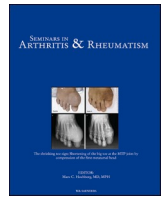




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Generating a list of potentially important contextual factors covering randomized trials, cohorts, and measurement property studies: An OMERACT initiative

Max Weinbrecht-Mischkewitz^{a,b,*}, Midhat Kamal^{a,c}, Farwa Asim^{a,d}, Francis Guillemin^e, Niti Goel^f, Marieke Voshaar^g, Annelies Boonen^{h,i}, Dorthe Bang Berthelsen^{a,j,k}, Karine Toupin-April^{l,m,n,o}, Maria A. Lopez-Olivo^p, Victor S. Sloan^{q,r}, Maarten Boers^s, C. Allyson Jones^t, Irene van der Horst-Bruinsma^u, Aidan G. Cashin^{v,w}, Saurab Sharma^{v,w}, Amye Leong^x, Rieke Alten^b, Beverley Shea^y, Lyn March^z, Peter Tugwell^{aa}, Robin Christensen^{a,j}, Sabrina Mai Nielsen^{a,j}, On behalf of the Contextual Factors Working Group

^a Section for Biostatistics and Evidence-Based Research, the Parker Institute, Bispebjerg and Frederiksberg Hospital, University of Copenhagen, Copenhagen, Denmark

^b Department of Internal Medicine, Rheumatology, Clinical Immunology and Osteology, Schlosspark-Klinik, University Medicine Berlin, Heubnerweg 2, 14059 Berlin, Germany

^c Department of Health Services Research and Section of Rheumatology and Clinical Immunology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

^d Department of Internal Medicine, Piedmont Hospital, Macon, GA, USA

^e Université de Lorraine, Inserm, INSPIRE, Nancy, France

^f Division of Rheumatology, Department of Medicine, Duke University School of Medicine, Durham, NC, USA

^g Department of Pharmacy, Sint Maartenskliniek, Radboudumc, Nijmegen, The Netherlands

^h Department of Internal Medicine, Division of Rheumatology, Maastricht University Medical Centre, Maastricht, The Netherlands

ⁱ Care and Public Health Research Institute (CAPHRI), Maastricht University, Maastricht, The Netherlands

^j Department of Clinical Research, Research Unit of Rheumatology, University of Southern Denmark, Odense University Hospital, Odense, Denmark

^k Department of Rehabilitation, Municipality of Guldborgsund, Nykøbing F, Denmark

^l School of Rehabilitation Sciences, Faculty of Health Sciences, University of Ottawa, Ottawa, Canada

^m Department of Pediatrics, Faculty of Medicine, University of Ottawa, Ottawa, Canada

ⁿ Children's Hospital of Eastern Ontario Research Institute, Ottawa, Canada

^o Institut du savoir Montfort, Ottawa, Canada

^p The University of Texas, MD Anderson Cancer Center, Houston, TX, USA

^q Sheng Consulting, LLC, USA

^r The Peace Corps, Washington, DC, USA

^s Department of Epidemiology and Data Science, Amsterdam University Medical Centers, Vrije Universiteit, Amsterdam, The Netherlands

^t Department of Physical Therapy, University of Alberta, Edmonton, Alberta, Canada

^u Department of Rheumatology, Radboud University Medical Centre, Nijmegen, The Netherlands

^v School of Health Sciences, Faculty of Medicine and Health, University of New South Wales, Sydney, New South Wales, Australia

^w Centre for Pain IMPACT, Neuroscience Research Australia, Sydney, Australia

^x Healthy Motivation, and Bone and Joint Decade, the Global Alliance for Musculoskeletal Health, Santa Barbara, CA, USA

^y Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada

^z Florence and Cope Professorial Department of Rheumatology, Royal North Shore Hospital and Kolling Institute, Faculty of Medicine and Health, University of Sydney, Sydney, New South Wales, Australia

^{aa} Department of Medicine, University of Ottawa, Ottawa, Ontario, Canada

* Corresponding author at: Department of Internal Medicine, Rheumatology, Clinical Immunology and Osteology, Schlosspark-Klinik, University Medicine Berlin, Heubnerweg 2, 14059 Berlin, Federal Republic of Germany

E-mail address: max.mischkewitz@charite.de (M. Weinbrecht-Mischkewitz).

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ABSTRACT

Objectives: To generate candidates for contextual factors (CFs) for each CF type (i.e., Effect Modifying Contextual Factors (EM-CFs), Outcome Influencing Contextual Factors (OI-CFs), and Measurement Affecting Contextual Factors (MA-CFs)) considered important within rheumatology.
Methods: We surveyed OMERACT working groups and conducted a Special Interest Group (SIG) session at the OMERACT 2023 meeting, where the results were reviewed, and additional CFs suggested.
Results: The working groups suggested 44, 49, and 21 generic EM-CFs, OI-CFs, and MA-CFs, respectively. SIG participants added 49, 44, and 55 factors, respectively.
Conclusion: Candidate CFs were identified, next step is a consensus-based set of endorsed (important) CFs.

Introduction

The Outcome Measures in Rheumatology (OMERACT) is an international organization focusing on developing core outcome sets (COS) for clinical trials in rheumatology, bringing together relevant stakeholders [1]. In 2012, ‘Contextual Factors’ (CFs) were introduced within OMERACT but understanding and identifying CFs proved difficult. The Contextual Factors Working Group (CFWG) [2] is addressing these challenges, and in 2020, the group presented a consensus-based definition of CFs (see Fig. 1). The definition describes three types: ‘Effect Modifying’ CFs (EM-CFs), ‘Outcome Influencing’ CFs (OI-CFs), and ‘Measurement Affecting’ CFs (MA-CFs).

The group is now working towards developing consensus on a set of important factors within each CF type that should always be considered within randomized trials (i.e., mainly EM-CFs), longitudinal observational studies (i.e., mainly OI-CFs), and studies on measurement properties (i.e., mainly MA-CFs), respectively. Currently, there is not enough evidence to identify ‘core’ CFs, because such a term would mandate measurement in all studies. The first step was to identify candidates for

important CFs, which can be included in a consensus process to finalize their selection as recommended CFs always to consider in rheumatology research.

Aim

To generate a list of candidate factors for each CF type (i.e., EM-CFs, OI-CFs, and MA-CFs) that could be considered important within rheumatology.

Methods

On March 14, 2023, we sent out a survey to the corresponding chairs of all OMERACT working groups. This survey was drafted by the emerging leader (SMN) and finalized with input from group members including patient research partners (PRPs) and asked, “When thinking of your working group’s area, which important contextual factors do you think of?” for each CF type (see Supplementary File S1). We recommended that chairs involve multiple stakeholders from the groups

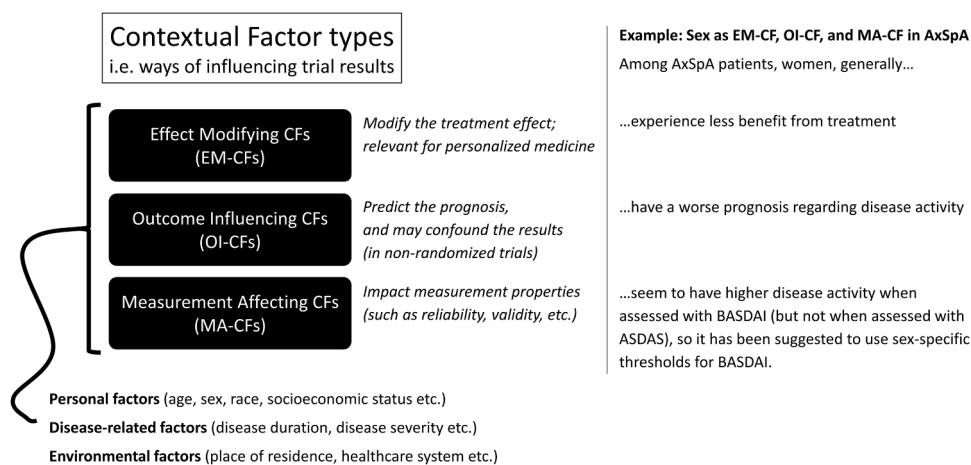


Fig. 1. Overview of the consensus-based definition of contextual factors with “Sex” as an example.

Overview of the consensus-based operational definition of contextual factors (CFs) presented at the OMERACT meeting in 2020 [8]. The three CF types each describe different ways that CFs can influence the results of a study. In short, EM-CFs modify the treatment effect (i.e., some patient subgroups experience greater or less effect from a treatment compared to other subgroups). OI-CFs are prognostic factors, i.e., factors which predict the course of a patient’s condition and may confound the results of non-randomized trials. MA-CFs influence the performance of outcome measurement instruments (e.g., reliability, validity, responsiveness, thresholds of meaning). To limit which specific factors can be considered CFs, the factors must be either personal, disease-related, or environmental. The CF types are not mutually exclusive, e.g., a specific factor may be an EM-CF, OI-CF, and/ or MA-CF. For example, evidence indicates that sex may be an EM-CF [9–11], an OI-CF [9,10], and an MA-CF [12–14] in axial spondyloarthritis. Figure adapted from Nielsen et al. [8].

ASDAS, Ankylosing Spondylitis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CFs, contextual factors; EM-CFs, Effect Modifying Contextual Factors; MA-CFs, Measurement Affecting Contextual Factors; OI-CFs, Outcome Influencing Contextual Factors.

including patients. We sent two email reminders to complete the survey and closed the survey for analysis after one month. Specific factors were extracted from the survey results by the emerging leader (SMN).

Before the CFWG Special Interest Group (SIG) session at the

OMERACT 2023 meeting in Colorado Springs, Colorado, United States, preparatory materials were developed for the participants by the emerging leader (SMN), with input from group members including PRPs. These included a lay summary for the session, an explanatory

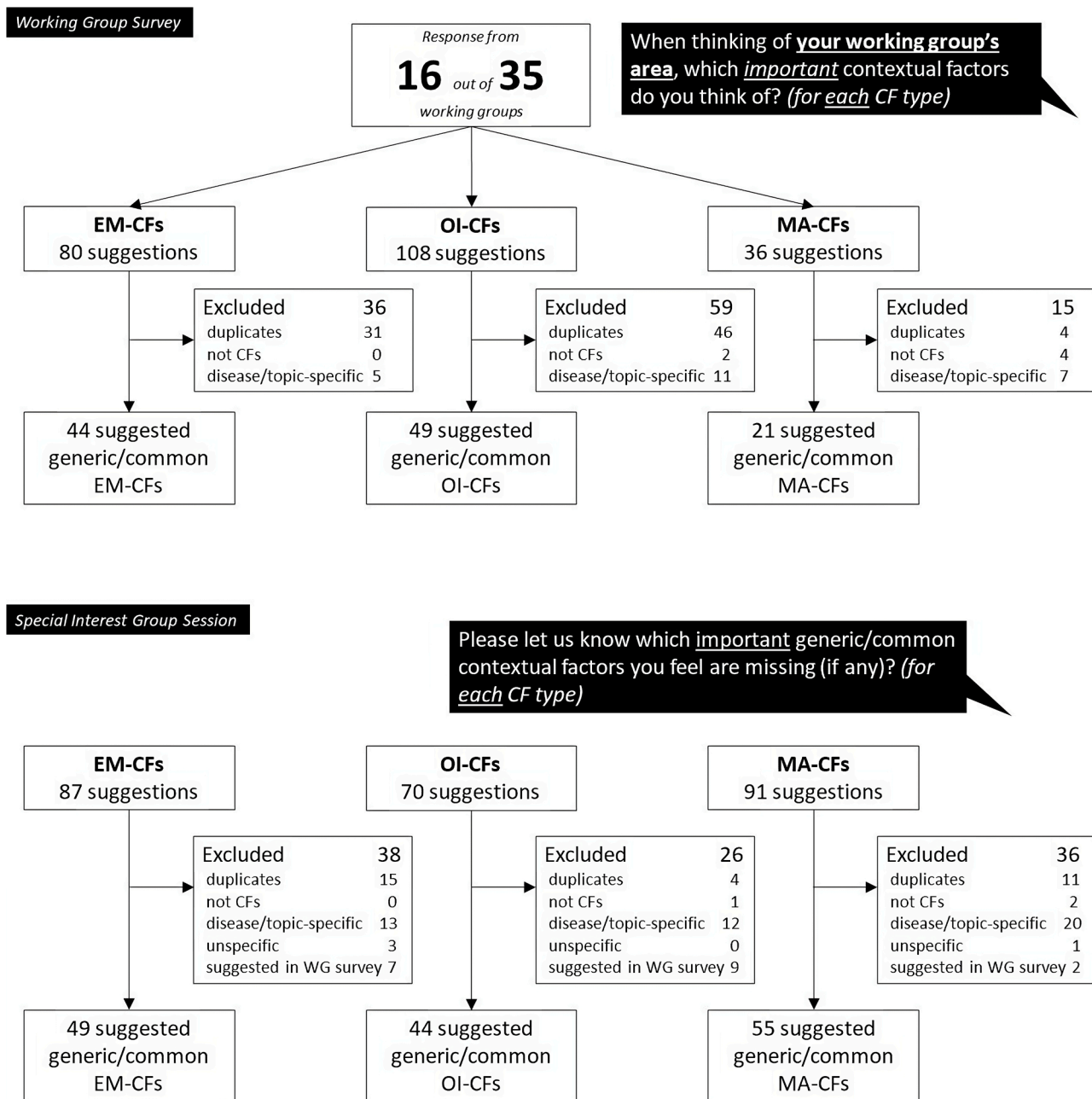


Fig. 2. Flow diagrams for suggested important contextual factors from the survey of OMERACT working groups (upper panel) and from the Special Interest Group session (lower panel).

'Generic/common' implies that the factors are possible to use across rheumatology, whereas 'disease/topic-specific' indicates that the factor by nature is specific to the disease or topic that the working group addresses. 'Unspecific' refers to factors considered not specific enough to be of practical value.

CFs, contextual factors; EM-CFs, Effect Modifying Contextual Factors; MA-CFs, Measurement Affecting Contextual Factors; OI-CFs, Outcome Influencing Contextual Factors.

video on CFs, a quiz, and a “cheat sheet” with definitions and examples of CFs (see Supplementary File S2) and were available in the OMERACT 2023 meeting app before the meeting.

The CFWG SIG session was held on May 5, 2023, and was open to all in-person and virtual OMERACT meeting attendants. The purpose of the SIG session was to generate important CF candidates, in addition to those identified from the survey. The session lasted 90 min and was initiated by one of the co-chairs (RC) presenting the agenda and meeting rules. Then the emerging leader (SMN) presented the aim of the session and the CF definition. Then an epidemiologist (FG) used an ‘edutainment’ approach to explain effect modifiers and confounders and the patient perspective was provided by a PRP (NG supported by MV). Thereafter, preliminary results from two ongoing CFWG studies (scoping reviews) were presented by two fellows (MWM and MK) and the results from the survey of OMERACT working groups by the emerging leader (SMN). Then the SIG participants were asked to suggest factors they felt were missing. The suggested factors could be added anonymously as text for each CF type via the free OMERACT app, followed by a moderated group discussion. The session was concluded with a wrap-up by a research experienced clinician (AB).

Table 1

Suggested candidates of important generic/common Effect Modifying Contextual Factors, Outcome Influencing Contextual Factors, and Measurement Affecting Contextual Factors from the survey of OMERACT working groups.

EM-CFs (n = 44)	OI-CFs (n = 49)	MA-CFs (n = 21)
Personal	Personal	Personal
Sex, Gender	Sex, Gender	Sex
Age	Age	Age
Race, Ethnicity	Race, Ethnicity	Socioeconomic status
Socioeconomic status	Socioeconomic status, Social status, Financial capacity	Education
Education	Education	Literacy, Language barriers
Job type	Job type, Type of main activity	Technology savvy
Lifestyle, Physical activity, Smoking, Drinking, Drugs	Lifestyle, Physical activity, Smoking, Drinking	
Weight, BMI, Obesity	Weight, BMI	
Language barriers		
Disease-related	Disease-related	Disease-related
Disease duration, Disease severity	Disease duration, Disease severity, Disease progression, Extend of the condition, Disease activity	Stage of disease
CRP, Inflammation with or w/o joint damage	Delay in diagnosis	Disease type
Joints involved, Muscles involved, Vessels involved	History of relapse	Chronic pain
Clinical phenotypes, Immune phenotypes	Other drug-treatments	Health literacy
Other drug-treatments	Health literacy, Coping, Helplessness, Beliefs, Illness perceptions, Adherence	
Health literacy, Beliefs, Adherence	Disability	
Comorbidities	Comorbidities, Concomitant fibromyalgia, Pain sensitization, OA, Other joint disease	
Liver function	Liver function	
Mental health, Anxiety, Depression	Mental health, Anxiety, Depression	
Genetics, Genetic factors	Genetics	
Environmental	Environmental	Environmental
Place of residence, Geographic location	Place of residence	Healthcare system, Healthcare practices, Access to healthcare
Weather, Temperature	Healthcare system, Access to healthcare, Access to treatments,	Societal attitudes towards the disease, Cultural attitudes towards the disease
Social security system, Insurance	Social security system, Insurance	Access to measurement tools
Patient-provider interaction	Patient-provider interaction	Difference in standards, Correct use of measuring tool, Experience of the clinician using the tool
		Investigator

The factors suggested in the survey of OMERACT working groups were sorted according to the classifications, personal, disease-related, and environmental factors, and similar factors were placed together and separated by comma.

Results

Survey of OMERACT working groups

We received responses from 16 out of 35 OMERACT working groups (see Fig. 2). A total of 80, 108, and 36 potential EM-CFs, OI-CFs, and MA-CFs, respectively, were suggested. After removing duplicates, factors not satisfying the CF definition, and disease/topic-specific CFs, there were 44, 49, and 21 unique EM-CFs, OI-CFs, and MA-CFs, respectively, considered important across rheumatology (see Table 1).

Special Interest Group session

At the SIG session, there were 48 attendees, including 10 (21 %) PRPs and 38 (79 %) others (clinicians, researchers, policymakers; see Supplementary Table S1). Almost all participants were from Europe and North America, and 27 (56 %) had attended an OMERACT meeting before. Four (8 %) attended virtually.

Participants of our SIG session suggested 87 additional EM-CFs, 70 additional OI-CFs, and 91 additional MA-CFs (see Fig. 2), of which 49, 44, and 55 unique factors, respectively, were eligible (see Table 2).

Table 2

Additional candidates of important Effect Modifying Contextual Factors, Outcome Influencing Contextual Factors, and Measurement Affecting Contextual Factors suggested during the Special Interest Group Session.

EM-CFs (n = 49)	OI-CFs (n = 44)	MA-CFs (n = 55)
Personal	Personal	Personal
Diet, Vegan diet, Appetite Sedentary lifestyle Personality traits, Resilience, Optimism Religion, Religious barriers Cultural barriers Sleep Self-efficacy Self-management Family status Financial Situation, Economy, Dependents	Gender attributes Appetite, Diet/nutrition, Vegan diet Sedentary lifestyle Resilience, Optimism Menopausal state Religion adherence Locus of control, Self-efficacy Financial Situation, Dependents	Gender Ethnicity BMI Cognitive function, Cognitive barriers, Cognitive dysfunction People of color skin, Skin tone Resilience Mental status, Emotional status Self-efficacy Financial Situation, Dependents Job type Trial fatigue
Disease-related	Disease-related	Disease-related
Insomnia severity Fatigue Pain tolerance Disease activity Autoantibody profile Kidney function Organ/organ system involvement Microbiota Epigenetics Physical function Concurrent non-drug treatments, History of failure to treatments Pharmacogenomic factors, Drug metabolism, Pharmacodynamic differences, Drug allergy Fibromyalgia Multimorbidity Individual concepts of health and sickness, Coping	Insomnia severity Fatigue Pain tolerance CRP Microbiota Misdiagnosis, Delay in referrals, Number of different physicians seen before diagnosis Adrenal function for those on long-term steroids Kidney function Joint damage Oral health Organ function Physical function Infection Disease subtypes, Autoantibodyprofile Medical history of family Drug metabolism, Drug administration route Coping mechanisms, Coping style	Age at diagnosis, Disease duration, Disease activity, Preexisting disease damage, Previous treatment Knowledge about the disease Burdens to others, Guilt Pain phenotype, Type of pain, Pain tolerance Mental health, Psychological status, Depression Physical function Comorbidities Fibromyalgia Brain fog, Depression brain fog Insomnia severity Fatigue
Environmental	Environmental	Environmental
Isolation Support, Support system, Social support, Family support Work environment Social determinants of health Economic cost Distance from provider Internet access Altitude Access to medications at country level	Isolation Support, Social support Social determinants of health Distance from provider Investigator, Physician or other staff running the trials Internet access Climate	Proxy-reporter, Person filling in the questionnaire Desirability bias, Advice received from others Experience of the investigator, Quality of training in using tools, Societal biases on the part of the investigators Built-in difficulty of the instrument, Number of tools of the instrument Time of day, Environment of administration and completion of tool, Environmental distractions at the time of measurement/assessment, Time constraints Redundancy of tools being used in a clinical trial, Redundancy in what is being measured Questionnaire burden, Survey fatigue Handling of lab samples

The additional factors suggested during the Special Interest Group session were sorted according to the classifications, personal, disease-related, and environmental factors, and similar factors were placed together and separated by comma.

During the discussion, a participant voiced concern that evidence is needed to ensure that a specific factor indeed is an EM-CF, OI-CF, and/or MA-CF. It was clarified that such evidence is lacking at this stage and therefore qualitative and consensus-based methods are needed to facilitate this kind of research. Further, there will likely be separate lists of important EM-CFs to consider for randomized trials, OI-CFs for cohort studies, and MA-CFs for measurement property studies. Hence, for a specific research purpose, researchers would only need to consult the list relevant to their study situation. Some participants also voiced difficulty distinguishing between EM-CFs and OI-CFs. A researcher reminded participants that identified factors could fit within several CF types.

A PRP asked what guidance the CFWG could provide working groups regarding considering CFs when developing their COS. An OMERACT Technical Advisory Group (TAG) member clarified that OMERACT guidance does not provide much detail, but it is a work in progress. It was mentioned that the CF “Comorbidities” might be too broad to be of practical value. A researcher agreed and remarked that specific comorbidities might be more useful, such as cardiovascular disease, or the presence of certain types of chronic pain. However, classifying different

types of chronic pain (e.g., nociceptive pain) might prove important. In general, identifying appropriate measurement tools for CFs will likely become very complicated, since this has never been done before within OMERACT. It was noted by another researcher that feasibility is important to consider, and could potentially be an issue for, e.g., microbiota and genetics.

Examples of important MA-CFs were mentioned. Pulse oximetry devices may tend to provide inappropriately high values for people of color since they were developed for people with lighter skin tones.

Discussion

As a result of the working group survey, 44, 49, and 21 candidates of important generic/common EM-CFs, OI-CFs, and MA-CFs, respectively, were identified. During the CFWG SIG session at OMERACT 2023, participants added another 49, 44, and 55 candidate CFs, respectively. Both the survey and the SIG session produced a substantial number of candidate important CFs suggested as more than one CF type, e.g., “Age” was considered to be an EM-CF, OI-CF and MA-CF.

At the SIG session discussion, the need for a future consensus-based approach to creating a list of important CFs was emphasized to facilitate research investigating the importance of specific factors as EM-CFs, OI-CFs, and/or MA-CFs. The focus of the CFWG is CFs across rheumatology, however, working groups might identify further factors, more specific to their working areas. Also, relevant initiatives within OMERACT may address specific important CFs, such as Adherence [3] and Pain [4]. For example, the pain workshop during the OMERACT 2023 meeting reviewed different types of chronic pain and discussed their importance for randomized trial eligibility criteria, for treatment effect, and for measurement validity and sensitivity [15], (i.e., OI-CFs, EM-CFs, and MA-CFs, respectively).

We consider the diverse international participation and significant PRP involvement at our SIG session (about 20 %) essential for multifaceted CF suggestions, and the online access with a chat option enabled even broader participation. Providing participants with training materials both before and during our SIG session, they were assisted in understanding the concept of CFs, which facilitated participation in polling and discussion. Importantly, the anonymous free text online polling via the OMERACT app ensured active participation. Though participants were from several continents, certain regions (such as Africa, South America, and Asia) remained underrepresented.

Research agenda

The candidates of important generic/common CFs identified from this work will be an important contribution to the results of the ongoing scoping reviews on EM-CFs and OI-CFs. A binning and winnowing process (i.e., a structured method of clustering and reducing a high number of suggestions) will then lead to a refined list of candidate CF domains to be used in a Delphi process to reach consensus on a short, focused list that should be considered in future research within rheumatology. When CF domains have been selected, CF instrument selection will be initiated, using adapted OMERACT methodology [5–7].

In the future, stratifying the results of randomized trials, adjusting the results of non-randomized trials and cohorts, and stratifying psychometric studies according to standardized lists of EM-CFs, OI-CFs, and MA-CFs, respectively, will facilitate research that could lead to improved treatment, improved trial interpretation, and improved outcome measurement, across patient subgroups, respectively.

Conclusion

Candidate factors were identified by the OMERACT community for each CF type. This will provide the basis for a consensus process to develop a set of important factors for each CF type that should be considered in future research within rheumatology.

CRedit authorship contribution statement

Max Weinbrecht-Mischkewitz: Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization, Project administration, Funding acquisition. **Midhat Kamal:** Conceptualization, Methodology, Investigation, Writing – original draft, Writing – review & editing. **Farwa Asim:** Conceptualization, Methodology, Investigation, Writing – original draft, Writing – review & editing. **Francis Guillemin:** Conceptualization, Methodology, Resources, Writing – review & editing. **Niti Goel:** Conceptualization, Methodology, Resources, Writing – review & editing. **Marieke Voshaar:** Conceptualization, Methodology, Resources, Writing – review & editing. **Annelies Boonen:** Conceptualization, Methodology, Writing – review & editing. **Dorthe Bang Berthelsen:** Methodology, Writing – review & editing. **Karine Toupin-April:** Methodology, Writing – review & editing. **Maria A. Lopez-Olivo:** Methodology, Writing – review & editing. **Victor S. Sloan:** Methodology, Writing – review & editing. **Maarten Boers:** Methodology, Writing

– review & editing, Visualization. **C. Allyson Jones:** Methodology, Writing – review & editing. **Irene van der Horst-Bruinsma:** Methodology, Writing – review & editing. **Aidan G. Cashin:** Methodology, Investigation, Writing – review & editing. **Saurab Sharma:** Methodology, Investigation, Writing – review & editing. **Amye Leong:** Methodology, Writing – review & editing. **Rieke Alten:** Methodology, Writing – review & editing, Funding acquisition. **Beverley Shea:** Conceptualization, Methodology, Writing – review & editing, Supervision. **Lyn March:** Conceptualization, Methodology, Writing – review & editing, Supervision. **Peter Tugwell:** Conceptualization, Methodology, Writing – review & editing, Supervision. **Robin Christensen:** Conceptualization, Methodology, Formal analysis, Writing – original draft, Writing – review & editing, Supervision, Funding acquisition. **Sabrina Mai Nielsen:** Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Project administration, Funding acquisition.

Declaration of competing interest

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Supplementary materials

Supplementary material associated with this article can be found, in

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