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Optimizing management of musculoskeletal pain disorders in primary physiotherapy care

Submission date
05/01/2021

Recruitment status
No longer recruiting

Registration date
18/01/2021

Overall study status
Completed

Last Edited
04/12/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] 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 (MSDs) are the number one cause of years lived with disability and reduced health worldwide. In Norway, every fourth patient in primary care suffers from MSDs. Treatment effects are however modest and knowledge of best practice limited. The SupportPrim project will address these challenges in two main steps:
Firstly, to optimize person-centered care, we will employ methods from artificial intelligence in terms of Case-Based Reasoning to build a clinical decision support system (cDSS) based on patient data already collected in primary care physiotherapy. Case-Based Reasoning aims to solve new problems based on the solutions to similar problems in the past. In other words, previous MSD cases will be used to help similar cases in the future, just as humans learn from their own experience. We will then assess the efficacy of the cDSS in physiotherapy practice in a cluster-randomized controlled trial.
Secondly, this effort will be expanded to general practice by implementing The STarT MSK screening Tool as the basis for stratified care for MSD patients. The efficacy of stratified care will be assessed in a cluster-randomized controlled trial in general practice.

Who can participate?
Adults over 18 years, presenting to a primary care physiotherapist with musculoskeletal pain disorder in any of these areas; shoulder, neck, upper/low back, hip, knee or with multisite pain as primary contact reason. Also 40 physiotherapists will participate.

What does the study involve?
The physiotherapists will be randomly allocated to receive access to the cDSS to aid their physiotherapy practice or to continue giving treatment as usual. Patients will be treated by the physiotherapists and data will be regularly collected for 12 months to assess if the cDSS is contributing to improved outcomes for patients.

What are the possible benefits and risks of participating?
Benefits for those in the intervention group is access to a comprehensive overview of the patient's characteristics and reported symptoms at initiation of treatment, as well as treatment advice (on-screen) based on previous, similar patients with successful outcome, which is to be used in a co-decision process between therapist and patient for optimal management of the

current patient.
Participation in the project does not entail any risks or disadvantages in relation to ordinary physiotherapy treatment, as management is at the discretion of the therapist.

Where is the study run from?
Norwegian University of Science and Technology in collaboration with 40 physiotherapists at different private primary care clinics throughout Norway

When is the study starting and how long is it expected to run for?
February 2019 to September 2022

Who is funding the study?
Norges Forskningsråd (Norwegian Research Council)

Who is the main contact?
Dr Ingebrigt Meisingset, Ingebrigt.meisingset@ntnu.no

Study website
https://www.ntnu.edu/supportprim

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
Project number NRC: 303331

Study information

Scientific Title
An AI-based clinical decision support system for personalized care of common musculoskeletal pain disorders in primary physiotherapy care

Acronym
SupportPrim

Study objectives
Relative to usual care, we hypothesize that personalized care provided by a clinical decision support system founded in artificial intelligence results in better globally perceived effects and improved function among patients with common musculoskeletal disorders in primary physiotherapy care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/09/2020, Regional Committee for Medical Research Ethics - Mid Norway (NTNU /REK midt, Det medisinske fakultet, Postboks 8905, 7491 Trondheim, Norway; +47 73 59 75 11; rek-midt@mh.ntnu.no), ref. 493080

Study design
Multicentre cluster-randomized controlled trial where individual physiotherapists serve as clusters

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Improved treatment outcome for patients with common musculoskeletal disorders such as neck, shoulder, low back, hip, knee and multisite pain

Interventions
To implement personalized care, we will employ innovative methods from artificial intelligence (AI) in terms of Case-Based Reasoning (CBR) to build a clinical decision support system (cDSS) based on patient data already collected in primary care physiotherapy. The CBR methodology

will be used to match new patients to previous, similar patients with successful outcome, i.e. it enables a patient-centered intervention based on what has been successful in previous, similar cases. Results from the CBR will be displayed in a clinical dashboard, i.e. the cDSS, for shared decision-making and optimal management of new patients with common musculoskeletal disorders.

Physiotherapists in the intervention group will be provided access to the cDSS, while physiotherapist randomized to the usual care group will carry on patient management as usual without access to the cDSS.

Duration of treatment and number of treatments is at the discretion of each therapist and it is up to each therapist to terminate the treatment. Patients are followed up for 12 months for the purposes of data collection.

Randomisation
We will randomise the therapists (clusters) in 1:1 ratio to the control and intervention groups (automated computerized procedure).

Intervention Type
Other

Primary outcome measure
1. Patients' assessment of their condition measured by Global perceived effect (GPE), a seven-point Likert scale, at 3, 6 and 12 months. The GPE scale will be dichotomized as “improved” (score 1-2) or "unchanged/worse" (score 3-7).
2. Clinically important improvement in function, measured by the Patient Specific Function Scale (PSFS; 0-10), where a 30% change is defined as a Minimal clinically important difference (MCID). PSFS will be measured at baseline, 2, 4, 8 and 12 weeks

Secondary outcome measures
At baseline and 3, 6 and 12 month follow-up secondary outcomes include:
1. Pain intensity (NRS; 0-10)
2. Pain drawing, number of pain sites
3. Pain mapping; how often, continuous (of and on), daily variation
4. EQ-5D-5L (quality of life), five items
5. 15D (health-related quality of life, two items; sleep and vitality
6. Musculoskeletal Health Questionnaire (MSK-HQ)
7. Number of treatments by 3 months (patient records)
8. Patient-specific functional scale (PSFS; 0-10)
9. Work ability (single item from Work Ability Index; current work ability compared with life-time best
10. Work status/sick leave (patient records)
11. Medication (patient records)
12. Patient-therapist relationship (3 questions); overall satisfaction, belief in therapist's competency, and communication
13. Benefits of physiotherapy and expectations to physiotherapist (2 questions)
14. Adherence to treatment plan (5 alternatives)
15. Goal achievement (not, partly, or fully achieved) (patient records)
16. Most important reason for success/non-success (text), at 3 months only
17. Still receiving physiotherapy after 3, 6 and 12 months (yes/no)
18. Physical activity, 3 questions; frequency, intensity and duration

19. Hopkins Symptom Check List, HSCL-10 (emotional distress)
20. Pain Self efficacy, 2 questions (from PSEQ 2-item)
21. Cost-utility based on patients deductibles and costs covered by the Norwegian Health Economics Administration (HELFO) and utility measured by EQ-5D

At 2, 4 and 8 weeks secondary outcomes collected by SMS (text-messages):
1. Patient-specific functional scale
2. Work ability
3. Global perceived effect score
4. Pain intensity, at 2 and 8 weeks only
5. Pain self-efficacy, at 2 and 8 weeks only

Overall study start date
01/02/2019

Completion date
01/09/2022

Eligibility

Key inclusion criteria
1. Patients presenting to a primary care physiotherapist 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. Physiotherapists with the patient participants in their current patient population

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 clusters (physiotherapists), 20 in the intervention and 20 in the control group, and 18 patients in each cluster giving a total of 720 patients. Revised 09/11/2021: To account for possible dropout at the cluster level four additional clusters were randomized, two to each arms (June 2021). Revised 30/11/2021: The original effect size was set to a 15% difference in global perceived effect (improved) between the groups at 3 months follow-up. With a preset power of 0.8 and alpha of 0.05 this gave a sample size of 560 patients. The researchers assumed an attrition rate at 3 months follow-up of 25-30% and thus planned to include 720 patients. Attrition rates proved to be much lower and after including 687 patients the attrition rate is 13%. Consequently, only 633 patients are needed to meet preset power to detect a difference of 15% between groups. Thus, the inclusion (baseline) is stopped at 687 patients by 01/12/2021.

Revised 03/05/2022: There was a time lag between clinicians reaching the predetermined number of recruited patients (n=18) and feedback from the research team to stop recruitment, resulting in some clinicians recruiting more than 18 patients. We consider it unethical not to include those extra patients in the study and therefore the total final enrolment is 724. No analyses have yet been performed and the participants' group allocation is still blinded to the researchers. We also noticed an error for start of randomization, which was set at June 2021. Now revised to the correct date which was 18/01/2021

Total final enrolment
298

Key exclusion criteria
1. Reduced cognitive function or skills in Norwegian (impeding reading, speaking or comprehension of Norwegian language)
2. Neurological diagnosis (e.g. multiple sclerosis, stroke, ALS, Parkinson, dementia)
3. On-going cancer
4. Pregnancy or pregnancy-related disorders
5. Scheduled for surgery or recent surgery or fracture within the last 6 months

Date of first enrolment
01/02/2021

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
Norway

Study participating centre
Norwegian University of Science and Technology in collaboration with 40 physiotherapists at different private primary care clinics throughout Norway
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Sponsor information

Organisation
Norwegian University of Science and Technology

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Sponsor type
University/education

Website
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ROR
https://ror.org/05xg72x27

Funder(s)

Funder type
Government

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
Planned publications in high-impact peer-reviewed journals. Communicating the study aims and general information through our institutional blog and project web-page. Dissemination in social media, national and international conferences. Anonymized participant-level data can be shared upon request after after acceptance of publications of main results.

Intention to publish date
01/03/2025

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. Dr Ingebrigt Meisingset, Ingebrigt.meisingset@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?
Participant information sheet			04/02/2021	No	Yes
Participant information sheet			04/02/2021	No	Yes
Statistical Analysis Plan	version 1.0	14/06/2022	01/07/2022	No	No
Statistical Analysis Plan	version 2.0	01/03/2023	01/03/2023	No	No