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A dynamic exercise programme to improve patients' disability in rheumatoid arthritis: a prospective randomised controlled trial

Submission date 01/01/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/07/2008	**Overall study status** Completed	
Last Edited 21/07/2008	**Condition category** Musculoskeletal Diseases	

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
PREDYP

Study objectives
The dynamic exercise programme improves quality of life in rheumatoid arthritis (RA) patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Protection of Human Subjects in Biomedical Research (Comités de Consultation pour la Protection des Personnes se prêtant à la Recherche Biomédicale [CCPPRB]), Grenoble II. Date of approval: 11/12/2002

Study design
Prospective, single-blind, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Roeder manipulative aptitude test, five-handle position grip test and grip and pinch strength test were carried out at baseline to avoid discrepancy in term of patients' skill between the two groups.

The dynamic exercise program was consistent with the 1990 recommendation of the American College of Sports Medicine. Three or four members of the medical staff (rheumatologist, physiotherapist or occupational therapist) took part in each session for 5 hours a day during a 4 week period. During the first week, patients benefited from hydrotherapy and occupational

therapy input. Knowledge of the disease and physical capacity was evaluated for each participant in order to design, after multidisciplinary co-ordination, a patient-specific exercise program. The second week of the program focused on the influence of RA on daily activities. Muscle strengthening against resistance (of pain-free joints) replaced the hydrotherapy. The occupational therapy program in the third week included skill exercises and daily activities with increasing difficulty (endurance and exercises against resistance). During the forth week the exercises focused on office tasks. Pain and fatigue were prevented by regular breaks and relaxation in order to improve pain tolerance and self-esteem.

Patients allocated to control group had usual care physical therapy according to French recommendations. Briefly, standard joint rehabilitation consisted of interactive lessons taught by rheumatologists, physiotherapists or occupational therapists and meetings for groups of 3 to 4 patients over the course of three days. Occupational therapy advices (verbal information, short movies, booklet) were given and splints were designed to prevent joint deformation and to help patients in daily living tasks.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Functional status, evaluated by the Health Assessment Questionnaire (HAQ) at 1 and 6 months and 1 year. HAQ total score ranges from 0 (no functional limitation) to 3 (dramatic functional impairment).

Secondary outcome measures
The following were assessed at 1, 6 and 12 months:
1. Functional, clinical, radiological, therapeutic and biological modifications in both groups using the following tools:
1.1. The French version of Arthritis Impact Score 2- short form (AIMS2-SF) is a specific questionnaire to assess quality of life in RA patients. AIMS2-SF was not converted to a score of 0 to 10 but was expressed on a scale from 0 to 50.
1.2. Nottingham Health Profile (NHP) is a 38 item generic health-related quality of life measure (range 0 to 600, higher score for greater health problems)
2. Patient dexterity, evaluated by occupational therapists using Sequential Occupational Dexterity Assessment (SODA) or self reported by patients using Duruoz Hand Index (DHI) and a self report questionnaire.
2.1. SODA consists of 12 standardized tasks evaluated by occupational therapists and ranges from 0 to 108.
2.2. The purpose of DHI (range 0-90) was to measure hand ability while performing personal hygiene, office tasks and other general activities
3. Simple Erosions Narrowing Score (SENS, range 0-86) considers erosions in 32 joints in the hands and 12 in the feet, and joint space narrowing in 30 and 12 joints respectively. The total SENS score was assessed by a single radiologist unaware of the group assignment.
4. Disease activity was determined using Disease Activity Score (DAS 28, range 0.14-9.3). A 28 joint count for swelling and tenderness was assessed by a rheumatologist unaware of the treatment allocation. Patients rated their general health on a 100 mm visual analogue scale. DAS 28 was calculated using the three previously mentioned parameters and Erythrocyte Sedimentation Rate (ESR).

5. Aerobic capacity was measured on an exercise bike as the distance covered in 5 minutes.
6. Use of oral and intra-articular drug, as well as other medical devices were recorded

Overall study start date
01/04/2004

Completion date
01/04/2005

Eligibility

Key inclusion criteria
1. 1987 modified American College of Rheumatology (ACR) criteria for RA
2. Treated with a disease-modifying anti-rheumatic drug

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. >10 mg glucocorticoid per day
2. No or unstable Disease Modifying Anti-Rheumatic Drug (DMARD) regimen
3. DAS28 variation >1.2 in the past 3 months
4. Age <18 or >70
5. Severe comorbidity causing a reduced life expectancy
6. Global functional status in RA class III or IV
7. Patients unable to follow the educational program or complete a questionnaire because of cognitive impairment, psychiatric disease, social frailty or language difficulty

Date of first enrolment
01/04/2004

Date of final enrolment
01/04/2005

Locations

Countries of recruitment
France

Study participating centre
Department of Rheumatology
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Sponsor information

Organisation
Association for Research on Osteoarticular Disease (ARPOA) (France)

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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Research organisation

Funder Name
Association for Research on Osteoarticular Disease (Association de Recherche en Pathologie Ostéo-Articulaire; ARPOA) (France)

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