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Assessment of socioeconomic impact of rheumatological care to patients with temporary work disability of musculoskeletal origin

Submission date 01/06/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/06/2007	**Overall study status** Completed	
Last Edited 27/06/2007	**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
FIS 98/1050

Study information

Scientific Title

Acronym
IT-ME-98

Study objectives
A population-based, clinical program offered to patients with recent-onset work disability caused by Musculoskeletal Disorders (MSDs) is cost-effective with respect to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol was approved by the institutional review board of the Hospital Clínico San Carlos and reviewed by the Fondo de Investigaciones Sanitarias (the research agency of the Ministry of Health). Date of approval June 2, 1998.

Study design
Randomized, controlled study, unblinded for both patients and physicians, of two years duration (recruitment one year, follow-up one year)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal disorders causing temporary work disability.

Interventions
The intervention was a specific clinical program. The control group received standard care.

At the first 45-minute visit, patients received a specific diagnosis, reassurance that no serious disease was present, instructions on self-management, instructions on taking medications on a fixed schedule, and information on indications for return to work before complete symptom

remission. Return to work was negotiated with patients and was never forced on them. Instructions on self-management included instructions to avoid bed rest, instructions to promote early mobilization of the painful regions, restrictions on the use of splint and neck collars, training in stretching and strengthening exercises, teaching of ergonomic care, delivery of booklets in instances of back or neck pain, and information on optimal levels of physical activity. Patients with higher degrees of disability or abnormal pain behavior received immediate extra reassurance, information on pain-relieving positions, and a telephone call or second visit within 72 hours.

Specific protocols were created for low-back, neck, shoulder, arm and hand, knee, and foot pain and included the three-level clinical-management system described below. Moving a patient from the lower to the upper levels of the system implied the need for further diagnostic or therapeutic procedures and was indicated 1) after a patient spent a predefined period at the lower level without return to work or substantial clinical improvement or 2) by the clinical judgment of the rheumatologist.

At the first level of the system, patients received the clinical management started at the first visit, including a diagnosis based on clinical criteria, pharmacologic treatment of pain and inflammation, pharmacologic treatment of anxiety and depression, peripheral intra- and periarticular injections, and education. Time spent at the first level averaged 2 to 6 weeks. At the second level, patients received maintenance of therapy plus referral for formal rehabilitation and laboratory tests, radiography, computerized tomography, magnetic resonance imaging, and electromyography. After 4 to 8 weeks with no improvement at the second level, patients were moved to the third level and received further diagnostic procedures or referral for surgical or other specialized care. Red flags were defined, including age greater than 50 years for patients with axial pain, previous trauma, cancer, serious medical illness, inflammatory pain, night pain, drug abuse, corticosteroid use, fever, weight loss, progressively deteriorating function, and progressive neurologic deficit. The presence of a red flag precluded the use of the level system, and the patient in question was managed according to clinical criteria, with a focus on excluding serious illness.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Efficacy was defined as the differences between groups in the following:
1. Duration of all episodes of MSD-related temporary work disability
2. Number of episodes of MSD-related temporary work disability per patient, assessed one year after the end of inclusion period
3. Number and outcome of proposals for permanent work disability

Secondary outcome measures
1. Relative efficacy is expressed as the percentage of days on temporary work disability saved per patient and as the total number of days on temporary work disability saved in the intervention group (number of episodes in the intervention group x [mean duration of episodes in control group - mean duration of episodes in intervention group]).
2. Cost-efficacy was defined as the amount of money required to save 1 day of temporary work disability.

3. Cost-benefit was defined as dollars invested divided by dollars saved.
Net benefit was defined as dollars saved minus dollars invested.

Overall study start date
01/03/1998

Completion date
01/03/2001

Eligibility

Key inclusion criteria
The issue of a common diseases temporary work disability initiation form, with an MSD-related cause reported by the primary care physician. The MSD-related causes included the following:
1. All arthropathies
2. Connective tissue disorders
3. Back disorders
4. Soft-tissue rheumatisms
5. Bone and cartilage disorders
6. Musculoskeletal pain not caused by cancer
7. Nerve entrapment syndromes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
13077 (7805 in control group and 5272 in intervention group)

Key exclusion criteria
1. Patients who had common diseases temporary work disability form with an MSD-related cause resulting from trauma or surgery.
2. Patients who had work accidents or professional diseases noted on the temporary work disability initiation form. Work accidents are primarily sudden, external, violent causes of disease occurring at work or during travel to work, and they represent less than 27% of cases of temporary work disability. Professional diseases include silicosis, asbestos-related mesotelioma, and noise-induced hearing loss, and they represent less than 1% of cases of temporary work disability.

Date of first enrolment
01/03/1998

Date of final enrolment
01/03/2001

Locations

Countries of recruitment
Spain

Study participating centre
Servicio de Reumatología
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Sponsor information

Organisation
The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

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Sponsor type
Government

Website
http://www.isciii.es/htdocs/en/investigacion/investigacion_presentacion.jsp

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Government

Funder Name
Research Funding Agency of the Spanish Ministry of Health (Fondo de Investigación Sanitaria; FIS)

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:	20/09/2005		Yes	No
Results article	Results:	15/03/2007		Yes	No