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Personalized treatment for patients with musculoskeletal disorders in general practice

Submission date
09/05/2022

Recruitment status
No longer recruiting

Registration date
11/05/2022

Overall study status
Completed

Last Edited
21/10/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Background and study aims
Musculoskeletal disorders pain complaints (MSK) represent every fourth patient in primary healthcare services in Norway. Common interventions for patients either lack documentation or at best have modest or short-term effects. Large inter-individual variations in symptoms, signs and patient histories make it difficult to adopt evidence-based guidelines in the clinical setting since they are based on one-size-fits-all evidence from clinical trials. Researchers have therefore developed a system to classify patients into five different groups, called phenotypes, based on scoring on patient characteristics related to biological, psychological and social aspects important for the prognosis of MSK pain complaints. The phenotypes separate patients clearly according to patient characteristics, expected clinical course and treatment outcome. Further, the researchers have developed matched treatment options for the five phenotypes which will be provided to the GPs and the patients in a digital decision support system. The aim of this study is to evaluate the effect of the decision-support system against usual care.

Who can participate?
Adults aged over 18 years presenting to a General Practitioner (GP) with musculoskeletal pain disorder in any of these areas; shoulder, neck, upper/low back, hip, knee or with multisite pain as primary contact reason.

What does the study involve?
The GPs will be randomly allocated to receive access to the decision support system to aid their decision making or to continue giving treatment as usual. The treatment recommendations are provided in four main categories: advice and guidance, work and employment, medications, and referrals. Patients will be treated by the GPs and data will be regularly collected for 12 months to assess if the decision-support system is contributing to improved outcomes for patients.

What are the possible benefits and risks of participating?
Benefits for those in the intervention group are access to a comprehensive overview of the patient's characteristics and reported symptoms at the initiation of treatment, as well as the matched treatment options. Other possible benefits are that the patients will receive more

adequate care, better outcome and reduced health care spending. There are no anticipated risks of participating as the matched treatment options are a part of already established treatment options in general practice.

Where is the study run from?
Norwegian University of Science and Technology (Norway)

When is the study starting and how long is it expected to run for?
January 2021 to June 2025

Who is funding the study?
Norwegian Research Council (Norway)

Who is the main contact?
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Study website
https://www.ntnu.edu/supportprim

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Project number NRC: 303331

Study information

Scientific Title
Stratified care for patients with musculoskeletal disorders in general practice - a cluster randomized controlled study

Acronym
SupportPrim

Study objectives
Relative to usual care, it is hypothesized that stratified care provided by a clinical decision support system results in better globally perceived effects and improved function among patients with common musculoskeletal disorders in general practice

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Committee for Medical Research Ethics Northern Norway defined the project as outside the Health Research Act and the project therefore does not need an ethical approval, application number 376060, date 07/12/2021

Study design
Multicentre cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Common musculoskeletal complaints, including pain in the neck, shoulder, low back, knee, hip and multisite pain

Interventions
General practitioners are randomized to the intervention group or the control group in a 1 to 1 ratio. The randomisation procedure will be performed by a third party, the Clinical Research Unit in Central Norway.

The GPs and their patients in the intervention group will get access to a clinician dashboard where the stratified care intervention will be provided. The stratified care intervention consists of three main steps. First, based on the pre-completion of various questionnaires by the patient, the patient profile in the clinician dashboard summarizes the patient characteristics and the patient's phenotype from 1-5 is calculated based on 11 established prognostic factors. Next, the GPs can fill in the diagnostic code (International Classification of Primary Care [ICPC]-2 code) and decide the patient's main problem. Third, the GP and the patient can view what treatment is

recommended based on the patient's phenotype and other specific factors. The patient and the GP decide a treatment plan together trough a shared decision-making process. The treatment recommendations are provided in four main categories: advice and guidance, work and employment, medications, and referrals. The GPs in the control group will receive usual care without access to the patient profile and treatment recommendations in the clinician dashboard. Patients will be treated by the GPs and data will be regularly collected for 12 months to assess if the decision-support system is contributing to improved outcomes for patients.

Intervention Type
Other

Primary outcome measure
This study has two primary outcomes:
1. Global perceived effect at 3 months. Global perceived effect is assessed with the question "Since treatment started, I am:" with 7 different response option: very much better, much better, little better, not better nor worse, little worse, much worse, very much worse. The response options are dichotomized into improved = very much better and much better, and not improved = the other response options. The primary outcome is the proportion reporting improved at 3 months.
2. Clinically important improvement in function at 3 months, measured by the Patient-Specific Function Scale (PSFS; 0-10), where a 30% change is defined as a minimal clinically important difference (MCID). The primary outcome is the proportion reporting MCID at 3 months.

Secondary outcome measures
Measured at baseline and 3, 6 and 12 month follow-up:
1. Pain intensity measured using a Numerical Rating Scale (NRS; 0-10)
2. Pain drawing: number of pain sites measured using the Nordic Pain questionnaire and the pain mannequin with 10 possible pain sites
3. Frequency of pain measured using the question “Is the pain continuous? With the response option “yes, I have pain all the time” and “no, the pain is on and off”
4. Quality of life measured using EQ-5D-5L, five items
5. Health-related quality of life (sleep and vitality) measured using 15D
6. General musculoskeletal health measured using the Musculoskeletal Health Questionnaire (MSK-HQ)
7. Number of treatments by 3 months measured using patient records
8. Patient-reported function measured using the Patient-specific functional scale (PSFS; 0-10) (only 6 and 12 months)
9. Work ability measured using a single item from Work Ability Index; current work ability compared with lifetime best
10. Work status/sick leave measured using patient records
11. Medication measured using patient records
12. Patient-GP relationship measured using three questions (overall satisfaction, belief in GP's competency, and communication)
13. Patient Acceptable Symptom State (PASS) measured by the question: "Considering your pain complaint, do you consider your current state as satisfactory?", with the response option yes/no.
14. Adherence to the treatment plan assessed using five alternatives
15. Goal achievement (not, partly, or fully achieved) measured using patient records
16. Most important reason for success/non-success (text) at 3 months only
18. Physical activity measured using three questions (frequency, intensity and duration)
19. Emotional distress measured using the Hopkins Symptom Check List (HSCL-10)
20. Pain self-efficacy measured using two questions from Pain Self-Efficacy Questionnaire

(PSEQ) 2-item
21. Cost-effectiveness analysed based on patients' deductibles and costs covered by the Norwegian Health Economics Administration (HELFO) and utility measured by EQ-5D
22. GP's compliance with the treatment advice from the decision support system measured using information from the GPs' medical records and the treatment plan decided by the GPs and patients
23. Compliance between treatment advice from the decision support system, treatment plan decided at the first consultation and the actual treatment provided according to the medical record

Measured at 2, 4 and 8 weeks by SMS (text messages). These will be analyzed as time to event:
1. Patient-specific functional scale (PSFS)
2. Work ability
3. Global perceived effect
4. Pain intensity at 2 and 8 weeks only
5. Pain self-efficacy at 2 and 8 weeks only

Overall study start date
01/01/2021

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Patients presenting to a primary care general practitioner with musculoskeletal pain disorder in any of these areas: shoulder, neck, upper/low back, hip, knee or with multisite pain as primary contact reason
2. Age above 18 years
3. Understand written and oral Norwegian, and can write Norwegian

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
In short, the predetermined effect size to be detected is a 15% difference in improvement (GPE) between the two groups, which requires 280 patients in each arm, in total 560 patients. To account for a 15-20% drop-out among the patients and 5-10% among the GPs, the researchers will include 22 GPs in each arm and 17 patients in each cluster, giving a total of 748 patients

Total final enrolment
299

Key exclusion criteria
1. Neurological diagnosis, such as (multiple sclerosis, stroke, amyotrophic lateral sclerosis, Parkinson's, dementia)
2. Ongoing cancer disease
3. Planned surgery related to the MSK complaint for seeking treatment, or have had surgery or fracture related to the MSK complaint in the last 6 months.
4. Pregnancy or complaints related to pregnancy

Date of first enrolment
18/05/2022

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
Norway

Study participating centre
Norwegian University of Science and Technology
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/05xg72x27

Funder(s)

Funder type
Research council

Funder Name
Norges Forskningsråd

Alternative Name(s)
Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Results and Publications

Publication and dissemination plan
1. Planned publications in high-impact peer-reviewed journals
2. Communicating the study aims and general information through an institutional blog and project web page
3. Dissemination in social media and national and international conferences.

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (Prof. Ottar Vasseljen, ottar.vasseljen@ntnu.no). Anonymized clustered and participant-level data can be shared after acceptance of publications of main results, providing a relevant research question and ethical approval of the study protocol is documented, including whether data sharing is covered by the current, approved consent from participants. Collaborative research efforts and work is appreciated.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/04/2023	12/04/2023	Yes	No
Statistical Analysis Plan	SAP preprint	06/10/2023	15/03/2024	No	No