ISRCTN68205910 https://doi.org/10.1186/ISRCTN68205910

Evaluation of a risk tailored intervention among low back pain patients in primary care

Submission date
10/03/2009

Recruitment status
No longer recruiting

Registration date
29/05/2009

Overall study status
Completed

Last Edited
07/01/2010

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
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

Evaluation of a risk tailored intervention among low back pain patients in primary care: a cluster randomised controlled trial

Study objectives
To assess the effectiveness of a risk tailored intervention among low back pain patients in primary care in improving patient outcomes.

Primary hypothesis:
The risk tailored intervention is more effective in reducing disability compared to treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Medical Faculty, University of Greifswald approved on the 2nd October 2008
2. Ethics Committee of the Medical Faculty, University of Göttingen approved on the 21st January 2009

Study design
Cluster randomised controlled trial, two treatment arms

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
Low back pain without specific origin

Interventions
The intervention consists of two elements:
1. A risk-factor screening and risk tailored educational intervention including information and counselling
2. A telephone/email consulting service concerning back pain related problems independent of risk group assignment

Both elements will be described subsequently:

Risk screening:
All patients fill out a brief risk screening inventory concerning yellow flags that are predictive of chronic back pain. Based on the results patients will be assigned to one of three risk groups (low /intermediate/high).

The tailored interventions are based on the risk factor assignment as follows:
1. Low level risk: patients receive advice on staying active by the general practitioner and will be handed an educational booklet. This booklet aims at reducing erroneous back related beliefs and fosters active health related behaviours. It argues against a biomechanical model by emphasising psychological and social aspects of back problems. Patients receive information regarding local health activities promoting physical exercise, sports, relaxation.
2. Physical risk group: in addition to the physicians' advices and the back book patients in will be offered participation in a guideline based intervention group that consists of two meetings of 120 minutes duration each. The main focus of these manualised meetings will be: education on "back myths" and risk factors, relaxation techniques, and motivation to stay active. Training selected physical exercises is a key element of these meetings. The groups will be conducted by experienced physiotherapists, and exercise therapists. The group size is limited to ten patients.
3. Psychological risk group: patients will receive physicians' advice and the back book. In addition, they will be invited to participate in a psychosocial risk factor group that comprises two additional meetings of 120 minutes duration each. These meetings will be conducted by psychologists with a specialisation in pain treatment. Patients receive a manualised cognitive-behavioural intervention that focusses on pain and strain prone situations as well as on catastrophising, depressive, and fear-avoidant cognitions. The group size is limited to five patients.
4. Combined physical and psychological risk group: patients will receive physicians' advice, the back book and an invitation to particiapte in both intervention groups as described above.

An attendance list will be taken for every course to monitor compliance. Patients receive an illustrated handbook designed specifically for the purpose of this trial with information on all covered topics. All therapeutic sessions will be structured based on a written manual. All participating therapists will have attended a training session of four hours.

Telephone, email counselling:
It is the aim of this counseling offer to answer back pain related questions that usually cannot be handled during a normal consultation. Local study coordinators (usually physiotherapists) will take on enquiries and pass them on to the collaborating MDs, psychologists, and sport scientists, as best suited. No diagnoses will be made during these contacts, neither will there be concrete therapeutic recommendations. A manual will be authored to standardise responses given during the telephone/email counselling.

This trial is carried out in cooperation with:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Functional disability as measured with the Hanover Functional Ability Questionnaire
2. Days of sick leave (over a 3-month recall period)

Secondary outcome measures
Patients' characteristics as measured by a questionnaire:
1. Graded chronic pain (Graded Chronic Pain Scale [GCPS])
2. Depression (Patient Health Questionnaire, German version [PHQ-D])
3. Quality of life (PHQ-D, 12-item short form [SF-12])
4. Fear Avoidance Beliefs Questionnaire (FABQ)
5. Physical activity
6. Catastrophising (Fatigue Severity Scale [FSS])
7. Health services utilisation

All measures will be assessed at baseline and, 6 and 12 months after inclusion in the study. Additionally, participation in the counselling groups and telephone/email contacts will be documented.

Overall study start date
16/03/2009

Completion date
30/03/2011

Eligibility

Key inclusion criteria
General Practitioners (GPs) in Göttingen and within 20 minutes driving distance of the study centre and Berlin (less than 15 km distance from the study centre) are invited to take part in the trial by letter. Addresses were obtained from the local health boards. In case of non-response to the letter, GPs are contacted by telephone or personally.

The GPs recruit patients according to the following inclusion criteria:
1. Men and women aged 20 - 60 years
2. Consultation for low back pain
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40 GPs, 1200 patients

Key exclusion criteria
Patient:
1. Severe comorbidities (e.g. congestive heart failure, tumour)
2. Back pain of specific origin
3. Insufficient German language proficiency
4. Ongoing juridical proceedings due to pension claims
5. Prior spine surgery
6. Ongoing specialised pain treatment
7. Rehabilitation because of back pain in the past five years

Date of first enrolment
16/03/2009

Date of final enrolment
30/03/2011

Locations

Countries of recruitment
Germany

Study participating centre

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Sponsor information

Organisation
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

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Sponsor type
Government

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ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany) (ref: 01EM0113)

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	05/01/2010		Yes	No