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Risk-based identification of patients with musculoskeletal pain and individualized care pathway in primary healthcare (RETAR study) – a benchmarking controlled trial

Submission date
29/07/2024

Recruitment status
Recruiting

Registration date
09/08/2024

Overall study status
Ongoing

Last Edited
05/03/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Musculoskeletal pain is one of the most common reasons for attending primary healthcare and is a leading cause of functional impairment worldwide. In the treatment, a risk classification-based approach, where the intensity of care is matched to the patient's prognosis, has been shown to be effective without increasing costs for low back pain patients, but only one study has evaluated this treatment approach in patients with musculoskeletal pain in general.

The primary goal of this trial is to develop and expedite the recovery of patients with MSK pain in primary healthcare by considering individualized risk profiles in their care. We will implement a new tool, risk of pain spreading (ROPS), that identifies prognostic factors for pain worsening and improvement, use this tool to construct individualized care pathways for primary care physiotherapists. We will investigate the effectiveness and implementation of this model by evaluating both patient-level and implementation/sustainability outcomes using the observational Benchmarking Controlled Trial (BCT) design, comparing the model to usual care. Given the implementation difficulties identified in a previous clinical trial using the StarT MSK Screening Tool, we will assess clinician and organizational level facilitators of and barriers to the implementation among others and develop an implementation strategy through formative measuring of implementation outcomes. Additionally, we will investigate patients' perceptions regarding the model.

We will collect prospectively data from five wellbeing services countries, of which one acts as a pilot unit and is not involved in the final analyses. The primary implementation outcomes will be the usage of the ROPS and the design of treatment according to the ROPS. The primary patient-level outcomes will be a change in functional ability between the baseline and follow-ups, measured with PROMIS-29+2 survey. Patients are followed from baseline up to 36 months.

Who can participate?
Adult patients who need physiotherapeutic care due to their musculoskeletal pain and who will

fulfill the inclusion criteria but none of the exclusion criteria. Musculoskeletal pain is referred to pain in the following anatomical areas: neck/shoulder, upper limb, lower limb, and/or back, or multisite pain (pain in many of these locations).

What does the study involve?
The trial will compare new treatment model for current/usual care by collecting control and intervention groups separately within each participating units. The treatment model will include a new tool that identifies prognostic factors for pain worsening and improvement (ROPS) and usage of this tool to construct individualized care pathways in the management of musculoskeletal pain, and will be targeted at intervention groups' patients. Control groups patients will receive usual care. We will collect prospectively data from five wellbeing services countries, of which one acts as a pilot unit and is not involved in the final analyses. The primary system-level outcomes will be the usage of the ROPS and the design of treatment according to the ROPS. The primary patient-level outcomes will be a change in functional ability between the baseline and follow-ups, measured with PROMIS-29+2 survey. Patients are followed from baseline up to 36 months.

What are the possible benefits and risks of participating?
The trial investigates methods that are not expected to cause any harm to patients. However, if any unexpected serious adverse event occurs, they will be reported to site collaborating investigator within 24 hours using a Safety Reporting Form for a clinical trial, and physiotherapists are guided to refer patients to the appropriate treatment facility. Anticipated disadvantages and inconveniences of the trial are related to the loss of time used to answer the questionnaires and to go through the treatment paths on one’s own time. However, participating in research can also cause unexpected inconveniences. They can be related, among other things, to working through difficult emotions during therapeutic working. This, on the other hand, can be considered to include in the process of therapeutic working. The patients' other care process including physiotherapy itself is not restricted in any way and the physiotherapist's appointment times may be more than in the current care model if needed. If worrying findings (mainly red flag findings/symptoms) are detected at the physiotherapist's visit, the physiotherapist assesses their significance and refers the patient to the appropriate treatment facility.

Where is the study run from?
The trial is led by the University of Oulu (Finland)

When is the study starting and how long is it expected to run for?
June 2024 to December 2034.

Who is funding the study?
The trial will be partly funded by the Finnish Government. Additional funding will be applied from Research Council of Finland and from several foundations.

Who is the main contact?
Professor Jaro Karppinen, jaro.karppinen@oulu.fi, University of Oulu
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Risk-based identification of patients with musculoskeletal pain and individualized care pathway in primary healthcare - A Benchmarking Controlled Trial

Acronym
RETAR

Study objectives
RQ1: Does a risk-based and individually structured care pathway for patients with MSK pain improve their physical functional in primary healthcare settings compared to current practices?
RQ2: Is a risk-based and individually structured care pathway of patients with MSK pain cost-effective compared to current practices?
RQ3: Which factors facilitate or act as barriers to the implementation of the risk-based, structured care pathway from the perspective of medical professionals, and can it be integrated into daily practice?
RQ4: What are patients' experiences regarding the risk-based, structured care model?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/06/2024, The regional medical research ethics committee of the Wellbeing services county of North Ostrobothnia (Pohjois-Pohjanmaan hyvinvointialueen alueellinen lääketieteellinen tutkimuseettinen toimikunta OYS Tutkimuspalveluyksikkö N5, Oulu, PL 10, 90029 OYS, Finland; -; eettinentoimikunta@pohde.fi), ref: 4/2024

Study design
Observational benchmarking controlled trial with a separate pilot

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improving outcomes in patients with musculoskeletal pain

Interventions
The intervention of the trial is the implementation of a new tool, risk of pain spreading (ROPS), including individualized care pathways based on the ROPS. Patients in the intervention group are divided into risk groups defined according to the ROPS (low, moderate, and high risk) and the content of the care is determined accordingly. Intervention groups are contrasted to control groups which are collected before the intervention in each participating units. Control group's patients are treated according to current practices, i.e. they are receiving usual care.

Risk-based care is tailored according to ROPS:
• Low-risk patients: physiotherapists are encouraged to keep the number of possible clinical follow-ups to a minimum and provide an information booklet for the patients (suitable booklets will be gathered during the pilot).
• Moderate-risk patients: "Identify and React" method. No recommendations are given for physiotherapists about the number of follow-ups.
• High-risk patients: "Identify and React" method. A control appointment for physiotherapist at 6 months. During the control visit, the "Identify and Act" method. No recommendations are given for physiotherapists about the number of clinical follow-ups.

"Identify and React" method
1. The physiotherapist discusses with the patient the prognostic factors identified using the ROPS and asks the patient whether the identified ROPS factors are already being taken care of or whether the patient needs treatment for them.
2. If the patient wishes for care, the physiotherapist presents the patient with a care pathway menu, which includes self-care support methods targeted at identified prognostic factors.
3. If the patient wishes for care, but does not want to implement self-care support methods, has gone through these in the past or finds them insufficient, the physiotherapist refers the patient to a healthcare professional that will evaluate further measures according to local procedures.

Intervention Type
Behavioural

Primary outcome(s)
Primary implementation/sustainability outcomes
1. The usage of the ROPS (Risk of Pain Spreading questionnaire) is measured continuously during the intervention phase with checklists targeted at physiotherapists participating in the trial
2. The design of care pathway according to the ROPS (has it occurred or not, and if it has, how) is measured continuously during the intervention phase with checklists targeted at physiotherapists participating in the trial

Primary patient-level outcome measure
1. Functional ability is primarily defined with the PROMIS-29+2 Profile and is measured between the baseline and the follow-up periods of 6, 12 and 36 months

Key secondary outcome(s))
Secondary implementation outcomes
1. Feasibility of the intervention is measured using face-to-face or video call semi-structured interviews and DIBQ-mp questionnaire (modified version of the Determinants of Implementation Behavior Questionnaire), targeted at physiotherapists and patients, at 1 and 12 months after the intervention
2. Adherence to the intervention is measured with questionnaires targeted at patients at 6, 12, and 36 months after the intervention

Secondary patient-level outcome measures
1. Use of health services (visits to different professionals during the follow-up period, care periods, number of and reasons for visits) is based on national registers and questionnaires and is measured at baseline and 6, 12, and 36 months
2. Sick leaves are based on national registers and questionnaires and are measured at baseline and 6, 12, and 36 months
3. Disability pensions are based on national registers and questionnaires and are measured at baseline and 6, 12, and 36 months
4. Health-related quality of life is measured using EuroQol five-dimension, five-level version, EQ-5D-5L, at baseline, and 6, 12, and 36 months
5. Intensity of pain is measured using Numerical Rating Scale (0-10) at baseline and 6, 12, and 36 months
6. Bothersomeness of pain is measured using Numerical Rating Scale (0-10) at baseline and 6, 12, and 36 months
7. Number of pain sites is measured using self-reported pain sites at baseline and 6, 12, and 36 months
8. Patient’s sense of enablement is measured using a modified version of the patient’s sense of

coping (Patient Enablement Instrument, PEI) at 6, 12, and 36 months
9. ROPS value is measured using ROPS questionnaire at baseline and 6, 12, and 36 months.
10. Patient' impression of change is measured using Patient's Global Impression of Change questionnaire at 6, 12, and 36 months
11. Patients' experiences are measured using Face-to-face or video call interviews at 1 and 12 months after the intervention

Completion date
31/12/2034

Eligibility

Key inclusion criteria
1. Patients who will be visiting physiotherapists in primary healthcare due to MSK pain. MSK pain is referred to pain in the following anatomical areas: neck/shoulder, upper limb, lower limb, and /or back, or multisite pain (pain in many of these locations).
2. At least 18 years of age
3. Possibility and ability to use a smart device (phone, computer, or tablet)
4. Consent to take part in the trial.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Red-flag symptoms/findings (acute urinary retention, faecal incontinence, perianal anesthesia, symptoms of paralysis or major numbness of the limbs, fever or unexplainable weight loss related to pain)
2. Trauma as a reason for pain in the past six months
3. Memory disorder
4. Cancer
5. Serious mental health disorder, such as schizophrenia or psychotic depression
6. Pregnancy
7. Operation on the area where musculoskeletal pain occurs within the past year
8. Insufficient Finnish language skills for participating in the interviews and answering the surveys

Date of first enrolment
13/02/2025

Date of final enrolment
31/12/2032

Locations

Countries of recruitment
Finland

Study participating centre
Wellbeing Services County of Lapland
P.O. Box 8041
Rovaniemi
Finland
96101

Study participating centre
Wellbeing Services County of South Savo
Porrassalmenkatu 35–37
Mikkeli
Finland
50100

Study participating centre
Wellbeing Services County of South Karelia
Valto Käkelän katu 3
Lappeenranta
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53130

Study participating centre
Wellbeing Services County of Päijät-Häme
Keskussairaalankatu 7
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Study participating centre
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Sponsor information

Organisation
University of Oulu

ROR
https://ror.org/03yj89h83

Funder(s)

Funder type
Government

Funder Name
Finnish Government

Results and Publications

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 permission restrictions.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes