiert und unter einem wissenschaftlichen ethischen Standard ausgewertet werden.
- die Weitergabe der Daten im In- und Ausland ausschließlich zu wissenschaftlichen Zweck und nur verschlüsselt erfolgt und die Angaben zur Person streng vertraulich behandelt werden.
- Patientendaten, die im Rahmen der Studie erhoben wurden, unter Verschluss gehalten werden.
- zur Pseudonymisierung bei der Transkription die Patienten nicht namentlich erwähnt werden, sondern deren Namen durch eine sechsstellige Codenummer ersetzt werden. Die Codenummern enthalten keine Zusätze, die aus personenbezogenen Merkmalen oder Teilen davon gewonnen werden können; sie enthalten ausschließlich Zahlen, die fortlaufend vergeben werden.
- die Auswertung der Daten in pseudonymisierter Form erfolgt. Die digitalen Aufzeichnungen, Transkripte und Fragebögen werden nach Abschluss der Auswertungen vernichtet.
- sollte ein Patient sein Einverständnis zur Teilnahme widerrufen, die Daten entschlüsselt und alle personenbezogenen Daten vernichtet werden. Die bis dahin erhobenen und gespeicherten Daten werden jedoch bei der Auswertung verwendet

Unterschrift der Patientin/des Patienten Datum, Ort

Ich habe heute Frau / Herrn _____ bestmöglich und verständlich über die datenschutzrechtlichen Belange der wissenschaftlichen Studie „Validierung der *ICF Core Sets für Schlaganfall* aus der Patientenperspektive - eine qualitative Studie“ im obigen Sinne aufgeklärt.

_____

Datum, Ort Unterschrift des aufklärenden Arztes oder einer Gesundheitsfachperson

Bitte dem Patienten eine Kopie nach Unterschrift aushändigen!

Appendix 9 Study 3 - copy of the original publication - - health professional perspective -

Content validity of the Extended ICF Core Set for stroke: an international Delphi survey of physical therapists

Authors: Glässel A, Kirchberger K, Kollerits B, Amann B, Cieza A.

Reference: Physical Therapy. 2011;91(8):1211-22.

Content Validity of the Extended ICF Core Set for Stroke: an International Delphi Survey of Physical Therapists

Andrea Glässel, Inge Kirchberger, Barbara Kollerits, Edda Amann, Alarcos Cieza

Background. The "Extended ICF Core Set for stroke" is an application of the *International Classification of Functioning, Disability and Health* (ICF) and represents the typical spectrum of problems in functioning of people with stroke.

Objective. The objective of this study was to validate this ICF Core Set from the perspective of physical therapists.

Design and Methods. Physical therapists experienced in stroke intervention were asked about their patients' problems and resources and about aspects of the environment that physical therapists treat in people with stroke in a 3-round electronic-mail survey using the Delphi technique. The responses were linked to the ICF. The degree of agreement was calculated using the kappa statistic.

Results. One hundred twenty-five physical therapists from 24 countries named 4,793 problems treated by physical therapists in people with stroke. They identified 10 second-level ICF categories that currently are not represented in the Extended ICF Core Set for stroke. Twelve responses of the participants were linked to the ICF component *personal factors*, and 15 responses were not covered by the current version of the classification. The kappa coefficient for the linking agreement was 0.39 (95% bootstrapped confidence interval=0.34–0.41).

Limitations. Two World Health Organization regions were not represented in the sample of physical therapists.

Conclusions. According to the physical therapists, the current version of the Extended ICF Core Set for stroke largely covers the types of problems that their interventions address. However, some aspects of functioning emerged that are not yet covered and may need further investigation.

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[Glässel A, Kirchberger I, Kollerits B, et al. Content validity of the Extended ICF Core Set for stroke: an international Delphi survey of physical therapists. *Phys Ther.* 2011;91:xxx–xxx.]

Annually about 15 million people worldwide experience a stroke.[1] Although stroke is one of the leading causes of mortality, 40% to 77% of those affected are still alive 1 year after the event.[2] One third of the survivors face long-term disability. Disability after stroke appears in the form of neurological dysfunctions (eg, motor, sensory, visual), limited ability to perform activities of daily living (ADL), and neuropsychological deficits (memory, attention, language).[3] Taking the diversity and complexity of consequences of a stroke into account, an interdisciplinary approach is most appropriate. Rehabilitation after stroke requires an interprofessional team including physicians, psychologists, occupational therapists, nurses, social workers, and physical therapists.[4,5]

Physical therapists are described as one of the key components of the interdisciplinary team in stroke rehabilitation.[6–8] Particularly, physical therapy aims at restoring motor control in locomotion, improving upper-limb function, enhancing the ability of people with stroke to cope with existing deficits in ADL, and achieving the best possible participation in the community. In order to reach these rehabilitation goals, physical therapists use different neurological intervention approaches and instruct and advise people with stroke and their families regarding prevention of complications, such as falls and shoulder pain.[9,10]

To optimize interventions aimed at improving function and minimizing disability, a proper understanding of an individual's functioning and health status is needed.[4] The World Health Organization's *International Classification of Functioning, Disability and Health* (ICF)[11] is based on an integrative model of health that provides a holistic, multidimensional, and interdisciplinary understanding of health and health-related conditions. According to the ICF, the problems associated with a disease may concern *body functions* and *body structures* and the performance of *activities and participation* in life situations. Health states and the development of disability are modified by contextual factors, including environmental factors and personal factors.[11] The ICF comprises 1,454 categories from the components *body functions*, *body structures, activities and participation*, and *environmental factors*, which are organized in a hierarchical structure (Fig. 1). Categories are divided into chapters, which constitute the first level of specification. Higher-levels categories (eg, second, third, or fourth level) are more detailed.

Both the content and the structure of the ICF point out the potential value for rehabilitation professions, especially physical therapy.[5] The ICF is increasingly applied in physical therapy and rehabilitation, especially in the field of neurorehabilitation, to facilitate interdisciplinary team communication, to structure the rehabilitation process, for goal setting and assessment, and for documentation and reporting.[12,13] Recently, ICF-based documentation tools have been developed for use in interdisciplinary rehabilitation management.[14]

However, the ICF as a whole is not feasible for use in routine clinical application. To facilitate the implementation of the ICF into clinical practice, "ICF Core Sets" have been developed.[15,16] The ICF Core Sets include a selection of ICF categories relevant for people with a specific health condition or a specific intervention phase (eg, acute or postacute care).[15] The development of the ICF Core Set followed a standard approach that included a formal decision-making and consensus process integrating evidence gathered from preparatory studies by expert neurologic health care professionals. Preparatory studies included a worldwide Delphi study with 36 experts, including 7 physical therapists; a systematic review of outcome measures used in 160 stroke clinical trials; and an empiric data collection on 93 German patients with stroke.[17–19] Based on the results of these studies, a panel of 36 stroke experts (25 physicians, 7 physical therapists, 2 psychologists, 1 social worker, and 1 sociologist) from 12 different countries decided on the composition of the "Comprehensive ICF Core Set for stroke" in a formal consensus process. The Comprehensive ICF Core Set for stroke includes a set of 130 ICF categories that cover the typical spectrum of problems in functioning in people with chronic stroke.[20] It was extended by 36 ICF categories from the ICF Core Sets for people with neurological conditions in the acute and early postacute phases to enable its use it in all clinical situations.[20,21]

Based on this Extended ICF Core Set for stroke, physical therapists can comprehensively describe the impairments, limitations in activities, restriction in participation, and influential environmental factors of a determined person with stroke and can create a functioning profile. The Extended ICF Core Set for stroke can facilitate assessment and offers the opportunity to clarify responsibilities among the team members by distributing the information gathered from specific ICF categories to the appropriate team members.[13,22]

The Extended ICF Core Set for stroke is now undergoing worldwide testing using a number of approaches, including international multicenter field studies, reliability studies,[23] and content validation from the health care professional perspective. Content validity from the health care professional perspective means that at least those problems in function-

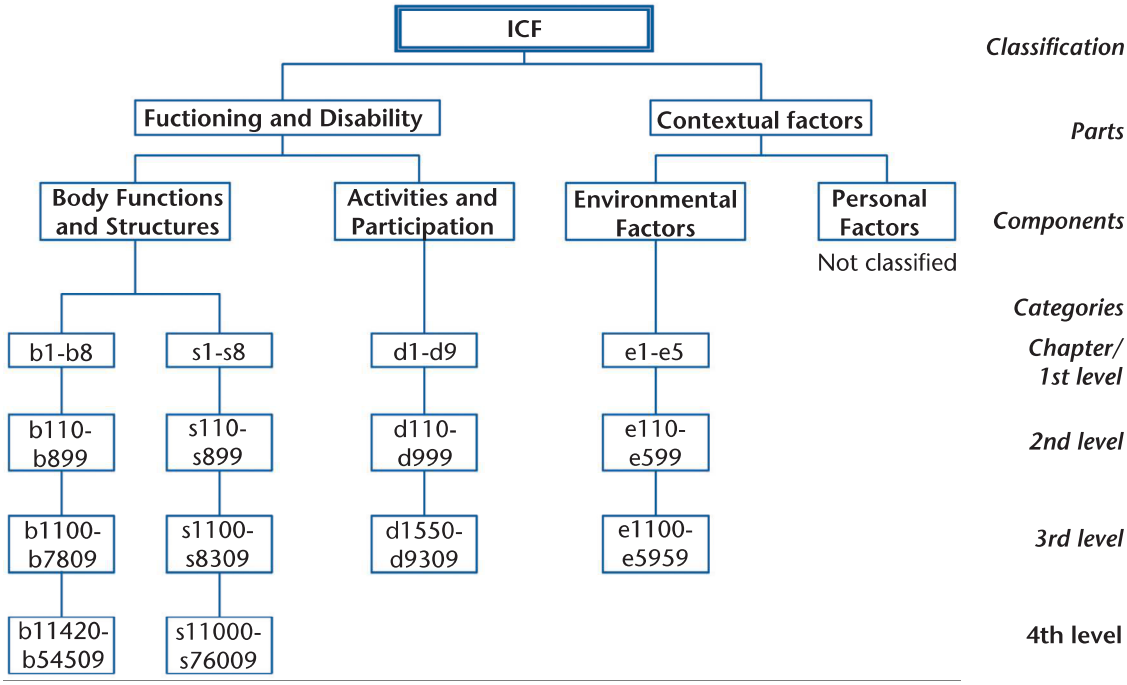

Figure 1.
Structure of the World Health Organization's *International Classification of Functioning, Disability and Health* (ICF). Reprinted with permission of the World Health Organization. All rights are reserved by the World Health Organization.

ing that are substantial targets of the specific interventions applied by health care professionals are represented in the ICF Core Set for stroke. This is a prerequisite for the implementation of the ICF Core Set for stroke in clinical practice. For example, if joint mobility is a main intervention target of physical therapists, it is essential that physical therapists document the extent and the change of joint mobility problems in a determined patient during the treatment course using the ICF Core Set for stroke. Consequently, if the corresponding ICF category for joint mobility is not included in the current version of the Core Set for stroke, the Core Set is lacking content validity from the perspective of physical therapists.

The purpose of this study was to examine the content validity of the Extended ICF Core Set for stroke from the perspective of physical therapists. The aims of this study were: (1) to identify the patient's problems, resources, and aspects of environment treated by physical therapists and (2) to analyze whether these issues are represented by the current version of the Extended ICF Core Set for stroke.

Method

A 3-round electronic-mail survey of physical therapists using the Delphi technique was conducted.[24–27] The purpose of the Delphi technique is to gain consensus from a panel of individuals who have knowledge of a topic being investigated.[28] These informed people are commonly called *experts*.[29] The Delphi method is a multistage process, with each stage building on the results of the previous one, and a series of rounds are used to both gather and provide information about a particular subject. The technique is characterized by its anonymity to avoid the dominance of single individuals in a group; by iteration, which allows panel members to change their opinions in subsequent rounds; and by controlled feedback, which shows the distribution of the group's responses as well as each individual's previous responses.[30]

Recruitment of Participants

In the preparatory phase of the study, international associations of physical therapists, such as the World Confederation for Physical Therapy (WCPT) and members of the European Region of WCPT, as well as universities with health care professional programs and members of the Association of Higher Education of Physical Therapy (ENPHE) were contacted. Associations with a focus on neurorehabilitation and certified physical therapists in neurological intervention from United States received an invitation to participate. A literature search and personal recommendations were used to identify experts.

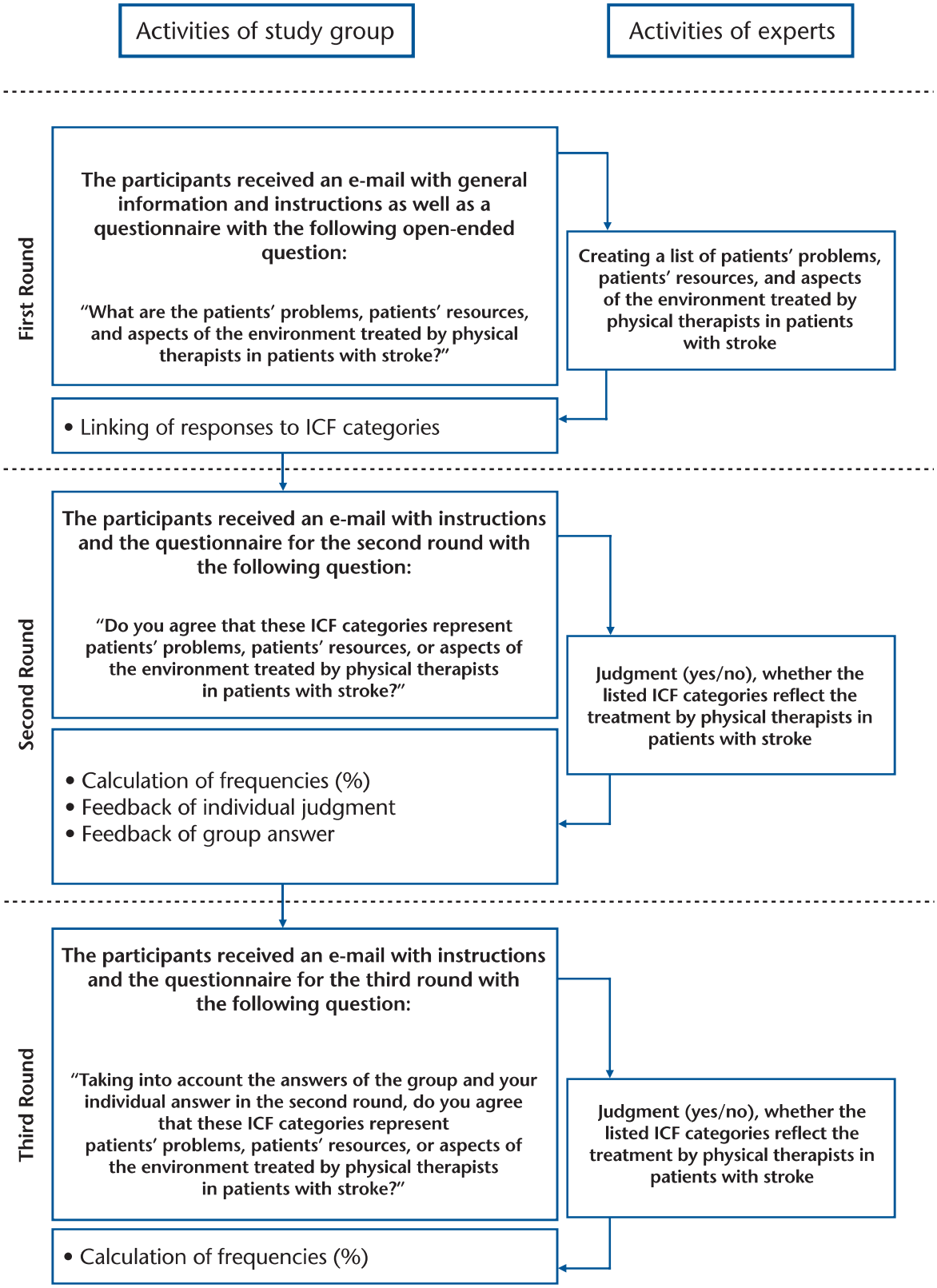

Figure 2.

Description of the Delphi exercise.

The sample was selected using a purposive sampling approach, which is commonly applied in Delphi studies.[25,31,32] Purposive sampling is based on the assumption that a researcher's knowledge about the population can be used to handpick the cases to be included in the sample.[33] In contrast to random sampling, purposive sampling does not ensure representativeness. Because no database of the target population of physical therapists worldwide who are experienced in the treatment of patients with stroke was available, random sampling was not possible in our study.

To ensure that the participants were experienced in the management of people poststroke, the initial letter specified that participants should be "physical therapy experts in the treatment of poststroke individuals." The first contact included an invitation to participate and a detailed description of the project's targets, the Delphi process, and the time line. The study was conducted from January to August 2005.

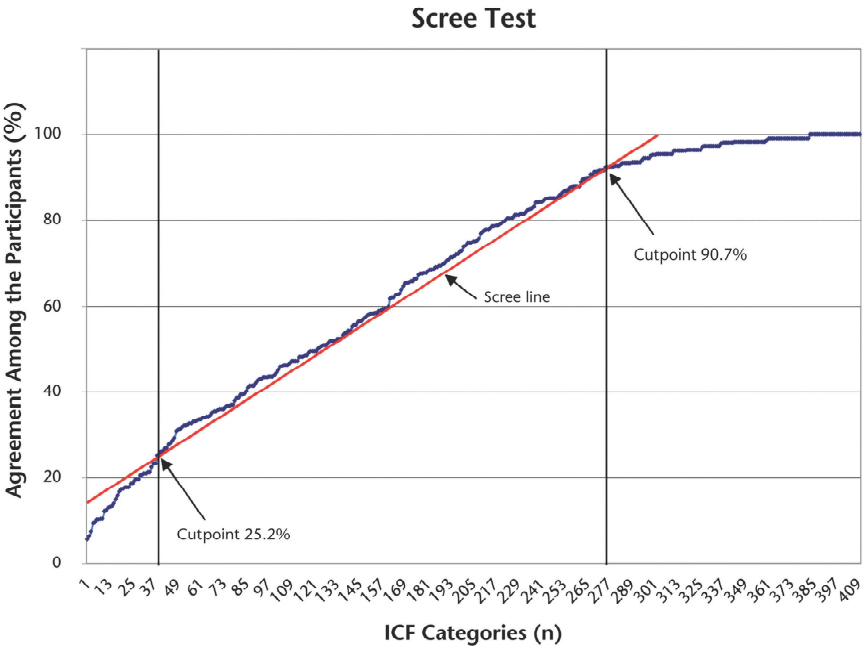

Figure 3.
Scree test results for second Delphi round. Selection of *International Classification of Functioning, Disability and Health* (ICF) categories without clear consensus using the modified Scree test. The ICF categories of the second Delphi round were ordered by percentage of expert agreement and plotted. The Scree line was placed onto the slope, along the points to see where they approximately form a straight line. Points close to the Scree line indicate an inadequate endorsement. *Cutpoints* were defined as the points where the slope markedly deviated from the Scree line. The ICF categories with an agreement of >25.2% and <90.7% were included in the third Delphi round.

Delphi Process

The process and verbatim questions of the electronic-mail survey using the Delphi technique are displayed in Figure 2. The participants had 3 weeks to mail their responses for each round. Reminders were sent 1 week and 2 days before the deadline and 1 week after the deadline. The study was conducted in the English language.

In the first round of the Delphi procedure, an information letter including instructions and an Excel* file containing an open-ended questionnaire was sent to all participants. The participants were requested to list all of the "patients' problems, patients' resources, and aspects of environment treated by physical therapists in patients with stroke." The phrasing of this question aimed at encouraging the participants to consider not only problems but also resources and environmental factors that are covered by the ICF model. The responses were collected and linked to the ICF. Additionally, the participants were asked to complete questions on demographic characteristics and professional experience.

In the second Delphi round, the participants received a list of the ICF categories linked to the responses of the first round. The participants were requested to agree or disagree that the respective ICF category represents patients' problems, patients' resources, or aspects of the environment treated by physical therapists in patients with stroke. Again, the number of participants considering the listed ICF categories as relevant was calculated.

In order to maintain the participants' motivation and increase the response rates, the participants of the third Delphi round received only a selection of ICF categories included in the second round. The Scree test was used to identify the categories that did not reach an adequate consensus.[34,35] The Scree test includes an examination of a graph of the percentage of agreement among the participants plotted along the vertical axis against the ICF categories plotted along the horizontal axis. A straightedge is placed along the points to see where they form an approximately straight line, the Scree line. Points close to the Scree line indicated an insufficient endorsement (Fig. 3). The participants

* Microsoft Corporation, One Microsoft Way, Redmond, WA 98052-6399.

received a list of the selected ICF categories, including the proportion and the identification numbers of the participants who had agreed that the categories represent patients' problems, patients' resources, or aspects of the environment treated by physical therapists in individuals after stroke. The participants were requested to answer the same question taking into account the answers of the group, as well as their previous response.

Linking

An ICF category is coded by the component letter and a suffix of 1 to 5 digits. The letters b, s, d, and e refer to the components *body functions* (b), *body structures* (s), *activities and participation* (d) and *environmental factors* (e) (Fig. 1). This letter is followed by a 1-digit number indicating the chapter, the code for the second level (2 digits), and the codes for the third and fourth levels (1 digit each). The component letter with the suffixes of 1, 3, 4, or 5 digits corresponds to the code of the ICF categories. Within each component, the categories are arranged in a stem/branch/leaf scheme. This scheme indicates that a more-detailed, higher-level category covers all the aspects applicable for the lower-level category, of which it is a member, but not vice versa.

Each response from the first Delphi round was linked to the most precise ICF category based on 10 linking rules established in a previous study.[36] If an answer contained more than one concept, several ICF categories could be linked. Answers related to *personal factors* were assigned the code "pf." If the content of an answer was not included in the ICF classification, this answer was coded "not covered."

The linking was performed by a physical therapist (A.G.) who specialized in stroke intervention. In addition, responses from 46 participants (36.8%) out of the 125 participants were linked independently by a psychologist (E.A., B.K.). The people involved in the linking process had some years of experience regarding the ICF. Because the linking process is extremely time-consuming and the linking of a sample of the 4,793 responses was expected to provide a good estimation of the true agreement, we refrained from linking all responses. Consensus between the physical therapist and the psychologist was used to decide which ICF category should be linked to each response. In cases of disagreement between the health care professionals, the suggested categories were discussed by a team consisting of psychologists (E.A., B.K., I.K.) and a physical therapist (A.G.) aimed at a joint decision.

Statistical Methods

Statistical analysis was performed using SAS for Windows, version 6.[†] Descriptive statistics were used to characterize the sample and frequencies of responses. The agreement between the individuals who performed the linking was described using the percentage of agreement and kappa statistics with bootstrapped confidence intervals.[37,38] The values of the kappa coefficient generally range from 0 to 1, where 1 indicates perfect agreement and 0 indicates no additional agreement beyond what is expected by chance only.

The percentage of participants who agreed with the question of the second and third Delphi rounds was calculated. Only ICF categories that reached consensus among the participants in the third round were considered for comparison with the Extended ICF Core Set for stroke. Lacking a universally accepted definition of consensus,[31] an agreement of at least 75% among the participants was considered sufficiently high, based on experiences in previous studies.[16,31]

[†] SAS Institute Inc, 100 SAS Campus Dr, Cary, NC 27513-2414.

Results

Recruitment and Participants

Seventy-eight national physical therapy associations and 54 European associations named 23 participants. Three participants were named by the European Federation of Neuro-Rehabilitation (EGNR). Seventeen certified experts in neurology from the United States agreed to participate. Nine universities with specialization in neurology named 11 participants, and 6 Bobath instructors agreed to participate. Two participants were identified by literature searches. Thirty-two international and 8 national partners from the ICF Network for stroke were contacted. Five of them agreed to participate. The remaining 80 physical therapists who participated in this study were contacted on the basis of personal recommendations of other participants ("snowball sampling"). In total, 146 physical therapists from 24 countries agreed to participate.

One hundred twenty-five (85.6%) out of 146 physical therapists who agreed to participate in the study completed the first-round questionnaire. The demographic and professional characteristics of these participants are shown in Table 1.

Delphi Process

In the first Delphi round, 4,793 patients' problems, patients' resources, or aspects of the environment treated by physical therapists in patients with stroke were named. One hundred eleven out of 125 participants (88.8%) filled in the second round questionnaire. One hundred one (90.9%) out of 111 physical therapists completed the third-round questionnaire.

Table 1.
Distribution of the Participants About 3 Delphi Rounds and Demographic and Professional Experience of the Participants From Round 1[a]

WHO Region[b]	Round 1 (n)	Round 2 (n)	Round 3 (n)	% Female	Age (y), Median (Range)	Professional Experience (y), Median (Range)	Practical Experience With Patients With Stroke (y), Median (Range)	Self-rating Stroke Treatment Expertise[c] (y), Median (Range)
Regions of the Americas	28	25	23	85.10	39.0 (31.0–51.0)	15.0 (6.0–30.0)	13.0 (5.0–28.0)	4.0 (3.0–5.0)
European region	91	81	73	80.20	42.0 (22.0–67.0)	16.0 (1.0–40.0)	13.0 (1.0–35.0)	4.0 (3.0–5.0)
Western Pacific region	4	3	3	100.00	43.5 (28.0–47.0)	21.5 (6.0–25.0)	16.5 (3.0–25.0)	4.0 (3.0–4.0)
African region	2	2	2	50.00	51.5 (35.0–68.0)	26.5 (11.0–42.0)	26.5 (13.0–40.0)	4.25 (4.0–4.5)
Total	125 (87.4%)	111 (88.8%)	101 (90.9%)	77.9%	40.0 (22–68)	16.0 (1–42)	13.0 (1–40)	4.0 (3–5)

[a] WHO=World Health Organization.
[b] Region of Americas: Brazil, Canada, Jamaica, and United States; European region: Austria, Belgium, Czech Republic, Finland, Germany, Hungary, Israel, Italy, Netherlands, Norway, Spain, Sweden, Switzerland, Turkey, and United Kingdom; Western Pacific region: Australia, Japan, and New Zealand; African region: Nigeria and South Africa; Eastern Mediterranean region: not represented; South East Asia region: not represented.
[c] 1=low, 5=excellent.

Linking of the Responses to the ICF

All components of the ICF were represented by 376 identified ICF categories. Seven fourth-level categories, 80 third-level categories, and 59 second-level categories were linked to the component *body functions*. Two fourth-level categories, 12 third-level categories, and 10 second-level categories were linked to the component *body structures*. Sixty-seven third-level categories and 53 second-level categories were linked to the component *activities and participation*. Twenty-seven third-level categories and 37 second-level categories were linked to the component *environmental factors*. Fifteen aspects were named that could be attributed to the not-yet-developed ICF component *personal factors*. Fifteen responses were not covered by the current version of the ICF. Agreement between the 2 people who performed the linking was reached in 42% of the responses. The kappa value for the linking was 0.39, with a 95% bootstrapped confidence interval of 0.34 to 0.41.

Representation of the Physical Therapists' Responses in the ICF Core Set for Stroke

In total, from the 376 ICF categories linked to the participants' responses, 185 reached an agreement of at least 75% in the final round and were considered for comparison with the Extended ICF Core Set for stroke.

Of the 83 ICF categories linked to *body functions*, 26 are included on the same level of classification and 48 are more-detailed third- and fourth-level categories, which are represented by the corresponding second-level categories (eg, "b1300 Energy level," which is represented in the Extended ICF Core Set for stroke by the second-level category "b130 Energy and drive functions") (Tab. 2). Ten ICF categories that correspond to the 4 second-level ICF categories "b445 Respiratory muscle function," "b720 Mobility of joint functions," "b765 Involuntary movement functions," and "b780 Sensations related to muscles and movement functions" are not represented in the Extended ICF Core Set for stroke (Tab. 2).

Of the component *body structures*, 23 ICF categories reached an agreement of ≥75%. Among these, 6 categories are included in the Extended ICF Core Set for stroke at the same level of classification, whereas 9 categories were represented at a different level of the classification. Three second-level ICF categories and 5 corresponding third-level categories are not represented in the Extended ICF Core Set for stroke (Tab. 2).

Of the 67 ICF categories from the ICF component *activities and participation* that reached an agreement of ≥75%, 23 are included at the same level of the classification and 42 more-detailed, third-level categories are represented in the Extended ICF Core Set for stroke by their corresponding second-level categories. Two ICF categories, namely "d435 Moving objects with lower extremities" and "d6504 Maintaining assistive devices," are not represented in the Extended ICF Core Set for stroke (Tab. 2).

Of the component *environmental factors*, 9 categories reached an

Table 2.
International Classification of Functioning, Disability and Health (ICF) Categories That Are Not Represented in the Current Version of the ICF Core Set for Stroke: Percentage of Participants Who Considered the Respective ICF Category as Relevant in the Final Round (Round 3)[a]

ICF Code Level 2	ICF Code Level 3	Title of ICF Category	Final Round (n=101), %
Body functions			
b445		Respiratory muscle functions	100.0
b720		Mobility of bone functions	98.2
b765		Involuntary movement functions	93.6
	b7650	Involuntary contractions of muscles	86.8
	b7651	Tremor	92.9
b780		Sensations related to muscles and movement functions	99.1
	b7800	Sensation of muscle stiffness	98.1
	b7801	Sensation of muscle spasm	95.5
Body structures			
s740		Structure of pelvic region	90.7
	s7402	Muscles of pelvic region	96.3
s760		Structure of trunk	92.5
s770		Additional musculoskeletal structures related to movement	94.0
	s7700	Bones	89.5
	s7701	Joints	96.3
	s7702	Muscles	96.2
	s7703	Extra-articular ligaments, fasciae, extramuscular aponeuroses, retinacula, septa, bursae, unspecified	90.7
Activities and participation			
d435		Moving objects with lower extremities	98.2
	d6504	Maintaining assistive devices	83.0
Environmental factors			
	e1401	Assistive products and technology for culture, recreation, and sport	77.7

[a] Only categories with agreement of ≥75% are shown.

agreement of ≥75%. Of these, 5 categories are included at the same level of classification in the Extended ICF Core Set for stroke, whereas 3 categories were represented at a different level of the classification. The ICF category "e1401 Assistive products and technology for culture, recreation and sport" is not represented in the Extended ICF Core Set for stroke (Tab. 2).

Twelve responses were assigned to the not-yet-developed ICF component *personal factors* and reached an agreement surpassing 75%. Most of them addressed attitudes supporting the independence of a person with stroke in managing his or her disease (eg, self-management, compliance, autonomy/independence). Autonomy, compliance, self-concept and self-management, illness knowledge, and coping were considered to comprise personal factors according to the ICF language. In addition, "brain plasticity" and "recovery" were identified as *personal factors* representing relevant aspects of stroke intervention by physical therapists (Tab. 3). Fifteen responses of the participants were not covered by any ICF component or specific ICF category out of the classification (Tab. 3).

Discussion

This study examined the content validity of the Extended ICF Core Set for stroke from the perspective of physical therapists. In this study, *content validity* refers to the extent to which the patients' problems, patients' resources, and environmental factors identified by physical therapists as relevant to their management of people with stroke are represented in the Extended ICF Core Set for stroke. An agreement of at least 75% among the participants in the final Delphi round was regarded as sufficient consensus. Consequently, ICF categories with an agreement of at least 75% that are not represented in the Extended ICF Core Set for stroke may indicate missing content validity and will be the main focus of the following discussion.

A 100% agreement among the participants was found regarding the category "b445 Respiratory muscle function." However, this ICF category is not included in the Extended ICF Core Set for stroke. Several studies have demonstrated that problems associated with strength (force-generating capacity) and endurance of respiratory muscles, as well as with muscles of the trunk and the position of the diaphragm, are important risk factors for secondary complications after stroke such as pneumonia.[39] In order to minimize these risks, physical therapists use respiratory exercises, including

training of respiration and specific intervention techniques, to activate or relax respiratory muscles.[40]

The participants addressed nearly all of the different categories from the ICF chapter "*Neuro-musculosceletal and Movement-Related Functions*," which covers functions of joints, bones, reflexes, and muscles.[11] These aspects clearly represent one main focus of the physical therapists' work in stroke rehabilitation. However, although the ICF category "b720 Mobility of bone functions" reached an agreement of 98.2% among the participants, it is not included in the ICF Core Set for stroke. Bone mobility is a prerequisite for activities such as grasping a glass. Bone mobility is treated by physical therapists using different manual techniques (eg, mobilization of the scapulae in people with shoulder pain after stroke).[41]

Furthermore, more than 90% of the participants agreed that the ICF category "b765 Involuntary movement functions" is a problem treated by physical therapists, which is not included in the ICF Core Set for stroke. This finding is clearly supported by literature, which reports a close relationship between stroke and spasticity (hypertonicity) and the incidence of clonus or tremor.[42,43] In addition, validation studies have identified this ICF category as being relevant for occupational therapists[44] and physicians.[45]

Regarding the ICF category "b780 Sensations related to muscles and movement functions," which is not represented in the ICF Core Set for stroke, again a high consensus among the participants was found. It is quite obvious that people with stroke experience stiffness and tightness of muscles. Muscle spasms and heaviness of muscles are commonly treated by physical therapists.[40]

Table 3.
Responses That Were Linked to the *International Classification of Functioning, Disability and Health* (ICF) Component Personal Factors and "Not Classified" Terms: Percentage of Participants Who Considered the Respective Concepts As Relevant in the Final Round (Round 3)[a]

Personal Factors	Final Round (n=101), %
Autonomy, independence	97.3
Brain plasticity/recovery	97.2
Self-concept, self-perception	95.9
Endurance/discipline, hardiness	93.8
Coping	92.8
Optimistic/positive attitude	92.8
Compliance	92.7
Self-management	91.8
Illness knowledge	91.8
Problems/worries/uncertainty about future	88.6
Sense of mastery	88.5
Life values, life goals, lifestyle	87.6
Not Classified	**Final Round (n=101), %**
Posture/postural alignment	99.1
Adaptation to bodily changes/compensation strategies	98.1
Secondary complications	98.1
Multiprofessional and interdisciplinary treatment	97.2
Therapeutic positioning	97.2
Assessment of the patient and evaluation	96.3
Impairment of body symmetry	96.3
Positive model for living with a handicap	95.8
Education of self and family about stroke	95.4
Physical therapy intervention	95.2
Perspective of life (living at home, profession)	92.7
Learning experience in dealing with limitations	92.7
Conveying problem to others and their understanding	91.8
Competence in self-relaxation	91.8
Self-observation	91.8

[a] Only concepts with agreement of ≥75% are shown.

With regard to the ICF component *body structures*, 3 ICF categories were found not to be included in the current version of the ICF Core Set for stroke. Spasticity and muscle imbalance in lower limbs, which are major problems after stroke, are associated with walking problems. Improvement of multijoint coordination and improvement of muscle activity in the lower limbs, including the pelvis, are relevant intervention goals for physical therapists. However, the ICF category "s740 Structure of pelvic region" is currently not included.

The ICF category "s760 Structure of trunk," including bones, muscles, and ligaments of the trunk, repre-

sents a main intervention area of physical therapy after stroke because hemiplegia not merely results in diverse problems in the upper and lower extremities but also affects the trunk and its corresponding structures.[46,47] Finally, the ICF category "s770 Additional musculoskeletal structures related to movement" addresses structures that still are not sufficiently mapped in the ICF. For instance, muscles of the neck frequently are affected in neglect.[48]

Regarding the ICF component *activities and participation*, the ICF category "d435 Moving objects with lower extremities" was regarded as relevant by the participants, but this category is not included in the ICF Core Set for stroke. Indeed, people with stroke have impairments in structure and functioning of the feet, such as decreased muscle power or problems with spasticity or flaccid muscles, that can lead to difficulties with pushing pedals on a bicycle or pressing the gas pedal of a car.[49,50] On the other hand, problems with riding a bicycle or driving a car are covered by the ICF category "d475 Driving," which is already part of the Extended ICF Core Set for stroke.

The high level of agreement among the participants regarding the ICF categories related to assistive devices such as "e115 Products and technology for personal use in daily living" highlights the relevance of a restoratory and compensatory rehabilitation strategy. Education and training on the use and maintenance of assistive devices are an inherent part of physical therapy. However, the ICF categories "e1401 Assistive products and technology for culture, recreation, and sport" and "d6504 Maintaining assistive devices" are not yet included in the Extended ICF Core Set for stroke.

Twelve aspects were linked to the not-yet-developed ICF component *personal factors*. Patients' self-management, illness knowledge, and ability to cope with the disease are relevant for patient education provided by physical therapists.[51] Various studies and systematic reviews support the positive effects of patient education regarding self-management[51] and coping with disease.[52] These results indicate that personal factors also are considered by physical therapists. Therefore, it could be most helpful for physical therapists if the ICF would provide a classification of the personal factors in the future. This classification will enable health care professionals to identify systematically all personal factors influencing the functioning of a certain person.

Posture/postural alignment was regarded as a relevant aspect by almost all of the participants; however, this aspect is not covered by the ICF. Although the ICF category "d415 Maintaining a body position" covers the static aspects of posture, the dynamic aspects of posture are missing. Thus, it could be useful to develop an ICF category addressing posture/postural alignment more specifically. However, when increasing the specificity of such an ICF category, it should be kept in mind that the ICF should be used by all health care professions and, therefore, physical therapy–specific terminology should be avoided.

In general, the participants named a large number of detailed aspects, represented by third- and fourth-level ICF categories, which are relevant for stroke intervention. This detailed information is necessary for assessment, therapy planning, and intervention in physical therapy. As the ICF Core Set includes only less-specific, second-level categories, this detailed information might be unfavorable for physical therapist practice on the one hand. On the other hand, the current version of the Extended ICF Core Set for stroke already includes 166 second-level ICF categories, and any further extension could compromise its feasibility in clinical practice.

The Delphi technique proved to be an appropriate method for this study objective. With response rates exceeding 87% in the present study, previously reported response rates of approximately 50%[30,33,53] were clearly surpassed. However, there are some limitations regarding the reliability and external validity of this study.

The agreement between the people who performed the linking was lower than in other studies that used comparable methods.[54–56] This finding may be related to the fact that the answers of the participants were longer and, therefore, the extraction of the meaningful concepts was more difficult than in similar studies regarding other health conditions. Consequently, the instructions for the first round were revised for their use in future studies. Furthermore, as we have only linked a sample of the responses, we cannot exclude that the agreement would have been different in another sample of responses.

Although we were successful in recruiting physical therapists from 24 countries, the African and Eastern Mediterranean world regions are not represented in the sample. Health care systems in these world regions may differ from those of other world regions, and it cannot be excluded that this difference also affects the intervention targets of physical therapists in stroke treatment. Thus, the sample is not representative of all physical therapists experienced in the intervention of people with stroke worldwide. Language barriers could have influenced the participation in some world regions because

the Delphi survey was conducted in English language only.

Although some restrictions of the current version of the Extended ICF Core Set for stroke were detected in this study, we found the categories of the current version of the Extended ICF Core Set for stroke largely represent what the physical therapists in our study agreed upon to take care of in their interventions.

The results of finalized or ongoing studies involving both health care professionals[44,45] and patients will further elucidate the validity of the Extended ICF Core Set for stroke from the different perspectives. A number of ICF categories identified as missing in the current version of the Extended ICF Core Set for stroke by occupational therapists[44] also were mentioned by the participants in our study. These ICF categories included "b720 Mobility of bone functions" and "b765 Involuntary movement functions" from the component *body functions*, "s760 Structure of trunk" and "s770 Additional musculoskeletal structures related to movement" from the component *body structures*, "d435 Moving objects with lower extremities" and "d650 Caring for household objects" from the component *activities and participation*, and "e140 Products and technology for culture, recreation, and sport" from the component *environmental factors*. In contrast to physical therapists and occupational therapists, physicians have found only 4 ICF categories that are relevant for their treatment but not yet part of the current version of the Extended ICF Core Set for stroke.[45] Of interest, the ICF category "b765 Involuntary movement functions" was mentioned as relevant by all 3 health care professions. Thus, this category would be a good candidate for inclusion in the Extended ICF Core Set for stroke.

The validation from the perspective of 3 different health care professions has shown that it might be useful to add relevant ICF categories to the Extended ICF Core Set for stroke.[44,45] On the other hand, studies that have applied the Extended ICF Core Set for stroke in a sample of people with stroke have identified ICF categories that are less relevant and might be excluded.[57,58]

However, the validation from the patient perspective is not yet completed. It seems reasonable that a final decision on the content of a revised version of the Extended ICF Core Set for stroke should be postponed until the results from the patient perspective are available and can be included in the discussion.

All authors provided concept/idea/project design. Ms Glässel, Dr Kirchberger, and Dr Cieza provided writing. Ms Glässel provided data collection. Ms Glässel, Dr Kirchberger, Dr Kollerits, and Dr Amann provided data analysis. Ms Glässel and Dr Kirchberger provided project management. Dr Kirchberger and Dr Cieza provided consultation (including review of manuscript before submission). The authors thank the participants of the Delphi exercise for their valuable contribution and their time in responding to the questionnaires.

This study forms part of Ms Glässel's doctoral thesis at the Faculty of Medicine, Ludwig-Maximilian University, Munich, Germany.

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The responsibility for the content of this publication lies within the ICF Research Branch.

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Appendix 10 Study 3 - short description of the Delphi survey - health professional perspective -

Kurzbeschreibung des Projekts: „Validierung des ICF Core Sets für Schlaganfall an Physiotherapeuten“

Institut für Gesundheits- und Rehabilitationswissenschaften, ICF-Forschungsstelle an der Klinik und Poliklinik für Physikalische Medizin und Rehabilitation der Universität München
Direktor: Prof. Dr. G. Stucki

In der Internationalen Klassifikation für Funktionsfähigkeit, Behinderung und Gesundheit (ICF), diem2001 von der WHO verabschiedet wurde, werden Beeinträchtigungen und Potenziale eines Patienten mehrdimensional abgebildet. Der Einsatz der ICF in der Rehabilitation erscheint vielversprechend, da die Erfassung der funktionalen Gesundheit, wie in der ICF durchgeführt, die Basis der rehabilitativen Diagnostik, Versorgung, Intervention und Evaluation der Ergebnisse darstellt.

Um das ICF Modell für die klinische Praxis nutzen zu können, entwickelte unsere Forschungsgruppe diagnosespezifische umfassende Core Sets aus der ICF-Klassifikation. Dies ist eine Auswahl von ICF-Kategorien, die für die Mehrzahl von Patienten mit einer bestimmten Erkrankung zur Beschreibung und Klassifikation ihrer Funktionsfähigkeit, Behinderung und Gesundheit relevant sind.

Die erste Version der ICF umfassende Core Sets für **Schlaganfall** wurde in einer internationalen Konsensuskonferenz von 39 Experten aus 12 unterschiedlichen Ländern und unterschiedlichen Gesundheitsberufen verabschiedet. Mit diesem Core Set wird es zukünftig möglich sein, eine international einheitliche Klassifikation von Patienten nach einem Schlaganfall vorzunehmen.

Vor ihrem routinemäßigen Einsatz ist eine **Validierung der Core Sets** erforderlich. Hierbei wird überprüft, ob die Interventionen der Berufsgruppen, die an der medizinischen Versorgung von Patienten nach einem Schlaganfall beteiligt sind, im ICF Core Set abgebildet sind. Im Rahmen dieser Studie soll das umfassende ICF Core Set für Schlaganfall aus der Perspektive von Physiotherapeuten validiert werden.

In einer internationalen Befragung, sollen die Physiotherapieexperten aus ihrer Sicht Auskunft darüber geben, welche Probleme und Ressourcen der Patienten aber auch Umweltaspekte der Patienten nach einem Schlaganfall sie behandeln. Die Befragung wird schriftlich per E-Mail (ggf. per Fax/Post) durchgeführt. Sie umfasst mehrere Befragungsrunden, wird nach der sog. Delphi-Methode durchgeführt und erstreckt sich über 12 Wochen. Der Zeitaufwand für das Ausfüllen und den Versand des Fragebogens beträgt nicht mehr als insgesamt 3 Stunden (verteilt auf mehrere Wochen). Als Teilnehmer kommen Physiotherapeuten in Frage, die Erfahrung in der Therapie und Versorgung von Patienten nach einem Schlaganfall haben.

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Appendix 11 Study 3 - cover letter Delphi survey round 1 - health professional perspective -

Dear participant in the Delphi exercise,

Your task within this **first Delphi-Round** is to list all patients' problems, patients' resources and aspects of environment treated by physical therapists in patients with stroke.

Please follow the following four steps to answer this **first Delphi-round**:

1. **List all patients' problems, patients' resources and aspects of environment treated by physical therapists in patients with stroke** in the columns of the attached file **"PT_1.xls".**
2. **Answer the questions on your professional background** in the same file.
3. **Send the fulfilled document "PT_1.xls" to** icf.delphi@phys.med.uni-muenchen.de by **April 24th**. Please, do not change the subject text of the e-mail: *"Validation of the ICF Core Set for STROKE: physical therapists first Delphi round"* If you are not able to email the file, please send a hardcopy of the file per fax (+49 89 2180 78278) or per mail by **April 24th.**
4. **Keep a copy** after you have completed your task in case something goes wrong during the mailing process.

It will take us about 3 weeks to compile the results and link the named problems, patient resources and aspects of environment to the respective ICF categories. You will receive the compiled results of the first Delphi round and will be asked further questions in a second round.

Your answers will remain confidential and anonymous. Only compiled results will be provided.

To obtain reliable results, we need the responses of as many experts as possible. Therefore, your participation in this Delphi exercise is highly appreciated.

Many thanks in advance for collaborating in this important international project!

Yours sincerely,

Prof. Dr. G. Stucki	Dr. A. Cieza	A. Gläßel (BSc. PT, cand. MSc)
(Department Head)	(Group Leader ICF Research Branch)	(Project coordinator)

Appendix 12 Study 3 - Delphi Survey Round 1 – Questionnaire (extraction) - health professional perspective -

Delphi Exercise Round 1 **Health Profession: Physical Therapists**

Please list in the following cells what physical therapists treat in patients with stroke.
Consider thereby not only patients problems, but also resources and aspects of environment.

Please try to use only one line per patients' problem, patients' resource or aspect of the environment.

Some information about yourself:

Age		**years**
Gender		
Professional background		
Specialty		
Current professional activity		
Professional experience		**years**
Practical experience with stroke patients		**years**
How many years did you treat stroke patients		
- exclusively		**years**
- predominantly		**years**
- frequently		**years**
- rarely ?		**years**

How would you rate your expertise in the treatment of stroke patients?

Please chose an number between 1 (low) and 5 (excellent)

Appendix 13 Study 3 - Delphi Survey Round 2 – Questionnaire - health professional perspective - (extraction)

Delphi Exercise Round 2 **Physical Therapists** ID

Do you agree that this ICF category represents patients' problems, patients' resources or aspects of the environment treated by physical therapists in patients with Stroke?

ICF code	ICF category title	ICF category description	YES/NO
b1	MENTAL FUNCTIONS	This chapter is about the functions of the brain: both global mental functions, such as consciousness, energy and drive, and specific mental functions, such as memory, language and calculation mental functions.	
b110	Consciousness functions	General mental functions of the state of awareness and alertness, including the clarity and continuity of the wakeful state.	
b1100	State of consciousness	Mental functions that when altered produce states such as clouding of consciousness, stupor or coma.	
b1101	Continuity of consciousness	Mental functions that produce sustained wakefulness, alertness and awareness and, when disrupted, may produce fugue, trance or other similar states.	
b114	Orientation problems	General mental functions of knowing and ascertaining one's relation to self, to others, to time and to one's surroundings.	
b1140	Orientation to time	Mental functions that produce awareness of day, date, month and year.	
b1141	Orientation to place	Mental functions that produce awareness of one's location, such as one's immediate surroundings, one's town or country.	
b1142	Orientation to person	Mental functions that produce awareness of one's own identity and of individuals in the immediate environment.	
b11421	Orientation to others	Mental functions that produce awareness of the identity of other individuals in one's immediate environment .	
b117	Intellectual functions	General mental functions, required to understand and constructively integrate the various mental functions, including all cognitive functions and their development over the life span.	

Appendix 14 Study 3 - Delphi Survey Round 3 – Questionnaire - health professional perspective - (extraction)

ID

Delphi Exercise Round 3 **Physical Therapists**

Taking into account the answer of the group and your individual answer in the second round, do you agree that this ICF category represents patients' problems, patients' resources or aspects of the environment treated by physical therapists in patients with Stroke?

ICF code	ICF category title	ICF category description	ID-number	% agreement	YES/NO
b1	MENTAL FUNCTIONS	This chapter is about the functions of the brain: both global mental functions, such as consciousness, energy and drive, and specific mental functions, such as memory, language and calculation mental functions.	1;2;3;5;7;10;11;12;14;15;20;22; 23;25;26;27;28;29;30;32;34;35; 36;37;38;39;40;42;43;44;45;46; 47;48;49;50;51;54;56;57;58;59; 60;61;65;66;68;69;70;71;72;73; 74;75;76;77;78;79;80;82;83;84; 85;87;89;90;91;94;95;96;99;10 1;102;104;106;107;	86,4%	
b110	Consciousness functions	General mental functions of the state of awareness and alertness, including the clarity and continuity of the wakeful state.		81,3%	
b1100	State of consciousness	Mental functions that when altered produce states such as clouding of consciousness, stupor or coma.		54,2%	
b1101	Continuity of consciousness	Mental functions that produce sustained wakefulness, alertness and awareness and, when disrupted, may produce fugue, trance or other similar states.		58,5%	
b114	Orientation problems	General mental functions of knowing and ascertaining one's relation to self, to others, to time and to one's surroundings.		85,0%	
b1140	Orientation to time	Mental functions that produce awareness of day, date, month and year.		67,3%	
b1141	Orientation to place	Mental functions that produce awareness of one's location, such as one's immediate surroundings, one's town or country.		80,4%	
b1142	Orientation to person	Mental functions that produce awareness of one's own identity and of individuals in the immediate environment.		78,5%	
b11421	Orientation to others	Mental functions that produce awareness of the identity of other individuals in one's immediate environment .		69,2%	
b117	Intellectual functions	General mental functions, required to understand and constructively integrate the various mental functions, including all cognitive functions and their development over the life span.		51,9%	
b126	Temperament and personality functions	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.		41,5%	
b1263	Psychic stability	Mental functions that produce a personal disposition that is even-tempered, calm and composed, as contrasted to being irritable, worried, erratic and moody.		43,5%	
b1265	Optimism	Mental functions that produce a personal disposition that is cheerful, buoyant and hopeful, as contrasted to being downhearted, gloomy and despairing.		62,0%	
b1266	Confidence	Mental functions that produce a personal disposition that is self-assured, bold and assertive, as contrasted to being timid, insecure and self-effacing.		65,7%	