Study protocol for the European Team Initiative for Care Research (ETIC)

Including the Scandinavian Team Arthritis Register (STAR), Project

Revision of Economical Plan (p 6) performed 19 April 2006.

Abstract

Background: With an increased proportion of elderly in the western society, socioeconomic costs of arthritis are continuously increasing. Despite improvement in medical pharmacological and surgical treatment, special rehabilitation strategies are often required. Team care research explores and evaluates arthritis care. However, the number of research studies in this field is limited, and evidence regarding the content, effectiveness and costs of different care models are lacking. Aims: To create a basis for registration of team care interventions in arthritis, and to investigate different aspects of structure, process and outcome of team care in hospitals and rehabilitation units in Europe. Methods: A common set of instruments will be used to assess structure, process and outcome of team care interventions in arthritis in at least 13 hospitals and rehabilitation centres in the Netherlands, Denmark, Sweden and Norway. In common databases, this will form the bases for a long term prospective observational study. Importance and relevance for EULAR: Criteria for team care research will be developed, by suggesting a core set in evaluating arthritis team care and by creating a basis for future intervention studies. Criteria for team care will be developed, by suggesting indications for and structure of team care for various rheumatic diseases (to be embedded in for example EULAR guidelines for the management of RA or OA)

Background

Team Care in rheumatology has a long tradition in Europe[1, 2]. A commonly used definition of multidisciplinary team in health care is “a group of health professionals from various disciplines who work towards a common goal” [3]. In this project we define team care as “all interventions and care given by a group of health professionals (at least three persons, patient included) with different professional background who works towards common goals.

Initially most of the team care was based on long-term inpatient care but with major changes in the medical and surgical treatment interventions as well as health care systems in western countries, changes have occurred also in team care models[1, 4-7]. Thus, nowadays team care is also being offered in outpatient and day clinics as well as by means of more flexible team formations[1, 7-10]. In many countries there is a close collaboration with other areas of health care such as general practice/primary health care, orthopaedic surgery etc.

Musculoskeletal disorders are a major threat to function and quality of life in western countries and the costs for the prevention, care and socioeconomic consequences of these diseases are continuously raising (WHO/Bone and Joint Decade, Technical Report 2004). Inflammatory joint diseases have been the main focus for rheumatological care for many years, but rheumatological care, research and development also include other disease groups including long standing musculoskeletal pain[11, 12] and osteoarthritis[13]. Major changes for the pharmacological treatment of inflammatory joint diseases have occurred over the past five years in western countries[14-16]. As the majority of patients with
rheumatic disorders will not benefit from these new biological treatments, there is still a major need for team care in the future. Despite the undisputable value of and place for team care and rehabilitation in clinical practice, the scientific basis for team care and rehabilitation is still to be developed in many aspects[2, 3, 10].

Rheumatological teams for patients with inflammatory diseases are available on regional hospitals, university hospitals and specialised rehabilitation centres. A comparison of the different settings for team care, will allow the detection of the active components of team care[3].

For patients with OA and musculoskeletal pain syndromes Primary Health Care, Orthopaedic surgery/specialised units or other Rehabilitation units are an alternative. However, rheumatology still has the longest experience and the best strategies for research and development in musculoskeletal disorders and thus the major development and evaluation of team care and rehabilitation should take place within rheumatology. The effectiveness of team care has been shown both in clinical follow-up studies[7, 8, 10, 17] and in controlled trials[4, 9, 10]. Some studies have also included comparisons between different types of team interventions [4, 9, 10] but no studies so far have studied the active components and individuals features of team care in patients with rheumatic diseases[1, 3].

**Objectives**

1. To create a basis for registration of team care interventions in arthritis relating to structure, process and outcome. The short-term objectives (6-12 months) of this project is to:
   a. Develop a European framework and network to assess structure, process and outcome of arthritis care and team care interventions.
   b. Create a standard for collecting data on team care in common databases (with different technical solutions including web based registers).

2. To collect data on structure, process and outcome of team care in hospitals and specialised rehabilitation centres. The intermediate (12-30 months) objectives is to:
   a. Study the influence of structure, process and team care synergies on outcomes in team care of patients with rheumatic diseases.
   b. Study patient characteristics and patient preferences relevant for rehabilitation outcome.
   c. Compare elements of current rehabilitation practice with the evidence from international published literature as a basis for quality improvement and benchmarking.

3. To develop European criteria for team care and team care research. The long-term objectives (>30 months) is to:
   a. Develop indications for team care for various rheumatic diseases (to be embedded in for example EULAR guidelines for the management of RA or OA).
   b. Create a basis for future intervention studies.
**Methods**

The study will be designed as a multicenter, longitudinal observational study, by collecting data from all relevant patients in the participating centres for one year at admission, discharge and at 6 months follow up.

**Patients**

Three main diagnostic categories of adult patients (18 years or older) will be included:
- Inflammatory joint diseases
- Osteoarthritis of any location (OA)
- Chronic musculoskeletal pain of any location

The number of patients per year, available for inclusion and follow-up in the collaborating centers which by December 2005 have agreed to participate will be approximately 2000.

**Instruments**

**Structure**

An instrument for assessing structural aspects of the rehabilitation units has been developed and is by December 2005 being validated. This instrument captures aspects on *team members* (professions, numbers, training etc), *team composition* and setting and infrastructure. The leaders of the participating institutions will be asked to fill in this questionnaire.

**Process**

The teamcare/rehabilitation process will be assessed by the *Rehabilitation Process Questionnaire* (RPQ), which is currently developed. The development of this questionnaire is based on other relevant instruments found in a literature review and empirical testing using both quantitative and qualitative methodologies. It aims to include main aspects of the rehabilitation process and follows the model shown in Table 1. The process of instrument development was designed to ensure content validity; that is the extent to which the items adequately address important aspects of rehabilitation process. The first stage of the model has been finished. The RPQ is by December 2005 under pilot testing in Norway.

**Outcomes**

To assess information concerning team care according to the International Classification of Functioning Disability and Health (ICF, 2001. International classification of functioning disability and health. Geneva, WHO Library Cataloguing-in-Publication-Data) different study methodology (qualitative and quantitative) and several outcome measures will be used. The intention is to measure body function and body structure, activity and participation as well as personal factors. Five generic self-administered questionnaires are mandatory:
- Short Form 36-item Health Survey [18]
- Visual Analogue Scale measuring Pain, Fatigue and Global severity [19]
- Health Assessment Questionnaires useful also for osteoarthritis[20] and chronic musculoskeletal pain[21].

The questionnaires will be assessed at start and stop of the intervention and will include one follow-up 6 months after the first assessment. Disease specific questionnaires are optional.
### Stage Methods

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<tr>
<th>Stage</th>
<th>Methods</th>
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<tbody>
<tr>
<td>1 Item construction</td>
<td>Literature review, patient interviews, consultation with expert groups,</td>
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<td>visiting rehabilitation institutions and rheumatology departments in hospitals</td>
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<td>2 Item pre-testing</td>
<td>Survey of representative sample of patients (100-150 patients)</td>
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<td>a) data quality – missing data, floor and ceiling effects</td>
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<td>b) dimensionality – factor analysis and Rasch analysis</td>
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<td>c) internal reliability – item-total correlation, Cronbach’s alpha</td>
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<td>3 Item-testing</td>
<td>Main survey</td>
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<td></td>
<td>a) data quality – missing data, floor and ceiling effects</td>
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<td></td>
<td>c) internal reliability – item-total correlation, Cronbach’s alpha</td>
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<td>4 Reliability</td>
<td>Sample of respondents to main survey</td>
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<td></td>
<td>a) weighed kappa for items</td>
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<td>b) intra-class correlation coefficient for scales</td>
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<td>5 Construct validity</td>
<td>Main survey</td>
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<td>a) literature review to identify variables known to influence rehabilitation process and patient experiences</td>
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<td>b) comparisons with general measures of satisfaction, aspects of health care process, health status and sociodemographic variables</td>
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### Organisation

#### Project Leaders

- **Contact person:** Ingemar F Petersson, MD, PhD, Ass. Professor Lund University Hospital, Lund and Research Director, R&D Department, Spenshult Hospital, Halmstad, Sweden, e-mail: ingemar.petersson@spenshult.se or ingemar.petersson@med.lu.se, mobile +46-70-5762200
- Kåre B Hagen, PT, PhD, Research director, National Resource Centre for Rehabilitation in Rheumatology (NRCRR), Diakonhjemmets Sykehus, Oslo, Norway, e-mail: kbh@ulrik.uio.no
- Lennart T H Jacobsson, MD, PhD, Professor in rheumatology, Malmö University Hospital, Malmö and R&D Department, Spenshult Hospital, Halmstad, Sweden, e-mail: lennart.jacobsson@ort.mas.lu.se
- Thea Vliet Vlieland, PT, MD, PhD, Associate professor, Dept of Rheumatology, Leiden University Medical Center (LUMC), Leiden, Holland, e-mail: T.P.M.Vliet_Vlieland@lumc.nl

#### Collaborating researchers

- Margreth Grotle, Kåre Birger Hagen and Till Uhlig, NRCRR, Diakonhjemmet Hospital, Oslo, Norway
- Lennart Jacobsson and Ingegerd Wikström, Malmö University Hospital, Malmö Seden
- Elisabet Lindqvist and Sofia Hagel, Dept Rheumatology, Lund University, Lund, Sweden
- Ann Breemander and Ingemar Petersson, Spenshult Hospital for Rheumatic Diseases, Halmstad, Sweden
- Inger Henriette Stovgaard, Kong Christian X’s Gigt Hospital, Graasten, Denmark
- Thea Vliet Vlieland, Dept of Rheumatology, Leiden University Medical Center (LUMC), Leiden, Holland
When possible, data collection will be connected to national or regional registers in rheumatology such as the Swedish Rheumatology Registers/Swedish RA registry.

**Collaborating rehabilitation centres:**
**Norway:** Skogli Rehabilitation Center, Lillehammer, Vikersund Kurbad, Vikersund, Jeløya Rehabilitation Center, Moss, Martina Hansen Hospital, Bærum, Lillehammer Rheumatological Hospital, Lillehammer, Dept of Rheumatology, HF Østfold Hospital, Sarpsborg, NRCRR, Diakonhjemmet Hospital, Oslo,
**Sweden:** Spenshult Hospital, Halmstad and Rheumatology Departments at the Lund and the Malmö University Hospitals
**Denmark:** Dr. Alexandrines Gigt Hospital Middelfart and Kong Christian X´s Gigt Hospital, Graasten
**The Netherlands:** Dept of Rheumatology, Leiden University Medical Center

**Project Coordinators:** Ann Bremander, Spenshult Hospital, Halmstad and Dept Ortopedics, Lund University, Lund, Sweden and Margreth Grotle, NRCRR, Diakonhjemmet Hospital, Oslo, Norway, Inger Henriette Stovgaard, Christian X´s Gigt Hospital, Graasten, Denmark Collaborating centres, Thea Vliet Vlieland, Dept of Rheumatology, Leiden University Medical Center (LUMC), Leiden, Holland

**Importance and relevance for EULAR**
For all western countries, especially European countries, there is a need for continuous development and research in the different areas of rheumatic diseases, their pathogenesis, disease course, different treatments as well as prognosis and outcomes.
New forms and models of team care and rehabilitation will for the future be a major part of rheumatological care for the large groups of patients.
The result of this project will improve the management of patients with rheumatic diseases because management and evaluation of team care will then be based on an exploration of the preferences and experiences of patients in different European countries.
As the major basis for team care research is in Europe, it is logical for the EULAR to support collaboration and network research in these area through the ETIC project.
Working together in this project will facilitate that the participating centres establish expertise and knowledge in team care research. It will enhance a common European understanding of the preferences and experiences of team care.
The newly developed as well as the established instruments will form a basis for a common a suggested core set in evaluating arthritis team care. Criteria for team care and team care research will be developed, by suggesting indications for and structure of team care for various rheumatic diseases (to be embedded e.g. in EULAR guidelines for the management of RA or OA) and by creating a basis for future intervention studies.
This research network will be an additional source for current and continuously updated knowledge of the arthritis care as a whole in different countries. It could in the future be well integrated into larger European collaborative projects where also national registers on disease course, pharmacological and surgical treatment contribute.

**Time plan**
The study will be completed in three years (January 2006-December 2008). The following milestones have been defined:
• June 2006 – October 2007 Data collection.
• June 2007 – December 2007 Interim analysis and preliminary reporting.
• January 2007- December 2008 Further Data analysis and final reporting.

_Economical plan_ Revision of Economical Plan (p 6) performed 19 April 2006.

Basic funding for development of study protocol and piloting have been provided internally from the Diakonhjemmet Hospital, Spenshult Hospital and the Rheumatology Departments at the Lund and the Malmö University Hospitals. For the main study the following budget is estimated:

2006
- Data collection and study coordination: Gross salary 3.5 days per week research coordinators for 1 year (according to the Norwegian Research Council, post-doctoral fellowships NOK 420,000,-) € 49,000
- Travel costs for one researcher per participating country for study coordination and data monitoring (1 meeting per year + one telephone conference € 50), € 350 flight + € 200 accommodation = € 550 x 4 +50 = € 2,250

_Total grant application for 2006 = € 51,250_

2007
- Data collection and study coordination: Gross salary 3.5 days per week research coordinators for 1 year (according to the Norwegian Research Council, post-doctoral fellowships NOK 420,000,-) € 49,000
- Travel costs for one researcher per participating country for study coordination and data monitoring (1 meeting per year + one telephone conference € 50), € 350 flight + € 200 accommodation = € 550 x 4 +50 = € 2,250
- One month full time work for a statistician + researcher for data check and analysis € 4,500

_Total grant application for 2007 = € 55,750_

2008
- Data collection and study coordination: Gross salary 3.5 days per week research coordinators for 1 year (according to the Norwegian Research Council, post-doctoral fellowships NOK 420,000,-) € 49,000
- Travel costs for one researcher per participating country for study coordination and data monitoring (1 meeting per year + one telephone conference € 50), € 350 flight + € 200 accommodation = € 550 x 4 +50 = € 2,250
- One month full time work for a statistician + researcher for data check and analysis € 4,500

_Total grant application for 2008 = € 55,750_

_Bibliography_ (and CV for Ingemar F Petersson)

References


**Curriculum Vitae**

**for**

Mr Ingemar Petersson, Sweden, Born February 23, 1955

**Education & Exams**

1980-1986 
Internship in Family Medicine, County Hospital and Family Medicine Centre, Halmstad, Sweden

1986-1989 
Internship in Rheumatology, County Hospital, Halmstad, and University Hospital, Lund, Sweden

1989--(continued) 
Consultant Rheumatologist, Spenshult (National Hospital for Rheumatic Diseases), Halmstad, Sweden

**Clinical positions**

1997--2004 
Clinical Director, Spenshult (Specialised National Hospital for Rheumatic Diseases with 100 beds an 200 employees), Halmstad, Sweden

2001-- 
Research Director, R&D-centre, Spenshult Hospital for Rheumatic Diseases, Halmstad, Sweden

2004-- 
Senior Medical Officer, Spenshult, Halmstad, Sweden

**Research positions**

Since 1990 connected to Department of Rheumatology, Lund University, Lund, Sweden, first as PhD-student, from 1997 and ongoing as a tutor for Master- and PhD-students. From September 2004, Associate Professor, Lund University. February 2005- Research Programme Coordinator for “Tissues in Motion”, Faculty of Medicine, University of Lund. From November 2004 Scientific Advisor on Rheumatic Diseases, Epidemiology and GCP guidelines for The National Swedish Competence Centre for Muskuloskeletal Disorders, Lund, Sweden.

**External reviewer**

External reviewer of applications for higher academic positions for rheumatologists at Tuft University School of Medicine, Tuft, New England, Medical Centre, Boston. Harvard Medical School, Boston, US, Reumafonds, Netherlands and Primary Care Sciences Research Centre; Keele University, England.
**External scientific assignments**

- Chair and co-organizer of the First International Workshop on Epidemiology of Osteoarthritis, Örenäs Castle, Sweden, 1996.
- Organizing second international workshop on Team care in Rheumatology (CARE II), Speshult, Sweden, September 2003.
- Invited speaker Rheumatology Units in Bristol and Manchester, UK, the Mayo Clinic, Rochester, US, and the EULAR Congress of Rheumatology Lissabon 2003.
- Chair person at a number of national and European scientific conferences within rheumatology (Lund 2002, Edinburgh 2001 etc.)
- Invited as a lecturer on a large number of different kind of meetings and different scientific conferences and at the King Gustav V Jubilee Fund for Research at the Royal Castle, Stockholm, November 2000.
- Co-organizing (including giving key note lectures and moderating sessions) third international workshop on Team care in Rheumatology (CARE III), Toronto, Canada, May 2005.
- Faculty opponent (First Opponent) Faculty of Medicine, University of Oslo/Diakonhjemmets Sykehus: Ankylosing Spondylitis: Disease Impact and Research Evidence of Physiotherapy Interventions (Hanne Dagfinrud), June 2005.
- Member of the Steering Committee of DICHOA- The European EULAR Initiative on Hand OA (Chair Professor Josef Smolen, Vienna)
- External reviewer for pre-PhD exams in Lund (Martin Englund 2004), Malmö (Ingegerd Wikström 2004), Linköping (Eva Hallert 2005).
- Member of the Faculty Board for PhD dissertation Gothenburg (Kerstin Wentz 2005), Uppsala (Tomas Weitoft 2005), Malmö (Brita Strömbeck 2006)

**Educational positions**

- During the 1990’s for nine whole weeks educational yearly courses for fellows in family medicine/general practice at Spenshult Hospital.
  - From 1999, yearly organizing the courses in rheumatological and orthopaedic rehabilitation for junior rheumatologists, and from 2003 also one yearly course in rheumatological examinations at Spenshult Hospital, Sweden.
- Tutor for masters- and PhD-students at the Medical Faculty, University of Lund, The Sahlgrenska Academy, Gothenburg and local Nurse´s Colleges.
Prizes and Awards
- 1998 the Pharmacia Award for Junior Researchers in Rheumatology
- 2003 The Swedish Schering-Plough for Health Care Research in Rheumatology
- 2003 The Wyeth/Enbrel Award for Clinical Rheumatological Research

Varia
- Member of the board of Swedish Society for Rheumatology (1988-1990).
- Attended two courses on Epidemiology, Clinical Trials and Statistics organised by Apoterkarsocieteten (Swedish Academy of Pharmaceutical Sciences), Stockholm, Sweden, 1990-95
- Taken part in more than ten Clinical Pharmacotherapeutical Trials in RA, OA, Spondylarthropathies, Muskuloskeletal Pain (1987-)
- Member of National Committee for quality measurements in muskuloskeletal pain and rheumatological disorders (1994-1996).
- Member of EULAR Standing Committee for Epidemiology (1998-)
- Member of the UEMS committee for Educational Development in Rheumatology in Europe (2002-)
- Member of American Collage of Rheumatology and Osteoarthritis Research Society International (OARSI).
- Member of the board for the Swedish Fund for the Bone&Joint Decade (2003-), chair from 2005-12-01.
- Invited as speaker and chair in national and international meetings (including EULAR meetings in Stockholm 2002 and Lisbon 2003).
- Textbook in Rheumatology (Chapter on Osteoarthritis, Member of the Editorial Board), Studentlitteratur, Sweden 2005.
- Invited expert in national health information TV programmes, 6 times 2001-2006 (SVT “Fråga Doktorn”, SVT Kunskapskanalen/Scientific and Educational Programmes)