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Randomised comparison of a multidisciplinary job-retention vocational rehabilitation program with usual outpatient care in patients with chronic arthritis at risk for job loss

Submission date
08/10/2006

Recruitment status
No longer recruiting

Registration date
15/01/2007

Overall study status
Completed

Last Edited
28/10/2008

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Multidisciplinary vocational rehabilitation for patients with chronic arthritis

Study objectives
This study was a randomised controlled trial comparing a job retention Vocational Rehabilitation program (VR group) with Usual outpatient Care (UC group), with 24 months of follow-up. After enrolment and baseline assessments had been completed, patients were randomly allocated to either the VR or the UC group. Randomisation was done with stratification for centre (academic versus non academic) and three diagnosis groups (Rheumatoid Arthritis [RA]; Ankylosing Spondylitis [AS], psoriatic arthritis, reactive arthritis; Systemic Lupus Erythematosus [SLE], or scleroderma), according to a randomisation list that was made up by a random digit generator. All clinical assessments were done by a trained research nurse who was blinded to the patients' treatment status. Assessments were done at baseline and after 6, 12, 18 and 24 months of follow-up. To maintain allocation concealment, patients were instructed not to inform the principal investigator or the research nurse about the type of care they received.

The aim of this trial is to investigate the effectiveness of a multidisciplinary job retention vocational rehabilitation program in patients with a rheumatic condition who were at risk for job loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Medical Ethics Committee Leiden University Medical Center in February 1999 (ref: P 69/98).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic arthritis (including rheumatoid, psoriatic and reactive)

Interventions
The job retention vocational rehabilitation program was delivered at the department of Rheumatology of the Leiden University Medical Center by a multidisciplinary team comprising a rheumatologist, a social worker, a physical therapist, an occupational therapist and a psychologist. Moreover, an occupational physician who was linked to the occupational health service of the Leiden University Medical Center was connected to the team. This occupational physician was not involved in the guidance of individual patients, but had a general advisory role. The organisation of the program was in the hands of a coordinator. All patients made at least two visits to the hospital in connection with the job retention vocational rehabilitation program.

The intervention consisted of a systematic assessment followed by education, vocational counselling, guidance, and medical or non-medical treatment. The basic assessment was done by a rheumatologist (current level of disease activity and joint destruction, presence of extra-articular manifestations or co-morbidity and extent and severity of activity limitations; prognosis regarding future impairments and activity limitations) and the coordinator (education level and previous jobs, systematic registration of the problems encountered in the current working situation, using a list of potential challenges and psychosocial situation). If necessary, additional team members were asked to see the patient in order to gather more information about specific aspects of the work situation.

Dependent on the specific problems of the individual patient, the intervention further consisted of education (such as providing written and oral information about the Dutch social security system regarding sick leave and work disability), counselling and guidance (such as the identification of resources for adapting the working environment or working hours, promotion of work self-efficacy), or treatment (such as adaptation of the medical treatment in consultation with the referring rheumatologist, exercise therapy, occupational therapy, functional training of relevant activities or mental restoration).

All information concerning the patient's health status, working situation and working challenges and the course of the process of education, counselling, guidance or treatment was listed in a final report. This report was then sent to the referring rheumatologist and the occupational physician connected with the patient's company if applicable. The total duration of the intervention varied, and lasted on average between four and 12 weeks.

Patients assigned to the UC group were treated and referred to other health professionals in relation to their working problem if regarded necessary by their rheumatologist. In addition, they all received the same written information about the Dutch social security system regarding sick leave and work disability as patients in the VR group.

The referring rheumatologists were informed about the treatment allocation. In both groups, physicians had free choice with respect to their medical prescriptions and other treatment strategies. All medical treatment and the use of health services during the intervention period and two-year follow-up were recorded in both groups.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The main outcome was the occurrence of job loss, defined as receiving an official full work disability pension or unemployment. The classification of job losses was based on the participants' records of their work status at every follow-up visit. Subjects being less then one year on full sick leave were classified as being in paid employment. In addition to job loss, the number of patients in whom the extent of the disability pension had increased (by receiving an official full disability pension or by receiving a new or a larger official partial disability pension) was recorded at every time point.

Secondary outcome measures
1. Satisfaction with the job, measured on a horizontal Visual Analogue Scale (VAS, range 0-10 cm). The anchor on the left was not at all satisfied and the anchor on the right was fully satisfied with the job. The VAS was only to be filled in by those subjects who had worked at least five days in the last month
2. Global assessments of pain and fatigue, measured on a VAS (0-10 cm). The anchors on the left were no pain and no fatigue whereas the anchors on the right were severe pain and severe fatigue
3. Physical functioning, using the Health Assessment Questionnaire (HAQ), a 20-item questionnaire comprising eight domains of activities of daily living
4. Anxiety and depression were measured by means of a Dutch version of the Hospital Anxiety and Depression Questionnaire (HADS). It contains two seven item scales: one for anxiety and one for depression both with a score range of zero to 21
5. Quality of life was measured using the RAND 36-item Health Survey. The RAND-36 was converted into two summary scales: the physical and mental component summary scales. The RAND includes the same items as the Medical Outcomes Study Short-Form (SF 36) and although the scoring procedures are somewhat different, the effects on final scores are minimal
6. From a social prospective, the cost-utility of a VR-program

Overall study start date
01/03/1999

Completion date
01/06/2001

Eligibility

Key inclusion criteria
1. Aged between 18 and 63 years
2. Has a chronic rheumatic disease (diagnosis Rheumatoid Arthritis [RA]; Ankylosing Spondylitis [AS], psoriatic arthritis, reactive arthritis; Systemic Lupus Erythematosus [SLE], or scleroderma)
3. All patients have a paid job (working full-time or part-time or being on sick leave, either with or without a partial work disability pension)
4. Having a self-perceived, disease related problem at work, threatening their ability to work

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
63 Years

Sex
Not Specified

Target number of participants
140

Key exclusion criteria
1. Reaching the pensionable age within two years
2. Having another disease or situation influencing work ability

Date of first enrolment
01/03/1999

Date of final enrolment
01/06/2001

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
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Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Sponsor details

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Sponsor type
Research organisation

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands) (grant ref: 940-36-009)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/10/2005		Yes	No