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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

Registration date
13/05/2019

Overall study status
Ongoing

Last Edited
01/09/2025

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 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

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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
Rivinkarintie 68 C

Kemi
Finland
94800

Study participating centre
Attendo Kempele
Voimatie 6 D
Kempele
Finland
90440

Study participating centre
Attendo Kerava
Kultasepänkatu 8
Kerava
Finland
04250

Study participating centre
Attendo Liminka
Kauppakatu 2
Liminka
Finland
91900

Study participating centre
Attendo Loimaa
Heimolinnankatu 10
Loimaa
Finland
32200

Study participating centre
Attendo Oulu Nuottasaari
Paperitehtaantie 1
Oulu
Finland
90120

Study participating centre
Attendo Rovaniemi
Valtakatu 11
Rovaniemi
Finland
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
Hevosenkenkä 3, Panorama Tower
Espoo
Finland
02600

Study participating centre
Mehiläinen Espoo Matinkylä
Lääkärikeskus, Työterveysasema
Piispanportti 10 A, 3. krs
Espoo
Finland
02200

Study participating centre
Mehiläinen Helsinki Forum
Lääkärikeskus, Työterveysasema

Mannerheimintie 20 B, 4. krs
Helsinki
Finland
00100

Study participating centre
Mehiläinen Helsinki Töölö
Lääkärikeskus, Sairaala, Työterveysasema
Pohjoinen Hesperiankatu 17
Helsinki
Finland
00260

Study participating centre
Mehiläinen Jyväskylä
Kauppakatu 35
Jyväskylä
Finland
40100

Study participating centre
Mehiläinen Kokkola
Rantakatu 2 B
Kokkola
Finland
67100

Study participating centre
Mehiläinen Kuopio
Kauppakatu 39 A
Kuopio
Finland
70100

Study participating centre
Mehiläinen Oulu
Lääkärikeskus, Sairaala, Työterveysasema
Kauppurienkatu 9
Oulu
Finland
90100

Study participating centre
Mehiläinen Turku Artukainen Työterveys
Työterveysasema
Pansiontie 45
Turku
Finland
20210

Study participating centre
Mehiläinen Turku Kauppiaskatu
Lääkärikeskus, Työterveysasema
Kauppiaskatu 8
Turku
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20100

Study participating centre
Mehiläinen Neo Turku
Lääkärikeskus, Sairaala, Työterveysasema
Joukahaisenkatu 6, NEO-talo
Turku
Finland
20520

Study participating centre
Työterveys Virta Lakeus
Työterveysasema Liminka
Liminganraitti 10
C-talo 2. kerros
Liminka
Finland
91900

Study participating centre
Työterveys Virta Oulu, Hallituskatu (Teletalo)
Työterveysasema Hallituskatu (Teletalo)
Hallituskatu 36 A, 5. krs.
Oulu
Finland
90100

Study participating centre
Työterveys Virta Oulu, Rehapolis
Työterveysasema Rehapolis
Kiviharjunlenkki 6, 2 krs.
Oulu
Finland
90220

Study participating centre
Terveystalo Kouvola
Tommolankatu 9
Kouvola
Finland
45130

Study participating centre
Terveystalo Oulu
Albertinkatu 16/Sepänkatu 17
Oulu
Finland
90100

Study participating centre
Terveystalo Tampere
Rautatienkatu 27
Tampere
Finland
33100

Study participating centre
Terveystalo Tampere Tullintori
Hammareninkatu 2 B, 4 krs
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
Finland
78250

Study participating centre
Terveystalo Varkaus
Linjurikatu Linjurikatu 12
Varkaus
Finland
78200

Study participating centre
Työplus Kokkola
Mariankatu 26
Kokkola
Finland
67200

Study participating centre
Pohjola Sairaala Oulu
Kiilakivenkuja 1
Oulu
Finland
90250

Sponsor information

Organisation
Center for Life Course Health Research, University of Oulu

Sponsor details
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90014
+358 294 48 0000
university.of.oulu@oulu.fi

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
Other publications	Interview study	29/08/2025	01/09/2025	Yes	No