

IDENTIFYING THE CONCEPTS CONTAINED IN OUTCOME MEASURES OF CLINICAL TRIALS ON FOUR INTERNAL DISORDERS USING THE INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH AS A REFERENCE

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Objectives: To systematically identify and compare the concepts contained in outcome measures of clinical trials on chronic ischaemic heart disease, diabetes mellitus, obesity, and obstructive pulmonary disease, including asthma using the International Classification of Functioning, Disability and Health (ICF) as a reference.

Methods: Randomized controlled trials between 1993 and 2003 were located in MEDLINE and selected according predefined criteria. The outcome measures were extracted and the concepts contained in the outcome measures were linked to the ICF.

Results: 166 trials on chronic ischaemic heart disease, 227 trials on diabetes mellitus, 428 trials on obesity, and 253 trials on obstructive pulmonary disease were included. Ten different health status questionnaires (fulfilling the inclusion criteria) were extracted in chronic ischaemic heart disease, 19 in diabetes mellitus, 47 in obesity, and 39 in obstructive pulmonary disease. Across conditions at least 75% (range 75–92%) of the extracted concepts could be linked to the ICF. In diabetes mellitus and obesity the most used ICF categories were *general metabolic functions (b540)*, in obstructive pulmonary disease *respiration functions (b440)* and in chronic ischaemic heart disease *heart functions (b410)*.

Conclusion: In all 4 health conditions the majority of studies were drug trials focusing on clinically relevant parameters and not on functioning. The ICF provides a useful reference to identify and quantify the concepts contained in outcome assessment used in clinical trials.

Key words: chronic ischaemic heart disease, diabetes mellitus, obesity, obstructive pulmonary disease and asthma, outcome assessment, systematic review, ICF.

J Rehabil Med 2004; suppl. 44: 37–42

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INTRODUCTION

Each of the 4 general internal disorders, chronic ischaemic heart disease (IHD), chronic obstructive pulmonary diseases (OPD) with asthma, diabetes mellitus (DM), and obesity carries a high burden of disease. IHD is projected to become the leading cause, and chronic OPD, the fifth leading cause of disability-adjusted life years (DALYs) (1). Obesity is already considered to be the fifth most serious risk factor for disease burdens measured in DALYs (2), and DM is responsible for 1.9% of all DALYs in developed countries (3). Thus, these conditions are highly relevant to most clinically active physicians and other health professionals. In a survey on the competencies that should be addressed in a medicine core clerkship, coronary artery disease, chronic OPD, and DM were among the disease-specific clinical competency areas warranting highest priority (4).

A large number of clinical tests as well as generic, symptom- or dimension- and condition-specific (5, 6) health status measures have been developed and are used in clinical trials on internal disorders to describe and evaluate functioning and health.

Based on the new International Classification of Functioning, Disability and Health (ICF) (7), which was endorsed by the World Health Assembly in May 2001 and provides a common language of functioning and health, it is now possible to identify and compare the concepts contained in different outcome measures (8).

The objective of this systematic review therefore was to identify and compare the frequency of concepts contained in the outcome measures of randomized controlled trials (RCT) for interventions in general internal disorders using the ICF as a reference tool.

METHODS

Study design

A systematic review was performed using the following 3 steps: (i) selection of studies; (ii) outcome measures extraction; and (iii) linkage of the concepts contained within the outcome measures to the corresponding categories of the ICF. Step 3 was carried out by 2 independent reviewers.

In step 1, selection of studies, RCT between the years 1993 and 2003 were located in MEDLINE[®], Silver Platter, 2000 Edition, using the

highly precise search strategy described by Dickersin et al. (9) (sets 1–8). Thereafter, the Dickersin search was combined with 4 condition-specific search strategies using the “and” operator.

To locate chronic IHD trials, the title and abstract terms “coronary thrombosis”, “coronary stenosis”, “coronary arteriosclerosis”, “angina unstable”, “angina pectoris”, “coronary disease” were combined using the “or” operator. To locate DM trials, the title and abstract term “diabetes mellitus” in all subheadings were combined using the “or” operator. To locate obesity trials, the explode-function “obesity-morbid” including all subheadings and the title and abstract terms “obesity”, “obese”, “overweight” were combined using the “or” operator. To locate OPD trials, the explode-function for “lung-disease-obstructive”, “asthma-exercise-induced”, “status-asthmaticus”, “bronchial-hyper-reactivity”, “and “respiratory-sounds” including all subheadings, the combined term “chronic obstructive” and “lung” or “pulmonary” or “airway*”, and the single terms “bronchit*”, “emphysem”, “COPD”, “COAD”, “asthma*” and “wheeze” were combined using the “or” operator. All searches were limited to English articles. The abstracts were checked applying general and condition-specific eligibility criteria. For the selected trials the original study reports were ordered and reviewed applying again the same eligibility criteria. The finally included studies entered step II of the review.

A study met general eligibility, if the study design was a RCT, the experimental intervention had a therapeutic aim, and the outcome measures had to be 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 population. In the case of multiple publications, 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 select persons with chronic IHD, the terms “angina pectoris”, “coronary arteriosclerosis”, “coronary stenosis” and “coronary thrombosis” have to be reported to describe the study population. Populations with “old” myocardial infarction (acute infarction older than 12 months), “aneurysm of the heart”, “coronary artery aneurysm” or “silent myocardial ischemia” were excluded. Further exclusion criteria were the following MESH terms: “Syndrome X”, “coronary aneurysm”, “coronary restenosis”, “coronary vasospasm”, “angina pectoris variant”. To select persons with DM, the term “diabetes mellitus” has to be reported to describe the study population. Specific populations with “prediabetic states” or “gestational diabetes” were excluded. To select persons with obesity, the diagnosis of “obesity” has to be reported to describe the study population. Populations with “coronary heart disease”, “stroke”, “osteoarthritis” and “diabetes mellitus” type I and II were excluded. To select persons with OPD, the diagnosis of “asthma” or “chronic obstructive pulmonary disease” (chronic bronchitis and/or pulmonary emphysema) has to be reported to describe the study population. “Upper obstructive respiratory tract disease” and “airways obstruction in lower respiratory tract” due to diseases with known aetiology and specific pathology (e.g. cystic fibrosis, lung cancer, bronchiolitis obliterans) were excluded. Persons aged below 18 years were excluded in each health condition considered.

In step 2, outcome measures extraction, all types of outcome measures including clinical tests, single item measures on different domains, biochemical, physiological, imaging tests, biopsy 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 (10, 11), e-mail consultation with the developers of the questionnaire in demand, internet searches, and then the items were extracted. Only questionnaires available in English language were included. Additionally, study population characteristics (disease duration, disease-subsets, etc.) and the type of experimental intervention (drug-, surgery-, non-pharmacological treatment, including complex rehabilitative, physical, complementary, nutritional, educational and psychological therapy, and combination of these categories) were extracted.

In step 3, linkage of the concepts contained within the outcome measures to the corresponding categories of the ICF, the concepts contained within the outcome measures were extracted and linked to the most specific ICF category by 2 independent health professionals according to a recently developed set of 10 linking rules (8). Concepts of outcome measures that could not be linked to the ICF were documented

and classified in 2 ways: (i) If a concept of an outcome measure was not sufficiently specified to make a decision 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. (ii) 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 Beck Depression Inventory (BDI) (12) or “Do you look forward to the future” from the Diabetes Health Profile Questionnaire (DHP) (13) were considered not to be covered by the ICF. Consensus between the 2 health professionals was used to decide which ICF category should be linked to each item/concept of the questionnaires. To resolve disagreements between the 2 health professionals concerning the selected categories, a third person trained in the linking rules was consulted. In a discussion led by the third person, the 2 health professionals who linked the items stated their pros and cons for the linking of the concept under consideration to a specific ICF category. Based on these statements, the third person made an informed decision.

Additionally, to control the plausibility of the linkage procedure the concepts of the outcome measures assigned to the same single ICF category were analysed (e.g. the concepts “not able to make a start”, “having little interest in things”, “feeling full of pep”, “having trouble resisting one’s craving” which were linked to the ICF category “energy and drive functions” (b130)).

Analyses

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

ICF categories are presented on the second level. If a concept of an outcome measure was linked to a third or fourth level ICF category, the overlying second-level category was considered. The ICF is organized in a hierarchical scheme, so that the lower-level category shares the attributes of the higher-level category (7). Only ICF categories with a frequency equal or greater than 10% are shown (pre-set frequency).

RESULTS

For each of the 4 health conditions, the number of studies located by the search strategy (step 1), the number of studies preliminarily selected by abstract checking, the number of studies selected after screening the original papers, and the number of studies included in the review are presented in Table I. For OPD, only 25% of the studies selected after screening the original papers were included in the review. This 25% of studies was selected randomly.

In step 2, 10 different questionnaires (different versions of a questionnaire were considered as one and the same

Table I. Selection of studies

| | CIHD | DM | OB | OPD |
|--|------|-----|------|------|
| Studies located by the search strategy | 345 | 815 | 1382 | 3721 |
| Studies preliminarily selected by abstract checking | 260 | 334 | 519 | 2174 |
| Studies selected after screening the original papers | 166 | 227 | 428 | 1014 |
| Studies included in the review | 166 | 227 | 428 | 253 |

CIHD = chronic ischaemic heart disease; DM = diabetes mellitus; OB = obesity; OPD = obstructive pulmonary disease.

questionnaire) including 2 condition-specific questionnaires, 5 dimension-specific questionnaires (dimensions such as pain, locus of control, depression, anxiety, coping, etc.), and 3 generic questionnaires were chosen for chronic IHD as outcome measures. Exclusively 6 studies contained 1 or more questionnaires. The Physical Symptoms Distress Index (14) was included in 2 studies. All other questionnaires were represented in 1 study each. Frequent outcome measures were "onset, frequency and duration of chest pain", "ST-segment changes" and "blood pressure" (data not shown). Most often used clinical and physiological outcome measures referred to cardiovascular parameters (i.e. blood pressure, heart rate, ECG-changes, anginal symptoms, nitroglycerine consumption, arrhythmia, cardiac output and volumes, exercise test parameters, arterial lesions and stenosis, myocardial infarction) and laboratory tests (i.e. haematology, coagulation parameters, lipids, creatinine kinase). Also variables such as mortality, length of stay, revascularization, and adverse events were frequently reported study outcomes. Pharmacological treatment was the most frequently used intervention type with a prevalence of 88% ($n = 146$ studies), followed by invasive surgery and minimal invasive surgery with 7.8% ($n = 13$ studies) and 3.6% ($n = 6$ studies), respectively.

In DM 19 different questionnaires, including 6 condition-specific questionnaires, 10 domain-specific questionnaires and 3 generic questionnaires, were chosen as outcome measures. At least 1 health status questionnaire per trial was selected in 21 (9.25%) studies. The most frequently used questionnaire was the Medical Outcomes Study 36-items Short-form Health Survey (SF-36) (15) with a prevalence of 1.8% ($n = 4$ studies). Most often used clinical and physiological outcome measures referred to laboratory parameters for metabolic and renal functioning (i.e. glucose, HbA1c, C-peptide, lipids, cholesterol, triglyceride, fatty acids, insulin, albumin, creatinine, filtration rates), nutritional parameters (i.e. caloric intake, eating habits), cardiovascular parameters (i.e. heart rate, blood pressure, ECG-changes, ischaemic symptoms) and also clinical events such as reaction to hypoglycaemia, physical activity, and compliance. Also variables such as adverse events, length of stay, body measurements (i.e. BMI, weight, fat distribution) were frequently reported study outcomes. Drug treatment was the most frequently used intervention type with a prevalence of 83.7% ($n = 190$ studies), followed by nutritional therapy with 14.5% ($n = 33$ studies) and education with 11.5% ($n = 26$ studies).

In obesity 47 different questionnaires, including 3 condition-specific questionnaires, 35 domain-specific questionnaires, and 9 generic questionnaires, were chosen as outcome measures. At least 1 health status questionnaire per trial was selected in 116 or 27.1% of the studies. The most frequently used questionnaires were the BDI (12), the Block Food Frequency questionnaire (16), and the Three-Factor Eating Questionnaire (17) 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. Nutritional therapy was the most frequently used intervention type with a prevalence of 55.8% ($n = 239$ studies), followed by drug treatment with 54% ($n = 231$ studies), active physical therapy with 22% ($n = 94$ studies), psychological intervention with 20.6% ($n = 88$ studies), and education with 18% ($n = 88$ studies).

For OPD 39 different questionnaires, including 16 condition-specific, 17 domain-specific questionnaires, and 6 generic questionnaires were chosen. At least 1 health status questionnaire per trial was selected in 64 (25%) studies. The most frequently used questionnaires were the Asthma Quality of Life Questionnaire (18), the Chronic Respiratory Questionnaire (19), and the St George's Respiratory Questionnaire (20) with a prevalence of 6% ($n = 15$ studies), 5% ($n = 13$ studies) and 4% ($n = 10$ studies), respectively. Most often used clinical and physiological outcome measures referred to lung function (i.e. FEV1, FVC, peak expiratory flow rate, lung volumina parameter), blood gas analysis (i.e. pCO_2 , pO_2 , pH, VO_2max), cardiovascular parameters (i.e. heart rate, blood pressure), exercise test parameters, on demand medication and symptoms like dyspnoea, chest tightness, coughing or wheezing. Also variables such as sleep and fatigue as well as adverse events were frequently reported study outcomes. Drug intervention was the most frequently used intervention type with a prevalence of 74% ($n = 187$ studies).

In step 3, at least 75% (range 75–92%) of the extracted concepts could be linked to the ICF across all 4 conditions. At most 5% (range 3–5%) of the concepts were considered not to be definable, and at most 21% (range 3–21%) of the concepts were considered not covered by the ICF.

In chronic IHD a total of 2805 concepts were extracted from the outcome measures; 2110 (75%) of the concepts could be linked to the ICF, 112 (4%) of the concepts were considered not to be sufficiently specified for an assignment to the ICF ("not definable option"), and 583 (21%) of the concepts were considered not covered by the ICF. In DM a total of 3409 concepts were extracted; 2848 concepts (84%) could be linked to the ICF, 166 concepts (5%) were considered not to be sufficiently specified, and 395 concepts (12%) were considered not covered by the ICF. In obesity a total of 16 034 concepts were extracted; 12 914 concepts (81%) could be linked to the ICF, 527 concepts (3%) were considered not to be sufficiently specified, and 2593 concepts (16%) were considered not covered by the ICF. In OPD a total of 8266 concepts were extracted; 7611 (92%) concepts could be linked to the ICF, 378 concepts

Table II. Relative frequency in percentage of International Classification of Functioning, Disability and Health (ICF) – categories linked to the concepts contained in the outcome measures for the ICF-component body functions

| ICF code | ICF category | CIHD (n = 166) | DM (n = 227) | OB (n = 428) | OPD (n = 253*) |
|----------|---|-------------------|-----------------|-----------------|-------------------|
| b126 | Temperament and personality functions | | | | 13 |
| b130 | Energy and drive functions | | | 21 | 13 |
| b134 | Sleep functions | | | 17 | 38 |
| b152 | Emotional functions | | | 21 | 25 |
| b160 | Thought functions | | | 13 | |
| b280 | Sensation of pain | 16 | | 13 | 23 |
| b410 | Heart functions | 87 | 22 | 28 | 17 |
| b415 | Blood vessel functions | 11 | | | |
| b420 | Blood pressure functions | 46 | 37 | 39 | |
| b430 | Haematological system functions | 33 | 21 | 12 | |
| b435 | Immunological system functions | | | | 13 |
| b440 | Respiration functions | | | 11 | 86 |
| b450 | Additional respiratory functions | | | | 31 |
| b455 | Exercise tolerance functions | 43 | | 21 | 31 |
| b460 | Sensations associated with cardiovascular and respiratory functions | | | | 51 |
| b525 | Defecation functions | | | | 11 |
| b530 | Weight maintenance functions | | | 14 | |
| b535 | Sensations associated with the digestive system | | | | 14 |
| b540 | General metabolic functions | 25 | 95 | 65 | 13 |
| b545 | Water, mineral and electrolyte balance functions | | 15 | 18 | |
| b555 | Endocrine gland functions | | 15 | 22 | |
| b610 | Urinary excretory functions | 16 | 32 | | |

CIHD = chronic ischaemic heart disease; DM = diabetes mellitus; OB = obesity; OPD = obstructive pulmonary disease.

* Randomly included studies out of 1014 selected studies.

(5%) were considered not to be sufficiently specified, and 277 concepts (3%) were considered not covered by the ICF.

Tables II–V show the relative frequency in percentage of ICF categories linked to the concepts contained within the outcome measures for each ICF component and health condition.

DISCUSSION

Using the ICF as a reference it was possible to identify and quantify the concepts within the outcome measures used in RCT for interventions in chronic IHD, DM, OB, and OPD. Most concepts within the outcome measures could be linked to the ICF (83.5%). Those, which could not be linked, were mostly not

covered by the ICF (12.6%). In these cases the content of the concepts did not lie in the defined universe of the ICF. This was most often the case for adverse events. Furthermore, health-related status measures on domain such as personal factors are not covered by the current ICF and could therefore not be linked. Concepts referring to personal factors included “habit” (i.e. “stop smoking”, “stop drinking”) (21) or “attitudes towards oneself” (i.e. “how useful is your education for your personality”, “no matter I am talking to, I am always a good listener”) (22). Similarly, “perception of surroundings” (i.e. “would you say it is safe to go out walking around here at night”) (22), and concepts on patient satisfaction (i.e. “How satisfied are you with ...”) are beyond the ICF and could not be linked. Only a small portion of concepts (3.9%) was not specified in enough detail for an assignment.

The broadest spectrum of ICF categories with frequencies over 10% was found in OPD, the narrowest in DM. In all 4 conditions the most used categories were condition-specific and focused on the component *body-functions*: The ICF categories with the highest relative frequencies are in chronic IHD *heart functions* (b410), in DM and obesity *general metabolic functions* (b540) and in OPD *respiration functions* (b440). Most of the concepts linked to these categories represented paraclinical tests, i.e. ECG-change in chronic IHD was linked to b410, spirometry in OPD to b440, and in obesity different laboratory tests to b540. The most used ICF categories throughout all 4 conditions were *heart functions* (17–87%) and *general metabolic functions* (13–95%). Within the *activities and participation* component the most prevalent categories were *looking after*

Table III. Relative frequency in percentage of International Classification of Functioning, Disability and Health (ICF) – categories linked to the concepts contained in the outcome measures for the ICF-component body structures

| ICF code | ICF category | CIHD (n = 166) | DM (n = 227) | OB (n = 428) | OPD (n = 253*) |
|----------|------------------------------------|-------------------|-----------------|-----------------|-------------------|
| s410 | Structure of cardiovascular system | 49 | | | |
| s760 | Structure of trunk | | | 13 | |

CIHD = chronic ischaemic heart disease; DM = diabetes mellitus; OB = obesity; OPD = obstructive pulmonary disease.

* Randomly included studies out of 1014 selected studies.

Table IV. Relative frequency in percentage of International Classification of Functioning, Disability and Health (ICF) – categories linked to the concepts contained in the outcome measures for the ICF-component “activities and participation”

| ICF Code | ICF category | CIHD (n = 166) | DM (n = 227) | OB (n = 428) | OPD (n = 253*) |
|----------|--------------------------------------|-------------------|-----------------|-----------------|-------------------|
| d350 | Conversation | | | | 10 |
| d410 | Changing basic body position | | | | 14 |
| d430 | Lifting and carrying objects | | | | 11 |
| d450 | Walking | | | 10 | 29 |
| d455 | Moving around | | | | 21 |
| d460 | Moving around in different locations | | | | 25 |
| d510 | Washing oneself | | | | 15 |
| d540 | Dressing | | | | 13 |
| d550 | Eating | | | 10 | |
| d570 | Looking after one’s health | 25 | 33 | 57 | |
| d620 | Acquisition of goods and services | | | | 13 |
| d640 | Doing housework | | | | 19 |
| d650 | Caring for household objects | | | | 13 |
| d910 | Community life | | | | 10 |
| d920 | Recreation and leisure | | | 13 | 20 |

CIHD = chronic ischaemic heart disease; DM = diabetes mellitus; OB = obesity; OPD = obstructive pulmonary disease.
 * Randomly included studies out of 1014 selected studies.

one’s health (d570) in chronic IHD, DM and obesity, being the only category for chronic IHD and DM reaching the pre-set 10% level. OPD covered a large spectrum of this component with slight accentuation on walking (d450) and moving around in different locations (d460). Further important categories were e.g. recreation and leisure (d920), doing housework (d640), washing oneself (d510) and changing basic body position (d410).

Within the environmental-factors component the category products or substances for personal consumption (e110) was present in chronic IHD, obesity, and OPD. In OPD further categories were climate (e225), time-related changes (e245) and air quality (e260). There were no environmental-factors categories with frequencies over 10% in DM. Within the body-structures component, the category structure of cardiovascular system (s410) was present in chronic IHD and the category structure of the trunk (s760) in obesity.

The outcome measures used in the studies influence the spectrum and the frequency of concepts linked to the ICF categories. The choice of the outcome measures on its part may depend on the intervention and the subset of patients studied. The results of this systematic review therefore have

to be interpreted with caution and are to be put into perspective. In all health conditions 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 therefore 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 that in drug trials there is a lack of awareness regarding the importance of patients functioning (physical, emotional, and social). 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 (23–25). Outcome research has shown that through the assessment health-related quality of life in addition to physiological parameters it is more likely to develop interventions that do not simply correct physiological abnormalities but truly improve health (26).

Our findings also indicate a need to define what should be measured in RCT to allow for a more comprehensive and comparable comparison of patient populations across studies and interventions.

Table V. Relative frequency in percentage of International Classification of Functioning, Disability and Health (ICF) – categories linked to the concepts contained in the outcome measures for the ICF component environmental factors

| ICF code | ICF category | CIHD (n = 166) | DM (n = 227) | OB (n = 428) | OPD (n = 253*) |
|----------|---|-------------------|-----------------|-----------------|-------------------|
| e110 | Products or substances for personal consumption | 13 | | 16 | 41 |
| e225 | Climate | | | | 12 |
| e245 | Time-related changes | | | | 28 |
| e260 | Air quality | | | | 11 |

CIHD = chronic ischaemic heart disease; DM = diabetes mellitus; OB = obesity; OPD = obstructive pulmonary disease.
 * Randomly included studies out of 1014 selected studies.

In conclusion, the ICF provides a useful reference to identify and quantify the concepts within the outcome measures used in RCT for interventions in chronic IHD, DM, obesity, and OPD.

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