

# Improving Patient Choice in Treating Low Back Pain

<b>Submission date</b> 23/12/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/08/2014	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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?
<a href="#">Protocol article</a>	protocol	25/02/2011		Yes	No
<a href="#">Results article</a>	results	21/08/2014		Yes	No