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Classification-based approach for low back pain in primary care

Submission date
04/04/2019

Recruitment status
No longer recruiting

Registration date
13/05/2019

Overall study status
Completed

Last Edited
10/02/2025

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Low back pain (LBP) is the most common disabling health condition worldwide. It causes suffering for individuals and financial burden for society. Over 90% of LBP patients are classified as non-specific. Unhelpful beliefs and inappropriate imaging are common. Imaging findings are usual also in people without LBP. LBP is understood as complex biopsychosocial symptom with many known multidimensional (symptom-related, lifestyle, psychological and social) risk factors for persistent or prolonged disability.
StarT Back Screening Tool (SBST) is developed for early identification of individual risk factors of LBP patients to enable targeted care. Using SBST as a screening method for classification-based approach has been shown to improve primary care efficiency for LBP patients. Biopsychosocially oriented patient education booklet, which include imagine guideline and resource, is a possible way to increase patients' understanding of LBP and decrease inappropriate imaging.
Aim of this study, is to investigate whether the implementation of classification-based biopsychosocial approach for LBP patients in primary care is effective and cost saving compared to best current care.

Who can participate?
Anyone aged 18-years who has had low back pain for longer than two weeks can take part.

What does the study involve?
The study involves low back pain patient information and imaging policy. Participating requires 20min time to answer web-based questionnaire four times in 3 years.

What are the possible benefits and risks of participating?
Participating in the study gives new knowledge and enables improvement of patient information in low back pain. There is no risk for individuals when participating in this study.

Where is the study run from?
Etelä-Savo Social and Health Care District (Essote), Finland

When is the study starting and how long is it expected to run for?
April 2017 to May 2020

Who is funding the study?
1. Department of General Medicine Mikkeli Central Hospital (Essote), Mikkeli, Finland
2. The Finnish Cultural Foundation

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
109/2016

Study information

Scientific Title
Classification-based biopsychosocial approach for low back pain in the primary care compared to best current care – A Benchmarking Controlled Trial

Acronym
Trust Your Back

Study objectives
The classification-based biopsychosocial approach for low back pain (LBP) patients in primary care improves patients' symptoms and work disability compared to best current care. We hypothesize that is also cost saving.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/01/2017, (P.O.Box 8000, FI-90014 University of Oulu, Oulo, Finland; university.of.oulu@oulu.fi; +358 294 48 0000), ref: 109/2016

Study design
Benchmarking Controlled Trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

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

Interventions
Implementation of a classification-based biopsychosocial approach for low back pain patients in primary care.
Organisational level
We will evaluate all possible pathways for low back pain (LBP) patients in each health care region. Direct access to physiotherapist will be emphasized. If the organization uses nurse appointments, premeditated phrases will be taught. Local practices within each health care area will be modified to enable easy access to care according to risk classification. All health care professionals participating in LBP patients' care will be informed about new care pathways. Education about the new strategies to professionals will be organized and written information to each health care area will be provided.
Professionals
We will enhance implementation of classification-based approach as right and equal (to all patients) information is transferred from health care professionals to patients. For this purpose, we will educate all health care professionals in the health care regions who treat LBP patients. Physiotherapists will receive four days (28h) education of screening methods and

biopsychosocially oriented individualized physical therapy. Main messages of the training include to avoid unhelpful/harmful messages and unnecessary imaging in non-specific LBP; and to assess individual psychosocial factors (using StarT Back Screening Tool (SBST) and the short version of Örebro Musculoskeletal Pain Screening Questionnaire).

For physicians, we will give one four-hour session and shorter booster sessions. The four main themes of education are: imaging issues, SBST, life style factors and work disability. We will discuss the relevance of lumbar MRI findings, e.g., the prevalence of findings among asymptomatic adults, and disadvantages of imaging. Key issues on pain medication will be taught. The role of physiotherapy will be emphasized. The physicians will also be taught the main principles of biopsychosocially oriented individualized care.

For nurses we will conduct two two-hour sessions, which include data on natural course of LBP, harm of nocebo messages given by health care providers to patients, risk classification using SBST and the current treatment principles and pathways. Premeditated phrases in electrical medical records will enhance patient history clarification and classification-based care guidance.

Professionals will use SBST systematically for all LBP patients and they will make individual care plan for the patients according to the risk profile. Patient education booklet, which is based on biopsychosocial model, delivers evidence-based information on etiology of LBP and appropriate imaging to patients and also reminds professionals of the biopsychosocial model of LBP. The booklet is translated to Finnish.

Patient level
All LBP patients receive the patient education booklet. Patients will be classified to low-, moderate- or high-risk groups during the first visit in health care based on the SBST. Physicians and physiotherapists will use the SBST as a classification method at the visit of LBP patient. Physicians and physiotherapists will plan the individual treatment process according to risk classification.

Low-risk patients will get advice on pain medication if needed, patient education leaflet based on biopsychosocial model. Referral to physiotherapist are scheduled only when necessary. Medium-risk patients will get advice of pain medication if needed, patient education leaflet based on biopsychosocial model and assessment by a physiotherapist. In addition to clinical examination and patient advice, physiotherapist evaluates patients' pain, fears and mal-adaptive behaviors. Physiotherapy will be individualized and biopsychosocially oriented. Patients are allowed to contact physiotherapist up to eight times over 12 weeks. Additional ad hoc contacts are possible. Co-occurring symptoms will be evaluated and treated if needed. Physiotherapist can refer patient to physician. If needed, the patient will be referred to sleep management group with the focus on non-pharmaceutical treatments, as well as to psychiatric nurse in the health center. Other co-morbidities such as smoking, overweight and type 2 diabetes, will be considered and the patient will be referred to further care if needed. High-risk patients will receive similar treatment protocol as medium-risk patients but with emphasis on psychosocial factors and as short delay for the therapy as possible (less than one week).

Intervention Type
Other

Primary outcome measure
Disability measured using Oswestry disability index (ODI) from baseline to the 12-month follow-up.

Secondary outcome measures
1. Pain and disability: Oswestry disability Index, change from baseline to 3-month follow-up
2. Roland Morris disability questionnaire change from baseline to 12-month follow-up
3. PROMIS (Patient-Reported Outcomes Measurement Information System) (short form 20a) change from baseline to 3- and 12-month follow-ups
4. Frequency of LBP during past 3 months change from baseline to 3- and 12-month follow-ups
5. LBP intensity (NRS) during past week change from baseline to 3- and 12-month follow-ups
6. Leg pain intensity (NRS) during past week change from baseline to 3- and 12-month follow-ups
7. SBST (STarT Back screening tool) change from baseline to 12-month follow-up.
8. Health-related quality of life: EQ-5D (EuroQol five dimensions) change from baseline to 12-month follow-up.
9. Direct costs;
9.1 Physician visit during past year
9.2 Physiotherapist visits during past year
9.3 Nurse visits during past year
9.4 Other health care professional visits (e.g. psychologist) during past year
9.5 Imaging due to LBP (x-ray/MRI/CT) during past year
9.6 Pain medication over the first year and 3 years
9.7 Back operation and other invasive procedures.
10. Indirect costs:
10.1 Days on sick leave during past year (LBP-related and All)
10.2 Disability pensions over the first year and at 3 years.

Overall study start date
05/05/2016

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. 18-65 years of age
2. LBP with or without radicular pain

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Our sample size calculation is based on hypothesis test: (i) to test superiority of Classification-based approach for Low Back Pain in the primary care compared to best current care. For the sample size calculation, we used web-based calculator for Inference for Means: Comparing Two Independent Samples: https://www.stat.ubc.ca/~rollin/stats/ssize/n2.html. Common standard deviation of ODI was 15% (evaluated using preliminary data of this study). Type I error rate is 0.05. A sample size of 284 patients would enable detection of difference of 5% in ODI given 80% power. With a 30% drop-out the final sample size is 406 patients.

Key exclusion criteria
1. First patient-reported contact to health care due to LBP and episode has lasted less than 2 weeks
2. A suspicion of a serious cause for LBP or LBP requiring urgent care.

Date of first enrolment
13/04/2017

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
Finland

Study participating centre
Etelä-Savo Social and Health Care District (Essote)
Porrassalmenkatu 35-37
Mikkeli
Finland
50100

Study participating centre
South Karelia Social and Health Care District (Eksote)
Valto Käkelän katu 3
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Study participating centre
Rovaniemi primary health care
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Sponsor information

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Sponsor type
University/education

Website
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ROR
https://ror.org/03yj89h83

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of General Medicine Mikkeli Central Hospital (Essote), Mikkeli, Finland

Funder Name
The Finnish Cultural Foundation

Results and Publications

Publication and dissemination plan
The results of the trial will be published in peer-reviewed international journals. The results will be disseminated through conventional media and social media.

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/04/2020	08/04/2020	Yes	No
Results article		20/04/2024	10/02/2025	Yes	No