Editorial

Time to Expand Our Horizons Regarding Real-Life Studies of Self-Management and Psychosocial Outcomes

While it is important that we continue to amass a robust evidence base regarding the effectiveness of self-management interventions through high quality randomized controlled trials (RCT), it is equally important that we understand more about the impact of the Arthritis Self-Management Programme (ASMP) and similar programs when they move away from rigidly controlled research settings and are implemented in the community. RCT usually have strict entry and exclusion criteria, which help to provide a more homogeneous sample for research purposes but may fail to represent the wide range of potential participants when the intervention is delivered in a real-life setting as a service. In this respect, implementation studies are useful but are rarely conducted. The transition study[1] reported in this issue of *The Journal* is an exception rather than the rule.

Widespread adoption of evidence-based, health-related education programs can be problematic and can result in the poor implementation of programs, which can fail to reach their target population[2,3]. Adoption can be enhanced if programs are shown to be feasible and effective in real life[2,3] in a range of locations[4]. Implementation studies are useful in this respect; they are more flexible than RCT where adjustment of recruitment procedures or program delivery violates a trial protocol, thus rendering data unusable. An implementation study allows adaptation of the program to match available resources and circumstances. Further, implementation studies can be set up to provide valuable information regarding who chooses to enroll in an intervention and why, who benefits most and who benefits least, and, as in the study by Osborne, *et al*[1], to examine what factors predict positive health change.

Implementation studies rarely have a control or comparison group and acknowledge that participants cannot be blinded to the intervention. This is particularly relevant when studying self-management programs, which require participants to be actively involved in terms of time, effort, commitment, and motivation. However, it is worth noting that these inherent participant "costs" of program attendance rarely feature in cost-effectiveness analysis.

Research in the self-management field has tended to focus on a core set of outcomes revolving around health status, health behaviors, and healthcare utilization. However, there is increasing evidence that the effects of the ASMP and similar programs reside in the psychosocial domain. Hence, a major shortcoming of the Osborne study[1] is the absence of information regarding psychosocial outcomes. This is somewhat paradoxical, given that the ASMP is based in the theoretical framework of self-efficacy and draws on cognitive behavioral techniques to assist participants in enhancing their perceived ability to select and apply the appropriate "tool" that will address their self-management needs at a given point in time. There is a large evidence base supporting the value of cognitive behavioral techniques (e.g., Lorig and Holman[5], Basler[6], Keefe and Caldwell[7]) in helping participants to make changes where simply telling patients to exercise more, to follow a healthy diet, and to practice relaxation may fail.

When psychological measures are included, there is a tendency to focus on psychological pathology, particularly depression. While understanding the influence of the ASMP on depression is important, it is not the whole story. Studies conducted in the UK have included measures of anxiety and depression[8,9] as well as positive affect[8]. Qualitative studies have revealed that participants report a much wider range of outcomes including a renewed hope, a sense of purpose, reduced isolation, and finding an appropriate peer group[10,11]. Further, interviews with ASMP lay tutors have revealed additional benefits such as feeling like a useful member of society, altruism, and increased self-worth[12]. How such outcomes are related to health status in the short and longer term and also the potential effect on future healthcare utilization remain to be investigated. In addition,

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some tutors begin to transfer their newly acquired skills to other areas such as advocacy groups or other community support networks. Such social outcomes have received little research attention.

Few RCT have a followup period longer than 12 months; hence, little is known about the longer-term effect of attending self-management interventions. For example, it is likely that people with arthritis who feel confident they can deal with the anxious and depressed moods caused by their arthritis may be less likely to require prescription medication for these conditions. In the UK, the National Institute for Clinical Excellence (NICE) guidelines for treating the most common episodes of mental health problems (e.g., mild anxiety and depression) recommend that patients should not be prescribed medication "because the risk-benefit ratio is poor." Rather, psychological therapies (e.g., self-help/self-management, cognitive behavioral therapy) with an established evidence base should be the first treatment option. However, few patients are routinely offered these therapies due to a shortage of trained therapists. Effective self-management programs have an important role to play in this regard, although longterm data are lacking. Implementation studies, such as the Osborne report in this issue[1], can be a valuable source of data regarding longterm influence.

Finally, expectations should be realistic about the changes that can result from attending a lay-led, group-based intervention delivered in the community in 6 weekly sessions (i.e., about 15 h in total), with no followup or booster sessions. As noted by Osborne, absolute changes in health status tend to be small. However, low-cost, community-based programs have the potential to reach a wide audience and thus could have "substantial public health impact." Moreover, programs such as the ASMP are open to anyone with arthritis and therefore can be accessed by people with milder disease who may not have the opportunity to attend hospital-based educational interventions. Implementation or transition studies have an important role to play in furthering knowledge about the effects of the ASMP and similar programs. Other issues that remain to be examined include methods for enabling health professionals to better support patients who embark on the self-management journey, ways to encourage greater participation, including those referred to as "hard to reach" (e.g., young adults, men), and how greater attendance at ASMP sessions can be encouraged in order to maximize outcomes.

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