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Cost-effectiveness of an early Cognitive Behavioral Treatment in work disability due to musculoskeletal disorders

Submission date
06/06/2007

Recruitment status
No longer recruiting

Registration date
27/06/2007

Overall study status
Completed

Last Edited
27/10/2021

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
Cost-effectiveness of an early Cognitive Behavioral Treatment in work disability due to musculoskeletal disorders

Acronym
Early CBT in TWD-MSD (Temporary Work Disability-MusculoSkeletal Disorders)

Study objectives
To evaluate whether a Cognitive Behavioral Treatment (CBT), complementary to a rheumatologic specific program, offered to patients with poor evolution of work disability caused by musculoskeletal disorders (MSDs) is cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Clinical Investigation, Hospital Clínico San Carlos, approved on 30 June 2004 (ref: 0-04/139).

Study design
Randomized controlled study.

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-related temporary work disability

Interventions
A psychologist will deliver CBT that is complementary to a rheumatologic specific program. One session lasts 45 minutes. The number of sessions is not previously fixed, and varies between 1 and a maximum of 8. The control group will receive standard care.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Efficacy was defined as the differences between groups in the following (assessed for each participant 6 months after inclusion into the study):
1. Duration of all MSD-TWD episodes
2. Number of MSD-TWD episodes per patient
3. Number or relapses of MSD-TWD episodes
4. Duration or relapses of MSD-TWD episodes
5. Number and outcome of proposal for permanent work disability

Secondary outcome measures
Cost measures

Overall study start date
15/10/2004

Completion date
15/04/2007

Eligibility

Key inclusion criteria
1. Musculoskeletal disorders-related temporary work disability for at least 3 weeks
2. Admitted to the rheumatologic specialized care

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
Patients with more than 8 weeks MSD-related temporary work disability.

Date of first enrolment
15/10/2004

Date of final enrolment
15/04/2007

Locations

Countries of recruitment

Spain

Study participating centre
Rheumatology
Madrid
Spain
28040

Sponsor information

Organisation
Musculoskeletal Disease Foundation and FREMAP Foundation

Sponsor details
Ercon Consultores
Calle Jorge Juan 78
Madrid
Spain
28009

Sponsor type
Research organisation

Website
http://www.fremap.es/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Foundation for Biomedical Investigation (Fundación para la Investigación Biomédica, Hospital Clinico San Carlos) (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		29/06/2009	27/10/2021	Yes	No