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Improving Patient Choice in Treating Low Back Pain

Submission date 23/12/2009	**Recruitment status** No longer recruiting
Registration date 11/02/2010	**Overall study status** Completed
Last Edited 26/08/2014	**Condition category** Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Martin Underwood

Contact details
Warwick Clinical Trials Unit
University of Warwick
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PB-PG-0808-17039

Study information

Scientific Title
Improving Patient Choice in Treating Low Back Pain: a cluster randomised controlled trial

Acronym
IMPACT-LBP

Study objectives
A decision support package designed for use in physiotherapy departments to help patients seeking care for their back pain will ensure better, more informed choices about their treatment and should improve patient satisfaction.

As of 09/09/2010 this record was updated to include extended trial dates; the initial dates at the time of registration were as follows:
Initial anticipated start date: 01/04/2010
Initial anticipated end date: 31/03/2012

Please note that as of 21/02/2013, the following changes were made to the trial record:
1. The scientific title was previously "Improving Patient Choice in Treating Low Back Pain: a single centre randomised controlled trial"
2. The target number of participants was updated from 150 to 158
3. The anticipated end date was updated from 31/05/2012 to 31/12/2012

Ethics approval required
Old ethics approval format

Ethics approval(s)
Warwickshire Research Ethics Committee (REC), 5th February 2010

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Back pain

Interventions

Curent interventions as of 21/02/2013:
Physiotherapists will be randomised to intervention or control. Those in the intervention arm will be trained on informed shared decision making which they will use during the consultation process. Physiotherapist NOT trained on informed shared decision making will continue to provide standard care that would normally be received if you were not in the trial.

Previous interventions until 21/02/2013:
Participants will be randomly allocated to one of the following two groups:
1. Physiotherapist trained on informed shared decision making: The physiotherapist will have been trained on informed shared decision making and they will use this during the consultation process.
2. Physiotherapist NOT trained on informed shared decision making: This will be standard care that would normally be received if you were not in the trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Satisfaction with treatment at three months using a five-point Likert Scale (very satisfied to very dissatisfied)

Secondary outcome measures
Measured at baseline and 3 months:
1. Roland Morris Disability Questionnaire (RMDQ) - the leading measure of LBP-related disability in primary care trials
2. Modified Von Korff - a measure of LBP and disability over the preceding month
3. 12-item short form health survey (SF-12) - a generic measure of health-related quality of life
4. EuroQol - a generic measure of health utility that is designed for use in RCTs
5. Hospital Anxiety and Depression Scale (HADS) - an established and validated self rating instrument for anxiety and depression
6. Pain Self-Efficacy Questionnaire (PSEQ) - an established measure self-efficacy for people with chronic pain
7. Fear Avoidance Beliefs Questionnaire (FABQ) - the physical sub-scale of FABQ measures attitude to movement in back pain
8. A question on change in ability to perform daily tasks
9. A question on change in low back pain since beginning treatment
10. Compliance - we will measure compliance from the physiotherapy departments attendance records. We will also collect data from participants on health service use and health transition
11. Immediate follow-up assessment will focus on satisfaction with the decision making process. We will use the 'Satisfaction with Decision Scale' to measure satisfaction with the health care decision.

Overall study start date
01/06/2010

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Patients seeking treatment for non specific low back pain
2. Aged greater than or equal to 18 years, either sex
3. Fluent spoken and written English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
158

Key exclusion criteria
1. Severe psychiatric or personality disorders
2. Terminal illness
3. Critical illness
4. Possible serious spinal pathology including tumour, sepsis or fracture

Date of first enrolment
01/06/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warwick Clinical Trials Unit
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
c/o Peter Hedges
University House
Coventry
England
United Kingdom
CV4 7AL

Sponsor type
University/education

Website
http://www2.warwick.ac.uk

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0808-17039)

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?
Protocol article	protocol	25/02/2011		Yes	No
Results article	results	21/08/2014		Yes	No