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Effectiveness of a multidisciplinary intervention in subacute low back pain in the working population

Submission date
17/04/2008

Recruitment status
No longer recruiting

Registration date
09/05/2008

Overall study status
Completed

Last Edited
18/02/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] 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
071610

Study information

Scientific Title
Effectiveness of a multidisciplinary intervention in the evolution of non-speficic subacute low back pain in the working population

Acronym
MILUPA

Study objectives
1. A multidisciplinary intervention (including physical, psychological, educational and pharmacological aspects), reduces intensity of pain, improves functional status and quality of life and diminishes progression towards chronicity in patients with non-specific subacute low back pain, compared to standard clinical practice
2. The multidisciplinary approach manages to reduce both the period of sick leave and duration of pharmacological treatment, compared to standard clinical practice
3. Patient satisfaction is higher with the multidisciplinary approach than that obtained with standard clinical care
4. Differences exist among individual features of those patients that develop non-specific chronic low-back pain and of those who recover

Added 01/02/10:
The study will be a randomised controlled clinical trial with Primary Health Care Centers randomly allocated to a multidisciplinary intervention or to usual clinical care

Please note that as of 01/02/10 this record has been extensively updated. All updates can be found in the relevant field with the above update date. Please also note that the number of participants has increased from 696 to 932 in total between both arms and the anticipated end date has been extended from 31/12/2010 to 31/12/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Jordi Gol i Gurina Primary Care Research Institute (IDIAP), Barcelona Date of approval: 04/04/2007 (ref: P07/25)

Study design
Multicentrre cluster 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
Not available in web format, please use the contact details below to request the educational leaflet,Handbook of your back (validated), or an educational DVD

Health condition(s) or problem(s) studied
Subacute low back pain

Interventions
Current information as of 01/02/10:
Control Group (Standard clinical practice): Individual intervention based on the application of the Clinical Practice Guidelines in the Pathology of the Lumbar Spine in Adults recommendations, published by the Institut Cátala de la Salut. Multidisciplinary Intervention Group: Individual intervention following the recommendations of clinical practice guidelines in addition to a biopsychosocial multidisciplinary intervention consisting of group educational sessions lasting a total of 10 hours and the Educational digital video disc (DVD).

Initial information at time of registration:
Control group (Standard clinical practice):
Individual intervention based on the application of the "Clinical Practice Guidelines in the Pathology of the Lumbar Spine in Adults" recommendations, published by the Catalan Institute of Health (Institut Cátala de la Salut).

Multidisciplinary intervention group:
Individual intervention following the recommendations of the clinical practice guidelines plus educational group intervention plus educational DVD.

Educational group intervention: Intervention will consist of 4 sessions over 1 month, 2 hours per session. The first 50 min of the session will be theoretical and the rest practical. There will be 2 sessions about physical measures to prevent back pain and 2 sessions on psychological aspects to control back pain. They will be given by a nurse trained by an expert psychologist and an expert physiotherapist.

Educational DVD: Educational DVD will cover general aspects of back pain and physical and psychological aspects to prevent it in usual life. It will also give answers to the most frequently asked questions about back pain.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Current information as of 01/02/10:
1. Disability (Roland Morris Questionnaire)
2. Pain intensity (Questionnaire Spanish version
3. Mc Gill Pain Questionnaire, Melzac, 1975)
4. Quality of Life Questionnaire (SF 12)
5. Duration of the current episode of LBP (pre-study and study duration)

6. Work sick leave (yes or not)
7. Duration in days of work sickleave
8. Percentage of change in pharmacological treatments.
9. Fear Avoidance Beliefs Questionnaire (FAB)
10. Goldberg Scale (Anxiety and Depression) Questionnaire
Outcomes will be measured at baseline, 3 moths, 6 and 12 months

Initial information at time of registration:
1. Pain intensity, assessed by the Spanish version of the Mc Gill Pain Questionnaire (Melzac, 1975)
2. Disability, assessed by the Roland Morris Questionnaire
3. Quality of Life, assessed by the 36-item Short Form health survey (SF-36)
4. Duration of the current episode of low back pain (pre-study and during the study)
5. Work sick leave (yes or no)
6. Duration in days of work sick leave
7. Percentage of change in pharmacological treatments
Outcomes will be measured at baseline, 3 and 12 months

Secondary outcome measures
Current information as of 01/02/10:
1. Satisfaction with care
2. Patients assesment of global perceived effect
Outcomes will be measured at baseline, 3, 6 and 12 months

Initial information at time of registration:
Satisfaction with care measured at baseline, 3 and 12 months

Overall study start date
01/01/2009

Completion date
31/12/2011

Eligibility

Key inclusion criteria
Current information as of 01/02/10:
1. Men and women aged between 18 and 65, who present a current episode of non-specific subacute low back pain, occurs suddenly after a period of a minimum of 6months without LBP and lasts between 15 days and 12 weeks (after ruling out the red flag signs for potentially severe illnesses, listed in the exclusion criteria section)
2. Attended during the study recruiting period
3. Who agree to and sign the informed consent
4. Who understand Catalan or Spanish
5. Who can be accessible for at least twelve months.

Initial information at time of registration:
1. Men and women
2. Aged between 18 and 65
3. Those who present a current episode of non-specific subacute low back pain, the duration of which should last from 15 days to less than 12 weeks (after ruling out the red flag signs for potentially severe illnesses, listed in the exclusion criteria section)

4. Attended during the study recruiting period
5. Who agree to and sign the informed consent
6. Who understand Catalan or Spanish
7. Who remain at the same address for at least six months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
466 patients per group (total 932) (added 01/02/10)

Total final enrolment
501

Key exclusion criteria
1. Unwillingness to participate in the multidisciplinary intervention trial
2. Pregnancy or breast-feeding mothers
3. Concomitant drug or other substances abuse
4. Anti-inflammatory intolerance or allergy
5. Patients who had treatment for physical problems in the preceding three months and those referred for intensive functional restoration programmes
6. Coexisting cognitive impairment or any other cause of inability to answer the various questionnaires
7. Severe psychiatric disorders: Psychosis, major depression, etc.
8. Presence of red flag signs for potentially severe illnesses

Added 01/02/10:
9. Patients referred for intensive functional restoration programmes
10. Confirmed diagnosis of fibromialgia

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Spain

Study participating centre
lInstitut dInvestigació i Recerca en Atenció Primària (IDIAP)
Barcelona
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08007

Sponsor information

Organisation
La Marató de TV3 Foundation (Fundació La Marató de TV3) (Spain)

Sponsor details
Ganduxer, 117
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idiap@idiapjgol.org

Sponsor type
Research organisation

Website
http://www.fundaciomaratotv3.cat

ROR
https://ror.org/00t5xc355

Funder(s)

Funder type
Research organisation

Funder Name
La Marató de TV3 Foundation (Fundació La Marató de TV3) (Spain)

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?
Protocol article	protocol	12/01/2010		Yes	No
Results article	results	12/12/2019	18/02/2021	Yes	No