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The cost-effectiveness and cost-utility of a biopsychosocial multidisciplinary intervention in non-specific sub-acute low back pain in the working population in Catalonia

Submission date
28/06/2011

Recruitment status
No longer recruiting

Registration date
04/08/2011

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Lower back pain is one of the main reasons for consulting a GP. It has an important impact on patients' quality of life and their ability to perform daily tasks. When lower back pain is diagnosed early intervention is necessary to avoid it becoming chronic (long-term). Psychological and social factors should be considered because they could affect the level of pain and increase the risk of chronic lower back pain. Given that the guidelines consider a range of interventions to be effective, it is important to assess the effectiveness of treatments compared with the current intervention. The aim of this study is to assess the cost-effectiveness and cost-utility of a educational group intervention in comparison with the usual care for lower back pain.

Who can participate?
Patients aged 18 to 65 with lower back pain

What does the study involve?
Participants are randomly allocated to one of two groups. Participants allocated to the control group receive usual clinical care and individual intervention. In addition to the same individual intervention as the control group, participants allocated to the intervention group also receive an educational booklet and an educational group intervention carried out by a GP, a nurse, a psychologist and a physiotherapist. The intervention consists of 2 sessions of 4 hours duration each and 1 session of 2 hours duration, including up to 12 participants. The effectiveness and costs of both interventions are measured.

What are the possible benefits and risks of participating?
Not provided at time of registration

When does the study take place?
July 2011 to December 2012

Where is the study run from?
38 Catalan primary health care centres (Spain)

Who is funding the study?
Fundació La Marató de TV3 (Spain)

Who is the main contact?
Dr Concepció Violan Fors

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Study protocol of cost-effectiveness and cost-utility of a biopsychosocial multidisciplinary intervention in the evolution of non-specific sub-acute low back pain in the working population in Catalonia: cluster randomised trial

Study objectives
The multidisciplinary biopsychosocial educational group intervention (MBEGI) is cost-effectiveness and cost-utility in comparison with the usual care of non-specific sub-acute low back pain (LBP) in the working population recruited in Barcelona and its surrounding Primary Health Care Centres (PHCC) since May 2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IDIAP Jordi Gol Ethics Committee, 27/04/2011

Study design
Cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sub acute low back pain

Interventions
Patients allocated to the control group will receive usual clinical care, and individual intervention based on the application of the Clinical Practice Guidelines in the Pathology of the Lumbar Spine in Adults. These recommendations are published by the Catalan Institute of Health (Institut Català de la Salut).

In addition to the same individual intervention as the control group, patients allocated to the intervention group will receive an educational booklet The Back Manual (a transculturally adapted Spanish version of the Back Book) and a biopsychosocial multidisciplinary group intervention. The group intervention will be carried out by a GP, a nurse, a psychologist and a physiotherapist. The programme consists of 2 sessions of 4 hours duration each and 1 session of 2 hours duration. Each group includes up to 12 participants. To guarantee the standardisation of the group sessions, only one qualified psychologist and one physiotherapist, both of them with extensive expertise in development of training groups, will apply the intervention in all PHCCs.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The primary effectiveness measures of the study consist of Roland Morris Disability Questionnaire (RDQ) (scale 0-24; lower score indicates lower disability), Mc Gill Pain Questionnaire (including VAS 1-10; lower score indicates less pain), and Goldberg questionnaire

on anxiety and depression
2. Duration of days of pain, the reduction of days off work, the reduction of prescription, the duration of pharmacological treatments and recurrent episodes of LBP and the incidence of chronic LBP at 12 months will be measured
3. The primary utility measure of the study is quality adjusted life years (QALYs), and will be calculated from the SF-12 scores (scale 0-100; lower score indicates poorer quality of life)

Secondary outcome measures
1. Inadequate behaviour and work factors assessed by Fear Avoidance Beliefs Questionnaire (FAB) (scale 0-24; lower score indicates lower fear-avoidance belief), and the Goldberg questionnaire of anxiety and depression (each scale 0-9; lower scores indicates less anxiety or depression)
2. All these questionnaires are validated in Spanish
3. Patients assessment of global perceived effect on health will be measured by self-assessment with a Likert 7-point scale

Overall study start date
15/07/2011

Completion date
15/12/2013

Eligibility

Key inclusion criteria
1. The current episode of LBP occurs suddenly after at least 6 months without LBP and lasts between 15 days and 12 weeks
2. Do not fulfil any of the exclusion criteria
3. Furthermore, patients must be between 18 and 65 years old
4. Can understand Catalan or Spanish
4. Available to participate for at least 12 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
932

Key exclusion criteria
1. They are unwilling to participate in the multidisciplinary intervention trial
2. LBP coexists with cognitive impairment, severe psychiatric disorders such as psychosis, or

severe major depression
3. Any other cause of disability impedes answering the various questionnaires
4. They are pregnant or breast-feeding
5. They might have anti-inflammatory intolerance or allergy
6. Treatment has been received for physical problems in the preceding 3 months
7. They have been referred for intensive functional restoration programmes
8. Tthey have a confirmed diagnosis of fibromyalgia
9. Furthermore, the general practioner has to ensure that the patient has no red flag signs or symptoms that are frequently associated with specific LBP or potentially severe illnesses

Date of first enrolment
15/07/2011

Date of final enrolment
15/12/2013

Locations

Countries of recruitment
Spain

Study participating centre
Gran Via Corts Catalanes
Barcelona
Spain
080007

Sponsor information

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

Sponsor details
Carrer de la TV3
s/n 08970 Sant Joan Despí
Barcelona
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08970

Sponsor type
Charity

Website
http://www.tv3.cat/marato

ROR
https://ror.org/00t5xc355

Funder(s)

Funder type
Charity

Funder Name
TV3 Marathon Foundation (Fundació La Marató de TV3) (Spain) (ref: 071610)

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	22/08/2011	17/12/2020	Yes	No