Aus der

Klinik und Poliklinik für Physikalische Medizin und Rehabilitation

der Ludwig-Maximilians-Universität München

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IDENTIFYING THE CONCEPTS CONTAINED IN OUTCOME

MEASURES OF CLINICAL TRIALS ON OBESITY USING THE

INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY

AND HEALTH AS A REFERENCE

Dissertation

zum Erwerb des Doktorgrades der Medizin

an der Medizinischen Fakultät der Ludwig-Maximilians-Universität zu München

vorgelegt von

Sebastian Baumann

aus Würzburg

2006

Mit Genehmigung der medizinischen Fakultät

der Universität München

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Tag der mündlichen Prüfung: 08.03.2007

Mein Dank gilt meinem Doktorvater, Herrn Professor Dr. med. Gerold Stucki, für das Heranführen an das kreative wissenschaftliche Arbeiten. Seine Energie und seine Begeisterung für das Projekt „International Classification of Functioning, Disability and Health" haben mich beeindruckt und motiviert.

Ganz besonders bedanke ich mich bei Frau Dr. Dipl. Psych. Alarcos Cieza, Gruppenleiterin des ICF-Core Set Development für die Beratung bei der Themenstellung, für meine Einarbeitung in das Themengebiet und für die Unterstützung in allen Fragen. Auch das Team stand mir bei Fragen immer hilfreich zur Seite.

Außerdem möchte ich mich bei meiner Lebenspartnerin Margaretha bedanken, die mich durch ihre Geduld und Aufmunterung bei der Fertigstellung dieser Schrift unterstützt hat.
Meinem Vater danke ich für die unterstützende Begleitung während meines Studiums.

Ich widme diese Arbeit meinem Freund und lieben Begleiter Dr. Heinrich Hohenauer.

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1. Deutsche Zusammenfassung

Die Prävalenz von Adipositas wird derzeitig, mit steigender Tendenz, auf circa 300 Millionen Menschen weltweit geschätzt. Nach dem gegenwärtigen wissenschaftlichen Kenntnisstand wird Adipositas als eine komplexe und multifaktorielle Erkrankung verstanden. Aus diesem Grund ist es in Adipositasstudien erforderlich, umfassende und weit reichende Messparameter und Studienendpunkte zu verwenden, um einerseits die Krankheitslast in ihrem gesamten Umfang zu erfassen und andererseits die Behandlungsergebnisse besser beurteilen zu können.

Eine genaue Untersuchung von Adipositasstudien der letzten zehn Jahre kann bei der Definition einer Vorgabe mithelfen, welche Messparameter grundsätzlich in Adipositasstudien verwendet werden sollten. Diese Vorgabe muss die für Adipositaspatienten spezifische Krankheitslast umfassend beschreiben. Durch die universelle Verwendung dieser Vorgabe kann in Zukunft das Auswerten und Vergleichen der Behandlungsergebnisse von Adipositasstudien vereinfacht werden.

Seitdem die Internationale Klassifikation der Funktionsfähigkeit, Behinderung und Gesundheit (ICF) von der Weltgesundheitsorganisation im Mai 2001 als einheitliche Sprache eingeführt wurde, ist es möglich Konzepte die in Messergebnissen beinhaltet sind zu identifizieren und zu vergleichen.

Ziel dieser Arbeit ist die systematische Identifizierung von Konzepten die in Messparametern klinischer Adipositasstudien der Jahre 1992 bis 2001 enthalten sind. Die identifizierten Konzepte werden dabei in das Ordnungssystem der ICF übersetzt („linking") und so bestimmten ICF-Kategorien zugeordnet. Des Weiteren wird in dieser Arbeit die Verwendung von adipositasspezifischen, generischen und dimensionsspezifischen Health-Status Fragebögen untersucht. Die Konzepte der in den Studien verwendeten Fragebögen werden dabei ebenso in das Ordnungssystem der ICF übersetzt („linking").

Ein systematischer Literaturreview wurde durchgeführt, um randomisierte kontrollierte Studien (RCTs) mit Adipositaspatienten zu lokalisieren und zu selektieren. Alle Verfahren zur Outcome-Erfassung in den ausgewählten RCTs wurden identifiziert. Die Inhalte dieser Messverfahren wurden anschließend untersucht, indem sie mit Hilfe der sogenannten Linking Methode zur ICF in Verbindung gesetzt wurden.

Insgesamt wurden 428 Studien mit Adipositaspatienten in den Literaturreview eingeschlossen. Es wurden 57 verschiedene Health-Status Fragebögen in den ausgewerteten Publikationen verwendet. Aus den 428 Studien wurden 16 034 Konzepte identifiziert, davon konnten 81% dem Kategoriensystem der ICF zugeordnet werden. Die am häufigsten verwendeten ICF-Kategorien, aufgeteilt

nach deren ICF-Klassifikationskomponente *Körperfunktionen, Aktivität und Partizipation, Umweltfaktoren* und *Körperstrukturen,* waren `Allgemeine Stoffwechselfunktionen´ (b540), `Sorge um die eigene Gesundheit´ (d570), `Produkte oder Substanzen für den persönlichen Konsum´ (e110) und `Struktur des Rumpfes´ (s760) mit den jeweils folgenden Häufigkeiten von 65%, 57%, 16% und 13%.

Diese Studie zeigt, daß die ICF ein nützliches Referenzsystem zur Identifizierung und Quantifizierung von Konzepten aus Verfahren zur Erfassung der Studienendpunkte in Adipositasstudien ist. Es scheint ein Mangel an ICF-Kategorien der ICF-Klassifikationskomponente *Körperstrukturen* in klinischen Adipositasstudien vorzuliegen. Außerdem besteht die Notwendigkeit patientenorientierte Messergebnisse, aus der für Adipositaspatienten stark relevanten ICF-Klassifikationskomponente *Aktivität und Partizipation,* vermehrt in Adipositasstudien einzuschließen.

2. Abstract

The prevalence of obesity is currently estimated at about 300 million people worldwide and is rising further on. Based on the current understanding of obesity as a complex, multifactorial condition, comprehensive outcomes are necessary for both the measurement of the burden of disease and the evaluation of treatment outcomes. An in-depth understanding of the outcome domains that have been used in studies of obesity in the last decade can bring us one step ahead in the definition of a set of domains that define "what should be measured" to comprehensively describe the burden of obesity and/or the evaluation of treatment outcomes.

Using the new International Classification of Functioning, Disability and Health (ICF), which was endorsed by the Word Health Assembly in May 2001 as a reference or common language, it is now possible to identify and compare the concepts contained in different outcome measures.

Objective The objective of this doctoral thesis was to examine the use of concepts contained in outcome measures of randomized controlled obesity trials (RCTs) between 1992 und 2001, using the ICF as a reference tool.

This doctoral thesis also examines the use of the obesity-specific, generic and dimension-specific health status measures and concepts contained in these measures using the ICF as a reference tool.

Methods: Randomized controlled trials between 1992 and 2001 were located in MEDLINE and selected according to predefined criteria. The outcome measures were extracted and the concepts contained in the outcome measures were linked to the ICF.

Results: A total of 428 trials were included in the study. Fifty-seven different health status questionnaires were extracted. Of 16 034 extracted concepts 81% could be linked to the ICF. The most used ICF categories within the components *body functions, activities and participation, environmental factors* and *body structures,* were *general metabolic functions* (b540), *looking after one's health* (d570) *products or substances for personal consumption* (e110) and *structure of the trunk* (s760) with frequencies of 65%, 57%, 16% and 13% respectively.

Conclusion: The ICF provides a useful reference to identify and quantify the concepts contained in outcome assessment used in clinical obesity trials. There seems to be a lack of health concepts evaluating specific aspects of body structures in obesity. Similarly, *environmental factors* with an impact on individual life on obesity patients seem to be poorly represented. The need exists to systematically include patient-oriented measures to address areas of the ICF component *activities and participation* that are extremely relevant to obese persons.

3. Introduction

The prevalence of obesity is currently estimated at about 300 million people worldwide (WHO 2002) and is rising (Freedman 2002 , Ogden 2002). Allusions to obesity as an epidemic or even pandemic health condition are common in both scientific and non-scientific literature (Abelson 2004, Curtis 2004, Aronne 2002). It is an exploding health issue in Europe and the United States, but it is not limited to the developed world: Mayans in Guatemala, South Africans, aboriginal Australians, and Pacific Islanders also show patterns of emerging obesity (Abelson 2004).

Obesity is a major risk factor for premature mortality in relation to fatal cardiovascular diseases, certain cancers, and other medical conditions (Mokdad 2004, Flegal 2004, Manson 2004, Calle 2003). In a recent estimate of death attributable to obesity in the United States, obesity was the second leading modifiable factor, after smoking, contributing to death in 2000 (Mokdad 2004). However, mortality is only a small part of the substantial burden of disease caused by obesity-related conditions (Manson 2003).

Besides the overwhelming direct and indirect health-care costs (Colditz 1999, Wolf 2002) due to obesity, it is already considered to be the fifth most serious risk factor for disease burden measured in disability-adjusted life years (DALYs) in developed and low-mortality developing countries (Peeters 2004). Moreover, at the individual level, obesity is associated with a decreased health

related quality of life (HRQOL) (Seidell 1995, Larsson 2002, Fontaine 1996, Fine 1999, Mathus-Vliegen 2004).

Based on the current understanding of obesity as a complex, multifactorial condition with interactions among genetic, metabolic, environmental, and personal factors (National Institute of Health 2000), comprehensive evaluation is necessary for both the measurement of disease burden and the assessment of treatment outcomes. The currently available outcome measures have been reviewed by a task force of the North American Association for the Study of Obesity (NAASO) (Wolf 2002). Outcome measures that can be used to assess the effectiveness of treatment are outlined, and outcome measures to address clinical, HRQOL, and economic endpoints, as well as habits regarding dietary intake and physical activity, are differentiated [Task Force on Developing Obesity Outcomes and Learning Standards (TOOLS), 2002].

Different from other conditions, instruments to measure obesity-specific health status have only recently been developed (Kolotkin 1997). New versions of existing instruments are continuously being developed with respect to their contents and psychometric properties. Therefore, any recommendation regarding a specific instrument is likely to soon be outdated.

To avoid this problem, at least to some extent, it would be preferable to first define "what should be measured" and only then to recommend how to

measure it or which instrument to use. This approach has already been successfully applied in rheumatology by the OMERACT group (Boers 1994). There are different approaches to develop a set of domains that define "what should be measured" to comprehensively describe the burden of a determined disease and/or the evaluation of treatment outcomes.

An in-depth understanding of the outcomes that have been used in studies of obesity in the last decade brings us one step further in this respect. Such knowledge requires not only a review of the clinical endpoints, the obesity-specific, generic and dimension-specific health-status instruments used, but, more specifically, a review of the concepts covered by the items in the measuring instruments and a review of other outcome measures, including clinical and laboratory tests. Using the new International Classification of Functioning, Disability and Health (ICF), which was endorsed by the Word Health Assembly in May 2001 as a reference or common language, it is now possible to identify, quantify and compare the concepts contained in different outcome evaluations (Cieza 2002).

The ICF is based on the integrative bio-psycho-social model of functioning, disability and health of the World Health Organization (WHO). The components of this model, as well as the understanding of their interactions, can be seen in Figure 1.

Figure 1: Biopsychosocial model of functioning, disability and health.
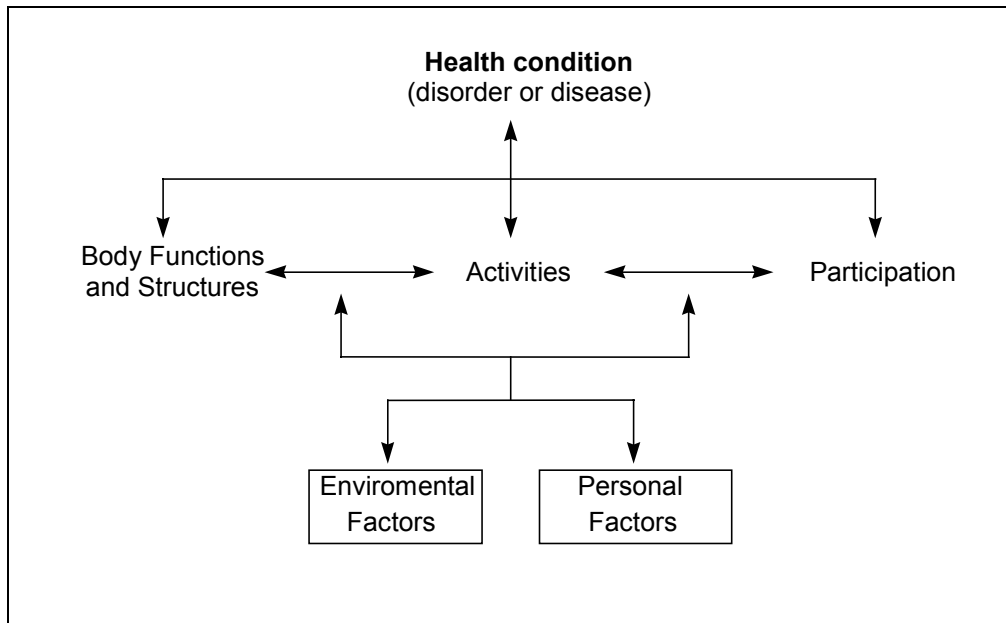
A **health condition** is an umbrella term for disease, disorder, injury or trauma and may also include other circumstances, such as ageing, stress, congenital anomaly, or genetic predisposition. It may also include information about pathogeneses and/or etiology. Interactions between the health condition and all components of functioning (body functions and structures, activity and participation) may exist.

Body functions are defined as the physiological functions of body systems, including psychological functions. Body structures are the anatomical parts of the body, such as organs, limbs and their components. Abnormalities of function, as well as abnormalities of structure, are referred to as impairments, which are defined as a significant deviation or loss (e.g. deformity) of structures (e.g. joints) and/or functions [e.g. reduced range of motion (ROM),

muscle weakness, pain and fatigue].

Activity is the execution of a task or action by an individual and represents the individual perspective of functioning. **Participation** refers to the involvement of an individual in a life situation and represents the societal perspective of functioning. Difficulties at the activity level are referred to as activity limitation (e.g. limitations in mobility such as walking, climbing steps, grasping or carrying). Problems an individual may experience in his/her involvement in life situations are denoted as participation restriction (e.g. restrictions in community life, recreation and leisure, but also in walking, if walking is an aspect of participation in terms of a life situation).

Contextual factors represent the entire background of an individual's life and living situation. Within the contextual factors, the environmental factors make up the physical, social and attitudinal environment in which people live and conduct their lives. These factors are external to individuals and can have a positive or negative influence, i.e., they can represent a facilitator or a barrier for the individual.

Personal factors are the particular background of an individual's life and living situation and comprise features that are not part of a health condition, i.e. gender, age, race, fitness, life-style, habits and social background. They can be referred to as those factors which define the person as a unique individual. Personal factors cannot be impaired, limited or restricted. They can, however,

have a positive or negative impact on disability and functioning, i.e., on (impaired) body functions and structures, on (limited) activities and (restricted) participation.

Since this bio-psycho-social view guided the development of the ICF, the components of the model correspond to the components of the classification. Within each component, there is a very exhaustive list of so-called ICF categories, which are the units of the classification. The ICF categories are hierarchically organized and are denoted by unique alphanumeric codes (see Figure 2). The categories are arranged in a stem/branch/leaf scheme within each component.

Each component consists of chapters (first level). Each chapter consists of second-level categories, which, in turn, are composed of categories at the third level, which include fourth-level categories. An example from the component Body Functions is presented bellow:

b2   Sensory functions and pain   (first/ chapter level)

b280 Sensation of pain (second level)

b2801   Pain in body part (third level)

b28013   Pain in back   (fourth level).

Figure 2: The different levels of the ICF. The ICF uses an alphanumeric system in which letters b, s, d and e are used to denote body functions, *body structures, activities and participation, and environmental factors, respectively. These letters are followed by a numeric code that starts with* a chapter number (one digit), followed by a second level (two digit), and third and forth levels (one digit for each).
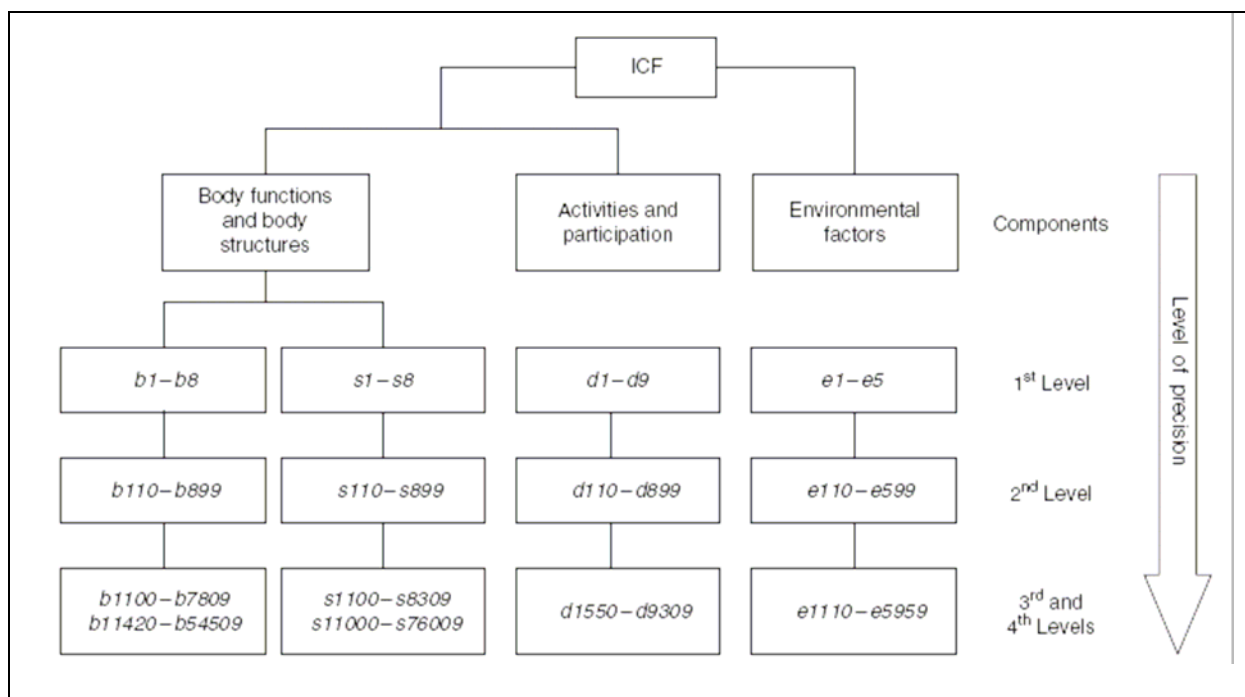
4. Methods

4.1 Design

A systematic review was performed in the following three steps: step 1, selection of studies, step 2, outcome measures extraction and step 3, linkage of the concepts contained in these outcomes measures to the corresponding categories in the ICF.

4.1.1 Step 1: Selection of Studies

RCTs between the years 1992-2001 were located in MEDLINE®, Silver Platter, 2000 Edition, by using Dickersin's et al. (Dickersin 1994) highly precise search strategy (sets 1-8). Thereafter, the Dickersin search was combined with the obesity-specific search strategy using the 'and' operator. The explode-function *obesity-morbid,* including the subheadings terms *obesity*, *obese*, *overweight,* were combined using the 'or' operator. All searches were limited to English articles. The search strategy is described in Figure 3.

Figure 3: Obesity-specific search strategy

```
#1   randomized-controlled-trial in pt
#2   randomized-controlled-trials
#3   random-allocation
#4   double-blind-method
#5   single-blind-method
#6   #1 or #2 or #3 or #4 or #5
#7    (TG=animal) not ((TG=human) and (TG= animal))
#8   #6 not #7
#9   obesity
#10 obese
#11 overweight
#12 #9 or #10 or #11
#13 English in la
#14 (#8 and #12 and #13) not (py=1989-1991)
#15 "Obesity-in-Diabetes"/ all subheadings
#16  #14 not #15
```

The abstracts were checked applying general and obesity-specific eligibility criteria. For the selected trials, the original study reports were ordered and reviewed again applying the same eligibility criteria. The studies finally included entered step 2 of the review.

A study met general eligibility, if the study design was a RCT, the experimental intervention had a therapeutic aim, the outcomes measures were evaluated on patients, and if none of the following exclusion criteria were fulfilled: reviews, secondary analyses, psychometric studies, primary prevention studies (healthy population at risk), mode-of-action studies, and studies with mixed populations. In the presence of multiple publications on one study, the paper with the highest impact factor was included.

To identify the appropriate study population in each health condition, condition-specific eligibility criteria were applied. To be included, the study had

to report the diagnosis of obesity to describe the study population. Studies on populations with coronary heart disease, stroke, osteoarthritis, and diabetes mellitus Types I and II were excluded.

A detailed overview with the inclusion and exclusion criteria is shown in table 1.

4.1.2 Step 2: Outcome Measures Extraction

In step 2, the "study characteristics" and all types of outcome measures were extracted and documented. The study characteristics included the variables regarding the description of the study population (age, body mass index, lean body mass index, blood pressure, disease duration, weight, recruitment pathway, e.g., inpatient care, specially care, primary care, occupational care, advertisement), the intervention type (e.g. nutritional therapy), the specific intervention (e.g. low-calorie diet), the number of treatment groups and the number of patients included in each treatment group. All types of outcome measures including clinical, biochemical, physiologic, and imaging tests, biopsies, one single item measures on different domains as well as questionnaires were extracted. If the items of a questionnaire were not specified in the publication, we attempted to obtain the questionnaire by reference checking, searches in databases or books on health status measures (Mc Dowell 1996, Bowling 1995), email-consultation with the developers of the questionnaire in demand, and internet searches, and then

the items were extracted. Only questionnaires available in English language were included.

4.1.3 Step 3: Linkage of the Concepts

In step 3, the concepts contained in the items of the identified questionnaires were identified and linked to the most specific ICF category by two independent health professionals according to a recently developed set of 10 linking rules (Cieza 2002). In the case of the clinical, biochemical, physiologic, imaging tests and biopsies, the goal (e.g. carbohydrate metabolism) with which they had been performed was documented and linked to the ICF also by two independent health professionals applying the same 10 linking rules. Consensus between health professionals was used to decide which ICF category should be linked. To resolve disagreements between the two health professionals concerning the selected categories, a third person trained in the linking rules and in the ICF was consulted. In a discussion led by the third person, the two health professionals stated their pros and cons for the selection of a specific ICF category. Based on these statements, the third person made an informed decision.

Concepts or identified goals of outcome measures that could not be linked to the ICF were documented and classified in two ways: If a concept or the identified goal of an outcome measure was not sufficiently specified to make a

decision about which ICF-category the concept should be linked to, the 'not definable' option was chosen (linking rule 9). To give an example, unspecified concepts such as 'functional status', 'health', 'disability' or 'symptoms' were considered not to be definable for linking. If a concept of an outcome measure was not represented by the ICF, the option 'not covered' was chosen (linking rule 10). To give an example, concepts such as 'plans about committing suicide', 'killing' extracted from the BDI (Beck Depression Inventory) (Beck 1961) were considered not to be covered by the ICF.

4.2 Analyses

Descriptive statistics were used to examine the frequency of ICF categories linked to the concepts and to the goals identified in the outcome measures. Large-scale cross tables generated from an SQL database (SQL Server 2000) were analyzed. If one and the same ICF category was assigned repeatedly in a study, the category was counted only once.

The ICF is organized in a hierarchical scheme so that the more specific, lower-level categories share the attributes of the less specific, higher-level category (WHO 2001). Only ICF categories with a percentage >10% at the 2nd level of the classification are shown (preset frequency).

5. Results

5.1 Step 1: Selection of the Studies

In step 1, 1382 trials were located by the search strategy. 519 studies were preliminarily selected by abstract checking, and 428 studies fulfilled the eligibility criteria by screening the respective original papers.

5.2 Step 2: Outcome Measure Extraction

In step 2, 9 different intervention types were identified in the 428 analysed studies: Nutritional therapy (55.6%), drug therapy (54,0%), active physical therapy (22,0%), psychological intervention (20,6%), education (18,0%), surgery (5,4%), complementary medicine (0,9%), standard medical care (0,5%) and passive physical therapy (0,2%).

201 studies examined the efficacy of one intervention (most often drug therapy with n= 103, nutritional therapy with n= 46, surgery with n= 19 and psychological intervention with n=13). 142 studies examined the efficacy of two interventions (including most often nutritional therapy with n= 112, drug therapy with n= 84, active physical therapy with n= 36, psychological intervention with n= 27 and education with n=21). The combination of nutritional therapy and drug therapy was used in 64 studies. 68 studies examined the efficacy of three interventions (involving most often nutritional therapy with n= 65, education with n=38, active physical therapy with n=35

psychological intervention with n=34 and drug therapy with n= 31). 14 studies examined 4 interventions (involving most often nutritional therapy with n= 14, education with n=13, psychological intervention with n= 12 and drug therapy with n= 8). Three studies examined the efficacy of five interventions.

96 different questionnaires were identified. 39 questionnaires were not available in English or no references for them were listed in the original literature and therefore they could not be identified. Thus, only 57 of the 96 questionnaires were linked to the ICF. Table 2 shows the questionnaires that were used in more than 2 studies, the number of studies in which they were used and the type of instrument (condition specific, dimension specific, eating disorder specific, generic or obesity specific). At least one health status questionnaire per trial was selected in 116 or 27,1% of the studies. The most frequently used questionnaires were the Beck Depression Inventory BDI (Beck et al. 1961), Block Food Frequency questionnaire (Block and Subar, 1992) and Three-Factor Eating Questionnaire TFEQ (Stunkard and Wadden, 1992) with a prevalence of 5,8% (n= 25 studies), 3,5% (n= 15 studies) and 3,5% (n= 15 studies), respectively.

Most often used clinical and physiological outcome measures referred to nutritional parameters (i.e. caloric intake (fat/protein/carbohydrate), eating habits), body measurements (i.e. BMI, weight, waist circumference, bodily fat distribution) cardiovascular parameters (i.e. heart rate, blood pressure, exercise tests), laboratory parameters (i.e. cholesterol, triglyceride, HDL, LDL,

fatty acids, glucose, insulin, thyroid function, metabolic rate), lung function (i.e. FEV1, FVC, peak expiratory flow rate, lung volumina parameters, ventilation rate, oxygen consumption/uptake, carbon dioxide production, respiratory quotient) as well as physical activity, sleep, fatigue and pain. Also patient compliance and adverse events were frequently reported study outcomes.

5.3 Step 3: Linkage of the Concepts

In step 3, a total of 16034 concepts and goals were extracted. 12914 concepts/goals (81%) could be linked to the ICF, 527 concepts/goals (3%) were considered not to be sufficiently specified for an assignment to the ICF, and 2593 concepts (16%) were considered to be not covered by the ICF. "Weight" that with 75% was the most frequent concept is a personal factor that could not be linked to the ICF, since personal factors are not classified yet.

The 12914 assignable concepts/goals contained in the outcome measures were linked to 360 different ICF categories at the second, third, and fourth levels of the classification. 169 ICF categories belonged to the ICF component 'Body Functions', 55 belonged to the component Body Structures, 115 to component Activities and Participation, and 21 to the component *Environmental Factors*.

The concepts contained in the outcome measures were linked to 173 different second-level ICF categories, also including the more specific third-, and fourth-

level categories. Of these second-level ICF categories 20 reached a frequency of at least 10% (14 *body functions*, 1 *body structure*, 4 *activities and participation*, 1 *environmental factor*). Most frequently measured *body functions* were *b540 general metabolic functions* (65 %), *b420 blood pressure functions* (39 %), and *b410 heart functions* (39 %). Within the ICF component *activities and participation* the category *d570 looking after one's health* (57 %) showed the highest relative frequencies. For the components *environmental factors* and *body structures* only the category e110 products or substances for personal consumption (16 %) and s760 structure of the trunk (13%) presented a relative frequency above 10%, respectively.

Tables 3 and 4 show the ICF categories that were linked to the concepts/goals contained in the different outcome measures of the studies. Both the frequencies and percentages of the 2nd-level categories taking into account that the 3rd and 4th level categories belong to the 2nd level, as well as the frequencies and percentages of the ICF categories from the 2nd to the 4th level are presented. Only ICF categories with a percentage >10% at the 2nd level of the classification are shown.

6. Discussion

Using the ICF as a reference, it was possible to identify and quantify the concepts within the outcome measures used in RCTs for interventions in obese patients. Most concepts in the outcome measures could be linked to the ICF. Those which could not be linked were mostly not covered by the ICF. In these cases, the content of the concepts did not lie within the defined contents of the ICF. This was most often the case for adverse events. Furthermore, outcome measures on health status containing dimensions like personal factors are not covered by the current ICF and could therefore not be linked. Concepts referring to personal factors included "weight", "habit", or "attitudes towards oneself" or concepts on patient satisfaction ("How satisfied are you with …"). Only a small number of concepts were not specified in enough detail for an assignment.

Most ICF categories that represent the outcomes measures used in RCTs from 1992 to 2001 selected for this review belong to the component *Body Functions*. The low number of categories from the component *Activities and Participation* is consistent with the low use of health-status instruments which typically represent activities and participation (Stucki 2003).

Most of the ICF categories with relative frequencies above 10% in the component *Body Functions* represent areas of functioning that are in line with the well-known major dangers of obesity, such as hypertension, dyslipidemia,

coronary-artery disease, sleep apnoea, or respiratory problems (Pi-Sunyer 1993). Endocrine gland functions are also represented in a high number of studies because intestinal hormones are an important area in obesity research (Batterham 2003). The category *haematological system functions* were selected to link the important marker HbA1C.

Specific mental functions within the ICF category *b130 energy and drive functions* were addressed in many studies. This reflects the well-known association between obesity and functions like *energy level*, *motivation, appetite*, *craving* and *impulse control* (Simansky 2005, van Hout 2004).

Sleep problems are also clearly associated with obesity (Grimm 2006, Lamberg 2006, Namyslowski 2005). Sleep deprivation has even been hypothesised to contribute toward obesity by decreasing leptin, increasing ghrelin, and compromising insulin sensitivity (Gangwisch 2005). Therefore, it is not surprising that all third-level categories contained in the second-level category *sleep functions* have also been taken into account in 17% of the investigations included in this review. Quality of sleep was the area most frequently investigated (Gupta 2002).

Emotional Functions are represented in 21% of the studies. This may reflect the fact that the question whether or not mood disorders and obesity are related has been a focus of scientific investigation and debate for at least the last 50 years. Since the available literature has not provided a definitive answer to that question yet, the study of this relationship will probably continue

to be an objective in clinical investigation in the years to come (McElroy 2004).

The category *sensation of pain* was an outcome in only 13% of the studies. Based on the fact that *pain* is considered as an independent contributor to impaired HRQL in obesity (Barofsky 1998), the author expected a higher number of studies including this outcome. It is interesting to note that not only generalized pain, but also localized pain in many different body locations was taken into account.

Limitations and restrictions in *Activities and Participation* are, indeed, of great relevance to obese patients (Stucki 2004). The areas with relative frequencies above 10% represent key issues for obese patients, including *walking* and *looking after one's health.* The latter includes *managing diet and fitness* and *maintaining one's health* at the third level of the classification. The ICF category *managing diet and fitness* was considered in almost half of the investigations. This reflects the fact that behavioral modification in obesity is not only relevant after psychological interventions, but also after treatments like surgery and that the effectiveness of any intervention has to be measured based not only as weight reduction, but also as behavioral modification at the level of maintaining diet and fitness.

It is important to note that the category *d550 eating* within the component *Activities and Participation* refers according to the ICF definition to "*carrying out the coordinated tasks and actions of eating food that has been*

served, bringing it to the mouth and consuming it in culturally acceptable ways, cutting or breaking food into pieces, opening bottles and cans, using eating implements, having meals, feasting or dining." The study outcomes assessing to what extent the activity of eating are performed in a socially proper way was linked to this ICF category. This was especially the case in studies with a study population with binge eating disorder, which represent nearly 35% of the clinically obese population (Marcus 1995).

Discrimination at work, in public, and interpersonally is common (Stunkard 1992, Rand 1990, Klesges 1990) in obese persons. Obese persons are often regarded as "dirty" ,"lazy", "stupid", "cheating", "lying", and "ugly" (Kushner 2000). The influence such attitudes take on the involvement in life situations of individuals, such as at work, in interpersonal interactions, and in social and recreational life is well-known (Chambliss 2004). Therefore, the fact that only the ICF category *recreation and leisure* was addressed as an outcome is quite remarkable. Further categories, such as *remunerative employment* and *family relationships* seem to be missing.

It is surprising that, although obesity is currently understood to be a complex condition with many interactions, especially between gene and environment (Thigpen 2004), only the ICF category *e110 products or substances for personal consumption*, which includes at the third level of the classification *e1100 food*, was reported as an outcome measured in the studies considered in this review.

The category *structure of trunk (s760)* is represented in 13% of the studies because it was considered the most specific ICF category to address the outcome *waist circumference*.

The results of this literature review can provide a preliminary basis for the definition of domains regarding "what should be measured" to comprehensively describe the burden of obesity and/or the evaluation of treatment outcomes. Nevertheless, it is important to put the results and their interpretation into perspective.

The outcomes measures used in the studies influence the spectrum and the frequency of concepts linked to the ICF categories and consequently the results of this study. The choice of the outcomes measures may depend on the intervention and the subset of patients studied. In addition, the majority of studies were drug trials focusing on clinically relevant parameters and not functioning.

Although it is beyond the scope of this paper to discuss whether the outcome measures used and the concepts linked to the ICF in this study are appropriate for specific study questions and whether or not they adequately represent the patient experience, these findings reflect drug trials apparently fail to assess the importance of patients' functioning and the influence of environmental factors on it. In different clinical fields there is growing evidence that correlations between clinical measures and how patients feel and how

they are able to function in daily activities are only weak to moderate (Bendtsen 2003, Juniper 2002, Moy 2001, Juniper 1995). Outcome research has shown that through the assessment of functioning and HRQL, in addition to physiological parameters, it is more likely to develop interventions that do not simply correct physiological abnormalities, but truly improve health (Conners 2002).

There exist many obesity-specific health-status measures (Wadden 2002). A recently published study, in presenting a content comparison of all obesity-specific health-status measures based on the ICF demonstrated that most of these instruments cover a wide spectrum of activities and areas of participation (Stucki 2006). Some of these instruments have been recommended by international organizations, such as the North American Association for the Study of Obesity (NAASO). If these recommendations are put into practice, a review similar to this one, but containing a greater number of outcome measures addressing ICF categories within the component *activities and participation*, could be available five years from now.

It is important to emphasise that the results presented in this paper exclusively provide information about the frequency of use of determined questionnaires. However, frequency of use does not automatically imply quality regarding the psychometric properties of a determined instrument. Therefore, the results of this review should not be used as a basis for the selection of instruments to be included in a concrete study. The first question

when selecting instruments is to decide what should be measured in consideration of the study endpoints, the population studied, and the intervention. The second question is to decide which instrument to use amongst all the possible instruments available. For information about the concepts addressed by different instruments, we refer readers to the paper by Stucki et al. However, further considerations, such as practicability and length of the instrument, response categories and psychometric characteristics are also indispensable.

Our findings do not constitute a recommendation for a minimal set of measuring instruments covering relevant ICF categories. However, if enough care is consistently taken in RCTs to define "what should be measured" to ensure a more comprehensive and comparable comparison of persons with obesity across studies and interventions, a reliable recommendation could be presented regarding what instruments to use.

Within this context, the project to develop ICF Core Sets for persons with different health conditions, including obesity, that is being performed in collaboration between the ICF Research Branch of WHO FIC CC (DIMDI) at the Department of Physical Medicine and Rehabilitation of the Ludwig-Maximilian University in Munich (http:\\www.ICF-Research-Branch.org) and WHO deserves mention (Stucki 2002, Stucki 2004, Cieza 2004). An ICF Core Set represents a minimal number of categories necessary to accurately reflect

functioning (Stucki 2002) for the particular health condition. Therefore, the so-called *Brief* ICF Core Set for obesity can serve as reference for recommendations concerning instruments to be used in studies involving obese patients in the future.

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7. Conclusion

The ICF provides a useful reference to identify and quantify the concepts within the outcome measures used in RCTs for obesity. The need exists to systematically include patient-oriented measures to address areas of the ICF component *activities and participation* that are extremely relevant to obese persons.

Table 1: Inclusion/exclusion criteria for the randomized clinical trials

Inclusion criteria	Exclusion criteria
Study population with obesity	Randomised n of 1 study (Synonym: "n=1" –trial)
Randomised Controlled Trial (RCT)	Partial randomisation
Prospective design	Clinical controlled trial (CCT)
Design with parallel groups, cross-over, or waiting list	Uncontrolled experimental study
Therapeutic intervention	Cross-sectional study
All intervention types	Longitudinal observational cohort study
English publication	Psychometric study
Journal with the highest impact factor in the case of multiple publications	Primary prevention study (healthy study population)
	Animal experiment
	Laboratory study
	Cadaver study
	Letter
	Comment
	Editorial
	Non-therapeutic intervention
	Mixed population
	Children and adolescents
	Coronary heart disease
	Stroke
	Osteoarthritis
	Diabetes Type I and II

Table 2: Questionnaires that were used in more than 2 studies, the number of studies in which they were used and type of instrument

Questionnaire	N	Type
Beck Depression Inventory BDI	25	DS
Block Food Frequency Questionnaire	15	DS*
Three-Factor Eating Questionnaire TFEQ	15	EDS
Binge Eating Scale - Eating Habits Checklist Gormally	14	EDS
Paffenbarger Physical Activity Index	12	DS
Short Form Health Survey SF-36	7	G
State-Trait-Anxiety-Inventory STAI	7	DS
Centre for Epidemiologic Studies – Depression Scale CES-D	6	DS
Restraint Scale - Herman & Polivy	5	EDS
Rosenberg Self-Esteem Scale RSE	5	DS
Fibromyalgia Impact Questionnaire FIQ	5	CS (Fibromyalgia)
Arthritis Impact Measurement Scale AIMS	3	CS (rheumatoid arthritis)
Eating Disorders Inventory EDI	3	EDS
Hospital Anxiety and Depression Scale HADS	3	DS
Maudsley Obsessional-Compulsive Inventory MOCI	3	CS (compulsive disorders)
General Internal-External Expectancy Locus of Control Scale I-E Scale	2	DS
Sickness Impact Profile SIP	2	G
Symptom Checklist 90 - SCL 90	2	CS (psychological problems and symptoms of psychopathology)
Arthritis Self-Efficacy Scale ASES	2	CS (rheumatoid arthritis)
Body Cathexis Scale	2	DS
Bulimic Investigatory Test Edinburgh BITE	2	EDS
Dutch Eating Behavior Questionnaire DEBQ	2	EDS
Eating Disorder Examination EDE	2	EDS
Food Preference Checklist – FPC	2	DS*
Hamilton Rating Scale of Depression	2	DS
Impact of Weight on Quality of Life Questionnaire IWQOL	2	EDS

CS: Condition specific; DS: Dimension specific; EDS: Eating disorder specific; G: Generic; OS: Obesity specific

* These instruments address food consumption behaviors and food handling practices and can be used in the general population. Therefore, they are considered dimension specific.

Table 3: ICF categories of the components *body functions* and *structures* that were linked to the concepts contained in the outcome measures. The 3rd and 4th columns refer to the frequencies and percentages of the 2nd- level categories taking into account that the 3rd and 4th level categories belong to the 2nd level. The 5th and 6th columns refer to the frequencies and percentages of the ICF categories from the 2nd to the 4th level. Only ICF categories with a percentage >10% at the 2nd level of the classification are presented.

ICF CODE	Title	N	% (n=428)	N	% (n=428)
	Body Functions				
b130	*Energy and drive functions*	*90*	*21*	*18*	*4*
b1300	Energy level			65	15
b1301	Motivation			6	1
b1302	Appetite			49	11
b1303	Craving			30	7
b1304	Impulse control			32	8
b134	*Sleep functions*	*73*	*17*	*16*	*4*
b1340	Amount of sleep			11	3
b1341	Onset of sleep			17	4
b1342	Maintenance of sleep			23	5
b1343	Quality of sleep			43	10
b1344	Functions involving the sleep cycle			8	2
b152	*Emotional functions*	*90*	*21*	*94*	*22*
b1520	Appropriateness of emotion			4	1
b1521	Regulation of emotion			8	2
b1522	Range of emotion			70	16
b160	*Thought functions*	*56*	*13*	*6*	*1*
b1600	Pace of thought			2	1
b1602	Content of thought			50	12
b1603	Control of thought			21	5
b280	*Sensation of pain*	*56*	*13*	*34*	*8*
b2800	Generalized pain			3	1
b2801	Pain in body part			4	1
b28010	Pain in head and neck			16	4
b28011	Pain in chest			5	1
b28012	Pain in stomach or abdomen			5	1
b28013	Pain in back			11	3
b28016	Pain in joints			11	3
b2802	Pain in multiple body parts			2	1
b410	*Heart functions*	*120*	*28*	*33*	*8*
b4100	Heart rate			100	23
b4101	Heart rhythm			1	0
b4102	Contraction force of ventricular muscles			8	2
b420	*Blood pressure functions*	*167*	*39*	*166*	*39*
b4200	Increased blood pressure			3	1
b430	*Haematological system functions*	*51*	*12*	*28*	*7*
b4301	Oxygen-carrying functions of the blood			9	2

b4302	Metabolite-carrying functions of the blood			1	0
b4303	Clotting functions			28	7
b440	**Respiration functions**	**47**	**11**	**17**	**4**
b4401	Respiratory rhythm			4	1
b4402	Depth of respiration			30	7
b455	*Exercise tolerance functions*	*90*	*21*	*22*	*5*
b4550	General physical endurance			16	4
b4551	Aerobic capacity			69	16
b4552	Fatiguability			4	1
b530	*Weight maintenance functions*	*60*	*14*	*58*	*14*
b540	*General metabolic functions*	*278*	*65*	*76*	*18*
b5400	Basal metabolic rate			77	18
b545	*Water, mineral and electrolyte balance functions*	*77*	*18*	*1*	*0*
b5450	Water balance			1	0
b5451	Mineral balance			58	14
b5452	Electrolyte balance			49	11
b555	*Endocrine gland functions*	*94*	*22*	*95*	*22*
	Body Structures				
s760	*Structure of trunk*	*56*	*13*	*50*	*12*
s7600	Structure of vertebral column			3	1
s76002	Lumbar vertebral column			3	1

Table 4: ICF categories of the components activities and participation and environmental factors that were linked to the concepts contained in the outcome measures. The 3rd and 4th columns refer to the frequencies and percentages of the 2nd- level categories taking into account that the 3rd and 4th level categories belong to the 2nd level. The 5th and 6th columns refer to the frequencies and percentages of the ICF categories from the 2nd to the 4th level. Only ICF categories with a percentage >10% at the 2nd level of the classification are presented.

ICF CODE	Title	N	% (n=428)	N	% (n=428)
Activities and Participation					
d450	*Walking*	*43*	*10*	*30*	*7*
d4500	Walking short distances			16	4
d4501	Walking long distances			15	4
d4502	Walking on different surfaces			4	1
d550	*Eating*	*43*	*10*	*44*	*10*
d570	*Looking after one's health*	*244*	*57*	*18*	*4*
d5701	Managing diet and fitness			211	49
d5702	Maintaining one's health			94	22
d920	*Recreation and leisure*	*56*	*13*	*41*	*10*
d9201	Sports			19	4
d9202	Arts and culture			1	0
d9204	Hobbies			4	1
d9205	Socializing			25	6
Environmental Factors					
e110	*Products or substances for personal consumption*	*68*	*16*	*20*	*5*
e1100	Food			54	13
e1101	Drugs			15	4

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9. Attachment (Anhang)

9.1 ICF- Definitions:

Body functions are the physiological functions of body systems (including psychological functions).

Body structures are the anatomical parts of the boy such as organs, limbs and their components.

Impairments are problems in body function or structure such as significant deviation or loss.

Activity is the execution of a task or action by an individual.

Participation is involvement in a live situation.

Activity limitations are difficulties an individual may have in executing activities.

Participation restrictions are problems an individual may experience in involvement in life situations.

Environmental factors make up the physical, social and attitudinal

environment in which people live and conduct their lives.

9.2 Curriculum Vitae

Angaben zur Person

Name		Sebastian Baumann
Geburtsdatum		22.08.1977
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Grundschule	1984 – 1988	Grundschule Esting
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Studium	WS 1998/99 - SS 2005	Humanmedizin an der Ludwig-Maximilians-Universität München
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Ärztliche Prüfung		09.05.2005

Wissenschaftliche Tätigkeit

Dissertation		Thema: "Identifying the concepts contained in outcome measures of

clinical trials on obesity using the international classification of functioning, disability and health as a reference" aus der Klinik und Poliklinik für Physikalische Medizin der Ludwig-Maximilians-Universität München bei Herrn Prof. Dr. med. G. Stucki

Besondere Kenntnisse / Interessen

Sprachen	Englisch
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