

Low back pain in German primary care - qualitative process evaluation of a feasibility study evaluating a practice nurse-led behavioural intervention

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| Submission date 14/01/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 19/02/2024 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 27/05/2025 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Chronic low back pain is a common condition. Cognitive behavioural therapy (CBT) can be helpful, but there are not enough CBT therapists. In order to meet the demand, specially trained practice nurses in primary care could be helpful. The aim of this pilot study is to evaluate the acceptability of this approach in a pragmatic group programme for patients with chronic back pain.

Who can participate?

Patients between 18 and 65 years old with chronic low back pain

What does the study involve?

Practice nurses from one general practice were instructed in performing the training of five sessions with a group of up to six patients. After completion of the training cycle, acceptability and satisfaction were evaluated through semi-structured interviews with practice nurses and patients.

What are the possible benefits and risks of participating?

Patients in rural areas could benefit from this otherwise difficult-to-access but effective method in their local GP practice. There are no foreseeable risks for patients.

Where is the study run from?

Universitätsmedizin Rostock (Germany)

When is the study starting and how long is it expected to run for?

February 2012 to November 2014

Who is funding the study?

Institut für Allgemeinmedizin Universitätsmedizin Rostock (Germany)

Who is the main contact?

Dr Gregor Feldmeier, gregor.feldmeier@med.uni-rostock.de

Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Practice-nurse-led behaviour-intervention for low back pain in German primary care – qualitative process evaluation of a feasibility study

Acronym

COPAIN

Study objectives

Behavioural therapy-oriented group training with psychoeducational elements for patients with chronic back pain can be carried out by practice nurses in German primary care.

Ethics approval required

Ethics approval required

Ethics approval(s)

Submitted 16/07/2012, Ethics Committee of the Rostock University Medical Centre (St.-Georg-Str. 108, Rostock, 18055, Germany; +49 (0)381 494 9900; ethik@med.uni-rostock.de), ref: A 2012-0087

Study design

Feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

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

Chronic back pain

Interventions

In collaboration with a psychologist, psychotherapist and general practitioner, a training concept for chronic pain management based on behavioural principles was developed. Practice nurses from one general practice were instructed to perform the training of five sessions with a group of up to six patients.

Intervention Type

Behavioural

Primary outcome measure

Implementability of a training program for patients, which included five sessions of 90 minutes each and focused in particular on the practice of progressive muscle relaxation according to Jacobson, assessed using a qualitative research method (a semi-structured interview with the practice nurses and patients) after completion of the training cycle

Secondary outcome measures

1. Pain intensity is measured with the Brief Pain Inventory (BPI) at Pre-intervention, before the 1st training session (T0), Post-intervention, after the last training session (T2) and as a follow-up, 3-6 months after the end of the training (T3)
2. Mental and physical state of health is measured using the Short Form Health Survey (SF-12) at Pre-intervention, before the 1st training session (T0), Post-intervention, after the last training session (T2) and as a follow-up, 3-6 months after the end of the training (T3)
3. Symptoms of depression and anxiety are measured using the Hospital Anxiety and Depression Scale (HADS) at Pre-intervention, before the 1st training session (T0), Post-intervention, after the last training session (T2) and as a follow-up, 3-6 months after the end of the training (T3)
4. Coping strategies and pain acceptance are measured by the Chronic Pain Acceptance Questionnaire (CPAQ) at Pre-intervention, before the 1st training session (T0) and Post-intervention, after the last training session (T2)
5. Pain-related disability in daily life is measured using the Roland and Morris Disability Questionnaire (RMDQ) at Pre-intervention, before the 1st training session (T0), Post-intervention, after the last training session (T2) and as a follow-up, 3-6 months after the end of the training (T3)

Overall study start date

08/02/2012

Completion date

20/11/2014

Eligibility

Key inclusion criteria

1. Between 18 and 65 years old
2. Suffered from back pain for at least 6 months
3. Able to perform the training cognitively and physically

Participant type(s)

Patient, Health professional

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

15

Total final enrolment

Key exclusion criteria

1. Migraine headaches
2. Severe concomitant illnesses
3. Severe underlying mental illnesses
4. Patients taking opiates were only included after direct consultation and consideration with the study team

Date of first enrolment

27/07/2012

Date of final enrolment

21/11/2012

Locations**Countries of recruitment**

Germany

Study participating centre

Rostock University Medical Center Institute of General Practice

Postbox 100888

Rostock

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18055

Sponsor information**Organisation**

Universitätsmedizin Rostock

Sponsor details

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Sponsor type

University/education

Website

<http://www.med.uni-rostock.de/>

ROR

<https://ror.org/04dm1cm79>

Funder(s)

Funder type

University/education

Funder Name

Institut für Allgemeinmedizin Universitätsmedizin Rostock

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/02/2024

Individual participant data (IPD) sharing plan

The datasets created as part of the current study are stored in a repository that is not publicly accessible (managed by Dr Gregor Feldmeier). The study data are not freely accessible but can be viewed if necessary after consultation with the person responsible for the study (Dr Gregor Feldmeier, gregor.feldmeier@med.uni-rostock.de).

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 26/05/2025 | 27/05/2025 | Yes | No |