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Implementing evidence based primary care for back pain

Submission date	Recruitment status	[X] Prospectively registered
22/06/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/09/2018	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
346/4540

Study information

Scientific Title
IMplementation to improve Patient Care through Targeted treatment for Back pain (IMPaCT Back)

Acronym
IMPaCT Back

Study objectives
Implementing a new system of sub-grouping and targeting treatment for Low Back Pain (LBP) in Primary Care will significantly improve clinical outcome and service provision.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval being sought from the Cheshire LREC in September 2007. A favourable ethical opinion was received in the October 2007 meeting (ref: 07/H1017/143).

Study design
A pragmatic, interventional, implementation study to compare a new system of care with current practice (before implementation care) in a pre-post design.

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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

Interventions
There will be an initial observational phase, to gather data on current clinical practice, care pathways and patient outcomes.

Intervention:
A novel system of sub-grouping and targeting treatment on potentially modifiable physical and psychological risk factors for LBP recurrence and chronicity.

Control:
This will be compared with current clinical practice (before implementation care).

The initial observational phase will take place over a four month period. Patients will be followed-up at two and six months after recruitment. The implementation of the new care system will take place over six months. There will then be a 12-month recruitment/observational phase, again with patient follow-up at two and six months.

Time points for follow-up are at baseline, and two and six months after recruitment. Data will be collected through questionnaires sent directly to patients. We will be using a battery of validated self-complete instruments, including the Roland-Morris disability questionnaire (primary outcome), the 12-item Short Form (SF-12) general health measure, EuroQol, HAD (Hospital Anxiety-Depression Scale), the Tampa scale of kinesiophobia, fear avoidance beliefs questionnaire, sub-scales from the pain catastrophising instrument, individualised goal scaling and questions about pain and satisfaction. The exact format of the questionnaire is currently being finalised.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Clinical outcome - back pain related disability (Roland-Morris questionnaire)
2. Clinical practice outcome - captured through questionnaires and medical record reviews
3. Service outcome - referral and re-consultation rates

Outcomes will be assessed at baseline, two and six months.

Secondary outcome measures
1. Patient individualised goal attainment
2. Pain intensity
3. Global change in condition and general health status
4. Psychological health
5. Quality of Life
6. Utility
7. Healthcare usage
8. Satisfaction with care
9. Employment status
10. Changes in clinical practice
11. Changes in service provision

Outcomes will be assessed at baseline, two and six months.

Overall study start date
01/10/2007

Completion date
01/04/2010

Eligibility

Key inclusion criteria
Adults consulting their general practitioner for low back pain.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
1000

Key exclusion criteria
1. Indication of "red flags" (potential serious pathology)
2. Unable to give informed consent

Date of first enrolment
01/10/2007

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care Musculoskeletal Research Centre
Newcastle-under-Lyme
United Kingdom
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Sponsor information

Organisation
Keele University (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.keele.ac.uk

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation (UK) (ref: 346/4540)

Funder Name
Keele University (UK)

Funder Name
Central and Eastern Cheshire Primary Care Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	explanation of treatment and training	01/02/2012		Yes	No
Protocol article	protocol	01/02/2012		Yes	No
Results article	results	01/03/2014		Yes	No