

What Else Can I Do But Take Drugs? The Future of Research in Nonpharmacological Treatment in Early Inflammatory Arthritis

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ABSTRACT. Nonpharmacological treatments, including physiotherapy and occupational therapy, have assumed a complementary role to drug therapy in managing inflammatory arthritis. Clinicians and researchers are facing 3 major challenges concerning the use of these treatments. First, strong evidence is only present in a few nonpharmacological interventions, such as exercise, patient education, and low level laser in the treatment of rheumatoid arthritis. The evidence on the majority of interventions is, however, weak or inconclusive. Second, knowledge is lacking on the elements associated with models of nonpharmacological care. The multidisciplinary team approach has been viewed as the standard for arthritis treatment; however, the team structure and the communication style among team members vary around the world. The influence of these elements on treatment success remains unclear. Finally, disparities in knowledge management and translation in nonpharmacological research have hindered the clinical use of these treatments and the growth of research in the field. To address the challenges, the author is recommending 4 research priorities for nonpharmacological treatments: 1. Evaluation of less well-studied interventions; 2. Understanding the relationships among rehabilitation-related variables and disability; 3. Development and evaluation of innovative care models; and 4. Design and evaluation of knowledge transfer innovations. (J Rheumatol 2005;32 Suppl 72:21-24)

Key Indexing Terms:

COMPLEMENTARY THERAPIES
RHEUMATOID ARTHRITIS

OUTCOME ASSESSMENT
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“My medication is working alright, but my joints are still a bit stiff and I still feel weak. I keep asking myself, what else can I do other than take drugs?”

– A 43-year-old patient with RA one year after diagnosis

Advances in pharmacological interventions, such as the newly emerged biologics, have brought fresh hopes to patients with inflammatory arthritis. However, not every patient benefits from the treatment. Systematic reviews on infliximab¹ and etanercept² in rheumatoid arthritis (RA) have consistently described improvements in roughly 60%, 40%, and 20% of patients, under the American College of Rheumatology (ACR) criteria for improvement ACR20, 50, and 70, respectively. This means that many patients still require additional interventions for managing the disease. For this reason, the current treatment approach for RA recommends the involvement of a multidisciplinary team, including specialists, family physicians, and rehabilitation professionals³⁻⁵. The complementary roles of physiotherapy and occupational therapy are supported by the ACR guidelines for the

management of RA⁶.

While pharmaceutical products must undergo proper clinical trials and economic analysis before they are considered by the drug benefit formulary in Canada, this rigorous evaluation process is not mandated for nondrug interventions. In order to confirm the value of nondrug treatment in early inflammatory arthritis, we need to address a few fundamental questions:

- Do nonpharmacological interventions work?
- Which is the most suitable model for providing nonpharmacological treatment for patients with early inflammatory arthritis?
- Which is the best way for translating evidence-based knowledge into practice?

Challenge 1: Determine the effectiveness of nonpharmacological treatments

Owing to the number of well-designed studies on exercise and inflammatory arthritis, we now have convincing evidence that dynamic exercise improves aerobic capacity, strength, and joint mobility among patients with RA⁷. Strong evidence has also been reported in systemic reviews on patient education⁸, joint protection⁹, and low level laser in RA¹⁰. However, the evidence on the majority of nonpharmacological treatments is either weak or inconclusive, mainly due to the poor methodological quality in the available studies^{9,11-15}. The dearth of information on the efficacy and effectiveness of nonpharmacological treatments has contributed to the confusion

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Li: Research in nonpharmacological treatment

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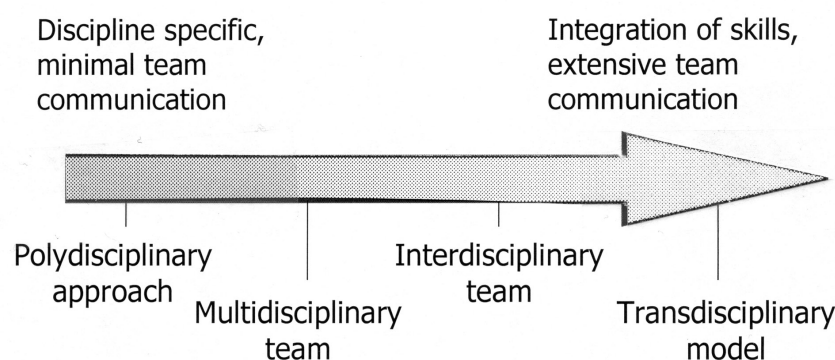


Figure 1. Levels of team care.

regarding their use for managing inflammatory arthritis.

One of the challenges in the evaluation of nondrug treatments is the selection of outcome measures. In a recent editorial, Stucki¹⁶ suggested that the problem stemmed from the lack of understanding in the relationships among mediators associated with nondrug treatments and arthritis-related disability. He particularly questioned the use of disease-specific health status instruments, such as the Health Assessment Questionnaire (HAQ), in the evaluation of rehabilitation interventions. Physical functional disability, as measured with the HAQ, is mainly determined by disease activity, structural damage, and pain. In fact, these disease-related variables explain 50% and 70% of the overall variance in HAQ scores. In contrast, muscle strength, which is directly influenced by rehabilitation, only accounts for an additional 12% of the variance. The relatively small contribution of rehabilitation-related variables (e.g., muscle strength) to disability may explain why it is difficult to demonstrate clinically and statistically important improvements in HAQ scores in exercise trials. Further, the HAQ penalizes the use of assistive and adaptive equipment, which is a common recommendation in occupational therapy for improving a person's ability to cope with the illness and the quality of life. This leads to the argument that favors the use of function-specific health status instruments over disease-specific health status instruments such as the HAQ for evaluating nondrug interventions. Therefore, a thorough understanding of the relationships among variables influenced by nondrug treatments and disability in early inflammatory arthritis will be essential for improving the selection of outcome measures in future studies.

Another challenge in nondrug treatment research is to secure adequate funding. Unlike pharmacological research, which attracts funding from both public and private sectors, nondrug research relies mainly on public funding. Compared to drug trials, nondrug research tends to be considered as lower profile. Hence, such research is often in a disadvantaged position when placed

in the same panel with drug trials in funding competitions. To foster the growth of well-designed research in nonpharmacological treatments, funding agencies might consider creating a separate category for adjudicating clinical research on nondrug, nonsurgical interventions.

Challenge 2: Identify suitable models for delivering arthritis care

The team model is currently regarded as the standard for arthritis treatment. Team care has been widely used in Europe; however, this is not the case in North America, partly due to budgetary constraints and a shortage of health professionals, especially in rural areas^{17,18}. Consequently, innovative care models, such as the clinical nurse-specialist model¹⁹⁻²¹, the physiotherapist/occupational therapist practitioner model^{22,23}, the primary therapist model²⁴, and telemedicine²⁵⁻²⁷, have emerged. Recent research has provided some evidence on the effectiveness of these alternative models^{20,28,29}; however, the "team" structure under these models is less well defined.

Further, in practice, team models exist in various forms depending on the level of communication among members and the integration of skills (Figure 1). In general, members in a multidisciplinary team operate in a discipline-specific manner with a less structured communication process. In contrast, transdisciplinary teams are less stringent with disciplinary boundaries and follow well-established communication procedures. The impact of the use of the different types of team models in the management of early inflammatory arthritis requires thorough evaluation.

Which study design would be the best for evaluating care models? For the clinical community and policymakers, information on the active ingredients and processes contributing to treatment outcome is as valuable as that on the efficacy of a treatment. To address the information needs, the Medical Research Council in the UK has proposed a thorough evaluation process for complex interventions³⁰. This process is modeled after the steps required in the evaluation of drugs from initial preclinical

cal research through to postmarketing surveillance. It begins with the “theoretical phase,” which focuses on establishing the theoretical basis that suggests the relationships between the intervention and effects (i.e., “pre-clinical phase”). The proposed relationships are then modeled in the Phase I study. In Phase II, preliminary tests are conducted to examine the evidence gathered thus far. This phase could permit testing of alternative forms of the intervention. The central step of evaluation lies in Phase III, the main randomized controlled trial (RCT). All standard features of a well-designed RCT should be applied in this phase. The final step (Phase IV) is a separate study to establish the longterm and real-life effectiveness of the intervention. This stage is likely to involve an observational study. This comprehensive process can be used as a guide for the evaluation of arthritis care models.

Challenge 3: Knowledge management and translation in nonpharmacological research

The gap between evidence and clinical practice is a particularly problematic area. Although management guidelines on inflammatory arthritis^{6,31,32} are available, there is often a lag between the publication of research and the release of new or updated guidelines. Thus, the onus is on health professionals to keep abreast of the current relevant research information.

To date, little is known on how health professionals acquire and use the emerging research information in clinical practice. Traditional methods of knowledge dissemination, such as publication in peer-reviewed journals and didactic sessions, generally have little value in improving professional practice. The former method assumes that health professionals have the time, energy, and skills to find and appraise primary research; however, that is often not the case in reality. In fact, many clinicians rely on other means, such as informal consultations with peers, as their first educational resource, rather than scientific journals³³. Among methods used in formal continuing education, interactive education sessions appear to have a modest effect in changing professional practice³⁴; however, the evidence does not support the use of didactic sessions, such as rounds, conferences, and courses. Also, other methods of guideline dissemination, such as reminders, dissemination of educational materials, audit and feedback, and educational outreach only result in modest to moderate improvement in care³⁵.

Research in nonpharmacological treatment will only contribute to better quality of care if the information reaches and is adopted by health professionals. For this reason, research in knowledge translation (KT) should be a focus in rheumatology. Established theoretical models, such as the Ottawa Model of Research Use^{36,37}, can be used for guiding the development and evaluation of KT

innovations. Further, it would be worthwhile to examine knowledge management and dissemination models that take place in a less formal environment, such as practice-related networks (e.g., Canadian Arthritis Network) and communities of practice. The latter has been widely used by the business community for disseminating best-practice knowledge among professionals³⁸ and is starting to gain recognition in the healthcare field³⁹⁻⁴¹. Communities of practice take advantage of the potential of learning that takes place in an informal environment, where professionals can exchange knowledge relevant to their trade. Such a model may be practical in the field of arthritis care, in which professionals have already engaged in informal learning at varying degrees.

Recommendations on research priorities

To address the challenges in nonpharmacological treatment research, the following priorities are recommended:

- Evaluation of less well-studied nondrug interventions, including worksite adaptation and manual therapeutic techniques
- Understanding the relationships among rehabilitation-related variables and disability
- Development and evaluation of innovative care models by focusing on: Who provides what treatment for whom, when, where, and how?
- Design and evaluation of knowledge transfer innovations.

REFERENCES

1. Blumenauer B, Judd M, Wells G, et al. Infliximab for the treatment of rheumatoid arthritis. *Cochrane Database Syst Rev* 2002;(3):CD003785.
2. Blumenauer B, Judd M, Cranney A, et al. Etanercept for the treatment of rheumatoid arthritis. *Cochrane Database Syst Rev* 2003;(4):CD004525.
3. Newcomer K, Jurisson ML. Rheumatoid arthritis: the role of physical therapy. *J Musculoskel Med* 1994;11:14-26.
4. Glazier R. Managing early presentation of rheumatoid arthritis. Systematic overview. *Can Fam Physician* 1996;42:913-22.
5. Duff IF, Carpenter JO, Neukom JE. Comprehensive management of patients with rheumatoid arthritis. *Arthritis Rheum* 1974;17:635-45.
6. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the management of rheumatoid arthritis: 2002 Update. *Arthritis Rheum* 2002;46:328-46.
7. Van den Ende CH, Vliet Vlieland TP, Munneke M, Hazes JM. Dynamic exercise therapy for rheumatoid arthritis. *Cochrane Database Syst Rev* 2000;CD000322.
8. Riemsma RP, Kirwan JR, Taal E, Rasker JJ. Patient education for adults with rheumatoid arthritis. *Cochrane Database Syst Rev* 2003; CD003688.
9. Steultjens EM, Dekker J, Bouter LM, van Schaardenburg D, van Kuyk MA, van den Ende CH. Occupational therapy for rheumatoid arthritis. *Cochrane Database Syst Rev* 2004; CD003114.
10. Brosseau L, Welch V, Wells G, et al. Low level laser therapy (classes I, II and III) in the treatment of rheumatoid arthritis.

- Cochrane Database Syst Rev 2000;CD002049.
11. Casimiro L, Brosseau L, Robinson V, et al. Therapeutic ultrasound for the treatment of rheumatoid arthritis. *Cochrane Database Syst Rev* 2002; CD003787.
 12. Casimiro L, Brosseau L, Milne S, Robinson V, Wells G, Tugwell P. Acupuncture and electroacupuncture for the treatment of RA. *Cochrane Database Syst Rev* 2002; CD003788.
 13. Brosseau L, Yonge KA, Robinson V, et al. Transcutaneous electrical nerve stimulation (TENS) for the treatment of rheumatoid arthritis in the hand. *Cochrane Database Syst Rev* 2003; CD004287.
 14. Robinson V, Brosseau L, Casimiro L, et al. Thermotherapy for treating rheumatoid arthritis. *Cochrane Database Syst Rev* 2002; CD002826.
 15. Verhagen AP, Bierma Zeinstra SM, Cardoso JR, de Bie RA, Boers M, de Vet HC. Balneotherapy for rheumatoid arthritis. *Cochrane Database Syst Rev* 2003; CD000518.
 16. Stucki G. Understanding disability. *Ann Rheum Dis* 2003;62:289-90.
 17. Randolph L, Seidman B, Pasko, T. Physician characteristics and distribution in the United States. Chicago: American Medical Association; 1997.
 18. Pincus T, Gibofsky A, Weinblatt ME. Urgent care and tight control of rheumatoid arthritis as in diabetes and hypertension: better treatments but a shortage of rheumatologists. *Arthritis Rheum* 2002;46:851-4.
 19. Hill J. Patient satisfaction in a nurse-led rheumatology clinic. *J Adv Nurs* 1997;25:347-54.
 20. Tjhuis GJ, Zwiderman AH, Hazes JM, van den Hout WB, Breedveld FC, Vliet Vlieland TP. A randomized comparison of care provided by a clinical nurse specialist, an inpatient team, and a day patient team in rheumatoid arthritis. *Arthritis Rheum* 2002;47:525-31.
 21. Hill J, Thorpe R, Bird H. Outcomes for patients with RA: A rheumatology nurse practitioner clinic compared to standard out patient care. *Musculoskeletal Care* 2003;1:5-20.
 22. Campos AA, Graveline C, Ferguson JM, et al. The physical therapy practitioner (PTP) in pediatric rheumatology: high level of patient and parent satisfaction with services. *Physiother Can* 2002;54:32-6.
 23. Campos AA, Graveline C, Ferguson JM, Lundon K, Schneider R, Laxer RM. The physical therapy practitioner: an expanded role for physical therapy in pediatric rheumatology. *Physiother Can* 2002;54:32-6.
 24. Li LC, Davis AM, Coyte PC, Lineker S, Bombardier C. Treatments provided by rheumatology primary therapists for managing rheumatoid arthritis [abstract]. *Arthritis Rheum* 2004;48 Suppl:S640.
 25. Davis P. The application of telehealth to rheumatology. *Clin Rheumatol* 2003;22:168-72.
 26. Leggett P, Graham L, Steele K, et al. Telerheumatology C diagnostic accuracy and acceptability to patient, specialist, and general practitioner. *Br J Gen Pract* 2001;51:746-8.
 27. Lewtas J. Telemedicine in rheumatology. *J Rheumatol* 2001;28:1745-6.
 28. van den Hout WB, Tjhuis GJ, Hazes JMW, Breedveld FC, Vliet Vlieland TPM. Cost effectiveness and cost utility analysis of multi disciplinary care in patients with rheumatoid arthritis: a randomised comparison of clinical nurse specialist care, inpatient team care, and day patient team care. *Ann Rheum Dis* 2003;62:308-15.
 29. Li LC, Davis AM, Coyte PC, Lineker S, Bombardier C. The effectiveness of the primary therapist model for managing people with rheumatoid arthritis: A randomized controlled trial. *J Rheumatol* 2005 (in press).
 30. Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321:694-6.
 31. Toussiot E, Wendling D. Current guidelines for the drug treatment of ankylosing spondylitis. *Drugs* 1998;56:225-40.
 32. Guidelines for referral and management of systemic lupus erythematosus in adults. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. *Arthritis Rheum* 1999;42:1785-96.
 33. Rappolt S, Tassone M. How rehabilitation therapists gather, evaluate, and implement new knowledge. *J Contin Educ Health Prof* 2002;22:170-80.
 34. Davis D, O'Brien MAT, Freemantle N, Wolf FM, Mazmanian P, Taylor-Vaisey A. Impact of formal continuing medical education: do conferences, workshops, rounds, and other traditional continuing education activities change physician behavior or health care outcomes? *JAMA* 1999;282:867-74.
 35. Grimshaw JM, Thomas RE, MacLennan G, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess* 2004;8:1-72.
 36. Logan J, Graham I. Toward a comprehensive interdisciplinary model of health care research use. *Science Communication* 1998;20:227-46.
 37. Graham K, Logan J. Using the Ottawa Model of Research Use to implement a skin care program. *J Nurs Care Qual* 2004;19:18-24.
 38. Wenger EC, Snyder WM. Communities of practice: the organizational frontier. *Harvard Business Review* 2000;78:139-45.
 39. Lathlean J, le May A. Communities of practice: an opportunity for interagency working. *J Clin Nurs* 2002;11:394-8.
 40. Parboosingh JT. Physician communities of practice: where learning and practice are inseparable. *J Contin Edu Health Prof* 2002;22:230-6.
 41. Honeyman A. Communities of practice. *Br J Gen Pract* 2002;52:621-2.