ISRCTN63723433 https://doi.org/10.1186/ISRCTN63723433

Improving COmmuNication skills aNd Exercise Compliance in physioTherapy (CONNECT)

Submission date
28/10/2011

Recruitment status
No longer recruiting

Registration date
11/01/2012

Overall study status
Completed

Last Edited
03/04/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Chronic low back pain (CLBP) is one of the most common reasons that people go for healthcare in countries around the world, including Ireland. While there are no known treatments that completely cure CLBP symptoms, being physically active, such as walking or swimming, can help this condition. Back exercises have also been found to be useful for this condition, and in Ireland are usually shown to patients by Chartered Physiotherapists. However, people with CLBP often have problems following the advice they have been given about physical activity and exercise. New research suggests that improving patients' motivation and confidence to exercise may increase their adherence to physical activity and exercise advice. To achieve this, previous interventions have focused on improving the communication skills of healthcare professionals. This communication skills training approach has been successful in other healthcare settings. The main aim of this study is to explore if an intervention to enhance physiotherapists' communication skills when discussing the treatment plan with their CLBP patients will improve patient adherence to their treatment.

Who can participate?
Patients aged between 18 and 70 years who have been referred for physiotherapy for chronic low back pain to one of the participating physiotherapy departments.

What does the study involve?
All participating physiotherapists will attend a 1-hour education session by an expert in low back pain. Physiotherapists in 6 of the 12 participating sites will also receive communication skills training, delivered over two 4-hour workshops by an expert in communication skills. To determine if this intervention is more effective for improving patients' adherence to treatment advice and their LBP symptoms than usual practice methods, the study will test the difference in the effects between the patients whose physiotherapists have completed the communication skills workshop (the experimental group) and the patients whose physiotherapists have not completed the workshop and will continue with their usual communication practice (the control group). After the first physiotherapy appointment, the patient will be given a pedometer and complete a simple questionnaire about their motivation to follow the advice from their

physiotherapist. Participants will continue attending their physiotherapy treatments as normal. Follow-up assessments will be conducted at Weeks 1, 4, 12, and 24. Follow-up assessments include questionnaires and the total step count from the pedometer for the previous 7 days.

What are the possible benefits and risks of participating?
All participants will receive physiotherapy treatment and a copy of the Back Book which may improve their understanding of low back pain. There are no known risks to participants.

Where is the study run from?
The study takes place at various physiotherapy outpatient departments at four hospitals and eight Primary Care Centres in Dublin, Ireland.

When is the study starting and how long is it expected to run for?
Patients will be enrolled in the study between April 2011 and February 2012. Follow-up assessment will continue until July 2012.

Who is funding the study?
Health Research Board, Dublin, Ireland.

Who is the main contact?
Dr Deirdre Hurley-Osing
deirdre.hurleyosing@ucd.ie

Contact information

Type(s)
Scientific

Contact name
Dr Deirdre Hurley-Osing

Contact details
School of Public Health
Physiotherapy and Population Science
University College Dublin
Health Sciences Centre
Belfield
Dublin
Ireland
4
+353 (0)1 716 6502
deirdre.hurleyosing@ucd.ie

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
hra_por/2010/102

Study information

Scientific Title
Testing a theory-based intervention designed to increase chronic low back pain patients adherence to physiotherapists recommendations

Acronym
CONNECT

Study objectives
1. Patients in the experimental arm will report significantly greater weekly physical activity (PA) participation compared with their pre-treatment PA levels and compared with patients in the control arm. They will also report greater self-rated adherence to physiotherapists' recommendations about exercise compared with the patients in the control arm.
2. Patients in the experimental arm will report significantly decreased pain, increased function, greater low back pain (LBP)-related well-being and greater perceived global improvement after treatment compared with their pre-intervention scores, and compared to the patients in the control arm.
3. Patients in the experimental arm will rate their physiotherapists as significantly more autonomy supportive than patients whose physiotherapists were assigned to the control arm.
4. Patients in the experimental arm will report significantly reduced fear-avoidance beliefs, significantly greater competence, autonomous motivation and significantly lower controlled motivation compared with their pre-treatment scores and compared with patients in the control arm
5. The influence of the experimental manipulation on outcomes (pain, function, and well-being) will be mediated by patients' rating of the physiotherapist's autonomy support, perceived competence, autonomous motivation, fear-avoidance beliefs and adherence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
A list of the eight research ethics committee approvals and the site(s) they cover:
1. Adelaide and Meath Hospital Ethics Approval, 22/022011
2. Connolly Hospital Ethics Approval, 11/03/2011
3. Beaumont Hospital Ethics Approval, 11/03/2011
4. St Vincent's University Hospital Ethics Approval, 03/032011
5. HSE Areas :Kildare/West Wicklow/Dublin South West Approval, 16/06/2011
6. HSE Area: North DublinApproval, 30/05/2011
7. HSE Area: Dublin North City Approval, 28/06/2011
8. HSE Areas: Dun Laoghaire, Dublin South East, Dublin South West, Wicklow and Dublin South City Approval, 25/05/2011

Study design
Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic low back pain

Interventions
Patients (n = 146) in the experimental arm will receive treatment from physiotherapists who have participated in self-determination theory (SDT)-communication skills training. Patients in the control arm (n = 146) will receive treatment from physiotherapists who have not received SDT-communication skills training.

SDT-communication skills training will be based on self-determination theory principles, implemented via the '5A' framework (ask, advise, agree, assist, arrange) and delivered in two 4-hour workshops.

All physiotherapists (in both the control and experimental arms of the study) will participate in a 1-hour workshop on evidence-based management guidelines for chronic low back pain (CLBP), including recommendations regarding exercise-based strategies and inclusion of advice on physical activity as part of home-based rehabilitation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Adherence; measured at weeks 1, 4, 12 and 24
1.1. The Injury-Rehabilitation Adherence Scale completed by the therapists
1.2. The Injury-Rehabilitation Adherence Scale completed by the patient
1.3. A Home-Exercise Compliance Assessment
2. Self-reported physical activity; measured at baseline (week 0) and at weeks 1, 4, 12 and 24 with the International Physical Activity Questionnaire
3. Low back pain symptoms; measured at baseline (week 0) and at weeks 4, 12 and 24 with pain intensity and pain bothersomeness
4. Pain-related activity limitation; measured at baseline (week 0) and at weeks 4, 12 and 24 measures with:
4.1. The Roland Morris Disability Questionnaire

4.2. The Patient Specific Functional Scale
5. Quality of life; measured at baseline (week 0) and at weeks 4, 12 and 24 with the European Quality of Life Questionnaire.

Baseline (week 0) refers to the 24 hours before the initial physiotherapy session.

Secondary outcome measures
1. Objective Physical Activity: measured at weeks 4, 12 and 24 with pedometers
2. Fear avoidance; measured at baseline (week 0) and at weeks 4, 12 and 24 with Fear Avoidance Back Beliefs Questionnaire
3. Global Perception of improvement; measured at baseline (week 0) and at weeks 4, 12 and 24 with the Global Perceived Effect scale
4. Motivation; measured at baseline (week 0), immediately after the initial physiotherapy session and at weeks 4, 12 and 24 with the Treatment Self-Regulation Questionnaire
5. Perceived competence; measured at baseline (week 0), immediately after the initial physiotherapy session and at weeks 4, 12 and 24 with the Perceived Competence Scale
6. Autonomy support; measured immediately after the initial physiotherapy session and at week 4, with the Health Care Climate Questionnaire completed by the patients

Overall study start date
01/04/2011

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. Between 18-70 years
2. Low back pain (LBP) of mechanical origin with/without radiation to the lower limb
3. Chronic (≥3 months)
4. English speaking and English literate
5. Access to a telephone

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants

292 participants, 50 physiotherapists

Key exclusion criteria
1. Spinal surgery or history of systemic/inflammatory disease
2. Scheduled for major surgery during treatment
3. Received treatment for CLBP within previous 3 months
4. Suspected or confirmed pregnancy
5. Unstable angina/uncontrolled cardiac dysrhythmias/severe aortic stenosis/acute systemic infection accompanied by fever
6. Patients with acute (< 6 weeks) or subacute LBP (6-12 weeks)

Date of first enrolment
01/04/2011

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Dublin
Ireland
4

Sponsor information

Organisation
Health Research Board (HRB) (Ireland)

Sponsor details
73 Lower Baggot St
Dublin
Ireland
2

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)

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?
Protocol article	protocol	15/06/2012		Yes	No
Results article	results	01/05/2015		Yes	No
Results article	results	01/09/2017		Yes	No