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Reducing Long-Term Disability Related to Pain: Evaluation of the Pain Disability Prevention Program in the Irish health service

Submission date 29/10/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/03/2011	**Overall study status** Completed	
Last Edited 19/01/2015	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.nuigalway.ie/pdp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Reducing Long-Term Disability Related to Pain: A Single centre, randomised controlled trial evaluating the Pain Disability Prevention Program in the Irish health service

Acronym
PDP Ireland

Study objectives
1. Those receiving 'PDPP plus medical treatment as usual' will demonstrate reduced disability, improved quality of life and reduced pain catastrophising than those receiving medical treatment as usual only.
2. Those who received the PDP intervention will report higher rates of readiness to return to work compared to those receiving medical treatment as usual.
3. That the PDPP will demonstrate a positive cost-benefit outcome, where the costs of treatment will be less than the savings associated with better outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National University of Ireland, Galway Research Ethics Committee (REC) approved on the 9th of November 2009

Study design
Single centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information sheet available at http://www.nuigalway.ie/research/pdp/downloads/patient_info_leaflet.pdf

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

Interventions
The intervention is a community based rehabilitation programme for patients with chronic pain who show elevated psycho-social risk factors for disability. Patients with pain for less than 12 months will be targeted. Patients will be randomised to either
1. Intervention group:
Patients will have 10 x 1-hour sessions with a clinical psychologist in their local area (as well as Medical Treatment as Usual). The psychologist will have completed specific Pain Pain Disability Prevention Programme training. The intervention (PDP) is a cognitive behaviourally based programme involving activity scheduling, cognitive restructuring, communication skills and problem solving.

2. Control group:
Medical Treatment as Usual.

The duration of the intervention will be 10 weeks. The total duration of follow up will be one year.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Pain Catastrophising, measured using the Pain Catastrophising Scale
2. Fear of movement measured using the Tampa Scale for kinesiophobia
3. Perceived Disability (Perceived Disability Scale)
4. Depression (Beck Depression Inventory)
5. Pain (McGill Pain Questionnaire) all
6. Healthcare costs will be measured using the Client Services Receipt Inventory, measuring healthcare utilisation for the 10 weeks prior to baseline, during the 10 week intervention and again after 12 months

Patients in both groups will be assessed pre-treatment, post-treatment (or after 10 weeks for the controls) and there will be a 1-year follow-up for both groups.

Secondary outcome measures
Readiness to return to work - with high unemployment, return to work may not be a feasible outcome measure. However we will examine changes in level of disability post intervention and readiness to return to work as a proxy for return to work.

Overall study start date
01/01/2011

Completion date
31/05/2014

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Patients referred by their GP with a current musculoskeletal injury and associated pain
The injury and pain must be of at least 1 month duration and not more than 12 months duration. Patients with a recurrence of pain associated with a pre-existing musculoskeletal injury may be included if the current pain represents a distinct recurrence. GPs must confirm the presence of the painful condition and approve participation in an activation programme.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140: 70 per condition

Key exclusion criteria
1. Patients with significant cognitive impairment or psychiatric illness (based on the recorded judgement of the GP) that would render them incapable of understanding and participating in the project
2. Pain related to a malignancy
3. Insufficient English language ability to answer questions and/or participate in treatment

Date of first enrolment
31/03/2011

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
Ireland

Study participating centre
National University of Ireland Galway
Clinical Psychology Dept

Galway
Ireland
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Sponsor information

Organisation
National University of Ireland, Galway (NUIG) (Ireland)

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Sponsor type
University/education

Website
http://www.nuigalway.ie/

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Government

Funder Name
Heath Research Board, Dublin (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	11/09/2013		Yes	No