Glossary

Term (alphabetical order)	Working definition
Ability to do unpaid work activity*	
Ability to maintain relationships/to maintain relationships in the presence of persistent pain*	
Activities to compensate pain*	
Actual work status	Full- or part-time employment.
Autonom function*	
Avoidance of movement	Avoidance of movement based on the fear of pain (Vlaeyen and Linton, 2000).
Body awareness*	
(Daily) chronic headache	Also chronic daily headache; headache that occurs on ≥15 days/month for >3 months (International Headache Society, 2014).
Chronic pain	¬Pain that persists beyond normal tissue healing time, which is assumed to be 3 months.
Clinical trial	An experiment to compare the effects of two or more healthcare interventions. Clinical trial is an umbrella term for a variety of designs of healthcare trials, including uncontrolled trials, controlled trials, and randomised controlled trials (The Cochrane Collaboration, 2014).
COMET	The COMET (Core Outcome Measures in Effectiveness Trials) Initiative brings together people interested in the development and application of agreed standardised sets of outcomes, known as 'core outcome sets' (ACOMET, 2014).
Confidence to live with pain*	
Consensus process	Coming to an agreement by generating a proposal, identifying unsatisfied concerns and modifying the proposal to generate as much agreement as possible; the transfer into decisions are made by predefined, definite rules (i.e. \geq 70% of agreement, < 20% of disagreement necessary).
Construct validity	An aspect of <i>¬validity</i> ; degree to which the scores of an HR-PRO instrument are consistent with hypotheses based on the assumption that the HR-PRO instrument validly measures the construct to be measured (Mokkink et al. , 2010).

Content validity	An aspect of <i>ralidity</i> ; degree to which the content of an HR-PRO instrument is an adequate reflection of the construct to be measured (Mokkink, Terwee, 2010).
Coping in general	The use of behavioral and cognitive techniques to manage stressful demands (Lazarus and S., 1984).
Core area	An aspect of health or a health condition that needs to be measured to appropriately assess the effects of a health intervention; broad concepts consisting of a number of \neg domains (Boers et al., 2013).
Core outcome set (COS)	Standardized set of outcomes which should be measured and reported (<i>¬</i> core domain set) or also how they should be measured (<i>¬</i> core outcome measurement set), as a minimum, in all effectiveness trials for a specific health area. For <i>¬</i> daily record keeping, the concept of COS was adopted for <i>¬</i> VAPAIN.
Core outcome set of domains	The minimum set of (sub)domains necessary to adequately cover all \neg core areas, i.e. fully measure all relevant concepts of a specific health condition within a specified setting; describes what to (Boers et al., 2014).
Core outcome set of measurement instruments	The minimum set of outcome measurement instruments that must be administered in each intervention study of a certain health condition within a specified setting to adequately cover a corresponding \neg core outcome set; describes <u>how</u> to measure (Boers, Kirwan, 2014).
COSMIN	"Consensus-based Standards for the selection of health Measurement Instruments"; an initiative to improve the selection of measurement instruments in medicine (COSMIN, 2014).
Daily physical activity*	
Daily record keeping	Daily record keeping is defined as assessment and documentation of outcomes in daily clinical practice/routine care (e.g. patients with comorbidities, limited time or resources).
Depressive symptoms	Mood dominated by the emotion of sadness and is associated with feelings of sorrow, hopelessness, and gloom (Kendall and Watson, 1989).
Difficulty concentrating due to pain*	

Disability (in general) Discrimination	Umbrella term, covering impairments (problem in body function or structure), activity limitations (difficulty encountered by an individual in executing a task or action), and participation restrictions (problem experienced by an individual in involvement in life situations) (World Health Organization, 2014b). An aspect of the <i>¬OMERACT Filter 2.0</i> ; captures issues of <i>¬</i> reliability and <i>¬</i> sensitivity to change (Boers, Kirwan, 2013).
(Sub)Domain	Component of <i>rcore area</i> ; a concept to be measured, a further specification of an aspect of health, categorized within a <i>rcore</i> area (Boers, Kirwan, 2013).
Engagement in leisure activities*	
Fatigue due to pain*	
Fear of pain	A distressing emotion aroused by impending pain.
Feasibility	An aspect of the <i>POMERACT Filter 2.0;</i> captures an essential element in the selection of measures, one that may be decisive in determining a measure's success (Boers, Kirwan, 2013).
Functional disability	Functional disability is defined as limitation with different types of functional activities and their extent of limitation.
General fear	A distressing emotion aroused by impending danger, evil, pain, etc., whether the threat is real or imagined (Dictionary.com, 2014).
General self-efficacy	General self-efficacy is the extent or strength of one's belief in one's own ability to complete tasks and reach goals (Bandura, 1993).
Health related Quality of life	The functional effect of a medical condition and/or its consequent therapy upon a patient. HRQOL is thus subjective and multidimensional, encompassing physical and occupational function, psychological state, social interaction and somatic sensation (ISOQOL, 2014).
HOME	HOME (Harmonising Outcome Measures for Eczema) is a group of people who are working together to agree a ⊿core set of outcome measures for use in all atopic eczema clinical trials (HOME, 2014).

ΙΜΜΡΑCΤ	The mission of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) is to develop consensus reviews and recommendations for improving the design, execution, and interpretation of clinical trials of treatments for pain (IMMPACT, 2014).
Internal consistency	An aspect of ⊿reliability; the degree of the interrelatedness among the items (Mokkink, Terwee, 2010).
Interpretability	the degree to which one can assign qualitative meaning - that is, clinical or commonly understood connotations – to an instrument's quantitative scores or change in scores (Mokkink, Terwee, 2010).
Measurement error	The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured (Mokkink, Terwee, 2010).
Mental health	A state of complete mental well-being and not merely the absence of disease or infirmity.
Multimodal pain therapy (functional restoration)	According to the German Pain Society interdisciplinary multimodal pain therapy is defined as the simultaneous, contextual, temporal and coordinated, comprehensive strategy to treat chronic pain patients integrating different somatic, physical as well as psychological treatment approaches with identical and within the therapeutic team consensual therapeutic aims (Arnold et al. , 2009). The standardized treatment is performed by a team of physicians of different disciplines, psychotherapists or clinical psychologists and other disciplines such as physiotherapists, ergo therapists, and others. The objective and subjective restoration with increased controllability and the sense of competence of the patients is the central aim of this resource-orientated approach (Arnold, Brinkschmidt, 2009).

OMERACT	OMERACT (Outcome Measures in Rheumatology) is an independent initiative of international health professionals interested in outcome measures in rheumatology. Over the last 20 years, OMERACT has served a critical role in the development and validation of clinical and radiographic outcome measures in rheumatoid arthritis, osteoarthritis, psoriatic arthritis, fibromyalgia, and other rheumatic diseases (OMERACT, 2014).
OMERACT Filter 2.0	A comprehensive framework and process for developing ⊿core outcome measurement sets, which has been fruitful within rheumatology (Boers, Kirwan, 2013).
Outcome	Any identified result in a <i>≯Domain</i> arising from exposure to a causal factor or a health intervention (Boers, Kirwan, 2013).
Pain (as a symptom)	Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (IASP, 2014).
Pain diary and medication for at least 4 continuous days* Pain frequency i.e. attacks in migraine*	
Pain intensity/severity	Pain intensity/severity is defined as how much a person hurts.
Pain site	Pain site is defined as the location of ↗pain (e.g. low back).
Pain-related catastrophizing	Exaggerated negative orientation toward noxious stimuli (Vlaeyen and Linton, 2000).
Pain-related coping	The use of behavioral and cognitive techniques to manage with the pain.
Pain-related disability	↗Disability due to pain.
Pain-related self-efficacy	The confidence people with ongoing pain have in performing activities while in pain (Asghari and Nicholas, 2001).
(Effect of MPT on) patient's individual treatment goals*	
Patient-relevant	All "patient-reported outcomes" (PROs) (⊅patient-reported) as well as treatment outcomes specifically relevant to patients but reported e.g. by physicians or spouses are defined as "patient-relevant outcomes."

Patient-reported	A patient-reported (PRO) is a measurement
	that is directly assessed by the patient, i.e. without the interpretation of the patient's
	responses by a physician or anyone else (to be differentiated from クpatient-relevant).
Patients global Impression of Change*	
Personal goal achievement*	
Physical function	Ability to carry out activities that require physical actions, ranging from self-care (activities of daily living) to more complex activities that require a combination of skills, often within a social context (PROMIS, 2014).
Physical health	A state of complete physical well-being and not merely the absence of disease or infirmity (World Health Organization, 2014a).
PROMIS	Patient Reported Outcomes Measurement Information System (PROMIS), funded by the National Institutes of Health (NIH), is a system of highly reliable (<i>¬</i> reliability), valid (<i>¬</i> validity), flexible, precise, and responsive (<i>¬</i> responsiveness) assessment tools that measure patient-reported (<i>¬</i> patient- reported) health status (PROMIS, 2014).
Psychological distress	Measures the degree of psychological and/or emotional problems being experienced by the individual (thefreedictionary.com, 2014).
Psychological/emotional distress/strain	Psychological/emotional distress/strain measures the degree of psychological and/or emotional problems being experienced by the individual (Osipow and Davis, 1988).
Quality of life	Quality of life is individuals perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.
Quality of relationships and engagement in social activities*	
Reasons for dropout or withdrawal from treatment*	
Reliability	The proportion of the total variance in the measurements which is due to 'true' differences between patients (Mokkink, Terwee, 2010).

Responsiveness	Responsiveness (<i>¬sensitivity to change</i>) is the ability of an HR-PRO instrument to detect change over time in the construct to be measured (Mokkink, Terwee, 2010).
Sensitivity to change	Please refer to <i>responsiveness.</i>
Sick leave	Absent days at work due to chronic pain.
Sickness impact	Change in behaviour as a consequence of illness <i>¬health-related quality of life</i> (de Bruin et al., 1994, Gilson et al., 1975).
Social health	A state of complete social well-being and not merely the absence of disease or infirmity.
Structural validity	An aspect of <i>¬validity</i> ; degree to which the scores of an HR-PRO instrument are an adequate reflection of the dimensionality of the construct to be measured (Mokkink, Terwee, 2010).
Systematic literature review	Are literature reviews that adhere closely to a set of scientific methods that explicitly aim to limit systematic error (bias), mainly by attempting to identify, appraise and synthesize all relevant studies (of whatever design) in order to answer a particular question (or set of questions) (Petticrew and Roberts, 2008).
Test-retest-reliability	An aspect of reliability (<i>¬reliability</i>); extent to which scores for patients who have not changed are the same for repeated measurement over time (Mokkink, Terwee, 2010).
Truth	An aspect of the <i>へOMERACT Filter 2.0</i> ; captures issues of face, <i>へcontent</i> , and <i>へconstruct validity</i> (Boers, Kirwan, 2013).
Use of analgesic medication/taken analgetics*	
Use of health care services/Use of health care resources*	
Validity	Degree to which an HR-PRO instrument measures the construct(s) it purports to measure (Mokkink, Terwee, 2010).

VAPAIN	VAPAIN (Validation and Application of a patient relevant core outcome set to assess effectiveness of multimodal PAIN therapy) is funded by the German Federal Ministry of Education and Research (BMBF 01GY1326). The project is a co-operation between the University PainCenter and the Center for Evidence-Based Healthcare.
	VAPAIN targets at the development of a methodological background to conduct studies to investigate effectiveness of multimodal pain therapy in clinical trials and daily record keeping. VAPAIN follows thereby initiatives such as ¬OMERACT, ¬COMET and ¬COSMIN, which have done much effort to enhance quality of clinical trials in health research over the last decades. The main focus of such initiatives is to ensure a more secure and profound decision about therapy approaches and target patient population. A careful handling of resources of society and patient as well will be supported by that way (VAPAIN, 2014).
Work/work resumption	Work/work resumption is defined as return to either full- or part-time employment, to the previous job, and to the same role or with changes in work status (change of duties, working location, and function) (Euler et al., 2013).
Working ability	Having the health and functional capacities (physical, mental, social), the education and competence, the values, attitudes as well as the motivation and the relevant occupational virtues required for managing some kind of job, assuming that the work tasks are reasonable and that the work environment is acceptable (Ilmarinen, 2001, Tengland, 2011).

References

Arnold B, Brinkschmidt T, Casser HR, Gralow I, Irnich D, Klimczyk K, et al. Multimodale Schmerztherapie. Schmerz. 2009;23:112-20.

Asghari A, Nicholas MK. Pain self-efficacy beliefs and pain behaviour. A prospective study. Pain. 2001;94:85-100.

Bandura A. Perceived Self-Efficacy in Cognitive Development and Functioning. Educ Psychol. 1993;28:117-48.

Boers M, Kirwan JR, Tugwell P. The OMERACT Handbok. OMERACT; 2014.

Boers M, Kirwan JR, Wells G, Beaton D, Gossec L, d'Agostino MA, et al. Developing Core Outcome Measurement Sets for Clinical Trials: OMERACT Filter 2.0. J Clin Epidemiol. 2013.

COMET. COMET (Core Outcome Measures in Effectiveness Trials) Initiative. 2014, 01.11. Online available at: <u>http://www.comet-initiative.org</u>.

COSMIN. COnsensus-based Standards for the selection of health Measurement INstruments. 2014, 01.11. Online available at: <u>http://www.cosmin.nl/</u>.

de Bruin AF, Diederiks JP, de Witte LP, Stevens FC, Philipsen H. The development of a short generic version of the Sickness Impact Profile. Journal of clinical epidemiology. 1994;47:407-18.

Dictionary.com. Fear. 2014, 25.03. Online available at: http://dictionary.reference.com/browse/fear?s=t.

Euler U, Wegewitz Uta E, Schmitt J, Adams J, van Dijk Jaap L, Seidler A. Interventions to support return-to-work for patients with coronary heart disease. Cochrane Database of Systematic Reviews: John Wiley & Sons, Ltd; 2013.

Gilson BS, Gilson JS, Bergner M, Bobbit RA, Kressel S, Pollard WE, et al. The sickness impact profile. Development of an outcome measure of health care. American journal of public health. 1975;65:1304-10.

HOME. About the HOME Initiative. 2014, 01.11. Online available at: http://www.homeforeczema.org/.

IASP. IASP Taxonomy. 2014, 25.03. Online available at: <u>www.iasp-pain.org/Education/Content.aspx?ItemNumber=1698</u>.

Idzerda L, Rader T, Tugwell P, Boers M. Can wWe Decide Which Outcomes Should Be Measured in Every Clinical Trial? A Scoping Review of the Existing Conceptual Frameworks and Processes to Develop Core Outcome Sets. 2014; 41:986-93.

Ilmarinen JE. Aging workers. Occupational and environmental medicine. 2001;58:546-52.

IMMPACT. Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials. 2014, 01.11. Online available at: <u>http://www.immpact.org/</u>.

International Headache Society. IHS Classification ICHD-II. 2014, 25.03. Online available at: http://www.ihs-classification.org/de/.

ISOQOL. What Is Health-Related Quality of Life Research? 2014, 25.03. Online available at: http://www.isoqol.org/about-isoqol/what-is-health-related-quality-of-life-research.

Kendall PC, Watson DE. Anxiety and depression: Distinctive and overlapping features. San Diego: Academic Press; 1989.

Lazarus RS, S. F. Stress, Appraisal, and Coping. New York: Springer; 1984.

Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol. 2010;63:737-45.

OMERACT. OMERACT (Outcome Measures in Rheumatology). 2014, 01.11. Online available at: http://www.omeract.org/index.html.

Osipow SH, Davis AS. The Relationship of Coping Resources to Occupational Stress and Strain. J Vocat Behav. 1988;32:1-15.

Petticrew M, Roberts H. Why Do We Need Systematic Reviews? Systematic Reviews in the Social Sciences: Blackwell Publishing Ltd; 2008. p. 1-26.

PROMIS. Domain Frameworks: PROMIS Adult Self-Reported Health. 2014, 25.03. Online available at: http://www.nihpromis.org/measures/domainframework1.

Tengland PA. The concept of work ability. Journal of occupational rehabilitation. 2011;21:275-85.

Terwee CB, Bot SDM, de Boer MR, van der Windt DAWM, Knol DL, Dekker J, Bouter LM, de Vet HCW. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epi. 2007; 60: 34-42.

The Cochrane Collaboration. Cochrane Glossary. 2014, 01.11. Online available at: http://www.cochrane.org/glossary/5#letterc.

thefreedictionary.com. Psychological distress. 2014, 25.03. Online available at: <u>http://medical-</u> <u>dictionary.thefreedictionary.com/psychological+distress</u>.

VAPAIN. VAPAIN (Validation and Application of a patient relevant core outcome set to assess effectiveness of multimodal PAIN therapy) 2014, 01.11. Online available at: <u>http://www.uniklinikum-dresden.de/das-klinikum/universitatscentren/usc/studien-projekte/vapain/vapain_eng</u>, 2014.

Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. Pain. 2000;85:317-32.

World Health Organization. WHO definition of Health. 2014, 25.03. Online available at: http://www.who.int/about/definition/en/print.html.

World Health Organization. WHO Disabilities. 2014, 25.03. Online available at: http://www.who.int/topics/disabilities/en/.