

# Classification-based approach for low back pain in primary care

<b>Submission date</b> 04/04/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 13/05/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/02/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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?

Anna Sofia Simula, [anna.simula@oulu.fi](mailto:anna.simula@oulu.fi)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)

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

#### Key secondary outcome(s)

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**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  
Lappeenranta  
Finland  
35130

**Study participating centre**  
**Rovaniemi primary health care**  
Hallituskatu 7, PL 8216  
Rovaniemi  
Finland  
96101

## **Sponsor information**

**Organisation**  
University of Oulu Center for Life Course Health Research

**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**

## Results and Publications

### 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?
<a href="#">Results article</a>		20/04/2024	10/02/2025	Yes	No
<a href="#">Protocol article</a>	protocol	06/04/2020	08/04/2020	Yes	No