ISRCTN04323845 https://doi.org/10.1186/ISRCTN04323845

The COPE LBP trial: Cognitive Patient Education for Low Back Pain

Submission date	Recruitment status	[_] Prospectively registered
17/04/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/05/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/02/2010	Musculoskeletal Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Margreth Grotle

Contact details
FORMI - Communication unit for musculoskeletal disorders
Oslo University Hospital
Oslo
Norway
0407

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The COPE LBP trial: Cognitive Patient Education for Low Back Pain - a cluster randomised controlled trial in primary care

Acronym
COPE

Study objectives
Our main hypothesis is that this cognitive intervention will result in higher physical function as compared to usual care. We also hypothesise that the cognitive intervention results in more decreased pain, more satisfied patients, better quality-of life, and is more cost-effective than usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Norwegian Regional Committee for Medical Research Ethics, Health Region South-East gave approval in January 2009 (ref: S-08362a, 2008/10435)

Study design
Stratified cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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
Non-specific low back pain

Interventions
Stratified cluster randomised controlled trial with family doctors (GP) and physiotherapists (PT) as unit for randomisation. Follow-up after intervention at 4 - 5 weeks, and at 3, 6, and 12 months.

The professionals will be trained in the specific model of LBP treatment based on the biopsychosocial understanding of LBP and the "intensive neurophysiology education". They will thereafter provide their LBP patients in their normal clinical settings with a four-session treatment program consisting of this education program in addition to their normal treatment. The messages provided to the patients by their caregiver will be specifically according to the manual for the trial.

The "intensive neurophysiology education" is developed by a group of British and Australian researchers as an education program for patients with LBP. The cognitive elements of this program is basically an understanding of pain which differs somewhat from the traditional "injury model". The core of this theory is the neurophysiology of pain as sensitisation and neuronal response to inactivity and movement control.

Based on this, the education program has three basic elements:
1. Reduction of what the patient perceive as threatening inputs to the brain
2. Targeting the patients own understanding of the pain
3. Exposure to the threatening inputs

Previous studies have documented additional effect of the "intensive neurophysiology education" when combined with physiotherapy treatment. The treatment will be given in four 30-minute sessions once a week for four consecutive weeks. The treatment is specified in a manual for this trial and all intervention doctors and physiotherapists have attended the 18 lessons course. They are also provided with a written summary of the content of each session.

Each of the sessions has a specific content of education and discussion in the one-to-one setting between the provider and the patient. Initially the discussion concerns the thoughts and fears of the patients and their LBP. Eventually, the education program will be more and more dealing with exposure to movements and daily activities the patient more or less deliberately avoid of fear from provoking pain. The patients will be given lessons between the sessions, in addition to registrations on function, pain and work absence.

Control group:
The providers of the two control groups will be asked to in a similar manner register and include all patients meeting the inclusion criteria. These patients will also answer on all questionnaires, and will meet their provider weekly for up to four weeks. These sessions have no defined content, but the providers will spend somewhat more time on these patients than the regular schedule asking more deeply what prevents the patient from resuming normal activity.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Function (disability) assessed by the Roland Morris Disability Questionnaire (RMQ), a self-administered questionnaire with score 0 - 24, with 0 corresponding to no disability.

Secondary outcome measures
1. Pain; measured on a numerical rating scale from 0 to 10
2. Return to work; reported as number of days from first visit to the health care provider until completely or partially return to work - and as a total number of days absent from work the following year
3. Overall satisfaction; measured on a numerical rating scale from 0 to 10
4. Health related quality of life; assessed by the EuroQoL-5D and Patient-Generated Index (PGI)

5. A cost-effectiveness analysis will be carried out by using both the return-to work outcome and the EuroQoL 5D, and by estimating the total cost of all the four groups of doctors and physiotherapists in this trial

Overall study start date
14/01/2009

Completion date
31/12/2011

Eligibility

Key inclusion criteria
Each practitioner will recruit up to 10 patients, aged 20 to 55 years (either sex), with non-specific subacute/chronic low back pain (LBP) of less than 1 year duration.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Provider's uncertainty of diagnosis
2. Possible nerve root pain or severe pathology
3. Signs of any 'red flags'
4. Particular interest or demand for a specific treatment

Date of first enrolment
14/01/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Norway

Study participating centre
FORMI - Communication unit for musculoskeletal disorders
Oslo

Norway
0407

Sponsor information

Organisation
Oslo University Hospital (Norway)

Sponsor details
FORMI - Communication unit for musculoskeletal disorders
Oslo
Norway
0407

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j9c2840

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Oslo University Hospital (Norway) - FORMI (Communication unit for musculoskeletal disorders) will defray costs until a formal funder has been found

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	16/02/2010		Yes	No