ISRCTN14389368 https://doi.org/10.1186/ISRCTN14389368

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?
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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
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

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 below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
13/04/2017

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

Age group

Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Current target number of participants as of 30/10/2019: We will use a cluster randomized study design with 4 intervention clusters and 4 control clusters. For sample size calculation, we used a web-based calculator for Inference for Means in clustered samples: http://www.sample-size.net /means-sample-sizeclustered/. Minimal Important Difference (MID) for PROMIS PF-20 change is about 2 points, Standard Deviation (SD) is 3.66. Type I error rate was 0.05, Intracluster Correlation Coefficient (ICC) is 0.025. A sample size of 128 patients would enable the detection of a difference of 2 points in PROMIS PF-20 with 80% power. With a high drop-out rate (45%), the final sample size was 284 patients (142 per intervention and control group). At baseline, the imaging rate (x-ray, MRI, CT) is expected to be 30%. We used a web-based calculator comparing proportion with a dichotomous outcome (imaging/nor imaging) between two samples (http://www.sample-size.net/sample-size-proportions/). A sample size of 268 patients would enable the detection of a 15% decrease in imaging proportion with 80% power (type I error 0.05). We estimated the Design Effect (DE) for unequal clusters in cluster randomized design to increase the statistical power of cluster randomized study: DEunequal=1+[(1+cv2)x m -1]p. 268 x 1,5(DEunequal)=408; when p(ICC)=0.01; coefficient of variation of cluster size (cv) is 0,208. cv=sd /m, (sd= standard deviation of mean cluster size; m=mean cluster size); sd=CSrange/4 (CS=cluster size) Previous target number of participants: Sample size was calculated for 6 clusters. At the beginning, we planned all 6 clusters from ESSOTE area. Recruitment in small health care units did not run expectedly and therefore more health care areas were included. Other areas are Rovaniemi, EKSOTE I and EKSOTE II, Kerava and Hyvinkää. For the sample size calculation we used web based calculator for Inference for Means: Comparing Two Independent Samples: https://www.stat.ubc.ca/~rollin/stats/ssize/n2.html. Common standard deviation of ODI was 15% (evaluated using preliminary data of this study). Type I error rate is 0.05. A sample size of 284 patients would enable detection of difference of 5% in ODI given 80% power. With a 30% drop-out the final sample size is 406 patients. At baseline, imaging rate is approximately 35%. A sample size of 276 patients would enable detection of 15% decrease in relative imaging proportion given 80% power (type I error 0.05). Sample size 406 is sufficient.

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
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Sponsor type
University/education

Website
https://www.oulu.fi/medicine/elite

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2023

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?
Interim results article	interim results	30/12/2019	02/01/2020	Yes	No
Results article		07/09/2021	01/03/2024	Yes	No