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

Submission date
14/01/2024

Recruitment status
No longer recruiting

Registration date
19/02/2024

Overall study status
Completed

Last Edited
27/05/2025

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact name
Dr Gregor Feldmeier

ORCID ID
https://orcid.org/0000-0001-7420-5752

Contact details
Institut für Allgemeinmedizin
Universitätsmedizin Rostock
Doberaner Straße 142
18057 Rostock
Rostock
Germany
18057
+49 (0)381 494 2481
gregor.feldmeier@med.uni-rostock.de

Additional identifiers

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
15

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
Germany
18055

Sponsor information

Organisation
Universitätsmedizin Rostock

ROR
https://ror.org/04dm1cm79

Funder(s)

Funder type
University/education

Funder Name
Institut für Allgemeinmedizin Universitätsmedizin Rostock

Results and Publications

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