

Management of low back pain in occupational health care using an approach that considers biological, psychological, and social factors

Submission date 22/04/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 13/05/2019	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/12/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Low back pain (LBP) is a complex condition in which biological, psychological, and social factors impact on both the experience of back pain and associated disability. For the vast majority of people with LBP, it is not possible to accurately identify the specific cause. Most people with new episodes of LBP recover quickly; however, recurrence is common and in a small proportion LBP becomes persistent and disabling.

In 2005, a multidimensional biopsychosocially oriented approach to assessment and management strategy LBP was proposed. This approach broadly focuses on personalised pain education, fear reduction, functional activation and adopting healthy lifestyle behaviours for people where serious pathology has been ruled out. The dose of the intervention is tailored to the patient presentation. This cognitive functional approach has been shown to demonstrate superior outcomes compared with the best evidence-based usual care strategy, consisting of manual therapy and exercises, at 12-month follow-up.

The aim of this study is to investigate whether a biopsychosocially oriented approach to LBP leads to improvement of patients' disability at 1 year compared to usual care in occupational health care units. We will also evaluate whether this approach is implemented in the intervention group units 1 year after the recruitment of the last patient and we will interview qualitatively the professionals of the intervention units in order to describe facilitators and barriers to the new treatment approach in occupational health care.

Who can participate?

All patients 18-65 years of age contacting health care due LBP with or without radicular pain were included in the study.

What does the study involve?

Patients will either be treated using the Start Back Tool or receive treatment as usual depending on the health care unit that they visit. Participating requires 20-min time for answering the web-based questionnaire four times over 3 years.

What are the possible benefits and risks of participating?

Patients participating the study are given new knowledge about their pain, which enables improvement of low back pain management. There are no risks for individuals with participation to this study.

Where is the study run from?

Center for Life Course Health Research, University of Oulu, Finland.

When is the study starting and how long is it expected to run for?

September 2017 to November 2018

Who is funding the study?

The Finnish Work Environment Fund (Työsuojelurahasto)

Who is the main contact?

Prof. Jaro Karppinen (scientific), jaro.karppinen@oulu.fi

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

79/2017 (protocol number of the Ethics Committee of the Northern Ostrobothnia Hospital District)

Study information

Scientific Title

Effectiveness of biopsychosocially oriented management of low back pain in occupational health care

Acronym

Back works

Study objectives

The aim of this study is to investigate whether a biopsychosocially oriented approach to LBP leads to improvement of patients' disability at 1 year compared to usual care in occupational health care units. We will also evaluate whether this approach is implemented in the intervention group units 1 year after the recruitment of the last patient and we will interview qualitatively the professionals of the intervention units in order to describe facilitators and barriers to the new treatment approach in occupational health care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/09/2017, Ethics Committee of the University Hospital of Oulu (PPSHP:n alueellinen eettinen toimikunta, Yhtymähallinto N5 (1 krs.), PL 10, 90029 OYS, Finland; +358 40 773 1529; minna.makiniemi@ppshp.fi) ref: 79/2017

Study design

Cluster randomized controlled study

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet (available only in Finnish).

Health condition(s) or problem(s) studied

Low back pain

Interventions

Implementation of classification-based biopsychosocial approach for low back pain patients in occupational health care.

Professionals

The intervention consists of education of professionals with in-house courses and web-based material that enhanced adherence to the biopsychosocial individualized approach for LBP care, evidence-based information for patients (using the new patient information leaflet), avoidance of unnecessary imaging and harmful messages. To help utilize this approach participants were taught to use SBT (STarT Back Screening Tool) and the short version of ÖMPSQ (Örebro Musculoskeletal Pain Screening Questionnaire) as screening tools for LBP patients. We started with a 4-day training in September 2017 with the involvement of the world leading pain psychologist, Prof. Steven Linton. Additionally, an experienced trainer, musculoskeletal physiotherapist, Kasper Ussing from Denmark, guided the study physiotherapists (PT). This training consisted of the theoretical basis of biopsychosocial approach in low back pain management, pain education, psychological risk factors, physical factors and behavioral responses to pain, interview and assessment, and tailored individualized management for LBP. Live patient demonstrations, clinical case problem solving and role plays were used to enhance the learning. Two experienced Finnish PT's (Mikko Lausmaa and Riikka Holopainen) supported the implementation by 1-2 coaching visits to each intervention unit. Additionally, we delivered a written educational package to other professionals participating in treatment of LBP patients in the participating units (nurses, psychologists).

Professionals were instructed to use SBT systematically and to make individual care plans for all LBP patients according to the risk profile. The patient education booklet, which is based on the 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. A two-days booster session was organized in June 2018.

Patient level

All LBP patients received the patient education booklet. Patients were classified to low-, moderate- or high-risk groups during the first visit in health care based on the SBT. Physicians and physiotherapists were instructed to plan the individual treatment process according to risk classification. The low-risk group: advice on pain medication if needed and patient education booklet based on biopsychosocial model. Medium-risk group: an evaluation by a physiotherapist in addition to the low-risk group intervention. High-risk group: similar treatment protocol as medium-risk patients but with emphasis on psychosocial factors and minimal delay for the therapy (preferably less than one week). For all patients, physiotherapists were supposed to evaluate patients' pain, fears and maladaptive behaviors in addition to clinical examination and patient advice. Physiotherapy was supposed to be individualized and biopsychosocially oriented. The number of physiotherapy contacts was not limited but rather physiotherapists were advised to construct individual care plan taking into account patient's ability/disability, possible barriers for recovery and personalized goals. Co-occurring symptoms and comorbidities were told to be taken into consideration and treated if needed. The physiotherapists were allowed to refer patients to other professionals such as occupational psychologists if needed.

Groups are formed using cluster randomization. One cluster is one health care unit or health care area. Participants who visit the intervention health care unit, are allocated to the intervention arm. Participants who visit control health care unit are automatically allocated to the control arm.

Intervention Type

Other

Primary outcome measure

Change in Oswestry Disability Index (ODI) from baseline to 12-month follow-up.

Secondary outcome measures

1. Pain and disability:

1.1 Oswestry Disability Index, change from baseline to 3-month follow-up

1.2 Roland Morris disability questionnaire change from baseline to 12-month follow-up

1.3 PROMIS (Patient-Reported Outcomes Measurement Information System) (short form 20a) change from baseline to 3- and 12-month follow-ups

1.4 Frequency of LBP during past 3 months change from baseline to 3- and 12-month follow-ups

1.5 LBP intensity (NRS, numerical rating scale) during past week change from baseline to 3- and 12-month follow-ups

1.6 Leg pain intensity (NRS) during past week change from baseline to 3- and 12-month follow-ups

1.7 SBT (STarT Back Tool) change from baseline to 12-month follow-up.

2. Health-related quality of life: EQ-5D (EuroQol five dimensions) change from baseline to 12-month follow-up.

3. Direct costs:

3.1 Physician visits during past year

3.2 Physiotherapist visits during past year

3.3 Nurse visits during past year

3.4 Other health care professional visits (e.g. psychologist) during past year

3.5 Imaging due to LBP (x-ray/MRI/CT) during past year

3.6 Pain medication over the first year and 3 years; Back operations and other invasive procedures.

4. Indirect costs

4.1 Days on sick leave during past year (LBP-related and all)

4.2 Disability pensions over the first year and at 3 years

Overall study start date

23/01/2017

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. 18 - 65 years of age

2. LBP with or without radicular pain

3. Signed consent form

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

According to power calculation (in a cluster randomized design), to obtain a 20% difference in the primary outcome (ODI) at 1 year with 80% power, a sample size of 600 is needed

Total final enrolment

315

Key exclusion criteria

1. Age under 18 or over 65 years
2. Serious cause for LBP or LBP requiring urgent care

Date of first enrolment

25/09/2017

Date of final enrolment

29/11/2018

Locations**Countries of recruitment**

Finland

Study participating centre**Attendo Haukipudas**

Teollisuustie 1

Haukipudas

Finland

90830

Study participating centre**Attendo Imatra**

Tainionkoskentie 68

Imatra

Finland

55120

Study participating centre**Attendo Kemi**

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Study participating centre
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Study participating centre

Attendo Rovaniemi

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96100

Study participating centre

Attendo Valkeakoski

Sääksmäentie 1
Valkeakoski
Finland
37600

Study participating centre

Attendo Vantaa

Vernissakatu 6
Vantaa
Finland
01300

Study participating centre

Mehiläinen Espoo

Mehiläinen Espoo Leppävaara
Lääkärikeskus, Työterveysasema
Hevosenkentä 3, Panorama Tower
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Study participating centre

Mehiläinen Espoo Matinkylä

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Espoo
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Study participating centre

Mehiläinen Helsinki Forum

Lääkärikeskus, Työterveysasema

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Pohjoinen Hesperiankatu 17
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Study participating centre
Mehiläinen Jyväskylä
Kauppakatu 35
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Mehiläinen Kokkola
Rantakatu 2 B
Kokkola
Finland
67100

Study participating centre
Mehiläinen Kuopio
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70100

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Työterveys Virta Lakeus
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Study participating centre
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Study participating centre
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90100

Study participating centre
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33100

Study participating centre
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Tampere
Finland
33100

Study participating centre

Terveystalo Lahti Työterveys
Hämeenkatu Hämeenkatu 15
Lahti
Finland
15110

Study participating centre
Terveystalo Varkaus
Terveystalo Varkaus Wredenkatu Wredenkatu 2
Varkaus
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78250

Study participating centre
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Linjurikatu Linjurikatu 12
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78200

Study participating centre
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67200

Study participating centre
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Sponsor information

Organisation
Center for Life Course Health Research, University of Oulu

Sponsor details

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Sponsor type

University/education

Website

<https://www.oulu.fi/medicine/elite>

ROR

<https://ror.org/03yj89h83>

Funder(s)**Funder type**

Government

Funder Name

Työsuojelurahasto

Alternative Name(s)

Finnish Work Environment Fund, Työsuojelurahasto Arbetarskyddsfonden, Työsuojelurahasto | Helsinki

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Finland

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

31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to national regulations.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	interim results	30/12/2019	02/01/2020	Yes	No
Results article		13/04/2021	15/12/2021	Yes	No
Protocol article		04/03/2021	06/11/2023	Yes	No