

Access trial: Clinical and cost outcomes of public versus private physiotherapy for low back pain

Submission date 05/08/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/09/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/09/2012	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
2003/1

Study information

Scientific Title

A randomised clinical trial of public hospital-based versus private clinic-based physiotherapy for low back pain - clinical and cost outcomes

Acronym

Access Trial

Study objectives

There was a difference in clinical outcomes and costs between public hospital-based and private clinic-based physiotherapy treatment of patients with low back pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Mater Misericordiae Hospital, Connolly Hospital and Sligo General Hospital Research Ethics Committees and the Irish College of General Practitioners Research Ethics Committee approved the study in 2005.

Study design

Pragmatic 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

Low back pain

Interventions

As this was a pragmatic trial the physiotherapists were permitted to use whatever form of treatment considered appropriate following individualised assessment; i.e. advice/education, manual therapy, exercise therapy, electrotherapy, cognitive behavioural therapy, multidisciplinary team management.

Total duration of treatment:

There was no limit on the total duration of treatment. Previous work by the research team had established the mean (SD) number of treatments for LBP in hospital settings as five visits over 6 weeks, and in the private setting as two visits over 1 week.

Total duration of follow-up:

12 months (three timepoints - 3, 6 and 12 months).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Roland Morris Disability Questionnaire, measured at 3, 6 and 12 months post-randomisation.

Secondary outcome measures

All measured at 3, 6 and 12 months post-randomisation:

1. 36-item Short Form health survey (version 2)
2. Fear Avoidance Beliefs Questionnaire
3. Back Beliefs Questionnaire
4. Euroqol Questionnaire
5. Patient Satisfaction with Outpatient Satisfaction Survey
6. Global Perceived Improvement Scale

Overall study start date

01/02/2005

Completion date

30/06/2007

Eligibility

Key inclusion criteria

1. Male or female
2. Aged 18 to 65 years
3. Low back pain defined as pain radiation into the buttock and/or one or both lower limbs for at least 3 weeks
4. Referral by a general practitioner for physiotherapy treatment of low back pain

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

160

Key exclusion criteria

1. Reflex and/or motor signs of nerve root, spinal cord or cauda equina compression as urgent surgical opinion is required for these patients
2. Recent spinal fracture as clinical outcomes are likely to be different and some treatment approaches may be contraindicated due to recent fracture, e.g. spinal manipulation
3. Physiotherapy for LBP in the previous 12 months as clinical outcomes are likely to be different with possible carry over effect of previous treatment
4. Medicolegal proceedings as clinical outcomes are likely to be different
5. History of psychological/psychiatric illness due to potential negative influence on patient outcomes
6. Lack of fluency in English which may limit patients ability to complete questionnaires

Date of first enrolment

01/02/2005

Date of final enrolment

30/06/2007

Locations**Countries of recruitment**

Ireland

Study participating centre

UCD School of Physiotherapy and Performance Science

Dublin

Ireland

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Sponsor information**Organisation**

Health Research Board (HRB) (Ireland)

Sponsor details

73 Lower Baggot St

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Sponsor type
Government

Website
<http://www.hrb.ie>

ROR
<https://ror.org/003hb2249>

Funder(s)

Funder type
Government

Funder Name
Health Research Board (HRB) (Ireland) (Project Grant: 2003/1)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

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?
Results article	results	15/01/2012		Yes	No