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The patient education booklet as part of low back pain (LBP) care in primary care compared with best current care.

Submission date
04/04/2019

Recruitment status
No longer recruiting

Registration date
13/05/2019

Overall study status
Completed

Last Edited
01/03/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
For most patients with low back pain no serious or specific cause for pain can be demonstrated. International guidelines recommend a biopsychosocial approach for LBP care and avoidance of inappropriate imaging. Implementation of guidelines is insufficient. Inaccurate beliefs about LBP and inappropriate imaging is common.
Professionals describe patients´ wish for imaging as a barrier for following imaging guidelines, while the patients ask for an explanation for their pain. New evidence-based patient education including information about imaging guidelines, the nature of LBP, and appropriate management strategies has been developed. Use of the booklet during the consultation could help clinicians to support patients in their care, and facilitate better understanding of LBP and recovery. This booklet was translated into Finnish and the booklet will be used in this trial in the intervention.

Who can participate?
Anyone aged 18-years who has had low back pain for longer than two weeks can take part.

What does the study involve?
The study involves low back pain patient information and imaging policy. Participating requires 20min time to answer web-based questionnaire four times in 3 years.

What are the possible benefits and risks of participating?
Participating the study gives new knowledge and enables improvement of patient information in low back pain. There is no risk for individuals when participating this study.

Where is the study run from?
Etelä-Savo Social and Health Care District (Essote), Finland

When is the study starting and how long is it expected to run for?
April 2017 to May 2020

Who is funding the study?
1. Department of General Medicine Mikkeli Central Hospital (Essote), Mikkeli, Finland
2. The Finnish Cultural Foundation

Who is the main contact?
Anna Sofia Simula, anna.simula@oulu.fi

Contact information

Type(s)
Scientific

Contact name
Mrs Anna-Sofia Simula

ORCID ID
https://orcid.org/0000-0003-0796-4892

Contact details
Center for Life Course Health Research
P.O.Box 8000
Oulu
Finland
50100
+358 294 48 0000
anna.simula@oulu.fi

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
109/2016

Study information

Scientific Title
A cluster randomized clinical trial of the use of the patient education booklet as part of low back pain (LBP) care in primary care compared with best current care.

Acronym
Booklet For Back

Study objectives

Implementation of the “Understanding Low back pain” patient education booklet to primary care will decrease imaging examinations due to LBP compared to best current care.

Implementation of the “Understanding Low back pain” patient education booklet to primary care will improve the effectiveness of LBP care in the primary care compared to best current care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/01/2017, Ethics Committee of the University Hospital of Oulu (P.O.Box 8000, FI-90014 University of Oulu, Oulo, Finland; university.of.oulu@oulu.fi; +358 294 48 0000), ref: 109 /2016

Study design
Cluster randomized controlled study.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low back pain

Interventions
The intervention is a short 30 min education training session for physiotherapists and physicians containing the main themes and theory of the new patient education booklet. The booklet is provided for use as part of care for all LBP patients in the intervention health care units. The professionals are supposed to use the booklet during the appointment, but they can use it as they want. Otherwise the care will be provided as usual.

Randomizing process: One cluster is one health care unit or health care area. Participant who visit intervention health care unit, include to intervention. Participants who visit control health care unit is automatically allocated to control.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 30/10/2019:
1. Change in PROMIS PF-20 (Patient-Reported Outcomes Measurement Information System, 20-item physical functioning short form) from baseline to 3-month follow-up.
2. The proportion of patients presenting with LBP who receive imaging examinations due to LBP over the first three months of follow-up.

Previous primary outcome measure:
1. Change in Oswestry disability index (ODI) from baseline to the 12-month follow-up
2. Number of imaging examinations due LBP over the 3-month follow up.

Key secondary outcome(s))
1. Pain and disability: Oswestry disability Index, change from baseline to 12-month follow-up
2. Roland Morris disability questionnaire change from baseline to 12-month follow-up
3. PROMIS (Patient-Reported Outcomes Measurement Information System) (short form 20a) change from baseline to 3- and 12-month follow-ups
4. Frequency of LBP during past 3 months change from baseline to 3- and 12-month follow-ups
5. LBP intensity (NRS) during past week change from baseline to 3- and 12-month follow-ups
6. Leg pain intensity (NRS) during past week change from baseline to 3- and 12-month follow-ups
7. SBST (STarT Back screening tool) change from baseline to 12-month follow-up.
8. Health-related quality of life: EQ-5D (EuroQol five dimensions) change from baseline to 12-month follow-up.
9. Direct costs:
9.1 Physician visit during past year
9.2 Physiotherapist visits during past year
9.3 Nurse visits during past year
9.4 Other health care professional visits (e.g. psychologist) during past year
9.5 Imaging due to LBP (x-ray/MRI/CT) during past year
9.6 Pain medication over the first year and 3 years
9.7 Back operation and other invasive procedures.
10. Indirect costs:
10.1 Days on sick leave during past year (LBP-related and All)
10.2 Disability pensions over the first year and at 3 years.

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. 18-65 years of age
2. LBP with or without radicular pain

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
420

Key exclusion criteria
1. First patient-reported contact to health care due to LBP and episode has lasted less than 2 weeks
2. A suspicion of a serious cause for LBP or LBP requiring urgent care.

Date of first enrolment
13/04/2017

Date of final enrolment
30/05/2020

Locations

Countries of recruitment
Finland

Study participating centre
Etelä-Savo Social and Health Care District (Essote)
Porrassalmenkatu 35-37
Mikkeli
Finland
50100

Study participating centre
South Karelia Social and Health Care District (Eksote)
Valto Käkelän katu 3
Lappeenranta
Finland
35130

Study participating centre
Rovaniemi primary health care
Hallituskatu 7, PL 8216
Rovaniemi
Finland
96101

Study participating centre
Kerava primary health care
Metsolantie 2

Kerava
Finland
04200

Study participating centre
Keski-Uudenmaan sote -kuntayhtymä
PL 46
Hyvinkää
Finland
05801

Sponsor information

Organisation
University of Oulu Center for Life Course Health Research

ROR
https://ror.org/03yj89h83

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of General Medicine Mikkeli Central Hospital (Essote), Mikkeli, Finland

Funder Name
Suomen Kulttuurirahasto

Alternative Name(s)
Finnish Cultural Foundation, SKR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location

Finland

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/09/2021	01/03/2024	Yes	No
Interim results article	interim results	30/12/2019	02/01/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes