OMERACT 7 Special Interest Group

The Design and Evaluation of Psychoeducational/ Self-Management Interventions

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ABSTRACT. A large number of interventions have been developed with the aim of improving patient self-management of arthritis. These interventions are complex, usually including multiple components, and have certain key features including participants' awareness of the arms of the study and their often having clear preferences for one or other arm. Because of these and other differences the randomized controlled trial is not necessarily ideal for studies of self-management interventions. This special interest group (SIG) considered designs that may be more appropriate. Self-management interventions use a wide range of outcome measures, which are often assessed at a range of time periods after the intervention. Evaluation of the efficacy of self-management interventions was discussed. One important issue is to link the expected influence of the intervention to the key assessment of outcome. The SIG also examined the factors that may influence the effectiveness of self-management interventions. (J Rheumatol 2005;32:2470–4)

Key Indexing Terms:
SELF-MANAGEMENT INTERVENTION DESIGN
STUDY EVALUATION OUTCOME ASSESSMENT ARTHRITIS

In recent years there has been a growing recognition that, as the main responsibility for managing a chronic illness on a day-to-day basis lies with the patient, interventions that can help patients to manage their illness more effectively should be available. These are termed "psychoeducational," or more commonly, "self-management" interventions. Barlow, *et al*[1] define self-management as "the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition," and self-management interventions typically address one or more of these areas. In arthritis, self-management interventions characteristically aim to improve patients' ability to manage their symptoms, to maintain physical function, and to cope with the psychological demands of living with a chronic illness.

A large number of different self-management interventions have been developed for people with arthritis. They are very variable and complex, and this has led to some difficulty in establishing whether certain components are more efficacious than others and for which outcomes. Aspects in which the interventions vary include their content, duration, by whom they are delivered, whether delivered in an individual or group format, and their theoretical approach. In many of the studies on self-management interventions the outcome measures have been varied, but have tended to follow standard clinical trials [World Health Organization (WHO)–International League of Associations for Rheumatology–OMERACT criteria] in looking at pain and disability. To varying degrees some have included inflammation and disease activity and others have used process variables (e.g., self-efficacy, health behavior, coping) as outcomes. The appropriateness of these and the suitability of standard randomized controlled trial (RCT) designs associated with these studies need to be considered. The aim of the OMERACT 7 special interest group (SIG) session was to set a research agenda to help define a systematic approach to the design and evaluation of self-management interventions in arthritis. This report briefly describes the issues that emerged from the SIG meetings and the research agenda identified.

The SIG organizers included rheumatologists and psychologists from Holland and the UK. Prior to OMERACT 7, participants were supplied with a limited set of related background reading material[2-7], and at the conference a preliminary meeting was held to discuss the key issues for presentation at the main meeting. The main meeting was attended by an international group of health professionals, including

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rheumatologists, psychologists, rheumatology nurse specialists, and patients participating in the OMERACT Patient Perspective Workshop.

At the main meeting the 3 presentations included an overview of the variables that have been measured in self-management interventions in rheumatoid arthritis (RA), issues in the design and analysis of self-management studies, and outcomes in relation to the WHO International Classification of Functioning, Disability and Health (ICF). The presentations were followed by a discussion session in which a potential research agenda was formulated.

Outcomes

The SIG was concerned with how best to decide which are the most appropriate outcomes in evaluations of self-management interventions.

In considering the outcomes measured in these interventions it is important to recognize how evaluation of these interventions differs from the standard, randomized placebo controlled study to examine the efficacy of a drug. There are 2 important issues where self-management studies differ. The first is in the blinding of participants and the second is in their complexity. In drug studies, both study participants and researchers are blind to who is receiving the active substance or the placebo in order to ascribe any effects to the drug under study. It is not possible to blind participants in self-management interventions and, under most ethical requirements for the conduct of studies, participants are required to be aware of the details of the different arms of a study prior to consent. In contrast to drug trials, where the placebo is identical in appearance to the active compound, in self-management interventions it is more difficult to establish a control condition that is perceived as credible.

Drug trials usually contrast a single or multiple dose of a medication to an alternative medication or a control condition. Outcome assessment would obviously vary according to the purpose of the drug (e.g., pain, inflammation, etc.), but would generally include disease measures plus patient and physician assessments of symptoms and, in some cases, quality of life. In contrast, self-management interventions typically include a variety of components aimed at improving patients' ability to manage many aspects of living with their illness. For example, an intervention may aim to develop patients' ability to manage their pain using relaxation and cognitive pain management skills, to improve their physical function by incorporating more activity into their day, and to improve their mood by influencing their beliefs about their illness and their ability to manage it. As a consequence, self-management interventions use a wide range of outcome measures, which are often assessed at a range of time periods after the intervention. Table 1 shows the range of selected outcomes measured in a subset of 24 studies of interventions with a behavioral approach, included in a systematic review of the effects of patient education for patients with RA[2].

Table 1. Selected outcomes in 24 studies.

General Outcome	No. of Studies
Physical function	22
Pain	21
Psychological status (various)	20
Joint counts	18
Disease activity (ESR, CRP)	12
Patient global	4
Doctor global	—
Social function	7
Social Support	2
Negative social interaction/support	2
Loneliness	2
Daily hassles/stress	2
Life satisfaction	2
Work disability	1
Interference with daily life	1
Number of reported problems	1
Grip strength	6
Morning stiffness	5
Walking time	4
Joint mobility/R.O.M.	3
Fatigue	2
Sleep	2
Stair climbing, lifting, rising (obs)	1
Visits to doctor	1
Coping	12
Physical exercise	6
Relaxation exercise	5
Joint protection	5
Self-management	2
Energy conservation	1
Diet	1
Communication with doctor	1
Medication adherence	1

Discussion during the SIG drew attention to the fact that in many studies the outcomes measured are not clearly linked to the hypothesized impact of the intervention. For example, studies may include measures of depression as an outcome even though the intervention does not directly target mood, and frequently the participants do not report a problem of depression at baseline. Overall, it was felt that when designing a self-management intervention, it is important to be clearer about what the intervention is designed to achieve, in what areas it is likely to have an effect, and to choose outcome measures accordingly.

One potentially useful framework that encourages a broader consideration of outcomes is the ICF, a description of which was presented at the SIG. The traditional medical model has as its starting point a disease or trauma to the body and assumes a direct causal link to the disease consequences. This model has as its focus the measurement of disease variables. In contrast, the ICF presents a broader view of human functioning, which incorporates how the disease affects the body and functioning, but also recognizes the importance of broader environmental and personal factors. The ICF provides a description of health and health-related domains at the level of body structure and function (both physiological and psychological function), activity, and participation. Restrictions are classified as impairments in body structures and function, activity limitation, and participation restriction. So, for example, a person may have an impairment in body function limiting mobility of the joint; there may be limitation in activity such as walking, and restrictions in participation in different aspects of a person's life, such as work and social relationships. Potentially a self-management intervention could target one or more of these domains. For example, an intervention that incorporates joint protection practices may expect to minimize joint swelling, an aspect of body structure. The inclusion of techniques to manage symptoms may expect to improve body function, for example in the sensation of pain, while the sensation of depression may show improvement with cognitive behavioral techniques. Interventions that incorporate exercise may show a reduction in activity limitation. A combination of these components, along with others such as those that aim to improve patients' ability to become problem-solvers in relation to their illness, may help to reduce restrictions in participation. Restrictions in participation may also be influenced by altering the environment, such as building access walkways, etc. (although this is an area beyond the remit of self-management interventions). It is important to recognize that some other potentially important domains are not included in the ICF framework. For example, the extent to which self-management interventions can reduce patients' need for healthcare[8] is an important consideration.

Several measures are available for assessing body function in sensations such as pain and depression[9] but are more limited in other sensations such as fatigue. Many are also available for assessing activity limitation[9]. Evaluations of self-management interventions that incorporate measures of participation are less frequent, although one well established measure, the Arthritis Impact Measurement Scales[10], does include an assessment of social activity. Input from patients at the SIG highlighted that several of the outcomes they consider very important, such as autonomy, feeling useful, and interference with daily life, would come under the umbrella of "participation restriction," but this domain has received less attention than others. It also became clear from the SIG discussions that a number of important outcomes are not frequently addressed in self-management studies. For example, fatigue emerged at this and other OMERACT sessions as being an important but neglected consequence of arthritis. Other outcomes that patients and healthcare professionals identified as potentially important are shown in Table 2.

Process Measures

In order to evaluate self-management interventions properly, we need to examine how they work, and to do this it is necessary to assess variables that may influence their effectiveness. These are commonly known as mediating or "process" variables and include illness beliefs and health behaviors. A number of theories have been put forward to explain the processes by which self-management interventions may work. Traditional models assumed that providing people with information would be sufficient to enable them to change their health behaviors, which in turn would improve outcomes. Several reviews in arthritis and other chronic illnesses[11-13] have, however, shown that knowledge, while necessary, is not sufficient to change behavior. Neither is the relationship between health behaviors and health outcomes necessarily a direct one[14], although behavior is clearly an important target of these interventions. Bandura's theory of self-efficacy[15] proposes that improvements in patients' self-efficacy, i.e., their confidence in their ability to manage different aspects of their illness, lead to improvements in health status, and self-management interventions influenced by this theory typically incorporate goal-setting and the teaching of problem-solving skills. Folkman and Lazarus's model of stress and coping[16,17] proposes that how people appraise a stressor (such as a chronic illness), and the resources they deploy to cope with that stressor, influence outcomes; and interventions based on this model aim to teach strategies for coping with different aspects of the illness. Other models have addressed processes such as participants' readiness to make changes in behavior[18] and in their beliefs about their illness[19]. A self-management intervention therefore could potentially show improvement through a number of different processes.

In order to fully understand the processes through which self-management interventions work, it is necessary to assess these variables, once again being clear about linking the variables measured to the theoretical framework on which the intervention is based. Some process measures, such as self-efficacy and coping, have been measured in a number of studies, but others have received much less attention. It was raised at the meeting that becoming an effective self-manager involves learning how to problem-solve. While many self-management interventions aim to teach this skill, the measurement of problem-solving ability has so far proved difficult. Measuring this and other process variables should lead to a better understanding of processes of change, which in turn can be used to design better interventions.

Table 2. Variables considered potentially important but not commonly examined in self-management interventions.

Autonomy	Resilience
Feeling Useful	Expectations
Interference with daily life	Motivation
Life satisfaction	Fatigue
Hope and optimism	Body image
Social Participation	Adjustment

Moderating Variables

Several other variables may need to be measured, not because a self-management intervention is likely to change them, but because they could moderate the effect of an intervention. These include age, sex, disease duration, disease activity, participants' expectations and preferences, and culture, among others. For example, it is possible that an intervention targeting participants' ability to manage pain could be more helpful in early disease than in later disease, by which time patients may have developed their own potentially habitual pain coping strategies. In the discussion it was suggested that participants' expectations about a program were considered to be particularly significant as possible moderators of outcomes.

Planning a Self-Management Intervention

Self-management interventions in arthritis have not always been developed with systematic reference to existing theory and research. One framework for planning self-management interventions, based on the Precede-Proceed model[20], was presented at the meeting. This provides a logical structure for thinking about how to develop the intervention and which outcome, mediating, and moderating variables are then appropriate to assess. The planning stage in developing an intervention should involve the following steps:

- Decide the aim of the intervention and which outcomes are to be targeted
- Identify behaviors and cognitive factors (such as beliefs) that potentially influence these outcomes so that the intervention to change them can be planned
- Determine how the intervention is to be implemented, and by whom
- Evaluate the intervention: take each aspect into account, assess whether the intervention has been implemented as planned, whether the targeted cognitions and behaviors have changed, and whether the outcomes have changed.

Study Design

RCT are considered the research gold standard and are widely used in evaluating self-management interventions in arthritis. They do, however, have some well recognized limitations[21]. One of these is that participants are likely to have a preference for one arm of the trial over another. An alternative design to the RCT, which takes participants' preferences into account, is the preference controlled trial[22], but this design involves more complex statistical analysis, requiring larger sample sizes. Thomas, *et al*[23] showed the importance of preferences: those who expressed a preference pre-treatment reported better outcomes than those with no pre-treatment preference, surprisingly, regardless of whether they were allocated to their preferred option. This and other studies highlight the importance of measuring participants' preferences and using them in the evaluation of outcome.

The large variability in self-management interventions makes analysis of their efficacy problematic. One approach is to use metaanalysis, and a recent Cochrane review in RA by Riemsma, *et al*[2] found short-term effects in physical function, joint count, patient global assessment, psychological status, and depression. This provides an overall picture, but the content of these interventions varied considerably. Further examination showed that interventions that took a behavioral approach were more likely to obtain positive findings than interventions providing information only or those adopting a counselling approach (offering social support and discussion). This finding is encouraging in helping to identify which components, or combinations of components, of these complex interventions are most efficacious; however, the number of studies was small so conclusions were tentative; moreover, the studies, although having a general classification, contained significant variability. In diabetes, several recent studies compare 2 or more variations of self-management to examine the role of a particular component, and more studies of this nature should help lead to progress in the field of self-management in arthritis.

Research Agenda

The SIG for The Design and Evaluation of Psychoeducational/Self-Management Interventions proved a very fruitful process for identifying ways in which research in this area can progress more systematically. The longer-term objective of the OMERACT process is to obtain a consensus on which measures to include in trials of self-management interventions in arthritis. The research agenda set from this first stage is to:

- Identify a comprehensive list of outcome variables to be assessed
- Identify a comprehensive list of mediating variables that should be assessed
- Examine how adequately these variables can be assessed with current instruments
- Present a report of the variables and measures at the next OMERACT conference
- Consider the design issues in self-management studies.

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