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Nonpharmacologic Interventions Need Outcomes for Evaluating Complex Interventions in Rheumatic Diseases

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ABSTRACT. *Introduction.* Nonpharmacologic interventions are themselves complex and are often combined with drugs and other interventions in the treatment of rheumatic diseases. Therefore, overall strategies for treatment are complex interventions. These should be evaluated regarding their processes and outcomes.

Methods. The CARE network, an international organization of health professionals (physicians and nonphysicians) and patients conducted a survey in 2008 to identify core outcomes in the ICF perspective, completed with a second survey (2009–2010) with patients in routine practice. These surveys have provided new information about domains to investigate as a basis for evaluating complex interventions.

Results. Outcome Measures in Rheumatology Clinical Trials (OMERACT) participants in this Special Interest Group agreed that current outcomes used in pharmacological research are not sufficient if the nonpharmacologic independent or combined contributions are to be assessed; other domains need to be addressed. This is an area of interest for further development.

Conclusion. Recommendations are proposed to develop research in the area of outcome for evaluation of complex interventions in rheumatic diseases. (J Rheumatol 2011;38:1803–5; doi:10.3899/jrheum.110408)

Despite the major changes in pharmacological and surgical treatments for rheumatic diseases over the past decades, many patients suffer from limitations in physical, mental, and social functioning. Musculoskeletal (MSK) disorders, especially rheumatic diseases, are major determinants of disability. The World Health Organization has developed a classification system, namely the International Classification of Functioning, Disability and Health (ICF), based on the biopsychosocial model of health to delineate domains for assessment and to provide a common language to describe health conditions. This classification helps develop and characterize outcomes addressing targeted domains.

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Nonpharmacologic interventions are necessary for a majority of patients with inflammatory as well as noninflammatory rheumatic diseases. These interventions comprise numerous complex and multifaceted modes of interventions including education programs, behavioral strategies, exercise, peer and nutritional counseling, and quite different therapeutic modalities such as cognitive behavioral therapy, ultrasound, transcutaneous electrical nerve stimulation, and acupuncture. These interventions target a wide area of limitations, as described by the ICF. More than organic system impairments, they seek to address broader constructs such as disability, social role functioning, activity, and participation in society. Evaluation of such interventions is not straightforward, since they are complex, frequently administered in combined forms, and often interacting with or completing drug treatment and/or surgical interventions. Thus, their evaluation can focus on the resources involved (structure), the way they are used (process), and the result in health indicators (outcomes). A comprehensive evaluation is necessary to ensure transferability from research into the practice setting. Current disease core sets of measures may be incomplete to capture this wide area and fail to fully evaluate the impact of these interventions.

Relating to the broader demands from individuals and society on more relevant outcome measures in MSK disorders, we need an open approach to determine domains to be covered in the future. A number of projects and methods in outcomes research for both pharmacological and nonpharmacological interventions contribute to such progress¹.

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Since 2002, the CARE network has worked through continuous research and information exchange^{1,2,3,4} including international workshops every other year (www.rheumacare.org). In the CARE network, the workshops have been used for both open discussions and plenary sessions, followed by breakout group and consensus processes. Including patients in the network since 2003 and using open discussions as well as Web-based surveys³ has provided aspects on domains both within and separate from the ICF. In addition, formal scientific presentations with the following interactions within the CARE network have provided new openings for projects on outcomes in nonpharmacological interventions⁵. Domains for nonpharmacological interventions seem to include broader aspects of life and society than domains for pharmacological interventions. The use of register-based information was also discussed to identify the impact of MSK diseases on the individual and on the society, i.e., on healthcare needs, sick leave, and costs.

The objective of the OMERACT Special Interest Group (SIG) was to examine the need and importance of outcomes suited to complex interventions including nonpharmacological interventions in a patient and a health professional perspective.

METHODS

CARE survey method. In preparation for the CARE V Conference in Oslo, Norway, April 2008⁵, a survey was developed based on the components of the ICF, and on research demonstrating factors that represent the specific components of this framework when applied to persons with arthritis⁶. This work yielded a survey consisting of 5 domains with items representing factors within each domain. Using an iterative, normative process, the survey was submitted to a sample of individuals involved in arthritis care, including a patient advocate, physical therapist, behavioral scientist, nurse, social worker, and rheumatologist for review and input. Based on the aggregated data from these individuals, the survey was refined and sent for final comments. Next, the survey was disseminated to attendees of the CARE V Conference. Respondents were asked to prioritize items on the survey for each domain. Seventy participants, including health professionals with different backgrounds including physicians, nurses, physiotherapists, and occupational therapists, as well as a small proportion of patients participating in the conference completed the survey. During 2009-2010, a targeted recruitment of patients from Canada, Sweden, and France responded to the survey, yielding a total of 108 respondents across the 2 data collection periods, providing a good and relevant source of information. The data were analyzed during spring 2010 and presented and discussed at the CARE VI conference in Nancy, France, April 2010 (www.rheumacare.org). There was relative agreement among patients and providers on which items within the impairment domain were in the top 10 of prioritized items. However, patients ranked pain higher than providers. Among the activities and participation ICF component, patients were more likely to include social activities than providers in their ranking of importance.

Thus, the CARE network and the CARE conferences have provided new information in the area of outcome domains in nonpharmacological interventions, including the perspective of patients, healthcare professionals, and representatives of society.

During the OMERACT SIG we presented the results of this survey on outcome measures (based on the ICF) relevant for nonpharmacological interventions. Among OMERACT attendees was a large representation of stakeholders: patients, researchers, and clinical care providers.

RESULTS

Based on the results of the CARE survey, the SIG participants (about 30 individuals, of which one-third were patients) agreed on 3 statements (manuscript in progress):

1. Current outcome measures of patient-reported outcomes are not sufficient for evaluating complex and nonpharmacological interventions.
2. Given the content of complex and nonpharmacological interventions, we do need to consider addressing domains other than those measured in pharmacological research.
3. "Outcomes in Nonpharmacological Research" is definitely an area of interest for further development.

Participants stressed the importance of involving patients early in research design, as well as in outcome design, so as to better inform researchers about their needs and expectations. They also pointed out the importance of broadening the domains of outcomes for complex interventions by involving both health professionals and patients.

DISCUSSION

As a joint initiative of OMERACT and CARE, this SIG targeted the value and relevance of outcomes currently available for complex interventions, and recommendations from the CARE VI meeting in April 2010 were presented.

Interventions designed to care for people with chronic arthritis conditions are often a sum of multiple components, over time, including a range of nonpharmacological interventions, e.g., psychosocial, behavioral, nutritional, surgery, rehabilitation, or alternative medicine. Moreover, pharmacological and nonpharmacological interventions are combined in a heterogenous and unstandardized manner, or more rarely in integrated programs. Patients experiencing such interventions in daily practice may have some general and some specific expectations for which currently available outcome measures are not appropriate.

Outcomes should give feedback to the patient, the physician, healthcare managers and policy-makers about the disease and its consequences, the side effects of interventions, and the contribution of comorbidity. Patients may feel it difficult to formulate and to talk about the consequences of their disease in their family, among friends, or in the work environment, and prefer patient peers to fully express their difficulties and needs. The complexity of many interventions calls for a variety of outcomes that do not easily map to the ICF domains and that should be considered a direct or indirect target of the intervention. Therefore, the ICF domains mostly considered by currently available questionnaires do not always fit in with daily life concerns of patients.

From this SIG, the notion of complex intervention appears a key concept to use for developing a comprehensive approach of patient care. Appropriate outcomes are clearly an area for research. OMERACT now involves patients in an integrated way for research. This will facilitate

convergence in identifying outcomes of interest. A first step will be in expressing patients' expectations from a given complex intervention. One shared concern expressed in this SIG was that the respective importance of currently used outcomes should be revisited, as evidenced by the CARE survey. It is not yet possible to identify outcomes that could be uniquely important for nonpharmacologic interventions and complex interventions, but not essential for pharmacologic treatments. It was not clear whether new tools specific for these interventions or specific to patients' general expectations should be developed. But it was clear that adequate choice and prioritization among existing measures was an issue, necessitating the targeting of relevant expectations.

Also, this posed a methodological challenge for the evaluation of complex intervention effectiveness, since there is a multiplicity of possible combinations of various interventions. Moreover, patients often have their own additional input. Specialized methods have been developed, such as cluster randomization or sham intervention, to address this complexity. Some particular problems, like impossibility of blinding, are in need of more research. Focusing on process or on outcomes is a clue to assessing effectiveness sequentially through the various aspects of the complex interventions.

SUMMARY AND RECOMMENDATIONS

- A framework is needed to classify and structure the composition of pharmacological, nonpharmacological, and surgical interventions in complex interventions for rheumatic diseases.
- Outcomes currently available do not fully and consistently cover the appropriate ICF category. Relevant outcomes or a core set of outcomes need to be developed to address complex interventions.

- A close collaboration with patients and clinical specialists as well as health professionals of all kinds is necessary for researchers to develop, choose, and validate outcomes.
- The evaluation of complex interventions shall use appropriate methods and designs to address this complexity, delineating process evaluation and outcome evaluation.

OMERACT and CARE are 2 organizations sharing common interests in this topic. Their activities and membership are complementary and should benefit this area. The CARE network has more insight into research on nonpharmacological interventions administered by health professionals and a long history of interest in team care. OMERACT participants endorse outcomes when presented with empirical research data, often issuing from pharmacological interventions. A joint effort to integrate both experiences will produce more than the simple addition of each of these experiences individually.

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