

Exploring interaction in back pain consultations

Submission date 20/04/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/05/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/06/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This is an initial study looking at the communication and decision-making that takes place in consultations between physiotherapists and people with back pain. Our goal is to provide some workshops for clinicians to help improve their communication skills and see whether this improves the outcome of treatment and experience of the service from the patients point of view.

Who can participate?

Physiotherapists working in Southern Health NHS Foundation Trust; and people with back pain (aged 18 years or over, able to communicate in English without assistance, with no signs or symptoms suggesting possible serious spinal pathology and no recent spinal surgery).

What does this study involve?

In this initial study, 60 people with back pain will be asked to complete a questionnaire booklet after they have attended their initial consultation. Twelve of these patients will also be asked their permission for a research assistant to watch and audio-record their consultation. The twelve physiotherapists will be randomly be allocated to one of two groups. One group will attend a workshop about communication skills (the content of which has been developed from earlier work) and the other group will have a workshop about manual therapy skills. The physiotherapists will be asked to evaluate the workshops (via an interview) and two months later, discuss whether the workshops have changed their clinical practice (via focus groups). Both workshops will be delivered by the same facilitator and will be supported by a training manual.

After the workshops, a further 60 people with back pain will be asked to complete the questionnaire booklet as before and once again, twelve of these will be asked if their consultation can be watched and audio-recorded by the research assistant.

What are the possible benefits and risks of participating?

There will be no direct benefit to those taking part before the workshops. The physiotherapists will receive additional teaching and any benefit to people with back pain (after the physiotherapists have attended the workshops) will be measured. Information obtained from this initial study will be used to devise a larger study involving other centres.

By taking part in this study, there are no anticipated risks of physical injury or harm.

Where is the study run from?

This study has been set up by the University of Southampton in collaboration with Southern Health NHS Foundation Trust.

When is the study starting and how long is it expected to run for?

April 2013 to 31st July 2013

Who is funding the study?

Arthritis Research UK (UK)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Feasibility randomised controlled trial: Exploring interaction in back pain consultations

Study objectives

This feasibility study is testing the efficacy of a theory-based intervention (a communication skills training package for physiotherapists), supported by a training manual.

The key research questions are:

1. Can an educational intervention (a communication skills training package for physiotherapists) increase patients' perceived involvement in decision-making processes and improve: perceptions of empathy; enablement; communication; experience; functional outcome; and cost-effectiveness?
2. Can the educational intervention increase clinician beliefs and behaviours that they are likely to increase patient involvement in decision-making processes?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Liverpool Central REC, 20/02/2013 Ref: 13/NW/0164

Study design

Randomised controlled feasibility study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Screening

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

Educational workshops (communication skills and manual therapy clinical skills).

Communication skills: 1-day workshop, supported by a training manual, focussing on 3 aspects of communication.

Manual therapy skills: 1-day workshop, supported by a training manual, focussing on specific aspects of delivering manual therapy treatments for people with back pain.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The Consultation And Relational Empathy (CARE) measure.

Primary and secondary measures are recorded at baseline (pre-workshops) and post-workshops (until a quota of 5 new patients have been assessed per participating physiotherapist). The semi-structured interviews to evaluate the workshops will take place within one week of the workshop and the focus group to discuss any impact on practice will be at 2 months.

Secondary outcome measures

1. Intensity of pain (numerical rating scale)
2. The Patient Enablement Instrument (PEI)
3. Brief Illness Perceptions Questionnaire
4. Patient Feedback questionnaire (Chartered Society of Physiotherapy)
5. 7-point enablement scales
6. Roland-Morris Disability Questionnaire
7. EQ5D-5L
8. Satisfaction with the consultation scale

Overall study start date

22/04/2013

Completion date

31/07/2013

Eligibility

Key inclusion criteria

Physiotherapists:

1. Registered with the Health and Care Professions Council
2. Band 6 grade working within the musculoskeletal outpatient service at Southern Health NHS Foundation Trust
3. Treating patients with back pain.

Patients:

1. Aged 18 or over, either sex
2. Referred to the outpatient physiotherapy service
3. Reporting back pain
4. With or without referred leg pain
5. Not having received any physical therapy (NHS or private) in the previous three months

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

12 physiotherapists & 120 patients.

Key exclusion criteria

Physiotherapists:

1. Not fulfilling the inclusion criteria or
2. If they have been involved in either of the first two studies in this research programme, from which the content of the educational workshop was derived.

Patients:

1. If they present with 'red flags' (signs / symptoms suggesting possible serious spinal pathology)
2. If they have received spinal surgery during this care episode
3. If they have another musculoskeletal disorder that is more troublesome than their back pain
4. If they have a serious psychiatric or psychological condition identified by the referring doctor; or
5. If they are unable to communicate in English without assistance

Date of first enrolment

22/04/2013

Date of final enrolment

31/07/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Building 45

Southampton

United Kingdom

SO17 1BJ

Sponsor information

Organisation

University of Southampton (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.southampton.ac.uk/>

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research UK (UK) 17830

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?
HRA research summary			28/06/2023	No	No